



PMI RESEARCH & DEVELOPMENT

# **Safety Update Report**

## **Tobacco Heating System 2.2 Regular**

### **Appendix C - Line Listings and Summary Tabulations of Adverse Events**

**Report Number:** PMI\_SURV\_2015\_SUR01

**Period Covered:** 01 May 2014 to 30 April 2015

**Product Name:** Tobacco Heating System 2.2 Regular

**Sponsor:** Philip Morris Products S.A.  
PMI Research & Development  
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2000 Neuchâtel, Switzerland

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## Appendix A – Line Listings and Summary Tabulations of Adverse Events

### Table of Contents

a. Line Listings of Serious and Non-serious Adverse Events (Argus database) .....	3
b. Line Listings of Non-serious Adverse Events (BaseCon database) .....	4
c. Summary Tabulation of Serious and Non-serious Adverse Events (Argus database) .....	5
d. Summary Tabulation of Non-serious Adverse Events (BaseCon database) .....	6

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**a. Line Listings of Serious and Non-serious Adverse Events (Argus database)**

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**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

**Advanced Condition used in this report:**

Advanced Condition: Periodic Line Listing for Safety Update Report (Created by nicole.miller)

Selection Criteria:

Product Name equal to THS 2.2 Regular (Ron) OR

Product Name equal to THS 2.2 Regular (Dorado I / Fitz) OR

Product Name equal to THS 2.2 Regular (Dorado II / Ron) OR

Product Name equal to THS 2.2 Regular (Dorado II / Albertino) OR

Product Name equal to THS 2.2 Regular (Dorado II / Fitz) OR

Product Name equal to THS 2.2 Regular (Ginebra / Fitz) OR

Product Name equal to IQOS Marlboro Essence OR

Product Name equal to IQOS Marlboro Regular



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 (87)								
PMI000001	ITALY Report From Study	33 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			Make me cough too much [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 04-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			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 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Gastrointestinal disorders Gastrointestinal disorders 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.								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 duration of use was short, around 2 minutes and 10 seconds, therefore 'each distraction was fatal'; sticks too expensive. The respondent also the heat irritated her tongue and palate. 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>							
PMI000003	ITALY Report From Study	40 Years Male	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			<p>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</p>	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  General disorders and administration site conditions  General disorders and administration site conditions</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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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.							
PMI000004	ITALY Report From Study	28 Years Male	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Nervous system disorders Case Narrative: Verbatim: product gives headache			the product gives headache [HEADACHE] N / N / Y	Unknown
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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Psychiatric disorders General disorders and administration site conditions Nervous system disorders			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



