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6.2 Effect on Tobacco Use Behavior Among Current Tobacco Users	Version 1.0

Module 6 : Research

6.2 Effect on Tobacco Use Behavior Among Current Tobacco Users

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1. INFORMATION ON TOBACCO USE BEHAVIOR AMONG TOBACCO USERS

1.1. Introduction

To measure the potential benefit of marketing a MRTP to the public, the FDA Modified Risk Tobacco Product Applications Guidance recommended investigating several areas, including (1) the effect on tobacco use behavior among current tobacco users, (2) the effect on tobacco use initiation among non-users, and (3) the effect of marketing on consumer understanding and perceptions¹. In this section, we provide data from both pre-market studies included in the original MRTPA², and postmarket studies conducted both within the United States and internationally, on the effect of *IQOS* on use behaviors among current tobacco users. In addition, we cross-reference Module 7 of the original MRTPA for the Authorized *IQOS* products with related appendices and data, and with subsequent amendments, and Module 7 of the supplemental PMTA for the Authorized *IQOS* 3 System (PM0000634), as well as Module 7 of the supplemental MRPTA for *IQOS* 3 System (MR0000192).

1.2. Pre-market U.S. Data

1.2.1. Background

In response to the above mentioned three areas of investigation, PMI developed and conducted a comprehensive U.S. pre-market Perception and Behavior Assessment (PBA) program to study consumer perception and behavior in relation to THS, currently commercialized under the brand name *IQOS*.

Below, we provide a summary of previously submitted evidence from the U.S. pre-market studies in relation to tobacco users. Specifically, evidence on the effect of the authorized reduced exposure claim, included as part of the THS Label, Labeling and Marketing Material (LLM), on behavioral intentions (THS-PBA-05-REC-US study) and the effect of THS product on use patterns (THS-PBA-07-US study) among tobacco users.

1.2.2. Effect of THS Label, Labeling and Marketing Material on Behavioral Intentions among Adult Smokers

PMP S.A. conducted the quantitative THS-PBA-05-REC-US study to assess the Intention to Try, Intention to Use, Comprehension of the modified risk claim and Risk Perception of the Authorized *IQOS* System (THS 2.2), among adult users and non-users of tobacco products following exposure to THS LLM with the authorized modified exposure claim. The results

¹ FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012.
<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

² MRTPA Modified Risk Granted Order - Exposure Modification of December 12, 2019, authorizing the marketing of the modified risk product *IQOS* 2.4 System Holder and Charger (STN: MR0000133).

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and methodologies of this TPPI study are described in more details in sections 6.2.2, 6.3.1, 6.4 and 7.3.2 of the original MRTPA (MR0000133)³ Of note, although this study was completed before the FDA's Guidance for Industry "Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies" was issued, this study was conducted in accordance with the principles stated in the Guidance⁴. A summary of the THS-PBA-05-REC-US study methodology is presented in Table 1.

For consistency, the term *THS Tobacco Sticks* that was previously used in the original study reports is replaced with *HeatSticks*.

Table 1 Methodology of THS-PBA-05-REC-US

Study Title: Quantitative Assessment of THS 2.2 Label, Labeling and Marketing Material with Reduced Exposure Claims
Study design: 4 cities, 5-arm parallel-group experiment. The 5 arms corresponded to 5 different combinations of communication materials and warning type, with each communication materials containing the reduced exposure claim. Each of the materials was tested by approximately equal numbers of subjects from different smoking status groups. Arm 1 corresponded to the THS 2.2 Brochure including the Surgeon General's (SG) warnings. Arm 2 corresponded to the THS 2.2 Brochure including the "Important Warning" developed by PMI ("PMI Warning"). Arm 3 corresponded to the <i>HeatSticks</i> Pack including the SG's warnings. Arm 4 corresponded to the <i>HeatSticks</i> Pack including the PMI Warning. Arm 5 corresponded to the THS 2.2 Direct Mail including the PMI Warning. The THS 2.2 Brochure was a multi-page leaflet, the <i>HeatSticks</i> Pack was a "standard pack" and the THS 2.2 Direct Mail was a multi-page direct mail document.
Subjects: <i>Full Sample</i> (N=2272) stratified into Adult Smokers with no Intention to Quit Combustible Cigarettes (CC) (N=479), Adult Smokers with the Intention to Quit CC (N=479), Adult Former Smokers (N=480) and Adult Never Smokers (N=480). An additional oversampling of 480 Adult Never Smokers from the legal age of smoking ⁵ to 25 years of age (<i>LA-25 Adult Never Smokers</i>) which includes 126 Adult Never Smokers from the <i>Main Sample</i> .
Main criteria for inclusion: <ul style="list-style-type: none"> • Aged 18 and above, or above state legal smoking age if above 18 years • Adult Smokers with no Intention to Quit CC⁶: currently smoking some days or every day, started more than 30 days ago with no intention to quit within 6 months; Adult Smokers with Intention to Quit CC⁶: currently smoking some days or every day, started more than 30 days ago with the intention to quit within 6 months; Adult Former Smokers: quit smoking CCs

³ FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012. <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

⁴ FDA. (2022). Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies: GUIDANCE. August 2022. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-products-principles-designing-and-conducting-tobacco-product-perception-and-intention>.

⁵ Legal age for smoking was 18 years old at the time of study conduct.

⁶ Include Regular Smokers (smoke at least 1 CC a day) and Intermittent Smokers (between 4 and 27 days per month, with no restrictions on total number of CC smoked over that period, between 10% and 40%).

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more than 30 days ago; Adult Never Smokers: never smoked or never smoked daily and less than 100 CC

Methods and Outcome Measure:

Intent to Use

2 sets of items from the Intent to Use Questionnaire (ITUQ) yielded descriptive measures of:

- Intention to Try (i.e., to sample at least once; 2 items)
- Intention to Use (i.e., for continued usage; 2 items)

Change in Intention to Quit Smoking and All Tobacco (only for Adult Smokers with Intention to Quit CC)

Closed-ended questions based on Prochaska and DiClemente's Stages of Change model ([Prochaska, 1983](#)) measured before and after exposure to THS message to determine change in Intention to Quit Smoking and All Tobacco

Comprehension

Closed questions on Global and Specific comprehension of THS communication materials

Risk Perception

ABOUTTM Perceived Risk Instrument composed of 3 domains ([Chrea et Al., 2018](#), [Cano et Al., 2018](#)):

- Perceived Health Risk measured by an 18-item scale
- Perceived Addiction Risk measured by a 7-item scale
- Perceived Harm to Others measured by 2 single items

Criteria for Evaluation:

Intent to Use:

Positive Intention to Try (operationalized as the sum of % Very Likely and % Definitely responses to the item on Intention to Try) and positive Intention to Use (operationalized as the sum of % Very Likely and % Definitely responses to the item on Intention to Use Regularly).

Change in Intention to Quit Smoking and All Tobacco:

Change in Intention to Quit Smoking and All Tobacco, respectively, compared pre- and post-exposure to the THS material, by study arm.

Level of Comprehension⁷:

Proportion of subjects correctly answering Comprehension questions, by study arm

Risk Perception⁸:

Perceived Health Risk, Perceived Addiction Risk and Perceived Harm to Others for THS and each comparator (i.e., CC, E-cigarettes, NRTs and Cessation)⁹, by study arm and smoking status group

Overall, the study found that the different instances of *IQOS* LLM tested that included the Surgeon General's (SG) warnings (tested across two Arms: (i) *IQOS* Brochure and (ii) the *HeatSticks* Pack)¹⁰, were associated with substantial positive Intention to Try and positive Intention to Use THS among the intended section of the population, that is Adult Smokers

⁷ See [section 6.4](#) of this application

⁸ See [section 6.4](#) of this application

⁹ Not assessed by Adult Never Smokers

¹⁰ Results for PMI warnings are not presented herein and have been described in more details in sections 6.2.2, 6.3.1, 6.4 and 7.3.2 of the original MRTPA.

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with No Intention to Quit CC. Specifically, positive Intention to Try ranged between 32.6% to 46.3% and positive Intention to Use ranged between 25.3% to 36.8% across the two study Arms, respectively. Positive Intention to Try and positive Intention to Use was also substantial among Adult Smokers with Intention to Quit CC, regardless of types of materials. Specifically, positive Intention to Try ranged between 37.5% to 39.6% and positive Intention to Use ranged between 22.9% to 29.2% across the two study Arms, respectively. However, among this population subgroup, these levels of Intent to Use *IQOS* may represent, to some degree, an interest in using *IQOS* as a temporary measure to aid quitting all tobacco. This was indicated by overall low levels of Change in Intention to Quit Smoking or All Tobacco. This is consistent with PMI's aim not to dissuade Adult Smokers With the Intention to Quit CC from quitting.

Based on the above data that was previously submitted to the FDA as part of the original MRTPA, the FDA TPL review¹¹ concluded that *'Together, these findings are supportive that marketing IQOS with a reduced exposure claim could appeal to current smokers who are most likely to benefit from their use, and this supports a likely benefit to population health.'*

The study results of THS-PBA-05-REC-US remain valid given that the reduced exposure claim has remained identical throughout the limited commercialization of *IQOS* in the United State. In addition, the *IQOS* LLM in the U.S. have been submitted and have been reviewed by FDA before commercial use and they are comparable to (i.e., represent non-material variations) of the *IQOS* LLM tested in THS-PBA-05-REC-US study.

1.2.3. Product Use Patterns from Observational Actual Use Study of THS

PMP S.A. conducted the quantitative THS-PBA-07-US study to investigate how U.S. adult current daily CC smokers use the *IQOS* system under near to real-world conditions. Data collected in this study were necessary to inform about the effect of *IQOS* on tobacco use behavior among current tobacco users. The results and methodologies of THS-PBA-07-US are described in more details in sections 6.2.2, 6.3.1, 6.4 and 7.3.2 of the original PMTA.¹² A summary of the THS-PBA-07-US study methodology is presented in Table 2.

For consistency, the term *THS Tobacco Sticks* that was previously used in the original study reports is replaced with *HeatSticks*.

¹¹ Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act – Technical Project Lead, p. 62, July 6, 2020.

¹² Original PMTA refers to PM0000424-426, 479 PMTA.

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Table 2 Methodology of THS-PBA-07-US

Study Title: Actual Use Study of THS 2.2 – THS-PBA-07-US

Study design: Single group, mid-term prospective observational study including 1-week baseline period and 6-week observational period followed by 1-week close out. Study conducted in 8 limited geographic areas of the United States, with an assessment of subject-reported stick-by-stick consumption of *HeatSticks* and of CC with participants receiving *HeatSticks* free of charge.

Subjects: Enrolled: 1336; Full Analysis Set (FAS): 1106.

Main criteria for inclusion:

- Aged 18 and above, or above state legal smoking age if above 18 years¹³
- Current daily smokers of regular and/or menthol CC, having smoked at least 100 CC in lifetime, currently smoking at least 1 CC/day, and having no intention of quitting within the next 30 days.
- Positive intention to use the THS system as assessed during screening.

Test Product: Tobacco Heating System 2.2 (THS 2.2) regular and menthol variants. *Ad-libitum* use

Duration of Use: Observational period of 6 weeks

Key Analyses:

Use patterns

Product use described per week according to the below product usage categories:

- *THS HeatSticks use* ($\geq 70\%$ of tobacco products used are THS *HeatSticks*)
 - Exclusive THS *HeatSticks* use: ($>95\%$ and $\leq 100\%$ of tobacco products used are THS *HeatSticks*)
 - Predominant THS *HeatSticks* use ($\geq 70\%$ and $\leq 95\%$ of tobacco products used are THS *HeatSticks*)
- *Combined use* ($>30\%$ and $<70\%$ of tobacco products used are THS *HeatSticks*)
- *CC use* ($\leq 30\%$ of tobacco products used are THS *HeatSticks*)

Analysis of usage categories over different time points via transition tables, created for each week to any other posterior week in the observational period starting with week 0 (i.e., Baseline period).

