

Intent to Use for a New Menthol HeatSticks Variant in Japan

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ABSTRACT

"Tobacco harm reduction" is a public health strategy intended to reduce the health burden of tobacco consumption by switching smokers from cigarettes (CC) to products which could potentially present reduced health risks compared to continued smoking, such as the Heat-Not-Burn Tobacco Heating System ("THS") currently commercialized in various markets under the IQOS brand name, whilst not generating initiation or relapse among never or former smokers. This market research study reports the levels of Intent to Use (positive Intention to Try and positive Intention to Use) among 1,953 adult Japanese participants (aged 21+ years) who were eligible and chose to participate in the study. The participants were shown one of three different THS and HeatSticks (the specially designed tobacco sticks to be used with THS) concepts (Concepts). Two of these three Concepts were presenting an already commercially available HeatSticks Variant (one regular and one menthol taste). The third Concept presented a new menthol *HeatSticks* variant. All three Concepts were associated with similar patterns of results. Considering the results in the context of market share of the HeatSticks variants (7% of total estimated sales of CC and HeatSticks, according to PMI estimates, January 2017), adult smokers, irrespective of the type of smoked CC, indicated a substantial positive Intention to Try (ranging between 15% and 32%) and positive Intention to Use (ranging between 10% and 25%). Conversely, adult non-smokers showed very low levels of positive Intention to Try (ranging between 0% and 2%) and positive Intention to Use (ranging between 0% and 1%). These patterns of intended use for the three THS and *HeatSticks* concepts are consistent with the objectives on tobacco harm reduction.

INTRODUCTION

Smoking causes serious diseases including cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease¹. Smoking prevalence in Japan has declined in recent years, however it remains that 19% of Japanese adults smoke cigarettes². "Tobacco harm reduction" is a public health strategy intended to reduce the health burden of tobacco consumption. One increasingly important tobacco harm reduction measure is encouraging smokers to switch from cigarettes (CC) to tobacco or nicotine-containing products which could potentially present less risk of harm compared to continued smoking, whilst not triggering initiation or relapse among never or former smokers. These alternative products may include e-cigarettes and Heat-not-Burn (HNB) tobacco products. The most widely commercialized HNB tobacco product is PMI's Tobacco Heating System ("THS") currently commercialized in various markets under the IQOS brand name. THS electronically heats tobacco in a specially designed tobacco stick (named *HeatStick*) to a maximum of 350 degrees centigrade, below the temperature necessary for tobacco to burn. The concept behind the THS system is that heating tobacco, rather than burning it, reduces or eliminates the formation of many harmful and potentially harmful constituents (HPHCs)^{3 4 5} that are produced at the higher temperatures associated with combustion.

THS was launched in November 2014 in a geographically limited area of Japan, and it was available nationwide starting from April 2016. Since its introduction in Japan, the market share of *HeatSticks* (i.e., the total *HeatSticks* sales volume as a percentage of the total estimated sales volume for cigarettes and *HeatSticks*) has steadily increased. By the end of 2016, quarterly market share had reached an estimated 4.9% and by January 2017 weekly market share had attained an estimated 6.8% (as shown in Figure 1).

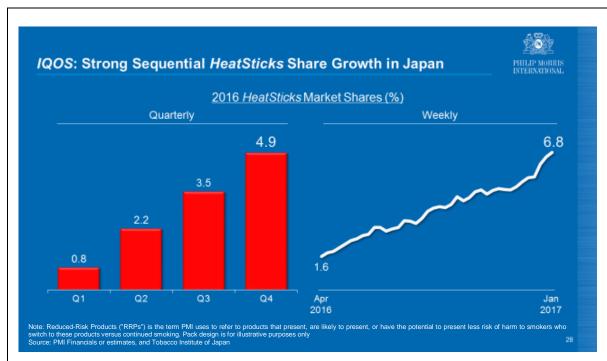


Figure 1: *HeatSticks* Shares – Japan (presented at the Consumer Analyst Group of New York (CAGNY) Conference, February 22, 2017)

Abbr.: $Q1 = 1^{st}$ Quarter, $Q2 = 2^{nd}$ Quarter, $Q3 = 3^{rd}$ Quarter, $Q4 = 4^{th}$ Quarter.

