

# Modeling the Population Health Impact of introducing a Reduced Risk Product into the Japan market



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## Introduction

Philip Morris International has developed a Population Health Impact Model (PHIM) to estimate the reduction in smoking attributable mortality due to the marketing a Reduced Risk Products (RRPs – the term PMP SA use to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes.

The PHIM developed for Japan, as the lead market for IQOS, considered the RRP uptake scenario with a 55% of the smoking population switching to heated tobacco products including IQOS after 10 years; 85% exclusively using heated tobacco products and IQOS and 15% dual use as the RRP Business case scenario. All simulations were counterfactual and run for the period 1990–2010.

## Methods

The PHIM assesses the population-level health impact of marketing an RRP as a function of the toxicity of the product, and the product use prevalence distribution at the population level. The Prevalence and Epidemiological Risk components use Japan specific data collected for the model and used for hindcasting.

For all Japan modeling applications, PHIM simulated samples of 10,000 hypothetical males and 10,000 hypothetical females aged between 10 and 79\*, in 1990 with a Japan representative distribution of smoking prevalence, and no use of IQOS or other heated tobacco products.

Individual tobacco histories are then updated each year until 2010 based on two alternative sets of estimated smoking transition probabilities (STPs) of switching between tobacco groups for two scenarios:

- ① Null scenario (without RRP)
- ② RRP scenario (with IQOS and heated tobacco products).

All RRP scenarios were conducted with testing an IQOS effective dose range (f value = 0.3 or 0.1). Difference in cumulative smoking attributable deaths between null and RRP scenario informed on overall population harm reduction in Japan. For more details and references see the leaflet.

## Results

### Null scenario and Verification

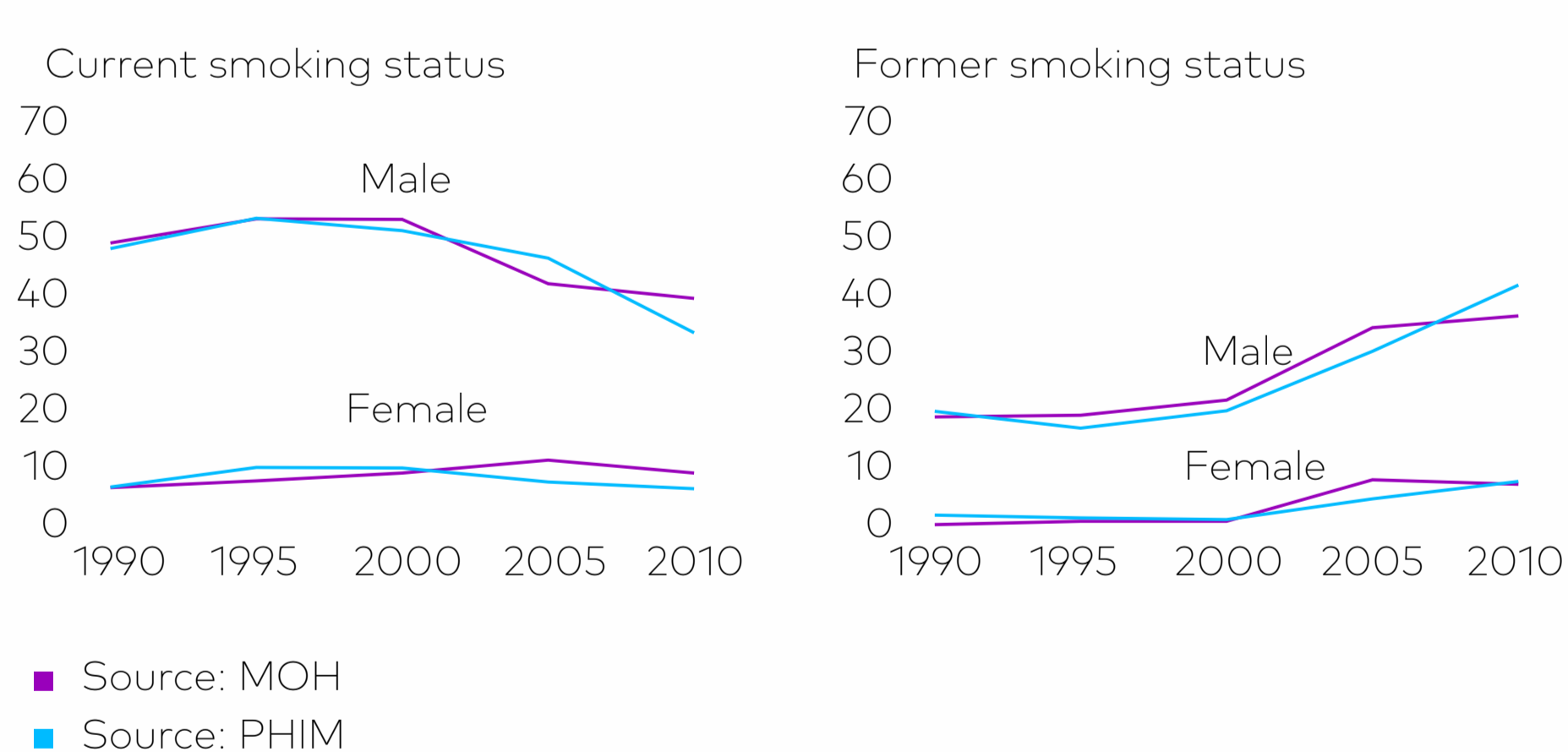
Prevalence component data obtained for Japan was used to develop a null scenario and to estimate smoking transition probabilities (STPs) based on MOH data for Japan. The STPs were developed per sex, for males and females due to large difference in smoking prevalence. Between 2000 and 2010 there was reduction in smoking prevalence largely attributed to the policies and regulations and the STPs developed have been additionally broken to two distinct periods: 1990–2000 and 2000–2010. The model was tested under the null scenario for Japan. The MOH estimates of smoking prevalence (current and former smokers) were compared with the PHIM simulation results.