Levels of Product Consumption

Average daily consumption of THS and CC during the observational period in comparison to Baseline consumption of CC as reported by the study participant in the e-diary.

The Full Analysis Sample (FAS) population consisted of 1106 participants, all had recorded consumption of at least 1 CC during the 1-week Baseline period and at least 1 consumption of a THS Tobacco Stick during the 6-week observational period.

¹³ Legal age for smoking was 18 years old at the time of study conduct.

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Overall, the study showed that a sizeable proportion of the U.S. daily smokers were likely to “switch” from CC to the *IQOS* system, with 14.6% of daily smokers likely to use it either exclusively or predominantly (i.e., “*THS HeatSticks use*”¹⁴) (Table 3). Around 7.5% of daily smokers were likely to use it exclusively (Table 3). “*THS HeatSticks use*” remained relatively stable over the 6-week observational period. With regard to dual use, the proportion of Combined use decreased over time, and, on average, CC consumption was reduced by about half for participants with Combined use at Week 6 compared to their baseline CC consumption (Table 4).

There was no evidence to suggest that the availability of *HeatSticks* would lead to an increase in total tobacco product consumption with average total tobacco product consumption (CC and *HeatSticks* combined) used per day being slightly lower during the observational period compared to baseline (9.3 CC and *HeatSticks* combined per day vs. 10.2 CC per day) for the overall sample. A proportion of participants continued to use CC after using *HeatSticks* (Table 3). Despite this, data indicates that once adult daily smokers have “switched” from CC to *HeatSticks*, their likelihood of switching back to CC is relatively low.

¹⁴ Defined as Exclusive *THS HeatSticks use*: (>95% and ≤100% of tobacco products used are *THS HeatSticks*) or Predominant *THS HeatSticks use* (≥70% and ≤95% of tobacco products used are *THS HeatSticks*)

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Table 3 Product Use by Usage Category (n, % and 95% CI) by Week for the FAS Population in THS-PBA-07-US

	Week 1 (n=1106)	Week 2 (n=1061)	Week 3 (n=1038)	Week 4 (n=1009)	Week 5 (n=997)	Week 6 (n=968)
THS <i>HeatSticks</i> use	215 (19.4) (17.1, 21.9)	181 (17.1) (14.8, 19.5)	170 (16.4) (14.1, 18.8)	162 (16.1) (13.8, 18.5)	156 (15.6) (13.4, 18.1)	141 (14.6) (12.4, 17.0)
Exclusive THS <i>HeatSticks</i> use	81 (7.3) (5.8, 9.1)	83 (7.8) (6.2, 9.7)	88 (8.5) (6.8, 10.4)	85 (8.4) (6.7, 10.4)	71 (7.1) (5.6, 8.9)	73 (7.5) (5.9, 9.4)
Predominant THS <i>HeatSticks</i> use	134 (12.1) (10.2, 14.2)	98 (9.2) (7.5, 11.2)	82 (7.9) (6.3, 9.8)	77 (7.6) (6.0, 9.5)	85 (8.5) (6.8, 10.5)	68 (7.0) (5.4, 8.9)
Combined use	459 (41.5) (38.5, 44.5)	360 (33.9) (31.0, 36.9)	326 (31.4) (28.5, 34.4)	267 (26.5) (23.7, 29.3)	243 (24.4) (21.7, 27.2)	217 (22.4) (19.8, 25.2)
CC use	431 (39.0) (36.0, 42.0)	518 (48.8) (45.7, 51.9)	542 (52.2) (49.1, 55.3)	576 (57.1) (53.9, 60.2)	596 (59.8) (56.6, 62.9)	607 (62.7) (59.5, 65.8)
No CC or THS <i>HeatSticks</i> use	1 (<0.1) (<0.1, 0.6)	2 (0.2) (<0.1, 0.7)	0 (0, 0.4)	4 (0.4) (0.1, 1.1)	2 (0.2) (<0.1, 0.8)	3 (0.3) (<0.1, 1.0)

n= number of values reported, CC= conventional cigarette; CI= Confidence Interval. FAS = Full Analysis Set.

Data Source: Study Report THS-PBA-07-US¹⁵ Appendix 15.2; FAS, Table 15.2.6.1.2

¹⁵ IQOS 2.4 System MRTPA (MR0000192) submitted Dec 5, 2016

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Table 4 THS *HeatSticks* and/or CC Consumed Daily (Mean±SD) at Baseline and During the Observational Period (Average across the 6 Weeks) in THS-PBA-07-US –Overall (FAS) and Stratified by Usage Category at Week 6

	Baseline (1 week)	Observational Period (6 weeks)		
	CC	All tobacco (THS+CC)	CC	THS <i>HeatSticks</i>
Stratified by Usage Category at Week 6				
THS <i>HeatSticks</i> use (n=141)	9.0 ±5.89	8.1±5.37	1.4±1.57	6.7±4.82
Combined use (n=217)	9.3 ±6.34	8.9±6.21	4.8±3.72	4.1±3.06
CC use (n=607)	10.9 ±7.69	9.9±6.75	8.3±6.32	1.7±1.99
Overall (FAS) (n=1106)	10.2 ±7.22	9.3±6.56	6.3±5.78	3.0±3.57

n= number of values reported, CC= conventional cigarette; SD= Standard Deviation, FAS= Full Analysis Set.

Data Source: Study Report THS-PBA-07-US¹⁶ Appendix 15.2; FAS, Table 15.2.3.11, Table 15.2.4.1, 15.2.4.2; Appendix 15.2; FAS By usage Week 6, Table 15.2.3.11, Table 15.2.4.1, 15.2.4.2

¹⁶ IQOS 2.4 System MRTPA (MR0000192) submitted Dec 5, 2016

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PMP S.A. also previously submitted a post hoc analysis of the THS-PBA-07-US study¹⁷ that aimed to analyze the study primary and secondary endpoints using the e-diary and follow-up interview data stratified by product dispensed (i.e., order type). This resulted into three *HeatSticks* order types¹⁸:

- Regular *HeatSticks* only
- Menthol *HeatSticks* only
- Both *HeatSticks* types

In terms of use behavior, the proportion of “*THS HeatSticks*” was highest at the end of the observational period among participants who ordered both *HeatSticks* types (22.7%) followed by participants who ordered menthol *HeatSticks* only (13.8%) and finally participants who ordered regular *HeatSticks* only (11.8%) (Table 5).

Table 5 Main Usage Categories at Week 6 (i.e., Early Stages of Use + Continued Use) - Stratification by *HeatSticks* Order Type - FAS

<i>n</i> (% row) 95% CI (%,%)	Main usage categories at Week 6				
	n (%)	<i>THS Tobacco Stick Use</i>	Combined use	CC use	No CC or <i>HeatSticks</i> use
FAS	968 (100%)	141 (14.6%) (12.4%, 17.0%)	217 (22.4%) (19.8%, 25.2%)	607 (62.7%) (59.5%, 65.8%)	3 (0.3%) (<0.1%, 1.0%)
By <i>HeatSticks</i> Order Type ¹					
Menthol <i>HeatSticks</i> only	427 (100%)	59 (13.8%) (10.6%, 17.5%)	81 (19.0%) (15.3%, 23.1%)	284 (66.5%) (61.8%, 71.0%)	3 (0.7%) (0.1%, 2.1%)
Regular <i>HeatSticks</i> only	365 (100%)	43 (11.8%) (8.6%, 15.6%)	93 (25.5%) (21.0%, 30.3%)	229 (62.7%) (57.5%, 67.8%)	0 (0%, 1.1%)
Both <i>HeatSticks</i> Types	172 (100%)	39 (22.7%) (16.6%, 29.7%)	42 (24.4%) (18.2%, 31.6%)	91 (52.9%) (45.1%, 60.6%)	0 (0%, 2.2%)

n= number of values reported, CC=conventional cigarette, CI= Confidence Interval, FAS = Full analysis set.

¹ 5 participants had no *HeatSticks* order type available. For those participants, the results are not included in this table.

Source: Study Report THS-PBA-07-US¹⁹ FAS, Table 15.2.6.1.2; FAS PostHoc ByHSOrderType incl30DaysFUP, Table 15.2.6.1.2.

¹⁷ Study Report Addendum dated April 28, 2017, submitted on September 8, 2017 (Response to August 4, 2017 Information for Request for MR0000059-MR0000061 and Amendment to MR0000059-MR0000061).

¹⁸ The results for participants with “*HeatSticks* order type not available” are not shown in the tables and figures due to the low number of participants in this subgroup.

¹⁹ IQOS 2.4 System MRTPA (MR0000192) submitted Dec 5, 2016

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In terms of total tobacco consumption, there was no evidence to suggest that the availability of menthol *HeatSticks*, regular *HeatSticks* or both *HeatSticks* types would lead to an increase in total tobacco product consumption (CC and *HeatSticks*). Total tobacco product consumption being slightly lower during the observational period compared to baseline (8.1 CC and *HeatSticks* combined per day vs. 9.1 CC per day) among participants who ordered menthol *HeatSticks* only and among participants who ordered regular *HeatSticks* only (10.0 CC and *HeatSticks* combined per day during the observational period vs. 11.0 CC per day during the baseline period). Total tobacco product consumption was similar during the observational period compared to baseline (10.8 CC and *HeatSticks* combined per day vs. 10.7 CC per day) among participants who ordered both *HeatSticks* types.

In relation to sensorial appeal, the proportion of participants who liked the taste (33.0%), smell (36.5%) and aftertaste (27.9%) (i.e., categories 5-7) was higher in participants who ordered menthol *HeatSticks* only compared to participants who ordered regular *HeatSticks* only (25.7%, 25.9% and 24.6%, respectively).

To conclude, given that *IQOS* has only been present in the U.S. market for a limited period and in very limited geographies, the findings of the U.S. pre-market Actual Use Study (THS-PBA-07-US), included in the original MRTPA and presented in this section, remain applicable.

1.2.4. Conclusion of U.S. Pre-market Studies

In summary, THS-PBA-05-REC-US study showed that exposure to THS communication materials generated a substantial level of Intention to Try and Intention to Use THS among the intended section of the population, i.e., Adult Smokers With no Intention to Quit CC. Results from the THS-PBA-05-REC-US study also suggest that the communication materials did not significantly alter intention to quit smoking and all tobacco among Adult Smokers with Intention to Quit CC, potentially indicating an interest in using THS as a temporary measure to aid quitting all tobacco.

In relation to the Actual Use study (THS-PBA-07-US), the data showed that 7.5% of adult smokers were using *IQOS exclusively*, with *HeatSticks* forming more than 95% of their total tobacco consumption at the end of a 6-week usage period. With regard to dual use, on average CC consumption was reduced by about half for participants with *Combined use* at Week 6 compared to their baseline CC consumption. Findings on total tobacco consumption indicated that the availability of *IQOS* did not lead to any increase in average daily total tobacco product consumption (*HeatSticks* and CC).

Results of a post hoc analysis showed that the likelihood of switching from CC to *HeatSticks* was highest among participants who ordered both *HeatSticks* (menthol + regular) types

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followed by participants who ordered menthol *HeatSticks* only likely resulting from the higher sensorial appeal of the menthol *HeatSticks*. Moreover, data showed that the availability of menthol *HeatSticks*, regular *HeatSticks* or both *HeatSticks* did not lead to an increase in total tobacco product consumption (CC and *HeatSticks*).