At the time of the market research study discussed in this paper, there were 4 different variants of *HeatSticks* available in the market, 2 menthol variants and 2 regular ones. Those variants were commercialized in similar packages (each pack containing 20 *HeatSticks*), which were identical except for the aspects that differentiate them as regular and menthol by name and by color.

The current cigarettes market in Japan is characterized by two specificities: (i) a significant penetration of menthol cigarettes (32% market share; PMI estimates, February 2017), and (ii) an increasing presence of "New Taste Direction" (NTD) type of cigarettes variants. NTD cigarettes are cigarettes with a capsule technology that allow adult smokers to change the taste of cigarettes by cracking a small sphere embedded in the filter and containing some kind of flavoring (usually menthol or fruit flavoring). In Japan, NTD cigarettes account for 7% of the total estimated cigarettes volumes (PMI estimates, January 2017).

PMI is considering introducing a new *HeatSticks* variant with a different menthol flavor, with the objective of expanding the choice for those adult smokers who are interested in using and therefore to increase their likelihood to successfully transition from cigarettes to THS. Considering that a prerequisite for a tobacco harm reduction strategy is that adult smokers adopt a product such as THS, and that adult non-smokers have negligible levels of interest, PMI decided to conduct a market research study before launching such a new variant. The purpose of this study was to describe the reactions of adult smokers, adult former smokers and adult never smokers, to this new variant. In particular, this study aimed at measuring the intended use of this new menthol variant among adult smokers and adult non-smokers following the exposure to a product concept.

AIM AND OBJECTIVE

The aim of this market research study was to describe the responses of adult smokers, adult former smokers and adult never smokers to three different THS and *HeatSticks* concepts (*Concepts*), in terms of *Intent to Use* (Intention to Try, Intention to Use).

The objective of this study was to evaluate the different Concepts and smoking groups in terms of:

1. Intent to Use

- a. THS (separately within all smoking groups)
- b. CC (separately within adult former smokers and adult never smokers)
- c. e-cigarettes (separately within adult former smokers and adult never smokers)

METHODS

Design

The market research study was a three-arm online parallel group experiment. The three arms corresponded to three different Concepts, each presenting THS and one *HeatSticks* variant:

- 1. THS and the New *HeatSticks* Menthol Variant concept (Concept 1)
- 2. THS and Best Selling *HeatSticks* Menthol Variant concept (Concept 2)
- 3. THS and Best Selling *HeatSticks* Regular Variant concept (Concept 3)

The 1,953 participants who satisfied the recruitment criteria and chose to take part in the research were allocated to one of the three concepts to be tested. Each of the three concept arms were balanced in terms of age groups, gender and smoking groups.

Sample and Smoking Groups

Participants were eligible if they were Japan residents and aged 21 years or above. Adult smokers were eligible if they were not using *IQOS* at the time of the study. The Full Sample (n=1,953) was comprised of five smoking groups: Adult Smokers (n=300), NTD Adult Smokers (n=302), Adult Former Smokers (n=451), Adult Never Smokers from 21 to 24 years of age (n=450) and Adult Never Smokers of 25 years of age and older (n=450). Participants were classified into the above five smoking groups according to the following definitions.

1. Adult Smokers (AS): Adults (21+ years of age) who, based on self-reporting, have smoked at least 100 CC in their lifetime, were currently smoking regularly defined as at least three CC (no brand restrictions) per day (disregarding religious fasting), and were regularly smoking either a regular (non-menthol) or a menthol type of CC.

- 2. NTD Adult Smokers (NTD AS): Adults (21+ years of age) who, based on self-reporting, have smoked at least 100 CC in their lifetime, are currently smoking at least three CC (no brand restrictions) per day (disregarding religious fasting), and are regularly smoking an NTD type of CC.
- 3. Adult Former Smokers (FS): Adults (21+ years of age) who were previously regular smokers and, at the time of their participation in the study, quit CC more than 30 days ago.
- 4. 25+ Adult Never Smokers (25+ NS): Adults of 25 years of age and older, who have never smoked at all, or adults who have never been regular smokers and have smoked less than 100 cigarettes in their lives.
- 5. 21-24 Adult Never Smokers (21-24 NS): Adults from 21 to 24 years of age, who have never smoked at all, or adults who have never been regular smokers and have smoked less than 100 cigarettes in their lives.

