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.

IQOS® U.S. SALES AND DISTRIBUTION REPORTING PLAN

Sponsor: Altria Client Services LLC (ALCS)
P.O. Box 26583
Richmond, VA 23261-6583

Sponsor Contact: (b) (6)
Altria Client Services LLC
601 E. Jackson Street
Richmond, VA 23219
Phone:
Email: (b) (6)

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VERSION HISTORY

Version	Version Date	Modification(s)	Reason(s) for Modification(s)
V1.0	8/6/2020	(b) (4)	
V2.0	11/4/2020		In its October 5th letter, FDA suggested to provide operational definitions and a list of major retail markets.
			Adequately assess the trend in sales and distribution of IQOS® and HeatSticks®
			Evaluate changes in the sales/distribution (used as a proxy for product use)

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[1] 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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[1] 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, (b) (4) (b) (4)

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 (b) (4) (b) (4) which covers all U.S. states. (b) (4) (b) (4) works with the distributors to correct and address any potential data issues in the file submission. In addition, (b) (4) (b) (4) (b) (4)

We will report Marlboro HeatSticks® volume and dollar sales by total U.S., U.S. census region, major retail markets and channels for each variant.

Major retail markets are defined as a (b) (4) (b) (4) Our first annual report for IQOS® PMSS will include county definitions for the current Atlanta, Richmond and Charlotte retail markets, as well as any additional major retail markets in which IQOS® is launched.

Altria/ PMP S.A. will report sales for the following seven mutually exclusive and comprehensive retail channel categories: PM USA-owned Retail Outlets, PM USA-owned ECommerce, Third Party-owned ECommerce, Third Party-owned Tobacco Specialty Shops, Convenience & Gas, Super Market/Grocery, and Drug, Marlboro HeatSticks® volume will be reported in number of packs. A pack consists of 20 HeatSticks®. Marlboro HeatSticks® dollar

sales will be reported (b) (4) (b) (4)

If IQOS® system holders and chargers are (b) (4) PM USA will utilize data from the (b) (4) o report the volume and dollar sales by Total U.S., U.S. census region, major retail markets, and channels.

Sales taxes will be excluded from all sales reporting.

Given that (b) (4) 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. 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 (b) (4) (b) (4) 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 total U.S, 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 (b) (4) (b) (4) as applicable. Dollar sales will be reported by total U.S, 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 total U.S., U.S. census region, major retail markets and channels matching the Reporting Template provided by FDA in its Information Letter on October 5, 2020. In addition to providing sales and distribution data for the reporting calendar year, we will provide a brief synthesis and summary of the sales and distribution data for that calendar year, describing high-level trends in sales for each MRTPA STN, including annual and quarterly growth rates, in our report.

REPORTING TABLE

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

FDA STN	UPC	Product Name	Product Sub-Name	Package	Package Size	Package Quantity	Flavor	Nicotine Content / Concentration	Reporting Calendar Year	Reporting Quarter	Prior Reporting Calendar Year	Prior Reporting Quarter	Geographic Area	Channel	Dollars	(Dollars) Percent Change from Prior Reporting Calendar Year	(Dollars) Percent Change from Prior Reporting Quarter	Units	(Units) Percent Change from Prior Reporting Calendar Year	(Units) Percent Change from Prior Reporting Quarter

5 REFERENCES

Food and Drug Administration, C. T. P. (2012). Guidance for Industry: Modified Risk Tobacco Product Applications. Rockville, MD: U.S. Department of Health and Human Services Retrieved from https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UC M297751.pdf