



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / iQOS

Appendix 7 Post-marketing Cumulative Line Listings

Report Number: PMI_SURV_2016_SSR03

Sponsor: Philip Morris Products S.A.
PMI Research & Development
Quai Jeanrenaud 5
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Version: Final 1.0

Date: 12 May 2016

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Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Advanced Condition used in this report:

Advanced Condition: Ser/Non-Serious Spont all THS Regular (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

JCo - 2.4 Regular THS Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: JCo - 2.4 Regular THS Ingredients (Created by Joshua Cox)

Selection Criteria:

(Ingredient equal to D2 Ron OR

Ingredient equal to Scion 1 Fitz)

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 (22)								
PMI000145	JAPAN Spontaneous	39 Years Male	THS 2.2 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	17-DEC-2014 to Unknown	17-MAY-2015	Had white swelling on the area covering the inner lips to the gum, part of which was abscessed purple [LIP SWELLING] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	17-DEC-2014 to Unknown	17-MAY-2015	Had white swelling on the area covering the inner lips to the gum, part of which was abscessed purple [ABSCESS ORAL] N / Y / Y the discoloured part recovered, but it turned slightly hard. [ORAL MUCOSAL DISCOLOURATION] N / Y / Y the discoloured part recovered, but it turned slightly hard [MUCOSAL INDURATION] N / Y / Y he informed that he holder could be hot [DEVICE ISSUE] N / Y / N	

Case Initial Receipt Date: 17-May-2015

Case Narrative: Verbatim: White swelling on the area covering the inner lips to the gum, part of which was abscessed purple. The holder could be hot.

Spontaneous case report received from a consumer.

INITIAL INFORMATION RECEIVED ON 17-MAY-2015:

This report concerns a 39-year-old male subject who used the iQOS Marlboro Regular and iQOS Marlboro Menthol.

No medical history and no concomitant medications were reported.

The consumer was a daily smoker (conventional cigarettes).

The consumer started using the iQOS Marlboro Regular and Menthol on 17-Dec-2014.

On 17-May-2015, the consumer experienced white swelling on the area covering the inner lips to the gum, part of which was abscessed purple. The customer mentioned that he used iQOS as he was drinking alcohol the previous night. He used Regular and Menthol and did not remember which one he was smoking on the day of the event. According to the consumer, the shape of the swollen part matched that of the HeatStick held on the mouth. After a day, the symptom improved and the discoloured part recovered, but it turned slightly hard.

The customer continued using the product, making sure not to hold it too deep after the symptom occurred, but he had no recurrence or exacerbation.

In addition, the consumer reported that the holder could be hot. The device was collected and replaced.

The severity of the adverse event was not reported and the events were considered to be non-serious.

At the time of reporting, the outcome was indicated as not recovered.

No follow-up information expected ? case closed.

On 18-Mar-2016, the case was updated to change coding of non-current product iQOS Marlboro Regular to equivalent current product configuration THS 2.2 Marlboro (Blue) and non-current product iQOS Marlboro Menthol to equivalent current product configuration THS 2.2 Marlboro Menthol (Green). No other change was done in the case.

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000226	SWITZERLAND Spontaneous	37 Years Male	THS 2.2 Marlboro Balance (Light Blue) / N/A UNK [UNK]	Respiratory	22-MAY-2015 to Unknown	22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [MALAISE] N / Y / Y	Recovered/Resolved
			THS 2.2 Marlboro Essence (Blue) / N/A UNK [UNK]	Respiratory	22-MAY-2015 to Unknown	22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [NAUSEA] N / N / Y	
						22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [DIZZINESS] N / N / Y	
<p>Case Initial Receipt Date: 23-May-2015 Case Followup Receipt Date: 23-May-2015 00:00 Event Intensity: Severe Severe Severe Event Stop Date: 22-MAY-2015 22-MAY-2015 22-MAY-2015</p> <p>Case Narrative: Verbatim: Yesterday (on 22May2015) I smoked 2 regular Heat-Sticks in short succession (perhaps, the 2nd, 15min after having finished the 1st). About 5 min afterwards, I dev extreme nausea, lightheadedness, and general malaise. I thought I would need to throw-up, so I had to stand out on the terrace sitting down for at least 45min. This feeling around 2 hours. I would categorize myself as a casual smoker, smoking approx. 5 cigarettes a week. When I go out with friends and drink I can easily smoke half a pack. The choice is MLB Gold. I' ve never felt like that after smoking, perhaps usually a small head-rush, but never sick like that.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2015, and received at the Safety department on 02-JUN-2015 and 03-JUN-2015:</p> <p>This report concerns a 37-year-old male subject who used IQOS Marlboro Balance and IQOS Marlboro Essence since 22-May-2015.</p> <p>The subject had no medical history and was not taking any concomitant medications.</p> <p>The consumer was an occasional smoker (5 to 10 cigarettes per week up to half a pack when going out).</p> <p>On the first day of use, the consumer used one Regular Heatstick and then, successively 2 Menthol Heatsticks (about 15 min interval). About 5 min afterwards, he developed extreme nausea, lightheadedness, and general malaise. He thought he would need to throw-up, so he had to stand out on the terrace sitting down for at least 45min. This feeling passed after around 2 hours. The consumer clarified that he had never felt like that after smoking, perhaps usually a small head-rush, but never sick like that.</p> <p>The severity of the adverse events was reported as severe and the events were considered to be non-serious.</p> <p>It was reported that the events resolved on the same day (22-May-2015) when usage of he product was discontinued. The products were not restarted.</p> <p>No follow-up information expected. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Balance to equivalent current product configuration THS 2.2 Marlboro Balance (Light Blue) and non-current product IQOS Marlboro Essence to equivalent current product configuration THS 2.2 Marlboro Essence (Blue). No other change was done in he case.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000279	JAPAN Spontaneous	66 Years Male	THS 2.2 Marlboro (Blue) / N/A UNK [UNK]	Respiratory			After having smoked a second stick, the patient vomited. [VOMITING] N / N / Y After having smoked one stick, the patient experienced an unpleasant taste. [DYSGEUSIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 18-Dec-2014</p> <p>Case Narrative: Verbatim: After having smoked one stick, the patient experienced an unpleasant taste. After having smoked a second stick, the patient vomited.</p> <p>Case report spontaneously reported by a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 18-DEC-2014: This report concerns a 66-year-old male subject who used the iQOS Marlboro Regular.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>The consumer started using the iQOS Marlboro Regular (Control number: iQOS ? 2014001) on an unspecified date. He reported that, after having smoked one stick, he experienced unpleasant taste and that, after having smoked a second stick, he vomited. The events were considered to be non-serious. The event intensity was not provided.</p> <p>At the time of reporting, the outcome was unknown.</p> <p>No follow-up information has been requested. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product iQOS Marlboro Regular to equivalent current product configuration THS 2.2 Marlboro (Blue). No other change was done in the case.</p>								
PMI000280	ITALY Spontaneous	Male	THS 2.2 Marlboro Essence (Blue) / N/A UNK [UNK]	Respiratory	14-DEC-2014 to Unknown	14-DEC-2014 14-DEC-2014	Block of catarrh (phlegm) in the throat [PRODUCTIVE COUGH] N / Y / Y Hypersalivation/want to spit [SALIVARY HYPERSECRETION] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 14-Jan-2015</p> <p>Event Intensity: Moderate Moderate</p> <p>Case Narrative: Verbatim: Block of catarrh (phlegm) in the throat, hypersalivation/want to spit.</p> <p>Case report spontaneously reported by a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 14-JAN-2015: This report concerns an adult male subject (aged between 24 and 30 years) who used iQOS Marlboro Regular.</p> <p>The consumer had an allergy to crustaceans (shellfish). He was not taking any concomitant medications.</p> <p>The consumer was a smoker who smoked on average 6 cigarettes Camel per day.</p> <p>The consumer started using iQOS Marlboro Regular (code on the pack not available) on 14-Dec-2014. On the same day, after one or two aspirations, the consumer experienced a block of catarrh (phlegm) in his throat, hypersalivation and wanted to spit. These events were considered to be non-serious and moderate in intensity.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The consumer did not experience these events before using IQOS. He stopped using IQOS for some days and the events resolved. A few days later, he tried again using IQOS and the events re-occurred. He stopped using IQOS on an unspecified date and the events resolved.</p> <p>The consumer reported that he smoked his cigarettes Camel before using IQOS. Then he used IQOS occasionally and exclusively, on average 5 heatsticks per week. He smoked his cigarettes Camel only during the period he stopped using IQOS and after he stopped using IQOS permanently. Then he smoked again his cigarettes Camel without any problems.</p> <p>No follow-up information has been requested. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Essence to equivalent current product configuration THS 2.2 Marlboro Essence (Blue). No other change was done in the case.</p>							
PMI000297	ITALY Spontaneous	39 Years Male	THS 2.2 Marlboro Essence (Blue) / N/A UNK [UNK]	Respiratory 01-DEC-2014 to Unknown	15-DEC-2014 15-DEC-2014 15-DEC-2014	Agitation [AGITATION] N / Y / Y Increased blood pressure [BLOOD PRESSURE INCREASED] N / N / Y Increased heart rate [HEART RATE INCREASED] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 15-Jan-2015 Event Intensity: Severe Severe Severe Event Stop Date: JAN-2015 JAN-2015 JAN-2015 Case Narrative: Verbatim: Increased heart rate, increased blood pressure, agitation.</p> <p>Case report spontaneously reported by a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 15-JAN-2015: This report concerns a 39-year-old subject who used both IQOS Marlboro Essence and IQOS Marlboro Balance.</p> <p>The consumer had no medical conditions and was not taking any concomitant medications.</p> <p>The consumer was a daily smoker (average consumption not provided).</p> <p>The consumer started using IQOS Marlboro Essence and IQOS Marlboro Balance (code on the pack not provided) on 01-Dec-2014. On 15-Dec-2014, after 10 days of regular use, he experienced increased heart rate, increased blood pressure and agitation, as if he had taken like 10 cups of coffee. These events were considered to be non-serious and severe in intensity. The consumer was wondering whether to go to the emergency department but he took aspirin 0.5g and the events resolved on an unspecified date in January 2015.</p> <p>It was reported that the events improved/disappeared when the consumer stopped using IQOS and that the events returned when the consumer restarted using IQOS.</p> <p>The consumer used IQOS Marlboro Essence and IQOS Marlboro Balance every day and exclusively, with an average of 20 heatsticks used per day.</p> <p>No follow-up information has been requested. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Essence to equivalent current product configuration THS 2.2 Marlboro Essence (Blue). No other change was done in the case.</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000298	ITALY Spontaneous	Female	THS 2.2 Marlboro Essence (Blue) / N/A UNK [UNK]	Respiratory	28-JAN-2015 to Unknown	28-JAN-2015	heartburn [DYSPEPSIA] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 29-Jan-2015 Event Intensity: Mild Case Narrative: Verbatim: Heartburn.</p> <p>Case report spontaneously reported by a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 29-JAN-2015: This report concerns a female consumer in her 40s who used IQOS Marlboro Essence.</p> <p>The consumer had no medical conditions and was not taking any concomitant medications.</p> <p>The consumer was a daily smoker (average consumption of 5 cigarettes per day).</p> <p>The consumer started using IQOS Marlboro Essence (code on the pack 80794448) on 28-JAN-2015. On the same day and immediately after smoking the first cigarette (presumably the IQOS Marlboro Essence heats ick), she experienced heartburn. She smoked another one on the following morning and the heartburn reappeared. The consumer reported that she had an appointment with the doctor on the following evening.</p> <p>It was reported that the event improved/disappeared when usage of the product was stopped and that the event returned when use of the product was restarted.</p> <p>The consumer used IQOS Marlboro Essence every day and exclusively, with an average of 1 heatsticks used per day.</p> <p>No follow-up information has been requested. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Essence to equivalent current product configuration THS 2.2 Marlboro Essence (Blue). No other change was done in the case.</p>								
PMI000318	JAPAN Spontaneous	28 Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory		04-SEP-2015	Felt sick and vomited after smoking one Balanced Regular and one Menthol [MALAISE] N / Y / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 05-Sep-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Felt sick and vomited after smoking one Balanced Regular and one Menthol.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 05-Sep-2015 and transferred to Safety department on 09-Sep-2015.</p> <p>This report concerns a 28-year-old male consumer who used THS 2.4 Marlboro balanced regular and Marlboro menthol since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p>								
			THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory		04-SEP-2015	Felt sick and vomited after smoking one Balanced Regular and one Menthol [VOMITING] N / N / Y	

