

EVIDENCE RELATED TO THE IMPACT ON TOBACCO USERS

EVALUATION OF EPIDEMIOLOGICAL STUDIES

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Study Overview and Results

- Pre-Market Studies
 - Actual use study: Perception and Behavior Assessment - 07 (PBA-07) in the US
 - Whole Offer Test (WOT) in Asia and Europe
- Post-Market Studies in Japan
 - Cross-sectional survey of smokers and non-smokers
 - Survey of IQOS purchasers

Summary and Limitations

OVERVIEW OF PRE-MARKET STUDIES

ACTUAL USE STUDY (PBA-07)



- **Study design**: longitudinal observational study
- **Study period and location**: September 2015-January 2016 in 8 US cities (N=1,106)
- **Recruitment method**: market-research consumer-based database
- **Eligibility**: aged ≥ 18 years; current daily smokers; no intention to quit in next 30 days; expressed positive intention to use *IQOS*
- **Baseline smoking patterns**: participants recorded in e-diary each time they used a combusted cigarette, for 1-week
- **IQOS use**:
 - Provided with free *IQOS* device and *HeatSticks* (regular and/or menthol)
 - Instructed to use *IQOS* and other tobacco products ad libitum for 6-weeks
 - Record in e-diary each time they use a combusted cigarette or *HeatStick*
- **Use of other tobacco products**: each day reported if they used any nicotine replacement therapy (yes/no), any e-cigarettes (yes/no) or any other tobacco products (yes/no) (e.g., smokeless, cigars)

WHOLE OFFER TEST (WOT)



- **Study design**: series of longitudinal observational studies
- **Study period and location**: 2013-2015 in Japan (N=638), South Korea (N=843), Italy (N=535), Germany (N=377), Switzerland (N=416)
- **Recruitment method**: market-research consumer-based database
- **Eligibility**: aged ≥ 19 years; smoked ≥ 6 months, smoke ≥ 3 cigarettes per day; expressed positive intention to use *IQOS*
- **Baseline smoking**: self-reported average number of combusted cigarettes smoked per day
- **IQOS use**:
 - Provided with free *IQOS* device and *HeatSticks* (regular and/or menthol)
 - Instructed to use *IQOS* and other tobacco products ad libitum for 4-weeks
 - Record in paper and pencil diary each time they use a combusted cigarette or *HeatStick*
- **Use of other tobacco products**: In Italy and Japan only, e-cigarette use (yes/no). No site collected information on the use of other tobacco products.

OVERVIEW OF JAPANESE POST-MARKET STUDIES

JAPANESE POST-MARKET STUDIES



- Study 1
 - Online survey conducted in September 2016
 - 2,000 adults aged ≥ 20 years recruited from online panel
 - Included cigarette smokers and non-smokers
 - Self-reported current use of combusted cigarettes, “heat-not-burn” products, and other tobacco products
- Study 2
 - Survey that started in January 2016
 - ~11,000 adults aged 21 years or older
 - Must have bought an *IQOS* device in past 3 weeks and registered their device in an online database
 - Must use ≥ 10 *HeatSticks* and/or cigarettes per week
 - Self-reported current use of *IQOS* and combusted cigarettes

PRE-MARKET STUDY RESULTS

IQOS “INITIATION” AND “SWITCHING” IN PRE-MARKET STUDIES



Country	“Initiated” IQOS use ¹ among all smokers	“Switched” to IQOS, ² among those who “initiated” IQOS use	“Exclusive” IQOS use, ³ among those who “initiated” IQOS use	“Switched” back to combusted cigarettes, ⁴ among those who previously “switched” to IQOS
United States	33.8% (N=1,106)	32.7% (N=374)	16.3% (N=374)	15.5% (N=195)
Japan	61.3% (N=638)	46.3% (N=391)	21.5% (N=391)	0.0% (N=180)
South Korea	76.3% (N=843)	47.4% (N=643)	20.1% (N=643)	6.4% (N=328)
Italy	36.1% (N=535)	29.0% (N=193)	13.0% (N=193)	10.3% (N=58)
Germany	50.1% (N=377)	37.0% (N=189)	15.3% (N=189)	7.5% (N=67)
Switzerland	49.5% (N=416)	18.0% (N=206)	7.8% (N=206)	8.5% (N=47)

