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Appendix E:

Reporting Plan - U.S. IQOS® Owners Panel

Please find on the following pages details about reporting plan for U.S. IQOS® Owners Panel.

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IQOS® OWNERS PANEL Reporting Plan

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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 5 th letter, FDA suggested to include data quality control process including data cleaning, quality control, or other technique to address outliers.

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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 “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, ALCS¹ 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. This IQOS® Owners Panel Reporting Plan is one component of the postmarket surveillance program. Specifically, it describes outcomes from the IQOS® Owners Panel, as commissioned in the U.S. by ALCS on behalf of Philip Morris USA (PM USA), that will be reported in support of IQOS® PMTA market order and that ALCS intends to report for the MRTPA order as well.

2 PURPOSE AND OBJECTIVES

2.1 Purpose

The purpose of this IQOS® Owners Panel Reporting Plan is to describe outcomes of the IQOS® Owners Panel that will be reported in support of the MRTP PMSS including switching and use patterns over time among adult (21 years of age or older) IQOS® owners.

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 distribute and sell 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 objectives of this reporting plan are to:

- 1) Describe adult IQOS® owners' switching behavior over time
- 2) Describe the usage of IQOS® and other tobacco products among adult IQOS® owners
- 3) Describe the demographic profile of adult IQOS® owners

3 OVERVIEW OF THE IQOS® OWNERS PANEL

ALCS will collect data on adult tobacco consumers who have purchased an IQOS® device through a longitudinal consumer panel, i.e. the IQOS® Owners Panel. The Owners Panel tracks individual adult consumer use trajectories with IQOS® and estimates the degree to which adult smokers 21 years or older switch over time, as well as the extent to which adult consumers stop using IQOS®. The Owners Panel also provides demographic information, as well as IQOS® and other tobacco product use behavior measurements.

(b) (4)

The IQOS® Owners Panel Study is based on a non-probability sampling approach. Based on experience from other countries with similar IQOS® consumer databases, it is assumed that IQOS® consumers listed in the IQOS® Consumer Database will comprise (b) (4). (b) (4) The recruiting mode is based on e-mail distribution to all adult consumers on the IQOS® Consumer Database.

To enable benchmarking of study results to other countries where IQOS® is available, study design and survey instruments have been adopted to resemble similar studies conducted by PMP S.A. in other countries where IQOS® is available.

3.1 IQOS® Owners Panel Study Duration

There is no pre-set study duration. Due to the novelty of the category, as well as the longitudinal nature of the study, it is anticipated the study will run indefinitely until PM USA determines it is no longer required.

3.2 IQOS® Owners Panel Study Recruitment

The IQOS® Owners Panel Study is restricted to adult tobacco consumers who own an IQOS® device for their personal use. Participants in the panel are grouped into cohorts with the cohort being defined as IQOS® owners who purchased or received IQOS® in the past 4 weeks and join the panel in that month. This will provide the ability to track differences or similarities by purchase cohorts defined by when they first acquired IQOS®.

The initial IQOS® launch in the US has been constrained to limited geographies, as such no maximum sample size has been defined for the short term. The number of participants in the IQOS® Owner Panel will increase over time as the IQOS® U.S. market expands and recruitment into the panel continues. Should the need arise to manage the size of the panel in order to manage costs, criteria to cap new panelists recruitment will be developed with a goal of maximizing the representativeness of the panel in relation to the composition of IQOS® owners in the database.

3.3 IQOS® Owners Panel Survey Instruments

There are two primary survey instruments: a recruitment survey and the main survey. The main survey is designed to be modular and will have a short and a long version. The long version will be deployed on the last week of every month with the short version deployed in the intervening weeks.

3.4 IQOS® Owners Panel Inclusion and Exclusion Criteria

Inclusion Criteria

(b) (4)

Exclusion Criteria

(b) (4)

(b) (4)

3.5 Data Quality Control Process

Various checks are performed to ensure the accuracy, integrity, and validity of the data. These include quality checking the survey instrument program logic before and after study launch. Survey logic is incorporated into the survey instrument to preclude inconsistent responses including additional verification questions if certain relevant responses are above a set threshold. For example, we have guardrails in the survey where we do not allow cigarette or Marlboro HeatSticks® consumption responses higher than 99 cigarettes/Marlboro HeatSticks® per day on days smoked in the past 7 days. In addition, a confirmation question is asked in the survey to verify any response that indicates consumption over 20 cigarettes/Marlboro HeatSticks® per day. Fraudulent checks are also in place to identify if multiple respondent IDs are conducting several interviews from the same device. Records that contain forms of data falsification are flagged. We will conduct all descriptive analyses first with the complete dataset and follow up with sensitivity analyses in which flagged respondents are excluded.

The survey also does not contain open-ended questions and verbatim responses are limited to typed-in “other” responses. Free text field responses that are of poor quality (e.g., gibberish/non-sensical verbatim response) are considered for possible removal. Any corrections made to the data set are thoroughly documented and an explanation/rationale is provided for each correction.

3.6 Outcome Measures

Outcome measures will be reported in three-month intervals to align with IQOS® PMTA reporting.

3.6.1 IQOS® Usage Level

Adult IQOS® usage level is defined as the percentage of Marlboro HeatSticks® consumption relative to the amount of Marlboro HeatSticks® and cigarette consumption. Specifically, it is defined as the daily consumption in the past 7 days and is calculated by using the total daily consumption of Marlboro HeatSticks® out of the total daily consumption of Marlboro HeatSticks® and cigarettes:

$$IQOS \text{ usage level} = \frac{\text{HeatSticks Consumption}}{\text{TOTAL Consumption}} \times 100,$$

where TOTAL Consumption = total number of HeatSticks® and cigarettes.