1.3. U.S. Sales Data and Postmarket Studies

1.3.1. Background

In April 2020, PM USA introduced the *IQOS* 2.4/2.4+ Systems for sale followed in March 2021 by *IQOS* 3 in selected markets²⁰. In April of 2021, PM USA expanded the sale of the Authorized *IQOS* and *Marlboro HeatSticks* (i) into retail stores statewide across Georgia, Virginia, North Carolina, and South Carolina and (ii) to the Northern Virginia metro market.

However, on November 28th, 2021, the importation ban and cease-and-desist orders (CDO) imposed by the ITC on the *IQOS* device, *Marlboro HeatSticks*, and infringing components went into effect. As a result, the *IQOS* system has not been marketed or distributed in the U.S. since the removal of *IQOS* products from the market on November 28th, 2021.²¹ Therefore, no new sales data are provided and previous sales data submitted as part of the 2022 Annual Report²² are summarized below.

1.3.2. Summary of U.S. Sales Data

For the year 2021, compared to 2020, total *IQOS* device sales increased by (b) (4) largely driven by expanded distribution in retail stores and the launch of the *IQOS* 3 device, which features a longer battery life and a faster re-charging time compared to *IQOS* 2.4/2.4+. On a quarter-by-quarter basis, *IQOS* device sales increased by (b) (4) from Q1 to Q2 before declining by approximately (b) (4) from Q2 to Q3 due to the CDO.

Year over year, *Marlboro HeatSticks* retail sales volumes also increased by (b) (4) *Marlboro HeatSticks* sales increased by (b) (4) (b) (4) from Q1 to Q2, followed by a decline of approximately (b) (4) from Q2 to Q3 due to the CDO.

²⁰ Source: Source: Altria Group, Inc. First-Quarter Results - April 29, 2021, available at: https://s25.q4cdn.com/409251670/files/doc_financials/2021/q1/Altria.pdf

²¹ In September 2021, the International Trade Commission (ITC) issued an order imposing an importation ban on the *IQOS* device and *Marlboro HeatSticks* into the U.S., and a cease and desist order on the marketing and sale of product already imported into the U.S.

²² 2022 Annual Report and PMSS report submitted on April 29, 2022

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Table 6 summarizes volume and percent change by quarter and full year 2021. In addition, full-year 2021 U.S. sales and distribution by calendar quarter is cross-referenced from Annex P01-5 of the 2022 Annual Report²³.

Table 6. Summary of Quarterly and Annual Volume Change (*HeatStick* Volume in Packs, 20 stick count)

		<i>IQOS</i> 2.4	<i>IQOS</i> 3	Total Devices	Amber	Blue Menthol	Green Menthol	Total <i>HeatSticks</i>
Volume	Q1 2021	(b) (4)						
	Q2 2021							
% Change								
Volume	Q2 2021							
	Q3 2021							
% Change								
Volume	Q3 2021							
	Q4 2021							
% Change								
Volume	2020							
	2021							
% Change								

1.3.3. U.S. Postmarket Studies

On July 7th, 2020, and on March 11th, 2022, FDA issued a Modified Risk Granted Order (MRGO) authorizing the *IQOS* 2.4 and *IQOS* 3 System Holders and Chargers and associated Marlboro *HeatSticks* to be marketed with a reduced exposure claim²⁴. The Order was conditioned upon agreement to conduct postmarket surveillance and studies (PMSS) in accordance with a protocol approved by FDA, as stated in the FDA Guidance “*The outcomes evaluated in PMSS should focus on the effect of the MRTP on consumer perception, behavior and health under real world conditions of use*”²⁵.

²³ 2022 Annual Report and PMSS report submitted on April 29, 2022 (Annex P01-5)

²⁴ *IQOS* 2.4 MR0000133 dated July 7, 2020 and *IQOS* 3.0 MR0000192 dated November 3, 2022.

²⁵ FDA. Modified Risk Tobacco Product Applications. Guidance for Industry. Rockville, MD: U.S. Department of Health and Human Services. March 2012.
<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297751.pdf>.

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For this reason, Altria Client Services (ALCS) on behalf of PMP S.A., conducted several postmarket studies to assess the effect of the MRTP among U.S. tobacco users²⁶. A summary of each study that was included in the latest version of our approved PMSS program is provided in [section 8-1 PMSS](#). As explained in [section 8.1](#), the cessation of sales of *IQOS* due to the ITC order has limited our ability to study and surveil *IQOS* use. As such, timing and plans for PMSS have been adjusted as documented in the letter sent to FDA on January 14, 2022²⁷. Changes include pausing *IQOS* with Marlboro *HeatSticks* Cross-Sectional Postmarket Adult Consumer Study (*IQOS* Cross-sectional PACS Study) (ALCS-CMI-17-36-HT) and ending reporting from the current U.S. *IQOS* Owners Panel.

Adult Tobacco Consumer Tracking study (ATCT) data collection, including surveillance of *IQOS* use is ongoing. However, only a small sample of *IQOS* users was collected through ATCT which precluded any analysis. As a result, we only provide summaries of findings from two studies conducted among tobacco users: the *IQOS* Cross-sectional PACS Study and the longitudinal *IQOS* Owner Panel. Latest data from ATCT, submitted as part of the PMSS module of the 2023 Annual Report, is cross-referenced²⁸.

Overall, data from these U.S. postmarket studies provide evidence related to *HeatSticks* consumption and *IQOS* use patterns over time. Evidence demonstrates that *IQOS*, as actually used by consumers, continues to be appropriate to promote public health and is expected to benefit the health of the population as a whole.

1.3.4. U.S. Postmarket Data on Product Use Patterns from *IQOS* Cross-sectional PACS

The purpose of the *IQOS* Cross-sectional PACS was to provide survey data from qualified adult ever established *IQOS* users to assess use and perceptions of the products and associations with other tobacco use behaviors. The study objectives were as follows:

1. To characterize adult ever established *IQOS* users and their tobacco use patterns
2. To characterize risk perceptions of *IQOS* (addressed in [Module 6-3](#) of the MRTPA renewal)
3. To describe initiation, complete switching from cigarette smoking to *IQOS*, transitions to/back to cigarette smoking, and quitting behaviors relevant to *IQOS* use.

A summary of the *IQOS* Cross-sectional PACS methodology is presented in [Table 7](#).

²⁶ Update PMSS plan submitted on April 7, 2022; Response to Deficiency letter submitted on June 27, 2022, Proceed Letter dated January 10, 2023 (PS0000169, PS0000194, PS0000231 and PS0000268).

²⁷ Letter « Adjustment to the Postmarket Surveillance and Studies (PMSS) Plan for MR0000059 - MR0000061 and MR0000133 » dated January 14, 2022.

²⁸ 2023 Annual report and PMSS plan submitted on April 28, 2023.

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Table 7 Methodology of IQOS Cross-sectional PACS Study

Study Title: *IQOS* with Marlboro *HeatSticks* Cross-sectional Postmarket Adult Consumer Study (*IQOS* Cross-sectional PACS)

Study design:

A self-administered online cross-sectional survey of adult established *IQOS* users.

Main criteria for inclusion:

Participants included ever established *IQOS* users 21 years of age or older recruited from the *IQOS* consumer database.

Ever established *IQOS* users were defined as adults who have ever used at least 100 Marlboro *HeatSticks*. Ever established *IQOS* users included the following two groups:

- **Current established *IQOS* users:** Adult ever established *IQOS* users who now use *IQOS* “every day” or “some days”.
- **Former established *IQOS* users:** Adult ever established *IQOS* users who now use *IQOS* “not at all.”

Methods and Outcome Measures:

A computerized questionnaire was used to characterize:

- Use Patterns including *IQOS* use not as intended
- Risk Perception of *IQOS*²⁹
- Initiation of tobacco with *IQOS*³⁰
- Initiation of *IQOS* as long-term former smokers and long-term former tobacco users
- Complete Switching from Cigarettes Smoking/All Tobacco to *IQOS*
- Transitions To/Back To Cigarette Smoking
- Quitting Behaviors

Overall, results from PACS demonstrate that *IQOS* use was in accordance with the principles of benefitting the health of the population as a whole. Specifically, results of the of *IQOS* Cross-sectional PACS demonstrate that current *IQOS* consumers largely (92%) consist of existing tobacco users, especially long-term cigarette smokers. During the limited duration when *IQOS* was marketed in the U.S., almost one in three *IQOS* users (35.08%) were using *IQOS* only (Table 9), and more than 80% of *IQOS* users who were still smoking indicated that they reduced their cigarette consumption, potentially signaling a journey toward switching.

²⁹ See [section 6.4](#)

³⁰ See [section 6.3](#)

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Unintended use of *IQOS* was low (i.e., misuse) and almost half of *IQOS* users preferred menthol *HeatSticks*.

Full study results have been submitted previously as part of the 2022 Annual Report³¹. Below we provide a summary of key findings:

A total of 688 individuals met all inclusion criteria and completed the *IQOS* Cross-sectional PACS survey. Of the 688 ever established users, 439 current and 24 former established users completed the survey before October 13.³² In total, 59.91% of the 439 current established *IQOS* users were males; the majority were non-Hispanic white (72.89%), followed by non-Hispanic Asians (14.35%) and Hispanic (5.47%) and non-Hispanic black (4.78%). The mean age was 45 years old with 1.59% being 21-24 years of age, and almost all were from the Southern region of the United States where *IQOS* was marketed and sold.

Over half of *IQOS* users preferred menthol *HeatSticks* (n= 231) compared to non-menthol *HeatSticks* (n= 208). Compared to *IQOS* users who preferred menthol (64.50%), a larger proportion of *IQOS* users who preferred non-menthol *HeatSticks* were Non-Hispanic White/Caucasian (82.21%), whereas a larger proportion of those who preferred menthol *HeatSticks* were non-Hispanic Asian (21.65%) or Non-Hispanic Black/African American (6.49%) (Table 8).

³¹ 2022 Annual report and PMSS plan submitted on April 29, 2022

³² On October 13, 2021 *IQOS* consumers were informed that *IQOS* will not be available after November 29, 2021. Considering that the communication may alter consumer behaviors, we focus on results based on those who completed the survey by October 13 in this report. Results for those who completed the survey after October 13 are available in Appendix A1. We do not observe any substantial differences in tobacco use patterns and perceptions about *IQOS* between those who completed the survey by and after October 13.

