Post Market Assessment of the Tobacco Heating System 2.2 (THS) Use in Japan

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Introduction and Aim

Philip Morris Products S.A. (PMP S.A.) is developing novel tobacco and nicotine containing products that have the potential to reduce harm or the risk of tobacco-related disease compared with smoking cigarettes.

In order to assess how these products are used in real life, PMP S.A. is conducting an assessment program for marketed products. This program consists of surveillance and studies to collect a set of quantitative and qualitative data on the use of the Tobacco Heating System (THS) in real-world conditions. The objective of assessing the marketed product is to further substantiate the results collected in the pre-market clinical assessment and perception and behavioral assessment programs. These studies are designed together to assess the impact that the marketing of THS has on consumer perceptions, behavior, exposures, and health.

Presently, two observational studies are being run in Japan where THS has been marketed since November 2014 under the name of IQOS: a cohort study and a cross-sectional survey. The cohort study is a five year prospective follow-up of Japanese adults, legally authorized to purchase tobacco products, which will describe the patterns of use of tobacco and nicotine containing products and self-reported health outcomes in cigarette (CC) smokers and THS users. The cross-sectional survey aims at assessing the current tobacco product use prevalence and patterns of tobacco product use. The survey will be repeated over a period of 3 years and includes a representative sample of the general population and a convenience of THS users.

Year 1 **Year 2** **Year 3**
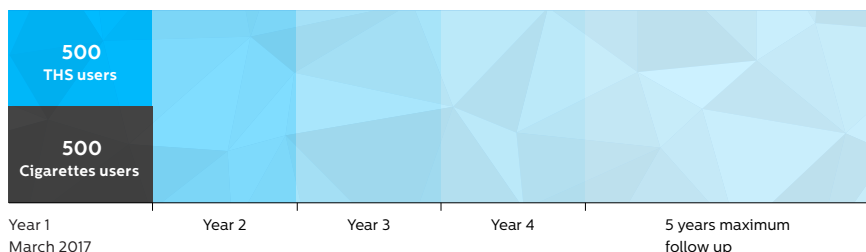
General Population

1221

Wave I   II   III   IV
Dec. 2016

Methods

The cohort study will include 2000 cigarette smokers and 2000 THS users recruited in 4 annual waves of 1000 participants per year (500 THS users and 500 cigarette smokers) until reaching the total study sample size of 4000 participants. The cohort will be followed-up for a maximum of 5 years. THS and cigarette smokers users will be identified via Philip Morris Japan's consumer database; and/or through advertisements, in which potential participants will be directed to the study website where they can obtain more information on the study and register their interest in participating in the study. Additionally, cigarette smokers will be identified through market research or other available databases.

500 THS users				
500 Cigarettes users				

| Year 1 March 2017 | Year 2 | Year 3 | Year 4 | 5 years maximum follow up |

The cross-sectional survey will be conducted in two different samples:

A general population sample which is a sample from the general adult population, of legal age to purchase tobacco and/or nicotine containing products in Japan (≥20 years of age); sampled using a random sampling approach; and including in a multi-purpose survey (Omnibus). The Japanese Omnibus survey's mode of administration is generally through a Face to Face, paper questionnaire that is read by the interviewer. However, PMP S.A.'s Tobacco Use Prevalence Questionnaire is be handed to the participant by the interviewer for self-completion.

The second is a targeted THS users sample which is is a convenience sample of THS users in Japan which is selected at random from PMP Japan's THS Users Database. A randomly-selected set of THS users registered in this database is invited to participate in the study by an email with a link to the Study Database. Participants that are not eligible (do not meet the inclusion/exclusion criteria) will be discontinued at the end of the Screener Questionnaire and will not complete the remainder of the questionnaire. Recruitment into these is done in four waves per year (n = 1200 and n = 500 per wave), respectively.

Results

The first wave of recruitment for the cohort study was completed in March 2017. In total, 500 CC smokers and 500 THS users have been enrolled in the study. The first results are expected in Q4 2017.

For the cross-sectional surveys, the analysis of the first wave of year one has been completed. The subject disposition was as follows:

In the general population, out of a total of 4,000 households visited, 1,222 responded (30.20 %) and 1,221 completed the questionnaire (30.08 %).

In the THS targeted sample, out of 3,199 email invites sent, 866 subjects clicked on the invite link (27.07 %) and 820 were eligible to participate (25.64 %). A sample of 500 were enrolled and completed the questionnaire.

The general sample's enrollment applied quotas that reflect the Japanese population distribution of age and gender, while the THS Targeted Sample aims at reflecting the age and gender distribution of the THS database. The demographic characteristics of both samples are presented on Table 1.