The following additional inclusion/exclusion criteria was applied:

- Must agree to the consent form and agree to take part in the study.
- Must not be pregnant or breastfeeding (females only).
- Must not work in the following areas market research, marketing, advertising, law, media, TV, journalism, tobacco industry (including production, sales or distribution), health care, health research;
- Must not have participated in a tobacco research study in the past 6 months.

Procedures

Candidate participants were sent an email with an individual link to the online questionnaire. The Computer-Assisted Web-Interviewing methodology was device agnostic to ensure consistency across the interviews irrespective of the platform used to access it, e.g., desktops, smartphones or tablets. The average time for completing the questionnaire varied between 4 minutes (for the 21-24 NS and the 25+ NS) and 7 minutes (for the AS and the NTD AS). Fieldwork took place between 13th July and 22nd July 2016.

Materials

Each arm of this study corresponded to a one of the different Concepts. Below are presented the visual stimuli that were used to elicit participants' Intent to Use (Figure 2, Figure 3 and Figure 4).



Figure 2: Concept 1 - THS and the New HeatSticks Menthol Variant

Note: Translation from Japanese is placed closer to the original text



Figure 3: Concept 2 - THS and Best Selling HeatSticks Menthol Variant

Note: Translation from Japanese is placed closer to the original text



Figure 4: Concept 3 - THS and Best Selling HeatSticks Regular Variant

Note: Translation from Japanese is placed closer to the original text

Additionally, the smoking groups composed of adult former smokers and adult never smokers were also exposed to stimuli materials illustrating cigarettes and e-cigarettes (below Figure 5 and Figure 6), before expressing their Intent to Use CC and e-cigarettes.





Measurements

Intent to Use (Intention to Try and Intention to Use) was measured using 2 questions from the Intent to Use Questionnaire (ITUQ). This self-reported instrument was developed by PMI on the basis of the best practices guidelines, including the current FDA guidance for patient-reported outcomes (PROs) in clinical trials (FDA (Food and Drug Administration) 2009).

Intention to Try was assessed with the question: "How likely or unlikely are you to try ..."

There were six response options, from *Definitely* to *Definitely not*. "Positive Intention to Try (at least once)" was derived as the combination of *Very likely* and *Definitely* responses.

Intention to Use regularly was assessed with the question: "If you try <CC, e-cigarettes, THS> and like it, how likely or unlikely are you to use <CC, e-cigarettes, THS> regularly ..."

There were six response options, from *Definitely* to *Definitely not*. "Positive Intention to Use regularly" was derived as the combination of *Very likely* and *Definitely* responses. In the case of the Intention to Use THS on a regular, ongoing basis, participants were also exposed to THS price information, i.e., ¥ 5,380 for the THS system and ¥ 460 for a pack of *HeatSticks*, irrespective of the Concept that was presented. This price information corresponded to the prices applied in the country at the moment of the study.

In order to limit the number of comparisons, assessments were selected on the basis of appropriateness. For example, in some cases, assessments for certain smoking groups were not done as this would have been inapplicable, e.g., assessing Intention to Try CC at least once for current Adult Smokers. Table 1 details the products (i.e., CC, e-cigarettes and THS) that were presented to the different smoking group combinations in this study. Intent to Use regularly was measured for CC, e-cigarettes and THS always in the same fixed order: i.e., CC, e-cigarette and THS.

Table 1 Measures of Intent to Use assessed in the study according to the Smoking Group

Measure	THS	CC	E-cigarettes
Intention to Try (at least once)	• All smoking groups	 21-24 Adult Never Smokers 25+ Adult Never Smokers 	21-24 Adult Never Smokers25+ Adult Never Smokers
Intention to Use (regularly)	• All smoking groups	Adult Former Smokers	• Adult Former Smokers

Analysis

Outcome measures were presented descriptively using summary statistics in accordance with the predefined criteria of evaluation, by Concept and smoking group. There was no missing data and therefore no adjustment for missing data was required. All analyses were performed with IBM® SPSS® Data Collection Base Professional (V6.0.1).

