



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / iQOS

Appendix 4 Pre-marketing Cumulative Line Listings THS Regular Products

Report Number: PMI_SURV_2016_SSR03

Sponsor: Philip Morris Products S.A.
PMI Research & Development
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**CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016**

Advanced Condition used in this report:

Advanced Condition: All THS Regular Ingredients Report From Study/OS (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

All THS Regular Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: All THS Regular Ingredients (Created by Joshua Cox)

Selection Criteria:

(Ingredient equal to D2 Ron OR

Ingredient equal to D2 Ron (cork tipping paper) OR

Ingredient equal to D1 Fitz OR

Ingredient equal to D2 Albertino OR

Ingredient equal to D2 Fitz OR

Ingredient equal to Ginebra Fitz OR

Ingredient equal to D2 Ron (half white tipping paper) OR

Ingredient equal to Ron OR

Ingredient equal to Scion 1 Fitz OR

Ingredient equal to Scion 1 Walt)

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (254)								
PMI000001	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				Make me cough too much [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: Make me cough too much Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 33-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that it made her cough too much. The event was considered to be non-serious (intensity not provided). Action taken with study product was not reported. At the time of reporting, the outcome of the event was unknown. No follow-up information has been requested ? case closed.								
PMI000002	ITALY Report From Study	59 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				The heat irritates my tongue and palate [GLOSSITIS] N / Y / Y The heat irritates my tongue and palate [STOMATITIS] N / Y / Y	Unknown
Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The heat irritates my tongue and palate. Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 59-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the duration of use was short, around 2 minutes and 10 seconds, therefore 'each distraction was fatal'; sticks too expensive. The respondent also								

**CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							the heat irritated her tongue and palate. The events were considered to be non-serious (intensity not provided).	
							Action taken with the product was not reported.	
							At the time of reporting, the outcome of the events was unknown.	
							No follow-up information is expected ? case closed.	
PMI000003	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				the taste of the tabaccos because I found it bitter [PRODUCT TASTE ABNORMAL] N / Y / Y it made me cough more of my traditional cigarettes [COUGH] N / N / Y I found it uncomfortable, the procedure (I Have to re - charge) [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Case Narrative: Verbatim: it made me cough more of my traditional cigarettes, the taste of the tabaccos because I found it bitter, I found it uncomfortable the procedure (I Have to re - charge)</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 40-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the smoking of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he found the taste of the tobacco bitter and it made him cough more than his traditional cigarettes. In addition, the respondent stated that he found the procedure uncomfortable because he had to re - charge. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000004	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the product gives headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: product gives headache Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the product gives headaches and reported that in the last week, he didn' t smoke it. The event was considered to be non-serious (intensity not pr Action taken with the product was considered as discontinued. At the time of reporting, the outcome of the event was unknown. No follow-up information is expected ? case closed.							
PMI000006	ITALY Report From Study	44 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the anxiety of the little light [ANXIETY] N / Y / Y it seems to me that it lasts too little [PRODUCT QUALITY ISSUE] N / Y / Y the taste of the tobacco makes my head turn [DIZZINESS] N / N / Y	Unknown
Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The taste of the tobacco makes my head turn, and the anxiety of the little light. It seems to me that it last too little. Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 44-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the taste of the tobacco makes her head turn. She reported the anxiety of the little light. It seems to her that it last too little (presumably t</p> <p>The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000007	ITALY Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: at the beginning he gave me headache.			at the beginning he gave me headache [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that at the beginning it gave her headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of repor ing, the outcome of the event was unknown.</p> <p>No follow-up information is expected - case closed.</p>							
PMI000008	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: I had dizziness while I smoked			I had dizziness while I smoked [DIZZINESS] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 36-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she had dizziness while she was smoking. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000009	ITALY Report From Study	52 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the sticks that take the throat, itchy throat [THROAT IRRITATION] N / Y / Y make you cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Case Narrative: Verbatim: The sticks that take the throat, sting the throat and make you cough</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 52-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the sticks take the throat (itchy throat) and make you cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000010	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			often I had headache [HEADACHE] N / N / Y had to inspire more because it looked to me too light / it warmed too much [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p>							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I had to inspire more because it looked to me too light / it warmed too much; often I had headache.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he often had headaches. In addition, the respondent mentioned that he had to inspire more because he product looked too light to him, and it warmed too much. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected - case closed.</p>								
PMI000012	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				the taste didn't satisfy me, it gave me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Case Narrative: Verbatim: The taste didn't satisfy me, it gave me headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste did not satisfy her and the product gave her headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000013	ITALY Report From Study	42 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 18-Dec-2014 Case Narrative: Verbatim: I don' t like it, it gives me nausea			I don't like it, it gives me nausea [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 42-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she didn' t like it, it gave her nausea and was not worth the price. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000014	ITALY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 18-Dec-2014 Case Narrative: Verbatim: I don't like the taste / the system, it is not worth its price, it gives me nausea.			it gives me nausea [NAUSEA] N / N / Y I don't like the taste / the system [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she did not like the taste, she did not like the system, it was not worth the price and it gave her nausea. The events were considered to be non-not provided).</p>							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected requested ? case closed.							
PMI000015	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I don't like the taste it leaves in the mouth [DYSGEUSIA] N / Y / Y The smell gives me headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 18-Dec-2014							
Case Narrative: Verbatim: I don't like the taste it leaves in the mouth, the smell gives me headache.							
Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 40-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that she did not like the taste it left in her mouth, the smell gave her headache. The events were considered to be non-serious (intensity not provided). The respondent mentioned that the cost was clearly disproportional.							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000016	ITALY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it "impastate" the mouth [ORAL DISCOMFORT] N / Y / Y aspirate gives me nausea [NAUSEA] N / N / Y the filter is too hot, the smoke is not dry but wet [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 18-Dec-2014							
Case Narrative: Verbatim: I don't like the filter is too hot, the smoke is not dry but wet and aspirate gives me nausea and "impastate" the mouth.							
Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she did not like that the filter was too hot, the smoke was not dry but wet and aspirate gave her nausea and "impastate" the mouth. The events considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000017	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			After some aspiration I had headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Case Narrative: Verbatim: after some aspiration I had headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that after some aspiration he had headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000018	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			those gave me headache [HEADACHE] N / N / Y those gave me a sense of nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jan-2015</p> <p>Case Narrative: Verbatim: I prefer the traditional cigarettes, those gave me headache and a sense of nausea</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she preferred the traditional cigarettes, those gave her headache and a sense of nausea. The events were considered to be non-serious (intensity provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000020	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			they give me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jan-2015</p> <p>Case Narrative: Verbatim: They give me headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that they (the heatsticks) gave him headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000022	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory		the first moment I had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 31-Oct-2014							
Case Narrative: Verbatim: The first moment I had to cough.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that in the first moment she had to cough. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000024	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory		Scratches in the throat [THROAT IRRITATION] N / Y / Y one ends up with a coughing fit [COUGH] N / N / Y Very strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 31-Oct-2014							
Case Narrative: Verbatim: Very strong, scratches in the throat and one ends up with a coughing fit.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks (presumably) were very strong, it scratches in the throat and one ends up with a coughing fit. The events were considered to be no (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000025	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]				In the beginning it was scratchy [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: In the beginning it was scratchy</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that in the beginning it was scratchy. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000026	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]				The first time I was very irritated by the taste. Now the taste is a little better. [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: The first time I was very irritated by the taste. Now the taste is a little better.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first time she was very irritated by the taste (presumably throat irritation). She reported that now (at the time of reporting) the taste was event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000028	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				when one has smoked several Heat Sticks in a row one feels nauseous [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: when one has smoked several Heat Sticks in a row, one feels nauseous.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that when one has smoked several Heat Sticks in a row, one feels nauseous. The event was considered to be non-serious (intensity not provided). In add respondent mentioned that it is convenient to use.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000029	SWITZERLAND Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it is pungent in the throat [OROPHARYNGEAL PAIN] N / N / Y it tastes chemical [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: It tastes chemical and is pungent in the throat.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 31-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it tastes chemical and is pungent in the throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000031	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it gives me nausea [NAUSEA] N / N / Y it gives me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I don' t like the taste, it gives me nausea and headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first time it looked interesting. In addition, she reported that she doesn' t like the taste, it gives her nausea and headache. The events were considered to be non-serious (intensity not provided).</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000032	SWITZERLAND Report From Study	35 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: now I have nausea.			Now I have nausea [NAUSEA] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 35-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that for the taste, she had been delighted on-site, but now she had nausea. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000034	SWITZERLAND Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: The regular heatstick that gives headaches.			The regular heatstick which gives headaches [HEADACHE] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 33-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the regular heatsticks (that she used during her first visit) gave her headache. The event was considered to be non-serious (intensity not provided) with regards to the Tobacco Heating System (THS) 2.2 Menthol, the respondent mentioned that she did not like the taste of the menthol, it was too strong.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000035	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>I did not feel good afterwards (eructation) [MALAISE] N / Y / Y</p> <p>I did not feel good afterwards (eructation) [ERUCTATION] N / Y / Y</p> <p>Bad after taste [DYSGEUSIA] N / Y / Y</p>	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: Bad after taste and I didn't feel good afterwards (eructation).</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he has a bad after taste and he didn't feel good afterwards (eructation). The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000036	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>Get unpleasant feeling in my throat [THROAT IRRITATION] N / Y / Y</p> <p>tobacco is too strong [PRODUCT QUALITY ISSUE] N / Y / N</p>	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Tobacco is too strong, get unpleasant feelings in my throat.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that tobacco was too strong, she got unpleasant feelings in her throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000037	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I get headaches [HEADACHE] N / N / Y slight drowsiness [SOMNOLENCE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: I get headaches, slight drowsiness.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she got headaches, slight drowsiness. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000040	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I have been sick.			I have been sick [MALAISE] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she had been sick (no further information provided). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000041	SWITZERLAND Report From Study	61 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I sometimes after the second HS ALWAYS [sic] get headaches.			Because I sometimes after the second HS always get headaches [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 61-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he "sometimes after the second heatstick always [sic] get headaches". The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000042	SWITZERLAND Report From Study	21 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			During the use of heatsticks I felt tension in the chest [CHEST DISCOMFORT] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: During the use of heatsticks I felt tension in the chest.								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:								
This report concerns a 21-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.								
No medical conditions and concomitant medications were reported.								
No information was provided on the use of conventional cigarettes.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.								
The respondent stated that during the use of the heatsticks, she felt tension in the chest. The event was considered to be non-serious (intensity not provided). In addition mentioned that she didn' t like the taste of the heatsticks.								
Action taken with the product was not reported.								
At the time of reporting, the outcome of the event was unknown.								
No follow-up information is expected ? case closed.								
PMI000043	SWITZERLAND Report From Study	27 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			The s icks weren't good for me, I had an oppressive feeling after smoking [SENSE OF OPPRESSION] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The sticks weren't good for me, I had an oppressive feeling after smoking.								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:								
This report concerns a 27-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.								
No medical conditions and concomitant medications were reported.								
No information was provided on the use of conventional cigarettes.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.								
The respondent stated that the sticks weren't good for her, she had an oppressive feeling after smoking. The event was considered to be non-serious (intensity not provided)								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Action taken with the product was not reported.				
			At the time of reporting, the outcome of the event was unknown.				
			No follow-up information is expected ? case closed.				
PMI000044	SWITZERLAND Report From Study	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			sometimes I have too strong headaches leading up to paralysis [MOVEMENT DISORDER] N / Y / Y pre-existing condition worsened [CONDITION AGGRAVATED] N / Y / Y sometimes I have too strong headaches leading up to paralysis [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Taste of "normal" cigarettes is better, a HeatStick smokes too quickly and, I grabbed a new one much sooner, or had the craving for a "real" cigarette. I am suffering from traumatic brain injury sometimes have too strong headaches leading up to paralysis these symptoms have increased under the HeatSticks.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>The respondent had a medical history of traumatic brain injury with strong headaches, sometimes leading to paralysis. No concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste of "normal" cigarettes was better, a HeatStick smoked too quickly, and he grabbed a new one much sooner, or had the craving for a "real" cigarette. The respondent was suffering from traumatic brain injury and would sometimes have too strong headaches leading up to paralysis. According to the respondent, these symptoms increased under the HeatSticks. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000045	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			was sick for one week [MALAISE] N / Y / Y Didn't taste [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: didn't taste and was sick for one week.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it didn't taste and she was sick for one week. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p> <p>10-FEB-2016: Case re-opened due capture missing listedness.</p>								
PMI000046	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			Throat pain [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: throat pain.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported throat pain. The event was considered to be non-serious (intensity not provided).</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000047	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			Heatsticks have scratched in my throat [THROAT IRRITATION] N / Y / Y Heatsticks have caused cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: Heatsticks have scratched in my throat and caused cough.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that Heatsticks have scratched in her throat and caused cough. The events were considered to be non-serious (intensity not provided). In addition, the mentioned that she could not get used to the taste.							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000049	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			I got headaches from the heats icks [HEADACHE] N / N / Y I found them too strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: I got headaches from the heatsticks, maybe, because I found them too strong.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she got headaches from the Heatsticks, maybe, because she found them too strong. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000050	SWITZERLAND Report From Study	23 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I was disgusted by the heatsticks.			I was disgusted by the heatsticks [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 23-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he was disgusted by the heatsticks. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000051	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014			I feel like the heatsticks hurt my lungs [BRONCHIAL IRRITATION] N / Y / Y my throat cannot take them [THROAT IRRITATION] N / Y / Y	Unknown

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I feel like the heatsticks hurt my lungs and my throat cannot take them.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she felt like the heatsticks hurt her lungs and her throat cannot take them. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of repor ing, the outcome of the events was unknown.</p> <p>No follow-up information is expected - case closed.</p>								
PMI000052	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			The heatsticks make me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The heatsticks make me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks made her cough. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned that sh used to the taste and there was less manipulations with conventional cigarettes.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000053	SWITZERLAND Report From Study	42 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I have been sick [MALAISE] N / Y / Y I had problems to insert the sticks in the holder [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The first week it was easy to smoke the sticks. After, I have been sick, and after I had problems to insert the sticks in the holder and I didn't call to get a ne stopped smoking the sticks.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 42-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first week it was easy to smoke the sticks. After, he has been sick, and after he had problems to insert the sticks in the holder. He didn't one and he stopped smoking the sticks. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000056	SWITZERLAND Report From Study	35 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the taste made me vomit [VOMITING] N / N / Y the taste has given me nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the taste has given me nausea and made me vomit.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the taste has given her nausea and made her vomit. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000058	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>The heatstick makes me cough more than the cigarette [COUGH]</p> <p>N / N / Y</p> <p>when I smoke a heatstick, I am not satisfied, I feel it doesn' t last long enough [PRODUCT QUALITY ISSUE]</p> <p>N / Y / N</p>	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The heatstick makes me cough more than the cigarette, in addition, if I forget to charge it and I want to smoke, I don' t have the patience to wait until it is charged. I smoke a heatstick, I am not satisfied, I feel it doesn' t last long enough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatstick makes her cough more than the cigarette. When she smokes a heatstick, she is not satisfied, she feels it doesn' t last long enough. The events were considered to be non-serious (intensity not provided). In addition, the respondent mentioned that if she forgets to charge it and she wants to smoke, she doesn' t have the patience to wait until it is charged.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000059	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The heatsticks leave a pasty taste in the mouth [DYSGEUSIA] N / Y / Y give the impression to have a coated tongue [TONGUE COATED] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the heatsticks leave a pasty taste in the mouth and give the impression to have a coated tongue</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks leave a pasty taste in the mouth and give the impression to have a coated tongue. The event were considered to be non-serious (in provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000060	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			less coughing [COUGH DECREASED] N / Y / Y better breathing [PRE-EXISTING CONDITION IMPROVED] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Better breathing, less coughing. Good tobacco taste, and no cold smoke. Fun to use.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent reported better breathing, less coughing. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned a good taste, no cold smoke, and fun to use.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000061	SWITZERLAND Report From Study	33 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I felt weak in the stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: I felt weak in the stomach.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 33-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he felt weak in the stomach. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000063	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The heatsticks caused headache and drowsiness [SOMNOLENCE] N / Y / Y The heatsticks caused headache and drowsiness [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the HeatSticks caused headache and drowsiness.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported that the heatsticks caused headache and drowsiness. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000064	SWITZERLAND Report From Study	32 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				scratched little [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: scratched little.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 32-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it scratched little. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000067	SWITZERLAND Report From Study	44 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			[too strong], irritant [THROAT IRRITATION] N / Y / Y too strong, [irritant] [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Too strong, irritant.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 44-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported: too strong, irritant (no further details provided). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000068	SWITZERLAND Report From Study	21 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			crushing feeling in the chest region [CHEST DISCOMFORT] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: a crushing feeling in the chest region.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 21-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported a crushing feeling in the chest region. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000069	SWITZERLAND Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it makes me cough.			it makes me cough [COUGH] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 31-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that it makes him cough. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000071	SWITZERLAND Report From Study	31 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: irritating			Irritating [THROAT IRRITATION] N / Y / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 31-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent reported: irritating (no further information provided). The event was considered to be non-serious (intensity not provided).							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000074	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Coughing a lot.			coughing a lot [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported coughing a lot. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000075	SWITZERLAND Report From Study	37 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it stays in the throat, one always has to drink after, it leaves a pasty taste.			it stays in the throat, one always has to drink after, it leaves a pasty taste [DYSGEUSIA] N / Y / Y it stays in the throat, one always has to drink after, it leaves a pasty taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 37-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stays in the throat, one always has to drink after and it leaves a pasty taste. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000076	SWITZERLAND Report From Study	28 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			it gives headache [HEADACHE] N / N / Y unpleasant aftertaste in the throat [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it gives headache, unpleasant aftertaste in the throat, it's imposing</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported it gives headache, unpleasant aftertaste in the throat and it's imposing. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000077	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			it dries up the throat [DRY THROAT] N / Y / Y I am coughing more than with my cigarette [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it dries up the throat, I am coughing more than with my cigarette.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it dries up the throat and she is coughing more than with her cigarette. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000080	SWITZERLAND Report From Study	55 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			sometimes I got strong headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Sometimes I got strong headaches.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 55-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that sometimes he got strong headaches. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>								

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000081	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it makes me cough with the first inhalations.			it makes me cough with the first inhalations [COUGH] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that it makes her cough with the first inhalations. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000082	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The flavour is pleasant if I use one or two sticks but after that it becomes nauseating and give me headaches.			it gave me headaches [HEADACHE] N / N / Y The flavour is pleasant if I use one or two sticks but after that it becomes nauseating [NAUSEA] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the flavour is pleasant if she uses one or two sticks but after that it becomes nauseating and gives her headaches. The events were considered to non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000083	SWITZERLAND Report From Study	23 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The taste is rapidly nauseating [NAUSEA] N / N / Y Makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The taste is rapidly nauseating. Does not last as long as a normal cigarette. Makes me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 23-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste is rapidly nauseating and it makes her cough. The events were considered to be non-serious (intensity not provided). In addition, the mentioned that it does not last as long as a normal cigarette.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000084	SWITZERLAND Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			sometimes a mean scratching in the throat [THROAT IRRITATION] N / Y / Y aftertaste (a bit stale/sour) [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Sometimes a mean scratching in the throat and the aftertaste (a bit stale/sour).</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 40-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported sometimes a mean scratching in the throat and the aftertaste (a bit stale/sour). The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000085	SWITZERLAND Report From Study	51 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			it provokes coughing [COUGH] N / N / Y smell unpleasant [PRODUCT ODOUR ABNORMAL] N / Y / N taste too dry, burned taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it provokes coughing, smell unpleasant, taste too dry, burned taste.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it provokes coughing, smell is unpleasant, taste is too dry, burned taste. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000088	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			at the end of the heatstick, the taste makes me feel nauseous [NAUSEA] N / N / Y If I smoke too much during the day I have a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: at the end of the heatstick, the taste makes me feel nauseous and if I smoke too much during the day I have a headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that at the end of the heatstick, the taste makes her feel nauseous and if she smokes too much during the day she had a headache. The events were cons be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000089	SWITZERLAND Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it irritates the throat [THROAT IRRITATION] N / Y / Y on the long term it gives headache [HEADACHE] N / N / Y it makes one feel like vomiting [NAUSEA] N / N / Y it's a little bitter [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it is a little bitter, it irritates the throat and on the long term it gives headache and makes one feel like vomiting.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is a little bitter, it irritates the throat and on the long term it gives headache and makes one feel like vomiting. The events were considered (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000090	SWITZERLAND Report From Study	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it made me nauseous [NAUSEA] N / N / Y too strong, the taste is bitter sour [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it made me nauseous, too strong, the taste is bitter sour.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated it made him nauseous, too strong and the taste was bitter sour. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000091	SWITZERLAND Report From Study	30 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The first draw was always (too) strong, had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The first draw was always (too) strong, had to cough. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 30-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the first draw was always (too) strong, he had to cough. The event was considered to be non-serious (intensity not provided). Action taken with the product was not reported. At the time of reporting, the outcome of the events was unknown. No follow-up information is expected ? case closed.							
PMI000092	SWITZERLAND Report From Study	21 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The aromatic taste, aftertaste [DYSGEUSIA] N / Y / Y tension in the chest [CHEST DISCOMFORT] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The aromatic taste, aftertaste, one cannot draw as intensely as with a normal cigarette, otherwise, tension in the chest. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 21-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent reported the aromatic taste, aftertaste, otherwise, tension in the chest. The events were considered to be non-serious (intensity not provided). In addition, mentioned that one cannot draw as intensely as with a normal cigarette, Action taken with the product was not reported.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000093	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			after a while it makes me feel nauseous [NAUSEA] N / N / Y Gives headaches [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: after a while it makes me feel nauseous. Gives headaches.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that after a while it makes her feel nauseous and gives headaches. The events were considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000094	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			cardboard taste [DYSGEUSIA] N / Y / Y much coughing [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: Cardboard taste, much coughing.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported cardboard taste and much coughing. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000096	SWITZERLAND Report From Study	50 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			Sometimes it makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: sometimes it makes me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 50-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that sometimes it makes her cough. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000099	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015 10-APR-2015	It smells disgusting so I feel like throwing up [NAUSEA] N / N / Y - It smells disgusting so I feel like throwing up [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 10-Apr-2015</p> <p>Case Narrative: Verbatim: It smells disgusting so I feel like throwing up</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 10-Apr-2015:</p> <p>This report concerns a 31-year-old male subject (Respondent Study ID: 1447535) who took part in the above mentioned market research study.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not provided) on 10-Apr-2015.</p> <p>On 10-Apr-2015, the respondent experienced feeling like throwing up and reported that "it smells disgusting". The events were considered to be non-serious. Severity criteria not provided.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000101	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	14-APR-2015 to 15-APR-2015	14-APR-2015 14-APR-2015	(I feel stuffy on my right chest as if I smoke a strong cigarette and) as if my lungs got filled up with something from the beginning) [BRONCHIAL SECRETION RETENTION] N / Y / Y I feel stuffy on my right chest as if I smoke a strong cigarette (and as if my lungs got filled up with something from the beginning) [CHEST DISCOMFORT] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 15-Apr-2015 Event Intensity: Moderate Case Narrative: Verbatim: I have tried 4 to 5 of them and I feel stuffy on my right chest as if I smoke a strong cigarette and as if my lungs got filled up with something from the beginning</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 15-Apr-2015: This report concerns a 42-year-old male subject (Respondent Study ID: 1319062) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (5 cigarettes to one pack per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number KLJ N2E X53E UG) on 14-Apr-2015.</p> <p>On the same day (14-Apr-2015), the respondent stated that he had tried 4 to 5 of them (presumably HeatSticks) and he felt stuffy on his right chest as if he smoked a strong cigarette as if his lungs got filled up with something from the beginning. The events were considered to be non-serious. Severity was reported as moderate.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 6-7 conventional cigarettes. He used the HeatSticks on 14-Apr-2015 in the afternoon and on 15-Apr-2015 morning.</p> <p>It was reported that the problem did not improve when usage of the product was stopped, and that the product was not restarted.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The use of the product was discontinued on 15-Apr-2015.								
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000103	KOREA, REPUBLIC OF	22 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	17-APR-2015 to 20-APR-2015	18-APR-2015 18-APR-2015	I' m allergic to dust, and it got worse after using HeatStick. [HYPERSENSITIVITY] N / Y / Y Skins of upper and lower eyelids got trouble [EYELID DISORDER] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 20-Apr-2015 Event Intensity: Unknown Unknown Case Narrative: Verbatim: I' m allergic to dust, and it got worse after using HeatStick. Skins of upper and lower eyelids got trouble.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 20-Apr-2015:								
This report concerns a 22-year-old male subject (Respondent Study ID: 1468690) who took part in the above mentioned market research study.								
Medical history of dust allergy and intervertebral disk was reported. Painkillers ('for the disk') were reported as concomitant medications.								
The respondent was a daily smoker (on average 20 cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number HTV 9RF HPQ RV1) on 17-Apr-2015.								
On 18-Apr-2015, the respondent experienced worsening of dust allergy and 'skins of upper and lower eyelids got trouble'. The events were considered to be non-serious. The respondent required medical advice. The respondent went to a dermatologist's clinic on 20-Apr-2015, who advised him not to use cigarette and heatstick at the same time.								
On the day of the event, the respondent used 4-5 HeatSticks and smoked 10 conventional cigarettes. He used the HeatSticks every day (but could not remember the date).								
The use of the product was discontinued on 20-Apr-2015. It was reported that the problem did not improve when usage of the product was stopped, and that the product was not								
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000105	KOREA, REPUBLIC OF	Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	13-APR-2015 to Unknown	13-APR-2015 13-APR-2015	Feel stuffy on back [SUFFOCATION FEELING] N / Y / Y Stuck with sputum a lot [SPUTUM RETENTION] N / Y / Y	Recovering/Resolving
Case Initial Receipt Date: 20-Apr-2015 Case Narrative: Verbatim: Feel stuffy on back and stuck with sputum a lot.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 20-Apr-2015:								

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a male subject in his 40' s (Respondent Study ID: 1130052) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number CRJ YMP N22 KGU) on 13-Apr-2015.</p> <p>On the same day (13-Apr-2015), the respondent stated that he felt "stuffy on back" and stuck with sputum a lot. The events were considered to be non-serious. The severity adverse events was not reported.</p> <p>It was reported that the events improved when the usage of the product was stopped, and that the product was not restarted.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000107	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015 10-APR-2015	got nauseous and had headache like the time when smoking other cigarettes [NAUSEA] N / N / Y got nauseous and had headache like the time when smoking other cigarettes [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 20-Apr-2015</p> <p>Case Narrative: Verbatim: when smoking common flavour, Y, got nauseous and had headache like the time when smoking other cigarettes.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015:</p> <p>This report concerns a 42-year-old male subject (Respondent Study ID: 1357612) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number K3V J9F P7N KA6) on 10-Apr-2015.</p> <p>On the same day (10-Apr-2015), the respondent stated that he got nauseous and had headache like at the time when smoking other cigarettes. The events were considered to be non-serious. The severity of adverse events was not reported.</p> <p>On the day of the event, the respondent used 2 HeatSticks.</p> <p>Action taken with use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000108	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	17-APR-2015 to Unknown	17-APR-2015 17-APR-2015 17-APR-2015	Got pounding in my head [HEADACHE] N / N / Y coughing [COUGH] N / N / Y sore throat [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-Apr-2015 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: got pounding in my head, coughing, and a sore throat.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-Apr-2015: This report concerns a 43-year-old male subject (Respondent Study ID: 1231958) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number B85 D5Q CA3 PA1) on 17-Apr-2015.</p> <p>On the same day (17-Apr-2015), the respondent experienced pounding in his head, coughing, and a sore throat. The events were considered to be non-serious. Severity was reported as mild.</p> <p>The product was used every day. On the day of the events, the respondent used 6 HeatSticks and smoked 6 conventional cigarettes.</p> <p>Action taken with use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000111	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	23-APR-2015 to Unknown	23-APR-2015 23-APR-2015	Throat is stinging (when inhaling smoke, feels like that dust sticks to throat) [SENSATION OF FOREIGN BODY] N / Y / Y Throat is stinging (when inhaling smoke, feels like that dust sticks to throat) [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-Apr-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Throat is stinging (when inhaling smoke, feels like that dust sticks to throat)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-Apr-2015:</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 43-year-old male subject (Respondent Study ID: 1468269) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 pieces - presumably cigarettes - per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number not provided) on 23-Apr-2015.</p> <p>Since the first day of use (23-Apr-2015), the respondent experienced stinging in the throat, which was described as "when inhaling smoke, feels like that dust sticks to the event was considered to be non-serious. Severity was reported as mild.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 4 conventional cigarettes. He used the HeatSticks every day.</p> <p>The use of the product was continued.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000113	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	22-APR-2015 Ongoing	26-APR-2015	When using HeatSticks in a row, throat is stinging (smarting) [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 28-Apr-2015</p> <p>Case Narrative: Verbatim: when using HeatSticks in a row, throat is stinging (smarting).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-Apr-2015:</p> <p>This report concerns a 34-year-old male subject (Respondent Study ID: 1211697) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number S5Z KLB W2L NFJ) on 22-Apr-2015.</p> <p>On 26-Apr-2015, the respondent experienced throat stinging (smarting) when using HeatSticks in a row. The event was considered to be non-serious. Adverse event severity was reported.</p> <p>The use of the product was continued without change.</p> <p>At the time of reporting, the event was resolved.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000114	KOREA, REPUBLIC OF Report From Study	54 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	20-APR-2015 to Unknown	21-APR-2015 21-APR-2015 21-APR-2015	Feels a bitter taste in throat [DYSGEUSIA] N / Y / Y Throat gets dry [DRY THROAT] N / Y / Y It tastes bad (not good) [PRODUCT TASTE ABNORMAL] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-Apr-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: feels a bitter taste in throat, throat gets dry, and it tastes bad (not good)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-Apr-2015: This report concerns a 54-year-old male subject (Respondent Study ID: 1248038) who took part in the above mentioned market research study.</p> <p>Medical history of hypertension was reported. The following concomitant medications were reported: hypertension medicine and vitamins (no further information provided).</p> <p>The respondent was a daily smoker (on average 13 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 87B FHH 9U7 U7F) on 20-Apr-2015.</p> <p>On 21-Apr-2015, the respondent experienced feeling a bitter taste in throat, throat gets dry, and it tastes bad (not good). The events were considered to be non-serious. Severe adverse events was reported as mild.</p> <p>The respondent used HeatSticks every day. It was reported that the problem returned when the product was restarted.</p> <p>The use of the product was continued.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000115	KOREA, REPUBLIC OF Report From Study	57 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	23-APR-2015 to 26-APR-2015	23-APR-2015	Coughs (usually not coughed when smoking with a general cigarette, but did when using HeatStick) [COUGH] N / N / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 28-Apr-2015 Event Intensity: Mild Case Narrative: Verbatim: coughs (usually not coughed when smoking with a general cigarette, but did when using HeatStick).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-APR-2015: This report concerns a 57-year-old male subject (Respondent Study ID: 1468837) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number HTR-XJ8-Z5V-70H) on 23-Apr-2015.</p> <p>On the same day (23-Apr-2015), the respondent experienced cough. He clarified that he would usually not cough when smoking conventional cigarettes, but did when using HeatSticks.</p> <p>The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The respondent used the product occasionally. On the day of the event, the respondent used 3 HeatSticks and smoked 20 conventional cigarettes.</p> <p>It was reported that the event improved when the use of the product was stopped. The use of the product was discontinued due to the cough on 26-Apr-2015 and was not restarted.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000116	KOREA, REPUBLIC OF Report From Study	22 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A Respiratory UNK [UNK]	22-APR-2015 to Unknown	22-APR-2015	Throat is stinging and hurting [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 28-Apr-2015</p> <p>Case Narrative: Verbatim: throat is stinging and hurting</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-APR-2015:</p> <p>This report concerns a 22-year-old male subject (Respondent Study ID: 1464521) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 6M1 8GV D7J JFY) on 22-Apr-2015.</p> <p>On the same day (22-Apr-2015), the respondent experienced throat stinging and hurting. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000118	KOREA, REPUBLIC OF Report From Study	58 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A Respiratory UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015	Feels nauseous when smoking cigarettes with the product [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 30-Apr-2015</p> <p>Event Intensity: Mild</p> <p>Event Stop Date: 30-APR-2015</p>							

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: feels nauseous when smoking cigarettes with the product.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-APR-2015: This report concerns a 58-year-old male subject (Respondent Study ID: 1375229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number reported as “test product”) on 30-Apr-2015.</p> <p>On the same day (30-Apr-2015), the respondent experienced feeling nauseous when smoking cigarettes with the product. The event was considered to be non-serious. Severity of adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 1 HeatStick. The number of conventional cigarettes smoked was not reported.</p> <p>It was reported that the problem improved when usage of the product was stopped, and that the product was not restarted.</p> <p>The outcome of the event was reported as recovered on 30-Apr-2015.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000119	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	25-APR-2015	Feels pain in chest (not stabbing pain but strong feeling from smoke coming into chest) [CHEST PAIN] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-Apr-2015</p> <p>Case Narrative: Verbatim: feels pain in chest (not stabbing pain but strong feeling from smoke coming into chest)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-APR-2015: This report concerns a 29-year-old male subject (Respondent Study ID: 1415934) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number LF9 EPF 18Z M6W) on 24-Apr-2015.</p> <p>On the next day (25-Apr-2015), the respondent experienced feeling pain in chest. The pain was described as not stabbing pain, but 'strong feeling from smoke coming into chest' event was considered to be non-serious. Severity of the event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000120	KOREA, REPUBLIC OF Report From Study	25 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to Unknown	26-APR-2015	has a little headache after using the products [HEADACHE] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 30-Apr-2015 Event Intensity: Mild Case Narrative: Verbatim: has a little headache after using the products Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 30-Apr-2015: This report concerns a 25-year-old male subject (Respondent Study ID: 1473115) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The respondent was a daily smoker (on average 4 cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number SY8 X20 VCN IGL) on 24-Apr-2015. On 26-Apr-2015, the respondent experienced a little headache after using the products. The event was considered to be non-serious. Severity of the adverse event was reported. On the day of the event, the respondent used 3HeatSticks and smoked 1 conventional cigarette. The product was used every day and was not discontinued due to the event. At the time of reporting, the event was not resolved.								
No follow-up information is expected ? case closed.								
PMI000121	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	30-APR-2015 to Unknown	30-APR-2015 30-APR-2015	Feels nauseous after using (the product Y) [NAUSEA] Unknown N / N / Y may appear as it has a very particular smell, and he used unusual things [PRODUCT ODOUR ABNORMAL] N / Y / N	
Case Initial Receipt Date: 30-Apr-2015 Case Narrative: Verbatim: feels nauseous after using (the product Y). (Symptoms) may appear as it has a very particular smell, and he used unusual things. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 30-Apr-2015: This report concerns a 50-year-old male subject (Respondent Study ID: 2341690) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was provided.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number reported as "test product") on 30-Apr-2015.</p> <p>On the same day (30-Apr-2015), the respondent felt nauseous after using the HeatStick. The respondent added that it may appear as it has a very particular smell. The events assessed as non-serious. Severity of the adverse events was not reported.</p> <p>On the day of the event, the respondent used 1 HeatStick.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000122	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015	Feels ... paralyzed tongue in the middle of answering details after using the test products / "paralyzed tongue" really means that it is similar to "feels as if it got numb" [HYPOAESTHESIA ORAL] N / Y / Y	Recovering/Resolving
					30-APR-2015	Feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products [OROPHARYNGEAL PAIN] N / N / Y	
					30-APR-2015	Feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products [DIZZINESS] N / N / Y	
<p>Case Initial Receipt Date: 30-Apr-2015 Case Followup Receipt Date: 14-May-2015 00:00 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-Apr-2015: This report concerns a 44-year-old male subject (Respondent Study ID: 2345991) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 40 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number reported as "test product") on 30-Apr-2015.</p> <p>On the same day (30-Apr-2015), the respondent experienced stinging in throat, woozy in head and paralyzed tongue. The events occurred after using the HeatStick. The events assessed as non-serious. Severity of the adverse events was reported as mild.</p> <p>On the day of the event, the respondent used 1 HeatStick and smoked 30 conventional cigarettes.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>It was reported that the events were not resolved, but that they improved when the use of the product was stopped.</p> <p>Action taken with the use of the product (after the first day of use) was unknown.</p> <p>No follow-up information is expected ? case closed.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015:</p> <p>The following clarification was received: The respondent didn't make any further comment, but the "paralyzed tongue" really means that it is similar to "feels as if it got</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000123	KOREA, REPUBLIC OF Report From Study	39 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A Respiratory UNK [UNK]	28-APR-2015 to Unknown	28-APR-2015	Feels twinge around oesophagus like when smoking strong cigarettes (only in inhaling the smoke deeply) [OESOPHAGEAL PAIN] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-May-2015 Event Intensity: Unknown Case Narrative: Verbatim: feels twinge around oesophagus like when smoking strong cigarettes (only in inhaling the smoke deeply)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 01-May-2015: This report concerns a 39-year-old male subject (Respondent Study ID: 2109623) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number QJZ SZ6 DRG TPB) on 28-Apr-2015.</p> <p>On the same day (28-Apr-2015), the respondent felt twinge around oesophagus. He specified that it was like when smoking strong cigarettes, and that it occurred only in inhaling the smoke deeply. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000124	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A Respiratory UNK [UNK]	25-APR-2015 to Unknown	25-APR-2015 25-APR-2015	Throat is hurting by using the product, HeatStick, because it's so strong. Has phlegm and coughs [PRODUCTIVE COUGH] N / Y / Y Throat is hurting by using the product, HeatStick, because it's so strong. Has phlegm and coughs [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
						25-APR-2015	Throat is hurting by using the product, HeatStick, because it' s so strong. Has phlegm and coughs [COUGH] N / N / Y	
						25-APR-2015	Throat is hurting by using the product, HeatStick, because it' s so strong [PRODUCT TASTE ABNORMAL] N / Y / N	
			<p>Case Initial Receipt Date: 01-May-2015</p> <p>Event Intensity: Mild Mild Mild Mild</p> <p>Case Narrative: Verbatim: Throat is hurting by using the product, HeatStick, because it' s so strong. Has phlegm and coughs</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 01-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 1385198) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (less than one pack of cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced throat hurting while using the product (due to the fact that the product is strong), phlegm and coughs. The events considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>On the day of the event, the respondent used 4-5 HeatSticks and smoked more than 10 conventional cigarettes.</p> <p>The product was used every day (on average 4-5 HeatSticks per day) and was not discontinued due to the event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>					
PMI000125	KOREA, REPUBLIC OF Report From Study	61 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	30-APR-2015 to Unknown	01-MAY-2015	Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white) [TONGUE DISCOLOURATION] N / Y / Y	Not Recovered/Not Resolved
						01-MAY-2015	Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white) [OROPHARYNGEAL PAIN] N / N / Y	
			<p>Case Initial Receipt Date: 04-May-2015</p> <p>Event Intensity: Moderate Moderate</p>					