TABLE 1. DEMOGRAPHIC CHARACTERISTICS

Demographic variable	Category	General Sample (n = 1220)	IQOS Sample (n = 500)
Gender	Male	589 (48.3 %)	408 (81.6 %)
	Female	631 (51.7 %)	92 (18.4 %)
Age	Mean (SD)	54.0 (18.00)	38.6 (10.01)
	Median	54.0	38.0
	Min, Max	20, 97	20, 120
Region	Hokkaido	54 (4.4 %)	16 (3.2 %)
	Tohoku	87 (7.1 %)	28 (5.6 %)
	Kanto	403 (33 %)	221 (44.2 %)
	Kinki	178 (14.6 %)	78 (15.6 %)
	Chubu	243 (19.9 %)	78 (15.6 %)
	Chugoku	76 (6.2 %)	27 (5.4 %)
	Shikoku	44 (3.6 %)	12 (2.4 %)
	Kyusyu	135 (11.1 %)	40 (8.0 %)
Education	Junior High School	102 (8.4 %)	25 (5.0 %)
	High School	603 (49.4 %)	164 (32.8 %)
	College/University	497 (40.7 %)	305 (61.0 %)
	Don't know/Not applicable	18 (1.5 %)	6 (1.2 %)

First Product Use: In the general population sample, 500 respondents (41%) had ever used at least one tobacco or nicotine containing product. The great majority (98.62% of users and 41.4% of the total sample) and only 0.2% of users (and 0.1% of the total sample) had started with the use of THS with HeatSticks In the THS targeted sample 97.4% of the sample had started tobacco or nicotine containing product use with cigarettes and 1.4% with THS with HeatSticks (Table 2).

Prevalence of Use: The prevalence of tobacco or nicotine containing product use was evaluated only in the general population sample. The prevalence on current smoking was 17.1% in the total population, 27.6% in men and 7.3% in women. The prevalence of use of THS was 1% in the total population, 1.7% in men and 0.3% in women. The prevalence of use of e-cigarettes was 0.5% in the total population, 0.5% in men and 0.5% in women. Any other tobacco use prevalence was 2.3% in the total population, 4.1% in men and 0.6% in women (Table 3).

TABLE 2. FIRST TOBACCO/NICOTINE PRODUCT USE IN DIFFERENT SAMPLES

General Sample	Male (n = 587)	Female (n = 630)	All respondents (n = 1217)
Cigarettes	378 (64.4%)	122 (19.4%)	500 (41.1%)
THS with HeatSticks	1 (0.2%)	0	1 (0.1%)
Cigars/pipes/kiseru/shisha	3 (0.5%)	1 (0.2%)	4 (0.3%)
Any other tobacco or nicotine containing product	1 (0.2%)	1 (0.2%)	2 (0.2%)
None	204 (34.8%)	506 (80.3%)	710 (58.3%)
THS Targeted Sample	Male (n = 408)	Female (n = 92)	All respondents (n = 500)
Cigarettes	399 (97.8%)	88 (95.7%)	487 (97.4%)
THS with HeatSticks	5 (1.2%)	2 (2.2%)	7 (1.4%)
E-cigarettes	2 (0.5%)	0	2 (0.4%)
Smokeless tobacco pipe	0	1 (1.1%)	1 (0.2%)
Cigars/pipes/kiseru/shisha	0	1 (1.1%)	1 (0.2%)
Any other tobacco or nicotine containing product	2 (0.5%)	0	2 (0.4%)

TABLE 3. PREVALENCE OF TOBACCO AND NICOTINE PRODUCTS USE

Product	Product use	Male (n = 588)	Female (n = 631)	All respondents (n = 1219)
THS use	Former	3 (0.5%)	0	3 (0.2%)
	Current	10 (1.7%)	2 (0.3%)	12 (1.0%)
CC smokers	Former	192 (32.7%)	50 (7.9%)	242 (19.9%)
	Current	162 (27.6%)	46 (7.3%)	208 (17.1%)
E-cigarette users	Tried	11 (1.9%)	7 (1.1%)	18 (1.5%)
	Former	13 (2.2%)	3 (0.5%)	16 (1.3%)
	Current	3 (0.5%)	3 (0.5%)	6 (0.5%)
Other tobacco/nicotine products users	Current	24 (4.1%)	4 (0.6%)	28 (2.3%)

Patterns of use: Patterns of use was evaluated in both samples. In this presentation the results for the THS targeted sample are shown. Single product use of THS was 61.4% in the total sample. Dual product use was seen in 27.6% of the total sample and dual use of CC plus THS occurred in 22.4% of the total sample, 22.1% of men and 23.9% of women. Additionally, 5.2% of the total sample used THS with another product (Table 4).

Frequency of tobacco product use: In the general population, smokers used an average of 15.4 (±10.55) cigarettes a day, THS users used an average of 12.9 (±6.49) HeatSticks a day and e-cigarette users used e-cigarettes an average of 12.9 (6.49) times a day (Table 5). In the THS targeted Sample smokers used an average of 13.9 (±10.34) cigarettes a day, THS users used an average of 15.8 (±7.57) HeatSticks a day and e-cigarette users used e-cigarettes an average of 12.7 (12.7) times a day (Table 6).