RESULTS

Demographics

Demographics and subject characteristics were similar for the three Concept arms (Table 2). Participants in this study were aged between 21 and 86 years. Mean age ranged from 39.9 to 40.1 years, with a similar number of participants from the three age categories (21-35, 36-50, and +51 years) across the three Concept arms. There was a near-equal proportion of males and females (the proportion of males ranged from 49.0% to 49.9%) and between 65.4% and 70.1% of study participants had at least a junior college/higher professional school degree.

Table 2: Summary of Demographics and Subject Characteristics by Arm

	·	Arm	
	Concept 1 (New HeatSticks	Concept 2 (Best Selling HeatSticks	Concept 3 (Best Selling HeatSticks
	*	Menthol Variant)	
Assessment	(n=651)	(n=651)	(n=651)
Age (years)	()	,	,
Mean (SD)	40.1 (14.5)	40.0 (14.4)	39.9 (14.9)
Median	38.0	38.0	38.0
Range	(21-81)	(21-86)	(21-81)
Age group			
21-35, n (%)	310 (47.6%)	309 (47.5%)	310 (47.6%)
36-50, n (%)	167 (25.7%)	167 (25.7%)	168 (25.8%)
51+, n (%)	174 (26.7%)	175 (26.9%)	173 (26.6%)
Gender			
Male, n (%)	319 (49.0%)	324 (49.8%)	325 (49.9%)
Female, n (%)	332 (51.0%)	327 (50.2%)	326 (50.1%)
Education level			
Elementary/Junior High School, n (%)	18 (2.8%)	20 (3.1%)	21 (3.2%)
High school/Old junior high school, n (%)	175 (26.9%)	162 (24.9%)	191 (29.3%)
Junior college/higher professional school, n (%)	133 (20.4%)	149 (22.9%)	124 (19.0%)
College/University/Graduate school, n (%)	316 (48.5%)	307 (47.2%)	302 (46.4%)
Prefer not to say, n (%)	9 (1.4%)	13 (2.0%)	13 (2.0%)

Abbreviations: SD = standard deviation.

Tobacco use

Subject tobacco use characteristics are summarized in Table 3. The large majority of AS and NTD AS started smoking regularly over 12 months ago (respectively 99.7% and 98.0%). Over sixty percent of NTD AS (60.6%) preferred menthol CC, which was almost double of the preference for menthol CC within AS (32.3%)

Reported current use of E-cigarettes was 4.0% within AS, 13.2% within NTD AS, 1.3% within FS, 0.2% within 25+ NS and 0.9% within LA-24 NS.

Table 3: Tobacco Product Use Characteristics

Assessment	Adult Smokers (AS) (n=300)	NTD Adult Smokers (NTD AS) (n=302)	Adult Former Smokers (FS) (n=451)	25+ Adult Never Smokers (25+ NS) (n=450)	21-24 Adult Never Smokers (21-24 NS) (n=450)
When started smoking regularly			- '	- '	
>30 days - <12 months, n (%)	1 (0.3%)	6 (2.0%)	NA	NA	NA
>12 months, n (%)	299 (99.7%)	296 (98.0%)	NA	NA	NA
Number of cigarettes per day currently					
Mean (SD)	15.4 (7.5)	15.7 (8.8)	NA	NA	NA
Median	15.0	15.0	NA	NA	NA
Range	(3-50) 47	(3-70) 67	NA	NA	NA
Cigarette type					
Menthol, n (%)	97 (32.3%)	183 (60.6%)	NA	NA	NA
Regular (Non-menthol), n (%)	203 (67.7%)	119 (39.4%)	NA	NA	NA
Current regular brand of cigarettes					
Kent, n (%)	42 (14.0%)	47 (15.6%)	NA	NA	NA
Marlboro, n (%)	28 (9.3%)	29 (9.6%)	NA	NA	NA
Mevius, n (%)	60 (20.0%)	143 (47.4%)	NA	NA	NA
Natural American Spirit, n (%)	9 (3.0%)	1 (0.3%)	NA	NA	NA
Winston, n (%)	18 (6.0%)	25 (8.3%)	NA	NA	NA
Other, n (%)	143 (47.7%)	57 (18.9%)	NA	NA	NA
Current product use					
E-cigarettes, n (%)	12 (4.0%)	40 (13.2%)	6 (1.3%)	1 (0.2%)	4 (0.9%)
Ploom Tech, n (%)	4 (1.3%)	8 (2.6%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
Snus, n (%)	3 (1.0%)	6 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: NA = not applicable; SD = standard deviation.