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 04-Sep-2015, the consumer felt sick and vomited after smoking one Balanced Regular and one Menthol heatsticks.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious.</p> <p>It was reported that the problem improved when usage of the product was stopped. Product was not restarted.</p> <p>No treatment was taken for the event.</p> <p>No further information is expected. Case closed.</p>							
PMI000321	JAPAN Spontaneous	76 Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory	02-SEP-2015 02-SEP-2015	Throat starts to hurt when smoking, and it becomes hard to breathe [DYSPOEA] N / Y / Y Throat starts to hurt when smoking, and it becomes hard to breathe [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 03-Sep-2015 Case Narrative: Verbatim: Throat starts to hurt when smoking, and it becomes hard to breathe.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 03-Sep-2015 and transferred to Safety department on 09-Sep-2015.</p> <p>This report concerns a 76-year-old male consumer who used THS 2.4 Marlboro Balanced Regular since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 02-Sep-2015, the consumer experienced throat starts to hurt when smoking, and he reported that it became hard to breathe.</p> <p>The severity of the adverse events was not reported. The events were considered to be non-serious.</p> <p>It was reported that the problem improved when usage of the product was stopped. Product was not restarted.</p> <p>The outcome of the events was reported as resolved (date not specified).</p> <p>No further information is expected. Case closed.</p>							
PMI000324	JAPAN Spontaneous	36 Years Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [qd]	Respiratory	03-SEP-2015 to Unknown 07-SEP-2015	Got a fever / Temperature rose to 40° and got a headache [PYREXIA] N / Y / Y Temperature rose to 40° and got a headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 13-Sep-2015 Case Followup Receipt Date: 13-Sep-2015 00:00 Event Stop Date: 10-SEP-2015 10-SEP-2015</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 Comment Text: Based on the follow-up information (i.e. no hospitalisation), the Pyrexia and Headache were assessed as non-serious.							
Pyrexia is unlisted, whereas Headache is listed, as per the Reference Safety Information (IB).							
Considering the plausible temporal relationship and the current knowledge on the product in question, the Pyrexia and Headache are assessed as related to the use of THS 2.4 Marlboro Balanced Regular. Of note, the adverse events may have been associated with an intercurrent condition (e.g. upper respiratory tract infection) in this patient who had been smoking approximately 20 conventional cigarettes per day.							
Case Narrative: Verbatim: Used it on the night of the 3rd. Got a fever in the evening of the 5th. Used it in the mornings of the 4th and 5th. Temperature stayed at 37.4 until the night of the 7th. During the night of the 7th, temperature rose to 40 and got a headache. Used it again on the 12th September and fever of around 37.25 has continued ever since.							
Spontaneous case report received from a consumer in Japan.							
INITIAL INFORMATION RECEIVED ON 13-Sep-2015 and transferred to Safety department on the same day. Additional information received at Safety department on 23-Oct-2015.							
This report concerns a 36-year-old male consumer who used THS 2.4 Marlboro Balanced Regular since 3-Sep-2015.							
No medical history and no concomitant medications were reported.							
The consumer was a daily smoker (approximately 20 conventional cigarettes per day).							
The consumer reported that he used the heatsticks on the night of 3-Sep-2015. He used it in the mornings of 4-Sep-2015 and 5-Sep-2015. He got a fever in the evening of 5-Sep-2015. Temperature stayed at 37.4° until the night of 7-Sep-2015. During the night of the 7-Sep-2015, temperature rose to 40° and he got a headache. The events resolved on 10-Sep-2015.							
He used the heatsticks again on the 12-Sep-2015 and fever of around 37.25° has continued ever since.							
The severity of the adverse events was reported as requiring medical advice. (Note: Initial information provided indicated that the consumer was hospitalized due to the events, however, additional information provided on 23-Oct-2015 confirmed that there was no hospitalization due to the events.) The events were considered to be non-serious.							
The events were treated with Calonal (paracetamol) from 08-Sep-2015 to 13-Sep-2015.							
The heatsticks were used every day, on average 10 units per day, exclusively. It was reported that the events improved when the product was discontinued and reappeared when the product was restarted. It is not specified if the product was permanently discontinued due to the adverse events.							
Follow-up information is expected.							
FOLLOW-UP INFORMATION transferred to Safety department on 23-Oct-2015 (initial receipt date is 13-Sep-2015).							
Verbatim: Pyrexia, Headache							
It was confirmed again that the consumer was not hospitalized due to the events.							
The events resolved when usage of the product was discontinued.							
No medical records were available. It was reported that the consumer had no medical history and no concomitant medications were taken.							
No further information was provided.							
No further information is expected. Case closed.							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000326	JAPAN Spontaneous	40 Years Female	THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory		02-SEP-2015	I felt sick because the smell was so bad [MALAISE] N / Y / Y	Unknown
			THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory		02-SEP-2015	The smell was so bad / It smelled as if I had smoked black beans [PRODUCT ODOUR ABNORMAL] N / Y / N	
			THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory				
Case Initial Receipt Date: 11-Sep-2015								
Case Narrative: Verbatim: I felt sick because the smell was so bad. It smelled as if I had smoked black beans. I want to return the product.								
Spontaneous case report received from a consumer.								
INITIAL INFORMATION RECEIVED ON 11-Sep-2015 and transferred to Safety department on 16-Sep-2015 (Note: invalid source document was received on 11-Sep-2015).								
This report concerns a 40-year-old female consumer who used THS 2.4 Marlboro regular, Marlboro balanced regular, Marlboro menthol since an unspecified date.								
No medical history and no concomitant medications were reported.								
Information on smoking habits (conventional cigarette and heatsticks) was not provided.								
On 02-Sep-2015, the consumer felt sick because the smell was so bad. She further explained that it smelled as if she had smoked black beans. She mentioned that she wanted to return the product.								
The severity of the adverse event was not reported. The event was considered to be non-serious.								
Action taken with the product was not reported.								
The outcome of the event was not reported.								
No further information is expected. Case closed.								
PMI000328	JAPAN Spontaneous	66 Years Male	THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	12-SEP-2015 to Unknown	12-SEP-2015	Began to feel nauseous after inhaling from the first Heat Stick once or twice and it returned within 5 minutes [NAUSEA] N / N / Y	Recovered/Resolved
						12-SEP-2015	Vomited about 4 times during the night [VOMITING] N / N / Y	
Case Initial Receipt Date: 13-Sep-2015								
Event Intensity: Moderate								
Event Stop Date: 13-SEP-2015								
13-SEP-2015								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: Began to feel nauseous after inhaling from the first Heat Stick once or twice and it returned within 5 minutes (vomited). Vomited about 4 times during the night.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 13-Sep-2015 and transferred to Safety department on 14-Sep-2015.</p> <p>This report concerns a 66-year-old male consumer who started using THS 2.4 Marlboro Regular on 12-Sep-2015.</p> <p>A medical history of Hepatitis C was reported. Gasuta-1 (stomach medicine) and sleeping pills (unspecified) were reported as concomitant medications.</p> <p>Information on smoking habits (conventional cigarette) was not provided.</p> <p>On 12-Sep-2015, the consumer began to feel nauseous after inhaling from the first Heatstick once or twice and it returned within 5 minutes. The consumer vomited about 4 times during the night.</p> <p>The severity of the adverse events was reported as moderate. The events were considered to be non-serious.</p> <p>No treatment was administered due to the events.</p> <p>On the day of the event, the product was used exclusively.</p> <p>The event improved when usage of the product was stopped. Product was not restarted.</p> <p>The outcome of the event was indicated as recovered on 13-Sep-2015.</p> <p>No further information is expected. Case closed.</p>							
PMI000338	JAPAN Spontaneous	35 Male	<p>THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]</p> <p>THS 2.4 Marlboro (Blue) / N/A UNK [UNK]</p> <p>THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]</p> <p>THS 2.4 Marlboro Mint (Light Green) / N/A UNK [UNK]</p>	Respiratory	15-SEP-2015 to 03-OCT-2015	<p>15-SEP-2015 Feeling uncomfortable [DISCOMFORT] N / Y / Y</p> <p>15-SEP-2015 The inside of my mouth feels uncomfortable [ORAL DISCOMFORT] N / Y / Y</p> <p>15-SEP-2015 The inside of my mouth feels uncomfortable; when the holder's LED is orange it hurts enough to make me groan [ORAL PAIN] N / Y / Y</p> <p>15-SEP-2015 I also get a slight headache [HEADACHE] N / N / Y</p>	Recovered/Resolved
<p>Case Initial Receipt Date: 03-Oct-2015</p> <p>Event Intensity: Mild</p> <p>Mild</p> <p>Mild</p> <p>Mild</p> <p>Event Stop Date: 03-OCT-2015</p> <p>03-OCT-2015</p> <p>03-OCT-2015</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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>03-OCT-2015</p> <p>Case Narrative: Verbatim: I smoke cigarettes (Marlboros) but no symptoms arise from them. If I use IQOS, symptoms emerge after about 5 minutes. Symptoms: Feeling uncomfortable; The inside of my mouth feels uncomfortable; When the holder's LED is orange it hurts enough to make me groan; also get a slight headache.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 03-Oct-2015 and transferred to Safety department on 06-Oct-2015.</p> <p>This report concerns a 35-year-old male consumer who used THS 2.4 Marlboro Regular, Marlboro Balanced Regular, Marlboro Menthol and Marlboro Mint, since 15-Sep-2015 (reference number provided: HUUK7EAXX03JP).</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The consumer used the heatsticks occasionally, about 10 per day on average, and the product was used together with other tobacco products (Marlboro).</p> <p>On 15-Sep-2015, the consumer experienced feeling uncomfortable and the inside of his mouth felt uncomfortable. He clarified that, when the holder's LED is orange, it hurts enough to make him groan. In addition, the consumer also got a slight headache. The events occurred within 5 minutes of using the product and did not occur when smoking conventional cigarettes.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was administered due to the event.</p> <p>The events resolved on 03-Oct-2015. It was mentioned that this was when the consumer stopped using the product. It was also reported that the events improved when product was discontinued and returned when product was restarted.</p> <p>No further information is expected. Case closed.</p>								
PMI000340	JAPAN Spontaneous	39 Years Male	THS 2.4 Marlboro (Blue) / N/A 10 [10 -qd]	Respiratory	30-SEP-2015 Ongoing	30-SEP-2015 30-SEP-2015	my throat got dry and felt unusual [DRY THROAT] N / Y / Y It felt unusual, it felt like I had something stuck in my throat [SENSATION OF FOREIGN BODY] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 06-Oct-2015</p> <p>Event Intensity: Mild Mild</p> <p>Case Narrative: Verbatim: Since I started using IQOS, from the first box my throat got dry and felt unusual. It felt like I had something stuck in my throat.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 06-Oct-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 39-year-old male consumer who used THS 2.4 Marlboro Regular since 30-Sep-2015.</p> <p>No medical history was reported. "Fanci brand vitamins" were reported as concomitant medication, which the consumer had been taking since 3 months.</p> <p>The consumer was an occasional smoker (approximately 5-6 conventional cigarettes per day since about 3 months - 40 per week). The consumer had previously stopped smoking 2 ½ years ago. The consumer used the heatsticks occasionally, 3 or 4 s icks when he went out drinking (also reported as 10 heatsticks every day).</p> <p>Since 30-Sep-2015 (from the first box), he consumer experienced throat get ing dry and feeling unusual. It felt like he had something stuck in his throat.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was administered due to the event.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The events were not resolved at time of reporting.								
It was reported that the product was not stopped.								
No further information is expected. Case closed.								
PMI000342	JAPAN Spontaneous	42 Years Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK] Case Initial Receipt Date: 08-Oct-2015 Event Intensity: Mild Event Stop Date: 02-OCT-2015 Case Narrative: Verbatim: Chest suddenly started to hurt when smoking, so stopped smoking. The pain continued for 2 days, and symptoms were cured by 2nd September. This is because they were not so serious as to cause sleep, but relatively mild.	Respiratory	30-SEP-2015 to 30-SEP-2015	30-SEP-2015	Chest suddenly started to hurt when smoking [CHEST PAIN] N / Y / Y	Recovered/Resolved
Spontaneous case report received from a consumer in Japan.								
INITIAL INFORMATION RECEIVED ON 08-Oct-2015 and transferred to Safety department on 09-Oct-2015.								
This report concerns a 42-year-old male consumer who used THS 2.4 Marlboro Balanced Regular since 30-Sep-2015.								
No medical history and no concomitant medications were reported.								
The consumer was a daily smoker (approximately 10-20 conventional cigarettes per day). The consumer only used 2 Heatsticks exclusively, on 30-Sep-2015.								
On 30-Sep-2015, the consumer's chest suddenly started to hurt when smoking, so he stopped smoking. The pain continued for 2 days, and symptoms were cured by 02-Oct-2015 (also reported as 02-Sep, presumably by mistake). The consumer further explained that "This is because they were not so serious as to cause sleep, but relatively mild". The consumer did not take any medicine due to the event and did not have a medical examination at a hospital.								
The severity of the adverse event was reported as mild. The event was considered to be non-serious.								
The event was resolved on 02-Oct-2015.								
It was reported that the event improved after usage of the product was stopped, and that the product was not restarted.								
No further information is expected. Case closed.								
PMI000348	JAPAN Spontaneous	46 Years Male	THS 2.4 Marlboro (Blue) / N/A UNK [UNK] THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK] Case Initial Receipt Date: 15-Oct-2015 Event Intensity: Mild Mild	Respiratory Respiratory	09-OCT-2015 to Unknown 09-OCT-2015 to Unknown	09-OCT-2015 09-OCT-2015	I got a headache [HEADACHE] N / N / Y felt nauseous at the same time [NAUSEA] N / N / Y	Recovered/Resolved