### RRP scenarios

The introduction of IQOS and other heated tobacco products can have a significant positive impact on population harm reduction in Japan over the 20 year period and is estimated as a reduction between 63,534 and 83,495 smoking attributable deaths if the 55% of smoking population move away from cigarettes. For the individuals that switch the reduction in risk is between 70 and 90% depending on IQOS or other heated tobacco products effective dose (f value = 0.3 or 0.1).

The impact on Japan population as a whole is even larger when we consider the RPP uptake as a supplement to the on-going efforts to prevent initiation and increase cessation (the WHO Target). The estimated reduction in smoking attributable deaths in Japan is between 82,398 and 101,845 (f value = 0.3 or 0.1) for WHO 2025 Target with RRP business case and between 72,633 and 92,402 (f value = 0.3 or 0.1) for WHO 2025 Projection with RRP business case.

Smoking prevalence in 50-54 y/o age group. Comparison between Japan MOH data and PMI simulation



Cumulative Impact of THS Introduction on the Disease-Specific Mortalities 20 Years after the Introduction of RRP by Disease, Sex and f-value for all Ages Combined, all diseases (Lung cancer, COPD, Stroke, IHD) simulated for period 1990–2010

Scenario	Reduction in Cumulative Attributable Deaths
No further smoking (all stop smoking after 1 year)	261176
Smoking replaced by RRP (exclusive RRP use after 1 year)	217356 (f=0.1) 141667 (f=0.3)
WHO 2025 Target (smoking prevalence on decline, leading to 30% reduction by 2025)	32849
WHO 2025 Projection (smoking prevalence on decline, leading to 14% reduction by 2025)	13119
<b>RRP business case (RRP uptake of 55% with 85% being exclusive RRP use and 15% dual use after 10 years)</b>	<b>83495 (f=0.1)</b> <b>63534 (f=0.3)</b>
WHO 2025 Target + RRP Business case	101845 (f=0.1) 82398 (f=0.3)
WHO 2025 Projection + RRP Business case	92402 (f=0.1) 72633 (f=0.3)

## Conclusions

Modeling for Japan is important to understand the overall population harm reduction by monitoring the IQOS and other heated tobacco products uptake, through development and testing RRP scenarios outcomes.

