Temporary Compliance Waiver Notice

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Module 6: Research

6.1 Summary of Health Risk Investigations

PMP S.A. is not providing any new information or data in the context of this supplemental MRTPA for the *IQOS* 3 System Holder and Charger.

The *IQOS* 3 System retains all functional elements of the *IQOS* 2.4 System and it is therefore comparable to the *IQOS* 2.4 System, as the three critical principles are preserved in the modified *IQOS* device: (i) System performance, (ii) System safety and (iii) Consumer behavior. Therefore, summaries of the evidence and data provided with the MRTPA for the *IQOS* 2.4 System (MR0000133) and with the supplemental PMTA for the *IQOS* 3 System (PM0000634) remain valid and do not require reanalysis or additional data.

Thus, the following sections of the MRTPA for the *IQOS* 2.4 System, with related appendices and data, and with subsequent amendments, provided prior to the issuance of the Modified Risk Granted Order – Exposure Modification, are cross-referenced in the context of this supplemental MRTPA:

Section 6.1	Health Risks of the Tobacco Product
Section 6.2	Effect on Tobacco Use Behavior Among Current Tobacco Users
Section 6.3	Effect on Tobacco Use Initiation Among Non Users
Section 6.4	Effect of Marketing on Consumer Understanding And Perceptions
Section 6.5	Effect on The Population as a Whole
Section 7.1	Product Analyses
Section 7.2	Pre-Clinical Studies
Section 7.3	Studies in Adult Human Subjects
Section 7.4	Population Health Impact Model
Section 7.5	Mechanistic and Systems Toxicology (Systox) Studies

Furthermore, the following sections of the supplemental PMTA for the *IQOS* 3 System, with related appendices and data, are cross-referenced in the context of this supplemental MRTPA:

Section 6.1 Summary of the Product Formulation

Section 6.2 Summary of Manufacturing

Section 6.3 Summary of Health Risk Investigations