



# Analysis of Whole Offer Test Data

## Japan, Italy, Germany, Switzerland and South Korea

### Synopsis

**Study Title:** Analysis of Whole Offer Test Data Japan, Italy, Germany, Switzerland and South Korea

**Registration Number:** Not Applicable

**Product Name:** THS (Tobacco Heating System) version 2.2

**Sponsor:** Philip Morris International

**Version Number:** 2.0

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## 1. BACKGROUND

PMI has conducted a consumer market research study in a number of countries for THS 2.2. This consumer market research study is called ‘Whole Offer Test’ (WOT) and was undertaken to evaluate the adult smoker response to different elements of THS 2.2 offer and the likelihood of switching from CC to THS 2.2.

THS 2.2 is comprised of a THS device and THS Tobacco Sticks named as “*HeatSticks*” designed to be exclusively used with the THS device.

The WOT has been conducted in five countries and in various locations within the same country. More specifically, Japan (JP; Nagoya, Osaka and Tokyo), Italy (IT; Bari, Milan and Rome), Germany (DE; Dresden, Hannover, and Munich), Switzerland (CH; Basel, Berne, Geneva, Lausanne and Zurich), and South Korea (KR; Busan and Seoul). This synopsis summarizes the key results included into the WOT Study Summary document (see Appendix [WOTSTUDYREPORT](#)) with respect to actual use of *HeatSticks*.

## 2. OBJECTIVES AND ENDPOINTS

The data from the WOTs has been analyzed according to five primary objectives and two secondary objectives, similar to the objectives of the THS-PBA-07-US (Actual Use Study of THS 2.2) study (see Appendix PBA07Sum for the study summary).

### Primary Objectives and Endpoints

- 1) *Start Using HeatSticks* - The proportion of participants that ‘start using’ *HeatSticks*.

Endpoints (expressed based on weekly reporting as well as cumulated study week by study week):

- Number of *HeatSticks* consumed; where ‘start using’ is defined as  $\geq 100$  *HeatSticks* consumed during the observational period, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 2) *Switch to HeatSticks* - The proportion of participants who ‘start using’ *HeatSticks* that ‘switch’ from CC to *HeatSticks*.

Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):

- Number of *HeatSticks* and CC consumed; where ‘switch’ is defined as  $\geq 70\%$  of tobacco products used are *HeatSticks*, after participant ‘starts using’ *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 3) *Combined Use of CC and HeatSticks* - The proportion of participants who ‘start using’ *HeatSticks* that have ‘combined use’ of CC and *HeatSticks*.

Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):

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- Number of *HeatSticks* and CC consumed; where ‘combined use’ is defined as >30% and <70% of tobacco products used are *HeatSticks*, after participant ‘starts using’ *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary
- 4) *Switch Back to CC* - The proportion of participants who ‘start using’ *HeatSticks* that ‘switch back’ to CC after ‘switching’ to *HeatSticks*.

Endpoints (expressed based on weekly reporting as well as by the end of the observational period, i.e. study week 4):

- Number of *HeatSticks* and CC consumed; where ‘switch back’ is defined as  $\leq 30\%$  of tobacco products used are *HeatSticks*, after participant ‘starts using’ and ‘switches’ to *HeatSticks*, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary
- 5) *Usage Categories for Continued Use of HeatSticks* - How *HeatSticks* are consumed during continued use ( $\geq 100$  *HeatSticks*, i.e. ‘start using’) according to ‘usage categories’ (e.g., ‘CC use’, ‘Combined use’, ‘*HeatStick* use’).

Endpoints (expressed based on weekly reporting):

- Number of *HeatSticks* and CC consumed as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

### **Secondary Objectives and Endpoints**

- 6) *Usage Categories for Early Stages of Using HeatSticks* - How *HeatSticks* are consumed during the early stages of use (1-99 *HeatSticks*) according to ‘usage categories’ (e.g., ‘CC use’, ‘Combined use’, ‘*HeatStick* use’).

Endpoints (expressed based on weekly reporting):

- Number of *HeatSticks* and CC consumed as reported by the study participant on a stick-by-stick basis in a paper and pencil diary

- 7) *Effect of Using HeatSticks on Total Tobacco Product Use* - The ‘effect’ of *HeatSticks* on the overall consumption of tobacco products (*HeatSticks* and CC).

Endpoints (expressed as difference between self-reported daily average CC consumption before the observational period and weekly reporting of CC+*HeatSticks* during the observational period):

- Number of *HeatSticks* and CC consumed, as reported by the study participant on a stick-by-stick basis in a paper and pencil diary, compared to the number of CC consumed as declared by the study participants before the observational period.