The PHIM output was made consistent with MOH data for the same period by using two different sets of STPs broken by two periods 1990–2000 and 2000–2010 to account for a high quitting rates between 2000–2010 related to regulatory interventions on smoking in Japan.

With the RRP uptake similar to this we have a overall population harm decline and a positive impact on population health in Japan, estimated as a smoking attributable deaths reduction between 63,534 and 83,495 after 20 years for the RRP business case, depending on IQOS effective dose (f value = 0.3 or 0.1) in comparison to 99,953 fewer smoking attributable deaths with assumption that all of 55% of smokers would quit.

Overall, based on this and others RRP scenario outcomes described in here, introducing an RRP into the Japan market will lead to a net public health benefit in terms of reduced tobacco related mortality. This benefit will be larger if the rate of uptake for IQOS and other heated tobacco products in Japan is faster or the proportion of the smoking population that switches is larger.

PHIM is a tool appropriate to monitor and assess post market development in Japan and other countries of interest.

For the complete list of conclusions and references please see the leaflet.

\* The simulation is based on an age range extending beyond the legal age for smoking in order to capture real life initiation patterns

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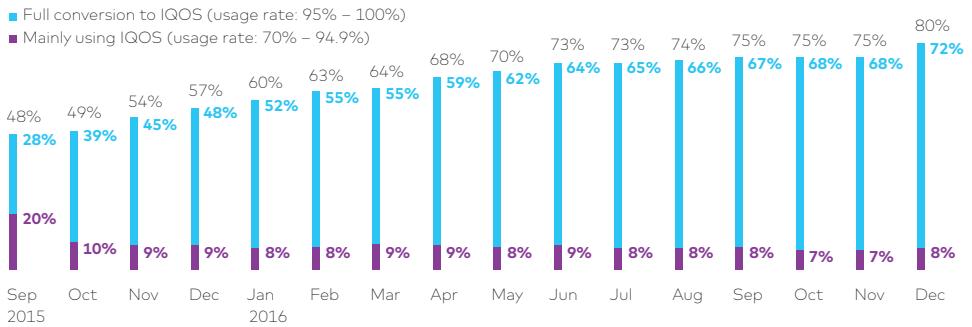
# Introduction

Philip Morris International has developed a Population Health Impact Model (PHIM) to estimate the reduction in smoking attributable mortality due to the marketing a Reduced Risk Products (RRPs). The PHIM has been developed for a number of countries, including Japan.

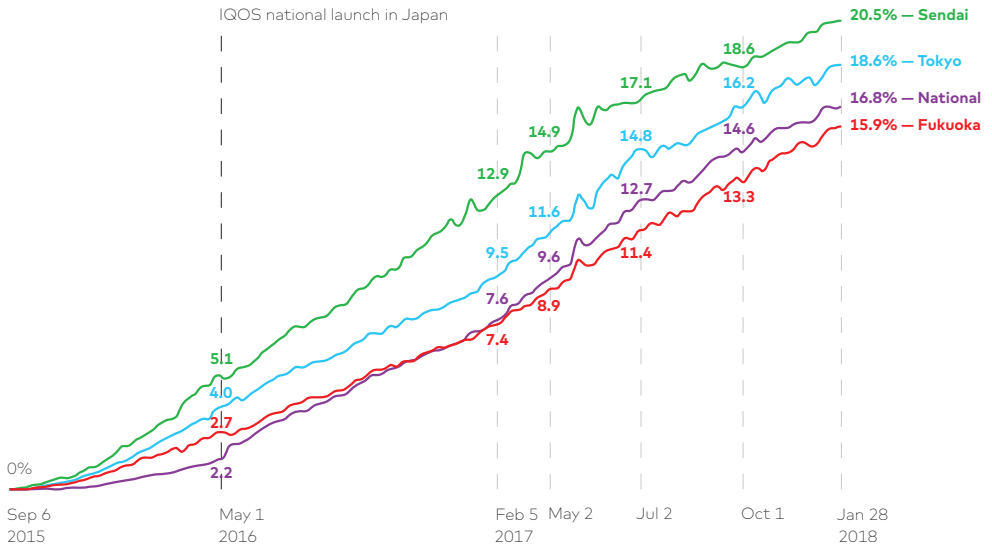
Japan is the lead market for IQOS. Since the national launch in 2015 a significant smoking population has switched to IQOS and other

