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Module 6: Research

6.2 Conclusions

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. Scientific studies and analyses provided with the initial 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.

Based on the demonstrated comparability of the *IQOS* 3 System to the *IQOS* 2.4 System in terms of overall performance, patterns of use, minimal use among non-users of tobacco products (including young adults) and successful switching of adult smokers to this modified-risk tobacco product, the exposure modification order for the *IQOS* 3 System is equally appropriate to promote the public health and is expected to benefit the health of the population as a whole.

Overall, the scientific evidence presented for the *IQOS* 3 System, demonstrates that “*the IQOS system heats tobacco but does not burn it,*” “*this significantly reduces the production of harmful and potentially harmful chemicals,*” and “*scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.*”

Therefore, the following sections of the MRTPA for the *IQOS* 2.4 System, with related appendices and data and 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 6.1.6 Conclusions on Health Risk of the Tobacco Product
- Section 6.2.4 Overall Conclusions on Tobacco Use Behavior among Current Tobacco Users
- Section 6.3.3 Conclusions on the Effect of THS on Tobacco Use Initiation among Non-Users

Furthermore, Section 6.4 *Conclusions* of the supplemental PMTA for the *IQOS* 3 System is also cross-referenced.

Confidentiality Statement

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