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 04-May-2015: This report concerns a 61-year-old male subject (Respondent Study ID: 2361695) who took part in the above mentioned market research study.</p> <p>No medical history was reported and the respondent did not know the names of his concomitant medications.</p> <p>The respondent was a daily smoker (on average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number YQD ZEU JOW 2MC) on 30-Apr-2015.</p> <p>On 01-May-2015, the respondent experienced hurting in the throat. He described the event like initial symptom of having a cold and tongue' s colours turn to white. The event considered to be non-serious. Severity of the adverse events was reported as moderate.</p> <p>The product was used every day. On the day of the event, the respondent used 13 HeatSticks and smoked 7 conventional cigarettes.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000126	KOREA, REPUBLIC OF Report From Study	63 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	29-APR-2015 to Unknown	29-APR-2015 29-APR-2015	Throat is stuffy, bloated, and uncomfortable [PHARYNGEAL OEDEMA] N / Y / Y Throat is stuffy, bloated, and uncomfortable [LARYNGEAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 02-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Throat is stuffy, bloated, and uncomfortable.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 02-May-2015: This report concerns a 63-year-old male subject (Respondent Study ID: 2360950) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not provided) on 29-Apr-2015.</p> <p>On the same day, (29-Apr-2015), the respondent experienced stuffy, bloated and uncomfortable throat. The events were considered to be non-serious. Severity of the adverse events reported as mild.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the events.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000127	KOREA, REPUBLIC OF Report From Study	52 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	29-APR-2015 to Unknown	29-APR-2015	Feels like initial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used too big amount) [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 02-May-2015 Event Intensity: Mild Event Stop Date: 30-APR-2015 Case Narrative: Verbatim: feels like initial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used too big amount). But, thereafter, it</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 02-May-2015: This report concerns a 52-year-old male subject (Respondent Study ID: 2107856) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 35 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number VOP 10X 95H LHR) on 29-Apr-2015.</p> <p>On the same day (29-Apr-2015), the respondent felt like initial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used too big amount). The respondent mentioned that thereafter, it was getting better soon. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 35 HeatSticks and smoked no conventional cigarette.</p> <p>The product was used every day and was not discontinued due to the events.</p> <p>The events resolved on 30-Apr-2015.</p> <p>No follow-up information is expected ? case closed. ?</p>							
PMI000129	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	28-APR-2015 to Unknown	30-APR-2015	Throat is parched [DRY THROAT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 04-May-2015 Event Intensity: Mild</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: throat is parched.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 04-May-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 1374070) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number P5B SM6 ZNM OH9) on 28-Apr-2015.</p> <p>On 30-Apr-2015, the respondent experienced parched throat. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 3 HeatSticks and smoked 10 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000130	KOREA, REPUBLIC OF Report From Study	Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	30-APR-2015 to Unknown	01-MAY-2015 01-MAY-2015	The throat does not feel fresh and is stuffy [PHARYNGEAL OEDEMA] N / Y / Y The throat does not feel fresh and is stuffy [LARYNGEAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 06-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: The throat does not feel fresh and is stuffy</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015: This report concerns a 33-year-old male subject (Respondent Study ID: 1237609) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 12 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 4SH HLB Q31 301) on 30-Apr-2015.</p> <p>On the next day (01-May2015), the respondent experienced "throat does not feel fresh and is stuffy". The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 10 HeatSticks and smoked 10 conventional cigarettes.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000131	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	27-APR-2015 to Unknown	27-APR-2015	The chest feels plugged [CHEST DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 06-May-2015</p> <p>Case Narrative: Verbatim: The chest feels plugged.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015:</p> <p>This report concerns a 50-year-old male subject (Respondent Study ID: 1469238) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 90T NF6 GRN AY3) on 27-Apr-2015.</p> <p>On the same day (27-Apr-2015), the respondent experienced a feeling of chest plugging. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000132	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	04-MAY-2015 to Unknown	04-MAY-2015 04-MAY-2015	Feels repulsive and bloated (from the 4th piece) [ABDOMINAL DISTENSION] N / Y / Y Feels repulsive and bloated (from the 4th piece) [FEELING ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 06-May-2015</p> <p>Case Narrative: Verbatim: feels repulsive and bloated (from the 4th piece).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015:</p> <p>This report concerns a 46-year-old male subject (Respondent Study ID: 2365469) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 4ES V6S MZB JK7) on 04-May-2015.</p> <p>On the same day (04-May -2015), the respondent "felt repulsive" and bloated (from the 4th piece). The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000134	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown		Feels repulsive and dizzy [FEELING ABNORMAL] N / Y / Y Feels repulsive and dizzy [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-May-2015</p> <p>Case Narrative: Verbatim: Feels repulsive and dizzy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 07-May-2015:</p> <p>This report concerns a 43-year-old male subject (Respondent Study ID: 1200024) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number STR BRD KLZ BEK) on 25-Apr-2015.</p> <p>On an unspecified day, the respondent experienced feeling repulsive and dizzy. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>The respondent did not provide consent to give further information.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000135	KOREA, REPUBLIC OF Report From Study	55 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK] UNK [UNK]	Respiratory Respiratory	27-APR-2015 to 30-APR-2015 04-MAY-2015 to 07-MAY-2015	04-MAY-2015 04-MAY-2015	When looking into the sky while standing s ill, it feels the world and ground rotates and it makes you feel nauseous. [VERTIGO] N / Y / Y When looking into the sky while standing s ill, it feels the world and ground rotates and it makes you feel nauseous. [NAUSEA] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 08-May-2015 Event Intensity: Severe Severe Case Narrative: Verbatim: When looking into the sky while standing still, it feels the world and ground rotates and it makes you feel nauseous</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 08-May-2015: This report concerns a 55-year-old male subject (Respondent Study ID: 1322273) who took part in the above mentioned market research study.</p> <p>Medical history of hypertension was reported. The following concomitant medications were reported: antihypertensive drug and digestant (twice for today).</p> <p>The respondent was a daily smoker (on average 23 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number U3N XX0 P4H V2G) on 27-Apr-2015.</p> <p>On 04-May-2015, the respondent experienced feeling like the world and ground rotates when looking into the sky (standing still) which makes the respondent feel nauseous. The events were considered to be non-serious. Severity of the adverse event was reported as severe.</p> <p>On the day of the event, the respondent used 5 HeatSticks and smoked 13 conventional cigarettes.</p> <p>The product was used every day since 28-Apr-2015 (start date also reported as 27-Apr-2015) until 07-May-2015, except for 01-May-2015, 02-May-2015 and 03-May-2015.</p> <p>It was reported that the events did not abate after product use was stopped and that the events returned when product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000136	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-MAR-2015 to Unknown	29-MAR-2015	Smoke from inhaling makes chest stuffy [CHEST DISCOMFORT] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 07-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Smoke from inhaling makes chest stuffy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 07-May-2015: This report concerns a 29-year-old male subject (Respondent Study ID: 2360940) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number YZA KVA 6U1 UHF) on 29-Mar-2015.</p> <p>On the same day (29-Mar-2015), the respondent stated that smoke from inhaling makes his chest stuffy. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 3 HeatSticks and smoked 7 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p> <p>?</p>					
PMI000137	KOREA, REPUBLIC OF Report From Study	62 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	14-APR-2015 to Unknown	15-APR-2015	Coughed when using product Y at first. [COUGH] N / N / Y	Recovered/Resolved
	<p>Case Initial Receipt Date: 11-May-2015 Event Intensity: Mild Event Stop Date: 17-APR-2015 Case Narrative: Verbatim: Coughed when using product Y at first.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 11-May-2015: This report concerns a 62-year-old male subject (Respondent Study ID: 1473117) who took part in the above mentioned market research study.</p> <p>No medical history was reported. The following concomitant medication was reported: Centrum (multi-vitamin).</p> <p>The respondent was a daily smoker (on average, 20 cigarettes per day).</p> <p>The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 14-Apr-2015 (Kit number 26G A9N 66N QJ1, not specified to which product it corresponds).</p> <p>On 15-Apr-2015, the respondent experienced cough at first, when using the Regular HeatSticks (product Y). The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 9 HeatSticks and smoked 12 conventional cigarettes.</p> <p>The product was used every day and was not stopped after occurrence of the event. In addition, it was reported that the problem did not return when use of the product was resumed.</p> <p>The event resolved on 17-Apr-2015.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000138	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	06-MAY-2015	Feels a twinge in inhaling because parts of gums (which had been treated before) become tightened [GINGIVAL PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown			
			Case Initial Receipt Date: 11-May-2015					
			Event Intensity: Moderate					
			Case Narrative: Verbatim: feels a twinge in inhaling because parts of gums (which had been treated before) become tightened.					
			Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 11-May-2015:					
			This report concerns a 34-year-old male subject (Respondent Study ID: 1463540) who took part in the above mentioned market research study.					
			No concurrent medical history and no concomitant medications were reported. The respondent had a dental treatment for tooth decay the previous year.					
			The respondent was a daily smoker (in average 20 cigarettes per day).					
			The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 25-Apr-2015 (Kit WTL HUQ NCE PQL, not specified to which product it corresponds).					
			On 06-May-2015, the respondent felt a twinge in inhaling because parts of gums (which had been treated before) became tightened. The respondent clarified that the pain last minutes and that he had no symptom when smoking regular cigarettes. The event was considered to be non-serious. Severity of the adverse event was reported as moderate.					
			The product was used on weekdays, not on weekends. The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event re when product was restarted.					
			At the time of reporting, the event was not resolved.					
No follow-up information is expected ? case closed.								
PMI000140	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PHARYNGEAL OEDEMA] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PRODUCTIVE COUGH] N / Y / Y	
			Case Initial Receipt Date: 14-May-2015					
			Event Intensity: Mild					
			Mild					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 14-May-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 1218229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using both products, the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number VXF KQM TGO, not specified to which product it corresponds) on 15-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced swelling of throat after using HeatSticks altogether in the evening and phlegm coming out a lot. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>It was reported that the events improved after product use was stopped and that the events returned when product was restarted.</p> <p>Action taken with the use of the product was unknown.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000141	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory		14-APR-2015	When using the product, feels hot because raised heat comes into mouth at once by putting heated Heat Stick on mouth [FEELING HOT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-May-2015 Event Intensity: Mild Case Narrative: Verbatim: When using the product, feels hot because raised heat comes into mouth at once by putting heated Heat Stick on mouth</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-May-2015: This report concerns a 50-year-old male subject (Respondent Study ID: 1353535) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 1YT 4KE Q60 UXA) on 14-Apr-2015.</p> <p>On 14-Apr-2015, the respondent experienced feeling hot when using the product. He explained that it is because raised heat comes into mouth at once by putting heated HeatStick on mouth. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 4conventional cigarettes.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The product was used every day from 14-Apr-2015 to 13-May-2015 and was not discontinued due to the occurrence of the adverse event.								
At the time of reporting, the event was not resolved.								
No follow-up information is expected ? case closed.								
PMI000142	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	14-APR-2015 to 04-MAY-2015	20-APR-2015 20-APR-2015	Feels repulsive and also has a headache after using (the product) [FEELING ABNORMAL] N / Y / Y Feels repulsive and also has a headache after using (the product) [HEADACHE] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 13-May-2015 Event Intensity: Moderate Event Stop Date: 04-MAY-2015 Case Narrative: Verbatim: feels repulsive and also has a headache after using (the product)								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 13-May-2015:								
This report concerns a 32-year-old male subject (Respondent Study ID: 1218311) who took part in the above mentioned market research study.								
No medical history was reported. Vitamin was reported as concomitant medication.								
The respondent was a daily smoker (in average 17 cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number S75 TEV 77LXTR) on 14-Apr-2015.								
On 20-Apr-2015, the respondent experienced feeling repulsive and also had headache after using the product. The events were considered to be non-serious. Severity of the adverse event was reported as moderate.								
On the day of the event, the respondent used 3 HeatSticks and smoked 15 conventional cigarettes.								
The product was used every day for the first three weeks, and then was discontinued.								
It was reported that the events improved after product use was stopped and that the product was not restarted. The last day of use of the product was 04-May-2015.								
The events resolved on 04-May-2015								
No follow-up information is expected ? case closed.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000143	KOREA, REPUBLIC OF Report From Study	60 Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	14-APR-2015 to 11-MAY-2015	14-APR-2015 14-APR-2015	has somewhat stinging on throat when feeling aftertaste during using the product [DYSGEUSIA] N / Y / Y has somewhat stinging on throat when feeling aftertaste during using the product [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: has somewhat stinging on throat when feeling aftertaste during using the product</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-May-2015: This report concerns a 60-year-old male subject (Respondent Study ID: 1293222) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamin and painkiller (both unspecified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 7 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number XAA Q4M T55 NIK) on 14-Apr-2015.</p> <p>On the same day (14-Apr-2015), the respondent experienced stinging on throat when feeling aftertaste during using the product. The events were considered to be non-serious. the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 7 HeatSticks and smoked 8 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the occurrence of the events. Last day of product use was 11-May-2015.</p> <p>It was reported that the events did not return when product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000144	KOREA, REPUBLIC OF Report From Study	24 Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	18-APR-2015 to Unknown		Coughs a lot when using (the products). Sometimes retches when using the products. [RETCHING] N / Y / Y Coughs a lot when using (the products). Sometimes retches when using the products. [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 16-May-2015 Case Narrative: Verbatim: Coughs a lot when using (the products). Sometimes retches when using the products.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 16-May-2015: This report concerns a 24-year-old male subject (Respondent Study ID: 1150153) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number MB5 VKV 1LJ A54) on 18-Apr-2015.</p> <p>On 16-May-2015, the respondent reported coughing a lot when using the products. He also reported that he sometimes retches when using the products. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product and event outcome were not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000147	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	18-APR-2015 to Unknown	20-APR-2015 20-APR-2015 20-APR-2015	Throat gets dry and does not feel fresh with a slight cough after using the product. [DRY THROAT] N / Y / Y Throat gets dry and does not feel fresh with a slight cough after using the product. [LARYNGEAL DISCOMFORT] N / Y / Y Throat gets dry and does not feel fresh with a slight cough after using the product. [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-May-2015</p> <p>Case Narrative: Verbatim: Throat gets dry and does not feel fresh with a slight cough after using the product.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 18-May-2015: This report concerns a 27-year-old male subject (Respondent Study ID: 1329176) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number UDE 1LO BJO LBF) on 18-Apr-2015. It was reported that the respondent box of the product. Further kit numbers provided were: Holder I: TY9Q UAT MHM 97YZ, Holder II: T36U M6R VN7 7FJ6 and Charger: TBJD Q6P ZZZ UC48.</p> <p>On 20-Apr-2015, the respondent experienced throat getting dry and not feeling fresh with a slight cough after using the product. The events were considered to be non-serious. The adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed. ?</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000148	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	20-APR-2015 to Unknown	20-APR-2015 20-APR-2015	Throat is stinging with slight cough while/after using HeatStick [OROPHARYNGEAL PAIN] N / N / Y Throat is stinging with slight cough while/after using HeatStick [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 19-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Throat is stinging with slight cough while/after using HeatStick.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 19-May-2015: This report concerns a 38-year-old male subject (Respondent Study ID: 2342524) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number A17 5BF 072 21K P6K) on 20-Apr-2015.</p> <p>On the same day (20-Apr-2015), the respondent experienced stinging throat with slight cough while/after using the HeatSticks. The events were considered to be non-serious. the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 17 HeatSticks and smoked no conventional cigarettes.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000149	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	21-APR-2015 to 18-MAY-2015	21-APR-2015 21-APR-2015	Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge. [FEELING HOT] N / Y / Y Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge. [DEVICE DIFFICULT TO USE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 20-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-May-2015:</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 34-year-old male subject (Respondent Study ID: 2357288) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamins and minerals (not further specified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 850 PSA Y6Q 8EM) on 21-Apr-2015.</p> <p>On the same day (21-Apr-2015), the respondent felt that the holder was uneasy to use because "its whole body got hot when holding it after charge" (note: presumably the b the respondent). The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 5 HeatSticks and smoked 7 conventional cigarettes.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000150	KOREA, REPUBLIC OF Report From Study	60 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	22-APR-2015 to 19-MAY-2015	22-APR-2015	Feels stinging on throat when using the product Y. [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 21-May-2015 Event Intensity: Mild Event Stop Date: 29-APR-2015 Case Narrative: Verbatim: Feels stinging on throat when using the product Y. Feels stinging in the first 1 week of using, then OK from that point of time.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 21-May-2015:</p> <p>This report concerns a 60-year-old male subject (Respondent Study ID: 1384757) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 9LA C5J JVH Q8V) on 22-Apr-2015. In addition, the respondent also used THS 2.2 Menthol (Dorado I / Vinny low menthol) (dates and kit number not specified); however, the adverse event was reported with use of THS 2.2 Regular.</p> <p>On the same day (22-Apr-2015), the respondent felt stinging on throat when using the product HeatSticks. The respondent clarified that he felt the stinging in the first wee product and that after that the event improved. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 15 HeatSticks and smoked 3 conventional cigarettes. The last day of use of the HeatSticks was 19-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The event resolved on 29-Apr-2015.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000152	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	22-APR-2015 to 20-MAY-2015	22-APR-2015	Feels slightly dizzy after using (the product) for about 10 minutes. [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 21-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Feels slightly dizzy after using (the product) for about 10 minutes. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 21-May-2015: This report concerns a 43-year-old male subject (Respondent Study ID: 1466209) who took part in the above mentioned market research study. No medical history was reported. Vitamins (not further specified) were reported as concomitant medications. The respondent was a daily smoker (in average 8 cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number RIP 5E3 GHP AGH) on 22-Apr-2015. On the same day (22-Apr-2015), the respondent felt slightly dizzy after using the product for about 10 minutes. The event was considered to be non-serious. Severity of the was reported as mild. The product was used every day. On the day of the event, the respondent used 3 HeatSticks and smoked 4 conventional cigarettes. The last day of use of the HeatSticks was 20-May-2015. It was reported that the event improved when usage of the product was stopped and returned when use of the product was restarted. At the time of reporting, the event was not resolved. No follow-up information is expected ? case closed.								
PMI000153	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	22-APR-2015 13-MAY-2015	During the test of the product, HeatStick, at first I felt heat (in mouth) like when smoking the last puff of normal cigarettes. [FEELING HOT] N / Y / Y Then, the chest feels heavy after 3 weeks of using (the product). [CHEST DISCOMFORT] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 22-May-2015 Event Intensity: Mild Mild Event Stop Date: 20-MAY-2015 20-MAY-2015								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: During the test of the product, HeatStick, at first I felt heat (in mouth) like when smoking the last puff of normal cigarettes. Then, the chest feels heavy after product).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1412271) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 3TH ZZC QAA VDD) on 22-Apr-2015.</p> <p>On the same day (22-Apr-2015), during the test of the product, the respondent felt heat (in mouth) like when smoking the last puff of normal cigarettes. Then, on 13-May-2015 weeks of using the product, he experienced heaviness of chest. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>Action taken with the use of the product was not reported. It was reported that the events improved when usage of the product was stopped and did not return when use of the restarted.</p> <p>The events resolved on 20-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000154	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to 21-MAY-2015	24-APR-2015	Feels heat on lips when putting the test product on mouth. [FEELING HOT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 22-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Feels heat on lips when putting the test product on mouth.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015: This report concerns a 36-year-old male subject (Respondent Study ID: 1215660) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamins (unspecified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 13 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number not provided) on 24-Apr-2015.</p> <p>Starting on the same day (24-Apr-2015), the respondent felt heat on his lips when putting the HeatStick on his mouth. The respondent specified that it didn' t feel too hot lukewarm heat. He clarified that it would be warm anyway because of heating, but he did not feel danger nor had negative feelings. The event was considered to be non-serious of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 4 HeatSticks and smoked 6 conventional cigarettes. The last HeatSticks were used on 21-May-2015</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The use of the product was not discontinued due to the occurrence of the adverse event.								
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000155	KOREA, REPUBLIC OF	36 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	22-APR-2015	Feels a slight pain on throat after using (the product). [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Report From Study								
Case Initial Receipt Date: 22-May-2015								
Case Narrative: Verbatim: Feels a slight pain on throat after using (the product).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 22-May-2015:								
This report concerns a 36-year-old male subject (Respondent Study ID: 1231135) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number FVQ VYR P1D Z2W) on 22-Apr-2015.								
On the same day (22-Apr-2015), the respondent felt a slight pain on throat after using the product. The event was considered to be non-serious. Severity of the adverse event reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000157	KOREA, REPUBLIC OF	39 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	23-APR-2015 to 20-MAY-2015	11-MAY-2015 11-MAY-2015	Feels smarting in mouth when using the product for about half an hour. [ORAL PAIN] N / Y / Y Feels stinging on throat when waking up in the morning after 3 weeks of using (the product). [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
Report From Study								
Case Initial Receipt Date: 22-May-2015								
Event Intensity: Mild								
Mild								
Case Narrative: Verbatim: Feels smarting in mouth when using the product for about half an hour. Feels stinging on throat when waking up in the morning after 3 weeks of using (the product).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 22-May-2015:								
This report concerns a 39-year-old male subject (Respondent Study ID: 2345759) who took part in the above mentioned market research study.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 6GN VUR GCE OYE) on 23-Apr-2015.</p> <p>On 11-May-2015, the respondent felt smarting in mouth when using the product for about half an hour. He also reported to feel stinging on throat when waking up in the morning weeks of using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 6 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were used on 20-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000159	KOREA, REPUBLIC OF Report From Study	59 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	25-APR-2015 to 12-MAY-2015	09-MAY-2015	Coughs violently; having bad coughs by sucking hard as trying to smoke fast. [COUGH] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2015 Event Intensity: Mild Event Stop Date: 10-MAY-2015 Case Narrative: Verbatim: Coughs violently; having bad coughs by sucking hard as trying to smoke fast.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 59-year-old male subject (Respondent Study ID: 2343688) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 83N Q16 PEW BVQ) on 25-Apr-2015.</p> <p>On 09-May-2015, the respondent experienced coughing violently. He explained that he was having bad coughs by sucking hard as he was trying to smoke fast. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 6 HeatSticks and smoked 10 conventional cigarettes. The last Heatsticks were used on 12-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The event resolved on 10-May-2015. It was indicated that the event did not return when product was restarted.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000160	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	23-APR-2015 to Unknown	23-APR-2015	Has a head-ache after smoking a few puffs when using the product for the first time. [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 23-May-2015 Case Narrative: Verbatim: Has a head-ache after smoking a few puffs when using the product for the first time. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 27-year-old male subject (Respondent Study ID: 2348221) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. Information on smoking habits was not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 2Z1 ORG 58C DUK) on 23-Apr-2015. On the same day (23-Apr-2015), the respondent experienced headache after smoking a few puffs (when using the product for the first time). The event was considered to be non Severity of the adverse event was not reported. Action taken with the use of the product was not reported. At the time of reporting, the outcome of the event was not reported. No follow-up information is expected ? case closed.							
PMI000161	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown	25-APR-2015 25-APR-2015 25-APR-2015	gets parched on throat and feels choked. [DRY THROAT] N / Y / Y gets parched on throat and feels choked. [CHOKING SENSATION] N / Y / Y Feels hot air coming from throat to chest when smoking HeatStick. [CHEST DISCOMFORT] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 23-May-2015 Case Narrative: Verbatim: Feels hot air coming from throat to chest when smoking HeatStick. And gets parched on throat and feels choked. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 1245346) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. Information on smoking habits was not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number JAD VZI JLH X5X) on 25-Apr-2015.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (25-Apr-2015), the respondent experienced feeling hot air coming from throat to chest when smoking a HeatStick. In addition, the respondent reported that he parched on throat and feeld choked. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>The outcome of the events was not reported; however, the respondent reported that "it is ok as not using it" (considered as recovered).</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000163	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Feels heat and seems to irritate throat. [FEELING HOT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Feels heat and seems to irritate throat. [THROAT IRRITATION] N / Y / Y	
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Case Narrative: Verbatim: Feels heat and seems to irritate throat.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015:</p> <p>This report concerns a 49-year-old male subject (Respondent Study ID: 1348800) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit numbers not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced feeling heat (location not specified) and reported that it seems to irritate the throat. The events were considered non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000164	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	02-MAY-2015	Feels heavy and stuck to swallow when using HeatStick at the end. [DISCOMFORT] N / Y / Y	Recovered/Resolved
						02-MAY-2015	Feels heavy and stuck to swallow when using HeatStick at the end. [DYSPHAGIA] N / Y / Y	
						02-MAY-2015	Has coughs caused by the heavy feelings. [COUGH] N / N / Y	
<p>Case Initial Receipt Date: 23-May-2015</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Event Intensity: Mild Mild Mild</p> <p>Event Stop Date: 22-MAY-2015 22-MAY-2015 22-MAY-2015</p> <p>Case Narrative: Verbatim: Feels heavy and stuck to swallow when using HeatStick at the end. Has coughs caused by the heavy feelings.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 27-year-old male subject (Respondent Study ID: 2106243) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number Y7K CJ6 PBD N2L) on 25-Apr-2015.</p> <p>On 02-May-2015, the respondent felt heavy and "stuck to swallow" when using HeatStick at the end. Has also reported that he coughed, which was caused by the heavy feelings. events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>It was reported that the problems improved when usage of the product was stopped and that the events returned when use of the product was restarted.</p> <p>The events resolved on 22-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000165	KOREA, REPUBLIC OF Report From Study	52 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]		25-APR-2015 to Unknown		Throat gets parched and feels hurt. [DRY THROAT] N / Y / Y Throat gets parched and feels hurt. [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Case Narrative: Verbatim: Throat gets parched and feels hurt.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 52-year-old male subject (Respondent Study ID: 2107376) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KWCT FDX M8A X8S) on 25-Apr-2015.</p> <p>On an unspecified date in Apr-2015, the respondent experienced his throat getting parched and feeling hurt. The events were considered to be non-serious. Severity of the adverse events was not reported.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the use of the product was not reported.							
At the time of reporting, the outcome of the events was not reported.							
No follow-up information is expected ? case closed.							
PMI000167	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	25-APR-2015 to 27-MAY-2015	25-APR-2015 25-APR-2015 26-APR-2015	Feels bad when my hand gets hot because the holder gets hot. [FEELING ABNORMAL] N / Y / Y Feels bad when my hand gets hot because the holder gets hot. [FEELING HOT] N / Y / Y Throat feels stinging to swallow because of hot steam after using (the product) a few times. [ODYNOPHAGIA] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-May-2015 Event Intensity: Mild Mild Mild Event Stop Date: 03-MAY-2015 Case Narrative: Verbatim: Feels bad when my hand gets hot because the holder gets hot. As its upper part gets hot, I would use the product by holding the bottom of the hot holder. Throat feels bad when swallowing because of hot steam after using (the product) a few times.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-May-2015: This report concerns a 47-year-old male subject (Respondent Study ID: 1117281) who took part in the above mentioned market research study.</p> <p>Medical history of hyperparathyroidism was reported. Medication for treating hyperparathyroidism (unspecified), "hepatic" medications (ursodesoxycholic acid 50 mg, thiamine 10 mg, riboflavin 5 mg), and multivitamin were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 27 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number R11 C89 SEH 08A MR0) on 25-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced feeling bad when his hand gets hot because the holder gets hot. The respondent explained that as its upper part gets hot, he would use the product by holding the bottom of the hot holder. On 26-Apr-2015, the respondent experienced stinging on throat when swallowing, because of hot steam after using the product a few times. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the events related to hot holder, the respondent used 9 HeatSticks and smoked 13 conventional cigarettes. On the day of the events related to stinging on throat, the respondent used 8 HeatSticks and smoked 16 conventional cigarettes. The last Heatsticks were used on 27-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse events.</p> <p>The events related to the hot holder were not recovered at time of reporting. The event of stinging throat resolved on 03-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000168	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to 21-MAY-2015	05-MAY-2015 05-MAY-2015	Vomited once or twice because of it (only 1 day, on May 5th) [VOMITING] N / Y / Y Had resistance to smoke and smell sometimes when feeling acidic tastes by using (the product). [PRODUCT TASTE ABNORMAL] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Mild Event Stop Date: 05-MAY-2015 05-MAY-2015 Case Narrative: Verbatim: Had resistance to smoke and smell sometimes when feeling acidic tastes by using (the product). Vomited once or twice because of it. But it was only 1 day on May 5</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 1381646) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number Y6A GQ6 7CW 3JC) on 24-Apr-2015.</p> <p>On 05-May-2015, the respondent vomited once or twice because of it (the Heatsticks). In addition, the respondent mentioned that he had resistance to smoke and smell sometimes feeling acidic tastes by using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 10 HeatSticks and smoked 10 conventional cigarettes. The last Heatsticks were used on 21-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The outcome of the events was reported as resolved on 05-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000169	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	27-APR-2015 to 20-MAY-2015	28-APR-2015	Felt hot on lips when smoking HeatStick [FEELING HOT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Event Stop Date: 20-MAY-2015 Case Narrative: Verbatim: Felt hot on lips when smoking HeatStick, and felt the same way when testing and every time using it for 4 weeks.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 46-year-old male subject (Respondent Study ID: 2104643) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number RLG R8D LAK 3IT) on 27-Apr-2015. The respondent mentioned that he used test product as well.</p> <p>On 28-Apr-2015, the respondent felt hot on lips when smoking HeatStick. He clarified that he felt the same way when testing and every time using the product for 4 weeks. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day (about 2 HeatSticks a day). On the day of the event, the respondent used 2 HeatSticks and smoked 12 conventional cigarettes. The last HeatStick was used on 20-May-2015.</p> <p>It was reported that the event improved when use of the product was stopped, and that the event returned when the product was restarted.</p> <p>The event resolved on 20-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000170	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015	11-MAY-2015	Has coughs every time when using HeatStick because of being in a hurry to smoke. [COUGH] N / N / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015			
			<p>Case Initial Receipt Date: 20-May-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: Never have coughed when using general cigarettes, but has coughs every time when using HeatStick because of being in a hurry to smoke.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-May-2015 and transferred to Safety department on 28-May-2015: This report concerns a 49-year-old male subject (Respondent Study ID: 2108635) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 14 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number TNY JGW LWS 3KZ, not specified for which one of the two products) on 28-Apr-2015.</p> <p>On 11-May-2015 (about two weeks after using the products), the respondent experienced coughing. He indicated that he never had coughed when using regular cigarettes, but had cough every time when using HeatStick because of being in a hurry to smoke. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used for 4 days (out of 7 days). On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were used on 18-May-2015.</p>					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000171	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	23-APR-2015	Felt heat and get ing hot from the front part of holder (where lips touch it) when using a few pieces of the product [FEELING HOT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2015</p> <p>Case Narrative: Verbatim: Felt heat and getting hot from the front part of holder (where lips touch it) when using a few pieces of the product on the date of testing it.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015:</p> <p>This report concerns a 31-year-old male subject (Respondent Study ID: 2357462) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number PN3 B6X YM4 RXG) on 23-Apr-2015.</p> <p>On the same day (23-Apr-2015), the respondent felt heat and getting hot from the front part of holder (where lips touch it) when using a few pieces of the product. The event considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000173	KOREA, REPUBLIC OF Report From Study	28 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to 21-MAY-2015	24-APR-2015	Felt stinging when smoking a few puffs by using the test product for the first ime / I felt slightly stinging after taking the product out of mouth. [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-May-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: Felt stinging when smoking a few puffs by using the test product for the first time, but usually felt either stinging or not by using general cigarettes, depending on the product. I gave no comment in the test, because it was not a big deal, but I felt slightly stinging after taking the product out of mouth.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-May-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID: 2359200) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history was reported. Powder type Vitamin C was reported as concomitant medication.</p> <p>The respondent was a daily smoker (in average 4 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 9TJ F4S NG8 X15) on 24-Apr-2015.</p> <p>On the first day of use (24-Apr-2015), the respondent felt stinging when smoking a few puffs. He explained that he felt slightly stinging after taking the product out of mouth. The respondent clarified that he usually felt either stinging or not by using conventional cigarettes, depending on products. He mentioned that he gave no comment in the test, not a big deal. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 3 HeatSticks and smoked no conventional cigarettes. The last Heatsticks were used on 21-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the problem returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000174	KOREA, REPUBLIC OF	51 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown		During the testing, heat comes into mouth stronger than when smoking regular cigarettes. Feels smoke in mouth throughout 4 weeks of using. [FEELING HOT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 29-May-2015</p> <p>Case Narrative: Verbatim: During the testing, heat comes into mouth stronger than when smoking regular cigarettes. Feels smoke in mouth throughout 4 weeks of using.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 29-May-2015:</p> <p>This report concerns a 51-year-old male subject (Respondent Study ID: 1215341) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number RMF YUK GRY AJ9) on 29-Apr-2015.</p> <p>The respondent reported that during the testing, heat came into mouth stronger than when smoking regular cigarettes. He felt smoke in mouth throughout 4 weeks of using. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000175	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [DRY MOUTH] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [SALIVARY HYPERSECRETION] N / Y / Y	
					29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [NAUSEA] N / N / Y		
Case Initial Receipt Date: 28-May-2015								
Case Narrative: Verbatim: Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. Didn' t comment (on that) because it happens usually when using regular cigarettes, and it was not a big deal, like testing (the products).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-May-2015: This report concerns a 36-year-old male subject (Respondent Study ID: 2354864) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number KUI MAM 29Y ONC, not specifying which one of the two products it corresponds) on 29-Apr-2015.								
Starting on the same day (29-Apr-2015), the respondent experienced dryness in mouth, feeling nauseous and having a lot of saliva in mouth by using both types of HeatSticks. The respondent explained that it happened in testing, and did happen in using as well. In addition, he explained that he didn' t comment on that because it happened usually when using regular cigarettes, and it was not a big deal. The events were considered to be non-serious. Severity of the adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000176	KOREA, REPUBLIC OF Report From Study	24 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	2015 to 22-MAY-2015	25-APR-2015	Feels parched on throat after using the product. It happens also when smoking regular cigarettes, but this time, when using HeatStick, is worse. [DRY THROAT] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 29-May-2015 Event Intensity: Mild								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Narrative: Verbatim: Feels parched on throat after using the product. It happens also when smoking regular cigarettes, but this time, when using HeatStick, is worse.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 29-May-2015: This report concerns a 24-year-old male subject (Respondent Study ID: 2359447) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
The respondent was a daily smoker (on average 10 cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number not provided) on an unspecified date.								
On 25-Apr-2015, the respondent felt parched on throat after using the product. He clarified that it happened also when smoking regular cigarettes, but this time, when using was worse. The event was considered to be non-serious. Severity of the adverse event was reported as mild.								
The product was used every day. On the day of the event, the respondent used 1 HeatStick and smoked 4 conventional cigarettes. The last Heatsticks were used on 22-May-2015.								
The use of the product was not discontinued due to the occurrence of the adverse event.								
At the time of reporting, the event was not resolved.								
No follow-up information is expected ? case closed.								
PMI000177	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DRY THROAT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DYSGEUSIA] N / Y / Y	
Case Initial Receipt Date: 28-May-2015								
Case Narrative: Verbatim: Used the product on Saturday after two weeks of not taking it. Felt parched on throat from its aftertaste when using both Y and Z.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 2359522) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number DRS 6EK MQK, not specifying which one of the two products it corresponds) on 29-Apr-2015.								
On 09-May-2015 (after 2 weeks of not using the product), the respondent felt parched on throat from the product's aftertaste when using both types of HeatSticks. The event was considered to be non-serious. Severity of the adverse event was not reported.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000180	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	29-APR-2015 to Unknown	29-APR-2015 29-APR-2015	Feels parched in swallowing since using the product for the first time. [DYSPHAGIA] N / Y / Y Feels parched in swallowing since using the product for the first time [DRY THROAT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-May-2015</p> <p>Case Narrative: Verbatim: Feels parched in swallowing since using the product for the first time.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015:</p> <p>This report concerns a 34-year-old male subject (Respondent Study ID: 2361433) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KGF 2RC LQQ KYS) on 29-Apr-2015.</p> <p>Since the first time he used the product (29-Apr-2015), the respondent felt parched in swallowing. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000181	KOREA, REPUBLIC OF Report From Study	33 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	01-MAY-2015 to Unknown	25-MAY-2015	Did not feel any problem in testing, but felt swollen on throat after about 3 weeks from using. [PHARYNGEAL OEDEMA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2015</p> <p>Case Narrative: Verbatim: Did not feel any problem in testing, but felt swollen on throat after about 3 weeks from using. So, does not use (the product) now.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-May-2015:</p> <p>This report concerns a 33-year-old male subject (Respondent Study ID: 2362201) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 4WS GTZ XSK 79D) on 01-May-2015.</p> <p>Approximately on 25-May-2015 (reported as about 3 weeks after starting the product), the respondent felt swollen on throat. The event was considered to be non-serious. Seven adverse event was not reported.</p> <p>The respondent indicated that he was not using the product anymore due to the event.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000182	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015 30-APR-2015	<p>Feels tickling in the throat and has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. [THROAT IRRITATION] N / Y / Y</p> <p>Has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. [COUGH] N / N / Y</p>	Unknown
<p>Case Initial Receipt Date: 30-May-2015</p> <p>Case Narrative: Verbatim: Feels tickling in the throat and has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. Th such problem if not puffing (the product) deeply.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-May-2015: This report concerns a 38-year-old male subject (Respondent Study ID: 2364502) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KJQ QNC JT6 4QT) on 30-Apr-2015.</p> <p>On the same day (30-Apr-2015), the respondent felt tickling in his throat and had coughs when using the test product. He explained that he felt and experienced the same when puffing the product deeply throughout the 4 weeks. According to the respondent, there was no such problem if he was not puffing the product deeply. The events were considered non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000189	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 19-May-2014 Event Intensity: Mild Event Stop Date: 19-MAY-2014 Case Narrative: Verbatim: The respondent vomited after using the product (1 time).	15-MAY-2014 to 19-MAY-2014	19-MAY-2014	The respondent vomited after using the product (1 time) [VOMITING] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 19-MAY-2014: This report concerns a 40-year-old male subject (Respondent Study ID: MIF0413102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number CU005509) on 15-May-2014. On 19-May-2014, he vomited once after using the product. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 19-May-2014. The event resolved on 19-May-2014. On the day of the occurrence of the event, the respondent used 1 stick and smoked 3 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000190	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK] Case Initial Receipt Date: 19-May-2014 Event Intensity: Mild Case Narrative: Verbatim: She feels a bit dizzy when smoking all the stick tobacco.	15-MAY-2014 to Unknown	16-MAY-2014	She feels a bit dizzy when smoking all the stick tobacco [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 19-MAY-2014: This report concerns a 36-year-old female subject (Respondent Study ID: MIF0414101L) who took part in the above mentioned market research study.</p> <p>The respondent's medical conditions included low blood pressure and allergy to grass family. The respondent was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU005513) on 15-May-2014. On 16-May-2014, she was feeling a bit dizzy when she smoked all the stick tobacco. The respondent stated that the problem occurred since she started using the product. In order to resolve this, she reduced the number of sticks ('304') and the number of puffs ('304 instead of 8010'). She tried to use the product only at home. She was asked to stop using the product but she refused because this product was used previously when she smoked cigarettes stronger than those she normally smoked. The event was considered to be non-serious and mild in intensity. It was reported that the event resolved.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
improved when the respondent stopped using the THS and that the event returned when the respondent restarted using the THS. The respondent did not stop using the product. At the time of this report, the event was still ongoing. On the day of the occurrence of the event, the respondent used 4 sticks and smoked 4 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000191	ITALY Report From Study	56 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]		19-MAY-2014 to 20-MAY-2014	20-MAY-2014 20-MAY-2014	Cough [COUGH] N / N / Y It scraped her throat [THROAT IRRITATION] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 21-May-2014 Event Intensity: Mild Mild Case Narrative: Verbatim: Cough, it scraped her throat. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 56-year-old female subject (Respondent Study ID: BUS0507101L) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a smoker who smoked on average 25 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004631) on 19-May-2014. On 20-May-2014, she experienced cough and reported that it scraped her throat. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 20-May-2014. At the time of this report, the events were still ongoing. On the day of the occurrence of the events, the respondent used 6 sticks and smoked 20 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000192	ITALY Report From Study	61 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]		15-MAY-2014 to 16-MAY-2014	15-MAY-2014 15-MAY-2014	Nausea only during product use [NAUSEA] N / N / Y Bad taste [PRODUCT TASTE ABNORMAL] N / Y / Y The charging procedure was difficult [PRODUCT QUALITY ISSUE] N / Y / Y	
Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Mild Case Narrative: Verbatim: Nausea only during product use, bad taste. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 61-year-old female subject (Respondent Study ID: BUS0420101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 15 to 18 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004767) on 15-May-2014. On 15-May-2014, she experienced nausea only during product use and also reported bad taste. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 16-May-2014 the events resolved on an unspecified date. On the day of the occurrence of the events, the respondent used 3 to 4 sticks and smoked 15 cigarettes.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 22-MAY-2014: The respondent reported that the product made her nauseous and that the charging procedure was difficult. The event was considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000193	ITALY Report From Study	50 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014 Case Narrative: Verbatim: Dizzy.	22-MAY-2014 to 22-MAY-2014	22-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 50-year-old male subject (Respondent Study ID: BUS0303101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004564) on 22-May-2014. On 22-May-2014, he was feeling dizzy. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. On the day of the occurrence of the event, the respondent used 4 sticks and smoked 6 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000194	ITALY Report From Study	42 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK] Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014 Case Narrative: Verbatim: Dizzy.	21-MAY-2014 to 22-MAY-2014	22-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 42-year-old male subject (Respondent Study ID: BUS021102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 to 15 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004674) on 21-May-2014. On 22-May-2014, he was feeling dizzy. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. On the day of the occurrence of the event, the respondent used 2 sticks and smoked 4 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000195	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK] Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: Headache, nausea, burning in throat, burning in stomach, too acrid/very chemical.	15-MAY-2014 to 18-MAY-2014	15-MAY-2014 15-MAY-2014 15-MAY-2014	Burning in stomach [DYSPEPSIA] N / Y / Y Headache [HEADACHE] N / N / Y Nausea [NAUSEA] N / N / Y Burning in throat [THROAT IRRITATION] N / N / Y Too acrid/very chemical [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014:</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 38-year-old male subject (Respondent Study ID: M1B0121102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 15 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU005116) on 15-May-2014. On 15-May-2014, he experienced headache, nausea and stomach burns. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 18-May-2014. At the time of this report, the events had improved but not resolved yet. On the day of the occurrence of the event, the respondent used 10 sticks and smoked 8 cigarettes.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 22-MAY-2014: The respondent reported that the product was too acrid, its taste was very chemical and that his throat and stomach burnt. The events were considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000197	ITALY Report From Study	21 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 24-May-2014 Event Intensity: Mild Event Stop Date: 19-MAY-2014 Case Narrative: Verbatim: Headache.	Unknown to 19-MAY-2014	16-MAY-2014	Headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker respondents took part in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest, they were randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 21-year-old female subject (Respondent Study ID: BUS0113102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. On 16-May-2014, she experienced headache. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 19-May-2014 and the event resolved on the same day. On the day of the occurrence of the event, the respondent used 3 sticks and smoked 3 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000198	ITALY Report From Study	37 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	17-MAY-2014 to 23-MAY-2014	17-MAY-2014 17-MAY-2014	Tachycardia [TACHYCARDIA] N / Y / Y Feeling like squeezing in chest [CHEST DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 24-May-2014 Event Intensity: Severe Severe Event Stop Date: 18-MAY-2014 18-MAY-2014 Case Narrative: Verbatim: Tachycardia, Feeling like squeezing in chest.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 37-year-old female subject (Respondent Study ID: MIF0122101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU005328) on 17-May-2014. On 17-May-2014, she experienced tachycardia and feeling like squeezing in chest. The events were considered to be non-serious and severe in intensity. It was reported that the events improved when the respondent stopped THS and that the events returned when the respondent restarted using the THS. The events resolved on 18-May-2014. The respondent stopped using the product on 23-May-2014. On the day of the occurrence of the event, the respondent used 1 stick and smoked 20 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000199	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	19-MAY-2014 to 21-MAY-2014	21-MAY-2014 21-MAY-2014 22-MAY-2014	Laryngitis [LARYNGITIS] N / Y / Y Tracheitis [TRACHEITIS] N / Y / Y Fever [PYREXIA] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 23-May-2014 Case Followup Receipt Date: 03-Jun-2014 00:00 Case Narrative: Verbatim: Laryngitis, tracheitis, fever.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 33-year-old female subject (Respondent Study ID: MIF0818101L) who took part in the above mentioned market research study.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 6 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU005216) on 19-May-2014. Since that date, she used only the THS (4 sticks on 19-May-2014, 3 sticks on 20-May-2014 and 4 sticks on 21-May-2014) and smoked no cigarettes. On 21-May-2014, she experienced laryngitis or tracheitis. She noticed that her throat was bigger than normal and dark red. She had a mild sore throat at the beginning. She reported that she could eat only ice cubes. The respondent stopped using the product on 21-May-2014. On 22-May-2014 (evening), she had fever (37.5 Degrees Celsius) and at the time of reporting, her fever was 38 Degrees Celsius. She added that she was not aware these events could happen and that she was going to lose work days. She added that, in 20 years as a smoker, she had never had such problems. On 23-May-2014, she went to see a doctor (without mentioning her use of THS) who prescribed her (unspecified) antibiotics. On 23-May-2014, she also took unspecified medications for her sore throat. The event was considered to be serious (medically significant). At the time of report, the events were still ongoing.								
She also asked whether her husband could use the THS and she was told 'no' as he had not signed the informed consent form.								
FOLLOW-UP INFORMATION RECEIVED ON 03-JUN-2014: The physician stated that the respondent booked an appointment for 23-May-2014 but she did not come to the surgery. As the physician did not see the respondent, she was not able to provide any further information. Based on the information received on follow-up, this case was downgraded to non-serious.								
No further follow-up information has been requested ? case closed.								
PMI000201	ITALY Report From Study	62 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]		24-MAY-2014 to 26-MAY-2014	24-MAY-2014 24-MAY-2014	Heat sensation on lips [ORAL DISCOMFORT] N / Y / Y THS heats too much [DEVICE MALFUNCTION] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 26-May-2014 Event Intensity: Mild Mild Event Stop Date: 24-MAY-2014 24-MAY-2014 Case Narrative: Verbatim: Heat sensation on lips, THS heats too much.								
Market Research Study P1_BT1_IT: Blinded blind test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker respondents participated in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest, they were randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 62-year-old female subject (Respondent Study ID: MIF0707101L) who took part in the above mentioned market research study.								
The respondent's medical condition included hypothyroidism for which she was taking unspecified medication.								
The respondent was a smoker who smoked on average 20 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number CU004818) on 24-May-2014. The respondent used 4 sticks on 24-May-2014, 2 sticks on 25-May-2014 and 1 stick on 26-May-2014. On 24-May-2014, she experienced heat sensation on lips during the usage of the THS. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the respondent stopped using the THS and that the event returned when the respondent restarted using the THS. The respondent added that she woke up at night with a discomfort on her lips. In her opinion, the THS heats too much. The event resolved on 24-May-2014. The respondent stopped using the product on 26-May-2014. On the day of the occurrence of the event, the respondent used 1 stick and smoked 10 cigarettes.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000203	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	20-MAY-2015 to 20-MAY-2015	20-MAY-2014	The taste/aroma gives me headache [HEADACHE] N / N / Y Maybe too light/ I do not feel it [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 30-May-2014 Event Intensity: Mild Event Stop Date: 20-MAY-2014 Case Narrative: Verbatim: The taste/aroma gives me headache, maybe too light/ I do not feel it. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 40-year-old female subject (Respondent Study ID: BUS0808101L) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a smoker who smoked on average 20 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004673) on 20-May-2014. On 20-May-2014, she experienced headache. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 20-May-2014 and the event resolved on the same day. On the day of occurrence of the event, the respondent used 4 sticks and smoked 20 cigarettes. INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 28-MAY-2014: The respondent reported that the product taste or aroma gave her headache. She was used to smoking cigarettes. The respondent found it hard to use the product. Maybe it was as she did not feel it (taste). The events were considered to be non-serious.							
No follow-up information has been requested ? case closed.							
PMI000205	ITALY Report From Study	21 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	22-MAY-2014 to 24-MAY-2014	22-MAY-2014 22-MAY-2014 22-MAY-2014 22-MAY-2014	Tongue tingling [PARAESTHESIA ORAL] N / Y / Y Cough [COUGH] N / N / Y Headache [HEADACHE] N / N / Y It scratched his throat [THROAT IRRITATION] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Mild Mild Mild Mild Event Stop Date: 24-MAY-2014 24-MAY-2014							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>24-MAY-2014</p> <p>24-MAY-2014</p> <p>Case Narrative: Verbatim: It scratched his throat, cough, headache, tongue tingling</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 21-year-old male subject (Respondent Study ID: BUS0513102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was taking Be-Total (vitamin B).</p> <p>The respondent was a smoker who smoked on average 5 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004492) on 22-May-2014. On 22-May-2014, the respondent used 1 stick and smoked 3 cigarettes. On 22-May-2014, he experienced cough, headache, tongue tingling and he reported that it scratched his throat. The events were considered to be non-serious and mild in intensity. The respondent did not use the THS on 23-May-2014. On 24-May-2014, the respondent used 3 sticks and smoked 1 cigarette. The respondent stopped using the product on 24-May-2014 and the events resolved on the same day.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000206	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]		23-MAY-2014 to 01-JUN-2014	24-MAY-2014	The aftertaste gives me headache [DYSGEUSIA] N / Y / Y The aftertaste gives me headache/Strong headache [HEADACHE] N / N / Y Has a very unpleasant taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Moderate Case Narrative: Verbatim: The aftertaste gives me headache, has a very unpleasant taste.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 32-year-old female subject (Respondent Study ID: BUS0201102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004623) on 23-May-2014: on that day, she used 1 stick and smoked 8 cigarettes. On 24-May-2014, she experienced strong headache. The event was considered to be non-serious and moderate in intensity. The event improved when the respondent stopped using the product.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
product on 24-May-2014. On 01-Jun-2014, the respondent used 1 stick and smoked 9 cigarettes and she experienced the same event. The respondent stopped using the product on 01-Jun-2014 and the event resolved.								
INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 26-MAY-2014: The respondent reported that the product aftertaste gave her headache and that the product had a very unpleasant taste. The events were considered to be non-serious.								
No follow-up information has been requested ? case closed.								
PMI000207	ITALY Report From Study	58 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory	20-MAY-2014 to 27-MAY-2014	16-MAY-2014 16-MAY-2014 16-MAY-2014	Tonsillitis [TONSILLITIS] N / Y / Y Sore throat [OROPHARYNGEAL PAIN] N / Y / Y Fever [PYREXIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: Tonsillitis, sore throat and fever								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responde in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week a interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 58-year-old male subject (Respondent Study ID: BUS0114101L) who took part in the above mentioned market research study.								
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 20 cigarettes per day.								
On 16-May-2014, the respondent experienced fever and sore throat and he reported that he had tonsillitis. The events were considered to be non-serious and mild in intensity								
On 20-May-2014, the respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004507). He used the product only twice on 20-May-2014 and 27-May-2014. On these dates, the respondent smoked 2 cigarettes and used 2 sticks.								
At the time of the report, the events were ongoing.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000208	ITALY Report From Study	41 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 04-Jun-2014 Event Intensity: Mild Case Narrative: Verbatim: Burning in the throat	29-MAY-2014 to 31-MAY-2014	31-MAY-2014	Burning in the throat [THROAT IRRITATION] N / Y / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 41-year-old male subject (Respondent Study ID: BUS0515102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 17 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004720) on 29-May-2014. On 31-May-2014, he experienced burning in his throat. The event was considered to be non-serious and mild in intensity. On the day of the occurrence of the event, the respondent used 10 sticks and smoked no cigarette. He reported that the event re-occurred when the respondent re-started the product. The respondent stopped using the product on 31-May-2014 and the event resolved on an unspecified date.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000209	ITALY Report From Study	21 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 05-Jun-2014 Event Intensity: Mild Event Stop Date: 27-MAY-2014 Case Narrative: Verbatim: Burning sensation in stomach, inflamed trachea.	22-MAY-2014 to 27-MAY-2014	24-MAY-2014 24-MAY-2014	Burning sensation in stomach [DYSPEPSIA] N / Y / Y Inflamed trachea [TRACHEAL INFLAMMATION] N / Y / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 21-year-old male subject (Respondent Study ID: BUS0812101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 15 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004491) on 22-May-2014. In the night of 23-May-2014, he experienced</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
burning sensation in his stomach and inflamed trachea, in an unusual way. The events were considered to be non-serious and mild in intensity. It was reported that the event when the product was stopped. A few days later, he re-started using the product but the events re-occurred. The respondent stopped using the product on 27-May-2014 and the resolved on the same day. On the day of the occurrence of the events, the respondent used 6 sticks and smoked 6 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000210	ITALY Report From Study	35 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory	21-MAY-2014 to 22-MAY-2014	21-MAY-2014	Acidity in stomach [DYSPEPSIA] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 05-Jun-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014 Case Narrative: Verbatim: Acidity in stomach Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 35-year-old female subject (Respondent Study ID: BUS0227102L) who took part in the above mentioned market research study. The respondent's medical conditions included some food intolerances and acidity in her stomach. The respondent was a smoker who smoked on average 15 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004495) on 21-May-2014. On that day, she used 2 sticks and smoked 15 cigarettes and, experienced acidity in her stomach. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the product was stopped and also reported that she took her tablet as she usually did for this type of symptom. On 22-May-2014, the respondent used 2 sticks and smoked 15 cigarettes. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. CORRECTIVE VERSION CREATED ON 11-AUG-2014: The reported term was re-coded to heartburn (dyspepsia) at PMI's request. No follow-up information has been requested ? case closed.								
PMI000211	ITALY Report From Study	56 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory	26-MAY-2014 to 30-MAY-2014	26-MAY-2014	It bothers me to smoke it because it makes me cough while with normal cigarettes it does not happen [COUGH] N / N / Y I don't like it because it is too flavoured [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 06-Jun-2014 Case Followup Receipt Date: 09-Jun-2014 00:00 Event Intensity: Mild								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I don't like it because it is too flavoured, it bothers me to smoke it because it makes me cough while with normal cigarettes it does not happen.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 06-JUN-2014: This report concerns a 56-year-old female subject (Respondent Study ID: MIF0405101L) who took part in the above mentioned market research study.</p> <p>The respondent's medical condition included high blood pressure for which she was taking the following concomitant medications: Lobivon (nebivolol), Osipine (barnidipine hydrochloride) and Karvea (irbesartan).</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004526) on 26-May-2014. On that day, she experienced cough. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the product was stopped. The respondent re-started and stopped the product and each time, the event re-occurred. The respondent stopped using the product on 30-May-2014. The event resolved on an unspecified date. On the day of the occurrence of the event, the respondent used 1 stick and smoked 15 cigarettes. The respondent used 7 sticks in total.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 02-JUN-2014: The respondent reported that she did not like the product because it was too flavoured. It bothered her to smoke it because it made her cough while with normal cigarettes it does not happen. The events were considered to be non-serious.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 09-JUN-2014: The respondent reported that she did not like the flavoured taste of the product because it caused her cough. The events were considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000213	ITALY Report From Study	51 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory		23-MAY-2014 23-MAY-2014	Gives a feeling of nausea/Nauseated [NAUSEA] N / N / Y Very strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014</p> <p>Case Narrative: Verbatim: Gives a feeling of nausea/nauseated, very strong</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 51-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on 23-May-2014. On the same day, the respondent reported that the product gave him a feeling of nausea (nauseated) and that the product was very strong. The events were considered to be non-serious. The outcome was unknown.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000214	ITALY Report From Study	54 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK] Case Initial Receipt Date: 20-May-2014 Case Narrative: Verbatim: Makes me cough		20-MAY-2014	Makes me cough [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 20-MAY-2014: This report concerns a 54-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on 20-May-2014. On the same day, the respondent reported that the product made her cough. The event was considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							
PMI000216	ITALY Report From Study	60 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 21-May-2014 Case Narrative: Verbatim: It made me cough. Too flavoured/I felt it too strong.		21-MAY-2014 21-MAY-2014	It made me cough [COUGH] N / N / Y Too flavoured, I felt it too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 60-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on 21-May-2014. On the same day, the respondent reported that the product was very different from his cigarettes. The product was too flavoured, he felt it too strong and it made him cough. The events were considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000217	ITALY Report From Study	30 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Cold sweat [COLD SWEAT] N / N / Y It takes a lot of time to recharge/to warm the cigarette [DEVICE MALFUNCTION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014 Case Narrative: Verbatim: Cold sweat, it takes a lot of time to recharge / to warm the cigarette.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 30-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II /Ron; Kit number not provided) on an unspecified date. The respondent reported the product gave him a lot of time to recharge, to warm the cigarette. The product did not satisfy him like his cigarettes. The product gave him a strange effect: it gave him sweat cold which he then stopped. However the respondent stated that, if the event persisted, he would stop using the product. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000218	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Gives a feeling of vomiting [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2014 Case Narrative: Verbatim: Gives a feeling of vomiting.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product gave him a feeling of vomiting. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000219	ITALY Report From Study	44 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Caused me headache [HEADACHE] N / N / Y Has a strong taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: Caused me headache, has a strange taste.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 44-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that they had a strange taste and that it caused him headache. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000220	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Gives me burning sensation of stomach [DYSPEPSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 29-May-2014 Case Narrative: Verbatim: Gives me burning sensation in stomach.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 38-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that they gave him burning sensation in stomach. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000221	ITALY Report From Study	43 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Leaves an aftertaste a bit bitter / I do not have a pleasant taste in the mouth / leaves a heavy taste in the mouth [DYSGEUSIA] N / Y / Y Causes me nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-May-2014</p> <p>Case Narrative: Verbatim: Causes me nausea, leaves an aftertaste a bit bitter / I do not have a pleasant taste in the mouth / leaves a heavy taste in the mouth.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 22-MAY-2014: This report concerns a 43-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that she left an aftertaste a bit bitter and a heavy taste in her mouth. She did not have a pleasant taste in her mouth. The product caused her nausea. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000222	ITALY Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It affects my throat [THROAT IRRITATION] N / N / Y Makes me cough [COUGH] N / N / Y I feel too much the taste of burnt [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014</p> <p>Case Narrative: Verbatim: It affects my throat, makes me cough, I feel too much the taste of burnt.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 51-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that she felt too much the taste of burnt, that the product affected her throat and made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000223	ITALY Report From Study	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Makes it dry [DRY THROAT] N / Y / Y Irritates/affects my throat [THROAT IRRITATION] N / N / Y Gives cough [COUGH] N / N / Y The taste of burnt affects my throat [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014</p> <p>Case Narrative: Verbatim: The taste of burnt affects my throat, irritates my throat, makes it dry, gives cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 47-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of burnt affected her throat, irritated her throat, made it dry and made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000227	ITALY Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Makes me nauseous [NAUSEA] N / N / Y It tastes very chemical [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014</p> <p>Case Narrative: Verbatim: Makes me nauseous, it tastes very chemical.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 27-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the taste of burnt made him nauseous and its taste was very chemical. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000228	ITALY Report From Study	37 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Itching in the throat [THROAT IRRITATION] N / Y / Y Makes me a little nauseous [NAUSEA] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014</p> <p>Case Narrative: Verbatim: Itching in the throat, Makes me a little nauseous, Too strong.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 37-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, gave her itching in the throat and made her a little nauseous. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000229	ITALY Report From Study	55 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			kneads the mouth [ORAL DISCOMFORT] N / Y / Y Makes me a little nauseous [NAUSEA] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2014</p> <p>Case Narrative: Verbatim: Makes me a little nauseous, Kneads the mouth, Too strong.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 55-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, made her a little nauseous and 'kneaded the mouth'. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000230	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			The aftertaste is chemical [DYSGEUSIA] N / Y / Y The chemical/nausea ing taste bothers me [NAUSEA] N / N / Y It makes me cough [COUGH] N / N / Y The chemical/nausea ing taste bothers me [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: It makes me cough, The chemical / nauseating taste bothers me, The aftertaste is chemical.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 33-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the chemical and nauseating taste of the product bothered her, that the aftertaste was chemical and the product made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000231	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Leaves the mouth very bitter/aftertaste really unpleasant [DYSGEUSIA] N / Y / Y Makes me nauseous [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-May-2014</p> <p>Case Narrative: Verbatim: Makes me nauseous, Leaves the mouth very bitter / aftertaste really unpleasant.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 31-MAY-2014: This report concerns a 32-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product left her mouth very bitter, that the aftertaste was really unpleasant and that the product made her nauseous. The events were considered to be non-serious. The outcome was unknown.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000232	ITALY Report From Study	24 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It makes me cough [COUGH] N / N / Y Tobacco is too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 02-Jun-2014</p> <p>Case Narrative: Verbatim: It makes me cough, Tobacco is too light.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at a central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 02-JUN-2014:</p> <p>This report concerns a 24-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made her cough and that the tobacco was too light. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000233	ITALY Report From Study	60 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			The taste it leaves in the mouth is bitter / leaves a taste of burnt straw in the mouth / aftertaste a bit bitter [DYSGEUSIA] N / Y / Y Causes a bit of cough [COUGH] N / N / Y It warms the throat [THROAT IRRITATION] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-May-2014</p> <p>Case Narrative: Verbatim: It warms the throat, Causes a bit of cough, The taste it leaves in the mouth is bitter / leaves a taste of burnt straw in the mouth / aftertaste a bit bitter.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at a central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 22-MAY-2014:</p> <p>This report concerns a 60-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product warmed her throat, caused a bit of cough and that the product left a bitter taste in the mouth / left a taste of burnt straw in the mouth / that the aftertaste was considered to be non-serious. The outcome was unknown.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000235	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			While smoking, I have chest pain [CHEST PAIN] N / Y / Y It is too strong/unpleasant [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 31-May-2014</p> <p>Case Narrative: Verbatim: While smoking I have chest pain, it is too strong/unpleasant.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 31-MAY-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong/unpleasant and that while smoking, she had chest pain. The events were considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							
PMI000236	ITALY Report From Study	28 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Gives me headache [HEADACHE] N / N / Y Taste too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Gives me headache, taste too strong.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 28-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of the product was too strong and it gave her headache. The events were considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000237	ITALY Report From Study	39 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Leaves a strange feeling of stomach cramp [ABDOMINAL PAIN UPPER] N / Y / Y	Unknown
Case Initial Receipt Date: 22-May-2014 Case Narrative: Verbatim: Leaves a strange feeling of stomach cramp. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 22-MAY-2014: This report concerns a 39-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product left a strange feeling of stomach cramp. The event was considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.							
PMI000238	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Sometimes I have headache [HEADACHE] N / N / Y It's very strong/not to be smoked often [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 28-May-2014 Case Narrative: Verbatim: It's very strong/not to be smoked often, sometimes I have headache. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 28-MAY-2014: This report concerns a 40-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was very strong, that sometimes he had headache and the product was not to be smoked often. The events were considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000239	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]			Sticks in the throat [THROAT IRRITATION] N / N / Y Gives headache [HEADACHE] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-May-2014 Case Narrative: Verbatim: Too strong, sticks in the throat, gives headache.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 28-MAY-2014: This report concerns a 36-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, that it stuck in her throat and gave her headache. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000240	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Ron) / Respiratory N/A UNK [UNK]			It made me nauseous, not very strong nausea but enough not to smoke 3 in a row [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-May-2014 Case Narrative: Verbatim: It made me nauseous, not very strong nausea but enough not to smoke 3 in a row.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 31-MAY-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made him nauseous and that the nausea was not very strong but enough not to smoke 3 sticks in a row. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000242	ITALY Report From Study	27 Years Male	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory		I feel it very much in the lungs [RESPIRATORY TRACT IRRITATION] N / Y / Y I feel it very much in the throat [THROAT IRRITATION] N / N / Y When inhaling, the taste is strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: When inhaling the taste is strong, I feel it very much in the lungs and also in the throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 27-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that when inhaling the taste of the product was strong, that he felt it very much in the lungs and also in the throat. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000244	ITALY Report From Study	50 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory		It has a "mechanic" taste, it does not stay in the mouth but goes directly in the pulmonary part, in the long run it was not pleasant anymore and it is very different from normal cigarettes [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: It has a "mechanic" taste, it does not stay in the mouth but goes directly in the pulmonary part, in the long run it was not pleasant anymore and it is very different from normal cigarettes.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 50-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product had a "mechanic" taste, that it did not stay in the mouth but went directly in the pulmonary part and in the long run, it was not pleasant anymore and it was very different from normal cigarettes.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The event was considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000245	ITALY Report From Study	61 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			When I smoke some of hem my throat itches [THROAT IRRITATION] N / N / Y Causing cough [COUGH] N / N / Y Too much flavoured [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 07-Jun-2014</p> <p>Case Narrative: Verbatim: Too much flavoured, when I smoke some of them my throat itches, causing cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JUN-2014: This report concerns a 61-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too much flavoured, that when she smoked some of them her throat itched, causing cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000246	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]				It caused nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jun-2014</p> <p>Case Narrative: Verbatim: It caused nausea.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JUN-2014: This report concerns a 26-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product caused nausea. The event was considered to be non-serious. The outcome was unknown.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000247	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It sticks in all airways [RESPIRATORY TRACT IRRITATION] N / Y / Y It sticks in my throat [THROAT IRRITATION] N / N / Y Too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Too light, it sticks in my throat and in all airways.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014:</p> <p>This report concerns a 38-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too light, it stuck in his throat and in all airways. The events were considered to be non-serious. The outcome was unknown.</p>								
No follow-up information has been requested ? case closed.								
PMI000248	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			I get hiccups, in fact I do not use light cigarettes for that reason [HICCUPS] N / N / Y It is too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014</p> <p>Case Narrative: Verbatim: It is too light, I get hiccups, in fact I do not use light cigarettes for that reason.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014:</p> <p>This report concerns a 28-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too light, that he got hiccups and that in fact, he did not use light cigarettes for that reason. The events were considered to be non-serious. The outcome was unknown.</p>								
No follow-up information has been requested ? case closed.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000249	ITALY Report From Study	42 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It makes me cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: It makes me cough. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 42-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made him cough. The event was considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								
PMI000250	ITALY Report From Study	46 Years Male	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]				It burnt my chest [CHEST PAIN] N / Y / Y Strange taste/bitterish taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 04-Jun-2014 Case Narrative: Verbatim: Strange taste/bitterish taste, it was burning my chest. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 46-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product had a strange taste/bitterish taste and it was burning his chest. The events were considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000251	ITALY Report From Study	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Makes me cough [COUGH] N / N / Y It tastes like paper [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014 Case Narrative: Verbatim: It tastes like paper, made me cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 47-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product tasted like paper and made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000252	ITALY Report From Study	45 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]			Excessively strong taste that remains in the throat and chest [RESPIRATORY TRACT IRRITATION] N / Y / Y Excessively strong taste that remains in the throat and chest [DYSGEUSIA] N / Y / Y Excessively strong taste that remains in the throat and chest [PRODUCT TASTE ABNORMAL] N / Y / Y Excessively strong taste that remains in the throat and chest [THROAT IRRITATION] N / N / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014 Case Narrative: Verbatim: Excessively strong taste that remains in the throat and chest.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 45-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that they had an excessively strong taste that remained in the throat and chest. The events were considered to be non-serious. The outcome was unknown.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000253	ITALY Report From Study	41 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It hurts my throat [OROPHARYNGEAL PAIN] N / N / Y While smoking, the taste has become cloying/spicy [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: While smoking, the taste has become cloying, spicy and it hurts my throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 41-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that while smoking, taste of the product became cloying, spicy and it hurt his throat. The events were considered to be non-serious. The outcome was unknown.</p>								
No follow-up information has been requested ? case closed.								
PMI000254	ITALY Report From Study	28 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			Nausea [NAUSEA] N / N / Y As I am smoking a lot, I am coughing all the time with this product [COUGH] N / N / Y It is like smoking hay/it's heavy. [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: Nausea, as I am smoking a lot I'm coughing all the time with this product, it is like smoking hay/it's heavy.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 28-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent experienced and reported that, as she was smoking a lot, she coughed all the time with the product and that it was like smoking hay/it was heavy. The events were considered to be non-serious.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							outcome was unknown.	
							No follow-up information has been requested ? case closed.	
PMI000255	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory			It itches the throat [THROAT IRRITATION] N / N / Y Makes me cough [COUGH] N / N / Y	Unknown
	<p>Case Initial Receipt Date: 07-Jun-2014</p> <p>Case Narrative: Verbatim: It itches the throat and makes me cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JUN-2014:</p> <p>This report concerns a 40-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product stung the throat and made him cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000256	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It gives a disgusting aftertaste [DYSGEUSIA] N / Y / Y It stings the chest [CHEST DISCOMFORT] N / N / Y It tastes like burning plastic [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
	<p>Case Initial Receipt Date: 29-May-2014</p> <p>Case Narrative: Verbatim: It stings the chest, it gives a disgusting aftertaste, it tastes like burning plastic.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 29-MAY-2014:</p> <p>This report concerns a 32-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product stung the chest, that it gave a disgusting aftertaste and it tasted like burning plastic. The events were considered to be non-serious. The outcome was unknown.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000257	ITALY Report From Study	64 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 05-Jun-2014 Case Narrative: Verbatim: It causes sensation of empty stomach.			It causes sensation of empty stomach [HUNGER] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 64-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the event caused sensation of empty stomach. The event was considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							
PMI000258	ITALY Report From Study	64 Years Male	THS 2.2 Regular (Ron) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 03-Jun-2014 Case Narrative: Verbatim: My voice decreased, It does not have the usual taste of a cigarette / it tastes like hay / I do not feel the tobacco at all.			My voice decreased [DYSPHONIA] N / Y / Y It does not have the usual taste of a cigarette / it tastes like hay / I do not feel the tobacco at all [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 64-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that his voice decreased and that the product did not have the usual taste of a cigarette / it tasted like hay / he did not feel the tobacco at all. The events were considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000261	ITALY Report From Study	32 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			I found it heavy on the chest [CHEST DISCOMFORT] N / N / Y It is not particularly aromatic [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: I found it heavy on the chest, it is not particularly aromatic.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 32-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product was heavy on the chest and it was not particularly aromatic. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000262	ITALY Report From Study	29 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			It gives me nausea [NAUSEA] N / N / Y Very bitter taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Very bitter taste, it gives me nausea.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 29-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product had a very bitter taste and gave him nausea. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000263	ITALY Report From Study	22 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Just finished smoking, I was coughing [COUGH] N / N / Y Taste too fresh / I do not feel it [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Taste too fresh/ I do not feel it, Just finished smoking I was coughing.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 22-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of the product was too fresh and that he did not feel it. When he just finished smoking, he was coughing. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000264	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It gives a feeling of nausea after smoking for a while [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014 Case Narrative: Verbatim: It gives a feeling of nausea after smoking for a while.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that this gave him a feeling of nausea after smoking for a while. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000265	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It gives me cough [COUGH] N / N / Y It itches the throat [THROAT IRRITATION] N / N / Y It has a taste of burnt/too bitter [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: It has a taste of burnt/too bitter, it gives me cough, it itches the throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product had a taste of burnt/was too bitter, it gave her cough and it itched her throat. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000266	ITALY Report From Study	39 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Over days it bothered me in the stomach [ABDOMINAL DISCOMFORT] N / Y / Y I found the taste more and more unpleasant [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Over days it bothered me in the stomach, I found the taste more and more unpleasant.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 39-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that over the days the product bothered her in the stomach and that she found the taste of the product more and more unpleasant. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000267	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	19-SEP-2014 to 23-SEP-2014	19-SEP-2014 19-SEP-2014 19-SEP-2014	Dull feeling in stomach [ABDOMINAL DISCOMFORT] N / Y / Y Aversion to the product [AVERSION] N / Y / Y Nausea after use of the product [NAUSEA] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 24-Sep-2014 Event Intensity: Moderate Moderate Moderate Case Narrative: Verbatim: Nausea after use of the product, dull feeling in stomach, aversion to the product.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 24-SEP-2014: This report concerns a 22-year-old female subject (Respondent Study ID: MU1748) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006689) on 19-Sep-2014. On the same day, experienced nausea after the use of the product. The nausea lasted about one hour. She also had a dull feeling in her stomach and felt an aversion to the product during the events were considered to be non-serious and moderate in intensity.</p> <p>The respondent used the product every day. On 19-Sep-2014, she used 5 sticks. On 20-Sep-2014, she used 2 sticks. On 21-Sep-2014, 22-Sep-2014 and 23-Sep-2014, she used 2 to sticks per day.</p> <p>The reported events improved when she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 23-Sep-2014. At the time of reporting, the events were ongoing.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000268	GERMANY Report From Study	19 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	24-SEP-2014 to 25-SEP-2014	24-SEP-2014	Strong headaches [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 25-Sep-2014 Event Intensity: Severe Event Stop Date: 25-SEP-2014 Case Narrative: Verbatim: Strong headaches.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 25-SEP-2014: This report concerns a 19-year-old female subject (Respondent Study ID: DR3774) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 15 cigarettes per day.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006150) on 24-Sep-2014. Immediately after one stick, she experienced strong headaches after the first inhalation. She tried again the product on 25-Sep-2014 in the morning and experienced headaches again. The event considered to be non-serious and severe in intensity.</p> <p>Out of the 2 sticks, she gave one to her father and her sister. She provided no information as to whether they, too, experienced any problems.</p> <p>On the day of the occurrence of the event, she smoked 4 cigarettes and used 1 stick. The reported event improved when she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 25-Sep-2014 and the event resolved on the same day.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000269	GERMANY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 25-Sep-2014 Event Intensity: Severe Event Stop Date: 23-SEP-2014 Case Narrative: Verbatim: Strong sore throat.	22-SEP-2014 to 24-SEP-2014	22-SEP-2014	Strong sore throat [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 25-SEP-2014: This report concerns a 53-year-old female subject (Respondent Study ID: DR3200) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 15 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006272) on 22-Sep-2014. On the same day, experienced strong sore throat after the first consumption. After the sore throat subsided, she tried the product again and the sore throat came back. The event was considered non-serious and severe in intensity.</p> <p>On the day of the occurrence of the event, the respondent used 2 sticks and smoked 5 cigarettes. The reported event improved when she stopped using the product and re-occurred when she restarted using the product. The event resolved on 23-Sep-2014. The respondent stopped using the product on 24-Sep-2014.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000270	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 26-Sep-2014 Event Intensity: Severe		19-SEP-2014 19-SEP-2014 19-SEP-2014 19-SEP-2014	General feeling of being unwell [MALAISE] N / Y / Y Unpleasant feeling in stomach escalating to nausea [ABDOMINAL DISCOMFORT] N / Y / Y Strong headache [HEADACHE] N / N / Y Unpleasant feeling in stomach escalating to nausea [NAUSEA] N / N / Y	Recovering/Resolving