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 taste of the tobacco makes my head turn, and the anxiety of the little light. It seems to me that it last too little.</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 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 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	<b>THS 2.2 Regular (Dorado</b> <b>II / Ron) / N/A</b> UNK [UNK]	Respiratory			at the beginning he gave me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Study ID: P1_WOT2_IT</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: Nervous system disorders</p> <p>Case Narrative: Verbatim: at the beginning he 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 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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.							
PMI000008	ITALY Report From Study	36 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Nervous system disorders Case Narrative: Verbatim: I had dizziness while I smoked			I had dizziness while I smoked [DIZZINESS] N / N / Y	Unknown
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 36-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 had dizziness while she was smoking. 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.							
PMI000009	ITALY Report From Study	52 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 04-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: The sticks that take the throat, sting the throat and make you cough			the sticks that take the throat, itchy throat [THROAT IRRITATION] N / Y / Y make you cough [COUGH] N / N / Y	Unknown
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 52-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Nervous system disorders  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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000012	ITALY Report From Study	26 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]				the taste didn't satisfy me, it gave me headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 18-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Nervous system disorders Case Narrative: Verbatim: The taste didn't satisfy me, it gave 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 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 the taste did not satisfy her and the product gave her headache. 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.								
PMI000013	ITALY Report From Study	42 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]				I don't like it, it gives me nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 18-Dec-2014 Study ID: P1_WOT2_IT Study Blinding Status: Not Blinded Event System Organ Class: Gastrointestinal disorders Case Narrative: Verbatim: I don't like it, it gives me nausea  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 42-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.								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]</b>			it gives me nausea [NAUSEA] N / N / Y I don't like the taste / the system [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Gastrointestinal disorders  Case Narrative: Verbatim: I don't like the taste / the system, it is not worth its price, it gives me 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 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> <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 requested ? case closed.</p>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000015	ITALY Report From Study	40 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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
<p>Case Initial Receipt Date: 18-Dec-2014  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Nervous system disorders  Case Narrative: Verbatim: I don't like the taste it leaves in the mouth, the smell gives 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 40-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 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.</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>							
PMI000016	ITALY Report From Study	53 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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
<p>Case Initial Receipt Date: 18-Dec-2014  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Gastrointestinal disorders  General disorders and administration site conditions</p>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 the filter is too hot, the smoke is not dry but wet and aspirate gives me nausea and "impastate" the mouth.</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 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]				After some aspiration I had headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Study ID: P1_WOT2_IT</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: Nervous system disorders</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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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.								
PMI000018	ITALY Report From Study	26 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders  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>								
No follow-up information is expected ? case closed.								
PMI000020	ITALY Report From Study	28 Years Male	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]				they give me headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 07-Jan-2015  Study ID: P1_WOT2_IT  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000022	SWITZERLAND Report From Study	49 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			the first moment I had to cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-Oct-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: The first moment I had to 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 31-OCT-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 in the first moment she had to 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000024	SWITZERLAND Report From Study	25 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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
<p>Case Initial Receipt Date: 31-Oct-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders  Respiratory, thoracic and mediastinal disorders  Case Narrative: Verbatim: Very strong, scratches in the throat and one ends up with a coughing fit.</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 31-OCT-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 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			In the beginning it was scratchy [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			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 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders 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> <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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000028	SWITZERLAND Report From Study	45 Years Male	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Gastrointestinal disorders Case Narrative: Verbatim: when one has smoked several Heat Sticks in a row, one feels nauseous.			when one has smoked several Heat Sticks in a row one feels nauseous [NAUSEA] 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 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 addition, 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>							
PMI000029	SWITZERLAND Report From Study	31 Years Male	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders General disorders and administration site conditions Case Narrative: Verbatim: It tastes chemical and is pungent in the throat.			it is pungent in the throat [OROPHARYNGEAL PAIN] N / N / Y it tastes chemical [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 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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders  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> <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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000032	SWITZERLAND Report From Study	35 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			Now I have nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Case Narrative: Verbatim: now I have nausea.</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 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> <p>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).</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>								
PMI000034	SWITZERLAND Report From Study	33 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			The regular heatstick which gives headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Case Narrative: Verbatim: The regular heatstick that gives 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 15-NOV-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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders  General disorders and administration site conditions  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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000036	SWITZERLAND Report From Study	26 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			Get unpleasant feeling in my throat [THROAT IRRITATION] N / Y / Y tobacco is too strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  General disorders and administration site conditions  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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			I get headaches [HEADACHE] N / N / Y slight drowsiness [SOMNOLENCE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Nov-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Nervous system disorders  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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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>								
PMI000040	SWITZERLAND Report From Study	45 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: General disorders and administration site conditions Case Narrative: Verbatim: I have been sick.	Respiratory			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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000041	SWITZERLAND Report From Study	61 Years Male	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			Because I sometimes after the second HS always get headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Case Narrative: Verbatim: I sometimes after the second HS ALWAYS [sic] get 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 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> <p>No follow-up information is expected ? case closed.</p>								
PMI000042	SWITZERLAND Report From Study	21 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			During the use of heatsticks I felt tension in the chest [CHEST DISCOMFORT] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Case Narrative: Verbatim: During the use of heatsticks I felt tension in the chest.</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 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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.</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>							
PMI000043	SWITZERLAND Report From Study	27 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			The s icks weren't good for me, I had an oppressive feeling after smoking [SENSE OF OPPRESSION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Case Narrative: Verbatim: The sticks weren't good for me, I had an oppressive feeling after smoking.</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 27-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 weren't good for her, she had an oppressive feeling after 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>							
PMI000044	SWITZERLAND Report From Study	39 Years Male	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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>Study ID: P1_WOT1_CH</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: General disorders and administration site conditions</p> <p>Nervous system disorders</p> <p>Nervous system disorders</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>							
PMI000045	SWITZERLAND	49 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			was sick for one week [MALAISE] N / Y / Y Didn't taste [PRODUCT QUALITY ISSUE] N / Y / -	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Study ID: P1_WOT1_CH</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: General disorders and administration site conditions</p> <p>General disorders and administration site conditions</p> <p>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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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>							
PMI000046	SWITZERLAND Report From Study	51 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			Throat pain [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Study ID: P1_WOT1_CH</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: Respiratory, thoracic and mediastinal disorders</p> <p>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> <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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000047	SWITZERLAND Report From Study	26 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			Heatsticks have scratched in my throat [THROAT IRRITATION] N / Y / Y Heatsticks have caused cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Respiratory, thoracic and mediastinal disorders  Case Narrative: Verbatim: Heatsticks have scratched in my throat and caused 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 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 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.</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>								
PMI000049	SWITZERLAND Report From Study	22 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			I got headaches from the heats icks [HEADACHE] N / N / Y I found them too strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  General disorders and administration site conditions  Case Narrative: Verbatim: I got headaches from the heatsticks, maybe, because I found them too strong.</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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			I was disgusted by the heatsticks [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Case Narrative: Verbatim: I was disgusted by 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 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000051	SWITZERLAND Report From Study	25 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			I feel like the heatsticks hurt my lungs [BRONCHIAL IRRITATION] N / Y / Y my throat cannot take them [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Respiratory, thoracic and mediastinal disorders  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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			The heatsticks make me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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>							
PMI000053	SWITZERLAND Report From Study	42 Years Male	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  General disorders and administration site conditions</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 new one and he 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 call to get a new 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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000056	SWITZERLAND Report From Study	35 Years Female	<b>THS 2.2 Regular (Dorado</b> <b>II / Ron) / N/A</b> UNK [UNK]	Respiratory			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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Gastrointestinal disorders  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> <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	<b>THS 2.2 Regular (Dorado</b> <b>II / Ron) / N/A</b> UNK [UNK]	Respiratory			The heatstick makes me cough more than the cigarette [COUGH] N / N / Y when I smoke a heatstick, I am not satisfied, I feel it doesn' t last long enough [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders  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 ch  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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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. 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 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>								
PMI000059	SWITZERLAND Report From Study	57 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders  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 eventy were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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.							
PMI000060	SWITZERLAND Report From Study	45 Years Male	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			less coughing [COUGH DECREASED] N / Y / Y better breathing [PRE-EXISTING CONDITION IMPROVED] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: General disorders and administration site conditions Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: Better breathing, less coughing. Good tobacco taste, and no cold smoke. Fun to use.  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 45-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 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.  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.							
PMI000061	SWITZERLAND Report From Study	33 Years Male	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			I felt weak in the stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Gastrointestinal disorders Case Narrative: Verbatim: I felt weak in the stomach.  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:							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory UNK [UNK]			<p>The heatsticks caused headache and drowsiness [SOMNOLENCE] N / Y / Y</p> <p>The heatsticks caused headache and drowsiness [HEADACHE] N / N / Y</p>	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Nervous system disorders  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> <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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000064	SWITZERLAND Report From Study	32 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			scratched little [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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>								
PMI000067	SWITZERLAND Report From Study	44 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			[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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders  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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			crushing feeling in the chest region [CHEST DISCOMFORT] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  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> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000069	SWITZERLAND Report From Study	31 Years Male	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			it makes me cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: it makes me 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			Irritating [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: irritating  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.								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: irritating (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>							
PMI000074	SWITZERLAND Report From Study	41 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			coughing a lot [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Case Narrative: Verbatim: Coughing a lot.</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 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]			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>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions</p>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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>Nervous system disorders</p> <p>Case Narrative: Verbatim: it stays in the throat, one always has to drink after, it leaves a pasty 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 37-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 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 pr</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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A UNK [UNK]</b>				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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Nervous system disorders</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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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.							
PMI000077	SWITZERLAND Report From Study	57 Years Female	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> 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
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders Respiratory, thoracic and mediastinal disorders Case Narrative: Verbatim: it dries up the throat, I am coughing more than with my cigarette.  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 57-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 dries up the throat and she is coughing more than with her cigarette. 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.							
PMI000080	SWITZERLAND Report From Study	55 Years Male	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			sometimes I got strong headaches [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Nervous system disorders Case Narrative: Verbatim: Sometimes I got strong 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:							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000081	SWITZERLAND Report From Study	51 Years Female	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			it makes me cough with the first inhalations [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Case Narrative: Verbatim: it makes me cough with the first inhalations.</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 it makes her cough with the first inhalations. 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000082	SWITZERLAND Report From Study	22 Years Female	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			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
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Gastrointestinal disorders  Case Narrative: Verbatim: The flavour is pleasant if I use one or two sticks but after that it becomes nauseating and give me 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 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 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	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Respiratory, thoracic and mediastinal disorders  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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Nervous system disorders  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> <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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000085	SWITZERLAND Report From Study	51 Years Male	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  General disorders and administration site conditions  General disorders and administration site conditions  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>							
PMI000088	SWITZERLAND Report From Study	22 Years Female	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders</p>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: 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	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders  Nervous system disorders  Gastrointestinal disorders</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> <p>No information was provided on the use of conventional cigarettes.</p>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> Respiratory 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  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Gastrointestinal disorders  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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			The first draw was always (too) strong, had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: Respiratory, thoracic and mediastinal disorders 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	<b>THS 2.2 Regular (Dorado II / Ron) / N/A</b> UNK [UNK]	Respiratory			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 Study ID: P1_WOT1_CH Study Blinding Status: Not Blinded Event System Organ Class: General disorders and administration site conditions Nervous system disorders 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.								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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,</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>								
PMI000093	SWITZERLAND Report From Study	22 Years Female	<b>THS 2.2 Regular (Dorado Respiratory II / Ron) / N/A</b> UNK [UNK]				after a while it makes me feel nauseous [NAUSEA] N / N / Y Gives headaches [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Gastrointestinal disorders  Nervous system disorders  Case Narrative: Verbatim: after a while it makes me feel nauseous. Gives 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 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 after a while it makes her feel nauseous and gives headaches. 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000094	SWITZERLAND Report From Study	41 Years Female	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			cardboard taste [DYSGEUSIA] N / Y / Y much coughing [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Respiratory, thoracic and mediastinal disorders  Case Narrative: Verbatim: Cardboard taste, much coughing.</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 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 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	<b>THS 2.2 Regular (Dorado</b> Respiratory <b>II / Ron) / N/A</b> UNK [UNK]			Sometimes it makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014  Study ID: P1_WOT1_CH  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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>							



