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7 Scientific Studies and Analyses	Version 1.0

## Module 7 : Scientific Studies and Analyses

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## 1. INTRODUCTION

Scientific studies and analyses provided with the initial MRTPA and PMTA for the Authorized *IQOS* 2.4 System Holder and Charger (PM0000479 and MR0000133), *Marlboro HeatSticks* (PM0000424 - PM0000426 and MR0000059 - MR0000061) and the *IQOS* 3.0 System Holder and Charger (PM0000634 and MR0000192) remain valid and do not require reanalysis.

Thus, the entire Module 7 of the original MRTPAs for the authorized *IQOS* products with related appendices and data, and with subsequent amendments is cross-referenced in the context of this MRTPA renewal.

However, more data from postmarket studies conducted in the U.S. and in international countries have been collected by PMI since the issuance of the MRGOs. Those additional data and analysis have been summarized in the appropriate sections of the Module 6.

### 1.1. Aerosol Chemistry and Physics

PMP S.A. is not providing any new data with this renewal.

The entire Module 7 of the initial MRTPA and PMTA for the Authorized *IQOS* 2.4 System Holder and Charger (PM0000479 and MR0000133), *Marlboro HeatSticks* (PM0000424 - PM0000426 and MR0000059 - MR0000061) and the *IQOS* 3.0 System Holder and Charger (PM0000634 and MR0000192) with related appendices and data, and with subsequent amendments are cross-referenced in the context of this MRTPA renewal.

### 1.2. Non-Clinical

PMP S.A. is not providing any new data with this renewal.

The entire Module 7 of the initial MRTPA and PMTA for the Authorized *IQOS* 2.4 System Holder and Charger (PM0000479 and MR0000133), *Marlboro HeatSticks* (PM0000424 - PM0000426 and MR0000059 - MR0000061) and the *IQOS* 3.0 System Holder and Charger (PM0000634 and MR0000192) with related appendices and data are cross-referenced in the context of this MRTPA renewal.

### 1.3. Clinical Individual Health

#### 1.3.1. Overall Summary of Clinical Evidence

Additional findings are presented in [Appendix 7-a07-clin-ind-health-additional-studies](#) (paragraph 1.1.5 and 1.1.6)

#### 1.3.2. Literature Review on *IQOS* Use and Disease Risk

Results are presented in [Appendix 7-a08-ind-health-lit-review-results](#).

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#### **1.4. Clinical Population Health – Literature Review**

Publications (if not previously submitted) are presented as appendices to [section 9 Literature References](#).

Results are presented in [Appendix 7-a09-pop-health-lit-review-results](#).

#### **1.5. Effect on Tobacco Use Behavior Among Current Tobacco Users**

New data is presented in [section 6.2 Effect on Tobacco Use Behavior Among Current Tobacco Users](#), in [Appendix 7-a01-description-adult-IQOS-owners-panels](#) and [Appendix 7-a02-all-contries-trend-analysis](#) and Publications (if not already submitted) are presented as appendices to [section 9 Literature References](#).

#### **1.6. Effect on Tobacco Use Initiation Among Non-Users**

New data is presented in [section 6.3 Effect on Tobacco Use Initiation Among Non-Users](#), in [Appendix 7-a03-P1-PMX-01-JP-study-report-year-5](#), [Appendix 7-a04-P1-PMX-02-IT-study-report-year-2](#) and Publications (if not already submitted) are presented as appendices to [section 9 Literature References](#).

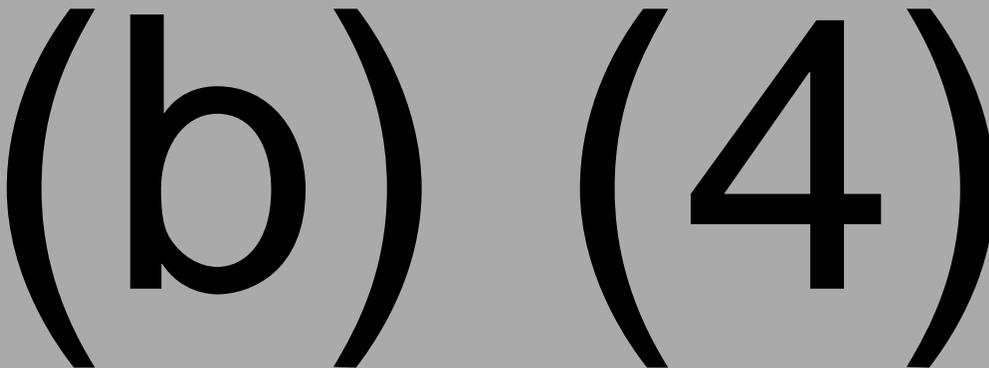
#### **1.7. Consumer Understanding and Perceptions**

New data is presented in [section 6.4 Consumer Understanding and Perceptions](#) and Publications (if not already submitted) are presented as appendices to [section 9 Literature References](#).

#### **1.8. Population Modelling and Analysis**

New data is presented in [section 6.5 Population Modelling and Analysis](#), in [Appendix 7-a05-transition-table](#) and Publications (if not already submitted) are presented as appendices to [section 9 Literature References](#).

#### **1.9. Computational toxicology**



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