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Severe Severe Severe					
			Case Narrative: Verbatim: General feeling of being unwell, unpleasant feeling in stomach escalating to nausea and strong headache.					
			Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.					
			INITIAL INFORMATION RECEIVED ON 26-SEP-2014: This report concerns a 22-year-old female subject (Respondent Study ID: MU5377) who took part in the above mentioned market research study.					
			The respondent had no medical conditions and was not taking any concomitant medications.					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. On 19-Sep-2014, she experienced general feeling of being unwell, unpleasant feeling in stomach escalating to nausea and strong headache. The events were considered to be non-serious and severe in intensity.					
			Upon due diligence, it was clarified that the respondent did not experience circulatory failure (as previously reported), did not faint due to the occurrence of these events, did not visit a doctor or hospital and did not receive any treatment.					
			The reported events improved when she stopped using the product.					
			No follow-up information has been requested ? case closed.					
PMI000271	GERMANY Report From Study	34 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	15-SEP-2014 to 25-SEP-2014	25-SEP-2014 25-SEP-2014	Unpleasant feeling in her stomach [ABDOMINAL DISCOMFORT] N / Y / Y Slight headache [HEADACHE] N / N / Y	Recovering/Resolving
			Case Initial Receipt Date: 26-Sep-2014 Event Intensity: Mild Mild					
			Case Narrative: Verbatim: Slight headache, unpleasant feeling in her stomach.					
			Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.					
			INITIAL INFORMATION RECEIVED ON 26-SEP-2014: This report concerns a 34-year-old female subject (Respondent Study ID: DR7911) who took part in the above mentioned market research study.					
			The respondent had no medical conditions and was not taking any concomitant medications.					
			The respondent was a daily smoker.					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (unspecified allocation arm; Kit number not provided) on 15-Sep-2014. The respondent used the product every day. On 25-Sep-2014, she experienced slight headache and unpleasant feeling in her stomach. The events were considered to be non-serious and mild in intensity.					
			The respondent stopped using the product on 25-Sep-2014 and at the time of this report, the reported events were improving.					
			No follow-up information has been requested ? case closed.					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
28-JAN-2015: Case re-opened to add product name. The respondent used THS 2.2 Regular (Dorado II / Ron) - half white tipping paper.							
PMI000274	ITALY	51 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	05-NOV-2014 to 05-NOV-2014	05-NOV-2014 05-NOV-2014	Stomachache [ABDOMINAL PAIN UPPER] N / Y / Y Headache [HEADACHE] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 12-Nov-2014 Event Intensity: Mild Mild Event Stop Date: 06-NOV-2014 06-NOV-2014 Case Narrative: Verbatim: Stomachache, Headache Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 12-NOV-2014: This report concerns a 51-year-old female subject (Respondent Study ID: B074) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. The respondent was a daily smoker who smoked on average 25 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number 92N4K4TDW84W) on 05-Nov-2014. She used 5 st on that day and experienced stomach ache and headache. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on the s day. The events resolved on 06-Nov-2014. No follow-up information has been requested ? case closed.							
PMI000275	SWITZERLAND	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	12-NOV-2014 to 13-NOV-2014	12-NOV-2014 12-NOV-2014	Increased heart rate [HEART RATE INCREASED] N / Y / Y feeling as if her chest area widens [CHEST DISCOMFORT] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 14-Nov-2014 Event Intensity: Severe Severe Case Narrative: Verbatim: Increased heart rate, Feeling as if her chest area widens Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 14-NOV-2014: This report concerns a 47-year-old female subject (Respondent Study ID: F176690) who took part in the above mentioned market research study. The respondent had no medical history and was not taking any concomitant medications or vitamins. The respondent was a daily smoker who smoked on average 20 cigarettes per day (140 cigarettes per month). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU008516) on 12-Nov-2014. On the same day,							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
experienced increased heart rate and felt as if her chest area widens. The events were considered to be non-serious and severe in intensity.								
The respondent used 2 sticks and she smoked 2 cigarettes on the day of the events. She also used the sticks on 13-Nov-2014 and stopped using the sticks on that same day. The reported events improved after the respondent discontinued the product and reoccurred when she used the sticks again. At the time of reporting, the events were resolved.								
No follow-up information has been requested ? case closed.								
PMI000276	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			16-NOV-2014 16-NOV-2014	Eructation [ERUCTION] N / Y / Y Unpleasant tobacco taste in mouth [DYSGEUSIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 16-Nov-2014								
Event Intensity: Mild								
Case Narrative: Verbatim: Eructation, unpleasant tobacco taste in mouth								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 16-NOV-2014:								
This report concerns a 45-year-old female subject (Respondent Study ID: F136909) who took part in the above mentioned market research study.								
The respondent had no medical history and was not taking any concomitant medications.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU004259) on an unspecified date. She reported she experienced eructation always about 20 minutes after the use of the stick. This was comparable to the type of eructation that occurred after the consumption of onions. she reported unpleasant tobacco taste in mouth. The events started on 16-Nov-2014. They were considered to be non-serious and mild in intensity.								
The respondent did not stop using the product and at the time of reporting, the events were ongoing. However, she wanted to quit the study.								
No follow-up information has been requested ? case closed.								
PMI000277	SWITZERLAND Report From Study	32 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]		14-NOV-2014 to 20-NOV-2014	14-NOV-2014 14-NOV-2014 14-NOV-2014 14-NOV-2014 14-NOV-2014	Burning sensation in lips [ORAL DISCOMFORT] N / Y / Y Burning sensation in mouth [ORAL DISCOMFORT] N / Y / Y Burning sensation in throat [THROAT IRRITATION] N / Y / Y Aftertaste [DYSGEUSIA] N / Y / Y Headache [HEADACHE] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 20-Nov-2014								
Event Intensity: Mild								
Mild								
Mild								
Mild								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Burning sensation in lips, mouth and throat, headache and aftertaste.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 20-NOV-2014: This report concerns a 32-year-old female subject (Respondent Study ID: F145851) who took part in the above mentioned market research study.</p> <p>The respondent had no medical history and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number C0003777) on 14-Nov-2014. On the same day, experienced burning sensation in lips, mouth up to the throat as well as aftertaste. She always washed the teeth after having smoked as the burning sensation was so strong. respondent also had headache and she thought this was due to the headsticks being stronger than the cigarettes she usually smoked. When she smoked her cigarettes, she did not experience any burning sensation. The events were considered to be non-serious and mild in intensity.</p> <p>The respondent used 3 sticks and smoked 3 cigarettes on the day of the events. She used the headsticks every day. The reported events improved after she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 20-Nov-2014.</p> <p>At the time of reporting, the events were ongoing.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000278	SWITZERLAND Report From Study	58 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]	17-NOV-2014 to 24-NOV-2014	17-NOV-2014 17-NOV-2014	Feels bad [FEELING ABNORMAL] N / Y / Y irritation in the mouth domain [STOMATITIS] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 25-Nov-2014</p> <p>Case Narrative: Verbatim: Feels bad, irritations in the mouth domain</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 25-NOV-2014: This report concerns a 58-year-old female subject (Respondent Study ID: F197579) who took part in the above mentioned market research study.</p> <p>The respondent had no medical history and was taking vitamins as concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 10-15 cigarettes per day (90 cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU003920) on 17-Nov-2014. Starting on the same day, the respondent felt bad and experienced irritations in the mouth domain. The events were considered to be non-serious (severity/intensity assessment of the reaction was not provided).</p> <p>The respondent used sticks every day. She had used 2 sticks and smoked 17 cigarettes on the days of the events. She stopped using the sticks on 24-Nov-2014. At the time of the events were not resolved.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000281	GERMANY Report From Study	23 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it itches [ORAL PRURITUS] N / Y / Y I became nauseated from it [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 19-Sep-2014 Case Narrative: Verbatim: it itches, I became nauseated from it</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior. INITIAL INFORMATION RECEIVED ON 19-SEP-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 23-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? lights; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it itches, it was not the same as a cigarette and she became nauseated from it.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000282	GERMANY Report From Study	58 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I feel sick [MALAISE] N / Y / Y I feel dizzy [DIZZINESS] N / N / Y I inhaled too strongly 2 x on the heat stick [WRONG TECHNIQUE IN PRODUCT USAGE PROCESS] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 02-Oct-2014 Case Followup Receipt Date: 11-Nov-2015 00:00 Case Narrative: Verbatim: I feel sick, I feel dizzy, I inhaled too strongly two times on the heatstick.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior. INITIAL INFORMATION RECEIVED ON 02-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 58-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified date.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent reported that she felt sick and dizzy. She also reported that apparently she inhaled too strongly two times on the heatstick and the heating unit became too the smoke was hot and unpleasant.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p> <p>NOTE: On 11-Nov-2015, the LLT Wrong technique in drug usage process has been recoded due to MedDRA 18.1 upgrade. Consequently, the PT for this event has been updated from Wrong technique in drug usage process to Wrong technique in product usage process. The other events with PTs Dizziness and Malaies have also been recoded in MedDRA 18.1 but no change applies to those terms.</p>							
PMI000283	GERMANY Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I was sick, bronchitis [BRONCHITIS] N / Y / Y I found that the sticks were stronger [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-Oct-2014 Case Narrative: Verbatim: I was sick, bronchitis; I found that the sticks were stronger.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that she was sick, bronchitis and that she found that the sticks were stronger (presumably stronger than normal cigarettes), therefore, she also smoked more normal cigarettes.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000284	GERMANY Report From Study	26 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 21-Oct-2014 Case Narrative: Verbatim: heatstick caused nausea			Heatstick caused nausea [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 21-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 26-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified d</p> <p>The respondent reported that heatstick caused nausea.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000285	GERMANY Report From Study	43 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 22-Oct-2014 Case Narrative: Verbatim: I was nauseated by the use of the heatstick; the smell of the heatstick was very unpleasant for me.			I was nauseated by the use of the Heat Stick [NAUSEA] N / N / Y the smell of the heats ick was very unpleasant for me [PRODUCT ODOUR ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 22-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 43-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspeci</p> <p>The respondent reported that she was nauseated by the use of the heatsticks, in particular in the morning, she could not tolerate them well. The smell of the heatstick was for her.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000286	GERMANY Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I developed headaches from the heatsticks [HEADACHE] N / N / Y didn't like the taste anymore [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 17-Oct-2014</p> <p>Case Narrative: Verbatim: I developed headaches from the heatsticks; didn't like the taste anymore</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 17-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she developed headaches from the heatsticks, and that after some time she didn' t like the taste anymore.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000287	GERMANY Report From Study	36 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Had to vomit [VOMITING] N / N / Y developed headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 20-Oct-2014</p> <p>Case Narrative: Verbatim: Had to vomit, developed headaches</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that he had to vomit and developed headaches after a short time.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000288	GERMANY Report From Study	24 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 20-Oct-2014 Case Narrative: Verbatim: Increased consumption of the tobacco stick led to a feeling of illness			increased consumption of the tobacco stick led to a feeling of illness [MALAISE] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 24-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that increased consumption of the tobacco stick led to a feeling of illness, therefore, he rather used regular cigarettes.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000289	GERMANY Report From Study	36 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 25-Oct-2014 Case Narrative: Verbatim: Felt a little nauseated from the heatsticks			felt a little nauseated from the heat sticks [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 25-OCT-2014 and transferred to safety department on 15-JAN-2015.</p>							

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 36-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she simply felt a little nauseated from the heatsticks.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000290	GERMANY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			feeling of 'heaviness in he lungs' [CHEST DISCOMFORT] N / Y / Y headache [HEADACHE] N / N / Y the heatsticks caused nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 28-Oct-2014</p> <p>Case Narrative: Verbatim: The heatsticks caused nausea, headache, feeling of "heaviness in the lung" .</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she just tolerate cigarettes better, the heatsticks caused nausea (headaches and a feeling of "heaviness in the lung").</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000291	GERMANY Report From Study	23 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I got headaches from the sticks [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 28-Oct-2014 Case Narrative: Verbatim: I got headaches from the sticks Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior. INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015. This report concerns a 23-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study. No medical conditions or concomitant medications were reported. Information about smoking habits was not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date. The respondent reported that he got headaches from the sticks. The event was considered to be non-serious (severity/intensity information not provided). The outcome of the event was not reported. No follow-up information has been requested ? case closed.							
PMI000292	GERMANY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			strange taste which almost made me nauseated [NAUSEA] N / N / Y it has a very strange , hard to describe taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 21-Oct-2014 Case Narrative: Verbatim: strange taste which almost made me nauseated, it has a very strange, hard to describe taste Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior. INITIAL INFORMATION RECEIVED ON 21-OCT-2014 and transferred to safety department on 15-JAN-2015. This report concerns a 28-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study. No medical conditions or concomitant medications were reported. Information about smoking habits was not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date. The respondent reported that it simply didn't taste like a cigarette, that it had a very strange, hard to describe taste, which almost made him nauseated.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The event was considered to be non-serious (severity/intensity information not provided).							
The outcome of the event was not reported.							
No follow-up information has been requested ? case closed.							
PMI000293	GERMANY Report From Study	62 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			strange aftertaste stays in your mouth for a long time [DYSGEUSIA] N / Y / Y smoke is very warm, which is unfamiliar and I found it concerning [DEVICE MALFUNCTION] N / Y / Y	Unknown
Case Initial Receipt Date: 28-Oct-2014							
Case Narrative: Verbatim: strange aftertaste stays in your mouth for a long time							
Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.							
INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.							
This report concerns a 62-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.							
No medical conditions or concomitant medications were reported.							
Information about smoking habits was not provided.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified date.							
The respondent reported that he did not like about the taste that it had a strange aftertaste, very atypical and it stayed in the mouth for a long time. He also reported that the smoke was very warm, which was unfamiliar and he found it concerning, since he didn't know what the consequences for his health could be.							
The event was considered to be non-serious (severity/intensity information not provided).							
The outcome of the event was not reported.							
No follow-up information has been requested ? case closed.							
PMI000294	GERMANY Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			leaves a bland taste in the mouth [DYSGEUSIA] N / Y / Y covers the nasal mucosa too much [NASAL DISCOMFORT] N / Y / Y I don't feel well [MALAISE] N / Y / Y	Unknown
Case Initial Receipt Date: 28-Oct-2014							
Case Narrative: Verbatim: leaves a bland taste in the mouth, covers the nasal mucosa too much, I don't feel well							
Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.							
INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 45-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? lights; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it leaves a bland taste in the mouth, that it covers the nasal mucosa too much and that she didn' t feel well. She also reported that one doesn't like smoking.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000295	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]				I sometimes get headaches [HEADACHE] N / N / Y I don't like the taste because it is so strange and nondescript [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 14-Oct-2014</p> <p>Case Narrative: Verbatim: I sometimes get headaches; I don't like the taste because it is so strange and nondescript.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 14-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that she didn' t like the smell, because it was so strange and nondescript. She did not associate that with a cigarette. When she smoked these sticks she sometimes even got headaches.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000296	GERMANY Report From Study	36 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			burning in the eyes [EYE IRRITATION] N / Y / Y was pungent, obtrusive [ORAL DISCOMFORT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 20-Oct-2014 Case Narrative: Verbatim: was pungent, obtrusive; burning in the eyes</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it was pungent, obtrusive, even burning in the eyes.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000305	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Feeling of nausea after consuming a good number of sticks [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014 Case Narrative: Verbatim: Feeling of nausea after consuming a good number of sticks.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product gave her a feeling of nausea after consuming a good number of sticks. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000330	RUSSIAN FEDERATION Report From Study	37 Years Male	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Headache Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage. INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015. This report concerns a 37-year-old male subject (Respondent Study ID: b2350) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The consumer was a daily smoker, approximately 30 marketed cigarettes (MC) per day and used on average 7 MC and 22 heatsticks per day during the study period. The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration. On an unspecified date, the consumer experienced headache. The event was considered to be non-serious. Severity grade was not provided. Action taken with the product was not reported. The outcome of the event was not provided. No follow-up information is expected ? case closed.							
PMI000331	RUSSIAN FEDERATION Report From Study	32 Years Female	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Cough Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage. INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015. This report concerns a 32-year-old female subject (Respondent Study ID: b8228) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The consumer was a daily smoker, approximately 15 marketed cigarettes (MC) per day, and used on average 9 MC and 7 heatsticks per day during the study period. The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration. On an unspecified date, the consumer experienced cough. The event was considered to be non-serious. Severity grade was not provided. Action taken with the product was not reported.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not provided.							
No follow-up information is expected ? case closed.							
PMI000332	RUSSIAN FEDERATION Report From Study	33 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Burning feeling in throat [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: burning feeling in throat							
Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.							
INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.							
This report concerns a 33-year-old male subject (Respondent Study ID: b8551) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
The consumer was a daily smoker, approximately 10 marketed cigarettes (MC) per day, and used on average 7 MC and 2 heatsticks per day during the study period.							
The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.							
On an unspecified date, the consumer experienced burning feeling in throat. The event was considered to be non-serious. Severity grade was not provided.							
Action taken with the product was not reported.							
The outcome of the event was not provided.							
No follow-up information is expected ? case closed.							
PMI000333	RUSSIAN FEDERATION Report From Study	25 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Nausea							
Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.							
INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.							
This report concerns a 25-year-old male subject (Respondent Study ID: b8219) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
The consumer was a daily smoker, approximately 12 marketed cigarettes (MC) per day, and used oin average 1 MC and 2 heatsticks per day during the study period.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced nausea. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000334	RUSSIAN FEDERATION Report From Study	44 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Unpleasant taste in throat [DYSGEUSIA] N / Y / Y Headache [HEADACHE] N / N / Y Dizziness [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Headache, dizziness, unpleasant taste in throat.</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 44-year-old male subject (Respondent Study ID: m8718) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 7 marketed cigarettes (MC) per day, and used on average 5 MC and 22 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced headache, dizziness, and unpleasant taste in throat. The events were considered to be non-serious. Severity grade was not p</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the events was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000335	RUSSIAN FEDERATION Report From Study	25 Years Female	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 30-Aug-2015 Case Narrative: Verbatim: Nausea</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Aug-2015 and forwarded to Safety department on 15-Sep-2015.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 25-year-old female subject (Respondent Study ID: m4518) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 6 marketed cigarettes (MC) per day, and used on average 5 MC and 2 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced nausea. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000336	RUSSIAN FEDERATION Report From Study	26 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Dizziness [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 30-Aug-2015 Case Narrative: Verbatim: Dizziness</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Aug-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 26-year-old male subject (Respondent Study ID: m9779) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 20 marketed cigarettes (MC) per day, and used on average 12 MC and 2 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced dizziness. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000341	UNITED STATES Report From Study	26 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] UNK [UNK]	Respiratory Respiratory	01-OCT-2015 to Unknown 01-OCT-2015 to 26-OCT-2015	03-OCT-2015 03-OCT-2015 2015 03-OCT-2015	I have a blister on my lip [LIP BLISTER] N / Y / Y chemical burn or machine heated up too hot and created blisters [BURNS SECOND DEGREE] N / Y / Y burns on hands [THERMAL BURN] N / Y / Y machine heated up too hot [DEVICE ISSUE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 10-Oct-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 27-Oct-2015 00:00 Event Intensity: Moderate Moderate Event Stop Date: 23-OCT-2015 23-OCT-2015 23-OCT-2015 Case Narrative: Verbatim: I have a blister on my lip, chemical burn or machine heated up too hot and created blisters, burns on hands. Machine heated up too hot.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 10-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID: 828735) who took part in the above mentioned market research study.</p> <p>The subject's medical history included heart disease (POTS), hypothyroid, adrenal insufficiency, low blood pressure and fibromyalgia. The following concomitant medications were reported: Inderal (propranolol hydrochloride), "Sansept", Ambien (zolpidem tartrate), Adderall (amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate), "Florisus", Klonopin (clonazepam), "Xanaflax", Bactrim (sulfamethoxazole, trimethoprim) and Zofran (ondansetron hydrochloride), doses, treatment dates and indications not provided.</p> <p>The respondent was a daily smoker (approximately 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (Kit number BCCJD1TSDDW) on 07-Oct-2015.</p> <p>On 08-Oct-2015, the respondent had a blister on her lip. The respondent mentioned that she was not sure if it was from the THS or from her regular cigarettes and smoking it too close to the filter. She went to see her doctor to have it looked at because she thought it might be herpes. The respondent said her doctor told her it was a blister caused by a burn and that it could have been caused by smoking a cigarette too close to the filter. She has not had a blister like this before and only noticed the blister after she had started using the IQOS device.</p> <p>The event severity was reported as moderate and required medical advice on 09-Oct-2015. The event was considered to be non-serious.</p> <p>The respondent used the Heatsticks occasionally and used one stick on the day of the event. The event did not improve when usage of the product was stopped and the product was not restarted.</p> <p>At time of reporting, the respondent had not recovered.</p> <p>No follow-up information is expected. Case closed.</p> <p>FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day.</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Verbatim: chemical burn or machine heated up too hot and created blisters.</p> <p>No additional medical history was reported. The following additional concomitant medications were reported: "Florines", "Coonevpan" and Fanapt (dosages, indications, treatment dates not provided).</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day, previously reported as 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 01-Oct-2015 (previously reported as 07-Oct-2015).</p> <p>The respondent reported that on 03-Oct-2015, she experienced chemical burn, or the machine heated up too hot and created a blister (previously reported as blister on my lip).</p> <p>The events' severity was reported as moderate. The events were considered to be non-serious.</p> <p>The respondent used the product every day (2 heatsticks and 5 conventional cigarettes on the day of the event).</p> <p>It was reported that the events improved when usage of the product was stopped and returned when the product was restarted (dates not further specified).</p> <p>Last day of product usage was indicated as 26-Oct-2015. However, the final action taken with the product was unknown.</p> <p>The events resolved on 23-Oct-2015.</p> <p>FOLLOW-UP INFORMATION WAS RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>Burns on hands were reported (no further information provided).</p> <p>No follow-up information is expected. Case closed.</p>							
PMI000346	UNITED STATES Report From Study	27 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [1 DF-UNK]	11-OCT-2015 to 11-OCT-2015	OCT-2015 16-OCT-2015 11-OCT-2015 11-OCT-2015 11-OCT-2015	she has a bad sinus infection [SINUSITIS] N / Y / Y she came down with a cold [NASOPHARYNGITIS] N / N / Y she took one puff of her first Heatstick and within 1 minute she threw up. [VOMITING] N / N / Y She stated that she was nauseated most of the day, and a lit le bit nauseated on 12/Oct/2015. [NAUSEA] N / N / Y The participant has not used another Heatstick since 11/Oct/2015 because the holder is stuck in the charger and she cannot get it out. [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 17-Oct-2015 Case Followup Receipt Date: 19-Oct-2015 00:00 21-Oct-2015 00:00 Event Intensity: Moderate Moderate Moderate Mild</p>							

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome	
			Event Stop Date: 11-OCT-2015 13-OCT-2015 Case Narrative: Verbatim: Initial information: Participant stated that, on 11-Oct-2015, she took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated most of the day, and a little bit nauseated on 12-Oct-2015. She stated she was not nauseated 13-Oct-2015. She also stated that she came down with a cold 16-Oct-2015, which has not resolved. She is all congested, and she is coughing now and then. The participant has not used another Heatstick since 11-Oct-2015 because the holder is stuck in the charger and she cannot get it out. Follow-up #1 information: Participant called in today, 19-Oct-2015, stating she was still not feeling well. She stated she still had her cold and was coughing, and would not be able to come to the enrollment center today to pick up her new IQOS device. During the call, she stated the onset date of her cold was 16-Oct-2015. Follow-up #2 information: Participant called in today, 21-Oct-2015, to report her cold has not resolved and she is still sick. She reported to experiencing the following cold symptoms: her whole head hurts, sneezing, headaches, and head is pounding. The participant also reported she has a bad sinus infection. Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 17-Oct-2015 and forwarded to Safety department on the same day. Additional information to the case was received on 19-Oct-2015 and on 21-Oct-2015. This report concerns a 27-year-old female subject (Respondent Study ID: 188110) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The respondent was a daily smoker (approximately 5 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 11-Oct-2015. On 11-Oct-2015, the respondent took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated most of the day, and a little bit nauseated on 12-Oct-2015. She came down with a cold on 16-Oct-2015. Symptoms of the cold included head congestion/head hurting, coughing now and then, sneezing, headaches, and pounding on her head. The participant also reported she had a bad sinus infection. She had not used another Heatstick since 11-Oct-2015 because the holder was stuck in the charger and she could not get it out. The events severity was reported as moderate on 17-Oct-2015 and 19-Oct-2015, and as mild on 21-Oct-2015. The events were considered to be non-serious. The respondent used the heatstick occasionally (once - she used 1 heatstick) and 2 conventional cigarettes on 11-Oct-2015. The events vomiting and nausea improved/stopped when usage of the product was stopped, and the other reported events did not improve when usage of product was stopped. The product was not restarted. The respondent took ibuprofen and a lot of juice. The outcome of the events were reported as 'not recovered'. However, the respondent mentioned that her vomiting resolved on 11-Oct-2015 and she was not nauseated on 13-Oct-2015. No follow-up information is expected ? case closed.						