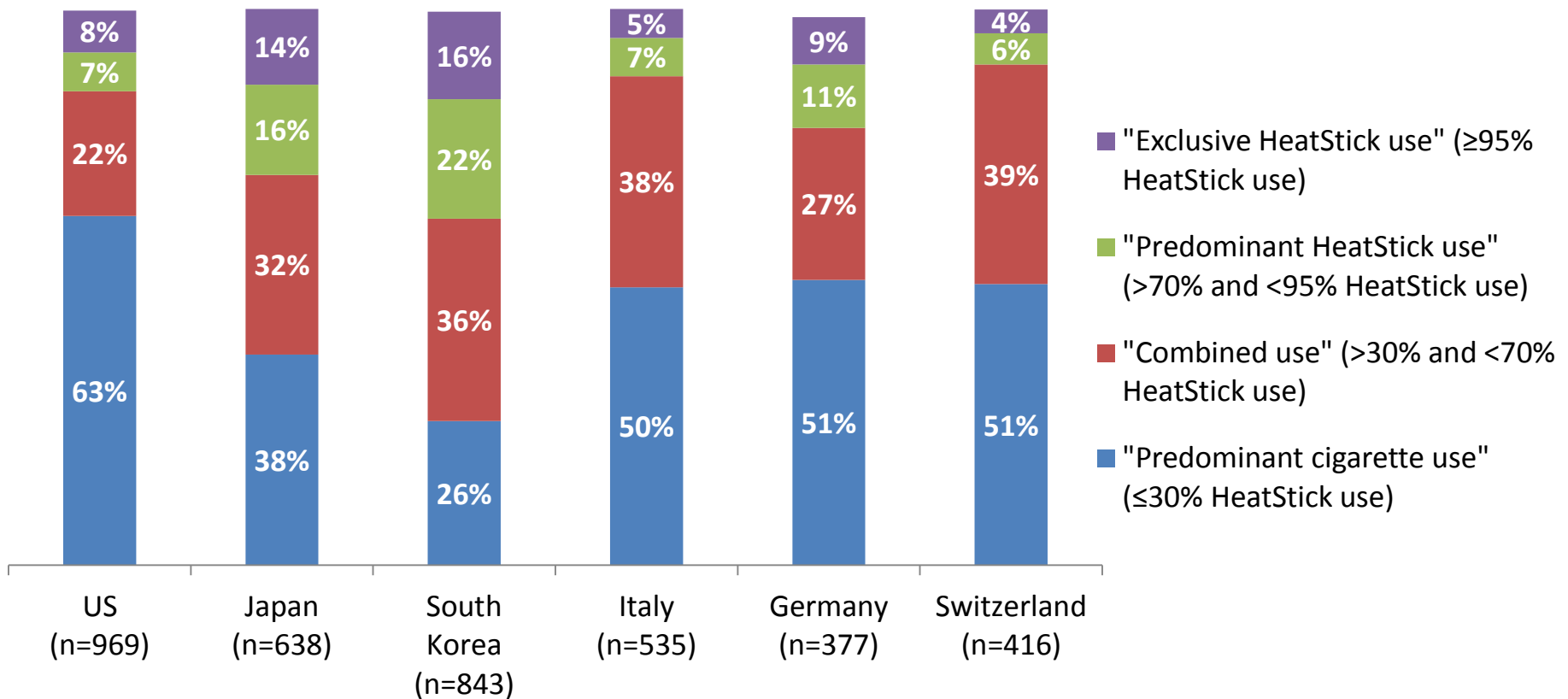
Data Source: Sections 7.3.2 and 7.3.3 of MRTPA.

¹ “Initiated” IQOS use is defined as using ≥ 100 HeatSticks. ² “Switched” to IQOS was defined as HeatSticks comprising $\geq 70\%$ of total combusted cigarette plus HeatStick consumption in the last week of the study. ³ “Exclusive” IQOS use was defined as HeatSticks comprising $\geq 95\%$ of total combusted cigarette plus HeatStick consumption in the last week of the study. ⁴ “Switched” back to combusted cigarettes was defined as HeatSticks comprising $\leq 30\%$ of total combusted cigarettes and HeatSticks consumed in a week after having “switched” to HeatSticks in an earlier week.

IQOS USE CATEGORIES BY COUNTRY



IQOS use categories during the last week of the PBA-07 study and Whole Offer Test.

