

	Confidential
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Appendix G: Reporting Plan - U.S. IQOS® Sales & Distribution Data	Version 1.0

# **Appendix G:** **Reporting Plan - U.S. IQOS® Sales &** **Distribution Data**

Please find on the following pages details about reporting plan for U.S. IQOS® Sales & Distribution Data.

## **Confidentiality Statement**

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*Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International and/or Altria Client Services LLC.*

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## **IQOS® U.S. SALES AND DISTRIBUTION REPORTING PLAN**

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## **1 INTRODUCTION**

### **1.1 Background**

Philip Morris Products S.A. (PMP S.A.) developed the IQOS® Tobacco Heating System and Marlboro HeatSticks® (hereinafter referred to as IQOS®) as novel tobacco and nicotine-containing products with the potential to reduce harm or the risk of tobacco-related disease associated with smoking cigarettes. PMP S.A. submitted Modified Risk Tobacco Product Applications for IQOS® to the U.S. Food and Drug Administration (FDA) seeking authorization to market the products as modified risk tobacco products. On July 7, 2020, FDA issued a “Modified Risk Granted Orders – Exposure Modification” authorizing IQOS® to be marketed with a reduced exposure claim. The Orders are conditioned upon agreement to conduct Postmarket Surveillance and Studies (PMSS) in accordance with protocols approved by FDA. This document is prepared as part of the PMSS program for IQOS® pursuant to the Orders.

### **1.2 Rationale**

The Federal Food, Drug and Cosmetic Act (FDCA) directs the Food and Drug Administration (FDA) to condition an exposure modification order received under FDCA § 911(g)(2) on the MRTP applicants’ agreement to conduct PMSS (FDCA §§ 911(g)(2)(C)(ii)). “The outcomes evaluated in postmarket surveillance and studies should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use” (Food and Drug Administration, 2012). For this reason, ALCS<sup>1</sup> on behalf of the applicant, PMP S.A., plans to conduct certain components of PMSS to assess the effect of the MRTP among U.S. consumers. The program will consist of a collection of data over time that supports an assessment of IQOS® in the postmarket setting.

The Sales and Distribution Reporting Plan is one component of the postmarket surveillance program. Specifically, it describes the procedures for monitoring and reporting IQOS® sales and distribution in the U.S by product, major markets, and channels where sold. This information is currently reported in support of the IQOS® PMTA marketing order and is intended to be used for the IQOS® MRTP reporting as well.

## **2 PURPOSE AND OBJECTIVES**

### **2.1 Purpose**

The purpose of this reporting plan is to describe how IQOS® U.S. sales and distribution data will be collected, monitored and reported in support of MRTP post-market surveillance.

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<sup>1</sup> Altria Client Services (ALCS) and the parent of PMP S.A., Philip Morris International Management S.A., have entered into a distribution agreement by which ALCS and its affiliates have exclusive rights to sell and distribute IQOS in the U.S. after FDA authorization. ALCS affiliate PM USA markets IQOS in the U.S. Therefore, PMSS that involves the study of consumers and consumption in the U.S. will be conducted by ALCS to be submitted as part of PMSS reporting by PMP S.A.

## **2.2 Objectives**

The objective of this reporting plan is to describe IQOS® U.S. sales and distribution data in total and by U.S. census region, major retail markets and channels.

## **3 OVERVIEW OF SALES AND DISTRIBUTION DATA**

IQOS® sales include sales of device kits, holders and Marlboro HeatSticks® which come in three varieties. HeatSticks® are sold through PM USA-owned retail outlets and third-party retail outlets. IQOS® system holders and chargers are sold through PM USA-owned retail outlets, IQOS® trained experts, and the IQOS® website, and may be sold in third-party retail outlets in the future.

### **3.1 IQOS® sales and distribution data in third-party retail outlets**

The data source for Marlboro HeatStick® volume sold in third-party retail outlets is the STARS database managed by Management Services Associates (MSA), which covers all U.S. states. The STARS database consists of tobacco product shipments from wholesalers to retail and is reported by wholesalers through a wholesale trade program to MSA. MSA performs quality reviews on the information to ensure that the data is accurate. MSA has a Distributor Support Center that works with the distributors to correct and address any potential data issues in the file submission. In addition, the reported volume is validated by evaluating PM USA's volume shipped to wholesale against reported wholesale inventory and the reported volume shipments to retail.