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000349	UNITED STATES Report From Study	61 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [qd]	Respiratory	12-OCT-2015 to Unknown	12-OCT-2015 12-OCT-2015	it burns her lips/she experiences the burning of her lips each time she uses the device [ORAL DISCOMFORT] N / Y / Y the HeatStick holder itself is often too hot to hold [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 19-Oct-2015 Event Intensity: Mild Case Narrative: Verbatim: The participant stated that, while using the IQOS, she does not puff that heavy, but reported it burns her lips. Participant stated the HeatStick holder itself is too hot to hold. Participant stated she experiences the burning of her lips each time she uses the device. Participant reported the events resolve after she stops using the device.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Oct-2015 and forwarded to Safety department on 20-Oct-2015.</p> <p>This report concerns a 61-year-old female subject (Respondent Study ID: 823066) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Unspecified pain medication was reported as concomitant medication, for spine problem (NOS).</p> <p>The respondent was a daily smoker (approximately 20-30 conventional cigarettes per day). The respondent reported she was a heavy smoker. When asked how many cigarettes she smokes per day, she stated "nearly 1 per minute".</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 60JNA8677NVS) on 12-Oct-2015.</p> <p>On 12-Oct-2015, the respondent experienced burning on her lips. She mentioned that she experienced this each time she used the device. In addition, she also reported that the device was often too hot to hold.</p> <p>The event's severity was reported as mild. The events were considered to be non-serious.</p> <p>The respondent used the Heatsticks every day. She used 7 Heatsticks and 15 cigarettes on the day of the event. The event improved when usage of the product was stopped and returned when the product was restarted.</p> <p>Action taken with study product is unknown.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000359	UNITED STATES Report From Study	41 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [qd]	Respiratory	26-SEP-2015 to 25-OCT-2015	14-OCT-2015 14-OCT-2015	He had to draw hard on the product to smoke it and the sucking gave him a headache / he continued to only smoke the product in the evenings, and each evening he got a headache [HEADACHE] N / N / Y He had to draw hard on the product to smoke it [DEVICE DIFFICULT TO USE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Mild</p>								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Event Stop Date: 25-OCT-2015</p> <p>Case Narrative: Verbatim: He stated that he had to draw hard on the product to smoke it and the sucking gave him a headache. Each subsequent day, he continued to only smoke the product in evenings, and each evening he got a headache.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 41-year-old male subject (Respondent Study ID: 532578) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 30 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number VV5VYCF2F8KP) on 26-Sep-2015.</p> <p>The participant started using the product on 26-Sep-2015, during the day and evening, as well as conventional cigarettes. He did not experience headaches during that time. 14-Oct-2015, he stopped using the product during the day, and began to use the product only in the evening (no conventional cigarettes in the evening). He continued to smoke conventional cigarettes during the day. On 14-Oct-2015, he had a headache by the time he went to bed. He stated that he had to draw hard on the product to smoke it and the gave him a headache. He reported he had no headache when he woke up. Each subsequent day, he continued to only use the product in the evenings, and each evening he got a headache. On 25-Oct-2015, he stated that he realized using the product was giving him the headaches. He had used 1 or 2 that evening when he realized the connection, he did use the product anymore and he did not get a headache.</p> <p>The events severity were reported as mild. The events were considered to be non-serious.</p> <p>The consumer used the Heatsticks every day (8-9 sticks per day) in combination with about 20 cigarettes per day.</p> <p>The participant discontinued the use of the product on 25-Oct-2015.</p> <p>The event resolved on 25-Oct-2015.</p> <p>No follow-up information is expected ? case closed. ?</p>								
PMI000361	UNITED STATES Report From Study	22 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	27-OCT-2015	his chest was hurting real bad [CHEST PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	26-OCT-2015 25-OCT-2015 25-OCT-2015	he started coughing up green stuff [SPUTUM DISCOLOURED] N / Y / Y As he smoked more of the product, it was like it was pulling air out of his lungs [CHEST DISCOMFORT] N / N / Y each time he smoked, he would cough [COUGH] N / N / Y	
			<p>Case Initial Receipt Date: 27-Oct-2015</p> <p>Event Intensity: Moderate Moderate Moderate Moderate</p>					

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: He stated that at first the smoking experience wasn't so bad, but then as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 27-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 22-year-old male subject (Respondent Study ID: 751825) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (approximately 15-20 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit numbers (01)5410706815337, (21)MHZKNOLUZYZR, (240)DK000024.01) on 25-Oct-2015.</p> <p>On 25-Oct-2015, the study respondent started using the product. He stated that, at first, the smoking experience wasn't so bad, but then, as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that, each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down. The participant stated the menthol caused the problem more than the regular flavor.</p> <p>The events severity was reported as moderate. The events were considered to be non-serious.</p> <p>The consumer used the Heatsticks every day. He used 10 Heatsticks and 10 cigarettes on the day of the events.</p> <p>The respondent stopped using the product on 27-Oct-2015. The events improved when usage of the products was stopped. The products were not restarted.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000370	UNITED STATES Report From Study	53 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	22-OCT-2015 to Unknown	25-OCT-2015	flu; started feeling off (NOS) on 25/OCT/2015; symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea) [INFLUENZA] N / Y / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 04-Nov-2015 Case Followup Receipt Date: 16-Nov-2015 00:00 Event Intensity: Severe Event Stop Date: NOV-2015 Case Narrative: Verbatim: he had had the flu (NOS) for the past week</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 04-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 53-year-old male subject (Respondent Study ID: 655433) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history was reported. No concomitant medication was reported.</p> <p>No information was provided regarding the respondent's smoking status.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number R8D4R2EWDD22) on an unknown date.</p> <p>The respondent stated that he started "feeling off" on 25-Oct-2015. He reported that he did not smoke while he had the flu and when he stopped using the product (date unknown) it was easier to breathe. He stated that he was seen by a doctor before 31-Oct-2015 (exact date unknown). The respondent was administered an inhaler and antibiotics (NOS).</p> <p>The event severity was reported as severe. The events were assessed as non-serious.</p> <p>The respondent used the Heatsticks every day. The number of Heatsticks and cigarettes used on the day of the event was not reported.</p> <p>It was reported that the event improved when usage of the product was stopped (stop date unknown). The product was not restarted.</p> <p>At time of reporting, the event was not resolved.</p> <p>Follow-up information will be requested.</p> <p>FOLLOW-UP INFORMATION RECEIVED on 16-Nov-2015 and forwarded to Safety department on the same day.</p> <p>Start date of the product THS 2.2 Regular (Dorado II / Ron) was reported as 22-Oct-2015.</p> <p>The participant stated that, for influenza, he was not formally diagnosed by a doctor. The participant stated that he was unsure when the symptoms began but believes that they began at the end of October 2015 (previously reported as 25-Oct-2015). The symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea). The participant denied using any medication to treat his flu related symptoms, opting to stay home.</p> <p>When asked about his previously reported symptom of breathlessness (dyspnea), the participant clarified that he had a prior history of asthma, for which he had been prescribed the as-needed inhaled medication ProAir (salbutamol sulfate) inhaled. Participant reported no other relevant medical history within the last year and denies using antibiotics or any other medications.</p> <p>The participant reported that the symptoms of alternating hot and cold sensation, sweating, exhaustion, loss of appetite, and breathlessness (dyspnea) resolved two weeks after onset; exact date is unknown. The symptom of weakness is ongoing, with an 80% subjective improvement reported by participant.</p> <p>No further information is expected. Case closed.</p>								
PMI000372	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			gave me headaches [HEADACHE] N / N / Y didn't like the taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory				
			Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: gave me headaches; didn't like the taste.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a female subject born in 1959 (Respondent Study ID: 181262) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) on an unspecified date (kit number).</p> <p>The respondent stated that the use of the device gave her headaches and that she didn't like its taste.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and conventionnal cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the drug was provided.</p> <p>At time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000380	UNITED STATES	49 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]		07-OCT-2015 to 07-NOV-2015	31-OCT-2015 31-OCT-2015	Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [MALAISE] N / Y / Y Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [ABDOMINAL DISCOMFORT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 09-Nov-2015 Event Intensity: Mild Mild Event Stop Date: 02-NOV-2015 02-NOV-2015 Case Narrative: Verbatim: Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on he same day.</p> <p>This report concerns a 49-year-old male subject (Respondent Study ID: 650328) who took part in the above mentioned market research study.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The following medical history was reported: high blood pressure (additional information not provided). The following concomitant medication was reported: lisinopril (additional information not reported).</p> <p>The respondent was a daily smoker (approximately 30 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 07-Oct-2015.</p> <p>On 31-Oct-2015, the respondent reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks. He is still smoking conventional cigarettes, and does not have the same sick feeling as he did after using the HeatSticks.</p> <p>The events severity was reported as mild. The events were assessed as non-serious.</p> <p>The respondent used the Heatsticks every day. He used 5 Heatsticks and 20 cigarettes on the day of the events.</p> <p>The events improved when usage of the product was stopped. The events reoccurred when the product was restarted. The last day of product use was on 07-Nov-2015 (final action taken with study product unknown).</p> <p>The events resolved on 02-Nov-2015.</p> <p>No further information is expected. Case closed.</p>								
PMI000398	UNITED STATES	33 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	19-AUG-2015 to 26-OCT-2015	2015 16-OCT-2015 16-OCT-2015 16-OCT-2015	make me sick [MALAISE] N / Y / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [HEADACHE] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [DIZZINESS] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 16-Nov-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Moderate Moderate Moderate Event Stop Date: 26-OCT-2015 26-OCT-2015 26-OCT-2015 Case Narrative: Verbatim: Participant reported headaches, lightheadedness, and nausea while using HeatSticks. Make me sick.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 17-Nov-2015.</p> <p>This report concerns a 34-year-old male subject (Respondent Study ID: 180716) who took part in the above mentioned market research study.</p> <p>Medical history was not reported. Concomitant medication was not reported.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number TE3HH5DSY0VWGD) on 19-Aug-2015.</p> <p>On 16-Oct-2015, the respondent experienced headaches, lightheadedness and nausea while using HeatS icks.</p> <p>The events severity was reported as moderate. The events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. He mentioned that he was a light smoker overall and did not further specify. He used 3 Heatsticks and 2 cigarettes on the day of the events.</p> <p>The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 26-Oct-2015.</p> <p>The events resolved on 26-Oct-2015.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>The study respondent mentioned that the product made him sick. No fur her information was given.</p> <p>No further information is expected. Case closed.</p>								
PMI000400	UNITED STATES Report From Study	57 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	17-OCT-2015 to 19-NOV-2015	17-OCT-2015 17-OCT-2015 17-OCT-2015 19-NOV-2015	tastes an aftertaste [DYSGEUSIA] N / Y / Y it makes her gag [RETCHING] N / Y / Y she feels sick to her stomach / feels like she wants to throw up [NAUSEA] N / N / Y she also noticed a headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 19-Nov-2015</p> <p>Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Event Stop Date: 19-NOV-2015 19-NOV-2015 19-NOV-2015 19-NOV-2015</p> <p>Case Narrative: Verbatim: tastes an aftertaste / it makes her gag / she feels sick to her stomach / feels like she wants to throw up / she also noticed a headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Nov-2015 and forwarded to Safety department on he same day.</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID: 200663) who took part in the above mentioned market research study.</p> <p>Medical history of allergies, high blood pressure, eczema, deaf in left ear was reported (no further information provided). The following concomitant medications were reported: Benadryl</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>(diphenhydramine hydrochloride), Lisinopril, Ranitidine (ranitidine hydrochloride), Loratadine, Hydrocortisone, Bactroban ointment (mupirocin calcium) (no further information provided).</p> <p>The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number PPQ30Z3MGJ47) on 17-Oct-2015.</p> <p>The respondent stated that, every time she smoked a heatstick, she tasted an aftertaste and it made her gag. While smoking the heatsticks, she felt sick to her stomach and felt like she wanted to throw up. On 19-Nov-2015, she also noticed a headache, after using the heatsticks.</p> <p>The events' severity was reported as moderate. The events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. She used the heatstick when she didn't have any cigarettes. The respondent used 3 Heatsticks and 3 cigarettes on the day of the event (presumably event of headache, occurring on 19-Nov-2015).</p> <p>The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 19-Nov-2015.</p> <p>The events resolved on 19-Nov-2015.</p> <p>No further information is expected. Case closed.</p>								
PMI000401	UNITED STATES Report From Study	45 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 19-Nov-2015 Event Intensity: Mild Event Stop Date: 15-OCT-2015 Case Narrative: Verbatim: throat burn	Respiratory	08-OCT-2015 to 15-OCT-2015	10-OCT-2015	throat burn [THROAT IRRITATION] N / Y / Y	Recovered/Resolved
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Nov-2015 and forwarded to Safety department on 20-Nov-2015.</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID: 188933) who took part in the above mentioned market research study.</p> <p>No medical history was reported. It was reported that the respondent took as concomitant medication vitamins once a day (no further information provided).</p> <p>The respondent was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number SQ9 ZUA GHS M5A) on 08-Oct-2015.</p> <p>On 10-Oct-2015, when he inhaled the smoke, the respondent experienced throat burn while using Heats icks, which lasted about 5 minutes.</p> <p>The severity of the event was reported as mild. The event was assessed as non-serious.</p> <p>The respondent used the heatsticks every day. The respondent used 4 heatsticks and 20 cigarettes on the day of the event.</p> <p>The event improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 15-Oct-2015.</p> <p>The event resolved on 15-Oct-2015.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected. Case closed.								
PMI000407	UNITED STATES Report From Study	27 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] UNK [UNK]	Respiratory	17-OCT-2015 to 11-NOV-2015	10-NOV-2015 10-NOV-2015	strep throat [PHARYNGITIS STREPTOCOCCAL] N / Y / Y respiratory infection [RESPIRATORY TRACT INFECTION] N / Y / Y	Recovered/Resolved
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] UNK [UNK]	Respiratory	2015 to 11-NOV-2015 17-NOV-2015 to Unknown			
Case Initial Receipt Date: 24-Nov-2015 Event Intensity: Severe Severe Event Stop Date: 17-NOV-2015 17-NOV-2015 Case Narrative: Verbatim: strep throat / respiratory infection								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 24-Nov-2015 and forwarded to Safety department on the same day.								
This report concerns a 27-year-old female subject (Respondent Study ID: 185638) who took part in the above mentioned market research study.								
No medical history and no concomitant medication were reported.								
The respondent was a daily smoker (approximately 10 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and Regular (Dorado II / Ron) (kit number 6USB5XGJ3YD1) on 17-Oct-2015. She started with menthol and then switched to regular (date not provided).								
The respondent stated that she had strep throat and a respiratory infection which began on 10-Nov-2015. On (b) (6), she saw a doctor at the hospital who did a test for strep throat which was positive. The doctor also told her she had a respiratory infection (NOS). The doctor told her she could not smoke. The doctor gave her amoxicillin and a shot (NOS) in her buttock, as treatment for the events.								
The events severity was reported as severe and required medical advice on (b) (6) and treatment (dates unspecified). The events were assessed as non-serious.								
The respondent used the heatsticks every day, except for when prohibited by doctor. The respondent used 1 Heatstick and 0 cigarette on the day of the event.								
The events improved when usage of the product was stopped, and did not return when use of the product was restarted. The last day of product use was on 24-Nov-2015 (day of reporting). No further information was reported regarding the final action taken with the product.								
The events resolved on 17-Nov-2015, when the respondent was told she could return to work and smoking.								
No further information is expected. Case closed.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000483	UNITED STATES Report From Study	30 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	SEP-2015 to DEC-2015	10-JAN-2016	Pregnancy [MATERNAL EXPOSURE T MING UNSPECIFIED] N / Y / N	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	SEP-2015 to DEC-2015			
			Case Initial Receipt Date: 03-Feb-2016 Case Followup Receipt Date: 16-Feb-2016 00:00 Case Comment Text: Maternal exposure timing unspecified was assessed as non-serious.					
			Expectedness and causality assessments are not applicable for Maternal exposure timing unspecified. However, expectedness for Maternal exposure timing unspecified has been captured as unlisted, by default, in the safety database.					
			No adverse events were reported in association with Maternal exposure timing unspecified.					
			This pregnancy report shall be followed-up until an outcome is reached, as per protocol.					
			Case Narrative: Verbatim: Pregnancy					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 03-FEB-2016 and forwarded to Safety department on 05-FEB-2016.					
			This report concerns a 30-year-old female subject (Respondent Study ID: 751296) who took part in the above mentioned market research study.					
			No medical history and no concomitant medication were reported.					
			The respondent was a daily smoker (approximately 2 conventional cigarettes per day).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and Regular (Dorado II / Ron) (kit numbers not provided) on an unknown date in Sep-2015.					
			The respondent reported a pregnancy. Date of awareness of pregnancy was 10-Jan-2016. Last menstrual period was in Dec-2015 (not further specified). The pregnancy was confirmed by a HCP. Delivery date was uncertain. It was reported that the respondent was not using any contraception at time of report. The respondent had one previous pregnancy and one delivery (no therapeutic or planned abortion).					
			The study respondent used the THS products up to an unspecified date in Dec-2015 (prior to awareness of pregnancy).					
			Further information is expected.					
			FOLLOW-UP INFORMATION received on 16-Feb-2016 and forwarded to Safety Department on 17-Feb-2016.					
			The following kit number was provided: V4P4S3WB2REL (not specified if it corresponds to THS 2.2 Regular or Menthol. Start date of product use was reported as Sep-2015, with a comment that the study participant was unsure of exact date and stated it took place at end the month. The respondent's eDiary entries showed initial recorded use of IQOS device on 26-Oct-2015 (Enrollment center issued kit on 26-Oct-2015).					
			The product stop date was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place at beginning of month. The respondent's					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>eDiary entries showed that the last date of recorded use was 08-Dec-2015.</p> <p>First day of last menstrual period was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place in middle of month.</p> <p>Estimated delivery date was reported as 28-Aug-2016.</p> <p>Participant denied history of any ongoing medical conditions, for which she was seeing a healthcare professional, for which she was taking medications, or for which she was previously assessed.</p> <p>Participant reported that initial doctor visit on 10-Jan-2016 resulted in a blood test which confirmed pregnancy (follow-up appointment with her doctor was scheduled on 18-Feb-2016).</p> <p>Further information is expected.</p>								
PMI000587	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	gave me a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015</p> <p>Case Narrative: Verbatim: gave me a headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 56-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 351173) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gave him a headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000588	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]	2015 to Unknown	2015	gave me headache [HEADACHE]	Unknown
					2015	N / N / Y bad taste lingered for hours, everything afterwards had that taste still [DYSGEUSIA]	
					2015	N / Y / Y bad taste [PRODUCT QUALITY ISSUE] N / Y / N	
Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: bad taste, gave me headache, bad taste lingered for hours, everything afterwards had that taste still. Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 46-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 820835) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (conventional cigarettes and heatsticks). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date. The respondent stated that the product gave him a headache. In addition, he mentioned that the product had a bad taste, the bad taste lingered for hours, everything afterwards had that taste still. The severity of the events was not reported. The events were assessed as non-serious. The outcome of the events were not reported. Action taken with the THS product was not reported. No further information is expected. Case closed.							
PMI000591	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]	2015 to Unknown	2015	Tobacco is stronger, hurts my chest [CHEST PAIN]	Unknown
					2015	N / Y / Y Tobacco is stronger, hurts my chest [PRODUCT QUALITY ISSUE] N / Y / N	
Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: tobacco is stronger, hurts my chest Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 39-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 355431) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the tobacco was stronger, and hurt his chest.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000592	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Got sick [MALAISE] N / Y / Y	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: got sick</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 21-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 458445) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p> <p>The respondent stated that she got sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000594	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	it makes me feel sick [MALAISE] N / Y / Y	Unknown
Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: it makes me feel sick Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 20-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 202403) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (conventional cigarettes and heatsticks). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unreported date. The respondent stated that the product made her feel sick. The severity of the event was not reported. The event was assessed as non-serious. The outcome of the event was not reported. Action taken with the THS product was not reported. No further information is expected. Case closed.								
PMI000598	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	It gave me a headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: It gave me a headache. Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 25-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 658140) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (conventional cigarettes and heatsticks). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date. The respondent stated that the product gave him a headache.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The severity of the event was not reported. The event was assessed as non-serious.								
The outcome of the event was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
PMI000599	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Sick [MALAISE] N / Y / Y	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Case Initial Receipt Date: 23-Nov-2015					
			Case Narrative: Verbatim: sick					
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.								
This report concerns a 23-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 757519) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.								
The respondent reported: "sick".								
The severity of the event was not reported. The event was assessed as non-serious.								
The outcome of the event was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome		
PMI000600	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	breathing trouble [DYSPNOEA] N / Y / Y	Unknown		
						2015	Sore throat [OROPHARYNGEAL PAIN] N / N / Y			
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown					
			Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sore throat, breathing trouble							
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.							
			INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.							
			This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 181832) who took part in the above mentioned market research study.							
			No medical history was reported. No concomitant medication was reported.							
			No information on smoking habits was reported (conventional cigarettes and heatsticks).							
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.							
			The respondent reported sore hroat and breathing trouble.							
			The severity of the events was not reported. The events were assessed as non-serious.							
			The outcome of the events was not reported.							
			Action taken with the THS product was not reported.							
No further information is expected. Case closed.										
PMI000603	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	I think they were giving me an upset stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown		
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown					
			Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: I think hey were giving me an upset stomach							
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.							
			INITIAL INFORMATION RECEIVED ON 07-Dec-2015 and forwarded to Safety department on 05-Apr-2016.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
This report concerns a 58-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 650514) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.								
The respondent stated that she thought the heatsticks were giving her an upset stomach.								
The severity of the event was not reported. The event was assessed as non-serious.								
The outcome of the event was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
Yes (5)								
PMI000109	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	17-APR-2015 to Unknown	22-APR-2015 22-APR-2015	Falling from first floor-height in one's daily life [FALL] Y / Y / Y Diagnosed 2 weeks of remedy for vertebral abnormality [SPINAL DISORDER] Y / Y / Y Hospitalized for hurting vertebral (not in an operation but in an abdominal binder) [SPINAL PAIN] Y / Y / Y	Not Recovered/Not Resolved
<div> <div>Case Initial Receipt Date: 23-Apr-2015</div> <div>Case Followup Receipt Date: 28-Apr-2015 00:00</div> <div>15-May-2015 00:00</div> <div>Event Intensity: Severe</div> <div>Severe</div> <div>Severe</div> <div>Case Comment Text: The Fall, Spinal disorder, and Spinal Pain are unlisted for THS 2.2 Regular, according to the Investigator Brochure. Considering the limited provided information (i.e. fall in one's daily life), the fall was probably incidental. The fall is a plausible explanation for the reported spinal disorder and spinal pain requiring hospitalisation and use of an abdominal binder. Therefore, the Company assesses the reported adverse events as not related to the use of the THS 2.2 Regular.</div> <div>Case Narrative: Verbatim: Hospitalized for hurting vertebral (not in an operation but in an abdominal binder).</div> </div>								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4-week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 23-Apr-2015:								
This report concerns a 44-year-old male subject (Respondent Study ID: 1181271) who took part in the above mentioned market research study.								
No medical history was reported. Medicine for schizophrenia (not further specified) was reported as concomitant medication.								
The respondent was a daily smoker (on average 10 cigarettes per day).								

CUM LL All Cases Pre-Marketing All THS Regular
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not reported) on 17-Apr-2015.</p> <p>Or (b) (6), the respondent was hospitalized for hurting vertebral. It was specified that he was "not in an operation but in an abdominal binder". In addition, it was reported that he was like this for the first time (being hurt for the first time). The event was considered to be severe in intensity, serious due to hospitalisation and it required medical advice.</p> <p>On the day of the event, the respondent used 5 heatsticks and smoked 1 conventional cigarette. It was reported that the usage of the product was not interrupted following the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>Follow-up information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 28-APR-2015:</p> <p>Verbatim: Injured by falling from first floor-height in one's daily life; diagnosed 2 weeks of remedy for vertebral abnormality and now in hospitalization with a abdominal binder.</p> <p>THS 2.2 product kit number was provided.</p> <p>Medical history of (slight) mental illness was reported. Medicine for psychiatric disorders (not further specified) was reported as concomitant medication.</p> <p>Or (b) (6), the respondent experienced a fall from first floor height. It was also reported that the respondent was "diagnosed 2 weeks of remedy for vertebral abnormality". The events were considered to be severe in intensity and reported as serious, due to hospitalization.</p> <p>On the day of the event, the respondent used 6 HeatSticks (previously reported as 5) and smoked 7 conventional cigarette. The respondent used the product every day. Use of the product was continued following the occurrence of the events.</p> <p>It was also reported that a request to stop the use of the product was made (not further specified).</p> <p>At the time of reporting, the events were ongoing.</p> <p>Follow-up information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 15-MAY-2015:</p> <p>Information was received that no further follow-up can be made for this case.</p> <p>Case closed.</p>								
³ PM1000128	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	03-MAY-2015	Fire breaks out on the charger: gets injured / was hurt by debris [INJURY ASSOCIATED WITH DEVICE] Y / Y / Y	Recovered/Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	03-MAY-2015	get something stuck in to his hand / his hand was smeared with ash / burned issue [THERMAL BURN] Y / Y / Y	
						03-MAY-2015	Fire breaks out on the charger: gets injured [DEVICE BATTERY ISSUE] N / Y / N	

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE DAMAGE] N / Y / -	
			Case Initial Receipt Date: 03-May-2015 Case Followup Receipt Date: 14-May-2015 00:00 21-May-2015 00:00 18-Apr-2016 00:00 Event Stop Date: 04-MAY-2015 04-MAY-2015 04-MAY-2015 Case Comment Text: The Injury associated with device and Thermal burn were assessed as serious (medically significant). The Device battery issue was assessed as non-serious. Injury associated with device and Thermal burn are unlisted for THS 2.2 Regular or THS 2.2 Menthol, according to the Investigator Brochure. The causality and listedness assessments are not applicable for Device battery issue. There is limited information in this case. However, considering the temporal relationship and the knowledge about the product in question, the Company assesses the reported adverse events as related to the use of the THS 2.2 Regular and THS 2.2 Menthol. Case Narrative: Verbatim: fire breaks out on the charger: gets injured Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 03-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1410947) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was provided. The respondent started using the Tobacco Heating System (THS) 2.2 on an unspecified date (reported as 24-May-2015 which is subsequent to report date, therefore, most likely, 24-Apr-2015). According to the information received, the respondent used both products, THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Men hol (Dorado I / Vinny low menthol) (Kit numbers not provided). On 03-May-2015, the respondent experienced fire breaking out of the charger and got injured (not further specified). The events were considered to be non-serious. Severity of he adverse events was not reported. Action taken with the use of he product was not reported. At the time of repor ing, the outcome of the events was not reported. Follow-up information is expected. FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015: Clarification was received that the respondent used two study products (THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol)) with a start date of 24-Apr-2015. It was not specified with which one of the products the event occurred. No further information on the type of injury was received.					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
FOLLOW-UP INFORMATION RECEIVED ON 21-MAY-2015:							
The device kit number WL9 L4K MN7 RSY was provided (not specified if it is for Menthol or Regular).							
The respondent mentioned that "he was hurt by debris of something", that "he got something stuck into his hand" (not further explained) and that he went to the emergency room due to his problem. He further clarified that "what he described as something stuck into his hand was because his hand was smeared with ash (but didn't explain more about the burned issue)".							
Regarding the charger, it was reported that the charger caught fire, and possibly exploded. It was also mentioned that "He dropped charger (the holder was in it) on the floor during they were charging. He also told that the holder was too hot because he dropped holder on the floor." It was not clearly explained if the charger was dropped before or after the injury occurred.							
The event improved when use of the product was stopped, and the product was not restarted.							
The outcome of the events was indicated as resolved on 04-May-2015.							
No further information is expected. Case closed.							
PMI000347	UNITED STATES Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] UNK [UNK]	08-OCT-2015 to 14-OCT-2015 27-OCT-2015 to Unknown	14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 15-OCT-2015 15-OCT-2015	Respondent was hit by a car [ROAD TRAFFIC ACCIDENT] Y / Y / Y concussion [CONCUSSION] Y / Y / Y knee strain [JOINT INJURY] Y / Y / Y back strain [MUSCLE STRAIN] Y / Y / Y abrasions [SKIN ABRASION] Y / Y / Y nausea [NAUSEA] N / N / Y dizziness [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 16-Oct-2015							
Case Followup Receipt Date: 27-Oct-2015 00:00							
Case Comment Text: The Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion were assessed as serious, due to requiring hospitalization. Nausea and Dizziness were assessed as non-serious.							
Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion are unlisted, whereas Nausea and Dizziness are listed, as per the Reference Safety Information (i.e. the IB).							
Based on the information (i.e. the participant was reportedly feeling fine before the accident; the participant was hit by a turning car, while cycling) provided in this report, the Road traffic accident and the directly derived adverse events (i.e. Concussion, Joint injury, Muscle strain, Skin abrasion), as well as the transient Nausea and Dizziness experienced while on treatment with Percocet initiated during hospitalisation, are assessed as not related to the use of Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron). Of note, the product use was restarted 12 days after the discharge from hospital.							
Case Narrative: Verbatim: Respondent was hit by a car.							
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.							
INITIAL INFORMATION RECEIVED ON 16-Oct-2015 and forwarded to Safety department on 19-Oct-2015.							

CUM LL All Cases Pre-Marketing All THS Regular
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 31-year-old male subject (Respondent Study ID 200851) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Information on concomitant medications was reported as "Perkacet and just an IV" (no further information provided).</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) kit number LE8Q6KAQRBQ3 on 08-Oct-2015.</p> <p>The consumer was hit by a car. The event required hospitalization or (b) (6). The event was assessed as serious (due to hospitalization).</p> <p>The last Heatstick was used on 14-Oct-2015. It was reported that the consumer would continue with the study once he was out of hospital.</p> <p>At time of reporting, the event had not recovered.</p> <p>Follow-up information will be requested.</p> <p>FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day.</p> <p>Verbatim: Diagnosis of concussion, knee strain, back strain, abrasions</p> <p>The participant stated that he was "feeling fine" right before his accident on (b) (6). He related that he was heading northbound riding his bicycle in the bike lane, when a vehicle that was heading southbound, turned into him striking him. The participant was then transported to the hospital via an ambulance where he was initially placed in the emergency room for 2 hours and then admitted in order to assess and observe for any symptoms stemming from concussion. The caller reported being discharged at 2-3 am the following day on (b) (6).</p> <p>The caller then reported that he returned to the hospital later in the day of his discharge (b) (6) because of the symptoms of nausea and dizziness. He was not admitted at that time but released after a brief assessment.</p> <p>The participant denied receiving any treatment while en route to the hospital. He stated he was given intravenous solution while in the hospital but was unsure of what exactly was in that solution, although the participant believed it was a saline solution. The participant admits to Percocet by mouth, during hospital stay and for at least 2 days after discharge.</p> <p>The participant denied having taken any medications to treat any other conditions prior to the incident.</p> <p>The participant denied any pre-existing conditions prior to the accident (no previously diagnosed conditions, no seasonal conditions such as allergies, and no self limiting conditions such as cold, flu, or headache).</p> <p>Prior to the accident, the respondent used the THS product on 14-Oct-2015. The product was re-started on 27-Oct-2015.</p> <p>At time of reporting, the serious events were ongoing. The respondent mentioned that he still had a swollen knee with pain during weight bearing and back pain for which he was receiving daily chiropractic treatment. He was also still being assessed for concussion; a MRI was scheduled. Nausea and dizziness resolved on an unspecified date.</p> <p>No further information is expected. Case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000367	UNITED STATES Report From Study	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]		09-SEP-2015 to 28-OCT-2015	(b) (6) 5	was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell [ACCIDENT] Y / Y / Y injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples [LIMB INJURY] Y / Y / Y injured her left leg and foot, the bone had been smashed (in an accident) [SKELETAL INJURY] Y / Y / Y Participant stated her foot is infected and that the infection had gotten into the bone [OSTEOMYELITIS] Y / Y / Y the nerves are dead and there is no flow (NOS) [NERVE INJURY] Y / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]		09-SEP-2015 to 28-OCT-2015	16-SEP-2015 16-SEP-2015		
<p>Case Initial Receipt Date: 02-Nov-2015 Case Followup Receipt Date: 10-Nov-2015 00:00 Event Intensity: Severe Severe Severe Severe Severe Event Stop Date: 16-SEP-2015 Case Comment Text: The Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury were assessed as serious, due to requiring hospitalization.</p> <p>Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury are unlisted for THS 2.2 Menthol and THS 2.2 Regular, as per the Reference Safety Information (i.e. the IB).</p> <p>Considering the circumstances provided in this report, the Accident and the ensuing adverse events (i.e. Limb injury, Lower limb fracture, Osteomyelitis, Nerve injury) are assessed as not related to the use of the products, in this patient, who had been a smoker of conventional cigarettes.</p> <p>Case Narrative: Verbatim: was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell / injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples / Participant stated her foot is infected and that the infection had gotten into the bone / the nerves are dead and there is no flow (NOS)</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 2-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID: 654390) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medications were reported.</p> <p>The respondent was a daily smoker (approximately 10 - 20 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) on an unknown date.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that she was in an accident on 16-Sep-2015. Her left leg and foot were injured and the bone had been smashed. She was hospitalized on an unknown date. On an unknown date, she had been released from the hospital, had been bed-ridden for 3 weeks, and had gone back to work on 8-Oct-2015. On (b) (6), she was hospitalized for the second time. She stated her foot was infected and that the infection had gotten into the bone, further stating that it was probably infected from the beginning. She also stated the nerves were dead, there was no flow and they will be doing who-knows how many surgeries. She stated that she would be in the hospital at least 4 months and that she was on a lot of medications. The study respondent requested to be withdrawn from the study.</p> <p>The events severity was reported as severe. The events were assessed as serious due to hospitalization.</p> <p>The respondent used the Heatsticks every day. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event. Last day of product usage was indicated as (b) (6).</p> <p>At time of reporting, the outcome of the events was unknown; however, the respondent was in hospital at time of reporting.</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION was received on 10-Nov-2015 and forwarded to the Safety department on 13-Nov-2015.</p> <p>The recipient stated that she was unsure of when she started to use the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) but she felt that it may have been around 09-SEP-2015.</p> <p>She stated that it was a wonderful morning (70 degrees), she was at work, when a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell. She mentioned that she was unsure of what exactly happened.</p> <p>The respondent stated that, after the accident, one of her supervisors or somebody at her work that was in a position of responsibility drove her to the hospital on (b) (6). Once at the hospital, the respondent stated that she was not formally admitted, but spent a few hours in the emergency room (ER) where she received intravenous antibiotics, a tetanus shot, and leg staples. On the same day, after being released from the ER, she was able to walk around and went to the mall site to explain her situation. The respondent stated that, since her release from the ER, her condition worsened and she was admitted to the hospital; she was unsure of the date, but that she believed it was about two Wednesdays prior to reporting date. She was currently still in the hospital.</p> <p>The respondent stated that the events were still ongoing as of 10-Nov-2015.</p> <p>No additional information was provided. The respondent refused to provide any more information. She wanted to know why these questions were asked stating that they sound like questions that a lawyer may ask. She stated that she was unwilling to provide these answers until she gets her explanation. The respondent stated that she is willing to be called back.</p> <p>Further information is expected.</p>							
PMI000394	UNITED STATES Report From Study	52 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]	OCT-2015 to 31-OCT-2015	30-OCT-2015 15-OCT-2015 NOV-2015 09-NOV-2015	he was told he was septic [SEPSIS] Y / Y / Y his gallbladder had gangrene [CHOLECYSTITIS INFECTIVE] Y / Y / Y He got pneumonia while he was in the hospital [PNEUMONIA] Y / Y / Y COPD [CHRONIC OBSTRUCTIVE PULMONARY DISEASE] N / Y / Y	Not Recovered/Not Resolved

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
						2015	decubitus ulcer on his back [DECUBITUS ULCER] N / Y / N Increased bowel movement frequency secondary to daily probiotic use [FREQUENT BOWEL MOVEMENTS] N / Y / N	
<p>Case Initial Receipt Date: 16-Nov-2015 Case Followup Receipt Date: 30-Nov-2015 00:00 10-Dec-2015 00:00 Event Intensity: Unknown Unknown Unknown Unknown Unknown Event Stop Date: 07-NOV-2015 09-NOV-2015 Case Comment Text: The Sepsis and Cholecystitis infective were assessed as serious, due to requiring hospitalization. Pneumonia was assessed as serious, due to being considered a medically important event, requiring intervention. Chronic obstructive pulmonary disease, Decubitus ulcer, and Frequent bowel movements were assessed as non-serious, based on the provided information. Sepsis, Cholecystitis infective, Pneumonia, Decubitus ulcer, Chronic obstructive pulmonary disease, and Frequent bowel movements are unlisted, as per the Reference Safety Information of THS 2.2 Regular (i.e. the IB). The Sepsis was likely a consequence of the Cholecystitis infective (described as gallbladder gangrene, requiring open cholecystectomy). Considering the current knowledge on the product in question, the Sepsis and Cholecystitis infective are assessed as not related to the use of THS 2.2 Regular. Despite the presence of alternative explanations (i.e. medical history, multiple concomitant medications, hospital environment, recent septic episode), the causal relationships between the use of THS 2.2 Regular and Pneumonia (in this case, nosocomial pneumonia) cannot be completely excluded and, therefore, is assessed as possible. It was reported that the Chronic obstructive pulmonary disease (COPD) was diagnosed about a month after this patient, who had been a smoker of conventional cigarettes, started using the THS 2.2. Considering his implausible temporal sequence, the COPD is assessed as not related to THS 2.2. A clear alternative explanation (i.e. inappropriate care during hospitalization) was provided for the occurrence of the decubitus ulcers. As well, the Increased bowel frequency were reportedly due to the use of concomitant probiotics. Therefore, Decubitus ulcer and Increased bowel frequency are assessed as not related to the use of THS 2.2 Regular.</p> <p>Case Narrative: Verbatim: Verbatim: he was told he was septic; his gallbladder had gangrene; he got pneumonia while he was in the hospital; decubitus ulcer on his back</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 52-year-old male subject (Respondent Study ID: 652030) who took part in the above mentioned market research study.</p> <p>Medical history was not reported. The following concomitant medications was reported: Atenolol, Lisinopril, Keppra (levetiracetam), Butatane (exact spelling unknown), Probiotic (Bifidobacterium lactis), others (NOS). The respondent stated there were 12 all together (additional information not provided).</p> <p>The respondent was a daily smoker (approximately 10-15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 015410786815337 / (21)SSKLOEB32GLA / (240) DK00024.01) on an unreported date.</p> <p>The recipient stated that, on (b) (6) he was admitted to the hospital, where he was told he was septic, and where they did all kinds of tests (NOS). He stated that, on 31-Oct-2015, he was told his gall bladder had gangrene and had to be removed. He stated his gall bladder was removed on 31-Oct-2015. He stated that he got pneumonia while he was in the hospital, he was told not to smoke, and he was undergoing breathing treatments (NOS). He stated he had 15 staples across his abdomen. He stated he was discharged from the hospital on (b) (6). He stated he had completely quit smoking (both conventional cigarettes and the IQOS device) and reported to feeling better after he quit smoking. He was still undergoing</p>								

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								breathing treatments.
								The events severity was not reported. The events were assessed as serious, due to hospitalization.
								The number of cigarettes and Heatsticks used on the day of the event was not reported.
								It was reported that the events improved when usage of the product was stopped (not specified if it was one event in particular that improved, or all events) and product was not restarted.
								At time of reporting, the events were not resolved.
								Further information is expected.
								FOLLOW-UP INFORMATION RECEIVED on 30-Nov-2015 and forwarded to Safety department on the same day.
								Medical history of high blood pressure and high cholesterol were reported. The respondent also reported that he had monthly visits to the doctor to have his International Normalized Ratio (INR) assessed. He denied any blood clotting issues, denied any conditions that may cause blood clots other than high blood pressure and cholesterol, and denied taking any medications that may require a monthly INR screening.
								Lisinopril and Lovastatin were reported as concomitant medications.
								The respondent reported that he was unsure of when he started using the THS product, but that he believed that he started using the THS product 3 weeks before he was admitted to the hospital on (b) (6).
								The respondent confirmed diagnosis of gangrenous gallbladder and diagnosis of sepsis. The respondent was assessed as having gallbladder issues during regular doctor's visit on 15-Oct-2015. He said that he was not feeling well several days before and that he reported this during his monthly doctor's visit to have his INR pulled on 15-Oct-2015. The physician then ordered bloodwork that confirmed that the participant was having issues with his gallbladder. The respondent was admitted to the hospital for surgery on (b) (6).
								An open cholecystectomy was found to be necessary because the gallbladder had become gangrenous and the respondent was found to be septic. The surgery was completed on 31-Oct-2015. The respondent described a possible Open Cholecystectomy, relating that the incision site crosses from the right upper quadrant to the left upper quadrant of abdomen and resembles a C-section scar just below his ribs. When asked if the procedure may not be an open-cholecystectomy the participant affirmed that this was in fact the name of the procedure. The participant related that it was used instead of the laparoscopic procedure because of the urgency of his condition.
								The respondent initially reported that the cause of his gangrene was sepsis. Upon follow-up questioning, he stated that he did not know what caused his gallbladder to become gangrenous. He denied having gallstones. He affirmed that sepsis was the result of gangrenous gallbladder.
								The respondent stated that the pneumonia started 3-4 days after surgery. He reported that pneumonia was the result of intubation and patient's insufficient turning by the hospital staff. He further clarified that the tracheal tube was in place for several days making it difficult for the medical staff to turn him regularly, which contributed to the pneumonia.
								The respondent reported that he was given the inhaled medications Spiriva (tiotropium bromide) and Symbecort (budesonide, formoterol fumarate dehydrate) as a breathing treatment, nicotine replacement therapy in the form of transdermal patch, an antibiotic whose name he can't remember, probiotics, and a pain medication whose name he can't remember.
								The respondent related that he stayed in the hospital for 10 days before he was discharged.
								He stated that he experienced decubitus ulcers on his back, which were ongoing, as the result of hospitalization and improper turning by hospital staff that were ongoing. The event severity of decubitus ulcers was not reported.
								The respondent stated that he stopped using the device after his surgery on 31-Oct-2015 because he was informed that smoking of any kind would delay healing at the incision site. He reported that he was still using his Spiriva and Symbecort.