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Table 8 Demographics and background information of current *IQOS* users

Measure	Current Established <i>IQOS</i> Users n = 439	Current Established <i>IQOS</i> Users Who Prefer Menthol <i>HeatSticks</i> n = 231	Current Established <i>IQOS</i> Users Who Prefer non-Menthol <i>HeatSticks</i> n = 208
Base (Total Participants)			
Gender [% (95% CI)]			
Male	59.91 (55.32; 64.49)	58.87 (52.53; 65.22)	61.06 (54.43; 67.68)
Age [% (95% CI)]			
21 - 24	1.59 (0.64; 3.26)	1.30 (0.27; 3.75)	1.92 (0.53; 4.85)
25 - 34	16.17 (12.73; 19.62)	20.78 (15.55; 26.01)	11.06 (6.80; 15.32)
35 - 44	34.40 (29.95; 38.84)	38.10 (31.83; 44.36)	30.29 (24.04; 36.53)
45 - 54	27.11 (22.95; 31.27)	24.68 (19.12; 30.23)	29.81 (23.59; 36.02)
55 - 64	16.17 (12.73; 19.62)	11.69 (7.55; 15.83)	21.15 (15.60; 26.70)
65+	4.56 (2.61; 6.51)	3.46 (1.51; 6.71)	5.77 (2.60; 8.94)
Median Age [years (25; 75 percentile)]	44 (37; 53)	42 (35; 50)	47.00 (39; 55)
Race/Ethnicity [% (95% CI)]			
NH White/Caucasian	72.89 (68.73; 77.05)	64.50 (58.33; 70.67)	82.21 (77.01; 87.41)
NH Black/African-American	4.78 (2.79; 6.78)	6.49 (3.32; 9.67)	2.88 (1.07; 6.17)
Hispanic/Latino	5.47 (3.34; 7.59)	5.63 (2.66; 8.60)	5.29 (2.25; 8.33)
NH Asian	14.35 (11.07; 17.63)	21.65 (16.33; 26.96)	6.25 (2.96; 9.54)
Household Income [% (95% CI)]			
Under \$60,000 (Net)	32.35 (27.97; 36.72)	34.20 (28.08; 40.32)	30.29 (24.04; 36.53)
\$60,000 or More (Net)	60.59 (56.02; 65.16)	58.44 (52.09; 64.80)	62.98 (56.42; 69.54)
Education [% (95% CI)]			
High School or Less (Net)	20.50 (16.72; 24.28)	18.61 (13.60; 23.63)	22.60 (16.91; 28.28)
Some College or More (Net)	78.82 (74.99; 82.64)	80.52 (75.41; 85.63)	76.92 (71.20; 82.65)
Employment Status [% (95% CI)]			
Employed (Net)	80.64 (76.94; 84.33)	82.25 (77.32; 87.18)	78.85 (73.30; 84.40)
Not Employed (Net)	19.36 (15.67; 23.06)	17.75 (12.82; 22.68)	21.15 (15.60; 26.70)

CI: Confidence Interval, n: Number of observations; NH: non-Hispanic.

Source: Final Study Report ALCS-CMI-17-36-HT³³, Table 2.

Around one third of current established *IQOS* users (35.08%) were currently using *IQOS* only, 42.60% were using *IQOS* and one other tobacco product, and 22.32% were using *IQOS* and two or more other tobacco products. The most commonly used other tobacco product used by half of dual users was cigarette, followed by e-cigarette/e-vapor and cigars or other tobacco products assessed (Table 9).

Using *IQOS* only was higher in the menthol *HeatSticks* users' group (38.10%) compared to non-menthol *HeatSticks* users' group (31.73%). Using *IQOS* plus one other tobacco product was lower in the menthol *HeatSticks* users' group (40.26%) compared to non-menthol

³³ 2022 Annual report and PMSS plan submitted on April 29, 2022, P01-1_-IQOS_Cross-Sectional_PACS_-Wave_1_Final_Study_Report

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HeatSticks users' group (45.19%). Specifically, using *IQOS* and cigarettes was lower in the menthol *HeatSticks* users' group (27.27%) compared to non-menthol *HeatSticks* users' group (31.25%) (Table 9). These findings potentially suggest that the availability of greater varieties of *HeatSticks* flavors may promote higher level of complete switching among smokers.

Among current dual users of *IQOS* and cigarettes, 23.81% of current established *IQOS* users who prefer menthol *HeatSticks*, prefer non-menthol cigarettes. This proportion was higher compared to the proportion of current established *IQOS* users who prefer non-menthol *HeatSticks* and prefer menthol cigarettes (3.08%). This data shows that the availability of menthol *HeatSticks* may facilitate the transition of a larger proportion of adult smokers from cigarettes to *IQOS*.

Table 9 Exclusive and dual/poly tobacco use of current *IQOS* users

	Current Established <i>IQOS</i> Users % (CI)	Current Established <i>IQOS</i> Users Who Prefer Menthol <i>HeatSticks</i> % (CI)	Current Established <i>IQOS</i> Users Who Prefer non- Menthol <i>HeatSticks</i> % (CI)
Base (Total Participants)	n = 439	n = 231	n = 208
Current use ('every day' or 'some days') of:			
<i>IQOS</i> only	35.08 (30.62; 39.54)	38.10 (31.83; 44.36)	31.73 (25.41; 38.06)
<i>IQOS</i> plus one other tobacco product	42.60 (37.97; 47.22)	40.26 (33.94; 46.58)	45.19 (38.43; 51.96)
- <i>IQOS</i> and cigarettes	29.16 (24.91; 33.41)	27.27 (21.53; 33.02)	31.25 (24.95; 37.55)
- <i>IQOS</i> and one other tobacco product, excluding cigarettes	13.44 (10.25; 16.63)	12.99 (8.65; 17.32)	13.94 (9.23; 18.65)
<i>IQOS</i> plus two or more other tobacco products	22.32 (18.43; 26.22)	21.65 (16.33; 26.96)	23.08 (17.35; 28.80)
- <i>IQOS</i> and two or more other tobacco products, including cigarettes	19.59 (15.88; 23.30)	19.48 (14.37; 24.59)	19.71 (14.31; 25.12)
- <i>IQOS</i> and two or more other tobacco products, excluding cigarettes	2.73 (1.21; 4.26)	2.16 (0.71; 4.98) (P)	3.37 (1.36; 6.81) (P)
Among Current Dual Users of <i>IQOS</i> , and cigarettes			
Base (Dual users of <i>IQOS</i> and cigarettes)	n = 128	n = 63	n = 65
Menthol cigarette preference	37.50 (29.11; 45.89)	73.02 (62.06; 83.98)	3.08 (0.37; 10.68) (P)
Non-Menthol cigarette preference	60.16 (51.67; 68.64)	23.81 (13.29; 34.33)	95.38 (87.10; 99.04)
Unknown	0.78 (0.02; 4.28) (P)	1.59 (0.04; 8.53) (P)	0.00 (0.00; 5.52)
Refused to answer	1.56 (0.19; 5.53) (P)	1.59 (0.04; 8.53) (P)	1.54 (0.04; 8.28) (P)

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CI: Confidence Interval, n: Number of observations, P: Low Statistical Precision
Source: Final Study Report ALCS-CMI-17-36-HT³⁴, Table 4.

The importance of having multiple *HeatSticks* variants is also evident when looking at data on *HeatSticks* varieties tried and used by current established *IQOS* users (Table 10). Data shows a clear evolution of use behavior over time as *IQOS* users go through a transition period where they try different *HeatSticks* varieties before ascertaining their choice. When asked about the *HeatSticks* varieties current established *IQOS* users were currently using, most responded Amber/Regular (51.03%). At the same time, there was an increase in the proportion of current established *IQOS* users who reported currently using of Green Menthol/Smooth Menthol *HeatSticks* (35.54%) and Blue Menthol/Fresh Menthol *HeatSticks* (27.33%) compared to their first *HeatSticks* varieties ever tried (30.30% and 15.95% respectively).

Together these findings indicate that offering a variety of *HeatSticks* varieties might be an important factor to promote adoption of *IQOS* overtime.

Table 10 *HeatSticks* varieties trial/usage

Measure	Current Established <i>IQOS</i> Users
Base (Total Participants)	n = 439
<i>HeatSticks</i> Varieties Ever Tried	
Amber/Regular <i>HeatSticks</i>	72.44 (68.26; 76.62)
Green Menthol/Smooth Menthol <i>HeatSticks</i>	69.48 (65.17; 73.78)
Blue Menthol/Fresh Menthol <i>HeatSticks</i>	57.63 (53.01; 62.25)
First <i>HeatSticks</i> Varieties Ever Tried	
Amber/Regular <i>HeatSticks</i>	53.76 (49.09; 58.42)
Green Menthol/Smooth Menthol <i>HeatSticks</i>	30.30 (26.00; 34.59)
Blue Menthol/Fresh Menthol <i>HeatSticks</i>	15.95 (12.52; 19.37)
Not Sure	0.00 (0.00; 0.84)
<i>HeatSticks</i> Varieties Currently Using*	
Amber/Regular <i>HeatSticks</i>	51.03 (46.35; 55.70)
Green Menthol/Smooth Menthol <i>HeatSticks</i>	35.54 (31.06; 40.01)
Blue Menthol/Fresh Menthol <i>HeatSticks</i>	27.33 (23.17; 31.50)
<i>HeatSticks</i> Varieties Currently Using*Most Often	
Amber/Regular <i>HeatSticks</i>	47.38 (42.71; 52.05)
Green Menthol/Smooth Menthol <i>HeatSticks</i>	30.07 (25.78; 34.36)
Blue Menthol/Fresh Menthol <i>HeatSticks</i>	22.55 (18.64; 26.46)

*This refers to current use at the time of the survey.CI: Confidence Interval, n: Number of observations
Source: Final Study Report ALCS-CMI-17-36-HT³⁵, Table 17.

³⁴ 2022 Annual report and PMSS plan submitted on April 29, 2022, P01-1 - IQOS_Cross-Sectional_PACS - _Wave_1_Final_Study_Report

³⁵ 2022 Annual report and PMSS plan submitted on April 29, 2022, P01-1 - IQOS_Cross-Sectional_PACS - _Wave_1_Final_Study_Report

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In total, 70.39% of current established *IQOS* users reported using *IQOS* daily, with a higher proportion among current established *IQOS* users who prefer menthol (73.16%) compared to those who prefer non-menthol (67.31%) *HeatSticks*. Quantity of *HeatSticks* used per day (Median: 14.0 *HeatSticks*/day in the past 30 days) were similar among current established *IQOS* users of menthol and regular *HeatSticks IQOS* (Table 11).

Table 11 Number of days participants used *IQOS* in past 30 days and number of *IQOS* Marlboro *HeatSticks* used in past 30 days

Measure	Current Established <i>IQOS</i> Users % (CI)	Current Established <i>IQOS</i> Users Who Prefer Menthol <i>HeatSticks</i> % (CI)	Current Established <i>IQOS</i> Users Who Prefer Non-Menthol <i>HeatSticks</i> % (CI)
Base (Total Participants)	n = 439	n = 231	n = 208
During the past 30 days, on how many days did you use <i>IQOS</i> with Marlboro <i>HeatSticks</i> ?			
30 days	70.39 (66.12; 74.66)	73.16 (67.45; 78.87)	67.31 (60.93; 73.68)
Mean number of days used	26.23 (25.56; 26.90)	26.55 (25.64; 27.45)	25.88 (24.87; 26.90)
Standard deviation of days used	7.16	6.95	7.39
Median number of days used	30.00 (25.00; 30.00)	30.00 (28.00; 30.00)	30.00 (24.00; 30.00)
Min/Max	0.00 / 30.00	0.00 / 30.00	0.00 / 30.00
During the past 30 days, on the days you used <i>IQOS</i> with Marlboro <i>HeatSticks</i> , how many Marlboro <i>HeatSticks</i> did you use per day, on average?			
Median number of <i>HeatSticks</i> ® per day on days used	15.00 (10.00; 20.00)	15.00 (10.00; 20.00)	15.00 (10.00; 20.00)
IQR	10.00	10.00	10.00
<i>HeatSticks</i> per day in the past 30 days			
Median number of <i>HeatSticks</i> ® per day	14.00 (7.00; 20.00)	14.00 (8.00; 20.00)	14.00 (6.67; 20.00)
IQR	13.00	12.00	13.33

CI: Confidence Interval, IQR: Interquartile Range, Max: Maximum, Min: Minimum, n: Number of observations, P: Low Statistical Precision

Source: Final Study Report ALCS-CMI-17-36-HT³⁶. Table 5.