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular</b> <b>(Ginebra / Fitz) / N/A</b> 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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Gastrointestinal disorders  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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000101	KOREA, REPUBLIC OF Report From Study	42 Years Male	<b>THS 2.2 Regular</b> <b>(Ginebra / Fitz) / N/A</b> 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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Moderate  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  General disorders and administration site conditions  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 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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000103	KOREA, REPUBLIC OF Report From Study	22 Years Male	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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
<p>Case Initial Receipt Date: 20-Apr-2015  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Unknown  Unknown  Event System Organ Class: Eye disorders  Immune system disorders  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 events 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 resolved.</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	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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
<p>Case Initial Receipt Date: 20-Apr-2015  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Respiratory, thoracic and mediastinal disorders</p>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: 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>								
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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: Nervous system disorders  Gastrointestinal disorders</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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 use of 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.								
PMI000108	KOREA, REPUBLIC OF Report From Study	43 Years Male	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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
Case Initial Receipt Date: 23-Apr-2015 Study ID: P1_WOT1_KO Study Blinding Status: Not Blinded Event Intensity: Mild Mild Mild Event System Organ Class: Respiratory, thoracic and mediastinal disorders Respiratory, thoracic and mediastinal disorders Nervous system disorders Case Narrative: Verbatim: got pounding in my head, coughing, and a sore 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-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.								
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 B85 D5Q CA3 PA1) on 17-Apr-2015.								
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.								
The product was used every day. On the day of the events, the respondent used 6 HeatSticks and smoked 6 conventional cigarettes.								
Action taken with 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.								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000111	KOREA, REPUBLIC OF Report From Study	43 Years Male	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Mild  Event System Organ Class: General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders  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:  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 throat" 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	<b>THS 2.2 Regular (Ginebra / Fitz) / N/A</b> 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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders</p>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: 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:  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>							
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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Mild  Event System Organ Class: Nervous system disorders  General disorders and administration site conditions  Respiratory, thoracic and mediastinal disorders</p> <p>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>							

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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/rResolving
<p>Case Initial Receipt Date: 28-Apr-2015  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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> <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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000116	KOREA, REPUBLIC OF Report From Study	22 Years Male	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> UNK [UNK]	Respiratory	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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: Respiratory, thoracic and mediastinal disorders  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:  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	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> UNK [UNK]	Respiratory	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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Event System Organ Class: Gastrointestinal disorders  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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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	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>Report From Study</p> <p>Case Initial Receipt Date: 30-Apr-2015</p> <p>Study ID: P1_WOT1_KO</p> <p>Study Blinding Status: Not Blinded</p> <p>Event System Organ Class: General disorders and administration site conditions</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>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000120	KOREA, REPUBLIC OF Report From Study	25 Years Male	<b>THS 2.2 Regular (Dorado II / Fitz) / N/A</b> 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  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Event System Organ Class: Nervous system disorders  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:  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> <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>								
PMI000121	KOREA, REPUBLIC OF Report From Study	50 Years Male	<b>THS 2.2 Regular (Ginebra / Fitz) / N/A</b> 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	
<p>Case Initial Receipt Date: 30-Apr-2015  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event System Organ Class: General disorders and administration site conditions  Gastrointestinal disorders  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.</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 50-year-old male subject (Respondent Study ID: 2341690) who took part in the above mentioned market research study.</p>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 provided.</p> <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 II / Fitz) / N/A UNK [UNK]	Respiratory	30-APR-2015 to Unknown	30-APR-2015  30-APR-2015  30-APR-2015	<p>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</p> <p>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</p> <p>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>	Recovering/rResolving
<p>Case Initial Receipt Date: 30-Apr-2015  Case Followup Receipt Date: 14-May-2015 00:00  Study ID: P1_WOT1_KO  Study Blinding Status: Not Blinded  Event Intensity: Mild  Mild  Mild</p> <p>Event System Organ Class: Respiratory, thoracic and mediastinal disorders  Nervous system disorders  Gastrointestinal disorders</p> <p>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>								



