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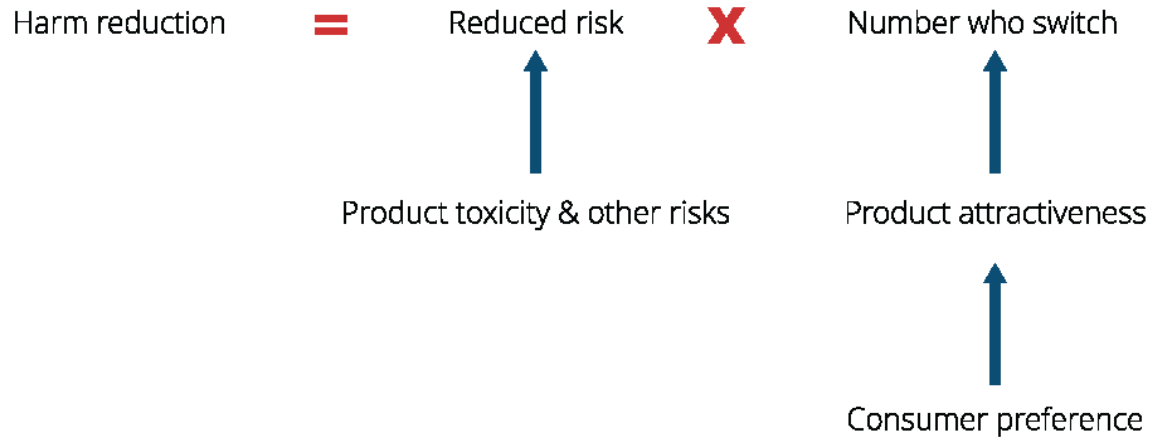
Grupo de Trabalho - Tabaco (PPL n.º 38/XIII/2.ª)

18 de janeiro de 2017

Tobacco Harm Reduction



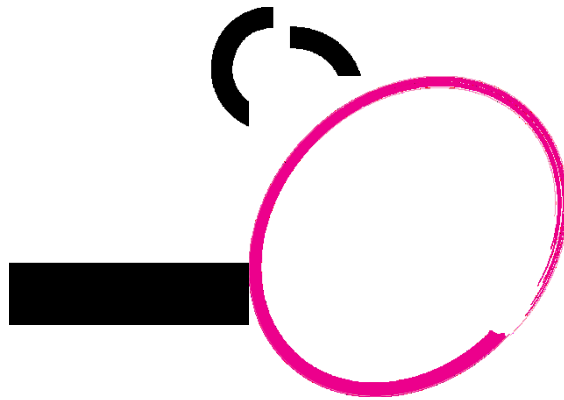
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- Smokii
- Worldwide it is estimated that by 2025 more than 1 billion people will still continue to smoke*
- Tobacco harm reduction encourages smokers to switch to less risky alternatives to combustible cigarettes

*NCI Tobacco Control Monograph Series 21 - The Economics of Tobacco and Tobacco Control", Authors: National Cancer Institute and WHO", January 2017.

About 100 HPHCs



- Cigarette smoke contains 7000+ constituents
- Many are recognized as harmful
- Most are formed by **burning** the tobacco
- Not known which are responsible for smoking-related disease