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### 3. METHODS

#### Study Design

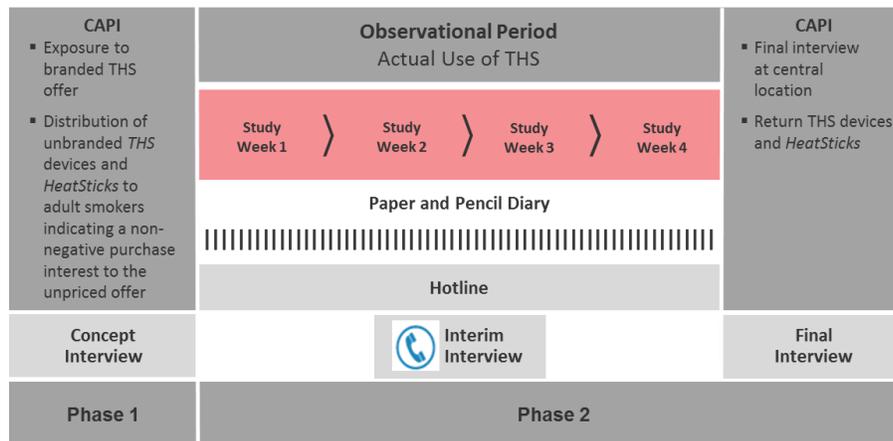
The WOT consists of a single group, descriptive actual use study of THS involving an assessment of participants' self-reported, using a paper and pencil diary, stick-by-stick consumption of *HeatSticks* and of conventional cigarettes (CC) among a sample of adult daily smokers of CC.

#### Study Procedures

The target population was adult smokers living in the country in which the study was conducted. The sampling frame consisted of adult smokers living in the area of each of the selected research centers. Each study included a quota sample of smokers aged between one year above the national legal smoking age (e.g., 19 years old) and 64 years. The sample was frequency matching the adult smoker population in terms of four characteristics: age, gender<sup>1</sup>, social status, and main CC brand.

Study participants were recruited using databases maintained by market research agencies. Study participants were screened according to eligibility criteria (see [section 5](#)). Enrollment was conducted through interviews at a central facility in the study locations.

The study consisted of two phases. Phase 1 focused on assessing the responses to THS and hypothetical communication materials (e.g., pack design and other branded materials). Phase 2 focused on the actual use of THS and *HeatSticks*.



**Figure 3-1: Study Approach**

<sup>1</sup> In South Korea, the sample consisted of male participants only.

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In Phase 2, study participants were able to take part in a four (4) week observational period. To be eligible for Phase 2, participants had to indicate a non-negative purchase interest, using a 5pt-scale, after trying a single *HeatStick*. During the observational period, participants had access to THS at no expense and were provided with an amount of *HeatSticks* corresponding with their self-reported daily consumption of CC multiplied by the number of days (i.e. 28 days) in the observational period. In contrast to Phase 1, during which participants were exposed to branded materials, the product taken home was unbranded. *HeatSticks* were Regular *HeatSticks* and/or Menthol *HeatSticks* (see [section 6](#) “Test Product” for details). Participants also had the possibility to order additional *HeatSticks* if needed through a dedicated telephone hotline. Participants were free to consume both CC and *HeatSticks ad libitum*. However, if they chose to consume CC, they had to purchase them at their own expense. Participants were asked to record their *HeatStick* and CC consumption on a stick-by-stick basis, using a paper and pencil daily diary. During the observational period, study participants were also asked to participate in interim interviews. This was to measure the overall liking of THS 2.2 after one week of usage, to ensure participants did not have any issues with the operation of the product and were comfortable with the diary completion instructions. At the end of the observational period, participants were asked to return to the central facility and hand back the THS and any unused *HeatSticks*.

Study participants were compensated for their participation according to local market research standards. Study participation was voluntary and respondents were asked to sign a confidentiality and consent form indicating they agreed with the conditions of the study. Study participants were free to withdraw from the study at any time without any obligation, penalty, or loss of the benefits to which they were entitled.

Starting with the Italian WOT, a “passive surveillance procedure” was included as part of the study procedures. This was done to collect safety data using Individual Safety Data Collection Forms (ISDCF) of spontaneously reported health problems collected by telephone hotline operators. This data is not included in this document but will be reported as part of the Tobacco Heating System (THS) safety reporting.