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Event Stop Date: 12-OCT-2015 12-OCT-2015</p> <p>Case Narrative: Verbatim: I purchased it in Omotesando, and smoked the regular and balance regular. Then I got a headache and felt nauseous at the same time, and they wouldn't stop. If I didn't smoke, then it would go away.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 15-Oct-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 46-year-old male consumer who used THS 2.4 Marlboro Balanced Regular and Marlboro Regular since 09-Oct-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>On 09-Oct-2015, the consumer got a headache and felt nauseous, at the same time, after having used both products. He specified that if he didn't use the products the symptoms would go away. The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was required due to the event.</p> <p>The consumer used the Heatsticks every day, approximately 3 per day, exclusively.</p> <p>The consumer indicated that the events improved when he stopped using the product and returned when usage of the product was restarted. Action taken with the product was not reported.</p> <p>The events were resolved on 12-Oct-2015.</p> <p>No further information is expected. Case closed.</p>								
PMI000351	JAPAN Spontaneous	46 Years Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory	13-OCT-2015 to Unknown	16-OCT-2015 16-OCT-2015 16-OCT-2015	I got heartburn and a headache, and felt nauseous [DYSPEPSIA] N / Y / Y I got heartburn and a headache, and felt nauseous [HEADACHE] N / N / Y I got heartburn and a headache, and felt nauseous [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 19-Oct-2015</p> <p>Event Intensity: Mild Mild Mild</p> <p>Event Stop Date: 16-OCT-2015 16-OCT-2015 16-OCT-2015</p> <p>Case Narrative: Verbatim: I smoked the first one fine. Two or three days later, when I smoked the second one, I got heartburn and a headache, and felt nauseous.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Oct-2015 and transferred to Safety department on 20-Oct-2015.</p> <p>This report concerns a 46-year-old male consumer who used THS 2.4 Marlboro Balanced Regular (Batch number ZZ01521423) since 13-Oct-2015.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarettes) was not provided.</p> <p>The consumer used his first heatstick fine. Two or three days later, on 16-Oct-2015, he got heartburn, experienced headache, and felt nauseous when he used the heatstick for the second time. The severity of the adverse events was reported as mild. The events were considered to be non-serious.</p> <p>The consumer used the Heatsticks exclusively.</p> <p>The consumer indicated that the events improved when he stopped using the product and that the product was not restarted.</p> <p>The events resolved on the same day (16-Oct-2015).</p> <p>No further information is expected. Case closed.</p>								
PMI000352	JAPAN Spontaneous	52 Years Female	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory	16-OCT-2015 to 16-OCT-2015	16-OCT-2015 16-OCT-2015	I got heartburn and felt nauseous [DYSPEPSIA] N / Y / Y I got heartburn and felt nauseous [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 20-Oct-2015 Event Intensity: Mild Mild Event Stop Date: 16-OCT-2015 16-OCT-2015 Case Narrative: Verbatim: First smoke : I could only get five puffs, then I changed the HS (Heat Stick), but when I took bigger, deeper breaths, I got heartburn and felt nauseous</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 20-Oct-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 52-year-old female consumer who used THS 2.4 Marlboro Balanced Regular (Batch/pack number HCK25EVR86TU ZZ01521603) on 16-Oct-2015.</p> <p>Current medical condition of high cholesterol was reported. No concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>On 16-Oct-2015, at 10:00 pm, the consumer experienced heartburn and felt nauseous after having taken deep breaths on the heatstick. The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was required due to the event.</p> <p>The consumer indicated that the events improved when she stopped using the product and that the product was not restarted.</p> <p>The events were resolved on the same day (16-Oct-2015) at midnight.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000353	SWITZERLAND Spontaneous	46 Years Male	THS 2.4 Marlboro (Blue) / N/A UNK [qd]	Respiratory	AUG-2015 to Unknown	AUG-2015	Consumption of 1½ product and, after that, spitting blood morning and evening [HAEMOPTYSIS] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 22-Oct-2015 Event Intensity: Mild Case Narrative: Verbatim: Consumption of 1½ product and, after that, spitting blood morning and evening.</p> <p>Spontaneous case report received from a consumer in Switzerland.</p> <p>INITIAL INFORMATION RECEIVED ON 22-Oct-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 46-year-old male consumer who used THS 2.4 Marlboro Blue (Batch/pack number not reported) since mid-Aug-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 40 conventional cigarettes per day).</p> <p>In mid-Aug-2015, the consumer used 1½ product and, after that, was spitting blood morning and evening. The severity of the adverse event was reported as mild. The event was considered to be non-serious. No treatment was required due to the event.</p> <p>The consumer used the Heatsticks every day, about 40 units per day, concomitantly with conventional cigarettes (half-half).</p> <p>The consumer indicated that usage of the product was decreased. No information on the event course after decrease was provided. It was indicated that the event returned when usage of the product was restarted.</p> <p>At the time of reporting the event was ongoing.</p> <p>No further information is available. Case closed.</p>								
PMI000371	JAPAN Spontaneous	49 Years Female	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A 2 DF [2 DF-qd]	Respiratory	02-NOV-2015 to Unknown	02-NOV-2015 02-NOV-2015	I burned myself [THERMAL BURN] N / Y / Y It was plugged up with tobacco / it felt hot the first time [DEVICE ISSUE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 02-Nov-2015 Event Intensity: Mild Event Stop Date: 02-NOV-2015 Case Narrative: Verbatim: I burned myself; It was plugged up with tobacco / it felt hot the first time</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 02-Nov-2015 and transferred to Safety department on 03-Nov-2015.</p> <p>This report concerns a 49-year-old female consumer who used THS 2.4 Marlboro Balanced Regular (Batch number 7MTJ.H3V.JABMHT) on 02-Nov-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 3 conventional cigarettes per day).</p> <p>On 02-Nov-2015, the device was plugged up with tobacco. The consumer removed it with something like a toothpick. She stated that she smoked her second one and she burned herself</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
(no further information provided). She reported that it felt hot the first time but she thought that she was just imagining it and so she smoked it a second time.								
The severity of the adverse event was reported as mild. The event was considered to be non-serious. No treatment was required due to the event.								
The consumer indicated that the event resolved on the same day, after usage of the product was discontinued (date not specified). Product was not restarted. The product was used exclusively, about 2 units per day (number of days not indicated).								
No further information is expected. Case closed.								
PMI000405	SWITZERLAND Spontaneous	54 Years Female	THS 2.4 Marlboro (Blue) / N/A UNK [qd]	Respiratory	13-NOV-2015 to 19-NOV-2015	19-NOV-2015	I suddenly had red spots (rash, urticaria) on the hands, knees, underarms, elbows and back, and on my face (forehead, nose) [URTICARIA] N / Y / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 20-Nov-2015 Event Intensity: Moderate Case Narrative: Verbatim: I suddenly had red spots (rash, urticaria) on the hands, knees, underarms, elbows and back, and on my face (forehead, nose).								
Spontaneous case report received from a consumer in Switzerland.								
INITIAL INFORMATION RECEIVED ON 20-Nov-2015 and transferred to Safety department on 21-Nov-2015.								
This report concerns a 54-year-old female consumer who started using THS 2.4 Marlboro (Blue) (Batch/Kit number HEBYG1UFWZ9Z) on 13-Nov-2015.								
Medical history of allergies to chemicals was reported. Analgesics (with physician's prescription) was reported as concomitant medication (no further information reported).								
The consumer was a daily smoker (approximately 10-12 conventional cigarettes per day).								
On 13-Nov-2015, the consumer purchased the IQOS and blue heatsticks. On 14-Nov-2015, she used 2 heatsticks and smoked 8 normal cigarettes. On 15-Nov-2015, she used 2 heatsticks and smoked 8 normal cigarettes. From 16-Nov-2015 to 18-Nov-2015, she used 7 to 8 heatsticks and smoked 2 normal cigarettes. On 19-Nov-2015, in the morning, the consumer suddenly had red spots (rash, urticaria) on the hands, knees, underarms, elbows and back, and on her face (forehead, nose).								
She immediately stopped using the product (IQOS heatsticks blue).								
The events' severity was reported as moderate. No treatment was required due to the events. The events were considered to be non-serious.								
The events did not improve when usage of the product was stopped, and product was not restarted.								
At time of reporting, the events were not recovered.								
No further information is expected. Case closed.								
PMI000414	JAPAN Spontaneous	52 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A 10 DF [10 DF-qd] THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory Respiratory	22-OCT-2015 to Unknown 22-OCT-2015 to Unknown	03-DEC-2015 03-DEC-2015	it got very hot and gave off steam, burning my lips [THERMAL BURN] N / Y / Y it got very hot and gave off steam [DEVICE ISSUE] N / Y / N	Recovered/Resolved
Case Initial Receipt Date: 04-Dec-2015 Event Intensity: Mild Event Stop Date: 04-DEC-2015								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: it got very hot and gave off steam, burning my lips</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 52-year-old male consumer who started using THS 2.4 Marlboro Menthol (Green) and THS 2.4 Marlboro (Blue) (Batch/Kit number unknown) on 22-Oct-2015.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The consumer stated that, on 03-Dec-2015, on the third Heat Stick, after starting to use it, it got very hot and gave off steam, burning his lips.</p> <p>The severity of the event of burning was reported as mild. No treatment was required due to the event. The events were considered to be non-serious.</p> <p>It was reported that the product was not stopped. However, it was also stated that the event did not return when use of the product was restarted. The final action taken with the drug is unknown. It was reported that the product was used every day (10 units per day), toge her with other tobacco product / nicotine-containing product.</p> <p>The event of burning lips recovered on 04-Dec-2015. No further information was provided regarding the product issue.</p> <p>No further information is expected. Case closed.</p>								
PMI000441	RUSSIAN FEDERATION Spontaneous	34 Years Female	THS 2.4 Parliament Fresh / N/A UNK [UNK]	Respiratory	12-NOV-2015 to Unknown	30-NOV-2015 30-NOV-2015	dry feeling in the throat [DRY THROAT] N / Y / Y I had a cough while using sticks [COUGH] N / N / Y	Recovered/Resolved
<p>THS 2.4 Parliament Blue / N/A UNK [UNK]</p> <p>Respiratory</p> <p>12-NOV-2015 to Unknown</p> <p>Case Initial Receipt Date: 03-Dec-2015 Event Intensity: Mild Mild Event Stop Date: 02-DEC-2015 02-DEC-2015 Case Narrative: Verbatim: I had a cough / dry feeling in the throat</p> <p>Spontaneous case report received from a consumer in Russia.</p> <p>INITIAL INFORMATION RECEIVED ON 03-Dec-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 34-year-old female consumer who started using THS 2.4 Parliament Fresh and also possibly THS 2.4 Parliament Blue (unclearly reported) (Batch/Kit numbers not provided) on 12-Nov-2015.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>On 30-Nov-2015, she experienced cough while using sticks, as well as dry feeling in the throat.</p> <p>The severity of the events was reported as mild. The events were considered to be non-serious and did not require medical advice or treatment.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The products were used every day (20 units per day, exact number of THS 2.4 Parliament Fresh and THS 2.4 Parliament Blue unknown), concomitantly with conventional cigarettes (20 units per day).								
It was reported that the events disappeared when products' usage was stopped, and did not re-occur when products were restarted. Final action taken with the products was not reported.								
The events resolved on 02-Dec-2015.								
No further information is expected. Case closed.								
Yes (1)								
PMI000465	JAPAN Spontaneous	Male	THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	(b) (6) to Unknown	(b) (6) (b) (6)	lost consciousness while coughing [SYNCOPE] Y / Y / Y coughing [COUGH] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 29-Dec-2015								
Event Intensity: Unknown								
Event Stop Date: 29-DEC-2015								
Case Comment Text: The Syncope was assessed as serious, as it was considered a medically important adverse event. The Cough was assessed as non-serious.								
Syncope is unlisted, whereas Cough is listed, as per the reference safety information (i.e. IB).								
The information provided in this report is limited, particularly regarding the age and medical history of this patient, who had been a smoker of conventional cigarettes. The temporal sequence cannot be accurately assessed, as the time of product usage, the adverse events' onset time, and their respective time-to-onset were not provided. Considering the current knowledge on the product in question, the possibility that, as reported in this case, cough may indeed be associated with loss of consciousness (i.e. cough syncope), as well as the reported adverse events' occurrence on the first day of product use, and the positive dechallenge, the adverse events are assessed as related to the use of THS 2.4.								
Case Narrative: Verbatim: I lost consciousness while coughing.								
Spontaneous case report received from a consumer in Japan.								
INITIAL INFORMATION RECEIVED ON 29-Dec-2015 and transferred to Safety department on the same day.								
This report concerns a male consumer (age unknown) who started using THS 2.4 Marlboro (Blue) (Batch/Kit number unknown) on 29-Dec-2015.								
No medical history was reported. No concomitant medication was reported.								
The consumer was a daily smoker (approximately 20 conventional cigarettes per day).								
The consumer stated that, on (b) (6), he had smoked 2 or 3 'cigarettes' after 3:00 p.m, and he lost consciousness while coughing. He was not admitted to the hospital, but he was taken there. He recovered inside the ambulance, on the same day.								
The severity of the events was not reported. No treatment with prescribed medicine was taken by the subject due to the events; however, medical advice was required on (b) (6). The event of Lost of consciousness was considered to be serious (medically significant) and the event of Coughing was considered to be non-serious.								
It was reported that the events resolved when usage of the product was stopped. The product was not restarted. On 29-Dec-2015, the consumer used exclusively the product.								
The outcome of the events was reported as resolved on (b) (6).								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous all THS Regular

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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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No further information is expected. Case closed.

Total number of case entries printed: 23

Total number of cases printed: 23

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Advanced Condition used in this report:

Advanced Condition: Ingredient All THS Menthol (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

All THS Menthol Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: All THS Menthol Ingredients (Created by nicole.miller)

Selection Criteria:

Ingredient equal to D1 Vinny High Menthol OR

Ingredient equal to D1 Kaiden OR

Ingredient equal to D1 Vinny Low Menthol

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 (29)								
PMI000145	JAPAN Spontaneous	39 Years Male	THS 2.2 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	17-DEC-2014 to Unknown	17-MAY-2015	Had white swelling on the area covering the inner lips to the gum, part of which was abscessed purple [LIP SWELLING] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	17-DEC-2014 to Unknown	17-MAY-2015	Had white swelling on the area covering the inner lips to the gum, part of which was abscessed purple [ABSCESS ORAL] N / Y / Y the discoloured part recovered, but it turned slightly hard. [ORAL MUCOSAL DISCOLOURATION] N / Y / Y the discoloured part recovered, but it turned slightly hard [MUCOSAL INDURATION] N / Y / Y he informed that he holder could be hot [DEVICE ISSUE] N / Y / N	

Case Initial Receipt Date: 17-May-2015

Case Narrative: Verbatim: White swelling on the area covering the inner lips to the gum, part of which was abscessed purple. The holder could be hot.

Spontaneous case report received from a consumer.

INITIAL INFORMATION RECEIVED ON 17-MAY-2015:

This report concerns a 39-year-old male subject who used the iQOS Marlboro Regular and iQOS Marlboro Menthol.

No medical history and no concomitant medications were reported.

The consumer was a daily smoker (conventional cigarettes).

The consumer started using the iQOS Marlboro Regular and Menthol on 17-Dec-2014.

On 17-May-2015, the consumer experienced white swelling on the area covering the inner lips to the gum, part of which was abscessed purple. The customer mentioned that he used iQOS as he was drinking alcohol the previous night. He used Regular and Menthol and did not remember which one he was smoking on the day of the event. According to the consumer, the shape of the swollen part matched that of the HeatStick held on the mouth. After a day, the symptom improved and the discoloured part recovered, but it turned slightly hard.

The customer continued using the product, making sure not to hold it too deep after the symptom occurred, but he had no recurrence or exacerbation.

In addition, the consumer reported that the holder could be hot. The device was collected and replaced.

The severity of the adverse event was not reported and the events were considered to be non-serious.

At the time of reporting, the outcome was indicated as not recovered.

No follow-up information expected ? case closed.

On 18-Mar-2016, the case was updated to change coding of non-current product iQOS Marlboro Regular to equivalent current product configuration THS 2.2 Marlboro (Blue) and non-current product iQOS Marlboro Menthol to equivalent current product configuration THS 2.2 Marlboro Menthol (Green). No other change was done in the case.

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000146	JAPAN Spontaneous	56 Years Male	THS 2.2 Marlboro Menthol (Green) / N/A UNK [UNK] UNK [UNK]	Respiratory	20-APR-2015 to Unknown 08-MAY-2015 to Unknown		felt an irritation on the tongue [GLOSSITIS] N / Y / Y hot steam came in when he inhaled [FEELING HOT] N / Y / Y He informed that he coughed, feeling that the taste directly went into the throat, instead of inhaling steam, which happened with specific holders only. [COUGH] N / N / Y He informed that he coughed, feeling that the taste directly went into the throat, instead of inhaling steam, which happened with specific holders only. [PRODUCT TASTE ABNORMAL] N / Y / N charger was defective [DEVICE BATTERY ISSUE] N / Y / N	Unknown

Case Initial Receipt Date: 14-May-2015

Case Narrative: Verbatim: The customer owns several holders and he informed that he coughed, feeling that the taste directly went into the throat, instead of inhaling steam, which happened with holders only. Consumer felt irritation of the tongue. Charger was defective.

Spontaneous case report received from a consumer.

INITIAL INFORMATION RECEIVED ON 14-MAY-2015 and received at safety department on 19-MAY-2015:
This report concerns a 56-year-old male subject who used the IQOS Marlboro Menthol.

No medical history and no concomitant medications were reported.

Information on smoking habits (conventional cigarettes) was not reported.

The consumer started using the IQOS Marlboro Menthol on 20-Apr-2015.

On an unspecified date, the consumer experienced cough and he was feeling that the taste directly went into the throat, instead of inhaling steam. The customer owned several holders and he informed that it happened with specific holders only. As the charger was defective, it was replaced (of note, the holder had no external damage, the light turned on when the customer used the replacement charger and felt an irritation on the tongue like the previous time. Also, while holding the filter on the mouth did not cause any problem, however, when he inhaled. It was confirmed that the phenomenon occurred with two of the three holders owned by the consumer.