Intent to Use

Intention to Try

The proportions of participants, within each smoking group, with positive Intention to Try THS at least once are shown in Table 4. Across Concept arms, positive Intention to Try THS at least once, when considering the market share of current *HeatSticks* variants (7% of total estimated sales of CC and *HeatSticks*¹), was substantial within AS (15%-18%) and NTD AS (25%-32%). The highest level of positive Intention to Try within adult smokers was associated with Concept 3 – "THS and Best Selling *HeatSticks* Regular Variant". The levels of positive Intention to Try were consistently very low within FS (1%-2%), 25+ NS (0%-1%) and 21-24 NS (0%-1%). Overall, these very low levels of positive Intention to Try THS at least once were similar to the negligible levels of positive Intention to Try CC and e-cigarettes at least once within the two never smoker groups (0%-1% irrespective of the Concept arm).

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¹ *HeatSticks* market share is the total *HeatSticks* sales volume as a percentage of the total estimated sales volume for cigarettes and *HeatSticks*.

Table 4: Proportion of Subjects with Positive Intention to Try THS, CC and e-cigarettes by Concept

	Statistics	Concept 1 (New HeatSticks Menthol variant)	Concept 2 (Best Selling HeatSticks Menthol Variant)	Concept 3 (Best Selling HeatSticks Regular Variant)
THS AS	n	100	100	100
	n (%)	18 (18%)	15 (15%)	18 (18%)
	(95% CI)	(11, 26)	(8, 22)	(11, 26)
NTD AS	n	100	101	101
	n (%)	29 (29%)	25 (25%)	32 (32%)
	(95% CI)	(20, 38)	(16, 33)	(23, 41)
FS	n	151	150	150
	n (%)	3 (2%)	2 (1%)	1 (1%)
	(95% CI)	(0, 4)	(0, 3)	(0, 2)
25+ NS	n	150	150	150
	n (%)	1 (1%)	0 (0%)	1 (1%)
	(95% CI)	(0, 2)	(0, 0)	(0, 2)
21-24 NS	n	150	150	150
	n (%)	0 (0%)	1 (1%)	0 (0%)
	(95% CI)	(0, 0)	(0, 2)	(0, 0)
CC 25+ NS	n n (%) (95% CI)	150 1 (1%) (0, 2)	150 0 (0%) (0, 0)	150 1 (1%) (0, 2)
21-24 NS	n	150	150	150
	n (%)	0 (0%)	1 (1%)	0 (0%)
	(95% CI)	(0, 0)	(0, 2)	(0, 0)
E-cigarettes 25+ NS	n n (%) (95% CI)	150 0 (0%) (0, 0)	150 0 (0%) (0, 0)	150 1 (1%) (0, 2)
21-24 NS	n	150	150	150
	n (%)	1 (1%)	1 (1%)	0 (0%)
	(95% CI)	(0, 2)	(0, 2)	(0, 0)

Abbreviations: AS = Adult Smokers; CC = conventional cigarettes; CI = confidence interval; FS, Adult Former Smokers; NS, Adult Never Smokers; NTD = New Taste Direction.

Note: positive Intention to Try was operationalized as the proportion of subjects whose response to the single item assessing intention to try THS at least once was either "Very Likely" or "Definitely".

Note: Only relevant combinations of *smoking status group* and *comparator* were assessed, namely, those deemed most directly relevant to study objectives (as shown in the table).