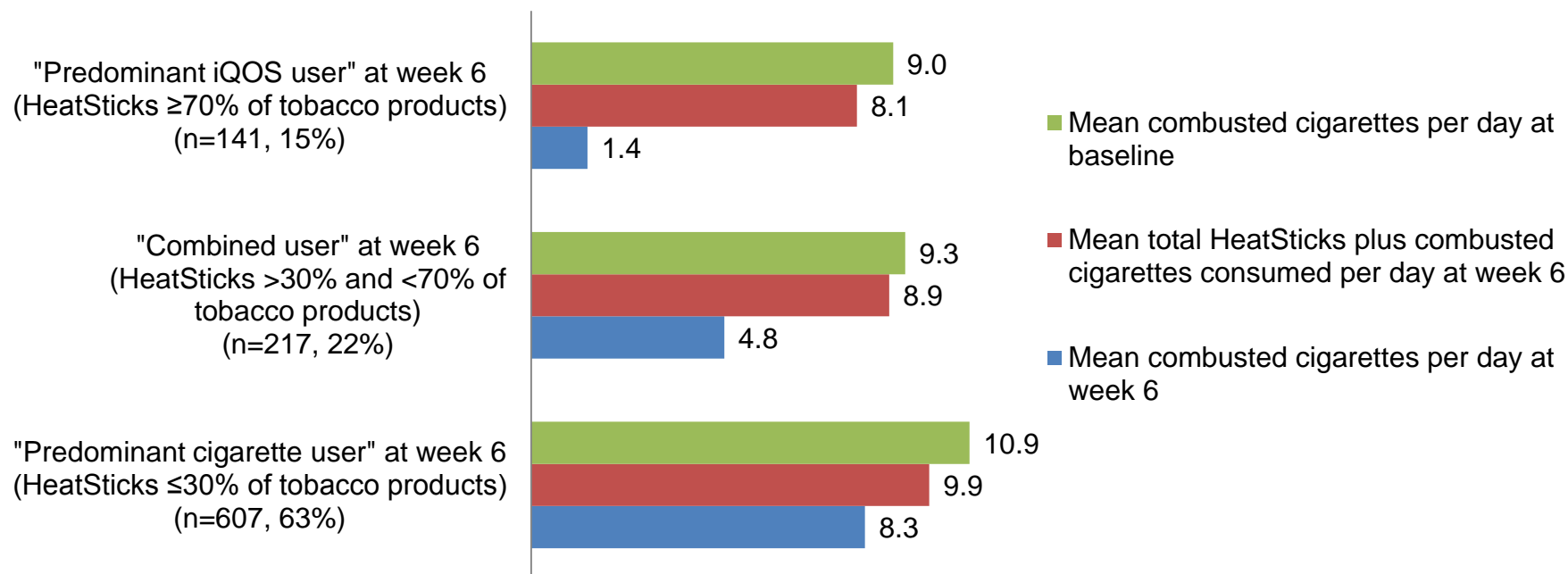


Data Source: Sections 7.3.2 and 7.3.3 of the MRTPA.

CHANGE IN COMBUSTED CIGARETTE CONSUMPTION



Mean combusted cigarettes per day at baseline and week 6, by /iQOS usage categories at week 6, in the US actual use study.



Data Source: Section 7.3.2 of the MRTPA.

POST-MARKET STUDY RESULTS

DUAL USE AMONG “HEAT-NOT-BURN” PRODUCT USERS IN JAPANESE POST-MARKET STUDY



Tobacco Product Used Concurrently	% of Current “Heat-Not-Burn” Users That Concurrently Use Other Tobacco Products ¹ (N=71)
At least one other tobacco product	91.8%
Cigarettes (including roll-your-own)	84.9%
Cigarettes, use daily	79.4%
Cigarettes, use less than daily	5.5%
E-cigarettes	58.9%
“Smokeless tobacco pipe” ²	38.4%
Chewing tobacco, snus, snuff	30.1%
Cigars/pipes/kiseru	24.7%

Data Source: March 16, 2017 amendment.