heated tobacco products. The RRP uptake scenario with a 55% of the smoking population switching to heated tobacco products including IQOS after 10 years; 85% exclusively using heated tobacco products and IQOS and 15% dual use (heated tobacco products in combination with cigarettes) as the RRP Business case scenario. All simulations were counterfactual and run for the period 1990-2010.

## IQOS user conversion rate in Japan (among IQOS user panel)



## Weekly market share of IQOS in Japan (offtake base) as on January 28, 2018



# Methodology

The PHIM assesses the population-level health impact of marketing an RRP as a function of the toxicity of the product or the risk to the individual user, and the product use prevalence distribution at the population level [1-2]. The Prevalence and Epidemiological Risk components use Japan specific data collected for the model and used for hindcasting.

Prevalence Component data for Japan:

- ① Population data from United Nations (UN2)
- ② Smoking prevalence from the Japan Ministry of Health (MOH)
- ③ Quit time distribution were derived from the study- "JA-2009" conducted by marketing research company "Interwired"(n=1,985 former smokers) [3]

Epidemiological Risk Component data

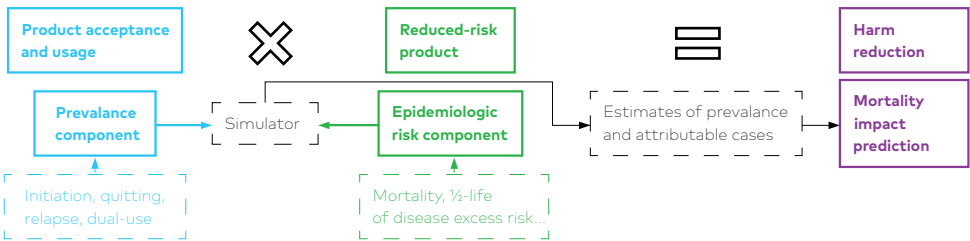
for Japan:

- ① Relative risk (RR) for lung cancer, COPD, IHD and stroke from published literature [3-10] in a period between 1990-2008.

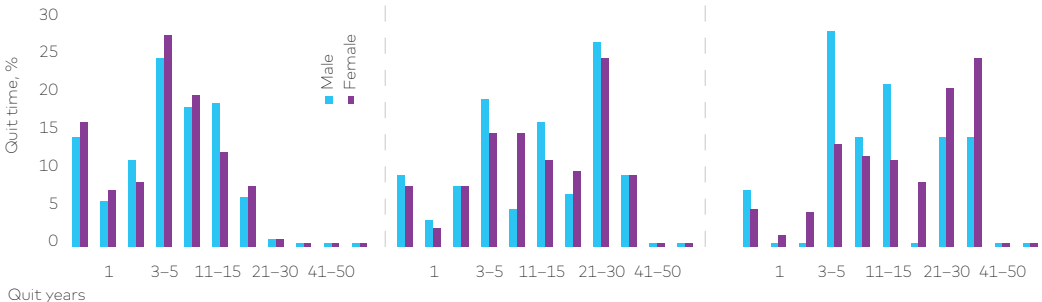
- ② Mortality rate of all 4 major smoking related diseases from Vital Statistics of Japan (VSJA).

For all Japan modeling applications, PHIM simulated samples of 10,000 hypothetical males and 10,000 hypothetical females aged between 10 and 79\*. In 1990 with a Japan representative distribution of smoking prevalence, and no use of IQOS or other heated tobacco products. Individual tobacco histories are then updated each year until 2010 based on two alternative sets of estimated smoking transition probabilities (STPs) of switching between tobacco groups for null (without RRP) and RRP scenario (with IQOS and heated tobacco products). All RRP scenarios were conducted with testing an IQOS effective dose range (f value = 0.3 or 0.1).