TABLE 4. PATTERNS OF CURRENT PRODUCT USE BY GENDER

Type of use	Pattern of use	Male (n = 408)	Female (n = 92)	All respondents (n = 500)
Single product use		246 (60.3%)	61 (66.3%)	307 (61.4%)
	THS	246 (60.3%)	61 (66.3%)	307 (61.4%)
Dual product use		112 (27.5%)	26 (28.3%)	138 (27.6%)
	THS + CC	90 (22.1%)	22 (23.9%)	112 (22.4%)
	THS + Other	22 (5.4%)	4 (4.3%)	26 (5.2%)
Poly product use		50 (12.3%)	5 (5.4%)	55 (11.0%)
	THS + CC + Other	41 (10.0%)	3 (3.3%)	44 (8.8%)
	THS – CC + Other	9 (2.2%)	2 (2.2%)	11 (2.2%)

TABLE 5. TOBACCO/NICOTINE PRODUCT CONSUMPTION BY GENDER (GENERAL POPULATION)

		Male	Female	All users
Smoking days in last 30 days	n	131	25	156
	Mean (SD)	22.7 (11.19)	27.2 (7.78)	23.5 (10.82)
	Min, Max	0, 30	5, 30	0, 30
Number of cigarettes per day	n	131	25	156
	Mean (SD)	13.9 (10.25)	14.0 (11.01)	13.9 (10.34)
	Min, Max	1, 80	1, 40	1, 80
Days of THS use in last 30 days	n	408	92	500
	Mean (SD)	28.6 (4.26)	29.3 (3.03)	28.7 (4.06)
	Min, Max	5, 30	7, 30	5, 30
Number of THS with HeatSticks per day	n	408	92	500
	Mean (SD)	15.9 (7.63)	15.2 (7.33)	15.8 (7.57)
	Min, Max	1, 50	3, 40	1, 50
Days of e-cigarette use in last 30 days	n	20	3	23
	Mean (SD)	17.9 (12.83)	22.3 (13.28)	18.5 (12.67)
	Min, Max	0, 30	7, 30	0, 30
Number of times per day	n	20	3	23
	Mean (SD)	11.2 (12.82)	19.0 (11.53)	12.2 (12.70)
	Min, Max	1, 50	7, 30	1, 50

**TABLE 6. TOBACCO/NICOTINE PRODUCT CONSUMPTION
BY GENDER (GENERAL POPULATION)**

		Male	Female	All current users
Smoking days in last 30 days	n	155	45	200
	Mean (SD)	29.3 (3.68)	29.4 (3.09)	29.3 (3.55)
	Min, Max	1, 30	10, 30	1, 30
Number of cigarettes per day	n	159	45	204
	Mean (SD)	15.9 (11.59)	13.6 (5.15)	15.4 (10.55)
	Min, Max	2, 120	2, 20	2, 120
Days of THS use in last 30 days	n	8	2	10
	Mean (SD)	25.6 (8.21)	30.0 (0.0)	26.5 (7.47)
	Min, Max	10, 30	30, 30	10, 30
Number of THS with HeatSticks per day	n	9	2	11
	Mean (SD)	12.4 (6.71)	15.0 (7.07)	12.9 (6.49)
	Min, Max	2, 20	10, 20	2, 20
Days of e-cigarette use in last 30 days	n	3	3	6
	Mean (SD)	12.0 (15.59)	23.3 (11.55)	17.7 (13.75)
	Min, Max	3, 30	10, 30	3, 30
Number of times per day	n	2	3	5
	Mean (SD)	6.0 (5.66)	17.7 (19.66)	13.0 (15.56)
	Min, Max	2, 10	3, 40	2, 40

Conclusions

The post market assessment studies of THS in Japan have started and have proven feasible. The first results of the cohort study will be available by the end of this year. The results from the first wave of the first year of the Japanese cross-sectional survey showed a prevalence of smoking of 17.1% in the general population and 27.6% in men and 7.3% in women. Additionally, the prevalence of use of THS was 1% in the total population, 1.7% in men and 0.3% in women. These results on the prevalence of smoking confirm those reported by the Japanese Health and Nutrition Survey of 2015 where the smoking prevalence was 17.0%[1] Furthermore, this survey is the first to report the frequency of THS use in the general population and to evaluate patterns of use of THS in conjunction with other tobacco and nicotine containing products in the Japanese population.

MORE INFORMATION

FOLLOW /PMISCIENCE

REFERENCES

1.   Japanese Health and Nutrition Survey 2015.
      http://www.mhlw.go.jp/seisakunitsuite/bunya/
      kenkou_iryou/kenkou/kenkounippon21/en/
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      Accessed on My 4th 2017.

REDUCED-RISK PRODUCTS

Reduced-Risk Products ("RRPs") is the term we use to refer to products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continued smoking. We have a range of RRPs in various stages of development, scientific assessment and commercialization. Because our RRPs do not burn tobacco, they produce far lower quantities of harmful and potentially harmful compounds than found in cigarette smoke.

COMPETING FINANCIAL INTEREST

GLOBAL FORUM ON NICOTINE
JUNE 15 – 17, WARSAW, POLAND