



Actual Use Study of the Potential Reduced-Risk Product (RRP): Tobacco Heating System (THS)

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Introduction and Objectives

Philip Morris International (PMI) is developing a number of new products, including potential Reduced-Risk Products (RRPs), which have the potential to reduce individual risk and population harm in comparison to smoking cigarettes. One of PMI's potential RRP is the "Tobacco Heating System." The THS is comprised of a device and tobacco sticks designed to be exclusively used with the device. The Sticks contain tobacco and when used with the THS device produce a nicotine containing aerosol, but without combustion of tobacco.

The THS-PBA-07-US Actual Use Study (AUS) is the final element of THS premarket Perception and Behaviour Assessment (PBA) program with the aim to provide evidence to one of the key areas of investigation highlighted in the MRTPA Draft Guidance related to the "effect the tobacco product and its marketing may have on tobacco use behaviour among current tobacco users."

The purpose of this AUS study was to investigate how U.S. adult daily smokers of cigarettes (CC) actually used THS.

THS PBA PROGRAM

Development and Validation of Measurement Tools

PBA 01

Risk & Intent to Use Scales Development & Validation Project

Development of Messaging and Communication Materials

THS-PBA-02-US

Qualitative Study to Develop THS 2.2 Potential Product Messages

THS-PBA-03-US

Quantitative Study to Assess THS 2.2 Potential Product Messages

THS-PBA-04-US

Qualitative Study to Develop THS 2.2 Potential Label, Labeling and Marketing Material

Assessment of Instructions for Use

THS-PBA-06-US

Usability and Comprehension Study of THS 2.2 Instructions for Use within Adult Smokers

Assessment of Communication Materials

THS-PBA-05-RRC-US

Quantitative assessment of THS 2.2 Label, Labeling and Marketing Material with Reduced Risk Claims

THS-PBA-05-RRC2-US

Second quantitative assessment of THS 2.2 Label, Labeling and Marketing Material with Reduced Risk Claims

THS-PBA-05-REC-US

Quantitative assessment of THS 2.2 Label, Labeling and Marketing Material with Reduced Risk Claims

Assessment of Behavior Among Current Smokers

THS-PBA-07-US

Observational Study of Actual Use of THS 2.2

Method

This AUS was designed as a mid-term prospective observational study, implying an assessment of subject reported stick-by-stick consumption of Tobacco Sticks and of CC with participants receiving Tobacco Sticks free of charge.

The target population was U.S. adult daily smokers of regular and/or menthol CC aged 18 years and above (according to minimum local or State legal smoking age). The study sample was composed of daily smokers with no intention to quit smoking within the next 30 days. The study was conducted in 8 geographic areas of the U.S.

The recruitment of candidate participants was done using market research databases. The study did not restrict enrollment using quotas, however, the sampling approximated the adult smoker distribution on sex, age, race and income contained in the CDC 2012 report.

First Subject In was on 21 September 2015 and Last Subject Out was on 07 January 2016. 1,336 participants were enrolled, 1,106 participants composed the Full Analysis Set (FAS).

The study design included a baseline, an observational and a close out period. The study began with a 1-week baseline period, during which participants recorded their stick-by-stick consumption of CC and other products containing nicotine.

The baseline period served to estimate the participants' regular smoking patterns

of CC. During a subsequent 6-week observational period, participants recorded their stick-by-stick consumption of both Tobacco Sticks and CC.

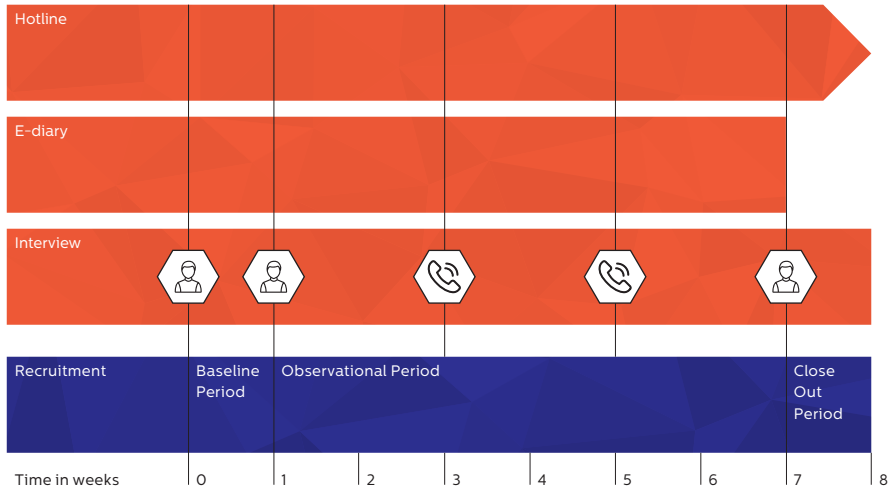
The observational period served to assess the development of consumption patterns of Tobacco Sticks.