³⁶ 2022 Annual report and PMSS plan submitted on April 29, 2022, P01-1_- IQOS_Cross-Sectional_PACS_- Wave_1_Final_Study_Report

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In terms of complete switching³⁷, 31.21% of current established *IQOS* users had switched completely from cigarettes after first trying *IQOS* (Table 12). Complete switching from cigarettes was slightly higher among current established *IQOS* who prefer menthol *HeatSticks* (32.03%) compared to those who prefer non-menthol *HeatSticks* (30.29%).

Table 12 Complete switching to *IQOS* after first trying *IQOS*

Measure	Current Established <i>IQOS</i> Users % (CI)	Current Established <i>IQOS</i> Users Who Prefer Menthol <i>HeatSticks</i> % (CI)	Current Established <i>IQOS</i> Users Who Prefer non-Menthol <i>HeatSticks</i> % (CI)
Base (Total Participants)	n = 439	n = 231	n = 208
Complete switching from all tobacco products to <i>IQOS</i> after first trying <i>IQOS</i>	25.06 (21.00; 29.11)	25.54 (19.92; 31.16)	24.52 (18.67; 30.37)
Complete switching from cigarettes to <i>IQOS</i> after first trying <i>IQOS</i>	31.21 (26.87; 35.54)	32.03 (26.02; 38.05)	30.29 (24.04; 36.53)
Complete switching from menthol cigarettes to <i>IQOS</i> after first trying <i>IQOS</i>	12.53 (9.43; 15.63)	22.94 (17.52; 28.37)	0.96 (0.12; 3.43) (P)
Complete switching from non-menthol cigarettes to <i>IQOS</i> after first trying <i>IQOS</i>	18.22 (14.61; 21.83)	8.23 (4.68; 11.77)	29.33 (23.14; 35.51)

CI: Confidence Interval, n: Number of observations, NA: Not Applicable, P: Low Statistical Precision, S: Low Sample Size

Source: Final Study Report ALCS-CMI-17-36-HT³⁸. Table 14.

Around 55.24% of current established *IQOS* users had a past 12-month cigarette quit attempt. Quit attempts during the past 12 months was similar for users who prefer menthol *HeatSticks* (54.72%) compared to users who prefer non-menthol *HeatSticks* (55.77%). Similar results were observed for motivation to stop smoking for users who prefer menthol *HeatSticks* and users who prefer non-menthol *HeatSticks*.

³⁷ In the *IQOS* Cross-Sectional PACS, *IQOS*-relevant complete switching is defined as being a current established smoker during the 30 days prior to trying *IQOS*, now using *IQOS* and “not at all” smoking, and the last time smoked was after trying *IQOS*.

³⁸ 2022 Annual report and PMSS plan submitted on April 29, 2022, P01-1 - *IQOS* Cross-Sectional PACS - Wave 1 Final Study Report

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Taken together with the evidence of limited change in intention to quit smoking and all tobacco observed in pre-market studies, these findings may indicate that the availability of *HeatSticks* is unlikely to reduce adult smokers' quit attempts and motivation to stop smoking.

1.3.5. U.S. Postmarket Data on Product Use Patterns from U.S. IQOS Owners Panel

In the United States, ALCS has set up a longitudinal *IQOS* Owner Panel that is very similar to PMP S.A.'s *IQOS* Owner Panels implemented in Germany, Italy, Japan, and South Korea, as communicated to the FDA in the annual reports³⁹ for the Authorized *IQOS* Systems. A summary of the methodology is provided in [section 8-1 PMSS](#).

Briefly, this U.S. *IQOS* Owner Panel was set up in April 2020 and ran up until November 29, 2021, when data collection ceased, as a result of the CDO and *IQOS* becoming unavailable in the U.S. market. In this section, we will present *IQOS* Owners Panel data from Quarterly Reports ending in May 31, 2021, in August 31, 2021, and November 30, 2021 that were submitted to FDA on July 30, October 30, 2021 and January 28, 2022⁴⁰. It is important to note that most of the data is limited to *IQOS* Owners from the Southern region of the United States (Georgia, Virginia, North Carolina, and South Carolina) where the *IQOS* System has mainly been marketed and sold. Moreover, because the latest Authorized *IQOS* System, the *IQOS* 3 System, was introduced by PM USA for sale in the above markets in March, 2021⁴¹, there is limited availability of data on individual *IQOS* Systems. Consequently, we report *IQOS* use patterns and the *IQOS* user profile by age and gender for the total number of U.S. *IQOS* System users only.

Overall, whilst data from the U.S. *IQOS* Owner Panels remain limited, results are promising as they demonstrate that *IQOS* use continues to be in accordance with the principles of benefitting the health of the population as a whole. This includes the majority of *IQOS* users who are using *IQOS* exclusively. Specifically, the data from U.S. *IQOS* Owner Panels ([Table 13](#)) show that from Q2 2021 to Q3 2021, the majority of *IQOS* users were using *IQOS* exclusively (i.e., 100% *IQOS* use). This was followed by a decline in 100% *IQOS* use to 43% in Q4. This decline corresponded to the CDO which was issued on 29 September 2021 and

³⁹ The 2020 Annual Report submitted on April 30, 2020 for PM0000424-PM0000426, PM0000479 covering the reporting period from April 30, 2019 to February 28, 2020 and the 2021 Annual Report submitted on April 30, 2020 for PM0000424-PM0000426, PM0000479 and PM0000634 as well as MR0000059-MR0000061 and MR0000133 and PMSS Report for MR0000059-MR0000061 and MR0000133 covering the reporting period from March 1, 2019 to February 28, 2020.

⁴⁰ See list details of quarterly report in [section 4.2 Marketing Plans](#)

⁴¹ Source: Altria Group, Inc. First-Quarter Results - April 29, 2021, available at: https://s25.q4cdn.com/409251670/files/doc_financials/2021/q1/Altria.pdf

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subsequent information letter sent to Panelists on 13 October 2021, stating that *IQOS* will be unavailable for sale in the United States as of 29 November 2021. It is, therefore, likely that this decline in 100% *IQOS* use reflects changes in behavior as a result of the information received by panelists, and which is equally reflected in the decline in sales, outlined previously in [Table 6](#).

In addition, the lower percentage of exclusive users observed in the U.S. panel compared to our international panels may be partially explained by (i) the currently limited number of *HeatSticks* variants available on the U.S. market (only 1 regular tobacco and 2 menthol flavors) and (ii) the limited number of Authorized *IQOS* Systems in the U.S.

Table 13 Quarterly data on *IQOS* Use Categories (%) and *IQOS* User Profile By Gender and Age (%)

	2021		
	Q2	Q3	Q4
<i>IQOS</i> Use Categories (%)			
100% Exclusive Use	52	51	43
Dual Use	28	33	27
Adult Smokers who no longer use <i>IQOS</i>	19	17	30
Gender (%)			
Female	43	43	45
Male	57	57	55
Age Group (%)			
21-29 years old	7	8	8
30-39 years old	22	22	20
40-49 years old	32	31	32
50-59 years old	23	23	23
60-69 years old	13	15	16
70+ years old	2	1	1

Note: Legal smoking age in the U.S. is 21 years. Q2, quarter ending 31st May 2021, Q3, quarter ending 31st August 2021, Q4, quarter ending 30th November 2021.

Source: ALCS *IQOS* Owner Panels – Q2 2021 to Q4 2021

1.3.6. Conclusion of U.S. Sales Data and Postmarket studies

In conclusion, results of the of *IQOS* Cross-sectional PACS demonstrate that current *IQOS* consumers largely (92%) consist of existing tobacco users, especially long-term cigarette smokers. During the limited duration when *IQOS* was marketed in the United States, almost one in three *IQOS* users (35.08%) had used *IQOS* only. Additionally, more than 80%

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of IQOS users who were still smoking indicated that they reduced their cigarette consumption, potentially signaling a journey toward switching. Unintended use of *IQOS* (i.e., misuse) was low. Results of the U.S. *IQOS* Owners Panel further corroborate the findings of the *IQOS* Cross-Sectional PACS by demonstrating that a significant proportion of adult *IQOS* users switched from cigarette smoking to exclusive *IQOS* use.

In relation to differences in use behavior between *IQOS* users who preferred menthol compared to non-menthol *HeatSticks*, data from the *IQOS* Cross-Sectional PACS shows that about half of *IQOS* users preferred menthol *HeatSticks*. Use of *IQOS* only was higher among current established *IQOS* users who preferred menthol *HeatSticks*. Though quantity of product use is similar among current established *IQOS* users who preferred menthol and non-menthol *HeatSticks*, the proportion of daily *IQOS* users was higher among those who preferred menthol *HeatSticks*. Quit attempts and motivation to stop were similar among current established *IQOS* users who preferred menthol and non-menthol *HeatSticks*. Based on the above points, findings potentially suggest that the availability of menthol *HeatSticks* flavors may promote higher level of complete switching among smokers and may facilitate the transition of adult smokers from cigarettes to *IQOS* use.

Overall, data from the *IQOS* Cross-Sectional PACS and *IQOS* Owners Panel support that *IQOS* continues to satisfy MRTP requirements.

1.4. International Sales Data and Postmarket Studies

1.4.1. Background

Since the launch of the first *IQOS* System in 2014 in Japan, a portfolio of *IQOS* Systems has been commercialized in more than 70 countries and has gained a sizeable consumer base approaching 20.3 million *IQOS* users worldwide. Moreover, we estimate that 70% (14.2 million) of *IQOS* consumers worldwide have stopped smoking cigarettes and switched to *IQOS*⁴². Beyond the geographical expansion of *IQOS*, one of the strategies that PMP S.A. has pursued to increase and accelerate the switching from smoking cigarettes to *IQOS* use has been to continuously improve *IQOS* users' experience. Below we present sales and postmarket data on *IQOS* use from international studies funded by PMI.

1.4.2. Summary of International Sales Data

The market share of *IQOS* (irrespective of the System) with *HEETS*⁴³ (i.e., the total *HEETS* sales volume as a percentage of the total estimated sales volume for cigarettes, *HEETS*, and

⁴² PMP S.A. Reports 2022 Q4 Results. Available on Earnings Release - Q4 2022 (gcs-web.com)

⁴³ Outside the U.S. and Japan, the *HeatSticks* have been commercialized under the brand name *HEETS*.

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other HTPs (Heated Tobacco Product)) in Germany, Italy, Japan and South Korea for Q4 2020 up until Q4 2022 is shown below (Table 14).

Overall, data shows a gradual increase in the market share of *IQOS* consistent with a global increase in the number of *IQOS* users.

Table 14 *IQOS* Market Shares in the Four Countries

Country	Q4 2020	Q4 2021	Q4 2022
Germany	2.6%	3.5%	7.9%
Italy	9.6%	12.7%	15.4%
Japan	22.0%	22.8%	24.3%
South Korea	6.7%	6.8%	6.7%

Source: PMI's. Financials or estimates⁴⁴

With respect to the positive effect of Menthol *HEETS* in facilitating the switch from combustible cigarettes to *IQOS*, international sales data provides a very clear picture of their impact in transitioning adult smokers away from cigarettes. Specifically, comparing in-market sales (IMS)⁴⁵ data for combustible cigarettes and *HEETS*⁴⁶ in Germany and Italy, which do not have a significant presence of menthol cigarettes, with data from other markets such as Japan and Korea, which have a higher prevalence of menthol cigarettes, provide relevant insights.