The severity of the adverse events was not reported and the events were considered to be non-serious.

Action taken with the use of the product was not reported.

At the time of reporting, the outcome of the events was not reported.

No follow-up information expected ? case closed.

On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Menthol to equivalent current product configuration THS 2.2 Marlboro Menthol (Green).
No other change was done in the case.

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000226	SWITZERLAND Spontaneous	37 Years Male	THS 2.2 Marlboro Balance (Light Blue) / N/A UNK [UNK]	Respiratory	22-MAY-2015 to Unknown	22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [MALAISE] N / Y / Y	Recovered/Resolved
			THS 2.2 Marlboro Essence (Blue) / N/A UNK [UNK]	Respiratory	22-MAY-2015 to Unknown	22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [NAUSEA] N / N / Y	
						22-MAY-2015	I developed extreme nausea, lightheadedness, and general malaise [DIZZINESS] N / N / Y	
<p>Case Initial Receipt Date: 23-May-2015 Case Followup Receipt Date: 23-May-2015 00:00 Event Intensity: Severe Severe Severe Event Stop Date: 22-MAY-2015 22-MAY-2015 22-MAY-2015</p> <p>Case Narrative: Verbatim: Yesterday (on 22May2015) I smoked 2 regular Heat-Sticks in short succession (perhaps, the 2nd, 15min after having finished the 1st). About 5 min afterwards, I dev extreme nausea, lightheadedness, and general malaise. I thought I would need to throw-up, so I had to stand out on the terrace sitting down for at least 45min. This feeling around 2 hours. I would categorize myself as a casual smoker, smoking approx. 5 cigarettes a week. When I go out with friends and drink I can easily smoke half a pack. The choice is MLB Gold. I' ve never felt like that after smoking, perhaps usually a small head-rush, but never sick like that.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2015, and received at the Safety department on 02-JUN-2015 and 03-JUN-2015:</p> <p>This report concerns a 37-year-old male subject who used IQOS Marlboro Balance and IQOS Marlboro Essence since 22-May-2015.</p> <p>The subject had no medical history and was not taking any concomitant medications.</p> <p>The consumer was an occasional smoker (5 to 10 cigarettes per week up to half a pack when going out).</p> <p>On the first day of use, the consumer used one Regular Heatstick and then, successively 2 Menthol Heatsticks (about 15 min interval). About 5 min afterwards, he developed extreme nausea, lightheadedness, and general malaise. He thought he would need to throw-up, so he had to stand out on the terrace sitting down for at least 45min. This feeling passed after around 2 hours. The consumer clarified that he had never felt like that after smoking, perhaps usually a small head-rush, but never sick like that.</p> <p>The severity of the adverse events was reported as severe and the events were considered to be non-serious.</p> <p>It was reported that the events resolved on the same day (22-May-2015) when usage of he product was discontinued. The products were not restarted.</p> <p>No follow-up information expected. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Balance to equivalent current product configuration THS 2.2 Marlboro Balance (Light Blue) and non-current product IQOS Marlboro Essence to equivalent current product configuration THS 2.2 Marlboro Essence (Blue). No other change was done in he case.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000299	ITALY Spontaneous	Male	THS 2.2 Marlboro Balance (Light Blue) / N/A UNK [UNK] Case Initial Receipt Date: 10-Dec-2014 Case Narrative: Verbatim: See green dots in his eyes only when using Balance variant.	Respiratory			See green dots in his eyes only when using Balance variant [CHROMATOPSIA] N / Y / Y	Unknown
<p>Case report spontaneously reported by a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 10-DEC-2014: This report concerns a male subject who used the IQOS Marlboro Balance.</p> <p>No medical conditions or concomitant medications were reported.</p> <p>The consumer started using the IQOS Marlboro Balance on an unspecified date. He reported that he was seeing green dots in his eyes only when using the product. The event was considered to be non-serious. The event intensity was not provided.</p> <p>At the time of reporting, the outcome was unknown.</p> <p>No follow-up information has been requested. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Balance to equivalent current product configuration THS 2.2 Marlboro Balance (Light Blue). No other change was done in the case.</p>								
PMI000300	JAPAN Spontaneous	52 Years Male	THS 2.2 Marlboro Menthol (Green) / N/A UNK [qd]	Respiratory	10-MAY-2015 to Unknown	10-MAY-2015 10-MAY-2015	His tongue hurts when he smokes it 2/3 times [GLOSSODYNIA] N / Y / Y Hhe has a strange feeling in his tongue even when not smoking it [PARAESTHESIA ORAL] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 10-Jun-2015 Case Followup Receipt Date: 10-Jun-2015 00:00 Case Narrative: Verbatim: His tongue hurts when he smokes it 2/3 times. At first his tongue hurt upon smoking it 2/3 times, but now he has a strange feeling in his tongue even when not smoking it.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 10-JUN-2015, and received at Safety department on 11-Jun-2015 and 15-Jun-2015 (additional clarification):</p> <p>This report concerns a 52-year-old male subject who used IQOS Marlboro Menthol since 10-May-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (on average 5-6 cigarettes per day).</p> <p>Since the first day of use (10-May-2015), the consumer experienced that his tongue was hurting when he smokes the product 2/3 times. The consumer explained that first his tongue was hurting upon smoking it 2/3 times, but at time of reporting he had a strange feeling in his tongue even when not smoking it.</p> <p>The severity of the adverse event was not reported. The event was considered to be non-serious.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The product was used every day (on average 20 HeatSticks per day) and the consumer was smoking 5-6 cigarettes per day at the same time. The product was not discontinued due to the occurrence of the event. The consumer reported that he still smokes one pack per day (not clear if regular cigarettes or HeatSticks) and has been instructed to stop using it, but he maintained that the symptoms were not severe enough for him to go to hospital.</p> <p>At time of reporting, the event was not resolved.</p> <p>No follow-up information expected. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Menthol to equivalent current product configuration THS 2.2 Marlboro Menthol (Green). No other change was done in the case.</p>								
PMI000314	JAPAN Spontaneous	45 Years Female	THS 2.2 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	AUG-2015 to Unknown	AUG-2015 AUG-2015	Metal-like aftertaste left in the mouth (the aftertaste was "like an electronic kind of taste") [DYSGEUSIA] N / Y / Y Uncomfortable sensation in the throat [LARYNGEAL DISCOMFORT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 26-Aug-2015</p> <p>Case Narrative: Verbatim: the patient reported an uncomfortable sensation in the throat, as well as a metal-like aftertaste left in the mouth (the subject only mentioned that the aftertaste was "like an electronic kind of taste").</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Aug-2015 and transferred to Safety department on 27-Aug-2015.</p> <p>This report concerns a 45-year-old female consumer who used IQOS Marlboro Menthol, since an unspecified day in Aug 2015.</p> <p>A medical history of allergies to metals was reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>In Aug-2015 (exact date unknown), the consumer smoked 3 test cigarettes over a 1-hour period. Afterward, the patient reported an uncomfortable sensation in her throat, as well as a metal-like aftertaste left in the mouth (the subject only mentioned that the aftertaste was "like an electronic kind of taste").</p> <p>The severity of the adverse events was not reported. The events were considered to be non-serious. No treatment was taken, given, prescribed or administered for the events.</p> <p>In addition, it was reported that the consumer has tried out tobacco products at a tobacco specialty store (dates not specified).</p> <p>It was reported that the events resolved without treatment after the use of the product was stopped. Use of the product was not restarted.</p> <p>No follow-up information expected. Case closed.</p> <p>On 18-Mar-2016, the case was updated to change coding of non-current product IQOS Marlboro Menthol to equivalent current product configuration THS 2.2 Marlboro Menthol (Green). No other change was done in the case.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000317	JAPAN Spontaneous	29 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A 10 DF [10 DF-qd]	Respiratory	02-SEP-2015 to 04-SEP-2015	02-SEP-2015 02-SEP-2015	Throat's condition worsened after smoking Heat Sticks for the first time / it felt raw and scratchy [THROAT IRRITATION] N / Y / Y It's gradually getting better now, but is still phlegmy [PRODUCTIVE COUGH] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 09-Sep-2015 Event Intensity: Moderate Moderate Event Stop Date: 09-SEP-2015 09-SEP-2015 Case Narrative: Verbatim: Throat's condition worsened after smoking Heat S icks for the first time. To explain symptoms in concrete terms, it felt raw and scratchy. It's gradually get ing better now, but is s ill phlegmy.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 9-Sep-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 29-year-old male consumer who used THS 2.4 Marlboro Menthol since 2-Sep-2015.</p> <p>A medical history of repeated headaches was reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The heatsticks were used every day between 02-Sep-2015 and 04-Sep-2015, on average 10 units per day, exclusively.</p> <p>On 2-Sep-2015, the consumer experienced worsening of throat condition, which was further described as throat feeling raw and scratchy. The consumer also reported that it was gradually getting better now, but was still phlegmy. The events resolved on 09-Sep-2015, after the product was discontinued. The product was not restarted.</p> <p>The severity of the adverse events was reported as moderate. The events were considered to be non-serious. The events were treated with Loxonin (loxoprofen, over-the-counter medicine) from 6-Sep-2015 to 07-Sep-2015.</p> <p>No follow-up information expected - case closed.</p>								
PMI000318	JAPAN Spontaneous	28 Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK] THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory Respiratory		04-SEP-2015 04-SEP-2015	Felt sick and vomited after smoking one Balanced Regular and one Menthol [MALAISE] N / Y / Y Felt sick and vomited after smoking one Balanced Regular and one Menthol [VOMITING] N / N / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 05-Sep-2015 Event Intensity: Mild Mild</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: Felt sick and vomited after smoking one Balanced Regular and one Menthol.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 05-Sep-2015 and transferred to Safety department on 09-Sep-2015.</p> <p>This report concerns a 28-year-old male consumer who used THS 2.4 Marlboro balanced regular and Marlboro menthol since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 04-Sep-2015, the consumer felt sick and vomited after smoking one Balanced Regular and one Menthol heatsticks.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious.</p> <p>It was reported that the problem improved when usage of the product was stopped. Product was not restarted.</p> <p>No treatment was taken for the event.</p> <p>No further information is expected. Case closed.</p>								
PMI000319	JAPAN Spontaneous	27 Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory		04-SEP-2015	Felt like vomiting after smoking a Menthol [NAUSEA] N / N / Y	Recovering/Resolving
<p>Case Initial Receipt Date: 05-Sep-2015</p> <p>Case Followup Receipt Date: 15-Oct-2015 00:00</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: Felt like vomiting after smoking a Menthol</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 05-Sep-2015 and transferred to Safety department on 09-Sep-2015. Updated information was received on 15-Oct-2015 (age of the consumer was corrected).</p> <p>This report concerns a 27-year-old female consumer who used THS 2.4 Marlboro menthol since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 04-Sep-2015, the consumer felt like vomit ing after smoking a Menthol heatstick.</p> <p>The severity of the adverse events was reported as mild. The event was considered to be non-serious.</p> <p>It was reported that the problem improved when usage of the product was stopped. Product was not restarted.</p> <p>No treatment was taken for the event.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.								
PMI000320	JAPAN Spontaneous	24 Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory		08-SEP-2015	Felt like something was stuck in throat, vomited [SENSATION OF FOREIGN BODY] N / Y / Y	Unknown
						08-SEP-2015	Felt like something was stuck in throat, vomited. [VOMITING] N / N / Y	
						09-SEP-2015	After smoking again the next day, felt nauseous again and got a headache [NAUSEA] N / N / Y	
						09-SEP-2015	After smoking again the next day, felt nauseous again and got a headache [HEADACHE] N / N / Y	
<p>Case Initial Receipt Date: 09-Sep-2015</p> <p>Event Intensity: Mild Mild Mild Mild</p> <p>Case Narrative: Verbatim: Felt like something was stuck in throat, vomited. After smoking again the next day, felt nauseous again and got a headache.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Sep-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 24-year-old female consumer who used THS 2.4 Marlboro Menthol since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 08-Sep-2015, the consumer experienced feeling like something was stuck in her throat, and vomited. After smoking again the next day, she felt nauseous again and got a headache.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious.</p> <p>It was reported that the problem did not improve when usage of the product was stopped. It was not reported if the product was permanently discontinued due to the events.</p> <p>The outcome of the events was not reported.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000322	JAPAN Spontaneous	40 Male	THS 2.4 Marlboro Menthol (Green) / N/A 20 [20 -qd]	Respiratory	03-SEP-2015 to Unknown	10-SEP-2015 10-SEP-2015 10-SEP-2015	The holder's temperature got extremely hot, and customer's right forefingers were burned (light injury) when they hastily tried to remove the HS; stinging, about the same as a blister [BURN ORAL CAVITY] N / Y / Y The holder' s temperature got extremely hot [DEVICE ISSUE] N / Y / N Heatstick burned and the blades were out of shape. The Heatstick didn't splinter. [PRODUCT QUALITY ISSUE] N / Y / N	Not Recovered/Not Resolved

Case Initial Receipt Date: 10-Sep-2015

Case Followup Receipt Date: 11-Nov-2015 00:00

Event Intensity: Mild

Case Narrative: Verbatim: The HS burned and the blades were out of shape ("dissolved" according to customer). HS didn't splinter. The holder's temperature got extremely hot, and customer's right forefingers were burned (light injury) when they hastily tried to remove the HS. Slightly s inging, but OK (about the same as a blister). As his happened when they slid the cap, the damage and change in shape is not from when it was removed.

Spontaneous case report received from a consumer.

INITIAL INFORMATION RECEIVED ON 10-Sep-2015 and transferred to Safety department on the same day.

This report concerns a 40-year-old male consumer who used THS 2.4 Marlboro Menthol since 03-Sep-2015.

No medical history and no concomitant medications were reported.

The consumer was a daily smoker (approximately 20 conventional cigarettes per day). It was reported that the Heatsticks were used exclusively, about 20 per day. The consumer reported that he bought 7-8 boxes of Heatsticks on 03-Sep-2015 and used them until 10-Sep-2015.

On 10-Sep-2015, the Heatstick burned and the blades were out of shape ("dissolved" according to customer). The Heatstick didn't splinter. The holder's temperature got extremely hot, and customer's right forefingers were burned (light injury) when they hastily tried to remove the Heatstick. The consumer explained that it was "slightly stinging, but OK (about the same as a blister)". According to the consumer, as this happened when they slid the cap, the damage and change in shape was not from when it was removed.

The severity of the adverse event was reported as mild. The event was considered to be non-serious.

No treatment was required for he event.

Action taken with the product was not unknown. It was mentioned that the event did not improve when product usage was stopped and did not return when product was restarted.

At time of reporting, the event was not recovered.

No further information is expected. Case closed.

NOTE:

On 11-Nov-2015, LLT Burned mouth has been recoded due to MedDRA 18.1 upgrade. Consequently the PT for this event was changed from Thermal burn to Burn oral cavity. The two other event PTs Device issue and Product quality issue have also been updated to MedDRA 18.1 but with no changes.