**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 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> <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>								
Yes (1)								
PMI000109	KOREA, REPUBLIC OF	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 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
<p>Case Initial Receipt Date: 23-Apr-2015</p> <p>Case Followup Receipt Date: 28-Apr-2015 00:00 15-May-2015 00:00</p> <p>Study ID: P1_WOT1_KO</p> <p>Study Blinding Status: Not Blinded</p> <p>Event Intensity: Severe Severe Severe</p> <p>Event System Organ Class: Injury, poisoning and procedural complications Musculoskeletal and connective tissue disorders Musculoskeletal and connective tissue disorders</p> <p>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.</p>								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: Hospitalized for hurting vertebral (not in an operation but in an abdominal binder).								
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).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) (Kit number not reported) on 17-Apr-2015.								
On 22-Apr-2015, 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.								
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.								
At the time of reporting, the event was not resolved.								
Follow-up information is expected.								
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.								
On 22-Apr-2015, 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.								
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.								
It was also reported that a request to stop the use of the product was made (not further specified).								
At the time of reporting, the events were ongoing.								
Follow-up information is expected.								
FOLLOW-UP INFORMATION RECEIVED ON 15-MAY-2015:								
Information was received that no further follow-up can be made for this case.								
Case closed.								

**Periodic Line Listing for Safety Update Report**  
**Period: 01-May-2014 through 30-Apr-2015**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: 88*

*Total number of cases printed: 88*



## **b. Line Listings of Non-serious Adverse Events (BaseCon database)**

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### **Confidentiality Statement**

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of law. No part of this document may be publicly disclosed without the written consent of Philip Morris International

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Case number <i>Company no.</i> Drug name Dosage Drug route of administration	Report type <i>(Sub type)</i>	Latest receipt date	First received date	Study ID  Patient ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) <i>Verbatim</i>  Other events	Outcome
	Seriousness											Medical history
	Narrative											
	treatment of cardiac insufficiency with Furosemid® (furosemide) and Spironol® (spironolactone) and antibiotic therapy with Augmentin® (amoxicillin/clavulanic acid) and ciprofloxacin for pneumonia, regression of signs of heart failure and pneumonia were observed. A chest X-ray on an unspecified date revealed residual post-inflammatory changes. The following medication was prescribed: Aspirin® (acetylsalicylic acid), Areplex® (clopidogrel), Atoris® (atorvastatin), Spironol® (spironolactone), Vivace® (Ramipril), Furosemid® (furosemide) and Vivacor® (Carvedilol). The subject recovered with sequelae NOS and was discharged in "good cardiological and general health status" on 06-Mar-2008. The investigator reassessed the event as moderate in intensity (previously severe) and changed the seriousness criteria from life-threatening and hospitalization to hospitalization only. Outcome: recovered with sequelae (date not specified) Follow-up information received on 28-Apr-2008: The investigator confirmed that the acute myocardial infarction resulted in an "ischemic deficit in the cardiac wall and apex, causing motion disturbance". "The regional wall motion abnormalities in the septum and apex with 40% EF (effective fraction)", recorded in the echocardiography at the discharge from hospital was considered as a sequelae of the myocardial infarction. Outcome: recovered with sequelae (06-Mar-2008). Follow-up information received on 03-Jun-2008: After revision of the documentation, the investigator reverted to the original assessment of the intensity which was "severe". No follow-up information is expected. This case is considered as medically closed with the information on hand.											
PMI000002 PMI000002 EHCSS-K6 Dosage: Unknown	Report from study  Serious	13-MAY-2008	13-MAY-2008	CS06-02  4771	PL	51 years/F	Not Listed	Severe	Reporter: Not related Company: Not related	14-NOV-2007 JAN-2008 05-FEB-2008 18-FEB-2008	<b>Splenic injury</b> <i>Post-traumatic spleen injury</i>	Recovered/ Resolved
	CS06-02: A 1-month, single-center, randomized, open-label, controlled clinical study to compare biomarkers of cardiovascular risk in smokers of electrically heated cigarettes (EHCSS-K6) and smokers of conventional cigarettes. INITIAL INFORMATION RECEIVED ON 13-May-2008: A 51 year-old female subject used the investigational product from 14-Nov-2007 to Jan-2008. On (b) (6), the subject was admitted to the hospital with "post-traumatic spleen injury" after being attacked in the street on 05-Feb-2008. The investigator assessed the event as severe in intensity. A splenectomy was performed on 09-Feb-2008 and the subject was discharged on (b) (6). Outcome: recovered The subject did not show up for a planned visit on 10-Dec-2007, therefore she was withdrawn from the study on 12-Dec-2007. A follow-up visit was performed on 23-Jan-2008. The investigator assessed the causal relationship between the event and the study drug as not related because of "other non-drug cause (post-traumatic injury)". No follow-up information is expected. This case is considered as medically closed with the information on hand.											No relevant medical history was reported.
PMI000003 PMI000003 EHCSS-K6 Dosage: 25-30 EHCSS-	Report from study  Serious	08-APR-2009	28-MAY-2008	CS06-02  4251	PL	48 years/M	Not Listed	Unknown	Reporter: Related Company: Related	01-MAR-2008 04-APR-2008 17-APR-2008 Unknown	<b>Deep vein thrombosis</b> <i>Upper extremity deep vein (brachial, axillary) thrombosis</i>	Recovered/ Resolved with sequela