Focusing on IMS data of one year before the menthol ban (April 2019) and one month before the menthol ban (April 2020) for combustible cigarettes in the European Union (EU), we can note the following: In April 2019, the proportion of IMS for menthol cigarettes was equal to 1.8% in Germany and 0.4% in Italy, respectively (Table 15). In the same period, in the same two countries, the proportion of IMS for Menthol *HEETS* was equal to 15.9% and 24.9%, respectively. One month before the enforcement of the menthol ban in EU (April 2020) the prevalence remained similar with the IMS for Menthol cigarettes being equal to 1.5% in

⁴⁴ Source: PMI's 2021-2022 Fourth-Quarter Results, available at:
<https://philipmorrisinternational.gcs-web.com/static-files/b4e1fc75-3dd5-419a-a0e7-8e333b0f3c67>
<https://philipmorrisinternational.gcs-web.com/static-files/4b77c96b-b87a-4bb2-b568-208a14bdaa4c>

⁴⁵ Sales to the retail channel, depending on the market and distribution model.

⁴⁶ i.e. the quantity of combustible cigarettes or *HeatSticks/HEETS* that is reaching a specific market in a specific month

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Germany and 0.3% in Italy, respectively, while the IMS for Menthol *HEETS* remained higher at 21.2% and 23.0%, respectively.

A similar tendency was also observable in Japan and Korea. In these two countries, IMS for menthol cigarettes accounted for 28.2% and 4.9%, respectively, in April 2019, while IMS for Menthol *HEETS* reached 71.1% and 60.6%, respectively. In April 2020, the IMS for Menthol cigarettes accounted for 29.4% in Japan and 8.1% in South Korea, while the IMS for Menthol *HEETS* remained higher at 72.4% and 67.1%, respectively. Together these findings potentially indicate that the availability of menthol *HEETS* may facilitate switching from smoking cigarettes to *IQOS* use.

Table 15 In-Market Sales (IMS) of menthol cigarettes and *HEETS* in the Four Countries

Country	Flavor Type	Unit Of Measure Vol Stick	IMS CC	IMS <i>HEETS</i>
Germany	Menthol	000 sticks	(b) (4)	(4)
	Regular	000 sticks		
	TOTAL	000 sticks		
	% of menthol	%		
Italy	NA	000 sticks		
	Menthol	000 sticks		
	Regular	000 sticks		
	TOTAL	000 sticks		
Japan	NA	000 sticks		
	Menthol	000 sticks		
	Regular	000 sticks		
	TOTAL	000 sticks		
Korea	NA	000 sticks		
	Menthol	000 sticks		
	Regular	000 sticks		
	TOTAL	000 sticks		
	% of menthol	%		

NA: Not applicable

Source: PMI Financials or estimates.

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1.4.3. PMP S.A. International Postmarket Data: IQOS Owner Panels

International behavior data on the use of the Authorized IQOS Systems with HEETS⁴⁷/HeatSticks (in this section and the following sections only referred to as “HEETS”) among tobacco users is gathered from IQOS Owner Panel studies in Germany, Italy, Japan, and South Korea. Data collection has continued since the submission of the original MRTPA⁴⁸. Below, we provide an update of the data collected from international IQOS Owner Panels.

The panels include a large proportion of IQOS owners who are registered in PMI’s country-specific IQOS Owner Database. Data is weighted to ensure that the sample is representative of the broader population of IQOS users as explained in [Appendix 7-a01-description-adult-IQOS-owners-panels](#). The panels provide data on the profile of IQOS users by gender and age, IQOS use patterns, and average daily consumption. Though these panels are conducted outside of the U.S., they allow for the assessment of use behaviors longitudinally across heterogeneous IQOS users and markets. In addition, these IQOS Owner Panels are similar in design to the IQOS Owner Panel that was implemented by ALCS in the U.S., and for which we have reported key results in [section 1.3.5](#).

By repeatedly collecting international “real world” consumer data, within and across different countries, over time through the IQOS Owner Panels, PMP S.A. continuously strengthens its insights into the use behaviors related to the Authorized IQOS Systems. Given that, a large proportion of IQOS owners register their IQOS System, and hence are part of PMI’s country-associated IQOS Owner Database in each country, and even though the tobacco product marketplace, the tobacco use norms, the tobacco regulations, and the culture differ between countries, the consistency of IQOS use patterns observed in international countries suggest that the use patterns among IQOS owners in the U.S. are unlikely to differ from those consistently observed in several international countries.

Thus, we believe that the totality of this evidence provides valuable data and information applicable to the U.S.

Below ([Table 16](#)), we provide a summary of key features of the IQOS Owner Panel studies that have been implemented in several countries worldwide, including Germany, Italy, Japan, and South Korea (a more detailed description of the IQOS Owner Panels and the related data

⁴⁷ Outside the U.S., the Marlboro HeatSticks have also been commercialized under the brand name “HEETS”

⁴⁸ In previous submissions, PMP S.A. also reported data obtained from the IQOS Owner Panel study in Switzerland, which has now been discontinued.

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analysis is available in [Appendix 7-a01-description-adult-IQOS-owners-panels](#) and [Appendix 7-a02-all-contries-trend-analysis](#)).

Table 16 Methodology of IQOS Owner Panels

Study Title: <i>IQOS Owner Panels</i>
<p>Study design:</p> <p>The study consists of three key phases:</p> <ul style="list-style-type: none"> • A recruitment phase • A weekly tracking phase lasting 12 weeks • A subsequent monthly (each 4 weeks) tracking phase. <p>Every two weeks, a new cohort of recent <i>IQOS</i> owners (<i>IQOS</i> owners who bought their <i>IQOS</i> System in the previous four weeks) is added to the existing panelists. After 12 months of participation, a sample of active panelists (minimum 100 per country) is invited to continue participating in the panel to keep track of older cohorts' behavior. No replacement is sought for panelists quitting the panel.</p> <p>The study is conducted using an online web-based methodology. The questionnaire is self-administered and can be completed using a computer, laptop, tablet, or smartphone.</p>
<p>Main criteria for inclusion:</p> <p>Participants are adult <i>IQOS</i> owners who registered their <i>IQOS</i> System in PMI's country-associated <i>IQOS</i> Owner Databases, agreed to take part in market research, and had a valid email address.</p>
<p>Objectives and Outcome Measures:</p> <p>The objectives of these longitudinal consumer panels of adult <i>IQOS</i> users are (i) to measure use patterns of <i>IQOS</i> over time, and (ii) to describe the socio-demographic profile of the adult <i>IQOS</i> users.</p> <p><i>IQOS Use Level:</i> The main measure of the studies is the "<i>IQOS Use Level</i>". The <i>IQOS Use Level</i> is derived from the relative consumption of <i>HEETS</i> used per day in relation to consumption of cigarettes smoked per day and other HTPs used per day.</p> $IQOS\ Use\ Level = \frac{HEETS\ Daily\ Consumption}{(HEETS + Combustible\ Cigarettes + Other\ HnB)\ Daily\ Consumption} \times 100$ <p>The <i>IQOS Use Level</i> (or relative consumption of <i>HEETS</i>) is then classified into <i>IQOS Use Categories</i>.</p>

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1.4.4. PMP S.A. International Postmarket Data: on Use Patterns, Tobacco Consumption, and Age and Gender Profile of the Authorized IQOS Systems Users from the IQOS Owner Panels

Below, we provide the updated data from the *IQOS* Owner Panels in Germany, Italy, Japan, and South Korea. In all four countries, the data were stratified according to the following subgroup definitions:

A. Total Authorized *IQOS* Systems Users

This subgroup includes panellists who use *IQOS* 2.4, 2.4+ and/or *IQOS* 3 but may use it alongside other *IQOS* Systems (*non-authorized in the U.S.*) or other competitor HTP devices.

B. Only Authorized *IQOS* Systems Users

This subgroup includes panellists who use only *IQOS* 2.4, 2.4+ and/or *IQOS* 3. Panellists who use other *IQOS* Systems (*non-authorized in the U.S.*) or other competitor HTP devices are excluded.

Total Authorized *IQOS* Systems Users reflects real world behaviors since *IQOS* users may be using the authorized *IQOS* system alongside other *IQOS* Systems. In contrast, Only Authorized *IQOS* Systems Users category was defined to ensure that the results are attributable to the authorized *IQOS* Systems used. The ‘Total Authorized *IQOS* Systems Users’ and ‘Only Authorized *IQOS* Systems Users’ subgroups are not mutually exclusive⁴⁹.

In line with the encouraging and growing results achieved with respect to market share, we also observed positive data about the ability of *IQOS* Systems with *HEETS*, including the Authorized *IQOS* Systems, to completely switch adult smokers away from cigarettes. Updated information about 100% *IQOS* Use, average daily total, *HEETS*, and cigarette consumption (sticks/day), and the profile of *IQOS* users by gender and age related to the Authorized *IQOS* Systems in comparison to other *IQOS* Systems for Italy, Germany, Japan, and South Korea are presented below.

Sociodemographic characteristics

The sociodemographic characteristics of *IQOS* users were relatively similar between Total Authorized *IQOS* Systems Users and Only Authorized *IQOS* Systems Users (Table 17).

⁴⁹ If a person used both *IQOS* 2.4 or 2.4+ and *IQOS* 3, they are counted once under **Total Authorized *IQOS* Systems Users** and once **Only Authorized *IQOS* Systems Users**.

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Across all countries, among Only Authorized *IQOS* Systems Users, average age of *IQOS* users ranged from a lowest 37.66 years old in Italy to a highest 47.45 years old in Japan. In European countries, the proportion of male and female was relatively equally distributed while in Japan and Korea, the proportion of male *IQOS* users was 76% and 93%, respectively.

Across all countries, the proportion of legal age (LA) for smoking+1 year to 24 users was lowest compared to other age groups. Specifically, the proportion of LA+1 year-24 years old ranged from a lowest 1% in Japan to a highest 17% in Italy among Only Authorized *IQOS* Systems Users. In Italy, the higher proportion of LA+1-24 years old also corresponds to the high proportion of cigarette smokers in this age group.⁵⁰

When assessing evolution over time, the sociodemographic characteristics of Total Authorized *IQOS* Systems Users and Only Authorized *IQOS* Users remained stable over time across all countries ([Appendix 7-a02-all-countries-trend-analysis](#)).

Table 17 Summary of Sociodemographic Characteristics for four countries – December 2022

	Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users (N)	2170	2183	2296	855
LA+1 year to 24*	6%	17%	1%	2%
25 to 34	22%	31%	8%	18%
35 to 44	23%	21%	23%	36%
45+	49%	32%	68%	44%
Mean**	44.48	37.90	49.20	43.38
Male	59%	47%	77%	92%
Female	41%	53%	23%	8%
Only Authorized <i>IQOS</i> Systems Users (N)	1313	1385	882	514
LA+1 year to 24	6%	17%	1%	2%
25 to 34	23%	31%	11%	21%
35 to 44	22%	21%	27%	37%
45+	49%	31%	61%	40%
Mean	44.10	37.66	47.45	42.26
Male	59%	47%	76%	93%
Female	41%	53%	24%	7%

* LA: Legal Age to purchase tobacco product is 18 years old in Germany and Italy, 19 years old in South Korea, and 20 years old in Japan)

** Mean of age shown in years

Source: *IQOS* Owner Panels – December 2022

⁵⁰ Italy Institute of National Statistics I.stat. Age detail in Aspects of daily life : Smoking - age, educational qualifications (istat.it). Available on <http://dati.istat.it/Index.aspx?QueryId=15513> [Accessed on April 26th 2023].

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100% IQOS Use Category

100% IQOS Use was relatively similar between Total Authorized IQOS Systems Users and Only Authorized IQOS Systems Users (Table 18).

In Germany, Italy, Japan, and South Korea, the data from December 2022 shows that the majority of IQOS users were using IQOS with HEETS exclusively (i.e., 100% IQOS use). Specifically, among Only Authorized IQOS Systems Users, 100% IQOS use ranged from a lowest 54% in Germany to a highest 64% in either Italy and South Korea.

