



PMI RESEARCH & DEVELOPMENT

Safety Summary Report

Passive Safety Surveillance for Perception & Behavior Assessment Study n° THS-PBA-07-US

Appendix 4 Summary Tabulation of Adverse Events

Report Number:	PMI_SURV_2016_SSR02
Study Title:	Actual Use Study of THS 2.2 – THS-PBA-07-US
Study ID:	THS-PBA-07-US
Safety ID	THS-PBA-07-US_PSS
Products Name:	Tobacco Heating System 2.2 / Regular and Menthol
Passive Safety Surveillance by:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Version:	Final v 2.0
Date:	30-Aug-2016
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Summary Tabulation of All Events from Premarket Study THS-PBA-07-US

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 18-Apr-2016

Advanced Condition used in this report:

Advanced Condition: JCo - Study THS-PBA-07-US minus Non-Valid QS (Created by Joshua Cox)

Query Set Selection Criteria:

JCo - Study ID = THS-PBA-07-US MINUS

Case Classification = Non Valid Case

Advanced Conditions used in this query set:

Advanced Condition: JCo - Study ID = THS-PBA-07-US (Created by Joshua Cox)

Selection Criteria:

Study ID equal to THS-PBA-07-US

Advanced Condition: Case Classification = Non Valid Case (Created by nicole.miller)

Selection Criteria:

Case Classification equal to Non valid case

Summary Tabulation of All Events from Premarket Study THS-PBA-07-US

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 18-Apr-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Gastrointestinal disorders	Abdominal discomfort	3	0	3
	Diarrhoea	1	0	1
	Dyspepsia	1	0	1
	Frequent bowel movements	1	0	1
	Lip blister	1	0	1
	Nausea	6	0	6
	Oral discomfort	3	0	3
	Retching	2	0	2
	Vomiting	1	0	1
	SubTotal	19	0	19
General disorders and administration site conditions	Adverse event	0	1	1
	Chest discomfort	1	0	1
	Chest pain	3	0	3
	Device defective	1	0	1
	Device difficult to use	6	0	6
	Device issue	4	0	4
	Feeling hot	1	0	1
	Malaise	7	0	7
	Product odour abnormal	1	0	1
	Product quality issue	5	0	5
	Product taste abnormal	2	0	2
	SubTotal	31	1	32

Summary Tabulation of All Events from Premarket Study THS-PBA-07-US

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 18-Apr-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Infections and infestations	Bronchitis	0	1	1
	Cholecystitis infective	0	1	1
	Ear infection	0	1	1
	Influenza	1	0	1
	Nasopharyngitis	2	0	2
	Osteomyelitis	0	1	1
	Pharyngitis streptococcal	1	0	1
	Pneumonia	0	1	1
	Respiratory tract infection	1	0	1
	Sepsis	0	1	1
	Sinusitis	1	0	1
	SubTotal	6	6	12
Injury, poisoning and procedural complications	Accident	0	1	1
	Burns second degree	1	0	1
	Concussion	0	1	1
	Head injury	0	1	1
	Joint injury	0	1	1
	Limb injury	0	1	1
	Maternal exposure timing unspecified	1	0	1
	Muscle strain	0	1	1
	Nerve injury	1	1	2

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For All Products (Number of Events)

For the Period 01-Jan-1900 Through 18-Apr-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Injury, poisoning and procedural complications	Respiratory fume inhalation disorder	1	0	1
	Road traffic accident	0	1	1
	Skeletal injury	0	1	1
	Skin abrasion	0	1	1
	Thermal burn	1	0	1
	Wrong technique in product usage process	1	0	1
	SubTotal	6	10	16
Nervous system disorders	Dizziness	4	0	4
	Dysgeusia	2	0	2
	Headache	13	0	13
	Hyperaesthesia	1	0	1
	Loss of consciousness	1	0	1
	Neuralgia	1	0	1
	Somnolence	1	0	1
	SubTotal	23	0	23
Psychiatric disorders	Mental status changes	1	0	1
	SubTotal	1	0	1
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	0	1

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For All Products (Number of Events)

For the Period 01-Jan-1900 Through 18-Apr-2016

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Respiratory, thoracic and mediastinal disorders	Cough	3	0	3
	Dysphonia	1	0	1
	Dyspnoea	1	0	1
	Laryngeal discomfort	1	0	1
	Oropharyngeal pain	2	0	2
	Pharyngeal disorder	1	0	1
	Sputum discoloured	1	0	1
	Throat irritation	3	0	3
	Tonsillar cyst	0	1	1
	SubTotal	14	1	15
Skin and subcutaneous tissue disorders	Decubitus ulcer	1	0	1
	SubTotal	1	0	1
Surgical and medical procedures	Hospitalisation	0	1	1
	SubTotal	0	1	1
Vascular disorders	Hypotension	1	0	1
	SubTotal	1	0	1
Total		102	19	121