Case number Company no. Drug name Dosage Drug route of administration	Report type (Sub type)	Latest receipt date	First received date	Study ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) Verbatim	Outcome
	Seriousness			Patient ID							Other events	
	Narrative											Medical history
K6 cigarettes per day												
	<p>Verbatim: Upper extremity deep vein (brachial, axillary) thrombosis PT: Deep vein thrombosis CS06-02: A 1-month, single-center, randomized, open-label, controlled clinical study to compare biomarkers of cardiovascular risk in smokers of electrically heated cigarettes (EHCSS-K6) and smokers of conventional cigarettes. INITIAL INFORMATION RECEIVED ON 28, 29 and 30-May-2008: A 48 year-old male subject with no history of vascular disease used EHCSS-K6 from 01-Mar-2008 to 04-Apr-2008. The subject had been smoking an average of 25 cigarettes a day for more than 20 years. During the study, the subject smoked 25-30 EHCSS-K6 cigarettes per day on average with decreasing tendency. After the study, the subject resumed smoking the same quantity and brand of cigarettes as before the study. On 12-Apr-2008, he began to complain of left upper extremity pain involving the axillary area, entire left arm and hand. The pain was accompanied by general oedema of the entire left extremity. He was diagnosed with "upper extremity deep vein (brachial, axillary) thrombosis" and hospitalized on (b) (6). The investigator assessed the event as moderate in intensity. The subject was treated with low molecular weight heparin from 17 to 23-Apr-2008 and Sintrom® (acenocumarol) since 17-Apr-2008. After achieving a therapeutic International Normalised Ratio (INR) range, the subject was discharged on (b) (6) without disease complications, in "good cardiological and general health status". He was further advised not to take pain killers or anti-inflammatory drugs and to eliminate risk factors of deep vein thrombosis (DVT). The subject was considered as recovered with sequelae on 23-Apr-2008. The investigator considered the sequelae to be "chronic DVT", treated with Sintrom (treatment was ongoing at the time of this report). The investigator considered the thrombosis to be caused by traveling in the tram in an abnormal position with the arm outstretched. Outcome: recovered with sequelae (23-Apr-2008) The investigator assessed the causal relationship between the event and the study drug as related because "cigarette smoking is one of the risk factors for deep vein thrombosis". Follow-up information received on 12-Jun-2008: The discharge summary report was received, confirming the diagnosis of an upper extremity axillary and brachial vein thrombosis which came partially to the radial vein. After leaving the hospital on 23-Apr-2008, the subject took 4mg of acenocumarol for 3 days and 3 mg the next day. The next doses of acenocumarol were to be determined by the subject's INR level which will be checked regularly as needed. His INR was 1.6 on 06-Jun-2008. The subject was reportedly traveling by bus for 1 week after visit 8 with a heavy bag under his armpit. His armpit was immobilized for approximately 1 hour, resulting in pain at night. The investigator suggested that the immobilization of the subject's arm or muscle injury provides a possible explanation for the adverse event. Follow-up information received on 28-Jul-2008: The investigator provided additional information on the subject's general health status and treatment. The subject did not experience any diseases, symptoms or complications after his discharge from the hospital. He remained in "good physical and medical condition", not requiring nursing care. The subject's International Normalized Ratio (INR) was monitored every 2 weeks. From 25-Apr-2008 to 14-Jul-2008, his INR was between 2.05 and 3.0 (normal range: 2.0-3.0). He continued treatment with acenocumarol, 3-4 mg daily, adjusted according to the INR. The dosing protocol rapidly achieved a stable INR (2.05-3.0) range after the thrombosis. A control visit was scheduled with a vascular surgeon the following month. A review of the available data on the subject was performed on 19-Sep-2008. With respect to biological risk factors, the subject had increased fibrinogen levels across the study, with a trend toward a higher increase at the end of the study. No abnormalities were found with respect to homocysteine levels and platelet function (ADP-induced platelet aggregation). In terms of exposure to the investigational product, the subject smoked ca 25% less K6 cigarettes on average than K6 smokers did. However, in contrast to the K6 smokers</p>											



Case number <i>Company no.</i> Drug name Dosage Drug route of administration	Report type <i>(Sub type)</i>	Latest receipt date	First received date	Study ID  Patient ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) <i>Verbatim</i>	Outcome
	Seriousness										Other events	
Narrative												Medical history
	<p>arm, the subject had an atypical biomarker of exposure profile with a high level of nicotine and carboxyhaemoglobin despite lower cigarette consumption. Based on these findings and despite the subject's self-reported full compliance to K6, it cannot be excluded that he smoked other tobacco products in addition to K6 cigarettes during the study. Follow-up information received on 08-Apr-2009: The investigator provided additional information on the subject's general health status and treatment. No other additional diseases, symptoms or complications occurred since the last follow-up report. The subject continued regular treatment with 2-3 mg of acenocumarol per day adjusted to his INR value (subject undergoes regular INR monitoring every 2-4 weeks). At the time of this report, the subject's last INR value was 2.1 (measured on 04-Apr-2009) and he was taking 2 mg of acenocumarol a day. Doppler ultrasonography performed within the last 3 months did not reveal any symptoms of thrombosis. The subject had stopped smoking 1 month ago and had regular control visits with a vascular surgeon every 6 months. The subject remained in good general physical condition and additional treatment was not required (except anticoagulation prophylaxis). Final outcome: recovered with sequelae (anticoagulation prophylaxis) on 23-Apr-2008. No follow-up information is expected. This case is considered as medically closed with the information on hand.</p>											
PMI000005 PMI000005 Not applicable Dosage: Unknown	Report from study  Serious	18-MAR-2009	23-JAN-2009	YVD-CS01-EU  7993	PL	40 years/F	Not Listed	Moderate	Reporter: Not related Company: Not related	Unknown Unknown 16-JAN-2009 20-JAN-2009	Ectopic pregnancy <i>Hospitalization for extrauterine pregnancy</i>	Recovered/Resolved with sequela
	<p>YVD-CS01-EU: A controlled, randomized, open-label, 3-arm parallel single-centre confinement study to investigate exposure to selected smoke constituents in smokers switching from conventional cigarettes to SMAR cigarettes for 5 days. INITIAL REPORT RECEIVED ON 23-JAN-2009: A 40-year-old female subject signed the Informed Consent Form (ICF) on 08-Jan-2009 and underwent the following screening procedures on the same day: Body mass index (BMI) measurement, vital signs measurement, demographic interview, physical examination, blood and urine sampling, CO breath test, spirometry, alcohol test and chest X-ray. No abnormalities were found. A pregnancy test was performed on the same day with negative results. Her LDL (low-density lipoprotein) cholesterol and total cholesterol were slightly elevated, but this was assessed as not significant by the investigator. Following screening, the subject qualified for the study and was admitted to the site on 15-Jan-2009. During admission to the site, the following procedures were performed: vital signs measurement (BP 110/070 mmHg, pulse 78 bpm, temperature 37.2°C), physical examination, blood and urine sampling, CO breath test and alcohol test, BMI measurement, toxicological test and spirometry. The subject reported that she had experienced abdominal pain and moderate metrorrhagia 2 days before admission to the site. A pregnancy test was performed twice with positive results and beta HCG level was 49.46 U/L, suggestive of a 4-week pregnancy (last menstrual period (LMP) was on 30-Dec-2008). The subject was informed about the positive pregnancy test immediately and subsequently withdrawn from the study on the same day (15-Jan-2009), prior to randomization. The subject was referred to a gynecologist and was subsequently admitted to hospital on (b) (6) due to suspicion of</p>											Family history: father - aoesphagus cancer