Moreover, when assessing evolution over time, the proportion of IQOS users who were using IQOS with HEETS exclusively remained stable over time across all countries (Appendix 7-a02-all-countries-trend-analysis).

Table 18 Summary of IQOS Use Categories for four countries – December 2022

	Germany	Italy	Japan	South Korea
Total Authorized IQOS Systems Users (N)	2088	2106	2080	786
100% IQOS	54%	65%	58%	58%
Converted ($\geq 95\%$)	57%	69%	62%	60%
Predominant (70%–<95%)	8%	10%	7%	11%
Combined use (30%–<70%)	9%	10%	11%	14%
Cigarette use (0%–<30%)	26%	12%	20%	15%
Only Authorized IQOS Systems Users (N)	1264	1340	850	481
100% IQOS	54%	64%	62%	64%
Converted ($\geq 95\%$)	57%	66%	63%	66%
Predominant (70%–<95%)	6%	11%	3%	6%
Combined use (30%–<70%)	8%	9%	8%	12%
Cigarette use (0%–<30%)	28%	13%	25%	15%

Note: All data presented are based on past 7-day consumption of IQOS and/or cigarettes, excluding other competitor HTPs

Source: IQOS Owner Panels – December 2022

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Average Daily Consumption

The average daily consumption of tobacco products was relatively similar between Total Authorized *IQOS* Systems Users and Only Authorized *IQOS* Systems Users (Table 19).

Among Only Authorized *IQOS* Systems Users, the data from December 2022 show that the average daily total consumption (including *HEETS*, CC, and other competitor HTPs) ranged from a lowest 10.7 sticks per day in Italy to a highest 14.0 sticks per day in Japan.

When assessing evolution over time, average daily consumption of tobacco products remained stable over time across all countries (Appendix 7-a02-all-contries-trend-analysis).

Table 19 Summary of Average daily consumption for four countries – December 2022

	Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users (N)	2170	2183	2296	855
Total Tobacco Sticks	13.3	11.2	16.0	13.9
PMI consumables*	8.6	9.0	10.6	10.2
<i>HEETS</i>	8.5	8.7	9.5	10.0
Cigarettes	4.3	1.9	3.4	2.5
Other**	0.5	0.3	2.0	1.2
Only Authorized <i>IQOS</i> Systems Users (N)	1313	1385	882	514
Total Tobacco Sticks	12.5	10.7	14.0	12.6
PMI consumables	7.8	8.6	9.4	9.6
<i>HEETS</i>	7.8	8.4	9.4	9.6
Cigarettes	4.7	2.2	4.7	3.0
Other	-	-	-	-

Note: All data presented are based on past 7-day consumption.

* PMI consumables include *HEETS* + *FITT* + *TEREA* + *SENTIA*. *FITT* is a KT&G consumable compatible with *Lil* and *IQOS* while *TEREA* and *SENTIA* are PMI consumables that are compatible with more novel induction-based *IQOS* devices commercialized outside of U.S.

** The following other competitor HTPs are available in the four markets: *Glo* (Germany); *Glo*, *Ploom* (Italy); *Glo*, *Ploom*, *Lil* (Japan); *Glo*, *Lil* (Korea)

Source: *IQOS* Owner Panels – December 2022

Below, we provide additional analysis from the *IQOS* Owner Panels in Germany, Italy, Japan, and South Korea, based on the subgroup definitions (Total Authorized *IQOS* Systems Users, Only Authorized *IQOS* Systems Users) stratified according to *HEETS* Type (menthol *HEETS*, regular *HEETS*, or both *HEETS*)

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Sociodemographic Characteristics by *HEETS* Type

Among Only Authorized *IQOS* Systems Users, the average age of menthol *HEETS* users ranged from a lowest 37.69 years in Italy to a highest 46.93 years in Japan. Meanwhile, the average age of regular *HEETS* users ranged from 37.05 years in Italy to 48.86 years in Japan. This shows that there is limited difference in terms of age, though in general the average age of regular *HEETS* users is slightly higher than menthol *HEETS* users ([Table 20](#)).

Table 20 Summary of sociodemographic across four countries by *HEETS* Type - December 2022

		Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users	N	313	415	1188	245
Menthol <i>HEETS</i>	LA+1 year to 24*	5%	11%	1%	2%
	25 to 34	28%	30%	8%	14%
	35 to 44	26%	23%	24%	33%
	45+ years	41%	36%	67%	51%
	Mean**	42.60	39.13	48.74	44.95
	Male	57%	52%	74%	94%
	Female	43%	48%	26%	6%
Regular <i>HEETS</i>	N	1324	1270	595	161
	LA+1 year to 24	5%	16%	0%	1%
	25 to 34	20%	35%	6%	15%
	35 to 44	24%	19%	20%	31%
	45+ years	51%	30%	74%	53%
	Mean	45.19	37.28	51.04	45.86
	Male	60%	49%	83%	92%
	Female	40%	51%	17%	8%
Both <i>HEETS</i>	N	233	175	58	NA
	LA+1 year to 24	7%	16%	0%	0%
	25 to 34	15%	32%	8%	NA
	35 to 44	24%	23%	15%	NA
	45+ years	54%	29%	77%	NA
	Mean	44.75	37.85	52.86	NA
	Male	51%	36%	82%	NA
	Female	48%	64%	18%	NA

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		Germany	Italy	Japan	South Korea
Only Authorized <i>IQOS</i> Systems Users Menthol <i>HEETS</i>	N	166	259	464	141
	LA+1 year to 24	7%	12%	1%	2%
	25 to 34	37%	34%	12%	18%
	35 to 44	20%	26%	29%	31%
	45+ years	37%	28%	58%	49%
	Mean	40.90	37.69	46.93	44.13
	Male	62%	53%	73%	94%
	Female	38%	47%	27%	6%
Regular <i>HEETS</i>	N	799	824	220	105
	LA+1 year to 24	5%	18%	1%	1%
	25 to 34	22%	34%	8%	13%
	35 to 44	24%	18%	24%	34%
	45+ years	49%	30%	67%	52%
	Mean	44.49	37.05	48.86	45.16
	Male	59%	49%	81%	94%
	Female	41%	51%	19%	6%
Both <i>HEETS</i>	N	120	118	NA	NA
	LA+1 year to 24	9%	12%	NA	NA
	25 to 34	13%	34%	NA	NA
	35 to 44	24%	30%	NA	NA
	45+	54%	24%	NA	NA
	Mean	44.45	37.16	NA	NA
	Male	53%	35%	NA	NA
	Female	47%	65%	NA	NA

* LA: Legal Age to purchase tobacco product is 18 years old in Germany and Italy, 19 years old in South Korea, and 20 years old in Japan)

** Mean of age shown in years

NA: Not applicable (base size too low to provide data)

Source: *IQOS* Owner Panels – December 2022

100% *IQOS* Use Category by *HEETS* Type

100% *IQOS* Use was somewhat higher among Only Authorized *IQOS* Systems Users who use Menthol *HEETS* compared to Total Authorized *IQOS* Systems Users who use Menthol *HEETS* (Table 21). This was particularly evident in Japan, where 100% *IQOS* Use among menthol

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HEETS users was 80% among Only Authorized *IQOS* Systems Users compared to 67% among Total Authorized *IQOS* Systems Users.

Among both subgroups of users, when comparing menthol vs. regular *HEETS* users, 100% *IQOS* Use was found to be higher among menthol *HEETS* users compared to regular *HEETS* users in three out of the four countries. Specifically, among Only Authorized *IQOS* Systems Users, 100% *IQOS* use ranged from a lowest 70% in Italy to a highest 80% in Japan among menthol *HEETS* users, while it ranged from a lowest 56% in South Korea to a highest 73% in Italy and Japan, equally, among regular *HEETS* users.

Table 21 Summary of 100% *IQOS* Use across four countries by *HEETS* Type - December 2022

	Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users				
Menthol <i>HEETS</i>	67% (n=313)	67% (n=415)	67% (n=1,188)	64% (n=245)
Regular <i>HEETS</i>	65% (n=1,324)	73% (n=1,270)	63% (n=595)	58% (n=161)
Both <i>HEETS</i>	57% (n=233)	75% (n=175)	57% (n=58)	NA NA
Only Authorized <i>IQOS</i> Systems Users				
Menthol <i>HEETS</i>	71% (n=166)	70% (n=259)	80% (n=464)	72% (n=141)
Regular <i>HEETS</i>	68% (n=799)	73% (n=824)	73% (n=220)	56% (n=105)
Both <i>HEETS</i>	58% (n=120)	73% (n=118)	NA NA	NA NA

NA: Not applicable (base size too low to provide data)

Source: *IQOS* Owner Panels – December 2022

Average Daily Consumption by *HEETS* Type

The average daily consumption of tobacco products was relatively similar between Total Authorized *IQOS* Systems Users and Only Authorized *IQOS* Systems Users ([Table 22](#)).

Among Only Authorized *IQOS* Systems Users, the average daily consumption of tobacco products was generally higher among Both *HEETS* users or regular *HEETS* users compared to

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Menthol *HEETS* users. The difference ranged between 0.5 to 1.9 tobacco sticks per day, except in South Korea where the average daily consumption of tobacco products was higher (1.5 tobacco sticks per day) among Menthol *HEETS* users.

Table 22 Summary of average daily consumption for four countries by *HEETS* Type - December 2022

	Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users				
Menthol <i>HEETS</i> (N)	313	415	1188	245
Total Tobacco Sticks	11.4	11.3	15.9	15.0
PMI consumables*	8.9	10.0	13.0	12.9
<i>HEETS</i>	8.8	9.6	11.9	12.6
Cigarettes	2.3	1.1	1.9	1.6
Other**	0.2	0.2	1.0	0.4
Regular <i>HEETS</i> (N)	1324	1270	595	161
Total Tobacco Sticks	13.7	12.1	17.1	13.6
PMI consumables	10.9	10.8	14.1	10.7
<i>HEETS</i>	10.8	10.5	12.7	10.5
Cigarettes	2.5	1.1	2.0	2.4
Other	0.3	0.2	1.0	0.6
Both <i>HEETS</i> (N)	233	175	58	NA
Total Tobacco Sticks	15.4	12.3	18.6	NA
PMI consumables	12.6	11.2	13.9	NA
<i>HEETS</i>	12.5	10.8	11.8	NA
Cigarettes	2.5	1.1	4.0	NA
Other	0.4	0.1	0.6	NA
Only Authorized <i>IQOS</i> Systems Users				
Menthol <i>HEETS</i> (N)	166	259	464	141
Total Tobacco Sticks	10.8	10.5	14.2	14.4
PMI consumables	8.4	9.3	12.3	12.5
<i>HEETS</i>	8.4	9.3	12.2	12.5
Cigarettes	2.4	1.1	2.0	2.0
Other	-	-	-	-
Regular <i>HEETS</i> (N)	799	824	220	105
Total Tobacco Sticks	12.7	11.6	14.7	12.9
PMI consumables	10.1	10.4	12.2	9.8
<i>HEETS</i>	10.0	10.4	12.2	9.8
Cigarettes	2.7	1.2	2.5	3.1
Other	-	-	-	-

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	Germany	Italy	Japan	South Korea
Both <i>HEETS</i> (N)	120	118	NA	NA
Total Tobacco Sticks	14.4	12.4	NA	NA
PMI consumables	11.8	11.0	NA	NA
<i>HEETS</i>	11.8	10.7	NA	NA
Cigarettes	2.6	1.4	NA	NA
Other	-	-	-	-

NA: Not applicable (base size too low to provide data)

* PMI consumables include *HEETS* + FIIT + TEREA + SENTIA. FIIT is a KT&G consumable compatible with Lil and *IQOS* while TEREA and SENTIA are PMI consumables that are compatible with more novel induction-based *IQOS* devices commercialized outside of U.S.