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000325	JAPAN Spontaneous	Female	THS 2.4 Marlboro Mint (Light Green) / N/A UNK [UNK]	Respiratory	12-SEP-2015 to Unknown	12-SEP-2015	upon smoking he second one, the patient felt extreme nausea [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 13-Sep-2015 Event Intensity: Mild Event Stop Date: 13-SEP-2015 Case Narrative: Verbatim: Purchased and used on Saturday, September 12th. No particular symptoms arose when smoking the first one, but upon smoking the second one, the patient felt extreme nausea. Symptoms continued until patient went to sleep. Patient had recovered by the time she got up on Sunday, September 13th.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 13-Sep-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a female consumer (age not specified) who used THS 2.4 Marlboro Mint, since 12-Sep-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 15-20 conventional cigarettes per day).</p> <p>On 12-Sep-2015, the consumer purchased the product. She reported that no particular symptoms arose when smoking the first one, but upon smoking the second one the patient felt extreme nausea. Symptoms continued until patient went to sleep. No treatment was administered for the event.</p> <p>The severity of the adverse event was reported as mild. The event was considered to be non-serious.</p> <p>The event improved when usage of the product was stopped. Product was not restarted.</p> <p>The outcome of the event was indicated as recovered on 13-Sep-2015.</p> <p>No further information is expected. Case closed.</p>								
PMI000326	JAPAN Spontaneous	40 Years Female	THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory		02-SEP-2015	I felt sick because the smell was so bad [MALAISE] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 11-Sep-2015 Case Narrative: Verbatim: I felt sick because the smell was so bad. It smelled as if I had smoked black beans. I want to return the product.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 11-Sep-2015 and transferred to Safety department on 16-Sep-2015 (Note: invalid source document was received on 11-Sep-2015).</p> <p>This report concerns a 40-year-old female consumer who used THS 2.4 Marlboro regular, Marlboro balanced regular, Marlboro menthol since an unspecified date.</p>								
			THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory		02-SEP-2015	The smell was so bad / It smelled as if I had smoked black beans [PRODUCT ODOUR ABNORMAL] N / Y / N	
			THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory				

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 02-Sep-2015, the consumer felt sick because the smell was so bad. She further explained that it smelled as if she had smoked black beans. She mentioned that she wanted to return the product.</p> <p>The severity of the adverse event was not reported. The event was considered to be non-serious.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the event was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000327	JAPAN Spontaneous	36 Years Female	THS 2.4 Marlboro Mint (Light Green) / N/A UNK [UNK]	Respiratory		07-SEP-2015	Tongue felt tingly for an hour [PARAESTHESIA ORAL] N / Y / Y Hurt after inhaling 10 times [PAIN] N / Y / Y The HS' plastic had melted and was out of shape [PRODUCT PHYSICAL ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 08-Sep-2015</p> <p>Case Narrative: Verbatim: Hurt after inhaling 10 times. Tongue felt tingly for an hour. The HS' plastic had melted and was out of shape.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 08-Sep-2015 and transferred to Safety department on 16-Sep-2015 (Note: invalid source document was received on 09-Sep-2015).</p> <p>This report concerns a 36-year-old female consumer who used THS 2.4 Marlboro Mint since an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On 07-Sep-2015, the consumer experienced pain after inhaling 10 times and tongue felt tingly for an hour. The heatstick's plastic had melted and was out of shape.</p> <p>The severity of the adverse events was not reported. The events were considered to be non-serious.</p> <p>Action taken with the product was not reported.</p> <p>The outcome of the events was not reported.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000329	JAPAN Spontaneous	Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory		Onset after therapy initiation: 2 days	Around 2 days after first using IQOS, I felt sluggish and tired [SLUGGISHNESS] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 18-Sep-2015</p> <p>Case Narrative: Verbatim: Around 2 days after first using IQOS, I felt sluggish and tired. My symptoms have gone away that I've stopped using it. I smoke Marlboro Long cigarettes and they don't cause these symptoms of sluggishness. My condition hasn't changed for the worse besides the tiredness.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 18-Sep-2015 and transferred to Safety department on 19-Sep-2015.</p> <p>This report concerns a female consumer (age unspecified) who used THS 2.4 Marlboro Men hol, since an unknown date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette and heatsticks) was not provided.</p> <p>On an unspecified date, 2 days after first using the product, the consumer felt sluggish and tired. Her symptoms have gone away since she has stopped using the product. The consumer also mentioned that she smokes Marlboro Long cigarettes and they don't cause these symptoms of sluggishness. In addition, she reported that her condition hasn't changed for the worse besides the tiredness.</p> <p>The severity of the adverse events was not reported. The events were considered to be non-serious.</p> <p>The event improved when usage of the product was stopped. Product was not restarted.</p> <p>The outcome of the event was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000337	JAPAN Spontaneous	42 Years Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	02-SEP-2015 to Unknown	04-SEP-2015	While cleaning it, the head-inducing blade broke and fell on top of my foot, giving me a burn [THERMAL BURN] N / Y / Y	Not Recovered/Not Resolved
							04-SEP-2015 While cleaning it, the head-inducing blade broke and fell on top of my foot, giving me a burn. [DEVICE DAMAGE] N / Y / N	
<p>Case Initial Receipt Date: 04-Oct-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: After using the iQos, a little after smoking an HS, I cleaned the holder with a cleaning brush. While cleaning it, the head-inducing blade broke and fell on top of a burn. The burn is still blistered as of 4th October 2015. It is on the top and instep of my foot. I have used less than 5 HS in total.</p> <p>Spontaneous case report received from a consumer.</p> <p>INITIAL INFORMATION RECEIVED ON 04-Oct-2015 and transferred to Safety department on the same day.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 42-year-old female consumer who used THS 2.4 Marlboro Menthol, since 02-Sep-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits (conventional cigarette) was not provided. The consumer used the heatsticks occasionally, about 5 per day in average (of note, contradictory information was provided, as the consumer also mentioned that she used less than 5 heatsticks in total) .</p> <p>On 04-Sep-2015, the consumer cleaned the holder with a cleaning brush. The "head-inducing" (presumably, heat-inducing) blade broke and fell on her foot, giving her a burn. At time of reporting the burn was still present as a blister.</p> <p>The severity of the adverse events was reported as mild. The event was considered to be non-serious. No treatment was administered due to the event.</p> <p>The event did not improve when usage of the product was stopped. Product was not restarted (stop date not provided).</p> <p>At time of reporting, the event was not recovered.</p> <p>No further information is expected. Case closed</p>								
PMI000338	JAPAN Spontaneous	35 Male	THS 2.4 Marlboro Balanced Regular (Light Blue) / N/A UNK [UNK]	Respiratory	15-SEP-2015 to 03-OCT-2015	15-SEP-2015 15-SEP-2015	Feeling uncomfortable [DISCOMFORT] N / Y / Y The inside of my mouth feels uncomfortable [ORAL DISCOMFORT] N / Y / Y	Recovered/Resolved
			THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	15-SEP-2015 to 03-OCT-2015	15-SEP-2015	The inside of my mouth feels uncomfortable; when the holder's LED is orange it hurts enough to make me groan [ORAL PAIN] N / Y / Y	
			THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	15-SEP-2015 to 03-OCT-2015	15-SEP-2015	I also get a slight headache [HEADACHE] N / N / Y	
			THS 2.4 Marlboro Mint (Light Green) / N/A UNK [UNK]	Respiratory	15-SEP-2015 to 03-OCT-2015			
			Case Initial Receipt Date: 03-Oct-2015					
			Event Intensity: Mild					
			Mild					
			Mild					
			Mild					
			Event Stop Date: 03-OCT-2015					
			03-OCT-2015					
			03-OCT-2015					
			03-OCT-2015					
			Case Narrative: Verbatim: I smoke cigarettes (Marlboros) but no symptoms arise from them. If I use IQOS, symptoms emerge after about 5 minutes. Symptoms: Feeling uncomfortable; The inside of my mouth feels uncomfortable; When the holder's LED is orange it hurts enough to make me groan; also get a slight headache.					
			Spontaneous case report received from a consumer in Japan.					
			INITIAL INFORMATION RECEIVED ON 03-Oct-2015 and transferred to Safety department on 06-Oct-2015.					