Case number Company no. Drug name Dosage Drug route of administration	Report type (Sub type)	Latest receipt date	First received date	Study ID  Patient ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) <i>Verbatim</i>	Outcome
	Seriousness										Other events	
Narrative												Medical history
	<p>extrauterine pregnancy and ovarian cyst rupture. The subject underwent surgery during which the extrauterine pregnancy was removed and left ovarian excision was performed. The SAE term was reported as "hospitalization and surgery due to extrauterine pregnancy and ovarian cyst rupture". The investigator assessed the event as moderate in intensity. The follow-up after surgery was without complications and the subject was discharged from hospital on (b) (6). The subject remains under regular gynecological care. The subject informed the investigator about the hospitalization and surgery on 22-Jan-2009 during safety follow-up telephone contact. Outcome: recovered with sequelae (NOS) The investigator assessed the causal relationship between the event and the study drug as not related because the event occurred "prior to randomization".</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 12-Mar-2009: The investigator provided additional medical information: The subject received amoxicillin/clavulanic acid as postoperative treatment from 16-Jan-2009 to 27-Jan-2009. Histopathological assessment of surgical material was performed and the following diagnoses were described: 1) hemorrhagic corpus luteum cyst and corpora albicans left ovary, 2) left tubal pregnancy. Following two gynecological control examinations, the subject's medical status was assessed as "normal". The ovarian cyst rupture was considered a complication of the extrauterine pregnancy. Therefore, the investigator changed the SAE term from "hospitalization and surgery due to extrauterine pregnancy and ovarian cyst rupture" to a single diagnosis: "hospitalization for extrauterine pregnancy". The outcome was reported as recovered with sequelae (excision of the left ovary) on 20-Jan-2009. FOLLOW-UP INFORMATION RECEIVED ON 18-Mar-2009: The investigator clarified the results of the following laboratory test which was done on 16-Jan-2009: fibrinogen level which was previously reported as 397 G/L was changed to 397 mg/dl (normal range: 200-400 mg/dl). No further information is expected. This case is considered as medically closed with the information on hand.</p>											
PMI000007 PMI000007 Tobacco Heating System 2.2 menthol Dosage: Used only once Respiratory(inhalation)	Report from study  Serious	17-FEB-2015	14-FEB-2014	ZRHM-REXA-08-US  1119	US	36 years/F	Not Listed	Severe	Company: Not related Reporter: Not related	11-FEB-2014 11-FEB-2014 12-FEB-2014 14-FEB-2014	Diabetic ketoacidosis <i>Diabetic ketoacidosis precipitated by sinusitis</i>  Sinusitis	Recovered/Resolved
	<p>Verbatim: Diabetic ketoacidosis precipitated by sinusitis Study ZRHM-REXA-08-US: A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting. INITIAL INFORMATION RECEIVED ON 14-FEB-2014 AND FOLLOW-UP INFORMATION RECEIVED ON 18-FEB-2014, 21-FEB-2014 AND 25-FEB-2014: This report was received from an investigator and concerned a 36-year-old female subject (subject ID 1119, height 175 cm, weight 105 kg) who was enrolled in the above mentioned study. The subject's medical history included diabetes mellitus type II, since 2008. The subject had no other relevant medical history and no history of sinus infection. Concomitant medication included metformin 1000 mg twice a day, oral since 2008 for diabetes mellitus type II (information reported by the subject at screening</p>											



