Temporary Compliance Waiver Notice

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Module 8: Postmarket Information

8.1 Postmarket Surveillance and Studies (PMSS) Plan

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.

Upon issuance by FDA of the Modified Risk Granted Order (MRGO) – Exposure Modification the *IQOS* 3 System will be incorporated into the Postmarket Surveillance and Studies (PMSS) Plan implemented for the *IQOS* 2.4 System which was accepted by the FDA on February 24, 2021[1].

Overall, the PMSS Plan for the *IQOS* 3 System, as with the *IQOS* 2.4 System, will generally comprise the following activities:

(b) (4)

Reporting of *IQOS* Sales and Distribution Data to assist in assessing uptake of *IQOS*.

(2) Safety Surveillance

[1] Letter of February 24, 2021 (STN: PS0000042) confirming that the FDA completed its review of the PMP S.A.'s amendments and revised protocols for the proposed Postmarket Surveillance and Studies (PMSS) submission for the *IQOS* 2.4 System with 3 variants of Marlboro *HeatSticks* (MR0000059 - MR0000061 and MR0000133) without any concerns and that PMP S.A. may proceed with initiation of the studies.

Consistent with the program in place to support PMTA reporting, the PMSS program will continue to capture, assess and report adverse experiences associated with the use of the *IQOS* System. The safety surveillance system includes ongoing signal detection and evaluation, as well as mechanisms for safety data communication and reporting.

(3) Monitoring of New Studies.

Consistent with the program in place to support PMTA reporting, we will continue to monitor and report significant findings from published studies and results from our own research studies relevant to *IQOS* and consumer perceptions, behavior, health and safety.

(4) Update of the PMP S.A.'s population health impact model as new inputs are obtained from in-market U.S. data sources.

(5) When this data becomes available, computational toxicology assessment of aerosols to predict potential adverse effects in users before toxicity may be evident.

Based on the above, the PMSS Plan for the *IQOS* 2.4 System provided and discussed in the context of the original MRTPA remains equally valid for and applicable to the *IQOS* 3 System. Therefore, this part of the MRTPA for the *IQOS* 2.4 System is cross-referenced, *i.e.*, Module 8 "*Post-Market Assessment Program*" and PMSS Plan for the MR0000133 submitted to the FDA after the issuance of the MRGO – Exposure Modification for the *IQOS* 2.4 System.