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>At time of the report, the respondent's condition was ongoing. The respondent reported healing at his incision site was ongoing. He reported that he required Physical Therapy twice a week and was visited by a nurse once a week.</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED on 10-DEC-2015 and forwarded to Safety department on the same day.</p> <p>Medical history of bilateral amputation below the knee and bilateral hip replacement, 6 years prior to current report was reported. In addition, the consumer was wheelchair bound for 6 years, at time of reporting.</p> <p>The respondent reported that any symptoms of sepsis resolved 7 days after date of surgery on 31-Oct-2015.</p> <p>He reported that symptoms from treatment of gangrenous gallbladder are ongoing. Healing of skin at incision site had concluded and was resolved as of 15-Nov-2015. Muscle pain at incision site was ongoing. He reported that his doctor informed him that the timeline for resolution of healing and the resolution of pain is 6 months to a year.</p> <p>He stated that pneumonia was resolved, meaning treatments for asthma had concluded, on day of hospital discharge, 10 days after the date of admittance (b) (6). He stated that breathing treatments were discontinued on day of discharge.</p> <p>The respondent stated that decubiti were ongoing, that he received daily dressing changes from his caregiver, that he had seen a woundcare nurse on 4 different occasions to date, and that he had been referred to a woundcare specialist. He further insisted that the decubiti were healing, but that he needed the consult, in order to obtain assistive devices, such as doughnut padding.</p> <p>He reported that the only medications he had as a result of his condition were probiotics and ProAir. He experienced increased bowel movement frequency secondary to daily probiotic use, described as having to go to the bathroom often. ProAir was prescribed at hospital discharge for Chronic Obstructive Pulmonary Disease (COPD) symptoms. The patient then reported a new condition, COPD, diagnosed at hospital discharge, 10 days after the admittance date of (b) (6).</p> <p>The event severity of COPD and increased bowel movement frequency was not reported.</p> <p>No further information is expected. Case closed.</p>								

Total number of case entries printed: 259
Total number of cases printed: 259

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
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Advanced Condition used in this report:

Advanced Condition: Ingredient D2 Ron/D2 Fitz (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredients D2 Ron/D2 Fitz

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Ingredients D2 Ron/D2 Fitz (Created by nicole.miller)

Selection Criteria:

Ingredient equal to D2 Ron OR

Ingredient equal to D2 Fitz OR

Ingredient equal to D2 Ron (half white tipping paper) OR

Ingredient equal to D2 Ron (cork tipping paper)

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (165)							
PMI000001	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: Make me cough too much			Make me cough too much [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 33-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it made her cough too much. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with study product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000002	ITALY Report From Study	59 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The heat irritates my tongue and palate.			The heat irritates my tongue and palate [GLOSSITIS] N / Y / Y The heat irritates my tongue and palate [STOMATITIS] N / Y / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 59-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the duration of use was short, around 2 minutes and 10 seconds, therefore 'each distraction was fatal'; sticks too expensive. The respondent also</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			the heat irritated her tongue and palate. The events were considered to be non-serious (intensity not provided).				
			Action taken with the product was not reported.				
			At the time of reporting, the outcome of the events was unknown.				
			No follow-up information is expected ? case closed.				
PMI000003	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the taste of the tabaccos because I found it bitter [PRODUCT TASTE ABNORMAL] N / Y / Y it made me cough more of my traditional cigarettes [COUGH] N / N / Y I found it uncomfortable, the procedure (I Have to re - charge) [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 04-Dec-2014							
Case Narrative: Verbatim: it made me cough more of my traditional cigarettes, the taste of the tabaccos because I found it bitter, I found it uncomfortable the procedure (I Have to re - charge)							
Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 40-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the smoking of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that he found the taste of the tobacco bitter and it made him cough more than his traditional cigarettes. In addition, the respondent stated that he found the procedure uncomfortable because he had to re - charge. The events were considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000004	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: product gives headache			the product gives headache [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gives headaches and reported that in the last week, he didn' t smoke it. The event was considered to be non-serious (intensity not pr</p> <p>Action taken with the product was considered as discontinued.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000006	ITALY Report From Study	44 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The taste of the tobacco makes my head turn, and the anxiety of the little light. It seems to me that it last too little.			the anxiety of the little light [ANXIETY] N / Y / Y it seems to me that it lasts too little [PRODUCT QUALITY ISSUE] N / Y / Y the taste of the tobacco makes my head turn [DIZZINESS] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 44-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the taste of the tobacco makes her head turn. She reported the anxiety of the little light. It seems to her that it last too little (presumably t</p> <p>The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000007	ITALY Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: at the beginning he gave me headache.			at the beginning he gave me headache [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that at the beginning it gave her headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of repor ing, the outcome of the event was unknown.</p> <p>No follow-up information is expected - case closed.</p>							
PMI000008	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: I had dizziness while I smoked			I had dizziness while I smoked [DIZZINESS] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 36-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she had dizziness while she was smoking. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000009	ITALY Report From Study	52 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the sticks that take the throat, itchy throat [THROAT IRRITATION] N / Y / Y make you cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Case Narrative: Verbatim: The sticks that take the throat, sting the throat and make you cough</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 52-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the sticks take the throat (itchy throat) and make you cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000010	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			often I had headache [HEADACHE] N / N / Y had to inspire more because it looked to me too light / it warmed too much [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I had to inspire more because it looked to me too light / it warmed too much; often I had headache.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he often had headaches. In addition, the respondent mentioned that he had to inspire more because the product looked too light to him, and it warmed too much. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected - case closed.</p>							
PMI000012	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the taste didn't satisfy me, it gave me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Case Narrative: Verbatim: The taste didn't satisfy me, it gave me headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste did not satisfy her and the product gave her headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000013	ITALY Report From Study	42 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 18-Dec-2014 Case Narrative: Verbatim: I don't like it, it gives me nausea			I don't like it, it gives me nausea [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 42-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she didn't like it, it gave her nausea and was not worth the price. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000014	ITALY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 18-Dec-2014 Case Narrative: Verbatim: I don't like the taste / the system, it is not worth its price, it gives me nausea.			it gives me nausea [NAUSEA] N / N / Y I don't like the taste / the system [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she did not like the taste, she did not like the system, it was not worth the price and it gave her nausea. The events were considered to be non-serious (intensity not provided).</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected requested ? case closed.							
PMI000015	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I don't like the taste it leaves in the mouth [DYSGEUSIA] N / Y / Y The smell gives me headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 18-Dec-2014							
Case Narrative: Verbatim: I don't like the taste it leaves in the mouth, the smell gives me headache.							
Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 40-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that she did not like the taste it left in her mouth, the smell gave her headache. The events were considered to be non-serious (intensity not provided). The respondent mentioned that the cost was clearly disproportional.							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000016	ITALY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it "impastate" the mouth [ORAL DISCOMFORT] N / Y / Y aspirate gives me nausea [NAUSEA] N / N / Y the filter is too hot, the smoke is not dry but wet [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 18-Dec-2014							
Case Narrative: Verbatim: I don't like the filter is too hot, the smoke is not dry but wet and aspirate gives me nausea and "impastate" the mouth.							
Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she did not like that the filter was too hot, the smoke was not dry but wet and aspirate gave her nausea and "impastate" the mouth. The events considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000017	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			After some aspiration I had headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Case Narrative: Verbatim: after some aspiration I had headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that after some aspiration he had headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000018	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			those gave me headache [HEADACHE] N / N / Y those gave me a sense of nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jan-2015</p> <p>Case Narrative: Verbatim: I prefer the traditional cigarettes, those gave me headache and a sense of nausea</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she preferred the traditional cigarettes, those gave her headache and a sense of nausea. The events were considered to be non-serious (intensity provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000020	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			they give me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jan-2015</p> <p>Case Narrative: Verbatim: They give me headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that they (the heatsticks) gave him headache. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000022	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			the first moment I had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 31-Oct-2014							
Case Narrative: Verbatim: The first moment I had to cough.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that in the first moment she had to cough. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000024	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			Scratches in the throat [THROAT IRRITATION] N / Y / Y one ends up with a coughing fit [COUGH] N / N / Y Very strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 31-Oct-2014							
Case Narrative: Verbatim: Very strong, scratches in the throat and one ends up with a coughing fit.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks (presumably) were very strong, it scratches in the throat and one ends up with a coughing fit. The events were considered to be no (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000025	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: In the beginning it was scratchy			In the beginning it was scratchy [THROAT IRRITATION] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that in the beginning it was scratchy. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000026	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: The first time I was very irritated by the taste. Now the taste is a little better.			The first time I was very irritated by the taste. Now the taste is a little better. [THROAT IRRITATION] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome	
			<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first time she was very irritated by the taste (presumably throat irritation). She reported that now (at the time of reporting) the taste was event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>						
PMI000028	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			when one has smoked several Heat Sticks in a row one feels nauseous [NAUSEA] N / N / Y	Unknown	
	Case Initial Receipt Date:	15-Nov-2014	Case Narrative: Verbatim: when one has smoked several Heat Sticks in a row, one feels nauseous.						
			<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that when one has smoked several Heat Sticks in a row, one feels nauseous. The event was considered to be non-serious (intensity not provided). In add respondent mentioned that it is convenient to use.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>						

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000029	SWITZERLAND Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it is pungent in the throat [OROPHARYNGEAL PAIN] N / N / Y it tastes chemical [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: It tastes chemical and is pungent in the throat.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 31-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it tastes chemical and is pungent in the throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000031	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it gives me nausea [NAUSEA] N / N / Y it gives me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I don' t like the taste, it gives me nausea and headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first time it looked interesting. In addition, she reported that she doesn' t like the taste, it gives her nausea and headache. The events were considered to be non-serious (intensity not provided).</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000032	SWITZERLAND Report From Study	35 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: now I have nausea.			Now I have nausea [NAUSEA] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 35-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that for the taste, she had been delighted on-site, but now she had nausea. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000034	SWITZERLAND Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: The regular heatstick that gives headaches.			The regular heatstick which gives headaches [HEADACHE] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 33-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the regular heatsticks (that she used during her first visit) gave her headache. The event was considered to be non-serious (intensity not provided) with regards to the Tobacco Heating System (THS) 2.2 Menthol, the respondent mentioned that she did not like the taste of the menthol, it was too strong.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000035	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>I did not feel good afterwards (eructation) [MALAISE] N / Y / Y</p> <p>I did not feel good afterwards (eructation) [ERUCTATION] N / Y / Y</p> <p>Bad after taste [DYSGEUSIA] N / Y / Y</p>	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: Bad after taste and I didn't feel good afterwards (eructation).</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he has a bad after taste and he didn't feel good afterwards (eructation). The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000036	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>Get unpleasant feeling in my throat [THROAT IRRITATION] N / Y / Y</p> <p>tobacco is too strong [PRODUCT QUALITY ISSUE] N / Y / N</p>	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Tobacco is too strong, get unpleasant feelings in my throat.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that tobacco was too strong, she got unpleasant feelings in her throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000037	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			I get headaches [HEADACHE] N / N / Y slight drowsiness [SOMNOLENCE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014</p> <p>Case Narrative: Verbatim: I get headaches, slight drowsiness.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she got headaches, slight drowsiness. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000040	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I have been sick.			I have been sick [MALAISE] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she had been sick (no further information provided). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000041	SWITZERLAND Report From Study	61 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I sometimes after the second HS ALWAYS [sic] get headaches.			Because I sometimes after the second HS always get headaches [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 61-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he "sometimes after the second heatstick always [sic] get headaches". The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000042	SWITZERLAND Report From Study	21 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: During the use of heatsticks I felt tension in the chest.			During the use of heatsticks I felt tension in the chest [CHEST DISCOMFORT] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 21-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that during the use of the heatsticks, she felt tension in the chest. The event was considered to be non-serious (intensity not provided). In addition mentioned that she didn' t like the taste of the heatsticks.							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000043	SWITZERLAND Report From Study	27 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The sticks weren't good for me, I had an oppressive feeling after smoking.			The s icks weren't good for me, I had an oppressive feeling after smoking [SENSE OF OPPRESSION] N / Y / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 27-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that the sticks weren't good for her, she had an oppressive feeling after smoking. The event was considered to be non-serious (intensity not provided)							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Action taken with the product was not reported.				
			At the time of reporting, the outcome of the event was unknown.				
			No follow-up information is expected ? case closed.				
PMI000044	SWITZERLAND Report From Study	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			sometimes I have too strong headaches leading up to paralysis [MOVEMENT DISORDER] N / Y / Y pre-existing condition worsened [CONDITION AGGRAVATED] N / Y / Y sometimes I have too strong headaches leading up to paralysis [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Taste of "normal" cigarettes is better, a HeatStick smokes too quickly and, I grabbed a new one much sooner, or had the craving for a "real" cigarette. I am suffering from traumatic brain injury sometimes have too strong headaches leading up to paralysis these symptoms have increased under the HeatSticks.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>The respondent had a medical history of traumatic brain injury with strong headaches, sometimes leading to paralysis. No concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste of "normal" cigarettes was better, a HeatStick smoked too quickly, and he grabbed a new one much sooner, or had the craving for a "real" cigarette. The respondent was suffering from traumatic brain injury and would sometimes have too strong headaches leading up to paralysis. According to the respondent, these symptoms increased under the HeatSticks. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000045	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			was sick for one week [MALAISE] N / Y / Y Didn't taste [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: didn't taste and was sick for one week.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it didn't taste and she was sick for one week. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p> <p>10-FEB-2016: Case re-opened due capture missing listedness.</p>								
PMI000046	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory			Throat pain [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: throat pain.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported throat pain. The event was considered to be non-serious (intensity not provided).</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000047	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			Heatsticks have scratched in my throat [THROAT IRRITATION] N / Y / Y Heatsticks have caused cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: Heatsticks have scratched in my throat and caused cough.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that Heatsticks have scratched in her throat and caused cough. The events were considered to be non-serious (intensity not provided). In addition, the mentioned that she could not get used to the taste.							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000049	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			I got headaches from the heats icks [HEADACHE] N / N / Y I found them too strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: I got headaches from the heatsticks, maybe, because I found them too strong.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she got headaches from the Heatsticks, maybe, because she found them too strong. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000050	SWITZERLAND Report From Study	23 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I was disgusted by the heatsticks.			I was disgusted by the heatsticks [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 23-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he was disgusted by the heatsticks. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000051	SWITZERLAND Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014			I feel like the heatsticks hurt my lungs [BRONCHIAL IRRITATION] N / Y / Y my throat cannot take them [THROAT IRRITATION] N / Y / Y	Unknown

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I feel like the heatsticks hurt my lungs and my throat cannot take them.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she felt like the heatsticks hurt her lungs and her throat cannot take them. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected - case closed.</p>							
PMI000052	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The heatsticks make me cough.	Respiratory		The heatsticks make me cough [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks made her cough. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned that she used to the taste and there was less manipulations with conventional cigarettes.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000053	SWITZERLAND Report From Study	42 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I have been sick [MALAISE] N / Y / Y I had problems to insert the sticks in the holder [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The first week it was easy to smoke the sticks. After, I have been sick, and after I had problems to insert the sticks in the holder and I didn't call to get a ne stopped smoking the sticks.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 42-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the first week it was easy to smoke the sticks. After, he has been sick, and after he had problems to insert the sticks in the holder. He didn't one and he stopped smoking the sticks. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000056	SWITZERLAND Report From Study	35 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			the taste made me vomit [VOMITING] N / N / Y the taste has given me nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the taste has given me nausea and made me vomit.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the taste has given her nausea and made her vomit. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000058	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			<p>The heatstick makes me cough more than the cigarette [COUGH]</p> <p>N / N / Y</p> <p>when I smoke a heatstick, I am not satisfied, I feel it doesn' t last long enough [PRODUCT QUALITY ISSUE]</p> <p>N / Y / N</p>	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The heatstick makes me cough more than the cigarette, in addition, if I forget to charge it and I want to smoke, I don' t have the patience to wait until it is charged. I smoke a heatstick, I am not satisfied, I feel it doesn' t last long enough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatstick makes her cough more than the cigarette. When she smokes a heatstick, she is not satisfied, she feels it doesn' t last long enough. The events were considered to be non-serious (intensity not provided). In addition, the respondent mentioned that if she forgets to charge it and she wants to smoke, she doesn' t have the patience to wait until it is charged.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000059	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The heatsticks leave a pasty taste in the mouth [DYSGEUSIA] N / Y / Y give the impression to have a coated tongue [TONGUE COATED] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the heatsticks leave a pasty taste in the mouth and give the impression to have a coated tongue</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks leave a pasty taste in the mouth and give the impression to have a coated tongue. The event were considered to be non-serious (in provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000060	SWITZERLAND Report From Study	45 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			less coughing [COUGH DECREASED] N / Y / Y better breathing [PRE-EXISTING CONDITION IMPROVED] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Better breathing, less coughing. Good tobacco taste, and no cold smoke. Fun to use.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent reported better breathing, less coughing. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned a good taste, no cold smoke, and fun to use.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000061	SWITZERLAND Report From Study	33 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I felt weak in the stomach.			I felt weak in the stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 33-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he felt weak in the stomach. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000063	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the HeatSticks caused headache and drowsiness.			The heatsticks caused headache and drowsiness [SOMNOLENCE] N / Y / Y The heatsticks caused headache and drowsiness [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported that the heatsticks caused headache and drowsiness. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000064	SWITZERLAND Report From Study	32 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]				scratched little [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: scratched little.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 32-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it scratched little. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000067	SWITZERLAND Report From Study	44 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			[too strong], irritant [THROAT IRRITATION] N / Y / Y too strong, [irritant] [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Too strong, irritant.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 44-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported: too strong, irritant (no further details provided). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000068	SWITZERLAND Report From Study	21 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			crushing feeling in the chest region [CHEST DISCOMFORT] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: a crushing feeling in the chest region.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 21-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported a crushing feeling in the chest region. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000069	SWITZERLAND Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it makes me cough.			it makes me cough [COUGH] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 31-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that it makes him cough. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000071	SWITZERLAND Report From Study	31 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: irritating			Irritating [THROAT IRRITATION] N / Y / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 31-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent reported: irritating (no further information provided). The event was considered to be non-serious (intensity not provided).							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000074	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Coughing a lot.			coughing a lot [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported coughing a lot. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000075	SWITZERLAND Report From Study	37 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it stays in the throat, one always has to drink after, it leaves a pasty taste.			it stays in the throat, one always has to drink after, it leaves a pasty taste [DYSGEUSIA] N / Y / Y it stays in the throat, one always has to drink after, it leaves a pasty taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 37-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stays in the throat, one always has to drink after and it leaves a pasty taste. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000076	SWITZERLAND Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it gives headache [HEADACHE] N / N / Y unpleasant aftertaste in the throat [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it gives headache, unpleasant aftertaste in the throat, it's imposing</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported it gives headache, unpleasant aftertaste in the throat and it's imposing. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000077	SWITZERLAND Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it dries up the throat [DRY THROAT] N / Y / Y I am coughing more than with my cigarette [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it dries up the throat, I am coughing more than with my cigarette.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it dries up the throat and she is coughing more than with her cigarette. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000080	SWITZERLAND Report From Study	55 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			sometimes I got strong headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: Sometimes I got strong headaches.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 55-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that sometimes he got strong headaches. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000081	SWITZERLAND Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it makes me cough with the first inhalations.			it makes me cough with the first inhalations [COUGH] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 51-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that it makes her cough with the first inhalations. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000082	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The flavour is pleasant if I use one or two sticks but after that it becomes nauseating and give me headaches.			it gave me headaches [HEADACHE] N / N / Y The flavour is pleasant if I use one or two sticks but after that it becomes nauseating [NAUSEA] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the flavour is pleasant if she uses one or two sticks but after that it becomes nauseating and gives her headaches. The events were considered to non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000083	SWITZERLAND Report From Study	23 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The taste is rapidly nauseating [NAUSEA] N / N / Y Makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The taste is rapidly nauseating. Does not last as long as a normal cigarette. Makes me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 23-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste is rapidly nauseating and it makes her cough. The events were considered to be non-serious (intensity not provided). In addition, the mentioned that it does not last as long as a normal cigarette.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000084	SWITZERLAND Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			sometimes a mean scratching in the throat [THROAT IRRITATION] N / Y / Y aftertaste (a bit stale/sour) [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Sometimes a mean scratching in the throat and the aftertaste (a bit stale/sour).</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 40-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported sometimes a mean scratching in the throat and the aftertaste (a bit stale/sour). The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000085	SWITZERLAND Report From Study	51 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			it provokes coughing [COUGH] N / N / Y smell unpleasant [PRODUCT ODOUR ABNORMAL] N / Y / N taste too dry, burned taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it provokes coughing, smell unpleasant, taste too dry, burned taste.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 51-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it provokes coughing, smell is unpleasant, taste is too dry, burned taste. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000088	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			at the end of the heatstick, the taste makes me feel nauseous [NAUSEA] N / N / Y If I smoke too much during the day I have a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: at the end of the heatstick, the taste makes me feel nauseous and if I smoke too much during the day I have a headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that at the end of the heatstick, the taste makes her feel nauseous and if she smokes too much during the day she had a headache. The events were cons be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000089	SWITZERLAND Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it irritates the throat [THROAT IRRITATION] N / Y / Y on the long term it gives headache [HEADACHE] N / N / Y it makes one feel like vomiting [NAUSEA] N / N / Y it's a little bitter [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it is a little bitter, it irritates the throat and on the long term it gives headache and makes one feel like vomiting.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is a little bitter, it irritates the throat and on the long term it gives headache and makes one feel like vomiting. The events were considered (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000090	SWITZERLAND Report From Study	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it made me nauseous [NAUSEA] N / N / Y too strong, the taste is bitter sour [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: it made me nauseous, too strong, the taste is bitter sour.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated it made him nauseous, too strong and the taste was bitter sour. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000091	SWITZERLAND Report From Study	30 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The first draw was always (too) strong, had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The first draw was always (too) strong, had to cough. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 30-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the first draw was always (too) strong, he had to cough. The event was considered to be non-serious (intensity not provided). Action taken with the product was not reported. At the time of reporting, the outcome of the events was unknown. No follow-up information is expected ? case closed.							
PMI000092	SWITZERLAND Report From Study	21 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			The aromatic taste, aftertaste [DYSGEUSIA] N / Y / Y tension in the chest [CHEST DISCOMFORT] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The aromatic taste, aftertaste, one cannot draw as intensely as with a normal cigarette, otherwise, tension in the chest. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 21-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent reported the aromatic taste, aftertaste, otherwise, tension in the chest. The events were considered to be non-serious (intensity not provided). In addition, mentioned that one cannot draw as intensely as with a normal cigarette, Action taken with the product was not reported.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000093	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			after a while it makes me feel nauseous [NAUSEA] N / N / Y Gives headaches [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: after a while it makes me feel nauseous. Gives headaches.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that after a while it makes her feel nauseous and gives headaches. The events were considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the events was unknown.							
No follow-up information is expected ? case closed.							
PMI000094	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			cardboard taste [DYSGEUSIA] N / Y / Y much coughing [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014							
Case Narrative: Verbatim: Cardboard taste, much coughing.							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported cardboard taste and much coughing. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000096	SWITZERLAND Report From Study	50 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: sometimes it makes me cough.			Sometimes it makes me cough [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 50-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that sometimes it makes her cough. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000103	KOREA, REPUBLIC OF Report From Study	22 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 20-Apr-2015 Event Intensity: Unknown Unknown	17-APR-2015 to 20-APR-2015	18-APR-2015 18-APR-2015	I' m allergic to dust, and it got worse after using HeatStick. [HYPERSENSITIVITY] N / Y / Y Skins of upper and lower eyelids got trouble [EYELID DISORDER] N / Y / Y	Mgt Recovered/Not Resolved

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I' m allergic to dust, and it got worse after using HeatStick. Skins of upper and lower eyelids got trouble.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015: This report concerns a 22-year-old male subject (Respondent Study ID: 1468690) who took part in the above mentioned market research study.</p> <p>Medical history of dust allergy and intervertebral disk was reported. Painkillers ('for the disk') were reported as concomitant medications.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number HTV 9RF HPQ RV1) on 17-Apr-2015.</p> <p>On 18-Apr-2015, the respondent experienced worsening of dust allergy and 'skins of upper and lower eyelids got trouble'. The events were considered to be non-serious. The e required medical advice. The respondent went to a dermatologist' s clinic on 20-Apr-2015, who advised him not to use cigarette and heatstick at the same time.</p> <p>On the day of the event, the respondent used 4-5 HeatSticks and smoked 10 conventional cigarettes. He used the HeatSticks every day (but could not remember the date).</p> <p>The use of the product was discontinued on 20-Apr-2015. It was reported that the problem did not improve when usage of the product was stopped, and that the product was not</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000105	KOREA, REPUBLIC OF Report From Study	Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]		13-APR-2015 to Unknown	13-APR-2015 13-APR-2015	Feel stuffy on back [SUFFOCATION FEELING] N / Y / Y Stuck with sputum a lot [SPUTUM RETENTION] N / Y / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 20-Apr-2015 Case Narrative: Verbatim: Feel stuffy on back and stuck with sputum a lot.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015: This report concerns a male subject in his 40' s (Respondent Study ID: 1130052) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number CRJ YMP N22 KGU) on 13-Apr-2015.</p> <p>On the same day (13-Apr-2015), the respondent stated that he felt “stuffy on back” and stuck with sputum a lot. The events were considered to be non-serious. The severity adverse events was not reported.</p> <p>It was reported that the events improved when the usage of the product was stopped, and that the product was not restarted.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000108	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	17-APR-2015 to Unknown	17-APR-2015 17-APR-2015 17-APR-2015	Got pounding in my head [HEADACHE] N / N / Y coughing [COUGH] N / N / Y sore throat [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-Apr-2015 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: got pounding in my head, coughing, and a sore throat.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-Apr-2015: This report concerns a 43-year-old male subject (Respondent Study ID: 1231958) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number B85 D5Q CA3 PA1) on 17-Apr-2015.</p> <p>On the same day (17-Apr-2015), the respondent experienced pounding in his head, coughing, and a sore throat. The events were considered to be non-serious. Severity was reported mild.</p> <p>The product was used every day. On the day of the events, the respondent used 6 HeatSticks and smoked 6 conventional cigarettes.</p> <p>Action taken with use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000111	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	23-APR-2015 to Unknown	23-APR-2015 23-APR-2015	Throat is stinging (when inhaling smoke, feels like that dust sticks to throat) [SENSATION OF FOREIGN BODY] N / Y / Y Throat is stinging (when inhaling smoke, feels like that dust sticks to throat) [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-Apr-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Throat is stinging (when inhaling smoke, feels like that dust sticks to throat)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-Apr-2015:</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 43-year-old male subject (Respondent Study ID: 1468269) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 pieces - presumably cigarettes - per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number not provided) on 23-Apr-2015.</p> <p>Since the first day of use (23-Apr-2015), the respondent experienced stinging in the throat, which was described as "when inhaling smoke, feels like that dust sticks to the event was considered to be non-serious. Severity was reported as mild.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 4 conventional cigarettes. He used the HeatSticks every day.</p> <p>The use of the product was continued.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000114	KOREA, REPUBLIC OF Report From Study	54 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	20-APR-2015 to Unknown	21-APR-2015 21-APR-2015 21-APR-2015	Feels a bitter taste in throat [DYSGEUSIA] N / Y / Y Throat gets dry [DRY THROAT] N / Y / Y It tastes bad (not good) [PRODUCT TASTE ABNORMAL] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-Apr-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: feels a bitter taste in throat, throat gets dry, and it tastes bad (not good)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-Apr-2015: This report concerns a 54-year-old male subject (Respondent Study ID: 1248038) who took part in the above mentioned market research study.</p> <p>Medical history of hypertension was reported. The following concomitant medications were reported: hypertension medicine and vitamins (no further information provided).</p> <p>The respondent was a daily smoker (on average 13 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 87B FHH 9U7 U7F) on 20-Apr-2015.</p> <p>On 21-Apr-2015, the respondent experienced feeling a bitter taste in throat, throat gets dry, and it tastes bad (not good). The events were considered to be non-serious. Severe adverse events was reported as mild.</p> <p>The respondent used HeatSticks every day. It was reported that the problem returned when the product was restarted.</p> <p>The use of the product was continued.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the events were not resolved.							
No follow-up information is expected ? case closed.							
PMI000115	KOREA, REPUBLIC OF Report From Study	57 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	23-APR-2015 to 26-APR-2015	23-APR-2015	Coughs (usually not coughed when smoking with a general cigarette, but did when using HeatStick) [COUGH] N / N / Y	Recovering/Resolving
Case Initial Receipt Date: 28-Apr-2015 Event Intensity: Mild Case Narrative: Verbatim: coughs (usually not coughed when smoking with a general cigarette, but did when using HeatStick). Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 28-APR-2015: This report concerns a 57-year-old male subject (Respondent Study ID: 1468837) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The respondent was a daily smoker (on average 20 cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number HTR-XJ8-Z5V-70H) on 23-Apr-2015. On the same day (23-Apr-2015), the respondent experienced cough. He clarified that he would usually not cough when smoking conventional cigarettes, but did when using HeatStick. The event was considered to be non-serious. Severity of the adverse event was reported as mild. The respondent used the product occasionally. On the day of the event, the respondent used 3 HeatSticks and smoked 20 conventional cigarettes. It was reported that the event improved when the use of the product was stopped. The use of the product was discontinued due to the cough on 26-Apr-2015 and was not restarted. No follow-up information is expected ? case closed.							
PMI000116	KOREA, REPUBLIC OF Report From Study	22 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	22-APR-2015 to Unknown	22-APR-2015	Throat is stinging and hurting [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 28-Apr-2015 Case Narrative: Verbatim: throat is stinging and hurting Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 28-APR-2015: This report concerns a 22-year-old male subject (Respondent Study ID: 1464521) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was provided.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 6M1 8GV D7J JFY) on 22-Apr-2015.</p> <p>On the same day (22-Apr-2015), the respondent experienced throat stinging and hurting. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000118	KOREA, REPUBLIC OF Report From Study	58 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A Respiratory UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015	Feels nauseous when smoking cigarettes with the product [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 30-Apr-2015 Event Intensity: Mild Event Stop Date: 30-APR-2015 Case Narrative: Verbatim: feels nauseous when smoking cigarettes with the product.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-APR-2015: This report concerns a 58-year-old male subject (Respondent Study ID: 1375229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number reported as "test product") on 30-Apr-2015.</p> <p>On the same day (30-Apr-2015), the respondent experienced feeling nauseous when smoking cigarettes with the product. The event was considered to be non-serious. Severity of adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 1 HeatStick. The number of conventional cigarettes smoked was not reported.</p> <p>It was reported that the problem improved when usage of the product was stopped, and that the product was not restarted.</p> <p>The outcome of the event was reported as recovered on 30-Apr-2015.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000119	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	25-APR-2015	Feels pain in chest (not stabbing pain but strong feeling from smoke coming into chest) [CHEST PAIN] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-Apr-2015</p> <p>Case Narrative: Verbatim: feels pain in chest (not stabbing pain but strong feeling from smoke coming into chest)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-Apr-2015:</p> <p>This report concerns a 29-year-old male subject (Respondent Study ID: 1415934) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number LF9 EPF 18Z M6W) on 24-Apr-2015.</p> <p>On the next day (25-Apr-2015), the respondent experienced feeling pain in chest. The pain was described as not stabbing pain, but 'strong feeling from smoke coming into chest' event was considered to be non-serious. Severity of the event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000120	KOREA, REPUBLIC OF Report From Study	25 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to Unknown	26-APR-2015	has a little headache after using the products [HEADACHE] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 30-Apr-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: has a little headache after using the products</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-Apr-2015:</p> <p>This report concerns a 25-year-old male subject (Respondent Study ID: 1473115) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 4 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number SY8 X20 VCN IGL) on 24-Apr-2015.</p> <p>On 26-Apr-2015, the respondent experienced a little headache after using the products. The event was considered to be non-serious. Severity of the adverse event was reported.</p> <p>On the day of the event, the respondent used 3HeatSticks and smoked 1 conventional cigarette.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The product was used every day and was not discontinued due to the event.							
At the time of reporting, the event was not resolved.							
No follow-up information is expected ? case closed.							
PMI000122	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015	Feels ... paralyzed tongue in the middle of answering details after using the test products / "paralyzed tongue" really means that it is similar to "feels as if it got numb" [HYPOAESTHESIA ORAL] N / Y / Y	Recovering/Resolving
					30-APR-2015	Feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products [OROPHARYNGEAL PAIN] N / N / Y	
					30-APR-2015	Feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products [DIZZINESS] N / N / Y	
Case Initial Receipt Date: 30-Apr-2015							
Case Followup Receipt Date: 14-May-2015 00:00							
Event Intensity: Mild							
Mild							
Mild							
Case Narrative: Verbatim: feels stinging throat, woozy in head and paralyzed tongue in the middle of answering details after using the test products							
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).							
INITIAL INFORMATION RECEIVED ON 30-Apr-2015:							
This report concerns a 44-year-old male subject (Respondent Study ID: 2345991) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
The respondent was a daily smoker (on average 40 cigarettes per day).							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number reported as "test product") on 30-Apr-2015.							
On the same day (30-Apr-2015), the respondent experienced stinging in throat, woozy in head and paralyzed tongue. The events occurred after using the HeatStick. The events assessed as non-serious. Severity of the adverse events was reported as mild.							
On the day of the event, the respondent used 1 HeatStick and smoked 30 conventional cigarettes.							
It was reported that the events were not resolved, but that they improved when the use of the product was stopped.							
Action taken with the use of the product (after the first day of use) was unknown.							
No follow-up information is expected ? case closed.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015:							
The following clarification was received: The respondent didn't make any further comment, but the "paralyzed tongue" really means that it is similar to "feels as if it got							
No follow-up information is expected ? case closed.							
PMI000123	KOREA, REPUBLIC OF	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	28-APR-2015 to Unknown	28-APR-2015	Feels twinge around oesophagus like when smoking strong cigarettes (only in inhaling the smoke deeply) [OESOPHAGEAL PAIN] N / Y / Y	Unknown
Report From Study							
Case Initial Receipt Date: 01-May-2015							
Event Intensity: Unknown							
Case Narrative: Verbatim: feels twinge around oesophagus like when smoking strong cigarettes (only in inhaling the smoke deeply)							
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).							
INITIAL INFORMATION RECEIVED ON 01-May-2015:							
This report concerns a 39-year-old male subject (Respondent Study ID: 2109623) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
No information on smoking habits was provided.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number QJZ SZ6 DRG TPB) on 28-Apr-2015.							
On the same day (28-Apr-2015), the respondent felt twinge around oesophagus. He specified that it was like when smoking strong cigarettes, and that it occurred only in inhale smoke deeply. The event was considered to be non-serious. Severity of the adverse event was not reported.							
Action taken with the use of the product was not reported.							
The outcome of the event was not reported.							
No follow-up information is expected ? case closed.							
PMI000124	KOREA, REPUBLIC OF	32 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown	25-APR-2015	Throat is hurting by using the product, HeatStick because it's so strong. Has phlegm and coughs [PRODUCTIVE COUGH] N / Y / Y	Not Recovered/Not Resolved
Report From Study							
					25-APR-2015	Throat is hurting by using the product, HeatStick, because it's so strong. Has phlegm and coughs [OROPHARYNGEAL PAIN] N / N / Y	
					25-APR-2015	Throat is hurting by using the product, HeatStick, because it's so strong. Has phlegm and coughs [COUGH] N / N / Y	

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
						25-APR-2015	Throat is hurting by using the product, HeatStick, because it' s so strong [PRODUCT TASTE ABNORMAL] N / Y / N	
			<p>Case Initial Receipt Date: 01-May-2015 Event Intensity: Mild Mild Mild Mild</p> <p>Case Narrative: Verbatim: Throat is hurting by using the product, HeatStick, because it' s so strong. Has phlegm and coughs</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 01-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 1385198) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (less than one pack of cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced throat hurting while using the product (due to the fact that the product is strong), phlegm and coughs. The events considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>On the day of the event, the respondent used 4-5 HeatSticks and smoked more than 10 conventional cigarettes.</p> <p>The product was used every day (on average 4-5 HeatSticks per day) and was not discontinued due to the event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>					
PMI000127	KOREA, REPUBLIC OF Report From Study	52 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]		29-APR-2015 to Unknown	29-APR-2015	Feels like ini ial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used too big amount) [NAUSEA] N / N / Y	Recovered/Resolved
			<p>Case Initial Receipt Date: 02-May-2015 Event Intensity: Mild Event Stop Date: 30-APR-2015</p> <p>Case Narrative: Verbatim: feels like initial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used too big amount). But, thereafter, it</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 02-May-2015: This report concerns a 52-year-old male subject (Respondent Study ID: 2107856) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p>					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (on average 35 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number VOP 10X 95H LHR) on 29-Apr-2015.</p> <p>On the same day (29-Apr-2015), the respondent felt like initial symptom of travel sickness (queasy when eating oily food) when using the products one after another (used to The respondent mentioned that thereafter, it was getting better soon. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 35 HeatSticks and smoked no conventional cigarette.</p> <p>The product was used every day and was not discontinued due to the events.</p> <p>The events resolved on 30-Apr-2015.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000129	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	28-APR-2015 to Unknown	30-APR-2015	Throat is parched [DRY THROAT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 04-May-2015 Event Intensity: Mild Case Narrative: Verbatim: throat is parched.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 04-May-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 1374070) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number P5B SM6 ZNM OH9) on 28-Apr-2015.</p> <p>On 30-Apr-2015, the respondent experienced parched throat. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 3 HeatSticks and smoked 10 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000131	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	27-APR-2015 to Unknown	27-APR-2015	The chest feels plugged [CHEST DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 06-May-2015 Case Narrative: Verbatim: The chest feels plugged. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 06-May-2015: This report concerns a 50-year-old male subject (Respondent Study ID: 1469238) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was reported. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 90T NF6 GRN AY3) on 27-Apr-2015. On the same day (27-Apr-2015), the respondent experienced a feeling of chest plugging. The event was considered to be non-serious. Severity of the adverse event was not reported. The product was used every day and was not discontinued due to the event. At the time of reporting, the event was not resolved. No follow-up information is expected ? case closed.							
PMI000132	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	04-MAY-2015 to Unknown	04-MAY-2015 04-MAY-2015	Feels repulsive and bloated (from the 4th piece) [ABDOMINAL DISTENSION] N / Y / Y Feels repulsive and bloated (from the 4th piece) [FEELING ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 06-May-2015 Case Narrative: Verbatim: feels repulsive and bloated (from the 4th piece). Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 06-May-2015: This report concerns a 46-year-old male subject (Respondent Study ID: 2365469) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was reported. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number 4ES V6S MZB JK7) on 04-May-2015. On the same day (04-May-2015), the respondent "felt repulsive" and bloated (from the 4th piece). The events were considered to be non-serious. Severity of the adverse event was not reported.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Action taken with the use of the product was not reported.							
At the time of reporting, the outcome of the events was not reported.							
No follow-up information is expected ? case closed.							
PMI000142	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	14-APR-2015 to 04-MAY-2015	20-APR-2015 20-APR-2015	Feels repulsive and also has a headache after using (the product) [FEELING ABNORMAL] N / Y / Y Feels repulsive and also has a headache after using (the product) [HEADACHE] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 13-May-2015 Event Intensity: Moderate Moderate Event Stop Date: 04-MAY-2015 04-MAY-2015 Case Narrative: Verbatim: feels repulsive and also has a headache after using (the product)							
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).							
INITIAL INFORMATION RECEIVED ON 13-May-2015:							
This report concerns a 32-year-old male subject (Respondent Study ID: 1218311) who took part in the above mentioned market research study.							
No medical history was reported. Vitamin was reported as concomitant medication.							
The respondent was a daily smoker (in average 17 cigarettes per day).							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number S75 TEV 77LXTR) on 14-Apr-2015.							
On 20-Apr-2015, the respondent experienced feeling repulsive and also had headache after using the product. The events were considered to be non-serious. Severity of the ad event was reported as moderate.							
On the day of the event, the respondent used 3 HeatSticks and smoked 15 conventional cigarettes.							
The product was used every day for the first three weeks, and then was discontinued.							
It was reported that the events improved after product use was stopped and that the product was not restarted. The last day of use of the product was 04-May-2015.							
The events resolved on 04-May-2015							
No follow-up information is expected ? case closed.							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000143	KOREA, REPUBLIC OF Report From Study	60 Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	14-APR-2015 to 11-MAY-2015	14-APR-2015 14-APR-2015	has somewhat stinging on throat when feeling aftertaste during using the product [DYSGEUSIA] N / Y / Y has somewhat stinging on throat when feeling aftertaste during using the product [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: has somewhat stinging on throat when feeling aftertaste during using the product</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-May-2015: This report concerns a 60-year-old male subject (Respondent Study ID: 1293222) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamin and painkiller (both unspecified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 7 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Fitz) (Kit number XAA Q4M T55 NIK) on 14-Apr-2015.</p> <p>On the same day (14-Apr-2015), the respondent experienced stinging on throat when feeling aftertaste during using the product. The events were considered to be non-serious. the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 7 HeatSticks and smoked 8 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the occurrence of the events. Last day of product use was 11-May-2015.</p> <p>It was reported that the events did not return when product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000148	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	20-APR-2015 to Unknown	20-APR-2015 20-APR-2015	Throat is stinging with slight cough while/after using HeatStick [OROPHARYNGEAL PAIN] N / N / Y Throat is stinging with slight cough while/after using HeatStick [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 19-May-2015 Event Intensity: Mild Mild</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Throat is stinging with slight cough while/after using HeatStick.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 19-May-2015: This report concerns a 38-year-old male subject (Respondent Study ID: 2342524) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number A17 5BF 072 21K P6K) on 20-Apr-2015.</p> <p>On the same day (20-Apr-2015), the respondent experienced stinging throat with slight cough while/after using the HeatSticks. The events were considered to be non-serious. the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 17 HeatSticks and smoked no conventional cigarettes.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000153	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	22-APR-2015 13-MAY-2015	During the test of the product, HeatStick, at first I felt heat (in mouth) like when smoking the last puff of normal cigarettes. [FEELING HOT] N / Y / Y Then, the chest feels heavy after 3 weeks of using (the product). [CHEST DISCOMFORT] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 22-May-2015 Event Intensity: Mild Mild Event Stop Date: 20-MAY-2015 20-MAY-2015 Case Narrative: Verbatim: During the test of the product, HeatStick, at first I felt heat (in mouth) like when smoking the last puff of normal cigarettes. Then, the chest feels heavy after product).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1412271) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 3TH ZZC QAA VDD) on 22-Apr-2015.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (22-Apr-2015), during the test of the product, the respondent felt heat (in mouth) like when smoking the last puff of normal cigarettes. Then, on 13-May-2015 weeks of using the product, he experienced heaviness of chest. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>Action taken with the use of the product was not reported. It was reported that the events improved when usage of the product was stopped and did not return when use of the restarted.</p> <p>The events resolved on 20-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000155	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	22-APR-2015 to Unknown	22-APR-2015	Feels a slight pain on throat after using (the product). [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-May-2015</p> <p>Case Narrative: Verbatim: Feels a slight pain on throat after using (the product).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015: This report concerns a 36-year-old male subject (Respondent Study ID: 1231135) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number FVQ VYR P1D Z2W) on 22-Apr-2015.</p> <p>On the same day (22-Apr-2015), the respondent felt a slight pain on throat after using the product. The event was considered to be non-serious. Severity of the adverse event reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000157	KOREA, REPUBLIC OF Report From Study	39 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	23-APR-2015 to 20-MAY-2015	11-MAY-2015 11-MAY-2015	Feels smarting in mouth when using the product for about half an hour. [ORAL PAIN] N / Y / Y Feels stinging on throat when waking up in the morning after 3 weeks of using (the product). [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 22-May-2015</p> <p>Event Intensity: Mild Mild</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Feels smarting in mouth when using the product for about half an hour. Feels stinging on throat when waking up in the morning after 3 weeks of using (the product).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015: This report concerns a 39-year-old male subject (Respondent Study ID: 2345759) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 6GN VUR GCE OYE) on 23-Apr-2015.</p> <p>On 11-May-2015, the respondent felt smarting in mouth when using the product for about half an hour. He also reported to feel stinging on throat when waking up in the morning weeks of using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 6 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were used on 20-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000160	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	23-APR-2015 to Unknown	23-APR-2015	Has a head-ache after smoking a few puffs when using the product for the first time. [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Case Narrative: Verbatim: Has a head-ache after smoking a few puffs when using the product for the first time.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 27-year-old male subject (Respondent Study ID: 2348221) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 2Z1 ORG 58C DUK) on 23-Apr-2015.</p> <p>On the same day (23-Apr-2015), the respondent experienced headache after smoking a few puffs (when using the product for the first time). The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000161	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown	25-APR-2015 25-APR-2015 25-APR-2015	gets parched on throat and feels choked. [DRY THROAT] N / Y / Y gets parched on throat and feels choked. [CHOKING SENSATION] N / Y / Y Feels hot air coming from throat to chest when smoking HeatStick. [CHEST DISCOMFORT] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Case Narrative: Verbatim: Feels hot air coming from throat to chest when smoking HeatStick. And gets parched on throat and feels choked.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 1245346) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number JAD VZI JLH X5X) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced feeling hot air coming from throat to chest when smoking a HeatStick. In addition, the respondent reported that he parched on throat and feelled choked. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>The outcome of the events was not reported; however, the respondent reported that "it is ok as not using it" (considered as recovered).</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000164	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown	02-MAY-2015 02-MAY-2015 02-MAY-2015	Feels heavy and stuck to swallow when using HeatStick at the end. [DISCOMFORT] N / Y / Y Feels heavy and stuck to swallow when using HeatStick at the end. [DYSPHAGIA] N / Y / Y Has coughs caused by the heavy feelings. [COUGH] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Event Intensity: Mild Mild Mild</p> <p>Event Stop Date: 22-MAY-2015 22-MAY-2015 22-MAY-2015</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Feels heavy and stuck to swallow when using HeatStick at the end. Has coughs caused by the heavy feelings.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 27-year-old male subject (Respondent Study ID: 2106243) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number Y7K CJ6 PBD N2L) on 25-Apr-2015.</p> <p>On 02-May-2015, the respondent felt heavy and "stuck to swallow" when using HeatStick at the end. Has also reported that he coughed, which was caused by the heavy feelings. events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>It was reported that the problems improved when usage of the product was stopped and that the events returned when use of the product was restarted.</p> <p>The events resolved on 22-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000165	KOREA, REPUBLIC OF Report From Study	52 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown		Throat gets parched and feels hurt. [DRY THROAT] N / Y / Y Throat gets parched and feels hurt. [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Case Narrative: Verbatim: Throat gets parched and feels hurt.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 52-year-old male subject (Respondent Study ID: 2107376) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KWCT FDX M8A X8S) on 25-Apr-2015.</p> <p>On an unspecified date in Apr-2015, the respondent experienced his throat getting parched and feeling hurt. The events were considered to be non-serious. Severity of the ad was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000167	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	Respiratory	25-APR-2015 to 27-MAY-2015	25-APR-2015 25-APR-2015 26-APR-2015	Feels bad when my hand gets hot because the holder gets hot. [FEELING ABNORMAL] N / Y / Y Feels bad when my hand gets hot because the holder gets hot. [FEELING HOT] N / Y / Y Throat feels stinging to swallow because of hot steam after using (the product) a few times. [ODYNOPHAGIA] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-May-2015 Event Intensity: Mild Mild Mild Event Stop Date: 03-MAY-2015 Case Narrative: Verbatim: Feels bad when my hand gets hot because the holder gets hot. As its upper part gets hot, I would use the product by holding the bottom of the hot holder. Throat f swallow because of hot steam after using (the product) a few times.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-May-2015: This report concerns a 47-year-old male subject (Respondent Study ID: 1117281) who took part in the above mentioned market research study.</p> <p>Medical history of hyperparathyroidism was reported. Medication for treating hyperparathyroidism (unspecified), "hepatic" medications (ursodesoxycholic acid 50 mg, thiami 10 mg, riboflavin 5 mg), and multivitamin were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 27 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number R11 C89 SEH 08A MRO) on 25-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced feeling bad when his hand gets hot because the holder gets hot. The respondent explained that as its upper part gets hot, he woul product by holding the bottom of the hot holder. On 26-Apr-2015, the respondent experienced stinging on throat when swallowing, because of hot steam after using the product times. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the events related to hot holder, the respondent used 9 HeatSticks and smoked 13 conventional cigarettes. On the day of the ev stinging on throat, the respondent used 8 HeatSticks and smoked 16 conventional cigarettes. The last Heatsticks were used on 27-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse events.</p> <p>The events related to the hot holder were not recovered at time of reporting. The event of stinging throat resolved on 03-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000169	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	27-APR-2015 to 20-MAY-2015	28-APR-2015	Felt hot on lips when smoking HeatStick [FEELING HOT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Event Stop Date: 20-MAY-2015 Case Narrative: Verbatim: Felt hot on lips when smoking HeatStick, and felt the same way when testing and every time using it for 4 weeks.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 46-year-old male subject (Respondent Study ID: 2104643) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number RLG R8D LAK 3IT) on 27-Apr-2015. The respondent mentioned that he used test product as well.</p> <p>On 28-Apr-2015, the respondent felt hot on lips when smoking HeatStick. He clarified that he felt the same way when testing and every time using the product for 4 weeks. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day (about 2 HeatSticks a day). On the day of the event, the respondent used 2 HeatSticks and smoked 12 conventional cigarettes. The last HeatStick was used on 20-May-2015.</p> <p>It was reported that the event improved when use of the product was stopped, and that the event returned when the product was restarted.</p> <p>The event resolved on 20-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000173	KOREA, REPUBLIC OF Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [qd]	24-APR-2015 to 21-MAY-2015	24-APR-2015	Felt stinging when smoking a few puffs by using the test product for the first time / I felt slightly stinging after taking the product out of mouth. [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 27-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Felt stinging when smoking a few puffs by using the test product for the first time, but usually felt either stinging or not by using general cigarettes, depending on the puff. The respondent gave no comment in the test, because it was not a big deal, but I felt slightly stinging after taking the product out of mouth.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 27-May-2015: This report concerns a 28-year-old male subject (Respondent Study ID: 2359200) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Powder type Vitamin C was reported as concomitant medication.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (in average 4 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 9TJ F4S NG8 X15) on 24-Apr-2015.</p> <p>On the first day of use (24-Apr-2015), the respondent felt stinging when smoking a few puffs. He explained that he felt slightly stinging after taking the product out of mouth. The respondent clarified that he usually felt either stinging or not by using conventional cigarettes, depending on products. He mentioned that he gave no comment in the test, not a big deal. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 3 HeatSticks and smoked no conventional cigarettes. The last Heatsticks were used on 21-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the problem returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000176	KOREA, REPUBLIC OF Report From Study	24 Years Male	THS 2.2 Regular (Dorado II / Fitz) / N/A UNK [qd]	2015 to 22-MAY-2015	25-APR-2015	Feels parched on throat after using the product. It happens also when smoking regular cigarettes, but this time, when using HeatStick, is worse. [DRY THROAT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 29-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Feels parched on throat after using the product. It happens also when smoking regular cigarettes, but this time, when using HeatStick, is worse.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 29-May-2015: This report concerns a 24-year-old male subject (Respondent Study ID: 2359447) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number not provided) on an unspecified date.</p> <p>On 25-Apr-2015, the respondent felt parched on throat after using the product. He clarified that it happened also when smoking regular cigarettes, but this time, when using HeatStick, was worse. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 1 HeatStick and smoked 4 conventional cigarettes. The last Heatsticks were used on 22-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000180	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	29-APR-2015 to Unknown	29-APR-2015 29-APR-2015	Feels parched in swallowing since using the product for the first time. [DYSPHAGIA] N / Y / Y Feels parched in swallowing since using the product for the first time [DRY THROAT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-May-2015</p> <p>Case Narrative: Verbatim: Feels parched in swallowing since using the product for the first time.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 2361433) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KGF 2RG LQQ KYS) on 29-Apr-2015.</p> <p>Since the first time he used the product (29-Apr-2015), the respondent felt parched in swallowing. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000181	KOREA, REPUBLIC OF Report From Study	33 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	01-MAY-2015 to Unknown	25-MAY-2015	Did not feel any problem in tes ing, but felt swollen on throat after about 3 weeks from using. [PHARYNGEAL OEDEMA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2015</p> <p>Case Narrative: Verbatim: Did not feel any problem in testing, but felt swollen on throat after about 3 weeks from using. So, does not use (the product) now.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-May-2015: This report concerns a 33-year-old male subject (Respondent Study ID: 2362201) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number 4WS GTZ XSK 79D) on 01-May-2015.</p> <p>Approximately on 25-May-2015 (reported as about 3 weeks after starting the product), the respondent felt swollen on throat. The event was considered to be non-serious. Severity of the adverse event was not reported.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent indicated that he was not using the product anymore due to the event.							
At the time of reporting, the outcome of the event was not reported.							
No follow-up information is expected ? case closed.							
PMI000182	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory II / Fitz) / N/A UNK [UNK]	30-APR-2015 to Unknown	30-APR-2015 30-APR-2015	Feels tickling in the throat and has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. [THROAT IRRITATION] N / Y / Y Has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 30-May-2015							
Case Narrative: Verbatim: Feels tickling in the throat and has coughs when using the test product. Feels and has the same when using and puffing (the product) deeply throughout 4 weeks. Th such problem if not puffing (the product) deeply.							
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).							
INITIAL INFORMATION RECEIVED ON 30-May-2015:							
This report concerns a 38-year-old male subject (Respondent Study ID: 2364502) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
Information on smoking habits was not provided.							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) (Kit number KJQ QNC JT6 4QT) on 30-Apr-2015.							
On the same day (30-Apr-2015), the respondent felt tickling in his throat and had coughs when using the test product. He explained that he felt and experienced the same whe puffing the product deeply throughout the 4 weeks. According to the respondent, there was no such problem if he was not puffing the product deeply. The events were consider non-serious. Severity of the adverse events was not reported.							
Action taken with the use of the product was not reported.							
At the time of reporting, the outcome of the events was not reported.							
No follow-up information is expected ? case closed.							

