



PMI RESEARCH & DEVELOPMENT

# Safety Update Report

## Tobacco Heating System / iQOS

### Appendix 5 Cumulative Summary Tabulation of Serious Adverse Events from Clinical Studies

**Report Number:** PMI\_SURV\_2016\_SUR01

**International Birth Date:** 04 Nov 2014

**Interval Covered:** 01 May 2015 to 31 Dec 2015

**Products Covered:** Tobacco Heating System 2.2 and 2.4 / All variants

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PMI Reduced Risk Products  
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### Cumulative Summary Tabulation of Serious Adverse Events from Clinical Studies

System Organ Class	Total				Number of unique events
Preferred Term	THS products	CC	SA	Enrolled but not randomized	
<b>Blood and lymphatic system disorders</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Anaemia	1	0	0	0	1
<b>General disorders and administrations site conditions</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Death [Death due to acute and chronic alcohol abuse] <sup>1</sup>	1	0	0	0	1
<b>Infections and infestations</b>	<b>0</b>	<b>2</b>	<b>0</b>	<b>0</b>	<b>3</b>
Pyelonephritis acute	0	1	0	0	1
Sinusitis	0	0	0	1	1
Urosepsis	0	1	0	0	1
<b>Injury, poisoning and procedural complications</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Head injury	1	0	0	0	1

<sup>1</sup> PT changed after DLP from [Death] to [Death due to acute and chronic alcohol abuse]

THS = Tobacco Heating System; CC = Conventional Cigarettes; SA = Smoking Abstinence.

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System Organ Class	Total				Number of unique events
Preferred Term	THS products	CC	SA	Enrolled but not randomized	
<b>Metabolism and nutrition disorders</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
Diabetic ketoacidosis	0	0	0	1	1
<b>Muskuloskeletal and connective tissue disorders</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>
Vertebral osteophyte	0	1	0	0	1
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>
Metastases to small intestine	1	0	0	0	1
Papillary thyroid cancer	0	1	0	0	1
<b>Nervous system disorders</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>3</b>
Cervical myelopathy	0	1	0	0	1
Loss of consciousness	1	0	0	0	1
Seizure	1	0	0	0	1
<b>Renal and urinary disorders</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>
Nephrolithiasis	0	1	0	0	1
<b>TOTAL</b>	<b>6</b>	<b>6</b>	<b>0</b>	<b>2</b>	<b>14</b>

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