The study concluded with a 1-week close out period, during which participants were not required to record any data, however, they were able to call the toll-free telephone hotline. This allowed for the continued surveillance of adverse events (AEs).

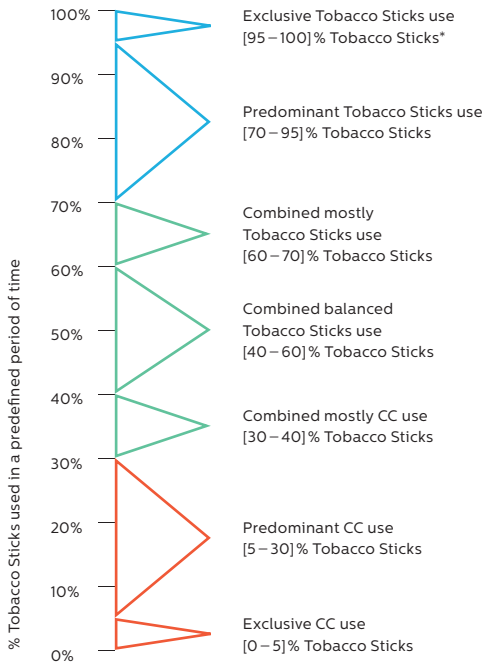
During the entire study, participants were able to consume CC, Tobacco Sticks and any other product containing nicotine *ad libitum*. They were requested to make an entry into an electronic diary every time they consumed a CC during the baseline period and a Tobacco Stick or a CC during the observational period.

The patterns of use were defined using the below usage categories.

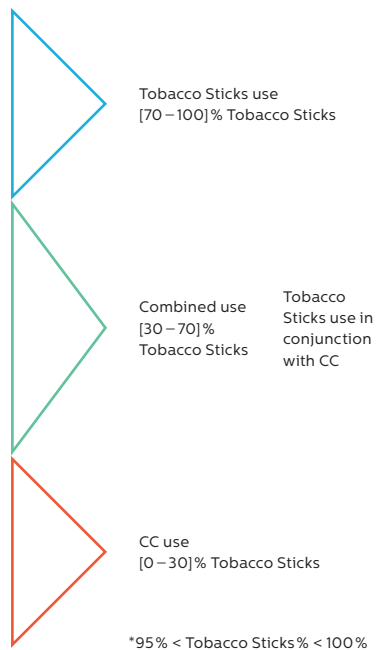
STUDY OVERVIEW



USAGE CATEGORIES



NOT USAGE CATEGORIES



Results

The data indicates that THS has the potential to be fully adopted by a sizeable proportion of participants, as 7.5% of the participants were using Tobacco Sticks exclusively at the end of the observational period.

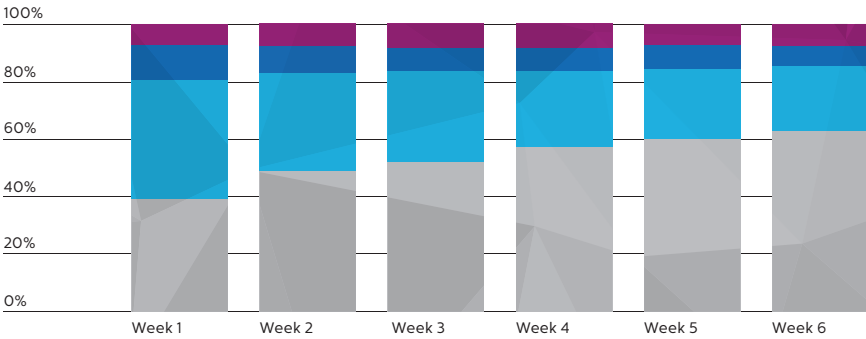
The proportion of participants who completely “switched” to THS was higher in

the subgroup of participants who ordered both Tobacco Sticks types compared to those who ordered menthol Tobacco Sticks only or regular Tobacco Sticks only.