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000193	ITALY Report From Study	50 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014 Case Narrative: Verbatim: Dizzy.	22-MAY-2014 to 22-MAY-2014	22-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 50-year-old male subject (Respondent Study ID: BUS0303101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004564) on 22-May-2014. On 22-May-2014, he was feeling dizzy. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. On the day of the occurrence of the event, the respondent used 4 sticks and smoked 6 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000198	ITALY Report From Study	37 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 24-May-2014 Event Intensity: Severe Severe Event Stop Date: 18-MAY-2014 18-MAY-2014 Case Narrative: Verbatim: Tachycardia, Feeling like squeezing in chest.	17-MAY-2014 to 23-MAY-2014	17-MAY-2014 17-MAY-2014	Tachycardia [TACHYCARDIA] N / Y / Y Feeling like squeezing in chest [CHEST DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 37-year-old female subject (Respondent Study ID: MIF0122101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p>							

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The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU005328) on 17-May-2014. On 17-May-2014, she experienced tachycardia and feeling like squeezing in chest. The events were considered to be non-serious and severe in intensity. It was reported that the events improved when the respondent stopped using the THS and that the events returned when the respondent restarted using the THS. The events resolved on 18-May-2014. The respondent stopped using the product on 23-May-2014. On the day of the occurrence of the event, the respondent used 1 stick and smoked 20 cigarettes.							
No follow-up information has been requested ? case closed.							
PMI000199	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	19-MAY-2014 to 21-MAY-2014	21-MAY-2014 21-MAY-2014 22-MAY-2014	Laryngitis [LARYNGITIS] N / Y / Y Tracheitis [TRACHEITIS] N / Y / Y Fever [PYREXIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 23-May-2014 Case Followup Receipt Date: 03-Jun-2014 00:00 Case Narrative: Verbatim: Laryngitis, tracheitis, fever. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker respondents in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at a central location, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 33-year-old female subject (Respondent Study ID: MIF0818101L) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a smoker who smoked on average 6 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU005216) on 19-May-2014. Since that date, she used only the THS (4 sticks on 19-May-2014, 3 sticks on 20-May-2014 and 4 sticks on 21-May-2014) and smoked no cigarettes. On 21-May-2014, she experienced laryngitis or tracheitis. She noticed that her throat was bigger than normal and dark red. She had a mild sore throat at the beginning. She reported that she could eat only ice cubes. The respondent stopped using the product on 21-May-2014. On 22-May-2014 (evening), she had fever (37.5 Degrees Celsius) and at the time of reporting, her fever was 38 Degrees Celsius. She added that she was not aware of these events could happen and that she was going to lose work days. She added that, in 20 years as a smoker, she had never had such problems. On 23-May-2014, she went to see a doctor (without mentioning her use of THS) who prescribed her (unspecified) antibiotics. On 23-May-2014, she also took unspecified medications for her sore throat. The events were considered to be serious (medically significant). At the time of report, the events were still ongoing. She also asked whether her husband could use the THS and she was told 'no' as he had not signed the informed consent form. FOLLOW-UP INFORMATION RECEIVED ON 03-JUN-2014: The physician stated that the respondent booked an appointment for 23-May-2014 but she did not come to the surgery. As the physician did not see the respondent, she was not able to provide any further information. Based on the information received on follow-up, this case was downgraded to non-serious. No further follow-up information has been requested ? case closed.							

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PMI000203	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	20-MAY-2015 to 20-MAY-2015	20-MAY-2014	The taste/aroma gives me headache [HEADACHE] N / N / Y Maybe too light/ I do not feel it [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014 Event Intensity: Mild Event Stop Date: 20-MAY-2014 Case Narrative: Verbatim: The taste/aroma gives me headache, maybe too light/ I do not feel it.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 40-year-old female subject (Respondent Study ID: BUS0808101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004673) on 20-May-2014. On 20-May-2014, she experienced headache. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 20-May-2014 and the event resolved on the same day. On the day of occurrence of the event, the respondent used 4 sticks and smoked 20 cigarettes.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 28-MAY-2014: The respondent reported that the product taste or aroma gave her headache. She was used to smoking cigarettes. The respondent found it hard to use the product. Maybe it was as she did not feel it (taste). The events were considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000205	ITALY Report From Study	21 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	22-MAY-2014 to 24-MAY-2014	22-MAY-2014 22-MAY-2014 22-MAY-2014 22-MAY-2014	Tongue tingling [PARAESTHESIA ORAL] N / Y / Y Cough [COUGH] N / N / Y Headache [HEADACHE] N / N / Y It scratched his throat [THROAT IRRITATION] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Mild Mild Mild Mild Event Stop Date: 24-MAY-2014 24-MAY-2014 24-MAY-2014 24-MAY-2014</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: It scratched his throat, cough, headache, tongue tingling</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 21-year-old male subject (Respondent Study ID: BUS0513102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was taking Be-Total (vitamin B).</p> <p>The respondent was a smoker who smoked on average 5 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number CU004492) on 22-May-2014. On 22-May-2014, the respondent used 1 stick and smoked 3 cigarettes. On 22-May-2014, he experienced cough, headache, tongue tingling and he reported that it scratched his throat. The events were considered to be non-serious and mild in intensity. The respondent did not use the THS on 23-May-2014. On 24-May-2014, the respondent used 3 sticks and smoked 1 cigarette. The respondent stopped using the product on 24-May-2014 and the events resolved on the same day.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000217	ITALY Report From Study	30 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Cold sweat [COLD SWEAT] N / N / Y It takes a lot of time to recharge/to warm the cigarette [DEVICE MALFUNCTION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014</p> <p>Case Narrative: Verbatim: Cold sweat, it takes a lot of time to recharge / to warm the cigarette.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 30-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported the product gave him a lot of time to recharge, to warm the cigarette. The product did not satisfy him like his cigarettes. The product gave him a strange effect: it gave him sweat cold which he then stopped. However the respondent stated that, if the event persisted, he would stop using the product. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000228	ITALY Report From Study	37 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Itching in the throat [THROAT IRRITATION] N / Y / Y Makes me a little nauseous [NAUSEA] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: Itching in the throat, Makes me a little nauseous, Too strong.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 37-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, gave her itching in the throat and made her a little nauseous. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000229	ITALY Report From Study	55 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			kneads the mouth [ORAL DISCOMFORT] N / Y / Y Makes me a little nauseous [NAUSEA] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2014 Case Narrative: Verbatim: Makes me a little nauseous, Kneads the mouth, Too strong.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 55-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, made her a little nauseous and 'kneaded the mouth'. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000252	ITALY Report From Study	45 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]			Excessively strong taste that remains in the throat and chest [RESPIRATORY TRACT IRRITATION] N / Y / Y Excessively strong taste that remains in the throat and chest [DYSGEUSIA] N / Y / Y Excessively strong taste that remains in the throat and chest [PRODUCT TASTE ABNORMAL] N / Y / Y Excessively strong taste that remains in the throat and chest [THROAT IRRITATION] N / N / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: Excessively strong taste that remains in the throat and chest.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014:</p> <p>This report concerns a 45-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that they had an excessively strong taste that remained in the throat and chest. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000257	ITALY Report From Study	64 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			It causes sensation of empty stomach [HUNGER] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: It causes sensation of empty stomach.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014:</p> <p>This report concerns a 64-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that they caused sensation of empty stomach. The event was considered to be non-serious. The outcome was unknown.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000262	ITALY Report From Study	29 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			It gives me nausea [NAUSEA] N / N / Y Very bitter taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Very bitter taste, it gives me nausea. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 29-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that they experienced a very bitter taste and gave him nausea. The events were considered to be non-serious. The outcome was unknown.							
No follow-up information has been requested ? case closed.							
PMI000267	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	19-SEP-2014 to 23-SEP-2014	19-SEP-2014 19-SEP-2014 19-SEP-2014	Dull feeling in stomach [ABDOMINAL DISCOMFORT] Not Recovered/Not Resolved N / Y / Y Aversion to the product [AVERSION] N / Y / Y Nausea after use of the product [NAUSEA] N / N / Y	
Case Initial Receipt Date: 24-Sep-2014 Event Intensity: Moderate Moderate Moderate Case Narrative: Verbatim: Nausea after use of the product, dull feeling in stomach, aversion to the product. Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior. INITIAL INFORMATION RECEIVED ON 24-SEP-2014: This report concerns a 22-year-old female subject (Respondent Study ID: MU1748) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a daily smoker who smoked on average 20 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006689) on 19-Sep-2014. On the same day, she experienced nausea after the use of the product. The nausea lasted about one hour. She also had a dull feeling in her stomach and felt an aversion to the product during the events were considered to be non-serious and moderate in intensity.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			The respondent used the product every day. On 19-Sep-2014, she used 5 sticks. On 20-Sep-2014, she used 2 sticks. On 21-Sep-2014, 22-Sep-2014 and 23-Sep-2014, she used 2 to sticks per day. The reported events improved when she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 23-Sep-2014. At the t reporting, the events were ongoing.				
			No follow-up information has been requested ? case closed.				
PMI000268	GERMANY Report From Study	19 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 25-Sep-2014 Event Intensity: Severe Event Stop Date: 25-SEP-2014 Case Narrative: Verbatim: Strong headaches.	24-SEP-2014 to 25-SEP-2014	24-SEP-2014	Strong headaches [HEADACHE] N / N / Y	Recovered/Resolved
			Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.				
			INITIAL INFORMATION RECEIVED ON 25-SEP-2014: This report concerns a 19-year-old female subject (Respondent Study ID: DR3774) who took part in the above mentioned market research study.				
			The respondent had no medical conditions and was not taking any concomitant medications.				
			The respondent was a daily smoker who smoked on average 15 cigarettes per day.				
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006150) on 24-Sep-2014. Immediately after one stick, she experienced strong headaches after the first inhalation. She tried again the product on 25-Sep-2014 in the morning and experienced headaches again. The event considered to be non-serious and severe in intensity.				
			Out of the 2 sticks, she gave one to her father and her sister. She provided no information as to whether they, too, experienced any problems.				
			On the day of the occurrence of the event, she smoked 4 cigarettes and used 1 stick. The reported event improved when she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 25-Sep-2014 and the event resolved on the same day.				
			No follow-up information has been requested ? case closed.				
PMI000269	GERMANY Report From Study	53 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 25-Sep-2014 Event Intensity: Severe Event Stop Date: 23-SEP-2014 Case Narrative: Verbatim: Strong sore throat.	22-SEP-2014 to 24-SEP-2014	22-SEP-2014	Strong sore throat [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
			Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.				
			INITIAL INFORMATION RECEIVED ON 25-SEP-2014: This report concerns a 53-year-old female subject (Respondent Study ID: DR3200) who took part in the above mentioned market research study.				
			The respondent had no medical conditions and was not taking any concomitant medications.				

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent was a daily smoker who smoked on average 15 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU006272) on 22-Sep-2014. On the same day, experienced strong sore throat after the first consumption. After the sore throat subsided, she tried the product again and the sore throat came back. The event was considered non-serious and severe in intensity.								
On the day of the occurrence of the event, the respondent used 2 sticks and smoked 5 cigarettes. The reported event improved when she stopped using the product and re-occurred when she restarted using the product. The event resolved on 23-Sep-2014. The respondent stopped using the product on 24-Sep-2014.								
No follow-up information has been requested ? case closed.								
PMI000270	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			19-SEP-2014	General feeling of being unwell [MALAISE] N / Y / Y	Recovering/Resolving
						19-SEP-2014	Unpleasant feeling in stomach escalating to nausea [ABDOMINAL DISCOMFORT] N / Y / Y	
						19-SEP-2014	Strong headache [HEADACHE] N / N / Y	
						19-SEP-2014	Unpleasant feeling in stomach escalating to nausea [NAUSEA] N / N / Y	
Case Initial Receipt Date: 26-Sep-2014								
Event Intensity: Severe Severe Severe Severe								
Case Narrative: Verbatim: General feeling of being unwell, unpleasant feeling in stomach escalating to nausea and strong headache.								
Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.								
INITIAL INFORMATION RECEIVED ON 26-SEP-2014: This report concerns a 22-year-old female subject (Respondent Study ID: MU5377) who took part in the above mentioned market research study.								
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number not provided) on an unspecified date. On 19-Sep-2014, she experienced general feeling of being unwell, unpleasant feeling in stomach escalating to nausea and strong headache. The events were considered to be non-serious and severe in intensity.								
Upon due diligence, it was clarified that the respondent did not experience circulatory failure (as previously reported), did not faint due to the occurrence of these events, did not visit a doctor or hospital and did not receive any treatment.								
The reported events improved when she stopped using the product.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000271	GERMANY Report From Study	34 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	15-SEP-2014 to 25-SEP-2014	25-SEP-2014 25-SEP-2014	Unpleasant feeling in her stomach [ABDOMINAL DISCOMFORT] N / Y / Y Slight headache [HEADACHE] N / N / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 26-Sep-2014 Event Intensity: Mild Mild Case Narrative: Verbatim: Slight headache, unpleasant feeling in her stomach.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 26-SEP-2014: This report concerns a 34-year-old female subject (Respondent Study ID: DR7911) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (unspecified allocation arm; Kit number not provided) on 15-Sep-2014. The respondent used the product every day. On 25-Sep-2014, she experienced slight headache and unpleasant feeling in her stomach. The events were considered to be non-serious and mild in</p> <p>The respondent stopped using the product on 25-Sep-2014 and at the time of this report, the reported events were improving.</p> <p>No follow-up information has been requested ? case closed.</p> <p>28-JAN-2015: Case re-opened to add product name. The respondent used THS 2.2 Regular (Dorado II / Ron) - half white tipping paper.</p>								
PMI000274	ITALY Report From Study	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	05-NOV-2014 to 05-NOV-2014	05-NOV-2014 05-NOV-2014	Stomachache [ABDOMINAL PAIN UPPER] N / Y / Y Headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 12-Nov-2014 Event Intensity: Mild Mild Event Stop Date: 06-NOV-2014 06-NOV-2014 Case Narrative: Verbatim: Stomachache, Headache</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 12-NOV-2014: This report concerns a 51-year-old female subject (Respondent Study ID: B074) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>The respondent was a daily smoker who smoked on average 25 cigarettes per day.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number 92N4K4TDW84W) on 05-Nov-2014. She used 5 sticks on that day and experienced stomach ache and headache. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on the same day. The events resolved on 06-Nov-2014.							
No follow-up information has been requested ? case closed.							
PMI000275	SWITZERLAND Report From Study	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	12-NOV-2014 to 13-NOV-2014	12-NOV-2014 12-NOV-2014	Increased heart rate [HEART RATE INCREASED] N / Y / Y feeling as if her chest area widens [CHEST DISCOMFORT] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 14-Nov-2014 Event Intensity: Severe Severe Case Narrative: Verbatim: Increased heart rate, Feeling as if her chest area widens							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 14-NOV-2014: This report concerns a 47-year-old female subject (Respondent Study ID: F176690) who took part in the above mentioned market research study.							
The respondent had no medical history and was not taking any concomitant medications or vitamins.							
The respondent was a daily smoker who smoked on average 20 cigarettes per day (140 cigarettes per month).							
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU008516) on 12-Nov-2014. On the same day, experienced increased heart rate and felt as if her chest area widens. The events were considered to be non-serious and severe in intensity.							
The respondent used 2 sticks and she smoked 2 cigarettes on the day of the events. She also used the sticks on 13-Nov-2014 and stopped using the sticks on that same day. The reported events improved after the respondent discontinued the product and reoccurred when she used the sticks again. At the time of reporting, the events were resolved.							
No follow-up information has been requested ? case closed.							
PMI000276	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]		16-NOV-2014 16-NOV-2014	Eruclation [ERUCLATION] N / Y / Y Unpleasant tobacco taste in mouth [DYSGEUSIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 16-Nov-2014 Event Intensity: Mild Mild Case Narrative: Verbatim: Eruclation, unpleasant tobacco taste in mouth							
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 16-NOV-2014: This report concerns a 45-year-old female subject (Respondent Study ID: F136909) who took part in the above mentioned market research study.							
The respondent had no medical history and was not taking any concomitant medications.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU004259) on an unspecified date. She reported she experienced eructation always about 20 minutes after the use of the stick. This was comparable to the type of eructation that occurred after the consumption of onions. she reported unpleasant tobacco taste in mouth. The events started on 16-Nov-2014. They were considered to be non-serious and mild in intensity.</p> <p>The respondent did not stop using the product and at the time of reporting, the events were ongoing. However, she wanted to quit the study.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000277	SWITZERLAND Report From Study	32 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	14-NOV-2014 to 20-NOV-2014	14-NOV-2014 14-NOV-2014 14-NOV-2014 14-NOV-2014 14-NOV-2014	Burning sensation in lips [ORAL DISCOMFORT] N / Y / Y Burning sensation in mouth [ORAL DISCOMFORT] N / Y / Y Burning sensation in throat [THROAT IRRITATION] N / Y / Y Aftertaste [DYSGEUSIA] N / Y / Y Headache [HEADACHE] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 20-Nov-2014 Event Intensity: Mild Mild Mild Mild Mild</p> <p>Case Narrative: Verbatim: Burning sensation in lips, mouth and throat, headache and aftertaste.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 20-NOV-2014: This report concerns a 32-year-old female subject (Respondent Study ID: F145851) who took part in the above mentioned market research study.</p> <p>The respondent had no medical history and was not taking any concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number C0003777) on 14-Nov-2014. On the same day, experienced burning sensation in lips, mouth up to the throat as well as aftertaste. She always washed the teeth after having smoked as the burning sensation was so strong. respondent also had headache and she thought this was due to the headsticks being stronger than the cigarettes she usually smoked. When she smoked her cigarettes, she did not experience any burning sensation. The events were considered to be non-serious and mild in intensity.</p> <p>The respondent used 3 sticks and smoked 3 cigarettes on the day of the events. She used the headsticks every day. The reported events improved after she stopped using the product and re-occurred when she restarted using the product. She stopped using the product on 20-Nov-2014.</p> <p>At the time of reporting, the events were ongoing.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000278	SWITZERLAND Report From Study	58 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	17-NOV-2014 to 24-NOV-2014	17-NOV-2014 17-NOV-2014	Feels bad [FEELING ABNORMAL] N / Y / Y irritation in the mou h domain [STOMATITIS] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 25-Nov-2014 Case Narrative: Verbatim: Feels bad, irritations in the mouth domain</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 25-NOV-2014: This report concerns a 58-year-old female subject (Respondent Study ID: F197579) who took part in the above mentioned market research study.</p> <p>The respondent had no medical history and was taking vitamins as concomitant medications.</p> <p>The respondent was a daily smoker who smoked on average 10-15 cigarettes per day (90 cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) half white tipping paper (Kit number CU003920) on 17-Nov-2014. Starting on the s day, the respondent felt bad and experienced irritations in the mouth domain. The events were considered to be non-serious (severity/intensity assessment of the reaction wa provided).</p> <p>The respondent used sticks every day. She had used 2 sticks and smoked 17 cigarettes on the days of the events. She stopped using the sticks on 24-Nov-2014. At the time of the events were not resolved.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000281	GERMANY Report From Study	23 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			it itches [ORAL PRURITUS] N / Y / Y I became nauseated from it [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 19-Sep-2014 Case Narrative: Verbatim: it itches, I became nauseated from it</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 19-SEP-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 23-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? lights; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it itches, it was not the same as a cigarette and she became nauseated from it.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000282	GERMANY Report From Study	58 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I feel sick [MALAISE] N / Y / Y I feel dizzy [DIZZINESS] N / N / Y I inhaled too strongly 2 x on the heat stick [WRONG TECHNIQUE IN PRODUCT USAGE PROCESS] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 02-Oct-2014 Case Followup Receipt Date: 11-Nov-2015 00:00 Case Narrative: Verbatim: I feel sick, I feel dizzy, I inhaled too strongly two times on the heatstick.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 02-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 58-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she felt sick and dizzy. She also reported that apparently she inhaled too strongly two times on the heatstick and the heating unit became too the smoke was hot and unpleasant.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p> <p>NOTE: On 11-Nov-2015, the LLT Wrong technique in drug usage process has been recoded due to MedDRA 18.1 upgrade. Consequently, the PT for this event has been updated from Wrong technique in drug usage process to Wrong technique in product usage process. The other events with PTs Dizziness and Malaies have also been recoded in MedDRA 18.1 but no change applies to those terms.</p>							
PMI000283	GERMANY Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I was sick, bronchitis [BRONCHITIS] N / Y / Y I found that the sticks were stronger [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 28-Oct-2014							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I was sick, bronchitis; I found that the sticks were stronger.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that she was sick, bronchitis and that she found that the sticks were stronger (presumably stronger than normal cigarettes), therefore, she also smoked normal cigarettes.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000284	GERMANY Report From Study	26 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Heatstick caused nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 21-Oct-2014</p> <p>Case Narrative: Verbatim: heatstick caused nausea</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 21-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 26-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that heatstick caused nausea.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000285	GERMANY Report From Study	43 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I was nauseated by the use of the Heat Stick [NAUSEA] N / N / Y the smell of the heats ick was very unpleasant for me [PRODUCT ODOUR ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 22-Oct-2014</p> <p>Case Narrative: Verbatim: I was nauseated by the use of the heatstick; the smell of the heatstick was very unpleasant for me.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 22-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 43-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that she was nauseated by the use of the heatsticks, in particular in the morning, she could not tolerate them well. The smell of the heatstick was for her.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000286	GERMANY Report From Study	25 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			I developed headaches from the heatsticks [HEADACHE] N / N / Y didn't like the taste anymore [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 17-Oct-2014</p> <p>Case Narrative: Verbatim: I developed headaches from the heatsticks; didn't like the taste anymore</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 17-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent reported that she developed headaches from the heatsticks, and that after some time she didn't like the taste anymore.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000287	GERMANY Report From Study	36 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			Had to vomit [VOMITING] N / N / Y developed headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 20-Oct-2014 Case Narrative: Verbatim: Had to vomit, developed headaches</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that he had to vomit and developed headaches after a short time.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000288	GERMANY Report From Study	24 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			increased consumption of the tobacco stick led to a feeling of illness [MALAISE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 20-Oct-2014 Case Narrative: Verbatim: Increased consumption of the tobacco stick led to a feeling of illness</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 24-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that increased consumption of the tobacco stick led to a feeling of illness, therefore, he rather used regular cigarettes.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000289	GERMANY Report From Study	36 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 25-Oct-2014 Case Narrative: Verbatim: Felt a little nauseated from the heatsticks			felt a little nauseated from the heat sticks [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 25-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 36-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? lights; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that she simply felt a little nauseated from the heatsticks.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000290	GERMANY Report From Study	26 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 28-Oct-2014			feeling of 'heaviness in the lungs' [CHEST DISCOMFORT] N / Y / Y headache [HEADACHE] N / N / Y the heatsticks caused nausea [NAUSEA] N / N / Y	Unknown

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: The heatsticks caused nausea, headache, feeling of "heaviness in the lung" .</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she just tolerate cigarettes better, the heatsticks caused nausea (headaches and a feeling of "heaviness in the lung").</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000291	GERMANY Report From Study	23 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 28-Oct-2014 Case Narrative: Verbatim: I got headaches from the sticks			I got headaches from the sticks [HEADACHE] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 23-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspeci</p> <p>The respondent reported that he got headaches from the sticks.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000292	GERMANY Report From Study	28 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			strange taste which almost made me nauseated [NAUSEA] N / N / Y it has a very strange , hard to describe taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-Oct-2014</p> <p>Case Narrative: Verbatim: strange taste which almost made me nauseated, it has a very strange, hard to describe taste</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 21-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 28-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it simply didn't taste like a cigarette, that it had a very strange, hard to describe taste, which almost made him nauseated.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000293	GERMANY Report From Study	62 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			strange aftertaste stays in your mouth for a long time [DYSGEUSIA] N / Y / Y smoke is very warm, which is unfamiliar and I found it concerning [DEVICE MALFUNCTION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-Oct-2014</p> <p>Case Narrative: Verbatim: strange aftertaste stays in your mouth for a long time</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 62-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent reported that he did not like about the taste that it had a strange aftertaste, very atypical and it stayed in the mouth for a long time. He also reported that also very warm, which was unfamiliar and he found it concerning, since he didn't know what the consequences for his health could be.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000294	GERMANY Report From Study	45 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			leaves a bland taste in the mouth [DYSGEUSIA] N / Y / Y covers the nasal mucosa too much [NASAL DISCOMFORT] N / Y / Y I don't feel well [MALAISE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-Oct-2014</p> <p>Case Narrative: Verbatim: leaves a bland taste in the mouth, covers the nasal mucosa too much, I don't feel well</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 28-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? lights; Kit number not provided) on an unspecified date.</p> <p>The respondent reported that it leaves a bland taste in the mouth, that it covers the nasal mucosa too much and that she didn't feel well. She also reported that one doesn't like smoking.</p> <p>The events were considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the events was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000295	GERMANY Report From Study	22 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]			I sometimes get headaches [HEADACHE] N / N / Y I don't like the taste because it is so strange and nondescript [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 14-Oct-2014</p> <p>Case Narrative: Verbatim: I sometimes get headaches; I don't like the taste because it is so strange and nondescript.</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 14-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (cork tipping paper ? full flavour; Kit number not provided) on an unspecified d</p> <p>The respondent reported that she didn' t like the smell, because it was so strange and nondescript. She did not associate that with a cigarette. When she smoked these stick</p> <p>she sometimes even got headaches.</p> <p>The event was considered to be non-serious (severity/intensity information not provided).</p> <p>The outcome of the event was not reported.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000296	GERMANY Report From Study	36 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]			burning in the eyes [EYE IRRITATION] N / Y / Y was pungent, obtrusive [ORAL DISCOMFORT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 20-Oct-2014</p> <p>Case Narrative: Verbatim: was pungent, obtrusive; burning in the eyes</p> <p>Market Research Study P1_WOT1_DE: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 and product usage behavior.</p> <p>INITIAL INFORMATION RECEIVED ON 20-OCT-2014 and transferred to safety department on 15-JAN-2015.</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>Information about smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (half white tipping paper ? full flavour; Kit number not provided) on an unspeci</p> <p>The respondent reported that it was pungent, obtrusive, even burning in the eyes.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The events were considered to be non-serious (severity/intensity information not provided).							
The outcome of the events was not reported.							
No follow-up information has been requested ? case closed.							
PMI000305	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]			Feeling of nausea after consuming a good number of sticks [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 05-Jun-2014							
Case Narrative: Verbatim: Feeling of nausea after consuming a good number of sticks.							
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.							
INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron; Kit number not provided) on an unspecified date. The respondent reported that the product gave her a feeling of nausea after consuming a good number of sticks. The event was considered to be non-serious. The outcome was unknown.							
No follow-up information has been requested ? case closed							
PMI000341	UNITED STATES Report From Study	26 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK] Respiratory UNK [UNK]	01-OCT-2015 to Unknown 01-OCT-2015 to 26-OCT-2015	03-OCT-2015 03-OCT-2015 2015 03-OCT-2015	I have a blister on my lip [LIP BLISTER] N / Y / Y chemical burn or machine heated up too hot and created blisters [BURNS SECOND DEGREE] N / Y / Y burns on hands [THERMAL BURN] N / Y / Y machine heated up too hot [DEVICE ISSUE] N / Y / N	Recovered/Resolved
Case Initial Receipt Date: 10-Oct-2015							
Case Followup Receipt Date: 09-Nov-2015 00:00							
27-Oct-2015 00:00							
Event Intensity: Moderate							
Moderate							
Event Stop Date: 23-OCT-2015							
23-OCT-2015							
23-OCT-2015							
Case Narrative: Verbatim: I have a blister on my lip, chemical burn or machine heated up too hot and created blisters, burns on hands. Machine heated up too hot.							
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.							
INITIAL INFORMATION RECEIVED ON 10-Oct-2015 and forwarded to Safety department on the same day.							
This report concerns a 26-year-old female subject (Respondent Study ID: 828735) who took part in the above mentioned market research study.							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome	
			<p>The subject's medical history included heart disease (POTS), hypothyroid, adrenal insufficiency, low blood pressure and fibromyalgia. The following concomitant medications were reported: Inderal (propranolol hydrochloride), "Sanept", Ambien (zolpidem tartrate), Adderall (amphetamine aspartate, amphetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate), "Florisus", Klonopin (clonazepam), "Xanax", Bactrim (sulfamethoxazole, trimethoprim) and Zofran (ondansetron hydrochloride), doses, treatment dates and indications not provided.</p> <p>The respondent was a daily smoker (approximately 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (Kit number BCCJD1TSDDW) on 07-Oct-2015.</p> <p>On 08-Oct-2015, the respondent had a blister on her lip. The respondent mentioned that she was not sure if it was from the THS or from her regular cigarettes and smoking it too close to the filter. She went to see her doctor to have it looked at because she thought it might be herpes. The respondent said her doctor told her it was a blister caused by a burn and that it could have been caused by smoking a cigarette too close to the filter. She has not had a blister like this before and only noticed the blister after she had started using the IQOS device.</p> <p>The event severity was reported as moderate and required medical advice on 09-Oct-2015. The event was considered to be non-serious.</p> <p>The respondent used the Heatsticks occasionally and used one stick on the day of the event. The event did not improve when usage of the product was stopped and the product was not restarted.</p> <p>At time of reporting, the respondent had not recovered.</p> <p>No follow-up information is expected. Case closed.</p> <p>FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day.</p> <p>Verbatim: chemical burn or machine heated up too hot and created blisters.</p> <p>No additional medical history was reported. The following additional concomitant medications were reported: "Florines", "Coonevpan" and Fanapt (dosages, indications, treatment dates not provided).</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day, previously reported as 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 01-Oct-2015 (previously reported as 07-Oct-2015).</p> <p>The respondent reported that on 03-Oct-2015, she experienced chemical burn, or the machine heated up too hot and created a blister (previously reported as blister on my lip).</p> <p>The events' severity was reported as moderate. The events were considered to be non-serious.</p> <p>The respondent used the product every day (2 heatsticks and 5 conventional cigarettes on the day of the event).</p> <p>It was reported that the events improved when usage of the product was stopped and returned when the product was restarted (dates not further specified).</p> <p>Last day of product usage was indicated as 26-Oct-2015. However, the final action taken with the product was unknown.</p> <p>The events resolved on 23-Oct-2015.</p> <p>FOLLOW-UP INFORMATION WAS RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p>						

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Burns on hands were reported (no further information provided).								
No follow-up information is expected. Case closed.								
PMI000346	UNITED STATES Report From Study	27 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [1 DF-UNK]	Respiratory	11-OCT-2015 to 11-OCT-2015	OCT-2015 16-OCT-2015 11-OCT-2015 11-OCT-2015 11-OCT-2015	she has a bad sinus infection [SINUSITIS] N / Y / Y she came down with a cold [NASOPHARYNGITIS] N / N / Y she took one puff of her first Heatstick and within 1 minute she threw up. [VOMITING] N / N / Y She stated that she was nauseated most of the day, and a little bit nauseated on 12/Oct/2015. [NAUSEA] N / N / Y The participant has not used another Heatstick since 11/Oct/2015 because the holder is stuck in the charger and she cannot get it out. [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 17-Oct-2015 Case Followup Receipt Date: 19-Oct-2015 00:00 21-Oct-2015 00:00 Event Intensity: Moderate Moderate Moderate Mild Event Stop Date: 11-OCT-2015 13-OCT-2015 Case Narrative: Verbatim:</p> <p>Initial information: Participant stated that, on 11-Oct-2015, she took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated most of the day and a little bit nauseated on 12-Oct-2015. She stated she was not nauseated 13-Oct-2015. She also stated that she came down with a cold 16-Oct-2015, which has not resolved. She is all congested, and she is coughing now and then. The participant has not used another Heatstick since 11-Oct-2015 because the holder is stuck in the charger and she cannot get it out.</p> <p>Follow-up #1 information: Participant called in today, 19-Oct-2015, stating she was still not feeling well. She stated she still had her cold and was coughing, and would not come to the enrollment center today to pick up her new IQOS device. During the call, she stated the onset date of her cold was 16-Oct-2015.</p> <p>Follow-up #2 information: Participant called in today, 21-Oct-2015, to report her cold has not resolved and she is still sick. She reported to experiencing the following symptoms: her whole head hurts, sneezing, headaches, and head is pounding. The participant also reported she has a bad sinus infection.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 17-Oct-2015 and forwarded to Safety department on the same day. Additional information to the case was received on 19-Oct-2015 and on 21-Oct-2015.</p> <p>This report concerns a 27-year-old female subject (Respondent Study ID: 188110) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (approximately 5 conventional cigarettes per day).</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 11-Oct-2015.</p> <p>On 11-Oct-2015, the respondent took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated most of the day, and a little bit na 12-Oct-2015. She came down with a cold on 16-Oct-2015. Symptoms of the cold included head congestion/head hurting, coughing now and then, sneezing, headaches, and pounding head. The participant also reported she had a bad sinus infection.</p> <p>She had not used another Heatstick since 11-Oct-2015 because the holder was stuck in the charger and she could not get it out.</p> <p>The events severity was reported as moderate on 17-Oct-2015 and 19-Oct-2015, and as mild on 19-Oct-2015. The events were considered to be non-serious.</p> <p>The respondent used the heatstick occasionally (once - she used 1 heatstick) and 2 conventional cigarettes on 11-Oct-2015.</p> <p>The events vomiting and nausea improved/stopped when usage of the product was stopped, and the other reported events did not improve when usage of product was stopped. The product was not restarted.</p> <p>The respondent took ibuprofen and a lot of juice. The outcome of the events were reported as 'not recovered'. However, the respondent mentioned that her vomiting resolved on 11-Oct-2015 and she was not nauseated on 13-Oct-2015.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000349	UNITED STATES Report From Study	61 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [qd]	12-OCT-2015 to Unknown	12-OCT-2015 12-OCT-2015	it burns her lips/she experiences the burning of her lips each time she uses the device [ORAL DISCOMFORT] N / Y / Y the HeatStick holder itself is often too hot to hold [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 19-Oct-2015 Event Intensity: Mild Case Narrative: Verbatim: The participant stated that, while using the IQOS, she does not puff that heavy, but reported it burns her lips. Participant stated the HeatStick holder itself is Participant stated she experiences the burning of her lips each time she uses the device. Participant reported the events resolve after she stops using the device.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Oct-2015 and forwarded to Safety department on 20-Oct-2015.</p> <p>This report concerns a 61-year-old female subject (Respondent Study ID: 823066) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Unspecified pain medication was reported as concomitant medication, for spine problem (NOS).</p> <p>The respondent was a daily smoker (approximately 20-30 conventional cigarettes per day). The respondent reported she was a heavy smoker. When asked how many cigarettes she smokes per day, she stated "nearly 1 per minute".</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 60JNA8677NVS) on 12-Oct-2015.</p> <p>On 12-Oct-2015, the respondent experienced burning on her lips. She mentioned that she experienced this each time she used the device. In addition, she also reported that t was often too hot to hold.</p> <p>The event's severity was reported as mild. The events were considered to be non-serious.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent used the Heatsticks every day. She used 7 Heatsticks and 15 cigarettes on the day of the event. The event improved when usage of the product was stopped and returned when the product was restarted.</p> <p>Action taken with study product is unknown.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000359	UNITED STATES Report From Study	41 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [qd]	26-SEP-2015 to 25-OCT-2015	14-OCT-2015 14-OCT-2015	He had to draw hard on the product to smoke it and the sucking gave him a headache / he continued to only smoke the product in the evenings, and each evening he got a headache [HEADACHE] N / N / Y He had to draw hard on the product to smoke it [DEVICE DIFFICULT TO USE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Mild Event Stop Date: 25-OCT-2015 Case Narrative: Verbatim: He stated that he had to draw hard on the product to smoke it and the sucking gave him a headache. Each subsequent day, he continued to only smoke the product in evenings, and each evening he got a headache.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 41-year-old male subject (Respondent Study ID: 532578) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 30 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number VV5VYCF2F8KP) on 26-Sep-2015.</p> <p>The participant started using the product on 26-Sep-2015, during the day and evening, as well as conventional cigarettes. He did not experience headaches during that time. 14-Oct-2015, he stopped using the product during the day, and began to use the product only in the evening (no conventional cigarettes in the evening). He continued to smoke conventional cigarettes during the day. On 14-Oct-2015, he had a headache by the time he went to bed. He stated that he had to draw hard on the product to smoke it and the gave him a headache. He reported he had no headache when he woke up. Each subsequent day, he continued to only use the product in the evenings, and each evening he got a headache. On 25-Oct-2015, he stated that he realized using the product was giving him the headaches. He had used 1 or 2 that evening when he realized the connection, he did use the product anymore and he did not get a headache.</p> <p>The events severity were reported as mild. The events were considered to be non-serious.</p> <p>The consumer used the Heatsticks every day (8-9 sticks per day) in combination with about 20 cigarettes per day.</p> <p>The participant discontinued the use of the product on 25-Oct-2015.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The event resolved on 25-Oct-2015.								
No follow-up information is expected ? case closed. ?								
PMI000361	UNITED STATES Report From Study	22 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	27-OCT-2015	his chest was hurting real bad [CHEST PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	26-OCT-2015 25-OCT-2015	he started coughing up green stuff [SPUTUM DISCOLOURED] N / Y / Y As he smoked more of the product, it was like it was pulling air out of his lungs [CHEST DISCOMFORT] N / N / Y each time he smoked, he would cough [COUGH] N / N / Y	
Case Initial Receipt Date: 27-Oct-2015								
Event Intensity: Moderate Moderate Moderate Moderate								
Case Narrative: Verbatim: He stated that at first the smoking experience wasn't so bad, but then as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down.								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 27-Oct-2015 and forwarded to Safety department on the same day.								
This report concerns a 22-year-old male subject (Respondent Study ID: 751825) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
The respondent was a daily smoker (approximately 15-20 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit numbers (01)5410706815337, (21)MHZKNOLUZYZR, (240)DK000024.01) on 25-Oct-2015.								
On 25-Oct-2015, the study respondent started using the product. He stated that, at first, the smoking experience wasn't so bad, but then, as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that, each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down. The participant stated the menthol caused the problem more than the regular flavor.								
The events severity was reported as moderate. The events were considered to be non-serious.								
The consumer used the Heatsticks every day. He used 10 Heatsticks and 10 cigarettes on the day of the events.								
The respondent stopped using the product on 27-Oct-2015. The events improved when usage of the products was stopped. The products were not restarted.								
At time of reporting, the events were not resolved.								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected. Case closed.							
PMI000370	UNITED STATES Report From Study	53 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	22-OCT-2015 to Unknown	25-OCT-2015	flu; started feeling off (NOS) on 25/OCT/2015; symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea) [INFLUENZA] N / Y / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 04-Nov-2015 Case Followup Receipt Date: 16-Nov-2015 00:00 Event Intensity: Severe Event Stop Date: NOV-2015 Case Narrative: Verbatim: he had had the flu (NOS) for the past week</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 04-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 53-year-old male subject (Respondent Study ID: 655433) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information was provided regarding the respondent's smoking status.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number R8D4R2EWDD22) on an unknown date.</p> <p>The respondent stated that he started "feeling off" on 25-Oct-2015. He reported that he did not smoke while he had the flu and when he stopped using the product (date unknown) it was easier to breathe. He stated that he was seen by a doctor before 31-Oct-2015 (exact date unknown). The respondent was administered an inhaler and antibiotics (NOS).</p> <p>The event severity was reported as severe. The events were assessed as non-serious.</p> <p>The respondent used the Heatsticks every day. The number of Heatsticks and cigarettes used on the day of the event was not reported.</p> <p>It was reported that the event improved when usage of the product was stopped (stop date unknown). The product was not restarted.</p> <p>At time of reporting, the event was not resolved.</p> <p>Follow-up information will be requested.</p> <p>FOLLOW-UP INFORMATION RECEIVED on 16-Nov-2015 and forwarded to Safety department on the same day.</p> <p>Start date of the product THS 2.2 Regular (Dorado II / Ron) was reported as 22-Oct-2015.</p> <p>The participant stated that, for influenza, he was not formally diagnosed by a doctor. The participant stated that he was unsure when the symptoms began but believes that they began at the end of October 2015 (previously reported as 25-Oct-2015). The symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea). The participant denied using any medication to treat his flu related symptoms, opting to stay home.</p> <p>When asked about his previously reported symptom of breathlessness (dyspnea), the participant clarified that he had a prior history of asthma, for which he had been prescribed the as-needed inhaled medication ProAir (salbutamol sulfate) inhaled. Participant reported no other relevant medical history within the last year and denies using antibiotics or any other</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
medications.								
The participant reported that the symptoms of alternating hot and cold sensation, sweating, exhaustion, loss of appetite, and breathlessness (dyspnea) resolved two weeks after onset; exact date is unknown. The symptom of weakness is ongoing, with an 80% subjective improvement reported by participant.								
No further information is expected. Case closed.								
PMI000372	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			gave me headaches [HEADACHE] N / N / Y didn't like the taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: gave me headaches; didn't like the taste.								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on 2-Nov-2015.								
This report concerns a female subject born in 1959 (Respondent Study ID: 181262) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
The respondent was a daily smoker (number of conventional cigarettes per day not provided).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) on an unspecified date (kit number).								
The respondent stated that the use of the device gave her headaches and that she didn't like its taste.								
The severity of the event was not reported. The event was assessed as non-serious.								
The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and conventional cigarettes used by the respondent on the day of the event.								
No information regarding the action taken with the drug was provided.								
At time of reporting, the outcome of the event was not reported.								
No follow-up information is expected. Case closed.								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000380	UNITED STATES Report From Study	49 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	07-OCT-2015 to 07-NOV-2015	31-OCT-2015 31-OCT-2015	Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [MALAISE] N / Y / Y Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [ABDOMINAL DISCOMFORT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 09-Nov-2015 Event Intensity: Mild Mild Event Stop Date: 02-NOV-2015 02-NOV-2015 Case Narrative: Verbatim: Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 49-year-old male subject (Respondent Study ID: 650328) who took part in the above mentioned market research study.</p> <p>The following medical history was reported: high blood pressure (additional information not provided). The following concomitant medication was reported: lisinipril (additional information not reported).</p> <p>The respondent was a daily smoker (approximately 30 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 07-Oct-2015.</p> <p>On 31-Oct-2015, the respondent reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks. He is still smoking conventional cigarettes, and does not have the same sick feeling as he did after using the HeatSticks.</p> <p>The events severity was reported as mild. The events were assessed as non-serious.</p> <p>The respondent used the Heatsticks every day. He used 5 Heatsticks and 20 cigarettes on the day of the events.</p> <p>The events improved when usage of the product was stopped. The events reoccurred when the product was restarted. The last day of product use was on 07-Nov-2015 (final action taken with study product unknown).</p> <p>The events resolved on 02-Nov-2015.</p> <p>No further information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000398	UNITED STATES Report From Study	33 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	19-AUG-2015 to 26-OCT-2015	2015 16-OCT-2015 16-OCT-2015 16-OCT-2015	make me sick [MALAISE] N / Y / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [HEADACHE] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [DIZZINESS] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 16-Nov-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Moderate Moderate Moderate Event Stop Date: 26-OCT-2015 26-OCT-2015 26-OCT-2015 Case Narrative: Verbatim: Participant reported headaches, lightheadedness, and nausea while using HeatSticks. Make me sick.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 17-Nov-2015.</p> <p>This report concerns a 34-year-old male subject (Respondent Study ID: 180716) who took part in the above mentioned market research study.</p> <p>Medical history was not reported. Concomitant medication was not reported.</p> <p>The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number TE3HH5DSY0VWGD) on 19-Aug-2015.</p> <p>On 16-Oct-2015, the respondent experienced headaches, lightheadedness and nausea while using HeatSticks.</p> <p>The events severity was reported as moderate. The events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. He mentioned that he was a light smoker overall and did not further specify. He used 3 Heatsticks and 2 cigarettes on the day of the events.</p> <p>The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 26-Oct-2015.</p> <p>The events resolved on 26-Oct-2015.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>The study respondent mentioned that the product made him sick. No further information was given.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.							
PMI000400	UNITED STATES Report From Study	57 Years Female	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	17-OCT-2015 to 19-NOV-2015	17-OCT-2015 17-OCT-2015 17-OCT-2015 19-NOV-2015	tastes an aftertaste [DYSGEUSIA] N / Y / Y it makes her gag [RETCHING] N / Y / Y she feels sick to her stomach / feels like she wants to throw up [NAUSEA] N / N / Y she also noticed a headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 19-Nov-2015</p> <p>Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Event Stop Date: 19-NOV-2015 19-NOV-2015 19-NOV-2015 19-NOV-2015</p> <p>Case Narrative: Verbatim: tastes an aftertaste / it makes her gag / she feels sick to her stomach / feels like she wants to throw up / she also noticed a headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 57-year-old female subject (Respondent Study ID: 200663) who took part in the above mentioned market research study.</p> <p>Medical history of allergies, high blood pressure, eczema, deaf in left ear was reported (no further information provided). The following concomitant medications were reported: Benadryl (diphenhydramine hydrochloride), Lisinopril, Ranitidine (ranitidine hydrochloride), Loratadine, Hydrocortisone, Bactroban ointment (mupirocin calcium) (no further information provided).</p> <p>The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number PPQ30Z3MGJ47) on 17-Oct-2015.</p> <p>The respondent stated that, every time she smoked a heatstick, she tasted an aftertaste and it made her gag. While smoking the heatsticks, she felt sick to her stomach and felt like she wanted to throw up. On 19-Nov-2015, she also noticed a headache, after using the heatsticks.</p> <p>The events' severity was reported as moderate. The events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. She used the heatstick when she didn't have any cigarettes. The respondent used 3 Heatsticks and 3 cigarettes on the day of the event (presumably event of headache, occurring on 19-Nov-2015).</p> <p>The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 19-Nov-2015.</p> <p>The events resolved on 19-Nov-2015.</p> <p>No further information is expected. Case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000401	UNITED STATES Report From Study	45 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	08-OCT-2015 to 15-OCT-2015	10-OCT-2015	throat burn [THROAT IRRITATION] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 19-Nov-2015 Event Intensity: Mild Event Stop Date: 15-OCT-2015 Case Narrative: Verbatim: throat burn Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 19-Nov-2015 and forwarded to Safety department on 20-Nov-2015. This report concerns a 45-year-old male subject (Respondent Study ID: 188933) who took part in the above mentioned market research study. No medical history was reported. It was reported that the respondent took as concomitant medication vitamins once a day (no further information provided). The respondent was a daily smoker (approximately 20 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number SQ9 ZUA GHS M5A) on 08-Oct-2015. On 10-Oct-2015, when he inhaled the smoke, the respondent experienced throat burn while using Heats icks, which lasted about 5 minutes. The severity of the event was reported as mild. The event was assessed as non-serious. The respondent used the heatsticks every day. The respondent used 4 heatsticks and 20 cigarettes on the day of the event. The event improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 15-Oct-2015. The event resolved on 15-Oct-2015. No follow-up information is expected. Case closed.								
PMI000407	UNITED STATES Report From Study	27 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] UNK [UNK]	Respiratory	17-OCT-2015 to 11-NOV-2015	10-NOV-2015 10-NOV-2015	strep hroat [PHARYNGITIS STREPTOCOCCAL] N / Y / Y respiratory infection [RESPIRATORY TRACT INFECTION] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 24-Nov-2015 Event Intensity: Severe Severe Event Stop Date: 17-NOV-2015 17-NOV-2015								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: strep throat / respiratory infection</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 24-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 27-year-old female subject (Respondent Study ID: 185638) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and Regular (Dorado II / Ron) (kit number 6USB5XGJ3YD1) on 17-Oct-2015. She started with menthol and then switched to regular (date not provided).</p> <p>The respondent stated that she had strep throat and a respiratory infection which began on 10-Nov-2015. On (b) (6), she saw a doctor at the hospital who did a test for strep throat which was positive. The doctor also told her she had a respiratory infection (NOS). The doctor told her she could not smoke. The doctor gave her amoxicillin and a shot (NOS) in her buttock, as treatment for the events.</p> <p>The events severity was reported as severe and required medical advice on 11-Nov-2015 and treatment (dates unspecified). The events were assessed as non-serious.</p> <p>The respondent used the heatsticks every day, except for when prohibited by doctor. The respondent used 1 Heatstick and 0 cigarette on the day of the event.</p> <p>The events improved when usage of the product was stopped, and did not return when use of the product was restarted. The last day of product use was on 24-Nov-2015 (day of reporting). No further information was reported regarding the final action taken with the product.</p> <p>The events resolved on 17-Nov-2015, when the respondent was told she could return to work and smoking.</p> <p>No further information is expected. Case closed.</p>							
PMI000483	UNITED STATES Report From Study	30 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory Respiratory	SEP-2015 to DEC-2015 SEP-2015 to DEC-2015	10-JAN-2016 Pregnancy [MATERNAL EXPOSURE TIMING UNSPECIFIED] N / Y / N	Unknown
<p>Case Initial Receipt Date: 03-Feb-2016</p> <p>Case Followup Receipt Date: 16-Feb-2016 00:00</p> <p>Case Comment Text: Maternal exposure timing unspecified was assessed as non-serious.</p> <p>Expectedness and causality assessments are not applicable for Maternal exposure timing unspecified. However, expectedness for Maternal exposure timing unspecified has been captured as unlisted, by default, in the safety database.</p> <p>No adverse events were reported in association with Maternal exposure timing unspecified.</p> <p>This pregnancy report shall be followed-up until an outcome is reached, as per protocol.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Narrative: Verbatim: Pregnancy								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 03-FEB-2016 and forwarded to Safety department on 05-FEB-2016.								
This report concerns a 30-year-old female subject (Respondent Study ID: 751296) who took part in the above mentioned market research study.								
No medical history and no concomitant medication were reported.								
The respondent was a daily smoker (approximately 2 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and Regular (Dorado II / Ron) (kit numbers not provided) on an unknown date in Sep-2015.								
The respondent reported a pregnancy. Date of awareness of pregnancy was 10-Jan-2016. Last menstrual period was in Dec-2015 (not further specified). The pregnancy was confirmed by a HCP. Delivery date was uncertain. It was reported that the respondent was not using any contraception at time of report. The respondent had one previous pregnancy and one delivery (no therapeutic or planned abortion).								
The study respondent used the THS products up to an unspecified date in Dec-2015 (prior to awareness of pregnancy).								
Further information is expected.								
FOLLOW-UP INFORMATION received on 16-Feb-2016 and forwarded to Safety Department on 17-Feb-2016.								
The following kit number was provided: V4P4S3WB2REL (not specified if it corresponds to THS 2.2 Regular or Menthol. Start date of product use was reported as Sep-2015, with a comment that the study participant was unsure of exact date and stated it took place at end the month. The respondent's eDiary entries showed initial recorded use of IQOS device on 26-Oct-2015 (Enrollment center issued kit on 26-Oct-2015).								
The product stop date was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place at beginning of month. The respondent's eDiary entries showed that the last date of recorded use was 08-Dec-2015.								
First day of last menstrual period was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place in middle of month.								
Estimated delivery date was reported as 28-Aug-2016.								
Participant denied history of any ongoing medical conditions, for which she was seeing a healthcare professional, for which she was taking medications, or for which she was previously assessed.								
Participant reported that initial doctor visit on 10-Jan-2016 resulted in a blood test which confirmed pregnancy (follow-up appointment with her doctor was scheduled on 18-Feb-2016).								
Further information is expected.								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000587	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: gave me a headache	2015 to Unknown	2015	gave me a headache [HEADACHE] N / N / Y	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 56-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 351173) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gave him a headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>							
PMI000588	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: bad taste, gave me headache, bad taste lingered for hours, everything afterwards had that taste still.	2015 to Unknown	2015 2015 2015	gave me headache [HEADACHE] N / N / Y bad taste lingered for hours, everything afterwards had that taste still [DYSGEUSIA] N / Y / Y bad taste [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 46-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 820835) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that the product gave him a headache. In addition, he mentioned that the product had a bad taste, the bad taste lingered for hours, everything afterwards had that taste still.</p> <p>The severity of the events was not reported. The events were assessed as non-serious.</p> <p>The outcome of the events were not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000591	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]		2015 to Unknown	2015 2015	Tobacco is stronger, hurts my chest [CHEST PAIN] N / Y / Y Tobacco is stronger, hurts my chest [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: tobacco is stronger, hurts my chest</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 39-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 355431) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the tobacco was stronger, and hurt his chest.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000592	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Got sick [MALAISE] N / Y / Y	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: got sick					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.					
			This report concerns a 21-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 458445) who took part in the above mentioned market research study.					
			No medical history was reported. No concomitant medication was reported.					
			No information on smoking habits was reported (conventional cigarettes and heatsticks).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.					
			The respondent stated that she got sick.					
			The severity of the event was not reported. The event was assessed as non-serious.					
			The outcome of the event was not reported.					
			Action taken with the THS product was not reported.					
			No further information is expected. Case closed.					
PMI000594	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	it makes me feel sick [MALAISE] N / Y / Y	Unknown
			Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: it makes me feel sick					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.					
			This report concerns a 20-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 202403) who took part in the above mentioned market research study.					
			No medical history was reported. No concomitant medication was reported.					