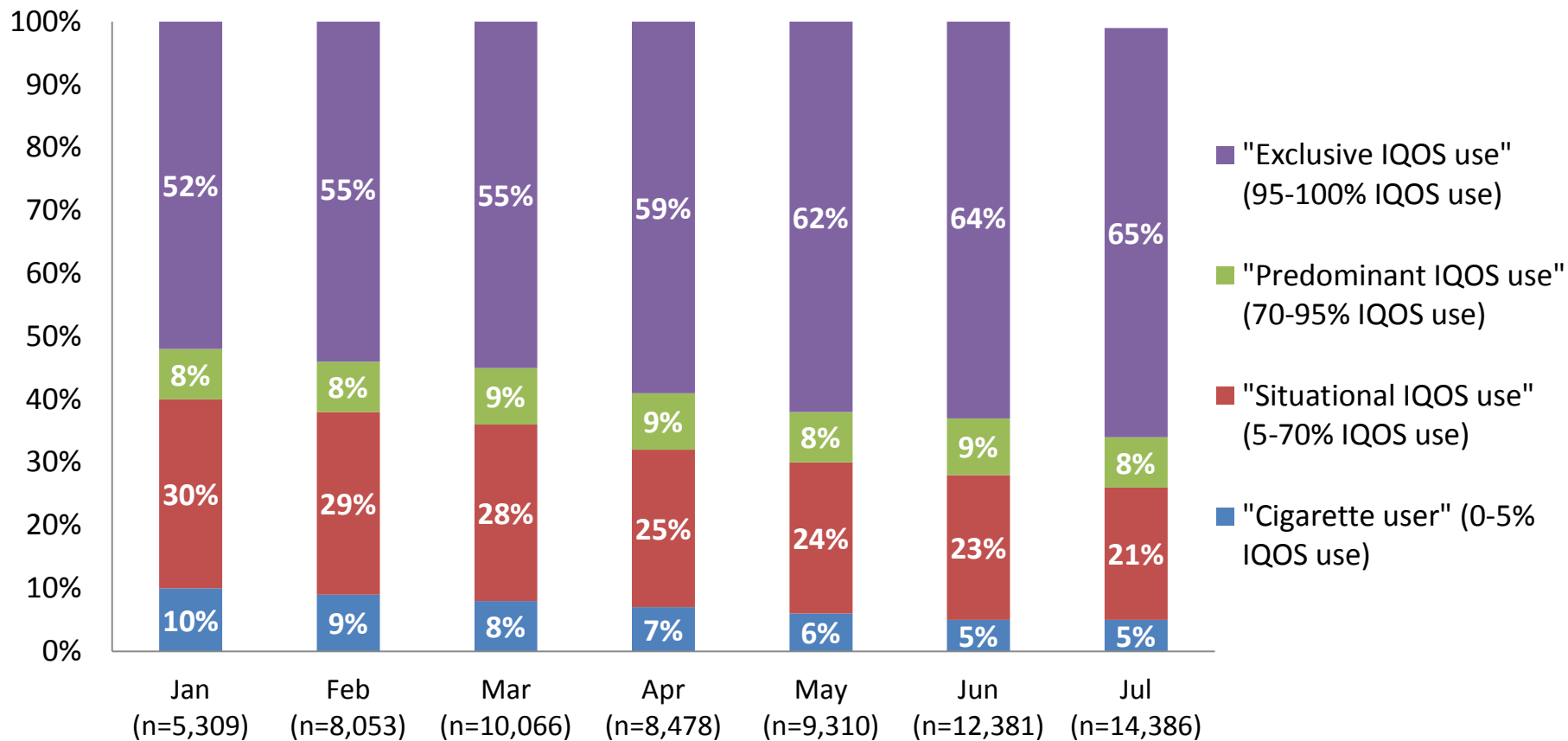
¹Participants were considered to be a current user of a tobacco product if they reported using that product daily or less than daily.

²A cigarette shaped pipe with no electronics that contains a tobacco cartridge which you can puff on. This product neither heats nor burns anything.

JAPANESE IQOS PURCHASERS



IQOS usage categories among IQOS purchasers in post-market survey



Data Source: Section 2.7 of the MRTPA.

SUMMARY: IQOS USE PATTERNS

- IQOS initiation (i.e., using ≥ 100 *HeatSticks*) varied across countries
 - 33.8% in the US
 - Ranged from 36.1% in Italy to 76.3% in South Korea in the WOT
- Dual use was common across all countries
- Low prevalence of complete switching to IQOS
 - In the US, 8% of participants were “exclusive” IQOS users in the last week of the study
 - In the WOT, “exclusive” IQOS use in the last week of the study ranged from 4% in Switzerland to 16% in South Korea
- All IQOS use groups in the US experienced a reduction in combusted cigarette consumption

SUMMARY: LIMITATIONS

- Unknown effect of dual use on reducing health risks and exposure to HPHCs
- Study design may impact behavior relative to true real-world conditions
 - Effect on behavior of receiving IQOS free of charge
 - Sustainability of IQOS use patterns over time
 - Unclear whether participants noticed or were impacted by reduced risk information on labeling material
- Generalizability of results to US smokers
 - Non-probability sample from marketing research databases
 - Prevalence of switching varied across countries, with highest prevalence in Asia
 - Differences in the availability of products across countries

CLARIFYING QUESTIONS?

