

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 1 of 8
Appendix G: Reporting Plan - U.S. <i>IQOS</i> Sales & Distribution Data	Version 3.0

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

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 2 of 8
Appendix G: Reporting Plan - U.S. <i>IQOS</i> Sales & Distribution Data	Version 3.0

TABLE OF CONTENTS

1. INTRODUCTION	3
1.1 Background	3
1.2 Rationale	3
2. PURPOSE AND OBJECTIVES	4
2.1 Purpose.....	4
2.2 Objectives	4
3. OVERVIEW OF SALES AND DISTRIBUTION DATA	4
3.1 Third-party retail outlets	5
4. DATA REPORTING	5

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 3 of 8
Appendix G: Reporting Plan - U.S. <i>IQOS</i> Sales & Distribution Data	Version 3.0

1. INTRODUCTION

1.1 Background

Philip Morris Products S.A. (PMP S.A.) developed the *IQOS* device and *HEETS* consumables (hereinafter referred to as *IQOS* products) 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 (MRTPAs) for *IQOS* products to the U.S. Food and Drug Administration (FDA) seeking authorization to market the products as modified risk tobacco products. Based on the evidence provided in the MRTPAs, the FDA issued “Modified Risk Granted Orders – Exposure Modification” authorizing *IQOS* products to be marketed with reduced exposure claims.^{1, 2}

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* products pursuant to the Orders.

1.2 Rationale

The Federal Food, Drug and Cosmetic Act (FDCA) directs the 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*”.³ For this reason, the applicant, PMP S.A.,⁴ plans to conduct certain components of PMSS Plan 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* products 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* products 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* products PMTA marketing orders and is intended to be used for the *IQOS* products MRTP reporting as well.

¹ July 7, 2020, Modified Risk Granted Orders – Exposure Modification for MR0000059-61 and MR0000133

² March 11, 2022, Modified Risk Granted Orders – Exposure Modification for MR0000192.

³ Guidance for Industry, Modified Risk Tobacco Products Applications, U.S. FDA, March 2012, available at: <https://www.fda.gov/media/83300/download>.

⁴ Prior to May 1, 2024, the PMSS Plan for *IQOS* products was jointly developed and executed by PMP S.A. and Altria Client Services.

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 4 of 8
Appendix G: Reporting Plan - U.S. <i>IQOS</i> Sales & Distribution Data	Version 3.0

2. PURPOSE AND OBJECTIVES

2.1 Purpose

The purpose of this reporting plan is to describe how *IQOS* products' U.S. sales and distribution data will be collected, monitored, and reported in support of MRTP postmarket surveillance.

2.2 Objectives

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

3. OVERVIEW OF SALES AND DISTRIBUTION DATA

IQOS products sales include sales of devices, accessories (holders and chargers), and *HEETS*⁵ consumables which come in multiple varieties. *IQOS* devices and device accessories will be sold through PMI-owned eCommerce and *IQOS* Trained Experts and may be sold in third-party retail outlets in the future (including third party-owned Tobacco Specialty Shops, Convenience & Gas, Super Market/Grocery, and Drug). *HEETS* will be sold through PMI-owned eCommerce, *IQOS* Trained Experts (e.g., Coaches), and (planned) third-party retail outlets.

PMI may add 3 additional channels in PMI-owned Retail Outlets, Third Party-Owned eCommerce, and PMI-Owned Contact Center Order-On-Behalf.

Sales and distribution estimates may be reported nationally (i.e., total U.S.), by U.S. census region (West, Midwest, South, and Northeast), major retail market, and channel. Major retail markets are defined as a cluster of zip codes or counties where *HEETS* are in distribution. These zip codes or counties are typically contiguous and surround a major U.S. city. The geographical limits of the major retail market may grow over time as *HEETS* distribution expands. In each reporting period, PMI will provide a list of zip codes or counties which define the area for every reported major retail market. Additionally, the number of major retail markets will expand as *IQOS* products continue to gain distribution in new U.S. markets. Our first annual report for *IQOS* products will include county definitions for the current Austin and other retail markets, as well as any additional major retail markets in which *IQOS* products are launched. Sales taxes will be excluded from all sales reporting.

⁵ March 28, 2024, PMI's notification to change brand names of the authorized *IQOS* products, namely: MR0000192 from *IQOS* 3.0 System Holder and Charger to *IQOS* Originals, MR0000059 from *Marlboro* Amber *HeatSticks* to *HEETS* Amber, MR0000060 from *Marlboro* Green Menthol *HeatSticks* to *HEETS* Green and MR0000061 from *Marlboro* Blue Menthol *HeatSticks* to *HEETS* Blue.