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 35-year-old male consumer who used THS 2.4 Marlboro Regular, Marlboro Balanced Regular, Marlboro Menthol and Marlboro Mint, since 15-Sep-2015 (reference number provided: HUUK7EAX03JP).</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day). The consumer used the heatsticks occasionally, about 10 per day on average, and the product was used together with other tobacco products (Marlboro).</p> <p>On 15-Sep-2015, the consumer experienced feeling uncomfortable and the inside of his mouth felt uncomfortable. He clarified that, when the holder's LED is orange, it hurts enough to make him groan. In addition, the consumer also got a slight headache. The events occurred within 5 minutes of using the product and did not occur when smoking conventional cigarettes.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was administered due to the event.</p> <p>The events resolved on 03-Oct-2015. It was mentioned that this was when the consumer stopped using the product. It was also reported that the events improved when product was discontinued and returned when product was restarted.</p> <p>No further information is expected. Case closed.</p>								
PMI000339	JAPAN Spontaneous	44 Male	THS 2.4 Marlboro Menthol (Green) / N/A 20 [20 -qd]	Respiratory	09-SEP-2015 to Unknown	01-OCT-2015	Occasionally felt hot [FEELING HOT] N / Y / Y My tongue has had a low-temperature burn since a few days ago [BURN ORAL CAVITY] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 06-Oct-2015 Event Intensity: Mild Mild Case Narrative: Verbatim: Occasionally felt hot since I bought and started to use them on September 9th. My tongue has had a low-temperature burn since a few days ago. I have been advised to stop using IQOS from today.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 06-Oct-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 44-year-old male consumer who used THS 2.4 Marlboro Menthol since 09-Sep-2015.</p> <p>Medical history of Diabetes mellitus and high blood pressure were reported. The consumer was taking medications for those conditions (not further specified).</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day). The consumer used the heatsticks exclusively, every day, about 20 per day in average.</p> <p>On 01-Oct-2015, the consumer reported that he occasionally felt hot since he bought and started using the product. In addition, his tongue has had a low-temperature burn since a few days.</p> <p>The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was administered due to the event.</p> <p>The events were not resolved at time of reporting.</p> <p>It was reported that the product was not stopped and was not restarted.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.								
PMI000344	JAPAN Spontaneous	42 Years Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	11-OCT-2015 to Unknown	11-OCT-2015 11-OCT-2015 11-OCT-2015	On the second or third one, she felt ill [MALAISE] N / Y / Y The symptoms were a headache and nausea [HEADACHE] N / N / Y The symptoms were a headache and nausea [NAUSEA] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 13-Oct-2015 Event Intensity: Moderate Moderate Moderate Event Stop Date: 12-OCT-2015 12-OCT-2015 12-OCT-2015 Case Narrative: Verbatim: Nothing happened when he just tried smoking it. On he second or third one, he felt ill. That day, he felt better after about two hours. The next day after he smoked it again, he felt ill all day long. The symptoms were a headache and nausea.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 13-Oct-2015 and transferred to Safety department on 14-Oct-2015.</p> <p>This report concerns a 42-year-old female consumer who used THS 2.4 Marlboro Menthol since 11-Oct-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a smoker (number of conventional cigarettes per day not reported). The consumer used the Heatsticks occasionally, about 4 s icks per week.</p> <p>On 11-Oct-2015, the consumer felt ill when she used the second or third Heatstick. That day, she felt better after about two hours. The next day, after she used it again, she felt ill all day long. The symptoms were headache and nausea. The consumer men ioned that when she smokes the conventional cigarettes she doesnot feel ill. The severity of the adverse event was reported as moderate. The events were considered to be non-serious.</p> <p>The events resolved on 12-Oct-2015.</p> <p>It was reported that the event improved after usage of the product was stopped, and returned when product was restarted.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000362	JAPAN Spontaneous	40 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory	11-OCT-2015 to 11-OCT-2015	11-OCT-2015 11-OCT-2015	Right after that I started feeling ill and got a headache [MALAISE] N / Y / Y Right after that I started feeling ill and got a headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 14-Oct-2015 Event Intensity: Mild Mild Event Stop Date: 11-OCT-2015 11-OCT-2015 Case Narrative: Verbatim: On 11 October, just after lunch, I smoked it soon after buying it. Right after that, I started feeling ill and got a headache. About an hour later, the symptoms w I' ve never used iQOS since then.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 14-Oct-2015 and transferred to Safety department on 26-Oct-2015.</p> <p>This report concerns a 40-year-old male consumer who used THS 2.4 Marlboro Menthol (Batch/pack number not reported) on 11-Oct-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>On 11-Oct-2015, the consumer started feeling ill and experienced headache, right after using the product. The severity of the adverse events was reported as mild. The events were considered to be non-serious. No treatment was required due to the events.</p> <p>The consumer indicated that the events resolved on the same day, after usage of the product was discontinued. The product was not restarted.</p> <p>No further information is expected. Case closed.</p>								
PMI000368	JAPAN Spontaneous	25 Male	THS 2.4 Marlboro Menthol (Green) / N/A UNK [UNK]	Respiratory		29-OCT-2015 29-OCT-2015	The holder got hot and burned me [THERMAL BURN] N / Y / Y The holder got hot and burned me [DEVICE ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 30-Oct-2015 Event Intensity: Mild Case Narrative: Verbatim: The holder got hot and burned me.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Oct-2015 and transferred to Safety department on 31-Oct-2015.</p> <p>This report concerns a 25-year-old male consumer who used THS 2.4 Marlboro Menthol (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
On 29-Oct-2015, the holder got hot and the consumer got burned. The severity of the adverse event was reported as mild. The event was considered to be non-serious. No treatment was required due to the event.								
The outcome of the event was not reported. Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000383	JAPAN Spontaneous	33 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A 1 DF [1 DF-qd]	Respiratory	09-NOV-2015 to 09-NOV-2015	09-NOV-2015	I stopped smoking at around 3:00 p.m., and at around 5:00 p.m. my stomach hurt and I got diarrhoea [ABDOMINAL PAIN UPPER] N / Y / Y	Not Recovered/Not Resolved
						09-NOV-2015	I stopped smoking at around 3:00 p.m., and at around 5:00 p.m. my stomach hurt and I got diarrhoea [DIARRHOEA] N / Y / Y	
						09-NOV-2015	After one or two puffs, I started to feel dizzy [DIZZINESS] N / N / Y	
						09-NOV-2015	then I got a headache [HEADACHE] N / N / Y	
						09-NOV-2015	My chest felt strange [CHEST DISCOMFORT] N / N / Y	
						09-NOV-2015	I became nauseous [NAUSEA] N / N / Y	
Case Initial Receipt Date: 09-Nov-2015								
Event Intensity: Moderate								
Moderate								
Moderate								
Moderate								
Moderate								
Case Narrative: Verbatim: After one or two puffs, I started to feel dizzy; then I got a headache.								
My chest felt strange, and I became nauseous. I stopped smoking at around 3:00 p.m. and, at around 5:00 p.m., my stomach hurt and I got diarrhoea.								
Spontaneous case report received from a consumer in Japan.								
INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and transferred to Safety department on the same day.								
This report concerns a 33-year-old male consumer who used THS 2.4 Marlboro Menthol (Batch/Kit number ZZ035L10413) on 09-Nov-2015.								
No medical history and no concomitant medications were reported.								
The consumer was a daily smoker (about 20 conventional cigarettes per day).								
On 09-Nov-2015, after one or two puffs, the consumer started to feel dizzy; then he got a headache. His chest felt strange, and he became nauseous. He stopped smoking at around 3:00 p.m. and, at around 5:00 p.m., the consumer's stomach hurt and he got diarrhoea.								
The severity of the adverse events was reported as between mild and moderate. The events were considered to be non-serious. No treatment was required due to the event.								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The consumer used only one Heatstick, on 09-Nov-2015, around 2:40 pm. He used conventional cigarettes on the same day, in the morning (11:00 am).</p> <p>At time of reporting, the events were not resolved.</p> <p>The events did not improve once the product was stopped. It was reported that product was not restarted.</p> <p>No further information is expected. Case closed.</p>								
PMI000384	JAPAN Spontaneous	37 Years Female	THS 2.4 Marlboro Menthol (Green) / N/A UNK [qd]	Respiratory	12-OCT-2015 to Unknown	07-NOV-2015	After I started smoking iQos, I got a slight burn when I smoked it continuously. It became a blister. [BURNS SECOND DEGREE] N / Y / Y	Not Recovered/Not Resolved
						07-NOV-2015	The blister runs down at an angle from my lower lip, and is like a cold sore [LIP BLISTER] N / Y / Y	
						07-NOV-2015	blister popped and a liquid came out, and it spit and bled; it was hurting when her lip touched the edge of a cup [BLISTER RUPTURE] N / Y / Y blister popped and a liquid came out, and it spit and bled; it was hurting when her lip touched the edge of a cup [PAIN] N / Y / Y	
<p>Case Initial Receipt Date: 09-Nov-2015</p> <p>Event Intensity: Mild Mild Mild Mild</p> <p>Case Narrative: Verbatim: I got a slight burn when I smoked it continuously. It became a blister. The blister runs down at an angle from my lower lip, and is like a cold sore. The blister popped and a liquid came out, and it spit and bled. It was hurting when her lip touched the edge of a cup.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 37-year-old female consumer who used THS 2.4 Marlboro Menthol (Batch/Kit number Z803518017) from 12-Oct-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>On 07-Nov-2015, after the consumer started smoking iQos, she got a slight burn when she smoked it continuously. It became a blister. The blister was running down at an angle from her lower lip, and it was like a cold sore. She further explained that the blister popped and a liquid came out, and it spit and bled. She stated that it was not causing any troubles in her daily life, but it was hurting when her lip touched the edge of a cup when she was drinking.</p> <p>The events severity was reported as mild. The events were considered to be non-serious. No treatment was required due to the events.</p> <p>At time of reporting, the events were not resolved.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The usage of the product was continued without change.								
No further information is expected. Case closed.								
PMI000399	JAPAN Spontaneous	53 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A UNK [qd] UNK [UNK]	Respiratory	06-OCT-2015 to Unknown	27-OCT-2015 27-OCT-2015 27-OCT-2015	sometimes my voice dies out [APHONIA] N / Y / Y I've got a lot of phlegm [PRODUCTIVE COUGH] N / Y / Y my throat hurts [OROPHARYNGEAL PAIN] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 14-Nov-2015</p> <p>Event Intensity: Mild Mild Mild</p> <p>Event Stop Date: 11-NOV-2015 11-NOV-2015 11-NOV-2015</p> <p>Case Narrative: Verbatim: my throat hurt and sometimes my voice dies out, and I've got a lot of phlegm</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 14-Nov-2015 and transferred to Safety department on 14-Nov-2015.</p> <p>This report concerns a 53-year-old male consumer who used THS 2.4 Marlboro Menthol (Batch/Kit number not provided) from 06-Oct-2015.</p> <p>Medical history of high blood pressure was reported and concomitant medication for high blood pressure was reported (further information not provided, unable to get name of</p> <p>The consumer was a daily smoker (approximately 15-16 conventional cigarettes per day).</p> <p>Around 06-Oct-2015, the respondent purchased white device. Around 13-Oct-2015, he purchased navy blue device. About three weeks after taking his first smoke with it, on 27- the respondent's throat hurt and sometimes his voice died out, and he'd got a lot of phlegm. He smoked about 20 cigarettes a day (unclear if it is meant conventional ciga heatsticks) but, since he developed these symptoms, he had reduced that to 15-16 cigarettes per day. A few days prior to reporting, the symptoms had gradually been getting better.</p> <p>The events' severity was reported as mild. The events were considered to be non-serious. No treatment was required due to the events.</p> <p>Product was not stopped. It was reported that the product was used every day, exclusively, about 15-16 units per day. However, usage of conventional cigarettes was also reported (15-16 units per day, unclear information).</p> <p>The events resolved on 11-Nov-2015.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000403	SWITZERLAND Spontaneous	38 Years Female	THS 2.4 Marlboro (White/Blue) / N/A UNK [UNK]	Respiratory	16-NOV-2015 to 16-NOV-2015	16-NOV-2015	Doctor suggested nicotine intoxication [TOBACCO POISONING] N / Y / Y The consumer tried the first IQOS at shop and experienced weakness (need to sit down) / more intense weakness/ weenkness (need to lie down) [ASTHENIA] N / Y / Y also tremor, panic, abdominal pain [TREMOR] N / Y / Y reported weakness, increased heart rate and nervousness [HEART RATE INCREASED] N / Y / Y reported weakness, increased heart rate and nervousness [NERVOUSNESS] N / Y / Y also tremor, panic, abdominal pain [PANIC REACTION] N / Y / Y also tremor, panic, abdominal pain [ABDOMINAL PAIN] N / Y / Y not feeling very well / malaise [MALAISE] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 18-Nov-2015 Event Stop Date: 16-NOV-2015 16-NOV-2015 16-NOV-2015 16-NOV-2015 16-NOV-2015 16-NOV-2015 16-NOV-2015 16-NOV-2015</p> <p>Case Narrative: Verbatim: weakness (need to sit down, need to lie down), not feeling very well / malaise, increased heart rate and nervousness, tremor, panic, abdominal pain. Doctor suggested nicotine intoxication.</p> <p>Spontaneous case report received from a consumer in Switzerland.</p> <p>INITIAL INFORMATION RECEIVED ON 18-Nov-2015 and transferred to Safety department on 19-Nov-2015.</p> <p>This report concerns a 38-year-old female consumer who used THS 2.4 Marlboro Menthol (Batch/Kit number 3KNN68AXUV1A) on 16-Nov-2015.</p> <p>No medical history was reported. The concomitant medication Xanax (alprazolam) was reported (anxiolytic).</p> <p>The consumer was a daily smoker (approximately 30 conventional cigarettes per day, for 25 years).</p> <p>On 16-Nov-2015, the consumer tried the first IQOS at shop and experienced malaise and weakness (need to sit down). She reported that she thought it was due to the fact that she did not eat enough (lack of sugar). After consuming the 2nd IQOS, she did not feel very well, experienced weakness, increased heart rate and nervousness. She explained that she tried to take</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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>small hits on the IQOS. The consumer has taken 3rd IQOS 2h later and complained on more intense weakness, needing 1 hour to calm down. She clarified that she had not smoked other cigarettes in between, and she did not at this time make the relation between the product and her state. The consumer has tried 4th IQOS at 17:00 and experienced weakness (she needed to lie down), also tremor, panic, and abdominal pain.</p> <p>As symptoms were still not gone, she called doctor at 20:00. Doctor suggested nicotine intoxication.</p> <p>The events' severity was reported as requiring medical advice, but no treatment was required due to the events. The events were considered to be non-serious.</p> <p>The events improved when usage of the product was stopped, and product was not restarted.</p> <p>The events resolved on the same day, although there were still some signs on the next day.</p> <p>No further information is expected. Case closed.</p>								
PMI000414	JAPAN Spontaneous	52 Years Male	THS 2.4 Marlboro Menthol (Green) / N/A 10 DF [10 DF-qd]	Respiratory	22-OCT-2015 to Unknown	03-DEC-2015	it got very hot and gave off steam, burning my lips [THERMAL BURN] N / Y / Y	Recovered/Resolved
			THS 2.4 Marlboro (Blue) / N/A UNK [UNK]	Respiratory	22-OCT-2015 to Unknown	03-DEC-2015	it got very hot and gave off steam [DEVICE ISSUE] N / Y / N	
			<p>Case Initial Receipt Date: 04-Dec-2015</p> <p>Event Intensity: Mild</p> <p>Event Stop Date: 04-DEC-2015</p> <p>Case Narrative: Verbatim: it got very hot and gave off steam, burning my lips</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 52-year-old male consumer who started using THS 2.4 Marlboro Menthol (Green) and THS 2.4 Marlboro (Blue) (Batch/Kit number unknown) on 22-Oct-2015.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The consumer stated that, on 03-Dec-2015, on the third Heat Stick, after starting to use it, it got very hot and gave off steam, burning his lips.</p> <p>The severity of the event of burning was reported as mild. No treatment was required due to the event. The events were considered to be non-serious.</p> <p>It was reported that the product was not stopped. However, it was also stated that the event did not return when use of the product was restarted. The final action taken with the drug is unknown. It was reported that the product was used every day (10 units per day), toge her with other tobacco product / nicotine-containing product.</p> <p>The event of burning lips recovered on 04-Dec-2015. No further information was provided regarding the product issue.</p> <p>No further information is expected. Case closed.</p>					

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000416	ITALY Spontaneous	44 Years Male	THS 2.4 Marlboro Balance (Light Blue) / N/A UNK [20 DF-UNK]	Respiratory	01-DEC-2015 to Unknown	07-DEC-2015 07-DEC-2015	breathing problems / cannot catch my breath / shortness of breath / I am panting [DYSPOEA] N / Y / Y extremely tired [FATIGUE] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 11-Dec-2015 Case Followup Receipt Date: 27-Jan-2016 00:00 Event Intensity: Moderate Moderate Case Narrative: Verbatim: breathing problems / cannot catch my breath / shortness of breath / I am panting; extremely tired</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 11-Dec-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 44-year-old male consumer who started using THS 2.4 Marlboro Balance (Light Blue) (Batch number SXW 982 K9F U1X) on 01-Dec-2015.</p> <p>No medical history was reported. Antibiotics (unspecified) were reported as concomitant medication, prescribed for a toothache 6 days prior to reporting.</p> <p>The consumer was a daily ex-smoker (approximately 20 conventional cigarettes/ cigars per day). He stopped smoking 10 days before the time of reporting.</p> <p>From 07-Dec-2015 (also reported as "since when I started smoking IQOS"), the consumer experienced breathing problems and felt extremely tired. The consumer further explained that, in the beginning, he couldn't catch his breath and he had shortness of breath, like after a long run. In the beginning, he would have a little shortness of breath only after smoking IQOS, but instead, then, he had shortness of breath even when he was smoking it. He especially felt these breathing problems in the 10-15 minutes after smoking IQOS. Even when he talked on the phone (at time of reporting the events), he was panting and he had smoked an IQOS just 5 minutes before. Previously, he would smoke 1 pack of conventional cigarettes per day, and he never had these problems. He went to see his family doctor to have a first check-up. He also mentioned that the following week, he was to undergo a chest X-ray and an electrocardiogram. He was a healthy person and he has never had health problems.</p> <p>The severity of the events was reported as moderate and required medical advice on 09-Dec-2015. The events were considered to be non-serious.</p> <p>No treatment was administered due to the events.</p> <p>The product was used every day (20 units per day), exclusively.</p> <p>It was reported that the events did not disappear when product usage was stopped, and re-occurred when product was restarted. Final action taken with the product was not reported.</p> <p>At time of the report, the events did not resolve.</p> <p>Further information was expected, however, all follow-up attempts were unsuccessful.</p>								
PMI000440	RUSSIAN FEDERATION Spontaneous	27 Years Female	THS 2.4 Parliament Fresh / N/A UNK [15 DF-UNK]	Respiratory	04-NOV-2015 to Unknown	17-NOV-2015	dizziness / I felt dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 25-Nov-2015 Event Intensity: Moderate Event Stop Date: 25-NOV-2015</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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: dizziness / I felt dizzy</p> <p>Spontaneous case report received from a consumer in Russia.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Nov-2015 and transferred to Safety department on 26-Nov-2015.</p> <p>This report concerns a 27-year-old female consumer who started using THS 2.4 Parliament Fresh (Batch/Kit number not provided) on 04-Nov-2015.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>On 17-Nov-2015, the consumer experienced dizziness. The consumer stated that the dizziness started after using (presumably using the product). She drank whiskey and cola, after she used a tobacco stick and severe dizziness started. That didn't use to be the case. She had to take hold of a friend. After she stopped using, the dizziness didn't repeat. Once she tried again, she felt dizzy.</p> <p>The severity of the event was reported as moderate. The event was considered to be non-serious.</p> <p>The product was used every day (15 units per day). It was reported that the event disappeared when product usage was stopped. It was also mentioned that the event repeated when product was restarted and that "it was not renewed". Final action taken with the product was not clearly reported.</p> <p>The event resolved on 25-Nov-2015.</p> <p>No further information is expected. Case closed.</p>								
PMI000441	RUSSIAN FEDERATION Spontaneous	34 Years Female	THS 2.4 Parliament Fresh / N/A UNK [UNK]	Respiratory	12-NOV-2015 to Unknown	30-NOV-2015 30-NOV-2015	dry feeling in the throat [DRY THROAT] N / Y / Y I had a cough while using sticks [COUGH] N / N / Y	Recovered/Resolved
<p>THS 2.4 Parliament Blue / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 03-Dec-2015</p> <p>Event Intensity: Mild Mild</p> <p>Event Stop Date: 02-DEC-2015 02-DEC-2015</p> <p>Case Narrative: Verbatim: I had a cough / dry feeling in the throat</p> <p>Spontaneous case report received from a consumer in Russia.</p> <p>INITIAL INFORMATION RECEIVED ON 03-Dec-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 34-year-old female consumer who started using THS 2.4 Parliament Fresh and also possibly THS 2.4 Parliament Blue (unclearly reported) (Batch/Kit numbers not provided) on 12-Nov-2015.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 20 conventional cigarettes per day).</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 30-Nov-2015, she experienced cough while using sticks, as well as dry feeling in the throat.</p> <p>The severity of the events was reported as mild. The events were considered to be non-serious and did not require medical advice or treatment.</p> <p>The products were used every day (20 units per day, exact number of THS 2.4 Parliament Fresh and THS 2.4 Parliament Blue unknown), concomitantly with conventional cigarettes (20 units per day).</p> <p>It was reported that the events disappeared when products' usage was stopped, and did not re-occur when products were restarted. Final action taken with the products was not reported.</p> <p>The events resolved on 02-Dec-2015.</p> <p>No further information is expected. Case closed.</p>								
Yes (1)								
PMI000323	SWITZERLAND Spontaneous	33 Years Female	THS 2.4 Marlboro (White/Blue) / N/A 10 DF [10 DF-qd]	Respiratory	13-JUL-2015 to Unknown	13-SEP-2015 13-SEP-2015	After having taken one or two puffs on my IQOS, I lost consciousness [LOSS OF CONSCIOUSNESS] Y/Y/Y The same day in the evening, I took one or two puffs and I got sick again / She didn't lose consciousness like the first time, but she felt dizzy [DIZZINESS] N/N/Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 14-Sep-2015</p> <p>Case Followup Receipt Date: 14-Sep-2015 00:00</p> <p>Event Intensity: Severe Severe</p> <p>Case Comment Text: Loss of consciousness was assessed as serious (medically significant event), and Dizziness was assessed as non-serious.</p> <p>Loss of consciousness is unlisted and Dizziness is listed, as per the Reference Safety Information (i.e. IB).</p> <p>The information provided in this non-medically confirmed report is limited, particularly regarding the relevant medical history, concomitant medications, and treatment administered. Although the reported adverse events have occurred after two months of daily product usage, considering the suggestive temporal sequence of events on the onset day, a causal relationship between the use of the product in question and the occurrence of the reported adverse events cannot be excluded and, therefore, is assessed as possible.</p> <p>Case Narrative: Verbatim: After having taken one or two puffs on my IQOS (heatstick menthol flavour), I lost consciousness. The same day, in the evening, I took one or two puffs and I got worried about the product.</p> <p>Spontaneous case report received from a consumer in Switzerland.</p> <p>INITIAL INFORMATION RECEIVED ON 14-Sep-2015 and transferred to Safety department on the same day.</p> <p>This report concerns a 33-year-old female consumer who used THS 2.4 Marlboro Menthol (code 1YMSJLXRWSCJ) since 13-Jul-2015.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day). In addition, it was reported that the consumer used 10 heatsticks per day on average, ex (discrepant information provided).</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spont All THS Menthol