Whilst in Italy and Japan study participants were asked to report their e-cigarette consumption in their diaries, in Switzerland, Germany and South Korea participants were not given instructions to report e-cigarette consumption.

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#### 4. NUMBER OF STUDY PARTICIPANTS ANALYZED

Table 4-1 presents the number of participants whose behavioral data was analyzed; i.e. participants who answered the interim phase, attended the final phase, and completed at least 26 days in the diary<sup>2</sup> (i.e. in the Full Analysis Set (FAS)):

**Table 4-1: Participants in the Full Analysis Set (FAS)**

Country	Participants	% Males	% Females	Mean Age (Min, Max)
1) Japan	638	70.85%	29.15%	43.53 (21, 64)
2) Italy	535	51.03%	48.97%	38.97 (19, 64)
3) Germany	377	51.72%	48.28%	40.29 (19, 64)
4) Switzerland	416	51.92%	48.08%	38.42 (19, 64)
4) South Korea	843	100.00%	0.00%	38.24 (20, 64)

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<sup>2</sup> A diary entry is considered as completed if the participant either reported the type of product used or declared “zero” consumption of CC and *HeatSticks*.

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## 5. MAIN CRITERIA FOR INCLUSION

For all five countries, the following inclusion criteria were applied:

- To be eligible for Phase 1, participants had to be:
  - Aged 1 year above the country legal smoking age. The upper age limit was 64 years old
  - Residing in the country for at least 1 year
  - Smokers of CC<sup>3</sup> in the last 7 days
  - Smokers of at least 3 CC per day. All to have been smoking for at least 6 months, and at least 100 CC since reaching legal smoking age (as self-reported by each participant during the recruitment phase)
  - Available during the observational period
  - Not participated in any market research on tobacco products in the last 6 months
  - Not intending to leave the country for more than 3 days during the observational period. (For Switzerland, the criterion was not intending to leave the country for more than one week, rather than 3 days, during the observational period).
- The following participants were excluded from the study:
  - Participants who could not show proof of age at the central facility when coming for Phase 1
  - Participants unwilling to sign confidentiality and consent forms
  - Pregnant or breastfeeding females
  - Individuals working in the fields of market research, marketing, advertising, media or journalism, law, the tobacco industry, the health industry, political lobbying

Additional specific criteria were applied to reflect local specificities:

- Italy and Germany: Only smokers of non-menthol CC were recruited
- South Korea: All participants were male

## 6. TEST PRODUCT

The test products were Regular *HeatSticks* and Menthol *HeatSticks*. Depending on the country, respondents were given Regular *HeatSticks* or either Regular *HeatSticks* or Menthol *HeatSticks*. More specifically:

- Regular *HeatSticks* only: in Italy and Germany
- Either Regular *HeatSticks* or Menthol *HeatSticks*: in Japan, Switzerland and Korea

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<sup>3</sup> In Italy, exclusive smokers of Roll Your Own (RYO) or Make Your Own (MYO) tobacco products in the last 7 days were also eligible.

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In all markets, with the exception of Japan, the products (i.e. Regular *HeatSticks* or Menthol *HeatSticks*) were allocated to participants regardless of the type of CC the participant was currently smoking. In Japan, adult smokers of regular CC received Regular *HeatSticks* and adult smokers of menthol CC received Menthol *HeatSticks*.

Alongside the tested products, participants were provided with the THS.

## **7. DURATION OF EXPOSURE**

In each country, the study was performed over a 28 day observational period.

## **8. STATISTICAL METHODS**

The WOT data was analyzed descriptively using STATA 12.1. The results are presented in frequency tables and measures of central tendency as well as dispersion are provided. 95% Confidence Intervals (95% CI) are reported to describe the precision of the results. Lower and upper CI limits are presented in square brackets. Results are presented, whenever appropriate, for each study week of the observational period as well as for the entire observational period. No specific hypotheses were tested.

## **9. SUMMARY OF RESULTS**

### **Primary Objectives**

#### *1) Start Using HeatSticks:*

The proportion of study participants who consumed at least 100 *HeatSticks* by the end of the observational period ranged from between 36.07% (Italy) to 76.28% (South Korea). Across all countries, the proportion of participants passing the threshold of 100 *HeatSticks* peaked in study weeks 2 or 3, and declined in study week 4. This suggests that the study duration of four observational weeks was sufficient to assess relevant behavioral patterns.