Case number Company no. Drug name Dosage Drug route of administration	Report type (Sub type)	Latest receipt date	First received date	Study ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) <i>Verbatim</i>	Outcome
	Seriousness			Patient ID							Other events	
Narrative												Medical history
												<p>and at check-in). The subject also reported later to a member of the investigational site that she occasionally took her metformin 3-4 times a day. The subject used the Tobacco Heating System (THS) 2.2 Menthol (Batch number B-08545) only once on 11-Feb-2014 at around 16:24. She actually used the product trial at the end of screening period, before randomization. This is why the subject used it only once. On (b) (6), the subject developed sinus infection and was hospitalized on the same day. The event was considered to be moderate in intensity. Additionally, the subject experienced headache, emesis and nausea on 12-Feb-2014: these three events were non-serious and emesis/nausea resolved on 12-Feb-2014. The subject was kept for observation due to sugar levels being uncontrolled. The subject was discharged on (b) (6). The subject recovered from her sinus infection on 22-Feb-2014. The subject was discontinued from the study on 12-Feb-2014 for not being compliant with her concomitant medication (metformin). The investigator considered the event of sinus infection to be unrelated to the investigational product and attributed the event to 'basis disease/pre-existing condition'. FOLLOW-UP INFORMATION RECEIVED ON 19-MAR-2014: The review of the hospital records showed that the subject was hospitalised due to sinus infection which precipitated diabetic ketoacidosis. Thus the SAE term was changed from 'Hospitalization/Sinus infection' to 'Diabetic ketoacidosis precipitated by sinusitis'. The event was considered to be moderate in intensity and at the time of this follow-up report, the subject was recovering from the event. The subject's medical history included diabetes mellitus type II, since 2008 (as previously reported by the subject) / insulin-dependent diabetes mellitus (as per hospital records). The hospital records showed that the subject had a previous history of diabetic ketoacidosis approximately one year ago and that she had a subcutaneous insulin pump which she stopped on the morning of 12-Feb-2014. None of this was mentioned by the subject when she was interviewed at the site while obtaining information on her past medical history. Concomitant medication also included metformin 2000 mg daily, oral since 2008 for diabetes and glucose tablet 4 grams daily, oral since 2013 for low blood sugar. The investigational site attempted to contact the subject to inquire about the information in the medical records, however, the telephone call was abruptly ended. The site was going to continue to make attempts to contact the subject but it appeared that the subject deliberately withheld very important health information. During her hospitalisation, the subject received the following treatments: oral ondansetron hydrochloride (4 mg as needed every 6 hours as needed, for nausea on 12-Feb-2014), prochlorperazine (rectal suppository, 25 mg daily, for nausea/vomiting on 12-Feb-2014), IV metoclopramide hydrochloride (10 mg daily, for nausea/vomiting on 12-Feb-2014), oral acetaminophen (650 mg every 6 hours as needed, for headache between 12-Feb-2014 and 13-Feb-2014), IV morphine sulphate (2 mg every 2 hours as needed, for sinus pain/headache on 12-Feb-2014), oral acetaminophen/hydrocodone (325mg/5mg every 4 hours as needed, for sinus pain/headache between 12-Feb-2014 and 14-Feb-2014), oral zolpidem tartrate (5 mg daily, for insomnia on 12-Feb-2014), oral temazepam (15 mg daily, for insomnia on 12-Feb-2014), oral docusate sodium (100 mg daily, for constipation on 12-Feb-2014), oral magnesium hydroxide (30 mL daily, for severe constipation on 12-Feb-2014), oral aluminum/magnesium/simethicone (30 mL every 6 hours as needed, for dyspepsia on 12-Feb-2014), oral calcium carbonate (1000 mg, for dyspepsia on 12-Feb-2014), IV pantoprazole (40 mg daily, for dyspepsia on 12-Feb-2014), subcutaneous insulin Novolin (as per sliding scale, for diabetes between 12-Feb-2014 and 13-Feb-2014), subcutaneous insulin Novolog (10 units daily, for diabetes between 13-Feb-2014 and 14-Feb-2014), oral azithromycin (500 mg daily, for sinus infection between 13-Feb-2014 and 14-Feb-2014), oral loratadine (10 mg daily, for sinus infection between 13-Feb-2014 and 14-Feb-2014), Flonase (fluticasone propionate, by nostril route, 2 sprays daily, for sinus infection between 13-Feb-2014 and 14-Feb-2014) and subcutaneous enoxaparin sodium (40 mg daily, for unknown indication between 12-Feb-2014 and 14-Feb-2014). The investigator considered the event of diabetic ketoacidosis precipitated by sinusitis to be unrelated to the</p>



Case number Company no. Drug name Dosage Drug route of administration	Report type (Sub type)	Latest receipt date	First received date	Study ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) <i>Verbatim</i>	Outcome
	Seriousness			Patient ID							Other events	
Narrative												Medical history
	<p>investigational product and attributed the event to 'basis disease/pre-existing condition'. FOLLOW-UP INFORMATION RECEIVED ON 08-APR-2014: The subject recovered from her diabetic ketoacidosis on 14-Feb-2014. No further information regarding the subject's insulin treatment was available. She did not report to the investigational site that she was using an insulin pump and this information was discovered in her hospital records. FOLLOW-UP INFORMATION RECEIVED ON 12-SEP-2014: The subject's medical history included attention deficit disorder with hyperactivity, attention deficit disorder, thalassemia, Reye's syndrome, leukocytosis, bilateral salpingo-oophorectomy and ovarian cancer. FOLLOW-UP INFORMATION RECEIVED ON 17-FEB-2015: Following SAE reconciliation, the intensity of the reported events was changed from 'moderate' to 'severe' and the action taken was changed from 'Subject discontinued study' to 'No action taken'. This case is considered satisfactorily documented – no further follow-up requested.</p>											

Cumulative Line listing of serious cases until 30-Apr-2015Criteria:

Latest information: up to 30-Apr-2015

Serious: = Yes

Records returned: 5

Case number Company no. Drug name Dosage Drug route of administration	Report type (Sub type)	Latest receipt date	First received date	Study ID  Patient ID	Country	Age/Sex	Case listedness	Severity	Causality	Therapy start Therapy stop Date of onset Reaction end date	Main event (PT) Verbatim  Other events	Outcome
	Seriousness											Medical history
PMI000001 PMI000001 Not applicable Dosage: Unknown	Report from study	03-JUN-2008	18-FEB-2008	CS06-02	PL	59 years/M	Not Listed	Severe	Reporter: Not related Company: Not related	Unknown Unknown 17-FEB-2008 06-MAR-2008	<b>Acute myocardial infarction</b> <i>Anterior acute myocardial infarction treated with primary angioplasty of the left coronary artery (LAD)</i>	Recovered/Resolved with sequela
	Serious			7178								<p>CS06-02: A 1-month, single-center, randomized, open-label, controlled clinical study to compare biomarkers of cardiovascular risk in smokers of electrically heated cigarettes (EHCSS-K6) and smokers of conventional cigarettes. INITIAL INFORMATION RECEIVED ON 18 AND 19-Feb-2008: A 59 year-old male subject who had undergone all screening procedures felt a strong pain on the left side of his chest at noon on 17-Feb-2008. He was admitted to the hospital and diagnosed with "anterior acute myocardial infarction". The investigator assessed the event as severe in intensity. A coronarography was performed with primary angioplasty of the left coronary artery (LAD: left anterior descending) and stenting. Additionally, the subject was treated with Reo-pro® (abciximab) due to increased arterial blood pressure in the first 24 hours after the infarction. Contrapulsation was performed. At the time of this report, the subject was in a "cardiological stable condition". Outcome: not recovered The subject signed the ICF (Informed Consent Form) on 13-Feb-2008. During screening, EGG examination, chest x-ray and physical examination including vital signs (BP 130/90, pulse 66/min) were normal. Results of laboratory tests performed on 13-Feb-2008 revealed increased levels of total cholesterol. The subject was disqualified on 14-Feb-2008 due to high cholesterol levels and was not randomized; therefore he was not exposed to the investigational product (EHCSS-K6). The investigator assessed the causal relationship between the event and the study drug as not related because the event occurred "prior to randomization". Follow-up information received on 13-Mar-2008: The subject was hospitalized on (b) (6). The investigator provided additional information concerning the diagnosis of myocardial infarction: troponin level –191.83 ng/dl (normal range not provided); echocardiography revealed regional wall motion abnormalities in septum and apex (segments of the lateral, inferior and anterior left ventricular walls); EF (ejection fraction) – 40%. The course of the disease was complicated by pneumonia and left ventricular insufficiency. After</p>