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 13-Sep-2015, the consumer lost consciousness after having taken one or two puffs of the product. On the same day, in the evening, she took one or two puffs and got sick.</p> <p>The severity of the adverse events was reported as severe. The events were considered to be serious (medically significant). The consumer required medical emergency intervention.</p> <p>It was reported that the problem improved when usage of the product was stopped and returned when use of the product was restarted. It was not reported if the product use was definitively stopped due to the events.</p> <p>The outcome of the events was reported as not resolved.</p> <p>Follow-up information is expected.</p> <p>FOLLOW-UP INFORMATION was provided to Safety department on 26-Oct-2015, with same initial receipt date than the initial report (14-Sep-2015).</p> <p>Verbatim: She didn't lose consciousness like the first time, but she felt dizzy.</p> <p>A more detailed description of the event initially reported as "got sick again" was provided: The consumer did not lose consciousness like the first time but she felt dizzy.</p> <p>It was confirmed that the consumer went to see a doctor following the events.</p> <p>The consumer used heatsticks exclusively.</p> <p>It was clarified that the event occurred after two or three puffs in the evening (second time).</p> <p>Outcome of the events and action taken with product at time of follow-up was not provided.</p> <p>No further information is expected. Case closed.</p>						

Total number of case entries printed: 30

Total number of cases printed: 30

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Advanced Condition used in this report:

Advanced Condition: Ingredient iQOS (unspecified) (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

iQOS (unspecified)

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: iQOS (unspecified) (Created by nicole.miller)

Selection Criteria:

Product Name equal to iQOS (unspecified)

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 (45)								
PMI000417	ITALY Spontaneous	46 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory		2015	it provokes slightly lower voice [DYSPHONIA] N / Y / Y	Unknown
		Case Initial Receipt Date:	09-Sep-2015					
		Event Intensity:	Unknown					
		Case Narrative:	Verbatim: it provokes slightly lower voice					
			Spontaneous case report received from a consumer in Italy.					
			INITIAL INFORMATION RECEIVED ON 09-Sep-2015 and transferred to Safety department on 15-Sep-2015.					
			This report concerns a 46-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.					
			No medical history was reported. No concomitant medication was reported.					
			No information on smoking habits was reported (for conventional cigarettes and for heatsticks).					
			On an unspecified date the consumer experienced lowered voice. The consumer reported that he finds the product perfect. He mentioned that it provokes slightly lower voice if 14 heatsticks are exceeded.					
			The severity of the event was not reported. The event was considered to be non-serious.					
			The outcome of the event was not reported.					
			Action taken with the product was not reported.					
			No further information is expected. Case closed.					
PMI000418	ITALY Spontaneous	28 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory	MAR-2015 Ongoing	2015	he has throat discomfort [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
		Case Initial Receipt Date:	11-Jun-2015					
		Event Intensity:	Unknown					
		Case Narrative:	Verbatim: he has throat discomfort					
			Spontaneous case report received from a consumer in Italy.					
			INITIAL INFORMATION RECEIVED ON 11-Jun-2015 and transferred to Safety department on 15-Sep-2015.					
			This report concerns a 28-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date (it was reported that the consumer had been using the product for 3 months, at time of reporting).					
			No medical history was reported. No concomitant medication was reported.					
			No information on smoking habits was reported (for conventional cigarettes or for heatsticks).					
			On an unspecified date, the consumer experienced throat discomfort.					