#### *2) Switch to HeatSticks:*

By the end of the observational period, between 17.96% (Switzerland) and 47.43% (South Korea) of study participants who had started using *HeatSticks*, had switched to *HeatSticks*. This suggests that a rather substantial portion of adult smokers are able to substitute CC, completely or almost completely, with *HeatSticks*. Across all countries, the majority of participants switched to *HeatSticks* in the first study week, indicating that *HeatSticks* are adopted quickly by most participants who start using *HeatSticks*.

#### *3) Combined Use of CC and HeatSticks:*

Amongst study participants who started using *HeatSticks*, between 39.90% (Japan) and 60.68% (Switzerland) used both CC and *HeatSticks* by the end of the observational period.

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4) *Switch Back to CC:*

The proportion of participants, amongst those who switched to *HeatSticks*, who had switched back to CC, by the end of the observational period was low in all countries, ranging between 0.00% (Japan) and 10.34% (Italy). This seems to indicate that when adult smokers switch to *HeatSticks* and use them predominantly, the likelihood of relapsing to CC is limited over a period of 4 weeks.

Table 9-1 shows an overview of results concerning study objectives 1 to 4 across all countries.

**Table 9-1: Country Results for Study Objectives 1 to 4 as assessed by the end of the observational period**

Assessment	Statistics	JP	IT	DE	CH	KR
Full Analysis Set (FAS)	n	638	535	377	416	843
1) Start Using <i>HeatSticks</i>	%	61.29%	36.07%	50.13%	49.52%	76.28%
Started by End of Study Week 4	n	391	193	189	206	643
2) Switch to <i>HeatSticks</i>	%	46.29%	29.02%	37.04%	17.96%	47.43%
3) Combined Use of CC and <i>HeatSticks</i>	%	39.90%	54.92%	43.39%	60.68%	40.12%
Switched to <i>HeatSticks</i>	n	180	58	67	47	328
5) Switch Back to CC	%	0.00%	10.34%	7.46%	8.51%	6.40%

Note: For study objective 1, the percentages refer to the total number of participants in the corresponding country's FAS. For study objectives 2 to 3, the percentages refer to the total number of participants who have started using *HeatSticks* by the end of the observational period in the corresponding country. For study objective 4, the percentages refer to the total number of participants who have started using *HeatSticks* by the end of the observational period and switched to *HeatSticks* by the end of study week 3 in the corresponding country.

5) *Usage Categories for Continued Use of HeatSticks:*

The proportion of participants who started using *HeatSticks* by study week 4 and adopted a usage behavior involving exclusive use of *HeatSticks* is between 7.77% (Switzerland) and 21.48% (Japan). This indicates that, for a portion of adult smokers, *HeatSticks* are able to represent an alternative to CC.

Table 9-2 shows an overview of results concerning study objective 5 across all countries.

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**Table 9-2: Country Results for Study Objective 5 as assessed by the end of the observational period**

Assessment		Statistics	JP	IT	DE	CH	KR
		<i>n</i>	391	193	189	206	643
Usage Categories	Exclusive <i>HeatStick</i> Use	Frequency	84	25	29	16	129
		Percentage	21.48%	12.95%	15.34%	7.77%	20.06%
		95% CI	[17.51%, 25.89%]	[8.56%, 18.53%]	[10.52%, 21.29%]	[4.50%, 12.31%]	[17.03%, 23.37%]
	Predominant <i>HeatStick</i> Use	Frequency	97	31	41	21	176
		Percentage	24.81%	16.06%	21.69%	10.19%	27.37%
		95% CI	[20.60%, 29.40%]	[11.18%, 22.02%]	[16.04%, 28.26%]	[6.42%, 15.16%]	[23.96%, 30.99%]
	Combined mostly <i>HeatStick</i> Use	Frequency	42	18	17	20	70
		Percentage	10.74%	9.33%	8.99%	9.71%	10.89%
		95% CI	[7.85%, 14.24%]	[5.62%, 14.34%]	[5.33%, 14.01%]	[6.03%, 14.60%]	[8.59%, 13.55%]
	Combined balanced Use	Frequency	79	62	48	72	136
		Percentage	20.20%	32.12%	25.40%	34.95%	21.15%
		95% CI	[16.34%, 24.53%]	[25.60%, 39.21%]	[19.36%, 32.22%]	[28.46%, 41.89%]	[18.06%, 24.51%]
	Combined mostly CC Use	Frequency	35	26	17	33	52
		Percentage	8.95%	13.47%	8.99%	16.02%	8.09%
95% CI		[6.31%, 12.23%]	[8.99%, 19.11%]	[5.33%, 14.01%]	[11.29%, 21.76%]	[6.10%, 10.47%]	
Predominant CC Use	Frequency	50	29	26	42	65	
	Percentage	12.79%	15.03%	13.76%	20.39%	10.11%	
	95% CI	[9.64%, 16.51%]	[10.30%, 20.86%]	[9.19%, 19.50%]	[15.11%, 26.54%]	[7.89%, 12.70%]	
Exclusive CC Use	Frequency	4	2	9	2	12	
	Percentage	1.02%	1.04%	4.76%	0.97%	1.87%	
	95% CI	[0.28%, 2.60%]	[0.13%, 3.69%]	[2.20%, 8.85%]	[0.12%, 3.46%]	[0.97%, 3.24%]	
Zero <i>HeatStick</i> and CC Use	Frequency	0	0	2	0	3	
	Percentage	0.00%	0.00%	1.06%	0.00%	0.47%	
	95% CI	[0.00%, 0.94%]	[0.00%, 1.89%]	[0.13%, 3.77%]	[0.00%, 0.18%]	[0.10%, 1.36%]	