Difference in cumulative smoking attributable deaths between null and RRP scenario informed on overall population harm reduction in Japan.



Quit time distribution for males and females in Japan (results from «JA-2009» study) for 30-34 years old 50-54 years old 70-74 years old



\* The simulation is based on an age range extending beyond the legal age for smoking in order to capture real life initiation patterns.

# Results

## Null Scenario and Verification

Prevalence component data obtained for Japan was used to develop a null scenario (scenario without introducing RRP) and to estimate smoking transition probabilities (STPs) based on MOH data for Japan. The STPs were developed per sex, for males and females due to large difference in smoking prevalence. Between 2000 and 2010 there was reduction in smoking prevalence largely attributed to the policies and regulations and the STPs developed have been additionally broken to two distinct periods: 1990-2000 and 2000-2010.

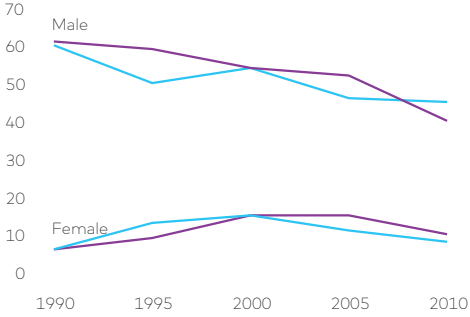
The model was tested under the null scenario for Japan. The MOH estimates of smoking prevalence (current and former smokers) were compared with the PHIM simulation results.

Smoking transition probabilities for these two distinct periods across all age groups (multiplied by million)

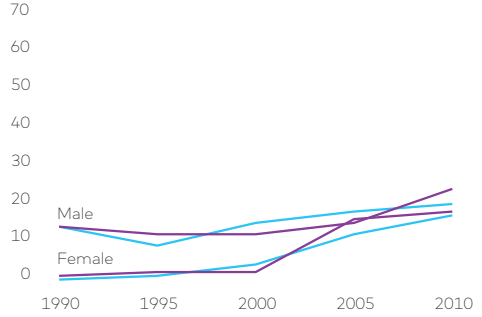
Age*	Males			Females		
	Initiation	Quitting	Reinitiation	Initiation	Quitting	Reinitiation
<b>1990–2000 Period: 1–120 month</b>						
10–14	4000	0	0	1500	0	0
15–19	11000	2000	960	2000	4000	1920
20–24	3500	2000	960	1000	2000	960
25–29	3500	2000	960	1000	2000	960
30–34	0	500	240	1000	1000	480
35–39	0	500	240	0	500	240
40–44	0	500	240	0	500	240
45–49	0	500	240	0	500	240
50–54	0	500	240	0	500	240
55–59	0	5000	2400	0	1000	480
60–64	0	5000	2400	0	1000	480
65–69	0	5000	2400	0	1000	480
70–74	0	5000	2400	0	1000	480
75–79	0	5000	2400	0	1000	480
<b>2000–2010 Period: 121–240 month</b>						
10–14	1000	0	0	250	0	0
15–19	9000	18000	8640	4000	16000	7680
20–24	1000	2500	1200	1000	16000	7680
25–29	1000	2500	1200	1000	16000	7680
30–34	0	2500	1200	1000	16000	7680
35–39	0	5000	2400	0	8000	3840
40–44	0	5000	2400	0	8000	3840
45–49	0	5000	2400	0	8000	3840
50–54	0	5000	2400	0	8000	3840
55–59	0	8000	3840	0	8000	3840
60–64	0	8000	3840	0	8000	3840
65–69	0	16000	7680	0	8000	3840
70–74	0	16000	7680	0	8000	3840
75–79	0	16000	7680	0	8000	3840

\* The simulation is based on an age range extending beyond the legal age for smoking in order to capture real life initiation patterns