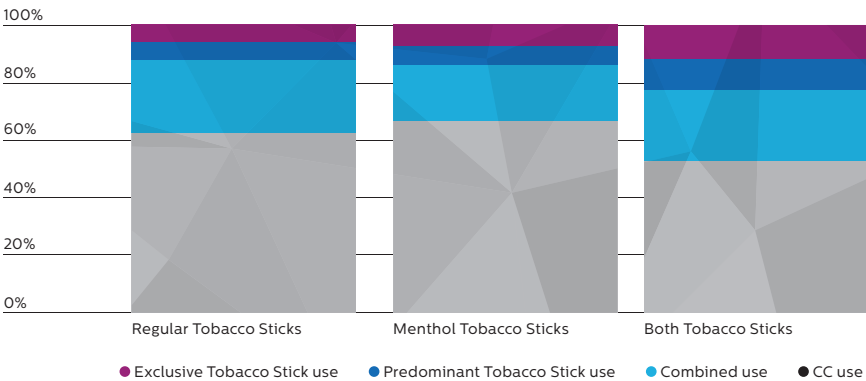
The average number of tobacco products (Tobacco Sticks and CC) consumed during the observational period per day was lower than the average number of CC per day consumed during the baseline period.

A similar pattern was found when looking at results stratified by usage category at Week 6. A certain number of AEs were spontaneously reported during the study.

USAGE CATEGORIES - FAS



USAGE CATEGORIES BY TOBACCO STICKS TYPE AT WEEK 6



● Exclusive Tobacco Stick use
 ● Predominant Tobacco Stick use
 ● Combined use
 ● CC use

AVERAGE NUMBER OF TOBACCO STICKS AND CC REPORTED – PER DAY

Mean (SD)	FAS overall (n=1,106)	Tobacco Sticks use at Week 6 (n=141)	Combined use at Week 6 (n=217)	CC use at Week 6 (n=607)
During baseline period				
Number of CC	10.2 (7.22)	9.0 (5.89)	9.3 (6.34)	10.9 (7.69)
During observational period				
Number of tobacco products (Tobacco Sticks and CC)	9.3 (6.56)	8.1 (5.37)	8.9 (6.21)	9.9 (6.75)
Number of CC	6.3 (5.78)	1.4 (1.57)	4.8 (3.72)	4.8 (3.72)
Number of Tobacco Sticks	3.0 (3.57)	6.7 (4.82)	4.1 (3.06)	1.7 (1.99)

n = number of values reported, CC = conventional cigarettes, FAS = Full Analysis Set.

The majority of the reported AEs were not health-related (e.g. product quality issues). Eight cases were assessed as serious and in 5 out of those 8 cases, a causal relationship between the use of THS and the reported events cannot be excluded. Based on the information on AEs, no safety concerns about THS emerged during this study.

Conclusions

Based on the study results several key conclusions can be drawn regarding the likely behaviour of U.S. adult daily smokers.

- 1 A sizeable proportion of adult daily smokers is likely to “switch” from CC to THS and is likely to use Tobacco Sticks exclusively or predominantly as a substitute to CC. The proportion of exclusive use is likely to remain overall stable over time.
- 2 It is likely that a certain proportion of adult daily smokers will use THS and CC in a combined way. The data also indicate that a substantial proportion of them is likely to return to CC over time unless they exclusively or predominantly use Tobacco Sticks.
- 3 The availability of several variants of Tobacco Sticks might be a better alternative to increase the transition of adult daily smokers from CC to THS.
- 4 There is no evidence that suggests that the availability of THS would lead to an increase in total tobacco product consumption (Tobacco Sticks and CC).
- 5 No safety concerns about the safety of THS is expected.

MORE INFORMATION



FOLLOW /PMISCIENCE



REFERENCES

CDC (Centers for Disease Control and Prevention), Department of Health and Human Services, Office of the Surgeon General. Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Rockville (MD). 2012. Food and Drug Administration, U.S. Department of Health and Human Services, Center for Tobacco Products. Modified Risk Tobacco Product Applications: Draft Guidance. 2012.

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 RRP’s in various stages of development, scientific assessment and commercialization. Because our RRP’s do not burn tobacco, they produce far lower quantities of harmful and potentially harmful compounds than found in cigarette smoke.

COMPETING FINANCIAL INTEREST

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