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## Secondary Objectives

### 6) *Usage Categories for Early Stages of Using HeatSticks:*

Among participants who had not passed the threshold of 100 *HeatSticks* by the end of study week 4, the absolute majority predominantly used CC, ranging from 69.01% in Italy to 84.04% in Germany, which seems to indicate that the adoption of *HeatSticks* is either rapid or does not occur at all.

### 7) *Effect of HeatSticks on Total Tobacco Product Use:*

The daily average total tobacco consumption (i.e., *HeatSticks* + CC) measured during the observational period was approximately two sticks lower than the self-reported consumption (CC only) before the observational period. This was consistent across all countries and study weeks. This difference between consumption rates as assessed by the two different methods (self-reported and daily paper and pencil diary) is coherent with other findings (Shiffman et al., 2002), both in terms of its magnitude and direction. Based on the study data, there is no evidence that would suggest that the availability of *HeatSticks* would lead to an increase in daily average total tobacco product consumption (i.e. CC+*HeatSticks*).

## 10. STRENGTHS AND LIMITATIONS OF THE STUDY

Below are highlighted some of the strengths of the WOT studies.

First, the sample of participants enrolled into the Phase 1 of the study was large and well controlled, which resulted into a substantial number of participants included into the observational period and FAS.

Second, the observational period of four weeks allowed for relevant behavioral patterns to manifest themselves.

Third, the data were assessed in two distinct regions, Europe and Asia, with five different countries and a minimum of two cities in each country. This extensive coverage allowed for the observation of a wide range of potential usage patterns across a broad geographic spectrum.

Fourth, the compliance rate was very high in all of the countries, supporting the reliability of results.

There were also some limitations to the WOT studies, mostly intrinsically related to the fact that these studies were conducted in a premarket setting.

First, study participants received the product (i.e. *HeatSticks*) for free.

Second, only participants who indicated a non-negative purchase intention at the concept stage were eligible to take part in the behavioral stage. Therefore, it cannot be ruled out that adult smokers negatively disposed towards the product might have had a different rate of adoption of *HeatSticks*.

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Third, despite the sampling strategy, the WOT studies generated results that cannot be considered as nationally representative or cannot provide generalizable results for the entire adult smoker population.

Finally, it cannot be excluded that some study participants altered their smoking behavior during the study period because of increased awareness of their behavior due to the use of the diary.

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## 11. LIST OF ABBREVIATIONS

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<b>Abbreviation</b>	<b>Definition</b>
CAPI	Computer Aided Personal Interview
CC	Conventional Cigarette(s)
CH	Switzerland
CI	Confidence Interval(s)
DE	Germany
FAS	Full Analysis Set
ISDCF	Individual Safety Data Collection Form
IT	Italy
JP	Japan
KR	South Korea
MYO	Make Your Own
PMI	Philip Morris International Management S.A.
RRP	Reduced Risk Product
RYO	Roll Your Own
THS	Tobacco Heating System
THS 2.2	Tobacco Heating System 2.2
WOT	Whole Offer Test

## 12. REFERENCE LIST

Shiffman, S., Gwaltney, C. J., Balabanis, M. H., Liu, K. S., Paty, J. A., Kassel, J. D., Hickcox, M. & Gnys, M. (2002). Immediate antecedents of cigarette smoking: An analysis from ecological momentary assessment. *Journal of Abnormal Psychology*, 111(4), 531-545.

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