We will report Marlboro HeatSticks® volume and dollar sales by U.S. census region, major retail markets and channels for each variant. Marlboro HeatSticks® volume will be reported in number of packs. A pack consists of 20 HeatSticks®. Marlboro HeatSticks® dollar sales will be reported as a combination of the shipment volume and the wholesale list price paid to PM USA.

If IQOS® system holders and chargers are sold through third-party retail outlets in the future, PM USA will utilize data from the STARS database to report the volume and dollar sales by U.S. census region, major retail markets, and channels.

Sales taxes will be excluded from all sales reporting.

Given that STARS data are reported weekly, the report beginning and ending dates will not always correspond with the first and last date of the Reporting Period. Therefore, volume and dollar sales data will be reported based on the reporting week closest to the reporting period date.

### **3.2 IQOS® sales and distribution data through PM USA-owned retail outlets, IQOS® trained experts, and online sales**

IQOS® system holders and chargers are sold through PM USA-owned retail outlets, IQOS® trained experts, and the IQOS® website. In addition, Marlboro HeatSticks® are also sold in PM USA-owned retail outlets. The data source for IQOS® system device kits and individually purchased holders volume sold through company-owned retail stores, IQOS® trained experts and through the IQOS® website is reported as adult consumer retail sales, since it is not included in wholesale-to-retail STARS reporting. The same applies for Marlboro HeatSticks® which are sold through PM USA-owned retail outlets. Volume and dollar sales data will be reported based on the actual calendar days of the reporting period.

We will report Marlboro HeatSticks® volume for each variant in number of packs by U.S. census region, major retail markets and channels. A pack consists of 20 HeatSticks®. IQOS® system device kit and holder volume will be reported in units sold. A device kit contains one holder and one charger. IQOS® system device kits and holders volume for each item will be reported in number of units by U.S. census region, major retail markets and channels.

We will report Marlboro HeatSticks® and IQOS® system device kits and individually purchased holders dollar sales as actual retail dollar sales at company-owned retail outlets and through the IQOS website, as applicable. Dollar sales will be reported by U.S. census region, major retail markets and channels. Sales taxes will be excluded from sales reporting.

## **4 DATA REPORTING**

The data on volume and dollar sales is collected from the channels described above to create a total of all volume and dollar sales from third-party retailers, PM USA-owned retail outlets, and PM USA-owned IQOS® website. These data will be reported by U.S. census region, major retail markets and channels as shown in the table templates in [Section 5](#). We will provide a synthesis and summary of sales and distribution data, including annual and quarterly growth rates, in our report.

## 5 REPORTING TABLES

**Table 1: Summary of Device Units & HeatSticks® Volume Sales by Geography and Channel (for HeatSticks®, in number of packs) (Reporting Period: MM/YY – MM/YY)**

Geography	Item Description	Total Sales	Company Owned <sup>2</sup>	ECommerce	Convenience Store	Supermarket / Grocery	Drug	Gas
Market	Device Kits							
Market	Device Holders							
Market	Marlboro HS Smooth Menthol							
Market	Marlboro HS Original Non-Menthol							
Market	Marlboro HS Fresh Menthol							
Census Region	Device Kits							
Census Region	Device Holders							
Census Region	Marlboro HS Smooth Menthol							
Census Region	Marlboro HS Original Non-Menthol							
Census Region	Marlboro HS Fresh Menthol							

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<sup>2</sup> “Company Owned” includes PM USA-owned retail outlets and IQOS® trained experts.

**Table 2: Summary of Device Units & HeatSticks® Dollar Sales by Geography and Channel (Reporting Period: MM/YY – MM/YY)**

Geography	Item Description	Total Sales	Company Owned <sup>3</sup>	ECommerce	Convenience Store	Supermarket / Grocery	Drug	Gas
Market	Device Kits							
Market	Device Holders							
Market	Marlboro HS Smooth Menthol							
Market	Marlboro HS Original Non-Menthol							
Market	Marlboro HS Fresh Menthol							
Census Region	Device Kits							
Census Region	Device Holders							
Census Region	Marlboro HS Smooth Menthol							
Census Region	Marlboro HS Original Non-Menthol							
Census Region	Marlboro HS Fresh Menthol							

<sup>3</sup> “Company Owned” includes PM USA-owned retail outlets and IQOS® trained experts.