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unreported date.</p> <p>The respondent stated that the product made her feel sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>							
PMI000598	UNITED STATES Report From Study	Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK]	2015 to Unknown	2015	It gave me a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-Nov-2015</p> <p>Case Narrative: Verbatim: It gave me a headache.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 25-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 658140) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gave him a headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000599	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Sick [MALAISE] N / Y / Y	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sick					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.					
			This report concerns a 23-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 757519) who took part in the above mentioned market research study.					
			No medical history was reported. No concomitant medication was reported.					
			No information on smoking habits was reported (conventional cigarettes and heatsticks).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.					
			The respondent reported: "sick".					
			The severity of the event was not reported. The event was assessed as non-serious.					
			The outcome of the event was not reported.					
			Action taken with the THS product was not reported.					
			No further information is expected. Case closed.					
PMI000600	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	breathing trouble [DYSPOEA] N / Y / Y	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Sore throat [OROPHARYNGEAL PAIN] N / N / Y	
			Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sore throat, breathing trouble					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.					

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 181832) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.								
The respondent reported sore throat and breathing trouble.								
The severity of the events was not reported. The events were assessed as non-serious.								
The outcome of the events was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
PMI000603	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	I think they were giving me an upset stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Case Initial Receipt Date: 07-Dec-2015					
			Case Narrative: Verbatim: I think they were giving me an upset stomach					
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 07-Dec-2015 and forwarded to Safety department on 05-Apr-2016.								
This report concerns a 58-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 650514) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.								
The respondent stated that she thought the heatsticks were giving her an upset stomach.								
The severity of the event was not reported. The event was assessed as non-serious.								

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not reported.							
Action taken with the THS product was not reported.							
No further information is expected. Case closed.							
Yes (3)							
PMI000347	UNITED STATES Report From Study	31 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A Respiratory UNK [UNK] UNK [UNK]	08-OCT-2015 to 14-OCT-2015 27-OCT-2015 to Unknown	14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 15-OCT-2015 15-OCT-2015	Respondent was hit by a car [ROAD TRAFFIC ACCIDENT] Y / Y / Y concussion [CONCUSSION] Y / Y / Y knee strain [JOINT INJURY] Y / Y / Y back strain [MUSCLE STRAIN] Y / Y / Y abrasions [SKIN ABRASION] Y / Y / Y nausea [NAUSEA] N / N / Y dizziness [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 16-Oct-2015 Case Followup Receipt Date: 27-Oct-2015 00:00 Case Comment Text: The Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion were assessed as serious, due to requiring hospitalization. Nausea and Dizziness were assessed as non-serious.</p> <p>Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion are unlisted, whereas Nausea and Dizziness are listed, as per the Reference Safety Information (i.e. the IB).</p> <p>Based on the information (i.e. the participant was reportedly feeling fine before the accident; the participant was hit by a turning car, while cycling) provided in this report, the Road traffic accident and the directly derived adverse events (i.e. Concussion, Joint injury, Muscle strain, Skin abrasion), as well as the transient Nausea and Dizziness experienced while on treatment with Percocet initiated during hospitalisation, are assessed as not related to the use of Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron). Of note, the product use was restarted 12 days after the discharge from hospital.</p> <p>Case Narrative: Verbatim: Respondent was hit by a car.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Oct-2015 and forwarded to Safety department on 19-Oct-2015.</p> <p>This report concerns a 31-year-old male subject (Respondent Study ID 200851) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Information on concomitant medications was reported as "Percocet and just an IV" (no further information provided).</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) kit number LE8Q6KAQRBQ3 on 08-Oct-2015.</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The consumer was hit by a car. The event required hospitalization on (b) (6). The event was assessed as serious (due to hospitalization).</p> <p>The last Heatstick was used on 14-Oct-2015. It was reported that the consumer would continue with the study once he was out of hospital.</p> <p>At time of reporting, the event had not recovered.</p> <p>Follow-up information will be requested.</p> <p>FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day.</p> <p>Verbatim: Diagnosis of concussion, knee strain, back strain, abrasions</p> <p>The participant stated that he was "feeling fine" right before his accident on (b) (6). He related that he was heading northbound riding his bicycle in the bike lane, when a vehicle that was heading southbound, turned into him striking him. The participant was then transported to the hospital via an ambulance where he was initially placed in the emergency room for 2 hours and then admitted in order to assess and observe for any symptoms stemming from concussion. The caller reported being discharged at 2-3 am the following day on (b) (6).</p> <p>The caller then reported that he returned to the hospital later in the day of his discharge (b) (6) because of the symptoms of nausea and dizziness. He was not admitted at that time but released after a brief assessment.</p> <p>The participant denied receiving any treatment while en route to the hospital. He stated he was given intravenous solution while in the hospital but was unsure of what exactly was in that solution, although the participant believed it was a saline solution. The participant admits to Percocet by mouth, during hospital stay and for at least 2 days after discharge.</p> <p>The participant denied having taken any medications to treat any other conditions prior to the incident.</p> <p>The participant denied any pre-existing conditions prior to the accident (no previously diagnosed conditions, no seasonal conditions such as allergies, and no self limiting conditions such as cold, flu, or headache).</p> <p>Prior to the accident, the respondent used the THS product on (b) (6). The product was re-started on 27-Oct-2015.</p> <p>At time of reporting, the serious events were ongoing. The respondent mentioned that he still had a swollen knee with pain during weight bearing and back pain for which he was receiving daily chiropractic treatment. He was also still being assessed for concussion; a MRI was scheduled. Nausea and dizziness resolved on an unspecified date.</p> <p>No further information is expected. Case closed.</p>							
PMI000367	UNITED STATES Report From Study	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	16-SEP-2015	was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell [ACCIDENT] Y / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	16-SEP-2015	injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples [LIMB INJURY] Y / Y / Y	
					16-SEP-2015	injured her left leg and foot, the bone had been smashed (in an accident) [SKELETAL INJURY] Y / Y / Y	

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							Participant stated her foot is infected and that the infection had gotten into the bone [OSTEOMYELITIS] Y / Y / Y the nerves are dead and there is no flow (NOS) [NERVE INJURY] Y / Y / Y	
			Case Initial Receipt Date: 02-Nov-2015 Case Followup Receipt Date: 10-Nov-2015 00:00 Event Intensity: Severe Severe Severe Severe Severe Event Stop Date: 16-SEP-2015 Case Comment Text: The Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury were assessed as serious, due to requiring hospitalization.					
			Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury are unlisted for THS 2.2 Menthol and THS 2.2 Regular, as per the Reference Safety Information (i.e. the IB).					
			Considering the circumstances provided in this report, the Accident and the ensuing adverse events (i.e. Limb injury, Lower limb fracture, Osteomyelitis, Nerve injury) are assessed as not related to the use of the products, in this patient, who had been a smoker of conventional cigarettes.					
			Case Narrative: Verbatim: was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell / injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples / Participant stated her foot is infected and that the infection had gotten into the bone / the nerves are dead and there is no flow (NOS)					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 2-Nov-2015 and forwarded to Safety department on the same day.					
			This report concerns a 51-year-old female subject (Respondent Study ID: 654390) who took part in the above mentioned market research study.					
			No medical history was reported. No concomitant medications were reported.					
			The respondent was a daily smoker (approximately 10 - 20 conventional cigarettes per day).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) on an unknown date.					
			The respondent stated that she was in an accident on 16-Sep-2015. Her left leg and foot were injured and the bone had been smashed. She was hospitalized on an unknown date. On an unknown date, she had been released from the hospital, had been bed-ridden for 3 weeks, and had gone back to work on 8-Oct-2015. (b) (6), she was hospitalized for the second time. She stated her foot was infected and that the infection had gotten into the bone, further stating that it was probably infected from the beginning. She also stated the nerves were dead, there was no flow and they will be doing who-knows how many surgeries. She stated that she would be in the hospital at least 4 months and that she was on a lot of medications. The study respondent requested to be withdrawn from the study.					
			The events severity was reported as severe. The events were assessed as serious due to hospitalization.					
			The respondent used the Heatsticks every day. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event. Last day of product usage was indicated as 28-Oct-2015.					

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>At time of reporting, the outcome of the events was unknown; however, the respondent was in hospital at time of reporting.</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION was received on 10-Nov-2015 and forwarded to the Safety department on 13-Nov-2015.</p> <p>The recipient stated that she was unsure of when she started to use the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) but she felt that it may have been around 09-SEP-2015.</p> <p>She stated that it was a wonderful morning (70 degrees), she was at work, when a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell. She mentioned that she was unsure of what exactly happened.</p> <p>The respondent stated that, after the accident, one of her supervisors or somebody at her work that was in a position of responsibility drove her to the hospital on (b) (6). Once at the hospital, the respondent stated that she was not formally admitted, but spent a few hours in the emergency room (ER) where she received intravenous antibiotics, a tetanus shot, and leg staples. On the same day, after being released from the ER, she was able to walk around and went to the mall site to explain her situation. The respondent stated that, since her release from the ER, her condition worsened and she was admitted to the hospital; she was unsure of the date, but that she believed it was about two Wednesdays prior to reporting date. She was currently still in the hospital.</p> <p>The respondent stated that the events were still ongoing as of 10-Nov-2015.</p> <p>No additional information was provided. The respondent refused to provide any more information. She wanted to know why these questions were asked stating that they sound like questions that a lawyer may ask. She stated that she was unwilling to provide these answers until she gets her explanation. The respondent stated that she is willing to be called back.</p> <p>Further information is expected.</p>							
PMI000394	UNITED STATES Report From Study	52 Years Male	THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]	OCT-2015 to 31-OCT-2015	30-OCT-2015 15-OCT-2015 NOV-2015 09-NOV-2015 2015	he was told he was septic [SEPSIS] Y / Y / Y his gallbladder had gangrene [CHOLECYSTITIS INFECTIVE] Y / Y / Y He got pneumonia while he was in the hospital [PNEUMONIA] Y / Y / Y COPD [CHRONIC OBSTRUCTIVE PULMONARY DISEASE] N / Y / Y decubitus ulcer on his back [DECUBITUS ULCER] N / Y / N Increased bowel movement frequency secondary to daily probiotic use [FREQUENT BOWEL MOVEMENTS] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 16-Nov-2015 Case Followup Receipt Date: 30-Nov-2015 00:00 10-Dec-2015 00:00 Event Intensity: Unknown Unknown Unknown Unknown</p>							

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Unknown					
			Event Stop Date: 07-NOV-2015 09-NOV-2015					
			Case Comment Text: The Sepsis and Cholecystitis infective were assessed as serious, due to requiring hospitalization. Pneumonia was assessed as serious, due to being considered a medically important event, requiring intervention. Chronic obstructive pulmonary disease, Decubitus ulcer, and Frequent bowel movements were assessed as non-serious, based on the provided information. Sepsis, Cholecystitis infective, Pneumonia, Decubitus ulcer, Chronic obstructive pulmonary disease, and Frequent bowel movements are unlisted, as per the Reference Safety Information of THS 2.2 Regular (i.e. the IB). The Sepsis was likely a consequence of the Cholecystitis infective (described as gallbladder gangrene, requiring open cholecystectomy). Considering the current knowledge on the product in question, the Sepsis and Cholecystitis infective are assessed as not related to the use of THS 2.2 Regular. Despite the presence of alternative explanations (i.e. medical history, multiple concomitant medications, hospital environment, recent septic episode), the causal relationships between the use of THS 2.2 Regular and Pneumonia (in this case, nosocomial pneumonia) cannot be completely excluded and, therefore, is assessed as possible. It was reported that the Chronic obstructive pulmonary disease (COPD) was diagnosed about a month after this patient, who had been a smoker of conventional cigarettes, started using the THS 2.2. Considering his implausible temporal sequence, the COPD is assessed as not related to THS 2.2. A clear alternative explanation (i.e. inappropriate care during hospitalization) was provided for the occurrence of the decubitus ulcers. As well, the Increased bowel frequency were reportedly due to the use of concomitant probiotics. Therefore, Decubitus ulcer and Increased bowel frequency are assessed as not related to the use of THS 2.2 Regular.					
			Case Narrative: Verbatim: he was told he was septic; his gallbladder had gangrene; he got pneumonia while he was in the hospital; decubitus ulcer on his back Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on the same day. This report concerns a 52-year-old male subject (Respondent Study ID: 652030) who took part in the above mentioned market research study. Medical history was not reported. The following concomitant medications was reported: Atenolol, Lisinopril, Keppra (levetiracetam), Butatane (exact spelling unknown), Probiotic (Bifidobacterium lactis), others (NOS). The respondent stated there were 12 all together (additional information not provided). The respondent was a daily smoker (approximately 10-15 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 015410786815337 / (21)SSKLOEB32GLA / (240) DK00024.01) on an unreported date. The recipient stated that, on (b) (6), he was admitted to the hospital, where he was told he was septic, and where they did all kinds of tests (NOS). He stated that, on 31-Oct-2015, he was told his gall bladder had gangrene and had to be removed. He stated his gall bladder was removed on 31-Oct-2015. He stated that he got pneumonia while he was in the hospital, he was told not to smoke, and he was undergoing breathing treatments (NOS). He stated he had 15 staples across his abdomen. He stated he was discharged from the hospital on (b) (6). He stated he had completely quit smoking (both conventional cigarettes and the IQOS device) and reported to feeling better after he quit smoking. He was still undergoing breathing treatments. The events severity was not reported. The events were assessed as serious, due to hospitalization. The number of cigarettes and Heatsticks used on the day of the event was not reported. It was reported that the events improved when usage of the product was stopped (not specified if it was one event in particular that improved, or all events) and product was not restarted. At time of reporting, the events were not resolved. Further information is expected. FOLLOW-UP INFORMATION RECEIVED on 30-Nov-2015 and forwarded to Safety department on the same day.					

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
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Medical history of high blood pressure and high cholesterol were reported. The respondent also reported that he had monthly visits to the doctor to have his International Normalized Ratio (INR) assessed. He denied any blood clotting issues, denied any conditions that may cause blood clots other than high blood pressure and cholesterol, and denied taking any medications that may require a monthly INR screening.

Lisinopril and Lovastatin were reported as concomitant medications.

The respondent reported that he was unsure of when he started using the THS product, but that he believed that he started using the THS product 3 weeks before he was admitted to the hospital on (b) (6).

The respondent confirmed diagnosis of gangrenous gallbladder and diagnosis of sepsis. The respondent was assessed as having gallbladder issues during regular doctor's visit on 15-Oct-2015. He said that he was not feeling well several days before and that he reported this during his monthly doctor's visit to have his INR pulled on 15-Oct-2015. The physician then ordered bloodwork that confirmed that the participant was having issues with his gallbladder. The respondent was admitted to the hospital for surgery on (b) (6).

An open cholecystectomy was found to be necessary because the gallbladder had become gangrenous and the respondent was found to be septic. The surgery was completed on 31-Oct-2015. The respondent described a possible Open Cholecystectomy, relating that the incision site crosses from the right upper quadrant to the left upper quadrant of abdomen and resembles a C-section scar just below his ribs. When asked if the procedure may not be an open-cholecystectomy the participant affirmed that this was in fact the name of the procedure. The participant related that it was used instead of the laparoscopic procedure because of the urgency of his condition.

The respondent initially reported that the cause of his gangrene was sepsis. Upon follow-up questioning, he stated that he did not know what caused his gallbladder to become gangrenous. He denied having gallstones. He affirmed that sepsis was the result of gangrenous gallbladder.

The respondent stated that the pneumonia started 3-4 days after surgery. He reported that pneumonia was the result of intubation and patient's insufficient turning by the hospital staff. He further clarified that the tracheal tube was in place for several days making it difficult for the medical staff to turn him regularly, which contributed to the pneumonia.

The respondent reported that he was given the inhaled medications Spiriva (tiotropium bromide) and Symbecort (budesonide, formoterol fumarate dehydrate) as a breathing treatment, nicotine replacement therapy in the form of transdermal patch, an antibiotic whose name he can't remember, probiotics, and a pain medication whose name he can't remember.

The respondent related that he stayed in the hospital for 10 days before he was discharged.

He stated that he experienced decubitus ulcers on his back, which were ongoing, as the result of hospitalization and improper turning by hospital staff that were ongoing. The event severity of decubitus ulcers was not reported.

The respondent stated that he stopped using the device after his surgery on 31-Oct-2015 because he was informed that smoking of any kind would delay healing at the incision site. He reported that he was still using his Spiriva and Symbecort.

At time of the report, the respondent's condition was ongoing. The respondent reported healing at his incision site was ongoing. He reported that he required Physical Therapy twice a week and was visited by a nurse once a week.

Further information is expected.

FOLLOW-UP INFORMATION RECEIVED on 10-DEC-2015 and forwarded to Safety department on the same day.

Medical history of bilateral amputation below the knee and bilateral hip replacement, 6 years prior to current report was reported. In addition, the consumer was wheelchair bound for 6 years, at time of reporting.

The respondent reported that any symptoms of sepsis resolved 7 days after date of surgery on 31-Oct-2015.

CUM LL All Cases Pre-Marketing Studies with THS Regular D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
								<p>He reported that symptoms from treatment of gangrenous gallbladder are ongoing. Healing of skin at incision site had concluded and was resolved as of 15-Nov-2015. Muscle pain at incision site was ongoing. He reported that his doctor informed him that the timeline for resolution of healing and the resolution of pain is 6 months to a year.</p> <p>He stated that pneumonia was resolved, meaning treatments for asthma had concluded, on day of hospital discharge, 10 days after the date of admittance (b) (6). He stated that breathing treatments were discontinued on day of discharge.</p> <p>The respondent stated that decubiti were ongoing, that he received daily dressing changes from his caregiver, that he had seen a woundcare nurse on 4 different occasions to date, and that he had been referred to a woundcare specialist. He further insisted that the decubiti were healing, but that he needed the consult, in order to obtain assistive devices, such as doughnut padding.</p> <p>He reported that the only medications he had as a result of his condition were probiotics and ProAir. He experienced increased bowel movement frequency secondary to daily probiotic use, described as having to go to the bathroom often. ProAir was prescribed at hospital discharge for Chronic Obstructive Pulmonary Disease (COPD) symptoms. The patient then reported a new condition, COPD, diagnosed at hospital discharge, 10 days after the admittance date of (b) (6).</p> <p>The event severity of COPD and increased bowel movement frequency was not reported.</p> <p>No further information is expected. Case closed.</p>

Total number of case entries printed: 168

Total number of cases printed: 168

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: All cases Excluding D2 Ron and D2 Fitz (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Regular THS Ingredients Minus D2 Ron/ D2 Fitz

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Regular THS Ingredients Minus D2 Ron/ D2 Fitz (Created by nicole.miller)

Selection Criteria:

(Ingredient equal to Ron OR

Ingredient equal to D1 Fitz OR

Ingredient equal to D2 Albertino OR

Ingredient equal to Ginebra Fitz OR

Ingredient equal to Scion 1 Fitz OR

Ingredient equal to Scion 1 Walt)

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (89)								
PMI000099	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015 10-APR-2015	It smells disgusting so I feel like throwing up [NAUSEA] N / N / Y - It smells disgusting so I feel like throwing up [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 10-Apr-2015 Case Narrative: Verbatim: It smells disgusting so I feel like throwing up</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 10-Apr-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 1447535) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not provided) on 10-Apr-2015.</p> <p>On 10-Apr-2015, the respondent experienced feeling like throwing up and reported that "it smells disgusting". The events were considered to be non-serious. Severity criteria not provided.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000101	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	14-APR-2015 to 15-APR-2015	14-APR-2015 14-APR-2015	(I feel stuffy on my right chest as if I smoke a strong cigarette and) as if my lungs got filled up with something from the beginning) [BRONCHIAL SECRETION RETENTION] N / Y / Y I feel stuffy on my right chest as if I smoke a strong cigarette (and as if my lungs got filled up with something from the beginning) [CHEST DISCOMFORT] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 15-Apr-2015 Event Intensity: Moderate Case Narrative: Verbatim: I have tried 4 to 5 of them and I feel stuffy on my right chest as if I smoke a strong cigarette and as if my lungs got filled up with something from the beginning</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 15-Apr-2015: This report concerns a 42-year-old male subject (Respondent Study ID: 1319062) who took part in the above mentioned market research study.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (5 cigarettes to one pack per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number KLJ N2E X53E UC) on 14-Apr-2015.</p> <p>On the same day (14-Apr-2015), the respondent stated that he had tried 4 to 5 of them (presumably HeatSticks) and he felt stuffy on his right chest as if he smoked a strong as if his lungs got filled up with something from the beginning. The events were considered to be non-serious. Severity was reported as moderate.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 6-7 conventional cigarettes. He used the HeatSticks on 14-Apr-2015 in the afternoon and on 15-Apr-2015 morning.</p> <p>It was reported that the problem did not improve when usage of the product was stopped, and that the product was not restarted.</p> <p>The use of the product was discontinued on 15-Apr-2015.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000107	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015 10-APR-2015	got nauseous and had headache like the time when smoking other cigarettes [NAUSEA] N / N / Y got nauseous and had headache like the time when smoking other cigarettes [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 20-Apr-2015</p> <p>Case Narrative: Verbatim: when smoking common flavour, Y, got nauseous and had headache like the time when smoking other cigarettes.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015: This report concerns a 42-year-old male subject (Respondent Study ID: 1357612) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number K3V J9F P7N KA6) on 10-Apr-2015.</p> <p>On the same day (10-Apr-2015), the respondent stated that he got nauseous and had headache like at the time when smoking other cigarettes. The events were considered to be non-serious. The severity of adverse events was not reported.</p> <p>On the day of the event, the respondent used 2 HeatSticks.</p> <p>Action taken with use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000113	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	22-APR-2015 Ongoing	26-APR-2015	When using HeatSticks in a row, throat is stinging (smarting) [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 28-Apr-2015								
Case Narrative: Verbatim: when using HeatSticks in a row, throat is stinging (smarting).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-Apr-2015:								
This report concerns a 34-year-old male subject (Respondent Study ID: 1211697) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number S5Z KLB W2L NFJ) on 22-Apr-2015.								
On 26-Apr-2015, the respondent experienced throat stinging (smarting) when using HeatSticks in a row. The event was considered to be non-serious. Adverse event severity was reported.								
The use of the product was continued without change.								
At the time of reporting, the event was resolved.								
No follow-up information is expected ? case closed.								
PMI000121	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	30-APR-2015 to Unknown	30-APR-2015 30-APR-2015	Feels nauseous after using (the product Y) [NAUSEA] Unknown N / N / Y may appear as it has a very particular smell, and he used unusual things [PRODUCT ODOUR ABNORMAL] N / Y / N	
Case Initial Receipt Date: 30-Apr-2015								
Case Narrative: Verbatim: feels nauseous after using (the product Y). (Symptoms) may appear as it has a very particular smell, and he used unusual things.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 30-Apr-2015:								
This report concerns a 50-year-old male subject (Respondent Study ID: 2341690) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number reported as “test product”) on 30-Apr-2015.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (30-Apr-2015), the respondent felt nauseous after using the HeatStick. The respondent added that it may appear as it has a very particular smell. The events assessed as non-serious. Severity of the adverse events was not reported.</p> <p>On the day of the event, the respondent used 1 HeatStick.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000125	KOREA, REPUBLIC OF Report From Study	61 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	30-APR-2015 to Unknown	01-MAY-2015 01-MAY-2015	Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white) [TONGUE DISCOLOURATION] N / Y / Y Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white) [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 04-May-2015 Event Intensity: Moderate Moderate Case Narrative: Verbatim: Throat is hurting (like initial symptom of having a cold and tongue' s colours turn to white).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 04-May-2015: This report concerns a 61-year-old male subject (Respondent Study ID: 2361695) who took part in the above mentioned market research study.</p> <p>No medical history was reported and the respondent did not know the names of his concomitant medications.</p> <p>The respondent was a daily smoker (on average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number YQD ZEU JOW 2MC) on 30-Apr-2015.</p> <p>On 01-May-2015, the respondent experienced hurting in the throat. He described the event like initial symptom of having a cold and tongue' s colours turn to white. The event considered to be non-serious. Severity of the adverse events was reported as moderate.</p> <p>The product was used every day. On the day of the event, the respondent used 13 HeatSticks and smoked 7 conventional cigarettes.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000126	KOREA, REPUBLIC OF Report From Study	63 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	29-APR-2015 to Unknown	29-APR-2015 29-APR-2015	Throat is stuffy, bloated, and uncomfortable [PHARYNGEAL OEDEMA] N / Y / Y Throat is stuffy, bloated, and uncomfortable [LARYNGEAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 02-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Throat is stuffy, bloated, and uncomfortable.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 02-May-2015: This report concerns a 63-year-old male subject (Respondent Study ID: 2360950) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not provided) on 29-Apr-2015.</p> <p>On the same day, (29-Apr-2015), the respondent experienced stuffy, bloated and uncomfortable throat. The events were considered to be non-serious. Severity of the adverse event reported as mild.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the events.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000130	KOREA, REPUBLIC OF Report From Study	Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	30-APR-2015 to Unknown	01-MAY-2015 01-MAY-2015	The throat does not feel fresh and is stuffy [PHARYNGEAL OEDEMA] N / Y / Y The throat does not feel fresh and is stuffy [LARYNGEAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 06-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: The throat does not feel fresh and is stuffy</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015: This report concerns a 33-year-old male subject (Respondent Study ID: 1237609) who took part in the above mentioned market research study.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 12 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 4SH HLB Q31 301) on 30-Apr-2015.</p> <p>On the next day (01-May2015), the respondent experienced "throat does not feel fresh and is stuffy". The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 10 HeatSticks and smoked 10 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000134	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	25-APR-2015 to Unknown		Feels repulsive and dizzy [FEELING ABNORMAL] N / Y / Y Feels repulsive and dizzy [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-May-2015</p> <p>Case Narrative: Verbatim: Feels repulsive and dizzy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 07-May-2015:</p> <p>This report concerns a 43-year-old male subject (Respondent Study ID: 1200024) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number STR BRD KLZ BEK) on 25-Apr-2015.</p> <p>On an unspecified day, the respondent experienced feeling repulsive and dizzy. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>The respondent did not provide consent to give further information.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000135	KOREA, REPUBLIC OF Report From Study	55 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK] UNK [UNK]	Respiratory Respiratory	27-APR-2015 to 30-APR-2015 04-MAY-2015 to 07-MAY-2015	04-MAY-2015 04-MAY-2015	When looking into the sky while standing s ill, it feels the world and ground rotates and it makes you feel nauseous. [VERTIGO] N / Y / Y When looking into the sky while standing s ill, it feels the world and ground rotates and it makes you feel nauseous. [NAUSEA] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 08-May-2015 Event Intensity: Severe Severe Case Narrative: Verbatim: When looking into the sky while standing still, it feels the world and ground rotates and it makes you feel nauseous</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 08-May-2015: This report concerns a 55-year-old male subject (Respondent Study ID: 1322273) who took part in the above mentioned market research study.</p> <p>Medical history of hypertension was reported. The following concomitant medications were reported: antihypertensive drug and digestant (twice for today).</p> <p>The respondent was a daily smoker (on average 23 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number U3N XX0 P4H V2G) on 27-Apr-2015.</p> <p>On 04-May-2015, the respondent experienced feeling like the world and ground rotates when looking into the sky (standing still) which makes the respondent feel nauseous. The events were considered to be non-serious. Severity of the adverse event was reported as severe.</p> <p>On the day of the event, the respondent used 5 HeatSticks and smoked 13 conventional cigarettes.</p> <p>The product was used every day since 28-Apr-2015 (start date also reported as 27-Apr-2015) until 07-May-2015, except for 01-May-2015, 02-May-2015 and 03-May-2015.</p> <p>It was reported that the events did not abate after product use was stopped and that the events returned when product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000136	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-MAR-2015 to Unknown	29-MAR-2015	Smoke from inhaling makes chest stuffy [CHEST DISCOMFORT] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 07-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Smoke from inhaling makes chest stuffy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 07-May-2015: This report concerns a 29-year-old male subject (Respondent Study ID: 2360940) who took part in the above mentioned market research study.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			<p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number YZA KVA 6U1 UHF) on 29-Mar-2015.</p> <p>On the same day (29-Mar-2015), the respondent stated that smoke from inhaling makes his chest stuffy. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 3 HeatSticks and smoked 7 conventional cigarettes.</p> <p>The product was used every day and was not discontinued due to the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p> <p>?</p>					
PMI000137	KOREA, REPUBLIC OF Report From Study	62 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	14-APR-2015 to Unknown	15-APR-2015	Coughed when using product Y at first. [COUGH] N / N / Y	Recovered/Resolved
	Case Initial Receipt Date: 11-May-2015 Event Intensity: Mild Event Stop Date: 17-APR-2015 Case Narrative: Verbatim: Coughed when using product Y at first.		<p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 11-May-2015: This report concerns a 62-year-old male subject (Respondent Study ID: 1473117) who took part in the above mentioned market research study.</p> <p>No medical history was reported. The following concomitant medication was reported: Centrum (multi-vitamin).</p> <p>The respondent was a daily smoker (on average, 20 cigarettes per day).</p> <p>The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 14-Apr-2015 (Kit number 26G A9N 66N QJ1, not specified to which product it corresponds).</p> <p>On 15-Apr-2015, the respondent experienced cough at first, when using the Regular HeatSticks (product Y). The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 9 HeatSticks and smoked 12 conventional cigarettes.</p> <p>The product was used every day and was not stopped after occurrence of the event. In addition, it was reported that the problem did not return when use of the product was resumed.</p> <p>The event resolved on 17-Apr-2015.</p>					

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000138	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	06-MAY-2015	Feels a twinge in inhaling because parts of gums (which had been treated before) become tightened [GINGIVAL PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown			
			Case Initial Receipt Date: 11-May-2015					
			Event Intensity: Moderate					
			Case Narrative: Verbatim: feels a twinge in inhaling because parts of gums (which had been treated before) become tightened.					
			Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 11-May-2015:					
			This report concerns a 34-year-old male subject (Respondent Study ID: 1463540) who took part in the above mentioned market research study.					
			No concurrent medical history and no concomitant medications were reported. The respondent had a dental treatment for tooth decay the previous year.					
			The respondent was a daily smoker (in average 20 cigarettes per day).					
			The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 25-Apr-2015 (Kit WTL HUQ NCE PQL, not specified to which product it corresponds).					
			On 06-May-2015, the respondent felt a twinge in inhaling because parts of gums (which had been treated before) became tightened. The respondent clarified that the pain last minutes and that he had no symptom when smoking regular cigarettes. The event was considered to be non-serious. Severity of the adverse event was reported as moderate.					
			The product was used on weekdays, not on weekends. The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event re when product was restarted.					
			At the time of reporting, the event was not resolved.					
No follow-up information is expected ? case closed.								
PMI000140	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PHARYNGEAL OEDEMA] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PRODUCTIVE COUGH] N / Y / Y	
			Case Initial Receipt Date: 14-May-2015					
			Event Intensity: Mild					
			Mild					

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 14-May-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 1218229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using both products, the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number VXF KQM TGO, not specified to which product it corresponds) on 15-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced swelling of throat after using HeatSticks altogether in the evening and phlegm coming out a lot. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>It was reported that the events improved after product use was stopped and that the events returned when product was restarted.</p> <p>Action taken with the use of the product was unknown.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000141	KOREA, REPUBLIC OF Report From Study	50 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory		14-APR-2015	When using the product, feels hot because raised heat comes into mouth at once by putting heated Heat Stick on mouth [FEELING HOT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-May-2015 Event Intensity: Mild Case Narrative: Verbatim: When using the product, feels hot because raised heat comes into mouth at once by putting heated Heat Stick on mouth</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-May-2015: This report concerns a 50-year-old male subject (Respondent Study ID: 1353535) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 1YT 4KE Q60 UXA) on 14-Apr-2015.</p> <p>On 14-Apr-2015, the respondent experienced feeling hot when using the product. He explained that it is because raised heat comes into mouth at once by putting heated HeatStick on mouth. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>On the day of the event, the respondent used 2 HeatSticks and smoked 4conventional cigarettes.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The product was used every day from 14-Apr-2015 to 13-May-2015 and was not discontinued due to the occurrence of the adverse event.								
At the time of reporting, the event was not resolved.								
No follow-up information is expected ? case closed.								
PMI000144	KOREA, REPUBLIC OF Report From Study	24 Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	18-APR-2015 to Unknown		Coughs a lot when using (the products). Sometimes retches when using the products. [RETCHING] N / Y / Y Coughs a lot when using (the products). Sometimes retches when using the products. [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 16-May-2015								
Case Narrative: Verbatim: Coughs a lot when using (the products). Sometimes retches when using the products.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 16-May-2015:								
This report concerns a 24-year-old male subject (Respondent Study ID: 1150153) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was reported.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number MB5 VKV 1LJ A54) on 18-Apr-2015.								
On 16-May-2015, the respondent reported coughing a lot when using the products. He also reported that he sometimes retches when using the products. The events were considered to be non-serious. Severity of the adverse event was not reported.								
Action taken with the use of the product and event outcome were not reported.								
No follow-up information is expected ? case closed.								
PMI000147	KOREA, REPUBLIC OF Report From Study	27 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	18-APR-2015 to Unknown	20-APR-2015 20-APR-2015 20-APR-2015	Throat gets dry and does not feel fresh with a slight cough after using the product. [DRY THROAT] N / Y / Y Throat gets dry and does not feel fresh with a slight cough after using the product. [LARYNGEAL DISCOMFORT] N / Y / Y Throat gets dry and does not feel fresh with a slight cough after using the product. [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 18-May-2015								
Case Narrative: Verbatim: Throat gets dry and does not feel fresh with a slight cough after using the product.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 18-May-2015:								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 27-year-old male subject (Respondent Study ID: 1329176) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number UDE 1LO BJO LBF) on 18-Apr-2015. It was reported that the respondent box of the product. Further kit numbers provided were: Holder I: TY9Q UAT MHM 97YZ, Holder II: T36U M6R VN7 7FJ6 and Charger: TBJD Q6P ZZZ UC48.</p> <p>On 20-Apr-2015, the respondent experienced throat getting dry and not feeling fresh with a slight cough after using the product. The events were considered to be non-serious. The adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed. ?</p>								
PMI000149	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	21-APR-2015 to 18-MAY-2015	21-APR-2015 21-APR-2015	Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge. [FEELING HOT] N / Y / Y Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge. [DEVICE DIFFICULT TO USE] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 20-May-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Feels uneasy to use (the holder) because its whole body gets hot when holding it after charge.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 2357288) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamins and minerals (not further specified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (on average 20 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 850 PSA Y6Q 8EM) on 21-Apr-2015.</p> <p>On the same day (21-Apr-2015), the respondent felt that the holder was uneasy to use because "its whole body got hot when holding it after charge" (note: presumably the body of the respondent). The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 5 HeatSticks and smoked 7 conventional cigarettes.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000150	KOREA, REPUBLIC OF Report From Study	60 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	22-APR-2015 to 19-MAY-2015	22-APR-2015	Feels stinging on throat when using the product Y. [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 21-May-2015 Event Intensity: Mild Event Stop Date: 29-APR-2015 Case Narrative: Verbatim: Feels stinging on throat when using the product Y. Feels stinging in the first 1 week of using, then OK from that point of time.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 21-May-2015: This report concerns a 60-year-old male subject (Respondent Study ID: 1384757) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
The respondent was a daily smoker (in average 20 cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number 9LA C5J JVH Q8V) on 22-Apr-2015. In addition, the respondent also used THS 2.2 Menthol (Dorado I / Vinny low menthol) (dates and kit number not specified); however, the adverse event was reported with use of THS 2.2 Regular.								
On the same day (22-Apr-2015), the respondent felt stinging on throat when using the product HeatSticks. The respondent clarified that he felt the stinging in the first week of using the product and that after that the event improved. The event was considered to be non-serious. Severity of the adverse event was reported as mild.								
The product was used every day. On the day of the event, the respondent used 15 HeatSticks and smoked 3 conventional cigarettes. The last day of use of the HeatSticks was 19-May-2015.								
The use of the product was not discontinued due to the occurrence of the adverse event.								
The event resolved on 29-Apr-2015.								
No follow-up information is expected ? case closed.								
PMI000152	KOREA, REPUBLIC OF Report From Study	43 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	22-APR-2015 to 20-MAY-2015	22-APR-2015	Feels slightly dizzy after using (the product) for about 10 minutes. [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 21-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Feels slightly dizzy after using (the product) for about 10 minutes.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 21-May-2015:								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 43-year-old male subject (Respondent Study ID: 1466209) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamins (not further specified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 8 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number RIP 5E3 GHP A6H) on 22-Apr-2015.</p> <p>On the same day (22-Apr-2015), the respondent felt slightly dizzy after using the product for about 10 minutes. The event was considered to be non-serious. Severity of the was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 3 HeatSticks and smoked 4 conventional cigarettes. The last day of use of the HeatSticks was 20-May-2015.</p> <p>It was reported that the event improved when usage of the product was stopped and returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000154	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to 21-MAY-2015	24-APR-2015	Feels heat on lips when putting the test product on mouth. [FEELING HOT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 22-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Feels heat on lips when putting the test product on mouth.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 22-May-2015:</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: 1215660) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Vitamins (unspecified) were reported as concomitant medications.</p> <p>The respondent was a daily smoker (in average 13 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number not provided) on 24-Apr-2015.</p> <p>Starting on the same day (24-Apr-2015), the respondent felt heat on his lips when putting the HeatStick on his mouth. The respondent specified that it didn' t feel too hot lukewarm heat. He clarified that it would be warm anyway because of heating, but he did not feel danger nor had negative feelings. The event was considered to be non-serious of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 4 HeatSticks and smoked 6 conventional cigarettes. The last HeatSticks were used on 21-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000159	KOREA, REPUBLIC OF Report From Study	59 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	25-APR-2015 to 12-MAY-2015	09-MAY-2015	Coughs violently; having bad coughs by sucking hard as trying to smoke fast. [COUGH] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 23-May-2015 Event Intensity: Mild Event Stop Date: 10-MAY-2015 Case Narrative: Verbatim: Coughs violently; having bad coughs by sucking hard as trying to smoke fast. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 59-year-old male subject (Respondent Study ID: 2343688) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The respondent was a daily smoker (in average 15 cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number 83N Q16 PEW BVQ) on 25-Apr-2015. On 09-May-2015, the respondent experienced coughing violently. He explained that he was having bad coughs by sucking hard as he was trying to smoke fast. The events were considered to be non-serious. Severity of the adverse event was reported as mild. The product was used every day. On the day of the event, the respondent used 6 HeatSticks and smoked 10 conventional cigarettes. The last Heatsticks were used on 12-May-2015. The use of the product was not discontinued due to the occurrence of the adverse event. The event resolved on 10-May-2015. It was indicated that the event did not return when product was restarted.								
No follow-up information is expected ? case closed.								
PMI000163	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK] THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory Respiratory	25-APR-2015 to Unknown 25-APR-2015 to Unknown	25-APR-2015 25-APR-2015	Feels heat and seems to irritate throat. [FEELING HOT] N / Y / Y Feels heat and seems to irritate throat. [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 23-May-2015 Case Narrative: Verbatim: Feels heat and seems to irritate throat. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 49-year-old male subject (Respondent Study ID: 1348800) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit numbers not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced feeling heat (location not specified) and reported that it seems to irritate the throat. The events were considered non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000168	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	24-APR-2015 to 21-MAY-2015	05-MAY-2015 05-MAY-2015	Vomited once or twice because of it (only 1 day, on May 5th) [VOMITING] N / Y / Y Had resistance to smoke and smell sometimes when feeling acidic tastes by using (the product). [PRODUCT TASTE ABNORMAL] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Mild Event Stop Date: 05-MAY-2015 05-MAY-2015 Case Narrative: Verbatim: Had resistance to smoke and smell sometimes when feeling acidic tastes by using (the product). Vomited once or twice because of it. But it was only 1 day on May 5</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 1381646) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra/ Fitz) (Kit number Y6A GQ6 7CW 3JC) on 24-Apr-2015.</p> <p>On 05-May-2015, the respondent vomited once or twice because of it (the Heatsticks). In addition, the respondent mentioned that he had resistance to smoke and smell sometimes feeling acidic tastes by using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 10 HeatSticks and smoked 10 conventional cigarettes. The last Heatsticks were used on 21-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The outcome of the events was reported as resolved on 05-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000170	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015	11-MAY-2015	Has coughs every time when using HeatStick because of being in a hurry to smoke. [COUGH] N / N / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015			
			Case Initial Receipt Date: 20-May-2015 Event Intensity: Mild Case Narrative: Verbatim: Never have coughed when using general cigarettes, but has coughs every time when using HeatStick because of being in a hurry to smoke.					
			Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 20-May-2015 and transferred to Safety department on 28-May-2015: This report concerns a 49-year-old male subject (Respondent Study ID: 2108635) who took part in the above mentioned market research study.					
			No medical history and no concomitant medications were reported.					
			The respondent was a daily smoker (on average 14 cigarettes per day).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number TNY JGW LWS 3KZ, not speci for which one of the two products) on 28-Apr-2015.					
			On 11-May-2015 (about two weeks after using the products), the respondent experienced coughing. He indicated that he never had coughed when using regular cigarettes, but ha cough every time when using HeatStick because of being in a hurry to smoke. The event was considered to be non-serious. Severity of the adverse event was reported as mild.					
			The product was used for 4 days (out of 7 days). On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were us 18-May-2015.					
			The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when use of the product was restarted.					
			At the time of reporting, the event was not resolved.					
			No follow-up information is expected ? case closed.					
PMI000171	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	23-APR-2015	Felt heat and get ing hot from the front part of holder (where lips touch it) when using a few pieces of the product [FEELING HOT] N / Y / Y	Unknown
			Case Initial Receipt Date: 26-May-2015 Case Narrative: Verbatim: Felt heat and getting hot from the front part of holder (where lips touch it) when using a few pieces of the product on the date of testing it.					
			Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 2357462) who took part in the above mentioned market research study.					
			No medical history and no concomitant medications were reported.					