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The severity of the event was not reported. The event was considered to be non-serious.								
The outcome of the event was not reported.								
The consumer mentioned that he would be continuing to use the product.								
No further information is expected. Case closed.								
PMI000419	ITALY Spontaneous	27 Years Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			She has suffered from cough since he has started to use iQOS [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 27-May-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: She has suffered from cough since she has started to use iQOS								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 27-May-2015 and transferred to Safety department on 15-Sep-2015.								
This report concerns a 27-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes or for heatsticks).								
On an unspecified date, the consumer experienced coughing. The consumer reported that she has been suffering from cough since she has started to use iQOS.								
The severity of the event was not reported. It was reported that the consumer had a medical check. The event was considered to be non-serious.								
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000420	ITALY Spontaneous	49 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			it caused me some headache [HEADACHE] N / N / Y it lasted a short time [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 21-May-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: it caused me some headache; it lasted a short time								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 21-May-2015 and transferred to Safety department on 15-Sep-2015.								
This report concerns a 49-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes or for heatsticks).</p> <p>On an unspecified date, the consumer experienced headache. The consumer also reported that "it lasted a short time".</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Usage of the product was discontinued.</p> <p>No further information is expected. Case closed.</p>							
PMI000421	ITALY Spontaneous	58 Years Female	iQOS (unspecified) / N/A Respiratory UNK [UNK]			it causes nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-May-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: it causes nausea</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 04-may-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 58-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes or for heatsticks).</p> <p>On an unspecified date, the consumer experienced nausea. The consumer suggested that maybe it was her dragging too much.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>The usage of the product was discontinued.</p> <p>No further information is expected. Case closed.</p>							
PMI000422	ITALY Spontaneous	70 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK]			it causes cough [COUGH] N / N / Y believes it is a bit too strong [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 20-Apr-2015</p> <p>Event Intensity: Unknown</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: it causes cough; believes it is a bit too strong</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 70-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes or for heatsticks).</p> <p>On an unspecified date, the consumer experienced cough. The consumer also reported that he believed that the product is a bit too strong. The consumer still thinks that taking 12/14 drags are less than one cigarette.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>							
PMI000423	ITALY Spontaneous	52 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK]			I have some issues with my gums [GINGIVAL DISORDER] N / Y / Y self-cleaning should be automatic and planned; the way it is now it is uncomfortable [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Apr-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: I have some issues with my gums; Self-cleaning should be automatic and planned, the way it is now it is uncomfortable</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Apr-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 52-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced issues with his gums. He reported that he did not know if they were caused by iQOS or not. In addition, he consumer mentioned that the self-cleaning should be automatic and planned, as it was uncomfortable the way it was.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000424	ITALY Spontaneous	53 Years Male	iQOS (unspecified) / N/A UNK [UNK]				it causes a bit of throat ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 18-Mar-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: it causes a bit of throat ache								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 18-Mar-2015 and transferred to Safety department on 15-Sep-2015.								
This report concerns a 53-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								
On an unspecified date, the consumer experienced throat ache. The consumer reported he didn't use the product a lot due to the throat ache it caused.								
The severity of the event was not reported. The event was considered to be non-serious.								
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000425	ITALY Spontaneous	23 Years Female	iQOS (unspecified) / N/A Respiratory UNK [UNK]				during use, strong headaches occur [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 15-Sep-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: during use, strong headaches occur								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON an unspecified date and transferred to Safety department on 15-Sep-2015.								
This report concerns a 23-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 an unspecified date, the consumer experienced strong headaches during use.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000426	ITALY Spontaneous	47 Years Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			sometimes I get a shot of dry cough while using it [COUGH] N / N / Y it burns [PRODUCT PHYSICAL ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 15-Sep-2015 Event Intensity: Unknown Unknown Case Narrative: Verbatim: sometimes I get a shot of dry cough while using it, and it burns</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED on an unknown date and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 47-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer reported that she was also using conventional cigarettes.</p> <p>On unspecified dates, the consumer experienced dry cough, and the product was burning.</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the product was not reported. The consumer stated that she prefers the "Essence" .</p> <p>No further information is expected. Case closed.</p>								
PMI000427	ITALY Spontaneous	48 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			When I use iQOS, it stings my throat [OROPHARYNGEAL PAIN] N / N / Y Some HTS stop working after a few drags [DEVICE MALFUNCTION] N / Y / N	Unknown
<p>Case Initial Receipt Date: 15-Sep-2015 Event Intensity: Unknown</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 I use iQOS, it stings my throat. Some heatsticks (HTS) stop working after a few drags.</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED on an unknown date and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 48-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced stinging in throat when using the product. In addition, the consumer reported that some heatsticks stop working after a few drags.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000428	ITALY Spontaneous	36 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			After using it for a month, I had throat discomfort [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 27-Feb-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: After using it for a month, I had throat discomfort</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 27-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 36-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced throat discomfort. The consumer reported this occurred after having used the product for one month.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Usage of the product was discontinued.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000429	ITALY Spontaneous	49 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK]			once, I had glands discomfort [UNEVALUABLE EVENT] N / Y / Y I am not satisfied with the brushes, they don't get to the end of the foil [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 25-Feb-2015</p> <p>Case Narrative: Verbatim: once, I had glands discomfort: I am not satisfied with the brushes, they don't get to the end of the foil.</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 25 Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 49-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced glands discomfort (not further specified). In addition, the consumer reported that he was not satisfied with the brushes, and didn't go to the end of the foil.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>At the time of the report the consumer was doing fine and did not want to stop using the product.</p> <p>No further information is expected. Case closed.</p>							
PMI000430	ITALY Spontaneous	50 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK]			my tongue stings a bit, at times [GLOSSODYNIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 19-Feb-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: my tongue stings a bit, at times</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 50-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The consumer reported that he uses about one pack of Heatsticks per day.</p> <p>The consumer reported that his tongue stings a bit, at times (dates not specified). As per reporter, it was maybe due to the fact that he used a lot of Heatsticks. The consumer mentioned that he replaced the kit twice, and once only the charger, but that he liked the product, and that conventional cigarettes bother him.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not reported.								
Product use was continued.								
No further information is expected. Case closed.								
PMI000431	ITALY Spontaneous	50 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			It causes headache [HEADACHE] N / N / Y	Unknown
Case Initial Receipt Date: 13-Feb-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: It causes headache								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 13-Feb-2015 and transferred to Safety department on 15-Sep-2015.								
This report concerns a 50-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								
On an unspecified date, the consumer experienced headache.								
The severity of the event was not reported. The event was considered to be non-serious.								
The outcome of the event was not reported.								
Action taken with the product was not reported, although consumer mentioned that he would return the product.								
No further information is expected. Case closed.								
PMI000432	ITALY Spontaneous	67 Years Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			It causes discomfort with the bronchial tube [CHEST DISCOMFORT] N / N / Y the tobacco is too aggressive [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 15-Sep-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: It causes discomfort with the bronchial tube; the tobacco is too aggressive								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON an unspecified date and transferred to Safety department on 15-Sep-2015.								
This report concerns a 67-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The consumer was a smoker.</p> <p>On an unspecified date, the consumer experienced discomfort with the bronchial tube. The consumer reported that the tobacco is too aggressive and she would like a lighter aroma, therefore, she was alternating heatsticks and conventional light cigarettes.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000433	ITALY Spontaneous	49 Years	iQOS (unspecified) / N/A UNK [UNK]	Respiratory	NOV-2014 to Unknown		<p>at times, it causes itch [PRURITUS] N / Y / Y</p> <p>at times, starts coughing after the use and throat is dry [DRY THROAT] N / Y / Y</p> <p>at times, starts coughing after the use and throat is dry [COUGH] N / N / Y</p>	Unknown
<p>Case Initial Receipt Date: 12-Feb-2015 Event Intensity: Unknown Unknown Unknown Case Narrative: Verbatim: at times, it causes itch; at times, starts coughing after the use and throat is dry</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 12-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 49-year-old consumer (gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date in Nov-2014.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>The consumer reported that, at times, it causes itch and, at times, the consumer starts coughing after the use, and throat is dry (dates unspecified).</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000434	ITALY Spontaneous	57 Years	iQOS (unspecified) / N/A Respiratory UNK [UNK]			Essence stings her throat and it causes a bit of throat ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Case Initial Receipt Date: 09-Feb-2015 Event Intensity: Unknown Case Narrative: Verbatim: Essence stings the throat and it causes a bit of throat ache</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 57-year-old consumer (gender not reported) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date. Of note, the consumer indicated that he/she doesn't like "balance" while the events were occurring with "essence" (possibly THS 2.2 Marlboro Essence (Blue)).</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date the consumer experienced stinging in throat and throat ache. The consumer also mentioned that the device is appreciated and had questions on self-cleaning and existence of other versions.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>It was reported that the use of the product was interrupted.</p> <p>No further information is expected. Case closed.</p>							
PMI000435	ITALY Spontaneous	49 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK]			the iQOS has overheated and caused discomfort to his tonsils [OROPHARYNGEAL DISCOMFORT] N / Y / Y the iQOS has overheated and caused discomfort to his tonsils [DEVICE MALFUNCTION] N / Y / N	Unknown
<p>Case Initial Receipt Date: 05-Feb-2015 Event Intensity: Unknown Case Narrative: Verbatim: the iQOS has overheated and caused discomfort to his tonsils</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 05-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 49-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p>							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 an unspecified date, the iQOS has overheated and caused discomfort to the consumer's tonsils. The consumer reported that he bought another one which did not cause this.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000436	ITALY Spontaneous	50 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			it dries up my throat but I feel well if I drink [DRY THROAT] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Sep-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: it dries up my throat</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON an unspecified date and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 50-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced dry throat, but according to the consumer, he felt well if he was drinking.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000437	ITALY Spontaneous	54 Years Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			maybe it causes sore throat [OROPHARYNGEAL PAIN] N / N / Y when I turn it on, a bad smell comes out [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Feb-2015</p> <p>Event Intensity: Unknown</p> <p>Case Narrative: Verbatim: maybe it causes sore throat; when I turn it on, a bad smell comes out</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 04-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 54-year-old female consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>The consumer stated that maybe she was allergic to propylene glycol. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>The consumer reported that, when she turns the heatsticks on, a bad smell comes out. She also reported that maybe it caused sore throat, al hough less than with electronic cigarette.</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000438	ITALY Spontaneous	36 Years	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			Does not feel well [MALAISE] N / Y / Y tongue gets swollen [SWOLLEN TONGUE] N / Y / Y it creates mouth ulcer [MOUTH ULCERATION] N / Y / Y does not like taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 29-Jan-2015 Event Intensity: Unknown Unknown Unknown Case Narrative: Verbatim: Does not feel well; does not like taste; tongue gets swollen; it creates mouth ulcer</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 29-Jan-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 36-year-old consumer (gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer did not feel well, experienced swollen tongue and reported that it created mouth ulcer. In addi ion, the consumer did not like the taste.</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>It was reported that the consumer stopped the use of the product.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000439	ITALY Spontaneous	49 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			nausea [NAUSEA] N / N / Y the original iQOS got broken [DEVICE MALFUNCTION] N / Y / N	Unknown
<p>Case Initial Receipt Date: 21-Jan-2015 Event Intensity: Unknown Case Narrative: Verbatim: nausea; the original iQOS got broken</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 21-Jan-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 49-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced nausea. The consumer reported that the original iQOS got broken and that he bought a new one.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Usage of the product was discontinued. The consumer returned the kit, also the functioning one.</p> <p>No further information is expected. Case closed.</p>								
PMI000442	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			has been suffering from heavy cough since started using iQOS [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 24-Mar-2015 Event Intensity: Unknown Case Narrative: Verbatim: has been suffering from heavy cough since started using iQOS</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 24-Mar-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>The consumer reported that he had been suffering from heavy cough since he/she started using iQOS.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000443	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			throat ache [OROPHARYNGEAL PAIN] N / N / Y nausea [NAUSEA] N / N / Y dizziness [DIZZINESS] N / N / Y	Unknown
Case Initial Receipt Date: 17-Mar-2015								
Event Intensity: Unknown								
Unknown								
Case Narrative: Verbatim: throat ache, nausea, dizziness								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 17-Mar-2015 and transferred to Safety department on 15-Sep-2015.								
This report concerns a consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								
On an unspecified date, the consumer experienced throat ache, nausea and dizziness.								
The severity of the events was not reported. The events were considered to be non-serious.								
The outcome of the events was not reported.								
Usage of the product was discontinued.								
No further information is expected. Case closed.								
PMI000444	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			cough while using it [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 13-Mar-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: coughs while using it								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 13-Mar-2015 and transferred to Safety department on 15-Sep-2015.								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced cough while using the product.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000445	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			it was causing stomach problems [GASTRIC DISORDER] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 10-Feb-2015 Event Intensity: Unknown Case Narrative: Verbatim: it was causing stomach problems</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 10-Feb-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer returned the product, as it was causing stomach problems.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>The use of the product was stopped, as he consumer returned the product and refused to buy another one.</p> <p>No further information is expected. Case closed.</p>								
PMI000446	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			It seems that iQOS causes stomach ache [ABDOMINAL PAIN UPPER] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 15-Sep-2015 Event Intensity: Unknown</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: It seems that IQOS causes stomach ache</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON an unspecified date and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified IQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced stomach ache.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000447	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 22-Jan-2015 Event Intensity: Unknown Case Narrative: Verbatim: cough	Respiratory			cough [COUGH] N / N / Y	Unknown
<p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 22-Jan-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified IQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced cough.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000448	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 19-Jan-2015 Event Intensity: Unknown Case Narrative: Verbatim: had tachycardia when he/she used iQOS.	Respiratory			had tachycardia when used iQOS [TACHYCARDIA] N / Y / Y	Unknown
<p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 19-Jan-2015 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced tachycardia.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Usage of the product was discontinued.</p> <p>No further information is expected. Case closed.</p>								
PMI000449	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 25-Nov-2014 Event Intensity: Unknown Case Narrative: Verbatim: suffers from tachycardia after use	Respiratory			suffers from tachycardia after use [TACHYCARDIA] N / Y / Y	Unknown
<p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Nov-2014 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a consumer (age and gender unspecified) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer suffered from tachycardia after use.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Usage of the product was discontinued.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.								
PMI000450	JAPAN Spontaneous	55 Years Male	iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 25-Apr-2015 Case Followup Receipt Date: 26-Apr-2015 00:00 Event Intensity: Unknown Case Narrative: Verbatim: sick feeling	Respiratory			sick feeling [MALAISE] N / Y / Y	Unknown
<p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Apr-2015 and 26-Apr-2015 and transferred to Safety department on 15-Sep-2015 and 15-Dec-2015, respectively.</p> <p>This report concerns a 55-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced sick feeling.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with use of the product was not reported.</p>								
No further information is expected. Case closed.								
PMI000451	JAPAN Spontaneous	66 Years Male	iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 24-Nov-2014 Event Intensity: Unknown Case Narrative: Verbatim: vomiting	Respiratory			vomiting [VOMITING] N / N / Y	Unknown
<p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 24-Nov-2014 and transferred to Safety department on 15-Sep-2015.</p> <p>This report concerns a 66-year-old male who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced vomiting. It was reported hat the consumer tried two heatsticks and the second one resulted in vomiting.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000453	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 10-Dec-2015 Event Intensity: Unknown Case Narrative: Verbatim: IQOS causes him to have headaches.	Respiratory			IQOS causes him to have headaches [HEADACHE] N / N / Y	Unknown
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 10-Dec-2015 and transferred to Safety department on 15-Dec-2015.								
This report concerns a consumer (age and gender unspecified) who started using an unspecified IQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								
On an unspecified date, the consumer experienced headaches.								
The severity of the event was not reported. The event was considered to be non-serious.								
The outcome of the event was not reported.								
Action taken with usage of the product was not reported.								
No further information is expected. Case closed.								
PMI000454	ITALY Spontaneous	44 Years Male	iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 15-Dec-2015 Event Intensity: Unknown Case Narrative: Verbatim: Since using IQOS, has shortness of breath.	Respiratory			Since using IQOS has shortness of breath [DYSPNOEA] N / Y / Y	Unknown
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON an unspecified date and transferred to Safety department on 15-Dec-2015.								
This report concerns a 44-year-old male consumer who started using an unspecified IQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 an unspecified date, since using iQOS, the consumer experienced shortness of breath.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with usage of the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000455	ITALY Spontaneous	31 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			throat is a little scratchy [THROAT IRRITATION] N / Y / Y it has a bad smell, pasta and beans/feet [PRODUCT ODOUR ABNORMAL] N / Y / N has more difficulty inser ing some HTS [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 25-Nov-2015 Event Intensity: Unknown Case Narrative: Verbatim: Throat is a little scratchy; it has a bad smell, pasta and beans/feet; sometimes, has more difficulty inserting some HTS.</p> <p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Nov-2015 and transferred to Safety department on 15-Dec-2015.</p> <p>This report concerns a 31-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced little scratchy throat. The consumer also reported that the product has a bad smell, described as pasta and bean/feet. In addition, the consumer reported that, sometimes, he has more difficulty inserting some HTS (not further specified, presumably, heatsticks), but likes those HTS better.</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Usage of the product continued without change. Consumer indicated that he did not want to quit.</p> <p>No further information is expected. Case closed.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000456	ITALY Spontaneous	56 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			non-specific physical problems [ADVERSE EVENT] N / Y / Y	Unknown
Case Initial Receipt Date: 06-Nov-2015 Case Narrative: Verbatim: non-specific physical problems Spontaneous case report received from a consumer in Italy. INITIAL INFORMATION RECEIVED ON 06-Nov-2015 and transferred to Safety department on 15-Dec-2015. This report concerns a 56-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (for conventional cigarettes and for heatsticks). On an unspecified date, the consumer experienced unspecified physical problems. The consumer said that the tobacco for IQOS is bad for you because he has had non-specific physical problems. The severity of the event was not reported. The event was considered to be non-serious. The outcome of the event was not reported. Action taken with the product was not reported. No further information is expected. Case closed.								
PMI000457	ITALY Spontaneous		iQOS (unspecified) / N/A UNK [UNK]	Respiratory			inhaling hurts his throat, makes it burn [THROAT IRRITATION] N / Y / Y inhaling hurts his throat, makes it burn [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown Unknown Case Narrative: Verbatim: inhaling hurts his throat, makes it burn Spontaneous case report received from a consumer in Italy. INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and transferred to Safety department on 15-Dec-2015. This report concerns a consumer (gender and age not reported) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (for conventional cigarettes and for heatsticks). The consumer reported that inhaling hurt his throat, makes it burn (date of event not specified).								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The severity of the events was not reported. The events were considered to be non-serious.								
The outcome of the events was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000458	ITALY Spontaneous	Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			heatsticks hurt her throat [OROPHARYNGEAL PAIN] N / N / Y heatsticks are too intense [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 13-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: heat-stick are too intense, they hurt her throat								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 13-Oct-2015 and transferred to Safety department on 15-Dec-2015.								
This report concerns a female consumer (age not reported) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (for conventional cigarettes and for heatsticks).								
The consumer reported that the heat-stick are too intense, they hurt her throat (date of event not specified). In addition, the consumer stated that she would like lighter heatsticks.								
The severity of the event was not reported. The event was considered to be non-serious.								
The outcome of the event was not reported.								
Action taken with the product was not reported.								
No further information is expected. Case closed.								
PMI000459	ITALY Spontaneous	Female	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			it burns her throat when she uses iQOS [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 09-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: it burns her throat when she uses iQOS								
Spontaneous case report received from a consumer in Italy.								
INITIAL INFORMATION RECEIVED ON 09-Oct-2015 and transferred to Safety department on 15-Dec-2015.								
This report concerns a female consumer (age not reported) who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced burning of throat when using iQOS.</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000460	ITALY Spontaneous	38 Years Male	iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 28-Sep-2015 Case Narrative: Verbatim: physical effects	Respiratory			physical effects [UNEVALUABLE EVENT] N / Y / Y	Unknown
<p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 28-Sep-2015 and transferred to Safety department on 15-Dec-2015.</p> <p>This report concerns a 38-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced physical effects (not further specified).</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000461	ITALY Spontaneous	60 Years Male	iQOS (unspecified) / N/A UNK [UNK] Case Initial Receipt Date: 25-Sep-2015 Event Intensity: Unknown Case Narrative: Verbatim: potential headaches	Respiratory			potential headaches [HEADACHE] N / N / Y	Unknown
<p>Spontaneous case report received from a consumer in Italy.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Sep-2015 and transferred to Safety department on 15-Dec-2015.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose 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 60-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced headaches (reported as potential headaches).</p> <p>The severity of the event was not reported. The event was considered to be non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000462	JAPAN Spontaneous	35 Years Male	iQOS (unspecified) / N/A UNK [UNK]	Respiratory			sick feeling [MALAISE] N / Y / Y sleepy [SOMNOLENCE] N / Y / Y headache [HEADACHE] N / N / Y sick to his stomach [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 15-May-2015</p> <p>Event Intensity: Unknown Unknown Unknown Unknown</p> <p>Case Narrative: Verbatim: consumer feels headache, sick feeling, sick to his stomach, and sleepy.</p> <p>Spontaneous case report received from a consumer in Japan.</p> <p>INITIAL INFORMATION RECEIVED ON 15-May-2015 and transferred to Safety department on 15-Dec-2015.</p> <p>This report concerns a 35-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (for conventional cigarettes and for heatsticks).</p> <p>On an unspecified date, the consumer experienced headache, sick feeling, sick to his stomach, and felt sleepy.</p> <p>The severity of the events was not reported. The events were considered to be non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the product was not reported.</p>								

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.							
PMI000471	ITALY Spontaneous	Male	iQOS (unspecified) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 18-Dec-2015 Event Intensity: Unknown Case Narrative: Verbatim: IQOS irritates his throat			IQOS irritates his throat [THROAT IRRITATION] N / Y / Y	Unknown
Spontaneous case report received from a consumer in Italy.							
INITIAL INFORMATION RECEIVED ON 18-DEC-2015 and transferred to Safety department on 15-JAN-2016.							
This report concerns a male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.							
No medical history was reported. No concomitant medication was reported.							
No information on smoking habits was provided (for conventional cigarettes and for heatsticks).							
From an unspecified date, iQOS irritated the consumer's throat.							
The severity of the event was not reported. The event was considered to be non-serious.							
The outcome of the event was not reported.							
Action taken with the product was not reported.							
No further information is expected. Case closed.							
PMI000472	ITALY Spontaneous	42 Years Male	iQOS (unspecified) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 17-Dec-2015 Event Intensity: Unknown Case Narrative: Verbatim: This is causing a little bit of a cough / Often, there is tobacco that remains inside			This is causing a little bit of a cough [COUGH] N / N / Y Often, there is tobacco that remains inside [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Spontaneous case report received from a consumer in Italy.							
INITIAL INFORMATION RECEIVED ON 17-DEC-2015 and transferred to Safety department on 15-JAN-2016.							
This report concerns a 42-year-old male consumer who started using an unspecified iQOS product (Batch/Kit number not provided) on an unspecified date.							
No medical history was reported. No concomitant medication was reported.							
Information on smoking habits was not reported for conventional cigarettes or for heatsticks (HTS).							
The consumer stated that he would like the HTS in Livorno. But, he also reported that this (presumably the heatsticks) was causing a little bit of a cough (date unspecified). He reported							

Cumulative listing up to 31-Dec-2015 Serious/Non-Serious Spontaneous iQOS Unspecified

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
								that often there is tobacco that remains inside.
								The severity of the events was not reported. The events were considered to be non-serious.
								The outcome of the events was not reported.
								Action taken with the product was not reported.
								No further information is expected. Case closed.
Total number of case entries printed: 45								
Total number of cases printed: 45								