### **c. Summary Tabulation of Serious and Non-serious Adverse Events (Argus database)**

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# Periodic Summary Tabulation for Safety Update Report (01-May-2014 to 30-Apr-2015)

For All Products (Number of Events)

For the Period 01-May-2014 Through 30-Apr-2015

## Advanced Condition used in this report:

Advanced Condition: Minus Data Migration Cases (Created by nicole.miller)

Query Set Selection Criteria:

Periodic Line Listing for Safety Update Report MINUS

Case Central Safety Date

Advanced Conditions used in this query set:

Advanced Condition: Periodic Line Listing for Safety Update Report (Created by nicole.miller)

Selection Criteria:

Product Name equal to THS 2.2 Regular (Ron) OR

Product Name equal to THS 2.2 Regular (Dorado I / Fitz) OR

Product Name equal to THS 2.2 Regular (Dorado II / Ron) OR

Product Name equal to THS 2.2 Regular (Dorado II / Albertino) OR

Product Name equal to THS 2.2 Regular (Dorado II / Fitz) OR

Product Name equal to THS 2.2 Regular (Ginebra / Fitz) OR

Product Name equal to IQOS Marlboro Essence OR

Product Name equal to IQOS Marlboro Regular

Advanced Condition: Case Central Safety Date (Created by nicole.miller)

Selection Criteria:

Case Central Safety Date equal to 06-MAY-2015

## Periodic Summary Tabulation for Safety Update Report (01-May-2014 to 30-Apr-2015)

For All Products (Number of Events)

For the Period 01-May-2014 Through 30-Apr-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Eye disorders	Eyelid disorder	1	0	1
	<b>SubTotal</b>	<b>1</b>	<b>0</b>	<b>1</b>
Gastrointestinal disorders	Abdominal discomfort	1	0	1
	Eructation	1	0	1
	Glossitis	1	0	1
	Hypoaesthesia oral	1	0	1
	Nausea	18	0	18
	Oral discomfort	1	0	1
	Stomatitis	1	0	1
	Tongue coated	1	0	1
	Vomiting	1	0	1
	<b>SubTotal</b>	<b>26</b>	<b>0</b>	<b>26</b>
General disorders and administration site conditions	Chest discomfort	4	0	4
	Chest pain	1	0	1
	Condition aggravated	1	0	1
	Malaise	4	0	4
	Pre-existing condition improved	1	0	1
	Product odour abnormal	3	0	3
	Product quality issue	11	0	11
	Product taste abnormal	8	0	8

## Periodic Summary Tabulation for Safety Update Report (01-May-2014 to 30-Apr-2015)

For All Products (Number of Events)

For the Period 01-May-2014 Through 30-Apr-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
General disorders and administration site conditions	Sensation of foreign body	1	0	1
	Sense of oppression	1	0	1
	<b>SubTotal</b>	<b>35</b>	<b>0</b>	<b>35</b>
Immune system disorders	Hypersensitivity	1	0	1
	<b>SubTotal</b>	<b>1</b>	<b>0</b>	<b>1</b>
Injury, poisoning and procedural complications	Fall	0	1	1
	<b>SubTotal</b>	<b>0</b>	<b>1</b>	<b>1</b>
Musculoskeletal and connective tissue disorders	Spinal disorder	0	1	1
	Spinal pain	0	1	1
	<b>SubTotal</b>	<b>0</b>	<b>2</b>	<b>2</b>
Nervous system disorders	Dizziness	3	0	3
	Dysgeusia	10	0	10
	Headache	24	0	24
	Movement disorder	1	0	1
	Somnolence	2	0	2
	<b>SubTotal</b>	<b>40</b>	<b>0</b>	<b>40</b>
Psychiatric disorders	Anxiety	1	0	1
	<b>SubTotal</b>	<b>1</b>	<b>0</b>	<b>1</b>



## Periodic Summary Tabulation for Safety Update Report (01-May-2014 to 30-Apr-2015)

For All Products (Number of Events)

For the Period 01-May-2014 Through 30-Apr-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Respiratory, thoracic and mediastinal disorders	Bronchial irritation	1	0	1
	Bronchial secretion retention	1	0	1
	Cough	19	0	19
	Cough decreased	1	0	1
	Dry throat	2	0	2
	Oropharyngeal pain	7	0	7
	Sputum retention	1	0	1
	Suffocation feeling	1	0	1
	Throat irritation	12	0	12
<b>SubTotal</b>		<b>45</b>	<b>0</b>	<b>45</b>
<b>Total</b>		<b>149</b>	<b>3</b>	<b>152</b>

#### **d. Summary Tabulation of Non-serious Adverse Events (BaseCon database)**

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#### **Confidentiality Statement**

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of law. No part of this document may be publicly disclosed without the written consent of Philip Morris International

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**Periodic Summary Tabulation of serious cases received from 01-May-2014 to 30-Apr-2015****Criteria:**

Date first received: from 01-May-2014 to 30-Apr-2015

Latest information: from 01-May-2014 to 30-Apr-2015

Serious = Yes

Use first received dates

Include Not Related events

Cumulative number of events reported, divided into 3 periods			
System Organ Class	Previous period (Up to: 30-APR-2014)	Current period (01-MAY-2014 to 30-APR-2015)	Total for all periods
<b>Infections and infestations</b>	<b>1</b>	<b>0</b>	<b>1</b>
(PT) Sinusitis	1	0	1
<b>Metabolism and nutrition disorders</b>	<b>1</b>	<b>0</b>	<b>1</b>
(PT) Diabetic ketoacidosis	1	0	1
<b>Total</b>	<b>2</b>	<b>0</b>	<b>2</b>