** The following other competitor HTPs are available in the four markets: Glo (Germany); Glo, Ploom (Italy); Glo, Ploom, Lil (Japan); Glo, Lil (Korea).

Source: *IQOS* Owner Panels – December 2022

Baseline Cigarette Type by *HEETS* Type

The majority of current regular *HEETS* users smoked regular cigarettes at baseline. However, there was a large proportion of regular cigarette smokers (at baseline) among menthol *HEETS* users, while the proportion of menthol cigarette smokers who adopted regular *HEETS* was very small.

Consistent with the sales data, this data indicates that the availability of menthol *HEETS* may facilitate the switch from combustible cigarettes to *IQOS*.

Table 23 Summary of adoption of different *HEETS* Type by baseline cigarettes flavor for four countries - December 2022

	Germany	Italy	Japan	South Korea
Total Authorized <i>IQOS</i> Systems Users				
Menthol <i>HEETS</i> (N)	214	-	1119	222
Menthol Cigarettes	10%	-	69%	12%
Regular Cigarettes	90%	-	31%	88%
Regular <i>HEETS</i> (N)	931	-	575	144
Menthol Cigarettes	2%	-	5%	2%
Regular Cigarettes	98%	-	95%	98%
Both <i>HEETS</i> (N)	161	-	58	NA
Menthol Cigarettes	2%	-	32%	NA
Regular Cigarettes	98%	-	68%	NA

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	Germany	Italy	Japan	South Korea
Only Authorized IQOS Systems Users				
Menthol HEETS (N)	112	-	437	127
Menthol Cigarettes	11%	-	70%	11%
Regular Cigarettes	89%	-	30%	89%
Regular HEETS (N)	565	-	209	95
Menthol Cigarettes	1%	-	6%	3%
Regular Cigarettes	99%	-	94%	97%
Both HEETS (N)	86	-	NA	NA
Menthol Cigarettes	2%	-	NA	NA
Regular Cigarettes	98%	-	NA	NA

NA: Not applicable (base size too low to provide data)

Source: IQOS Owner Panels – December 2022

1.4.5. PMP S.A. International Postmarket Data: The effect of modified risk claims on use behaviors from the IQOS Owner Panels

Recently PMI published a study that aimed to analyze whether and how the perceived RF and/or RH of IQOS impacted “exclusive” (100%) IQOS use in Japan, Italy, Germany, and Russia⁵¹ (Fischer et Al., 2023). The study found that perceived reduced formation of harmful chemicals (RF) or perceived reduced risk of harm (RH) of a smoke-free tobacco product relative to combustible tobacco product may influence IQOS adoption and use patterns among adult smokers.

Briefly, between 2016 and 2020, adult participants from IQOS Owner Panels in Japan (N=6257), Italy (N=8137), Germany (N=8474), and Russia (N=7231) were asked to repeatedly indicate the reasons for using IQOS, including reasons referring to RF and RH, during their first 48 weeks in the cohort. Logistic and Cox regression were used to analyze the relationships between RF and/or RH indications for using IQOS and exclusive or stable exclusive IQOS use. RF reasons for using IQOS included statements such as “The tobacco vapor of IQOS has significantly less harmful chemicals than the smoke of conventional cigarettes, but using IQOS is not risk free”. RH reasons for using IQOS comprised statements such as “Because switching completely to IQOS is likely to present less risk of harm than continuing to smoke cigarettes (this does not mean IQOS is risk-free)”. These statements were part of a list of response items that panelists could select as one of the reasons for using IQOS. Patterns of Tobacco Product

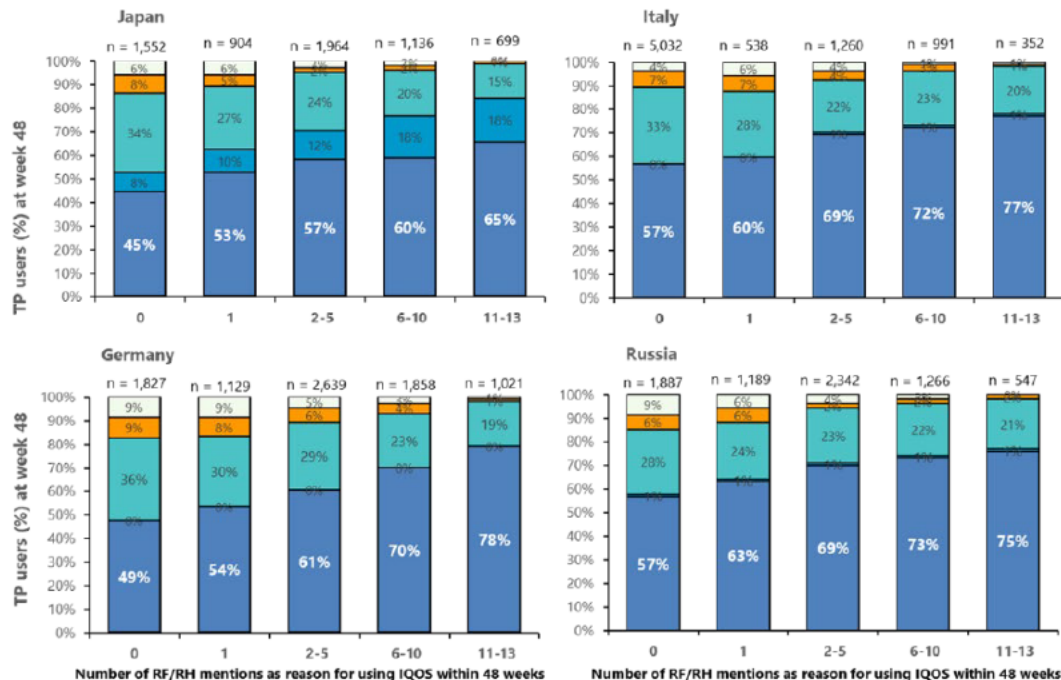
⁵¹ The IQOS Owner Panel study in Russia is currently not active.

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(TP) use at week 48 in Japan, Italy, Germany, and Russia by number of RF and/or RH mentions can be found in Figure 1.



□ Other TP use ■ Exclusive CC use (100%) ■ Dual use (IQOS & CC / IQOS & CC & other HTPs / CC & other HTPs) ■ Exclusive HTP use (Other HTPs & <100% IQOS) ■ Exclusive IQOS use (100%).

Figure 1 Patterns of TP use at week 48 in Japan, Italy, Germany, and Russia by number of RF and/or RH mentions.

Note: CC, manufactured and hand-rolled cigarettes; HTP, heated TP; Other TP, participants with no TP use in the past 7 days and/or no intention to use TPs in future; RF, reduced formation of harmful chemicals; RH, reduced risk of harm; TP, tobacco product.

Results also indicated that at week 48, exclusive IQOS use in Japan (odds ratio [OR]=1.89), Italy (OR=3.35), Germany (OR=3.48), and Russia (OR=3.05) was higher among participants who more frequently (highest vs. lowest category of number of RF and/or RH indications) indicated RF and/or RH as a reason for using IQOS. In Japan, where other HTPs were also marketed, this was also true for the overall HTP category. Also, in Japan where RF and RH could be indicated separately as reasons for using IQOS, indicating RH (OR=2.92) compared to RF (OR=1.81) resulted in a greater likelihood of exclusive IQOS use within the highest category of RF or RH indications.

In Japan (hazard ratio [HR]=0.74), Italy (HR=0.80), Germany (HR=0.82), and Russia (HR=0.85), IQOS users who indicated RF and/or RH as a reason for using IQOS had a lower

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risk of becoming a stable non-exclusive than stable exclusive *IQOS* user. Moreover, perceived RF and RH were also associated with a 10–25% lower number of weeks until reaching stable exclusive *IQOS* use.

Together these findings indicate that perceived RF and RH is associated with lower likelihood of non-exclusive *IQOS* use, and thus higher likelihood of switching to exclusive use. Moreover, the findings suggest that perceived RF and RH is associated with accelerated stable exclusive. Finally, it appears that perceived RH of *IQOS* seems to be a stronger driver for exclusive *IQOS* use than perceived RF.

1.4.6. Conclusion of International Sales Data and PMP S.A. Postmarket studies

International sales data shows a gradual increase in the market share of *IQOS* consistent with a global increase in the number of *IQOS* users as well as a positive effect of Menthol *HEETS* in facilitating the switch from combustible cigarettes to *IQOS*.

With respect to use behavior patterns, the international *IQOS* Owner panel data from Germany, Italy, Japan, and South Korea show that (i) the most common use pattern is 100% *IQOS* use, and (ii) 100% *IQOS* use is higher among menthol *HEETS* users compared to regular *HEETS* users in three out of the four countries. In addition, international data from *IQOS* Owner Panels indicate that the perceived RF and/or RH of *IQOS* have a significant impact on complete switching to *IQOS* and on the acceleration of complete switching to *IQOS*.

On the balance of the evidence and given the consistency of the findings observed across the different international countries, it can be concluded that use patterns in the U.S. are unlikely to differ from those use patterns consistently observed in several international countries.

1.5. Independent Studies

PMP S.A. literature review of independent studies submitted to the FDA as part of PMP S.A.'s Annual Reporting⁵² related to the Marketing Order for the Authorized *IQOS* Systems show that (i) the prevalence of *IQOS* with *HEETS/HeatSticks* use among adult tobacco or nicotine containing product (TNP) users is growing, although there are differences across countries, and/or (ii) the most common use pattern is 100% exclusive use of *IQOS* or other HTPs⁵³. Since PMP S.A.'s 2023 Annual Reporting⁵⁴, PMP S.A. has not

⁵² For the list of Annual Reports see [section 4.2 Marketing Plan](#)

⁵³ Ministry of Health Labour and Welfare. The National Health and Nutrition Survey (NHNS) Japan, 2019 Summary. 2019. [in Japanese]. Available at: https://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html

⁵⁴ 2023 Annual Report and PMSS report submitted on April 28, 2023

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identified any further independent studies in the context of information on prevalence of use and use patterns of *IQOS* or other HTPs among adult TNP users.

1.6. Conclusion

The combined evidence from the U.S. pre-market and post-market studies, together with international postmarket studies and independent studies, indicate that current adult cigarette smokers will represent the segment of the population that is most likely to use *IQOS*, whenever *IQOS* will be commercially available in the U.S with the authorized modified risk claim.

In addition, the combined evidence from pre- and post-market studies indicates that i) a large proportion of adult *IQOS* users switch away from cigarettes, with a larger proportion of adult users using *IQOS* exclusively in international markets, where *IQOS* has been present for a longer period compared with the U.S. (ahead of the CDO).

Data from the international markets also reveals the positive effect on complete switching from cigarettes to *IQOS* when *IQOS* is perceived as a modified risk product. Moreover, data indicates that the consumption of cigarettes is declining suggesting that there is a replacement of cigarettes use by *HeatSticks* consumption rather than an overall increase in total tobacco consumption.

Finally, results of both pre-market and post-market studies potentially suggest that the availability of different *HeatSticks* flavors may promote higher level of complete switching among smokers, thereby facilitating the transition of adult smokers from cigarettes to *IQOS* use.

Taken together, this evidence points towards continued commercialization of *IQOS* with the reduced exposure claim to be expected to benefit the health of the population as a whole, which is consistent with section 911(g)(2)(B) of the FD&C Act.

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2. REFERENCE STUDIES

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