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 5 of 8
Appendix G: Reporting Plan - U.S. IQOS Sales & Distribution Data	Version 3.0

3.1 Third-party retail outlets

This section assumes that *HEETS* are sold via third-party retail outlets such as Third Party-owned Tobacco Specialty Shops, Convenience & Gas, Super Market/Grocery, and Drug Stores. In-Market Sales data provided by MSA will be the data source for *HEETS* volume. These data will be provided by MSA and cover all U.S. states. In-Market Sales data capture 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 are 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 PMI's U.S. volume shipped to wholesale against the reported wholesale inventory and the reported volume shipments to retail.

HEETS volume and dollar sales extracted from the MSA In-Market Sales data will be reported for each variant nationally and by U.S. census region, major retail market, and channel. *HEETS* volume will be reported in number of packs. Dollar sales will be reported as the product of shipment volume multiplied by the wholesale list price paid to PMI in the United States.

If *IQOS* devices are sold through third-party retail outlets in the future, PMI will utilize data from the MSA database to report the volume and dollar sales nationally and by U.S. census region, major retail market, and channel.

Given that MSA 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 adjusted based on the calculated percent of the week which spans across the two months.

4. DATA REPORTING

The data on volume and dollar sales will be collected from the channels described above to create a total of all volume and dollar sales for each product. These data will be reported nationally and by U.S. census region, major retail market, and channel. See [Table 1](#) for listing of variables and outcomes to be included in the *IQOS* sales and distribution reporting dataset. A brief synthesis and summary of sale and volume outcomes will also be provided within the dataset, including annual and quarterly growth rates. Higher-level sales and distribution summaries may also be within the annual PMSS report (e.g., see [Table 2](#)).

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 6 of 8
Appendix G: Reporting Plan - U.S. IQOS Sales & Distribution Data	Version 3.0

Table 1. IQOS Sales and Distribution Reporting Variables and Outcomes

	<i>IQOS Device</i>	<i>HEETS</i>
Product Characteristic Variables		
UPC	✓	✓
Product Name	✓	✓
FDA STN	✓	✓
Package	N/A	✓
Package Size	N/A	✓
Package Quantity	N/A	✓
Flavor	N/A	✓
Nicotine Content	N/A	✓
Reporting Variables		
Reporting Year	✓	✓
Reporting Quarter	✓	✓
Prior Reporting Year	✓	✓
Prior Reporting Quarter	✓	✓
Major Retail Market	✓	✓
Channel	✓	✓
Reporting Outcomes – U.S. Dollars		
Total U.S. Dollars	✓	✓
Percent Change – Prior Year	✓	✓
Percent Change – Prior Quarter	✓	✓
Reporting Outcomes – Units		
Total Units	✓	✓
Percent Change – Prior Year	✓	✓
Percent Change – Prior Quarter	✓	✓

UPC = Universal Product Code; FDA STN = FDA Submission Tracking Number; N/A = Not applicable

✓ = Variable/Outcome value available for product.

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 7 of 8
Appendix G: Reporting Plan - U.S. IQOS Sales & Distribution Data	Version 3.0

Table 2. IQOS Product Volume and Sales Nationally and by U.S. Census Region, Major Retail Market, and Channel
(Reporting Period: MM / DD - MM / DD)

	IQOS Originals		Total HEETS		[Variant 1] HEETS		[Variant 2] HEETS	
	USD	# Units	USD	# Units	USD	# Packs	USD	# Packs
U.S. Total								
Census Region								
West								
Midwest								
South								
Northeast								
Major Retail Market								
[Market 1]								
[Market 2]								
Channel								
eCommerce								
<i>IQOS Trained Experts</i>								
Third-Party Retail	NA	NA						
<i>Tobacco Specialty Shops</i>	NA	NA						
<i>Convenience & Gas</i>	NA	NA						
<i>Super Market / Grocery</i>	NA	NA						
<i>Drug Stores</i>	NA	NA						

Confidentiality Statement

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 Products S.A.

Philip Morris Products S.A.	Confidential
PMSS for MR0000059-MR000061, MR0000133 & MR0000192	Page 8 of 8
Appendix G: Reporting Plan - U.S. <i>IQOS</i> Sales & Distribution Data	Version 3.0

Version History

Version	Version Date	Modification(s)	Reason(s) for Modification(s)
V1.0	8/6/2020	First Version	
V2.0	10/21/2020	Revised to provide our approach to defining and listing major retail markets as part of our annual submission for <i>IQOS</i> PMSS	In its October 5 th letter, FDA suggested to provide operational definitions and a list of major retail markets.
		Added unit and dollar sales percent change from prior reported calendar year and quarter	Adequately assess the trend in sales and distribution of <i>IQOS</i> and <i>HeatSticks</i>
		Added MRTPA Submission Tracking Numbers (STN) to reporting table	Evaluate changes in the sales/distribution (used as a proxy for product use)
V3.0	4/29/2024	Revised to describe approach and processes followed by PMI, after ending the commercial relationship with Altria Group, Inc.	As of May 1, 2024, PMI is solely responsible for fulfilling postmarket requirements for <i>IQOS</i> products

Confidentiality Statement

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 Products S.A.