Note: Those participants (25+ NS and 21-24 NS) already currently using e-cigarettes have been included, and were asked how likely or unlikely they were to continue using e-cigarettes regularly

Intention to Use regularly

The proportions of participants, within each smoking group, with positive Intention to Use THS on a regular, ongoing basis are shown in Table 5. Across Concept arms, positive Intention to Use THS on a regular, ongoing basis, when considering the market share of current *HeatSticks* variants (7% of total estimated sales of CC and *HeatSticks*), was substantial within NTD AS (18% - 25%) and higher compared to AS (10% - 15%). The levels of positive Intention to Use THS on a regular, ongoing basis were very low within FS (1%), 25+ NS (0% - 1%) and 21-24 NS (0% - 1%). Overall, and with FS, these very low levels of positive Intention to Use THS on a regular, ongoing basis were similar to very low levels of positive Intention to Use CC and e-cigarettes regularly (0%-2%).

Table 5: Proportion of Subjects with Positive Intention to Use THS, CC and e-cigarettes by Concept

	Statistics	Concept 1 (New <i>HeatSticks</i> Menthol variant)	Concept 2 (Best Selling <i>HeatSticks</i> Menthol Variant)	Concept 3 (Best Selling HeatSticks Regular Variant)
THS				
AS	n	100	100	100
	n (%)	15 (15%)	11 (11%)	10 (10%)
	(95% CI)	(8, 22)	(5, 17)	(4, 16)
NTD AS	n	100	101	101
	n (%)	20 (20%)	18 (18%)	25 (25%)
	(95% CI)	(12, 28)	(10, 25)	(16, 33)
FS	n	151	150	150
	n (%)	1 (1%)	1 (1%)	2 (1%)
	(95% CI)	(0, 2)	(0, 2)	(0, 3)
25+ NS	n	150	150	150
	n (%)	0 (0%)	0 (0%)	1 (1%)
	(95% CI)	(0, 0)	(0, 0)	(0, 2)
21-24 NS	n	150	150	150
	n (%)	0 (0%)	1 (1%)	0 (0%)
	(95% CI)	(0, 0)	(0, 2)	(0, 0)
CC				
FS (use again)	n	151	150	150
	n (%)	3 (2%)	1 (1%)	0 (0%)
	(95% CI)	(0, 4)	(0, 2)	(0, 0)
E-cigarettes				
FŠ	n	151	150	150
	n (%)	2 (1%)	0 (0%)	1 (1%)
	(95% CI)	(0, 3)	(0, 0)	(0, 2)

Abbreviations: AS = Adult Smokers; CC = conventional cigarettes; CI = confidence interval; FS, Adult Former Smokers; NS, Adult Never Smokers; NTD = New Taste Direction.

Note: positive Intention to Use was operationalized as the proportion of subjects whose response to the single item assessing intention to use THS on a regular, ongoing basis was either "Very Likely" or "Definitely".

Note: Only relevant combinations of *smoking status group* and *comparator* were assessed, namely, those deemed most directly relevant to study objectives (as shown in the table).

Note: Those participants (FS) already currently using e-cigarettes have been included and were asked how likely or unlikely they were to continue using e-cigarettes regularly

DISCUSSION

For all three tested Concepts, when considering the market share of current *HeatSticks* variants (7% of total estimated sales of CC and *HeatSticks*), a substantial proportion of NTD AS indicated both positive Intention to Try THS at least once (ranging from 25% - 32%) and Intention to Use THS on a regular, ongoing basis (ranging from 18% - 25%). In particular, the highest point estimate for both Intent to Use measures was associated with Concept 3 (i.e., THS and Best Selling *HeatSticks* Regular Variant) whilst the lowest was associated with Concept 2 (i.e., THS and Best Selling *HeatSticks* Menthol Variant). The levels of Intent to Use indicated for the Concept presenting the New *HeatSticks* Menthol variant (Concept 1) were not very dissimilar to the above. This suggests that the New *HeatSticks* Menthol variant has a potential to attract NTD AS that is similar to the two best-selling *HeatSticks* variants already commercially available in the Japan.