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number PN3 B6X YM4 RXG) on 23-Apr-2015.</p> <p>On the same day (23-Apr-2015), the respondent felt heat and getting hot from the front part of holder (where lips touch it) when using a few pieces of the product. The event considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000174	KOREA, REPUBLIC OF Report From Study	51 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown		During the testing, heat comes into mouth stronger than when smoking regular cigarettes. Feels smoke in mouth throughout 4 weeks of using. [FEELING HOT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 29-May-2015</p> <p>Case Narrative: Verbatim: During the testing, heat comes into mouth stronger than when smoking regular cigarettes. Feels smoke in mouth throughout 4 weeks of using.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 29-May-2015:</p> <p>This report concerns a 51-year-old male subject (Respondent Study ID: 1215341) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number RMF YUK GRY AJ9) on 29-Apr-2015.</p> <p>The respondent reported that during the testing, heat came into mouth stronger than when smoking regular cigarettes. He felt smoke in mouth throughout 4 weeks of using. The event considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000175	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [DRY MOUTH] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [SALIVARY HYPERSECRETION] N / Y / Y	
					29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [NAUSEA] N / N / Y		
Case Initial Receipt Date: 28-May-2015								
Case Narrative: Verbatim: Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. Didn't comment (on that) because it happens usually when using regular cigarettes, and it was not a big deal, like testing (the products).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-May-2015: This report concerns a 36-year-old male subject (Respondent Study ID: 2354864) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number KUI MAM 29Y ONC, not specifying which one of the two products it corresponds) on 29-Apr-2015.								
Starting on the same day (29-Apr-2015), the respondent experienced dryness in mouth, feeling nauseous and having a lot of saliva in mouth by using both types of HeatSticks. The respondent explained that it happened in testing, and did happen in using as well. In addition, he explained that he didn't comment on that because it happened usually when using regular cigarettes, and it was not a big deal. The events were considered to be non-serious. Severity of the adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000177	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DRY THROAT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DYSGEUSIA] N / Y / Y	
			Case Initial Receipt Date: 28-May-2015					

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Used the product on Saturday after two weeks of not taking it. Felt parched on throat from its aftertaste when using both Y and Z.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 2359522) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number DRS 6EK MQK, not specifying which one of the two products it corresponds) on 29-Apr-2015.</p> <p>On 09-May-2015 (after 2 weeks of not using the product), the respondent felt parched on throat from the product's aftertaste when using both types of HeatSticks. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000189	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 19-MAY-2014	19-MAY-2014	The respondent vomited after using the product (1 time) [VOMITING] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 19-May-2014 Event Intensity: Mild Event Stop Date: 19-MAY-2014 Case Narrative: Verbatim: The respondent vomited after using the product (1 time).</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 19-MAY-2014: This report concerns a 40-year-old male subject (Respondent Study ID: MIF0413102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number CU005509) on 15-May-2014. On 19-May-2014, he vomited once after using the product. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 19-May-2014. The event resolved on 19-May-2014. On the occurrence of the event, the respondent used 1 stick and smoked 3 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000190	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to Unknown	16-MAY-2014	She feels a bit dizzy when smoking all the stick tobacco [DIZZINESS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 19-May-2014 Event Intensity: Mild Case Narrative: Verbatim: She feels a bit dizzy when smoking all the stick tobacco. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 19-MAY-2014: This report concerns a 36-year-old female subject (Respondent Study ID: MIF0414101L) who took part in the above mentioned market research study. The respondent's medical conditions included low blood pressure and allergy to grass family. The respondent was not taking any concomitant medications. The respondent was a smoker who smoked on average 20 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU005513) on 15-May-2014. On 16-May-2014, she was feeling a bit dizzy when she smoked all the stick tobacco. The respondent stated that the problem occurred since she started using the product. In order to resolve this, she reduced the number of sticks ('304') and the number of puffs ('304 instead of 8010'). She tried to use the product only at home. She was asked to stop using the product but she refused because this product was previously when she smoked cigarettes stronger than those she normally smoked. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the respondent stopped using the THS and that the event returned when the respondent restarted using the THS. The respondent did not stop using the product. At the time of this report, the event was still ongoing. On the day of the occurrence of the event, the respondent used 4 sticks and smoked 4 cigarettes. No follow-up information has been requested ? case closed.								
PMI000191	ITALY Report From Study	56 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory	19-MAY-2014 to 20-MAY-2014	20-MAY-2014 20-MAY-2014	Cough [COUGH] N / N / Y It scraped her throat [THROAT IRRITATION] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 21-May-2014 Event Intensity: Mild Case Narrative: Verbatim: Cough, it scraped her throat. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 56-year-old female subject (Respondent Study ID: BUS0507101L) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a smoker who smoked on average 25 cigarettes per day.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004631) on 19-May-2014. On 20-May-2014, she experienced cough and reported that it scraped her throat. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 20-May-2014. At the report, the events were still ongoing. On the day of the occurrence of the events, the respondent used 6 sticks and smoked 20 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000192	ITALY Report From Study	61 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 16-MAY-2014	15-MAY-2014 15-MAY-2014	Nausea only during product use [NAUSEA] N / N / Y Bad taste [PRODUCT TASTE ABNORMAL] N / Y / Y The charging procedure was difficult [PRODUCT QUALITY ISSUE] N / Y / Y	
<p>Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Mild Case Narrative: Verbatim: Nausea only during product use, bad taste.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 61-year-old female subject (Respondent Study ID: BUS0420101L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 15 to 18 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004767) on 15-May-2014. On 15-May-2014, she experienced nausea only during product use and also reported bad taste. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 16-May-2014. The events resolved on an unspecified date. On the day of the occurrence of the events, the respondent used 3 to 4 sticks and smoked 15 cigarettes.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 22-MAY-2014: The respondent reported that the product made her nauseous and that the charging procedure was difficult. The event was considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000194	ITALY Report From Study	42 Years Male	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory	21-MAY-2014 to 22-MAY-2014	22-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Narrative: Verbatim: Dizzy.								
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 42-year-old male subject (Respondent Study ID: BUS021102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 to 15 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU004674) on 21-May-2014. On 22-May-2014, he was feeling dizzy. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. On the day of the occurrence of the event, the respondent used 2 sticks and smoked 4 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000195	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]		15-MAY-2014 to 18-MAY-2014	15-MAY-2014 15-MAY-2014 15-MAY-2014	Burning in stomach [DYSPEPSIA] N / Y / Y Headache [HEADACHE] N / N / Y Nausea [NAUSEA] N / N / Y Burning in throat [THROAT IRRITATION] N / N / Y Too acrid/very chemical [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Event Intensity: Mild Mild Mild</p> <p>Case Narrative: Verbatim: Headache, nausea, burning in throat, burning in stomach, too acrid/very chemical.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 38-year-old male subject (Respondent Study ID: MIB0121102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 15 cigarettes per day.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number CU005116) on 15-May-2014. On 15-May-2014, he experienced headache, nausea and stomach burns. The events were considered to be non-serious and mild in intensity. The respondent stopped using the product on 18-May-2014. At the time of this report, the events had improved but not resolved yet. On the day of the occurrence of the event, the respondent used 10 sticks and smoked 8 cigarettes.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 22-MAY-2014: The respondent reported that the product was too acrid, its taste was very chemical and that his throat and stomach burnt. The events were considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000197	ITALY Report From Study	21 Years Female	THS 2.2 Regular (Dorado I / Fitz) / N/A Respiratory UNK [UNK]		Unknown to 19-MAY-2014	16-MAY-2014	Headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 24-May-2014 Event Intensity: Mild Event Stop Date: 19-MAY-2014 Case Narrative: Verbatim: Headache.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 21-year-old female subject (Respondent Study ID: BUS0113102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. On 16-May-2014, she experienced headache. The event was considered to be non-serious and mild in intensity. The respondent stopped using the product on 19-May-2014 and the event resolved on the same day. On the day of the occurrence of the event, the respondent used 3 sticks and smoked 3 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000201	ITALY Report From Study	62 Years Female	THS 2.2 Regular (Dorado I / Fitz) / N/A Respiratory UNK [UNK]		24-MAY-2014 to 26-MAY-2014	24-MAY-2014 24-MAY-2014	Heat sensation on lips [ORAL DISCOMFORT] N / Y / Y THS heats too much [DEVICE MALFUNCTION] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2014 Event Intensity: Mild Event Stop Date: 24-MAY-2014 24-MAY-2014 Case Narrative: Verbatim: Heat sensation on lips, THS heats too much.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 62-year-old female subject (Respondent Study ID: MIF0707101L) who took part in the above mentioned market research study.</p> <p>The respondent's medical condition included hypothyroidism for which she was taking unspecified medication.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number CU004818) on 24-May-2014. The respondent used 4 sticks on 24-May-2014 sticks on 25-May-2014 and 1 stick on 26-May-2014. On 24-May-2014, she experienced heat sensation on lips during the usage of the THS. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the respondent stopped using the THS and that the event returned when the respondent restarted using the product. The respondent added that she woke up at night with a discomfort on her lips. In her opinion, the THS heats too much. The event resolved on 24-May-2014. The respondent stopped using the product on 26-May-2014. On the day of the occurrence of the event, the respondent used 1 stick and smoked 10 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000206	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	23-MAY-2014 to 01-JUN-2014	24-MAY-2014	The aftertaste gives me headache [DYSGEUSIA] N / Y / Y The aftertaste gives me headache/Strong headache [HEADACHE] N / N / Y Has a very unpleasant taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Moderate Case Narrative: Verbatim: The aftertaste gives me headache, has a very unpleasant taste.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker respondents took part in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 32-year-old female subject (Respondent Study ID: BUS0201102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 10 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004623) on 23-May-2014: on that day, she used 1 stick and smoked 8 cigarettes. On 24-May-2014, she experienced strong headache. The event was considered to be non-serious and moderate in intensity. The event improved when the respondent stopped using the product on 24-May-2014. On 01-Jun-2014, the respondent used 1 stick and smoked 9 cigarettes and she experienced the same event. The respondent stopped using the product on 01-Jun-2014 and the event resolved.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 26-MAY-2014: The respondent reported that the product aftertaste gave her headache and that the product had a very unpleasant taste. The events were considered to be non-serious.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000207	ITALY Report From Study	58 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory	20-MAY-2014 to 27-MAY-2014	16-MAY-2014 16-MAY-2014 16-MAY-2014	Tonsillitis [TONSILLITIS] N / Y / Y Sore throat [OROPHARYNGEAL PAIN] N / Y / Y Fever [PYREXIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 03-Jun-2014 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: Tonsillitis, sore throat and fever Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 58-year-old male subject (Respondent Study ID: BUS0114101L) who took part in the above mentioned market research study. The respondent had no medical conditions and was not taking any concomitant medications. The respondent was a smoker who smoked on average 20 cigarettes per day. On 16-May-2014, the respondent experienced fever and sore throat and he reported that he had tonsillitis. The events were considered to be non-serious and mild in intensity. On 20-May-2014, the respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004507). He used the product only twice on 20-May-2014 and 27-May-2014. On these dates, the respondent smoked 2 cigarettes and used 2 sticks. At the time of the report, the events were ongoing.								
No follow-up information has been requested ? case closed.								
PMI000208	ITALY Report From Study	41 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory	29-MAY-2014 to 31-MAY-2014	31-MAY-2014	Burning in the throat [THROAT IRRITATION] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 04-Jun-2014 Event Intensity: Mild Case Narrative: Verbatim: Burning in the throat Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 41-year-old male subject (Respondent Study ID: BUS0515102L) who took part in the above mentioned market research study.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 17 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004720) on 29-May-2014. On 31-May-2014, he experienced burning in his throat. The event was considered to be non-serious and mild in intensity. On the day of the occurrence of the event, the respondent used 10 sticks and smoked no cigarette. reported that the event re-occurred when the respondent re-started the product. The respondent stopped using the product on 31-May-2014 and the event resolved on an unspecified date.								
No follow-up information has been requested ? case closed.								
PMI000209	ITALY Report From Study	21 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory	22-MAY-2014 to 27-MAY-2014	24-MAY-2014 24-MAY-2014	Burning sensation in stomach [DYSPEPSIA] N / Y / Y Inflamed trachea [TRACHEAL INFLAMMATION] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 05-Jun-2014 Event Intensity: Mild Mild Event Stop Date: 27-MAY-2014 27-MAY-2014 Case Narrative: Verbatim: Burning sensation in stomach, inflamed trachea.								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 21-year-old male subject (Respondent Study ID: BUS0812101L) who took part in the above mentioned market research study.								
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 15 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I/Fitz; Kit number CU004491) on 22-May-2014. In the night of 23-May-2014, he experienced burning sensation in his stomach and inflamed trachea, in an unusual way. The events were considered to be non-serious and mild in intensity. It was reported that the event resolved on the same day. On the day of the occurrence of the events, the respondent used 6 sticks and smoked 6 cigarettes.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000210	ITALY Report From Study	35 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory	21-MAY-2014 to 22-MAY-2014	21-MAY-2014	Acidity in stomach [DYSPEPSIA] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 05-Jun-2014 Event Intensity: Mild Event Stop Date: 23-MAY-2014 Case Narrative: Verbatim: Acidity in stomach Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at a central location, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 35-year-old female subject (Respondent Study ID: BUS0227102L) who took part in the above mentioned market research study. The respondent's medical conditions included some food intolerances and acidity in her stomach. The respondent was a smoker who smoked on average 15 cigarettes per day. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004495) on 21-May-2014. On that day, she used 2 sticks and smoked 15 cigarettes and, experienced acidity in her stomach. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the product was stopped and also reported that she took her tablet as she usually did for this type of symptom. On 22-May-2014, the respondent used 2 sticks and smoked 15 cigarettes. The respondent stopped using the product on 22-May-2014 and the event resolved on 23-May-2014. CORRECTIVE VERSION CREATED ON 11-AUG-2014: The reported term was re-coded to heartburn (dyspepsia) at PMI's request. No follow-up information has been requested ? case closed.								
PMI000211	ITALY Report From Study	56 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory	26-MAY-2014 to 30-MAY-2014	26-MAY-2014	It bothers me to smoke it because it makes me cough while with normal cigarettes it does not happen [COUGH] N / N / Y I don't like it because it is too flavoured [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 06-Jun-2014 Case Followup Receipt Date: 09-Jun-2014 00:00 Event Intensity: Mild Case Narrative: Verbatim: I don't like it because it is too flavoured, it bothers me to smoke it because it makes me cough while with normal cigarettes it does not happen. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at a central location, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 06-JUN-2014: This report concerns a 56-year-old female subject (Respondent Study ID: MIF0405101L) who took part in the above mentioned market research study.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent's medical condition included high blood pressure for which she was taking the following concomitant medications: Lobivon (nebivolol), Osipine (barnidipine hydrochloride) and Karvea (irbesartan).</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number CU004526) on 26-May-2014. On that day, she experienced cough. The event was considered to be non-serious and mild in intensity. It was reported that the event improved when the product was stopped. The respondent re-started and stopped the product and each time, the event re-occurred. The respondent stopped using the product on 30-May-2014. The event resolved on an unspecified date. On the day of the occurrence of the event the respondent used 1 stick and smoked 15 cigarettes. The respondent used 7 sticks in total.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 02-JUN-2014: The respondent reported that she did not like the product because it was too flavoured. It bothered her to smoke it because it made her cough while with normal cigarettes it didn't happen. The events were considered to be non-serious.</p> <p>INFORMATION COLLECTED DURING THE INTERVIEW WHICH TOOK PLACE ON 09-JUN-2014: The respondent reported that she did not like the flavoured taste of the product because it caused her cough. The events were considered to be non-serious.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000213	ITALY Report From Study	51 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory		23-MAY-2014 23-MAY-2014	Gives a feeling of nausea/Nauseated [NAUSEA] N / N / Y Very strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: Gives a feeling of nausea/nauseated, very strong</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker respondents were interviewed in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest, they were randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 51-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on 23-May-2014. On the same day, the respondent reported that the product gave him a feeling of nausea (nauseated) and that the product was very strong. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000214	ITALY Report From Study	54 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK] Case Initial Receipt Date: 20-May-2014 Case Narrative: Verbatim: Makes me cough		20-MAY-2014	Makes me cough [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 20-MAY-2014: This report concerns a 54-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on 20-May-2014. On the same day, the respondent reported that the product made her cough. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000216	ITALY Report From Study	60 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 21-May-2014 Case Narrative: Verbatim: It made me cough. Too flavoured/I felt it too strong.		21-MAY-2014 21-MAY-2014	It made me cough [COUGH] N / N / Y Too flavoured, I felt it too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 60-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on 21-May-2014. On the same day, the respondent reported that the product was very different from his cigarettes. The product was too flavoured, he felt it too strong and it made him cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000218	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 26-May-2014 Case Narrative: Verbatim: Gives a feeling of vomiting.			Gives a feeling of vomiting [NAUSEA] N / N / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that this caused him a feeling of vomiting. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000219	ITALY Report From Study	44 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK] Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: Caused me headache, has a strange taste.			Caused me headache [HEADACHE] N / N / Y Has a strong taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 44-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that this caused him a strange taste and that it caused him headache. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000220	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Gives me burning sensation of stomach [DYSPEPSIA] N / Y / Y	Unknown
Case Initial Receipt Date: 29-May-2014 Case Narrative: Verbatim: Gives me burning sensation in stomach. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 38-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that this gave him burning sensation in stomach. The event was considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.							
PMI000221	ITALY Report From Study	43 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Leaves an aftertaste a bit bitter / I do not have a pleasant taste in the mouth / leaves a heavy taste in the mouth [DYSGEUSIA] N / Y / Y Causes me nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 22-May-2014 Case Narrative: Verbatim: Causes me nausea, leaves an aftertaste a bit bitter / I do not have a pleasant taste in the mouth / leaves a heavy taste in the mouth. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 22-MAY-2014: This report concerns a 43-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that this left an aftertaste a bit bitter and a heavy taste in her mouth. She did not have a pleasant taste in her mouth. The product caused her nausea. The events were considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000222	ITALY Report From Study	51 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It affects my throat [THROAT IRRITATION] N / N / Y Makes me cough [COUGH] N / N / Y I feel too much the taste of burnt [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014</p> <p>Case Narrative: Verbatim: It affects my throat, makes me cough, I feel too much the taste of burnt.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 51-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that she felt too much the taste of burnt, that the product affected her throat and made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000223	ITALY Report From Study	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Makes it dry [DRY THROAT] N / Y / Y Irritates/affects my throat [THROAT IRRITATION] N / N / Y Gives cough [COUGH] N / N / Y The taste of burnt affects my throat [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 21-May-2014</p> <p>Case Narrative: Verbatim: The taste of burnt affects my throat, irritates my throat, makes it dry, gives cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 21-MAY-2014: This report concerns a 47-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of burnt affected her throat, irritated her throat, made it dry and made her cough. The events were considered to be non-serious. The outcome was unknown.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.							
PMI000227	ITALY Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			Makes me nauseous [NAUSEA] N / N / Y It tastes very chemical [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014</p> <p>Case Narrative: Verbatim: Makes me nauseous, it tastes very chemical.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014:</p> <p>This report concerns a 27-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product made him nauseous and its taste was very chemical. The events were considered to be non-serious. The outcome was unknown.</p>							
No follow-up information has been requested ? case closed.							
PMI000230	ITALY Report From Study	33 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			The aftertaste is chemical [DYSGEUSIA] N / Y / Y The chemical/nauseating taste bothers me [NAUSEA] N / N / Y It makes me cough [COUGH] N / N / Y The chemical/nauseating taste bothers me [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: It makes me cough, The chemical / nauseating taste bothers me, The aftertaste is chemical.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014:</p> <p>This report concerns a 33-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			chemical and nauseating taste of the product bothered her, that the aftertaste was chemical and the product made her cough. The events were considered to be non-serious. The outcome was unknown.					
			No follow-up information has been requested ? case closed.					
PMI000231	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			Leaves the mouth very bitter/aftertaste really unpleasant [DYSGEUSIA] N / Y / Y Makes me nauseous [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 31-May-2014								
Case Narrative: Verbatim: Makes me nauseous, Leaves the mouth very bitter / aftertaste really unpleasant.								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 31-MAY-2014:								
This report concerns a 32-year-old female subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product left her mouth very bitter, that the aftertaste was really unpleasant and that the product made her nauseous. The events were considered to be non-serious. The outcome was unknown.								
			No follow-up information has been requested ? case closed.					
PMI000232	ITALY Report From Study	24 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It makes me cough [COUGH] N / N / Y Tobacco is too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 02-Jun-2014								
Case Narrative: Verbatim: It makes me cough, Tobacco is too light.								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 02-JUN-2014:								
This report concerns a 24-year-old female subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made her cough and that the tobacco was too light. The events were considered to be non-serious. The outcome was unknown.								

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Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000233	ITALY Report From Study	60 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			The taste it leaves in the mouth is bitter / leaves a taste of burnt straw in the mouth / aftertaste a bit bitter [DYSGEUSIA] N / Y / Y Causes a bit of cough [COUGH] N / N / Y It warms the throat [THROAT IRRITATION] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-May-2014</p> <p>Case Narrative: Verbatim: It warms the throat, Causes a bit of cough, The taste it leaves in the mouth is bitter / leaves a taste of burnt straw in the mouth / aftertaste a bit bitter.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 22-MAY-2014: This report concerns a 60-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product warmed her throat, caused a bit of cough and that the product left a bitter taste in the mouth / left a taste of burnt straw in the mouth / that the aftertaste was considered to be non-serious. The outcome was unknown.</p>								
No follow-up information has been requested ? case closed.								
PMI000235	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			While smoking, I have chest pain [CHEST PAIN] N / Y / Y It is too strong/unpleasant [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 31-May-2014</p> <p>Case Narrative: Verbatim: While smoking I have chest pain, it is too strong/unpleasant.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 31-MAY-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong/unpleasant and that while smoking, she had chest pain. The events were considered to be non-serious. The outcome was unknown.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000236	ITALY Report From Study	28 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			Gives me headache [HEADACHE] N / N / Y Taste too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Gives me headache, taste too strong. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 28-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of the product was too strong and it gave her headache. The events were considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000237	ITALY Report From Study	39 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			Leaves a strange feeling of stomach cramp [ABDOMINAL PAIN UPPER] N / Y / Y	Unknown
Case Initial Receipt Date: 22-May-2014 Case Narrative: Verbatim: Leaves a strange feeling of stomach cramp. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 22-MAY-2014: This report concerns a 39-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product left a strange feeling of stomach cramp. The event was considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000238	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Sometimes I have headache [HEADACHE] N / N / Y It's very strong/not to be smoked often [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-May-2014 Case Narrative: Verbatim: It's very strong/not to be smoked often, sometimes I have headache.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 28-MAY-2014: This report concerns a 40-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was very strong, that sometimes he had headache and the product was not to be smoked often. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000239	ITALY Report From Study	36 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]			Sticks in the throat [THROAT IRRITATION] N / N / Y Gives headache [HEADACHE] N / N / Y Too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 28-May-2014 Case Narrative: Verbatim: Too strong, sticks in the throat, gives headache.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 28-MAY-2014: This report concerns a 36-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong, that it stuck in her throat and gave her headache. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000240	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It made me nauseous, not very strong nausea but enough not to smoke 3 in a row [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-May-2014</p> <p>Case Narrative: Verbatim: It made me nauseous, not very strong nausea but enough not to smoke 3 in a row.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 31-MAY-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made him feel nauseous and that the nausea was not very strong but enough not to smoke 3 sticks in a row. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000242	ITALY Report From Study	27 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]				I feel it very much in the lungs [RESPIRATORY TRACT IRRITATION] N / Y / Y I feel it very much in the throat [THROAT IRRITATION] N / N / Y When inhaling, the taste is strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: When inhaling the taste is strong, I feel it very much in the lungs and also in the throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 27-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that when inhaling the taste of the product was strong, that he felt it very much in the lungs and also in the throat. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000244	ITALY Report From Study	50 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It has a "mechanic" taste, it does not stay in the mouth but goes directly in the pulmonary part, in the long run it was not pleasant anymore and it is very different from normal cigarettes [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: It has a "mechanic" taste, it does not stay in the mouth but goes directly in the pulmonary part, in the long run it was not pleasant anymore and it is very different from normal cigarettes.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 50-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product had a "mechanic" taste, that it did not stay in the mouth but went directly in the pulmonary part and in the long run, it was not pleasant anymore and it was very different from normal cigarettes. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000245	ITALY Report From Study	61 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			When I smoke some of them my throat itches [THROAT IRRITATION] N / N / Y Causing cough [COUGH] N / N / Y Too much flavoured [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 07-Jun-2014</p> <p>Case Narrative: Verbatim: Too much flavoured, when I smoke some of them my throat itches, causing cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JUN-2014: This report concerns a 61-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too much flavoured, that when she smoked some of them her throat itched, causing cough. The events were considered to be non-serious. The outcome was unknown.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information has been requested ? case closed.								
PMI000246	ITALY Report From Study	26 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			It caused nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 07-Jun-2014 Case Narrative: Verbatim: It caused nausea. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 07-JUN-2014: This report concerns a 26-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product caused nausea. The event was considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000247	ITALY Report From Study	38 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It sticks in all airways [RESPIRATORY TRACT IRRITATION] N / Y / Y It sticks in my throat [THROAT IRRITATION] N / N / Y Too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Too light, it sticks in my throat and in all airways. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 38-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too light, it stuck in his throat and in all airways. The events were considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000248	ITALY Report From Study	28 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			I get hiccups, in fact I do not use light cigarettes for that reason [HICCUPS] N / N / Y It is too light [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014 Case Narrative: Verbatim: It is too light, I get hiccups, in fact I do not use light cigarettes for that reason.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 28-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product was too light, that he got hiccups and that in fact, he did not use light cigarettes for that reason. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000249	ITALY Report From Study	42 Years Female	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: It makes me cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 42-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product made him cough. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000250	ITALY Report From Study	46 Years Male	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]			It burnt my chest [CHEST PAIN] N / Y / Y Strange taste/bitterish taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: Strange taste/bitterish taste, it was burning my chest.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 46-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product had a strange taste/bitterish taste and it was burning his chest. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000251	ITALY Report From Study	47 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Makes me cough [COUGH] N / N / Y It tastes like paper [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Jun-2014</p> <p>Case Narrative: Verbatim: It tastes like paper, made me cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 04-JUN-2014: This report concerns a 47-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the product tasted like paper and made her cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000253	ITALY Report From Study	41 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			It hurts my throat [OROPHARYNGEAL PAIN] N / N / Y While smoking, the taste has become cloying/spicy [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014 Case Narrative: Verbatim: While smoking, the taste has become cloying, spicy and it hurts my throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 41-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that while smoking, taste of the product became cloying, spicy and it hurt his throat. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000254	ITALY Report From Study	28 Years Female	THS 2.2 Regular (Dorado II / Albertino) / N/A UNK [UNK]	Respiratory			Nausea [NAUSEA] N / N / Y As I am smoking a lot, I am coughing all the time with this product [COUGH] N / N / Y It is like smoking hay/it's heavy. [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014 Case Narrative: Verbatim: Nausea, as I am smoking a lot I'm coughing all the time with this product, it is like smoking hay/it's heavy.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 28-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent experienced and reported that, as she was smoking a lot, she coughed all the time with the product and that it was like smoking hay/it was heavy. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000255	ITALY Report From Study	40 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It itches the throat [THROAT IRRITATION] N / N / Y Makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jun-2014 Case Narrative: Verbatim: It itches the throat and makes me cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JUN-2014: This report concerns a 40-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product itched the throat and made him cough. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000256	ITALY Report From Study	32 Years Female	THS 2.2 Regular (Ron) / Respiratory N/A UNK [UNK]			It gives a disgusting aftertaste [DYSGEUSIA] N / Y / Y It stings the chest [CHEST DISCOMFORT] N / N / Y It tastes like burning plastic [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 29-May-2014 Case Narrative: Verbatim: It stings the chest, it gives a disgusting aftertaste, it tastes like burning plastic.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 32-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that the product stung the chest, that it gave a disgusting aftertaste and it tasted like burning plastic. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000258	ITALY Report From Study	64 Years Male	THS 2.2 Regular (Ron) / N/A UNK [UNK]	Respiratory			My voice decreased [DYSPHONIA] N / Y / Y It does not have the usual taste of a cigarette / it tastes like hay / I do not feel the tobacco at all [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014</p> <p>Case Narrative: Verbatim: My voice decreased, It does not have the usual taste of a cigarette / it tastes like hay / I do not feel the tobacco at all.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014:</p> <p>This report concerns a 64-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ron; Kit number not provided) on an unspecified date. The respondent reported that his voice decreased and that the product did not have the usual taste of a cigarette / it tasted like hay / he did not feel the tobacco at all. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000261	ITALY Report From Study	32 Years Male	THS 2.2 Regular (Dorado I / Fitz) / N/A UNK [UNK]	Respiratory			I found it heavy on the chest [CHEST DISCOMFORT] N / N / Y It is not particularly aromatic [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: I found it heavy on the chest, it is not particularly aromatic.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014:</p> <p>This report concerns a 32-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product was heavy on the chest and it was not particularly aromatic. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000263	ITALY Report From Study	22 Years Male	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Just finished smoking, I was coughing [COUGH] N / N / Y Taste too fresh / I do not feel it [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Taste too fresh/ I do not feel it, Just finished smoking I was coughing.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 22-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that the taste of the product was too fresh and that he did not feel it. When he just finished smoking, he was coughing. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000264	ITALY Report From Study	35 Years Male	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It gives a feeling of nausea after smoking for a while [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 03-Jun-2014</p> <p>Case Narrative: Verbatim: It gives a feeling of nausea after smoking for a while.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 35-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product gave him a feeling of nausea after smoking for a while. The event was considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000265	ITALY Report From Study	40 Years Female	THS 2.2 Regular (Dorado Respiratory I / Fitz) / N/A UNK [UNK]			It gives me cough [COUGH] N / N / Y It itches the throat [THROAT IRRITATION] N / N / Y It has a taste of burnt/too bitter [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 05-Jun-2014</p> <p>Case Narrative: Verbatim: It has a taste of burnt/too bitter, it gives me cough, it itches the throat.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 05-JUN-2014: This report concerns a 40-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Fitz; Kit number not provided) on an unspecified date. The respondent reported that the product had a taste of burnt/was too bitter, it gave her cough and it itched her throat. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							
PMI000266	ITALY Report From Study	39 Years Female	THS 2.2 Regular (Dorado Respiratory II / Albertino) / N/A UNK [UNK]			Over days it bothered me in the stomach [ABDOMINAL DISCOMFORT] N / Y / Y I found the taste more and more unpleasant [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014</p> <p>Case Narrative: Verbatim: Over days it bothered me in the stomach, I found the taste more and more unpleasant.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week at the central location, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 39-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Albertino; Kit number not provided) on an unspecified date. The respondent reported that over the days the product bothered her in the stomach and that she found the taste of the product more and more unpleasant. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000330	RUSSIAN FEDERATION Report From Study	37 Years Male	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Headache</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 37-year-old male subject (Respondent Study ID: b2350) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 30 marketed cigarettes (MC) per day and used on average 7 MC and 22 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced headache. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000331	RUSSIAN FEDERATION Report From Study	32 Years Female	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Cough</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 32-year-old female subject (Respondent Study ID: b8228) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 15 marketed cigarettes (MC) per day, and used on average 9 MC and 7 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced cough. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not provided.							
No follow-up information is expected ? case closed.							
PMI000332	RUSSIAN FEDERATION Report From Study	33 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Burning feeling in throat [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: burning feeling in throat							
Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.							
INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.							
This report concerns a 33-year-old male subject (Respondent Study ID: b8551) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
The consumer was a daily smoker, approximately 10 marketed cigarettes (MC) per day, and used on average 7 MC and 2 heatsticks per day during the study period.							
The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.							
On an unspecified date, the consumer experienced burning feeling in throat. The event was considered to be non-serious. Severity grade was not provided.							
Action taken with the product was not reported.							
The outcome of the event was not provided.							
No follow-up information is expected ? case closed.							
PMI000333	RUSSIAN FEDERATION Report From Study	25 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Nausea							
Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.							
INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.							
This report concerns a 25-year-old male subject (Respondent Study ID: b8219) who took part in the above mentioned market research study.							
No medical history and no concomitant medications were reported.							
The consumer was a daily smoker, approximately 12 marketed cigarettes (MC) per day, and used oin average 1 MC and 2 heatsticks per day during the study period.							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced nausea. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000334	RUSSIAN FEDERATION Report From Study	44 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Unpleasant taste in throat [DYSGEUSIA] N / Y / Y Headache [HEADACHE] N / N / Y Dizziness [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 02-Sep-2015 Case Narrative: Verbatim: Headache, dizziness, unpleasant taste in throat.</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 02-Sep-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 44-year-old male subject (Respondent Study ID: m8718) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 7 marketed cigarettes (MC) per day, and used on average 5 MC and 22 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced headache, dizziness, and unpleasant taste in throat. The events were considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the events was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000335	RUSSIAN FEDERATION Report From Study	25 Years Female	THS 2.4 Regular (Scion 1 Respiratory Walt) / N/A UNK [UNK]			Nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 30-Aug-2015 Case Narrative: Verbatim: Nausea</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Aug-2015 and forwarded to Safety department on 15-Sep-2015.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 25-year-old female subject (Respondent Study ID: m4518) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 6 marketed cigarettes (MC) per day, and used on average 5 MC and 2 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Walt) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced nausea. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000336	RUSSIAN FEDERATION Report From Study	26 Years Male	THS 2.4 Regular (Scion 1 Respiratory Fitz) / N/A UNK [UNK]			Dizziness [DIZZINESS] N / N / Y	Unknown
<p>Case Initial Receipt Date: 30-Aug-2015 Case Narrative: Verbatim: Dizziness</p> <p>Market Research Study P1_BT1_RU: Single stick test followed by 1 week home usage.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Aug-2015 and forwarded to Safety department on 15-Sep-2015.</p> <p>This report concerns a 26-year-old male subject (Respondent Study ID: m9779) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker, approximately 20 marketed cigarettes (MC) per day, and used on average 12 MC and 2 heatsticks per day during the study period.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.4 Regular (Scion 1 Fitz) on an unspecified date and for an unspecified duration.</p> <p>On an unspecified date, the consumer experienced dizziness. The event was considered to be non-serious. Severity grade was not provided.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not provided.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Yes (2)								
PMI000109	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [qd]	Respiratory	17-APR-2015 to Unknown	22-APR-2015 22-APR-2015 (b) (6)	Falling from first floor-height in one's daily life [FALL] Y / Y / Y Diagnosed 2 weeks of remedy for vertebral abnormality [SPINAL DISORDER] Y / Y / Y Hospitalized for hurting vertebral (not in an operation but in an abdominal binder) [SPINAL PAIN] Y / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 23-Apr-2015 Case Followup Receipt Date: 28-Apr-2015 00:00 15-May-2015 00:00 Event Intensity: Severe Severe Severe Case Comment Text: The Fall, Spinal disorder, and Spinal Pain are unlisted for THS 2.2 Regular, according to the Investigator Brochure. Considering the limited provided information (i.e. fall in one's daily life), the fall was probably incidental. The fall is a plausible explanation for the reported spinal disorder and spinal pain requiring hospitalisation and use of an abdominal binder. Therefore, the Company assesses the reported adverse events as not related to the use of the THS 2.2 Regular. Case Narrative: Verbatim: Hospitalized for hurting vertebral (not in an operation but in an abdominal binder).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4-week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-Apr-2015: This report concerns a 44-year-old male subject (Respondent Study ID: 1181271) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Medicine for schizophrenia (not further specified) was reported as concomitant medication.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not reported) on 17-Apr-2015.</p> <p>(b) (6), the respondent was hospitalized for hurting vertebral. It was specified that he was "not in an operation but in an abdominal binder". In addition, it was reported that he was like this for the first time (being hurt for the first time). The event was considered to be severe in intensity, serious due to hospitalisation and it required medical advice.</p> <p>On the day of the event, the respondent used 5 heatsticks and smoked 1 conventional cigarette. It was reported that the usage of the product was not interrupted following the event.</p> <p>At the time of reporting, the event was not resolved.</p> <p>Follow-up information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 28-APR-2015: Verbatim: Injured by falling from first floor-height in one's daily life; diagnosed 2 weeks of remedy for vertebral abnormality and now in hospitalization with a abdominal binder. THS 2.2 product kit number was provided. Medical history of (slight) mental illness was reported. Medicine for psychiatric disorders (not further specified) was reported as concomitant medication.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>(b) (6) the respondent experienced a fall from first floor height. It was also reported that the respondent was "diagnosed 2 weeks of remedy for vertebral abnormality". The events were considered to be severe in intensity and reported as serious, due to hospitalization.</p> <p>On the day of the event, the respondent used 6 HeatSticks (previously reported as 5) and smoked 7 conventional cigarette. The respondent used the product every day. Use of the product was continued following the occurrence of the events.</p> <p>It was also reported that a request to stop the use of the product was made (not further specified).</p> <p>At the time of reporting, the events were ongoing.</p> <p>Follow-up information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 15-MAY-2015:</p> <p>Information was received that no further follow-up can be made for this case.</p> <p>Case closed.</p>								
3 PMI000128	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	03-MAY-2015	Fire breaks out on the charger: gets injured / was hurt by debris [INJURY ASSOCIATED WITH DEVICE] Y / Y / Y	Recovered/Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	24-APR-2015 to Unknown	03-MAY-2015	get something stuck in to his hand / his hand was smeared with ash / burned issue [THERMAL BURN] Y / Y / Y	
					03-MAY-2015	Fire breaks out on the charger: gets injured [DEVICE BATTERY ISSUE] N / Y / N the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE DAMAGE] N / Y / -		
<p>Case Initial Receipt Date: 03-May-2015 Case Followup Receipt Date: 14-May-2015 00:00 21-May-2015 00:00 18-Apr-2016 00:00 Event Stop Date: 04-MAY-2015 04-MAY-2015 04-MAY-2015 Case Comment Text: The Injury associated with device and Thermal burn were assessed as serious (medically significant). The Device battery issue was assessed as non-serious.</p> <p>Injury associated with device and Thermal burn are unlisted for THS 2.2 Regular or THS 2.2 Menthol, according to the Investigator Brochure.</p> <p>The causality and listedness assessments are not applicable for Device battery issue.</p> <p>There is limited information in this case. However, considering the temporal relationship and the knowledge about the product in question, the Company assesses the reported adverse events as related to the use of the THS 2.2 Regular and THS 2.2 Menthol.</p>								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Narrative: Verbatim: fire breaks out on the charger: gets injured								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 03-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1410947) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 on an unspecified date (reported as 24-May-2015 which is subsequent to report date, therefore, most likely, 24-Apr-2015). According to the information received, the respondent used both products, THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Men hol (Dorado I / Vinny low menthol) (Kit numbers not provided).								
On 03-May-2015, the respondent experienced fire breaking out of the charger and got injured (not further specified). The events were considered to be non-serious. Severity of the adverse events was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the events was not reported.								
Follow-up information is expected.								
FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015:								
Clarification was received that the respondent used two study products (THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol)) with a start date of 24-Apr-2015. It was not specified with which one of the products the event occurred.								
No further information on the type of injury was received.								
FOLLOW-UP INFORMATION RECEIVED ON 21-MAY-2015:								
The device kit number WL9 L4K MN7 RSY was provided (not specified if it is for Menthol or Regular).								
The respondent mentioned that "he was hurt by debris of something", that "he got something stuck into his hand" (not further explained) and that he went to the emergency room due to his problem. He further clarified that "what he described as something stuck into his hand was because his hand was smeared with ash (but didn't explain more about the burned issue)".								
Regarding the charger, it was reported that the charger caught fire, and possibly exploded. It was also mentioned that "He dropped charger (the holder was in it) on the floor during they were charging. He also told that the holder was too hot because he dropped holder on the floor." It was not clearly explained if the charger was dropped before or after the injury occurred.								
The event improved when use of the product was stopped, and the product was not restarted.								
The outcome of the events was indicated as resolved on 04-May-2015.								
No further information is expected. Case closed.								

CUM LL All Cases Excluding D2 Ron and D2 Fitz
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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
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Total number of case entries printed: 91

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