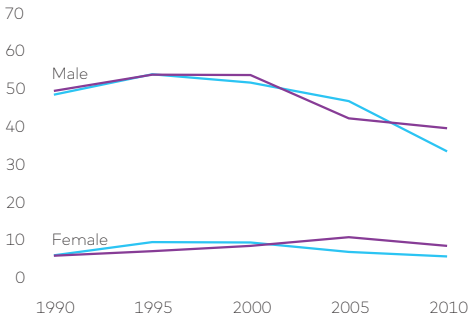
**Smoking prevalence for current smokers for 30–34 years old**



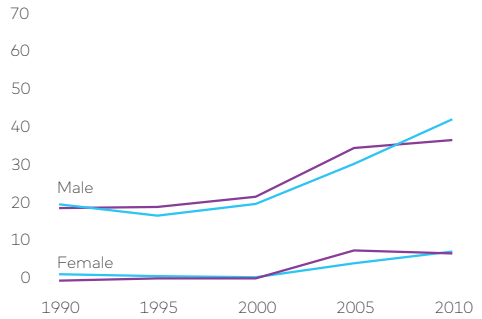
**Smoking prevalence for former smokers for 30–34 years old**



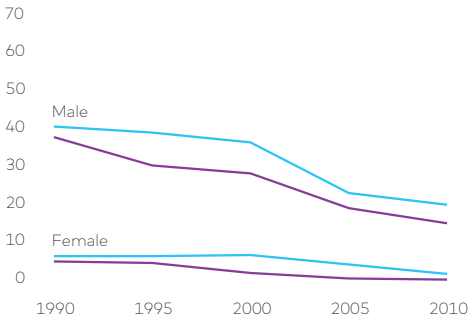
**50–54 years old**



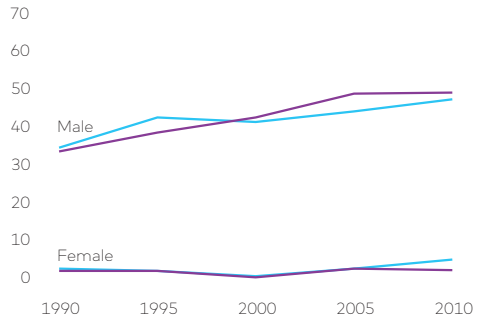
**50–54 years old**



**70–74 years old**



**70–74 years old**



■ Source: MOH  
■ Source: PHIM

# Results

## RRP Scenarios

The introduction of IQOS and other heated tobacco products can have a significant positive impact on population harm reduction in Japan over the 20 year period and is estimated as a reduction between 63,534 and 83,495 smoking attributable deaths if the 55% of smoking population move away from cigarettes. For the individuals that switch the reduction in risk is between 70 and 90% depending on IQOS or other heated tobacco products effective dose (f value = 0.3 or 0.1).

The impact on Japan population as a whole is even larger when we consider the RPP uptake as a supplement to the ongoing efforts to prevent initiation and increase cessation (the WHO Target). The estimated reduction in smoking attributable deaths in Japan is between 82,398 and 101,845 (f value = 0.3 or 0.1) for WHO 2025 Target with RRP business case and between 72,633 and 92,402 (f value = 0.3 or 0.1) for WHO 2025 Projection with RRP business case.

### Cumulative Impact of THS Introduction on the Disease-Specific Mortalities 20 Years after the Introduction of RRP by Disease, Sex and f-value for all Ages Combined, all diseases (Lung cancer, COPD, Stroke, IHD) simulated for period 1990–2010

Scenario	Cumulative Attributable Deaths (All combined)
Null scenario	700033
Scenario	Reduction in Cumulative Attributable Deaths
No further smoking (all stop smoking after 1 year)	261176
Smoking replaced by RRP (exclusive RRP use after 1 year)	217356 (f=0.1) 141667 (f=0.3)
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# Conclusions