The levels of positive Intention to Try THS at least once and Intention to Use THS on a regular, ongoing basis were lower, although still rather large, within AS. They ranged between 15% and 18% for Intention to Try and between 10% and 15% for Intention to Use regularly. This seems to indicate that AS tend to have a slightly lower overall interest in a novel tobacco proposition compared to NTD Adult Smokers. However, within this smoking group (AS), the New *HeatSticks* Menthol variant was associated with slightly higher points of estimates compared to the two best-selling *HeatSticks* variants. This suggests that the New *HeatSticks* Menthol variant may be able to generate a level of interest within AS at least comparable to the two best-selling *HeatSticks* variants.

These are important results because both NTD AS and AS are sections of the population for which THS is intended, who could benefit from completely switching from cigarettes to a

product that could potentially present less risk of harm compared with continued cigarette smoking.

Within FS, 25+ NS and 21-24 NS, and for all the three tested Concepts, positive Intention to Try THS at least once and positive Intention to Use THS on a regular, ongoing basis were expressed by very low proportions of participants. Positive Intention to Try THS at least once ranged between 0% and 2% irrespective of the assessed Concept and across the three nonsmokers groups. Similarly, for the positive Intention to Use THS on a regular, ongoing basis, with levels between 0% and 1%. These low levels of positive Intention to Try THS at least once and positive Intention to Use THS on a regular, ongoing basis were consistent with the very low levels of Intent to Use found for the comparator products CC and e-cigarettes. Thus, within FS, 25+ NS and 21-24 NS, the low levels of Intent to Use THS on a regular, ongoing basis may have reflected a general interest in tobacco or nicotine-containing products for some adult non-smokers. This suggestion is also partly supported by the level of interest in ecigarettes within former smokers reported in the literature^{6, 7, 8}. Therefore, these results associated with the Concept presenting the New HeatSticks Menthol variant (Concept 1) are consistent with PMI's stated objective to market novel products intended for current adult smokers who would otherwise continue to smoke.

The main strength of this market research study was that the sample was well controlled in terms of age, gender and smoking status. Additionally, and in order to increase the ecological validity, participants were exposed to THS and *HeatSticks* price information and branded concepts in the appearance that could be used for commercialization. Finally, two of the assessed Concepts were the two best-selling currently existing *HeatSticks* variants, which represented very realistic comparators. A first limitation of the study was that it was

conducted online and therefore did not allow participants to "physically" interact with the tested concept. A second limitation of the study is that stated intentions on product use tend to be limited predictors of real world behavior⁹, which may be influenced by several factors that are not reproducible in a market research setting. Nonetheless, considering that before the actual marketing, the effect of a new *HeatSticks* variant on initiation among tobacco non-users cannot be assessed, this study provides valuable information on behavioral intention, which is an appropriate method to best predict the behavior of tobacco non-users with respects to a new tobacco product ^{10, 11, 12} and therefore, the likely impact in terms of public health effect.

CONCLUSIONS

To be consistent with the tobacco harm reduction strategy, the introduction of a new *HeatSticks* variant (as an additional taste choice for THS) should meet two conditions: (i) it should encourage adult smokers to switch from cigarettes, (ii) and it should have a low potential to create initiation or relapse among never smokers or former smokers. The data from this market research indicated that, when considering the market share of current *HeatSticks* variants (7% of total estimated sales of CC and *HeatSticks*), the levels of Intent to Use were substantial within the adult smokers (in particular within NTD Adult Smokers, between 18% and 25%) and very low within the adult non-smokers participating in this study (from 0% to 1%). Therefore, the study findings suggest that the introduction of the New *HeatSticks* Menthol Variant would be consistent with the objective of tobacco harm reduction.

TECHNICAL APPENDIX

On behalf of PMI, Ipsos carried out an online survey between 13th and 22nd July among a quota sample of 1,953 residents in Japan (aged 21+) who chose to take part in the study. Participants were classified into the five smoking groups according to the definitions on Page 8, and the recruitment criteria applied is outlined on Page 9. Table 2 provides a breakdown of the sample demographics.

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