The following groups are defined based on the IQOS® usage level as:

- Adult participants who completely switched from cigarettes to IQOS®: IQOS® usage level = 100%
- Adult participants who dual use with cigarettes and IQOS®: IQOS® usage level < 100% and IQOS® usage level ≥ 5%
- Adult participants who no longer use IQOS®: IQOS® usage level < 5%

We will report the percentage of participants in the IQOS® Owners Panel that fall into these groups. See Section 4.2 Reporting Table 1.

3.6.2 Demographic Profile

Demographic characteristics of participants in the IQOS® Owners Panel including gender, age, race, ethnicity and geography, will be reported for the following groups:

- Total Adult IQOS® Owners
- Adult participants who completely switched from cigarettes to IQOS®
- Adult participants who dual use with cigarettes and IQOS®
- Adult participants who no longer use IQOS®

See Section 4.2 Reporting Tables 2-6.

3.6.3 Other Tobacco Products Used

Participants who used other tobacco products in the past 7 days will be reported for the following groups:

- Total Adult IQOS® Owners
- Adult participants who completely switched from cigarettes to IQOS®
- Adult participants who dual use with cigarettes and IQOS®
- Adult participants who no longer use IQOS®

Other tobacco products include the following:

- Fancy, hand-rolled cigars
- Less expensive, everyday cigars sold in convenience stores

- Moist smokeless tobacco or dip in loose or pouch form, sold in a round can
- Chewing tobacco in leaf or plug form, sold in a resealable bag
- Snus (a spit-less, smokeless tobacco pouch product)
- E-Cigarettes or E-Vapor
- Other tobacco-derived nicotine products, such as pouches, lozenges, etc. (e.g., Zyn, on!)
- None of the above

See Section 4.2 Reporting Table 7.

3.7 Weighting

IQOS® device sales are used to weight the data to better reflect the market dynamics. Weights will apply to a specific Monthly Report according to this formula:

- Recruited within past 4 weeks:
 - Individual weight = Sales (Month of Recruitment -1) / Valid Respondents (Month of Recruitment)
e.g. anyone recruited in July will be weighted to June device sales.
- Recruited > 4 weeks:
 - Individual weight = Sales (Cumulated until Month of Recruitment -2) / Valid Respondents (>4 weeks)
e.g. considering January as launching month for IQOS® and July starting month for panel, anyone recruited in first two recruitments and purchased >4 Weeks from registration will be weighted to January - May cumulated device sales.

4 IQOS® OWNERS PANEL REPORTING

4.1 Estimated Reporting Timeline

We plan to report results from the IQOS® Owners Panel in April 30 of each year following the year of authorization of an MRTP as shown in Table 1. Should the timing of this reporting be accelerated or delayed, we will notify FDA in accordance with the market order.

Table 1: Estimated timeline for the first IQOS® Consumer Panel Reporting

Milestone	Estimated Date
Ending of the reporting period	Feb 28, 2021
Complete reporting tables	Apr 30, 2021*

Note: *Time between end of reporting period and completion of reporting tables accounts for data analysis.

4.2 IQOS® Consumer Panel Reporting Templates

Each of the following tables will be reported to show the information in three-month intervals.

Reporting Table 1: Adult Participants in the IQOS® Owners Panel by IQOS® Usage Level

IQOS® Usage Level	Number of People	% of total IQOS® Owners
Adult participants who completely switched from cigarettes to IQOS® (IQOS® usage level = 100%)		
Adult participants who dual use with cigarettes and IQOS® ($5\% \leq \text{IQOS}^\circledast \text{ usage level} < 100\%$)		
Adult participants who no longer use IQOS® (IQOS® usage level $< 5\%$)		

Reporting Table 2: Adult Participants in the IQOS® Owners Panel by Gender

Gender	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
Female				
Male				

Reporting Table 3: Adult Participants in the IQOS® Owners Panel by Age

Age	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
21-29				
30-39				
40-49				
50-59				

Age	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
60-69				
70+				

Reporting Table 4: Adult Participants in the IQOS® Owners Panel by Race

Race	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
White or Caucasian				
Black or African American				
Asian or Pacific Islander				
American Indian or Alaska Native				
Mixed racial background				
Other race				

Reporting Table 5: Adult Participants in the IQOS® Owners Panel by Hispanic Descent

Hispanic or Latino	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
Yes				
No				

Reporting Table 6: Adult Participants in the IQOS® Owners Panel by of IQOS® by Geography

Geography	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
Midwest				
Northeast				
South				
West				

Reporting Table 7: Proportion of Adult Participants in the IQOS® Owners Panel Who Used Other Tobacco Products

Other Tobacco Products used in the Past 7 days (Excludes traditional cigarettes)	Total IQOS® Owners %	Participants who completely switched from cigarettes to IQOS® %	Participants who dual use with cigarettes and IQOS® %	Participants who no longer use IQOS® %
Fancy, hand-rolled cigars				
Less expensive, everyday cigars sold in convenience stores				
Moist smokeless tobacco or dip in loose or pouch form, sold in a round can				
Chewing tobacco in leaf or plug form, sold in a resealable bag				
Snus (a spit-less, smokeless tobacco pouch product)				
E-Cigarettes or E-Vapor				
Other tobacco-derived nicotine products, such as pouches, lozenges, etc (e.g., Zyn, on!)				
None of the above				