- ① Japan is our lead market for IQOS and has a significant population of heated tobacco product users, including IQOS. Since IQOS national launch in Japan, sales volume of cigarettes gone down by 27% (reduction of 494 billion cigarettes in 2017- PMI source).
- ② Modeling for Japan is important to understand the overall population harm reduction by monitoring the IQOS and other heated tobacco products uptake, through development and testing RRP scenarios outcomes. Based on the recent post- market projections, the prevalence of IQOS has far exceeded the original estimates. The more realistic RRP business case scenario of 55% of smoking population switching to IQOS and other heated products was developed by updating some of the modeling assumptions to fit what we are actually seeing now when IQOS and other heated tobacco products are in the market.
- ③ Prior to modeling the impact of introducing IQOS in Japan, we conducted an extensive literature review to obtain Japan specific data on smoking prevalence, quit time distribution, relative risk of four main smoking related diseases and mortality at population level, by sex and across different age groups. The PHIM modeling was verified against the MOH data for the same (1990-2010). The PHIM output was made consistent with MOH data for the same period by using two different sets of STPs broken by two periods 1990-2000 and 2000-2010 to account for a high quitting rates between 2000-2010 related to regulatory interventions on smoking in Japan.
- ④ With the RRP uptake similar to this we have a overall population harm decline and a positive impact on population health in Japan, estimated as a smoking attributable deaths reduction between 63,534 and 83,495 after 20 years for the RRP business case, depending on IQOS effective dose (f value = 0.3 or 0.1) in comparison to 99,953 fewer smoking attributable deaths with assumption that all of 55% of smokers would quit.
- ⑤ Overall, based on this and others RRP scenario outcomes described in here, introducing an RRP into the Japan market will lead to a net public health benefit in terms of reduced tobacco related mortality. This benefit will be larger if the rate of uptake for IQOS and other heated tobacco products in Japan is faster or the proportion of the smoking population that switches is larger.
- ⑥ PHIM is a tool appropriate to monitor and assess post market development in Japan and other countries of interest.



## Our RRP

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 in various stages of development, scientific assessment and commercialization. Because our RRP do not burn tobacco, they produce an aerosol that contains far lower quantities of harmful and potentially harmful constituents than found in cigarette smoke.

## Competing financial interest

The research described in this brochure was sponsored by the Philip Morris International group of companies

## Global Forum on Nicotine

June 14–16, 2018  
Warsaw, Poland

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## References

- [1] Weitkunat R et al, A novel approach to assess the population health impact of introducing a Modified Risk Tobacco Product. *Regulatory Toxicology and Pharmacology* (2015).
- [2] Peter L et al, Estimating the effect of differing assumptions on the population health impact of introducing a Reduced Risk Tobacco Product in the USA, *Regulatory Toxicology and Pharmacology* (2017).
- [3] Online survey conducted by Interwired-DIMSDRIVE (from Nov 25th till Dec 10th 2009) in Japan; DIMSDRIVE Monitor with total of 9,638 people, n=1,985 former smokers
- [4] Hiroyasu I et al, Smoking cessation and mortality from Cardiovascular Disease among Japanese Men and Women, *American Journal of Epidemiology* (2005)
- [5] Ueshima et al, Cigarette Smoking as a risk factor for Stroke Death in Japan, *Stroke* (2004)
- [6] Mannami et al, Cigarette Smoking and risk of stroke and its subtypes among middle-aged Japanese Men and Women, *Stroke* (2004)
- [7] Aoki et al, Attributable and absolute risk of lung cancer death by smoking status: Findings from Japan Collaborative cohort study, *International Journal of Cancer* (2003)
- [8] Akiba et al, Cigarette smoking and Cancer mortality risk in Japanese Men and Women, *Environmental Health perspectives* (1990)
- [9] Sobue et al, Cigarette smoking and subsequent risk of lung cancer by histologic type in middle-aged Japanese men and women, *International Journal of Cancer* (2002)
- [10] Marugame et al, Lung cancer death rates by smoking status: Comparison of the Three- Prefecture cohort study in Japan to the Cancer Prevention study II in the USA, *Japanese Cancer association* (2005)