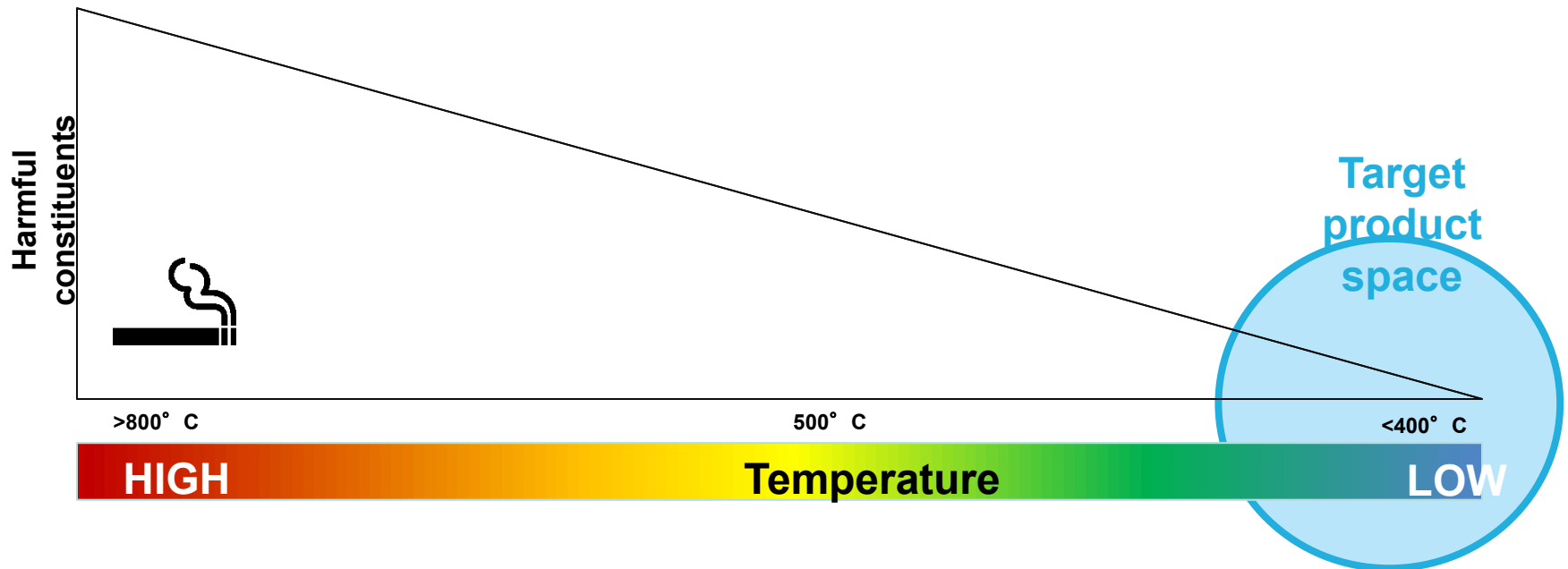
**selective reduction
not an effective approach**

Heating Instead of Burning Reduces Constituents



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- Reducing temperature reduces overall constituents
- Reducing overall constituents seen as a promising avenue to reduce risk (US Institute of Medicine)



Developing Scientific Evidence: An Overview of PMI's Approach



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Aerosol Chemistry

Reduced Formation of Harmful and Potentially Harmful constituents

Non-Clinical Studies

Reduced Toxicity and Risk in Laboratory Models

Clinical Studies

Reduced Exposure in Adult Smokers

Reduced Risk in Adult Smokers

Population Impact Assessment

Perception and Behavior Assessment in Adult Smokers and Non-Smokers

Population Impact Modeling

Post-Market Surveillance

Prevalence

Safety Surveillance

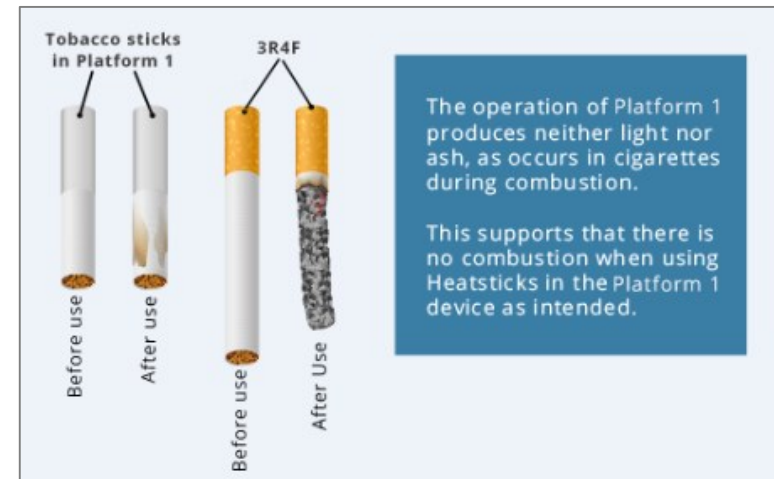
Lack of Combustion



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We have demonstrated that the operation of Platform 1 (*IQOS*) does not result in the combustion of tobacco

- Without combustion, there is no smoke
- Our studies demonstrating lack of smoke have been verified by a number of external scientific experts including in Italy, Poland, Japan and the US

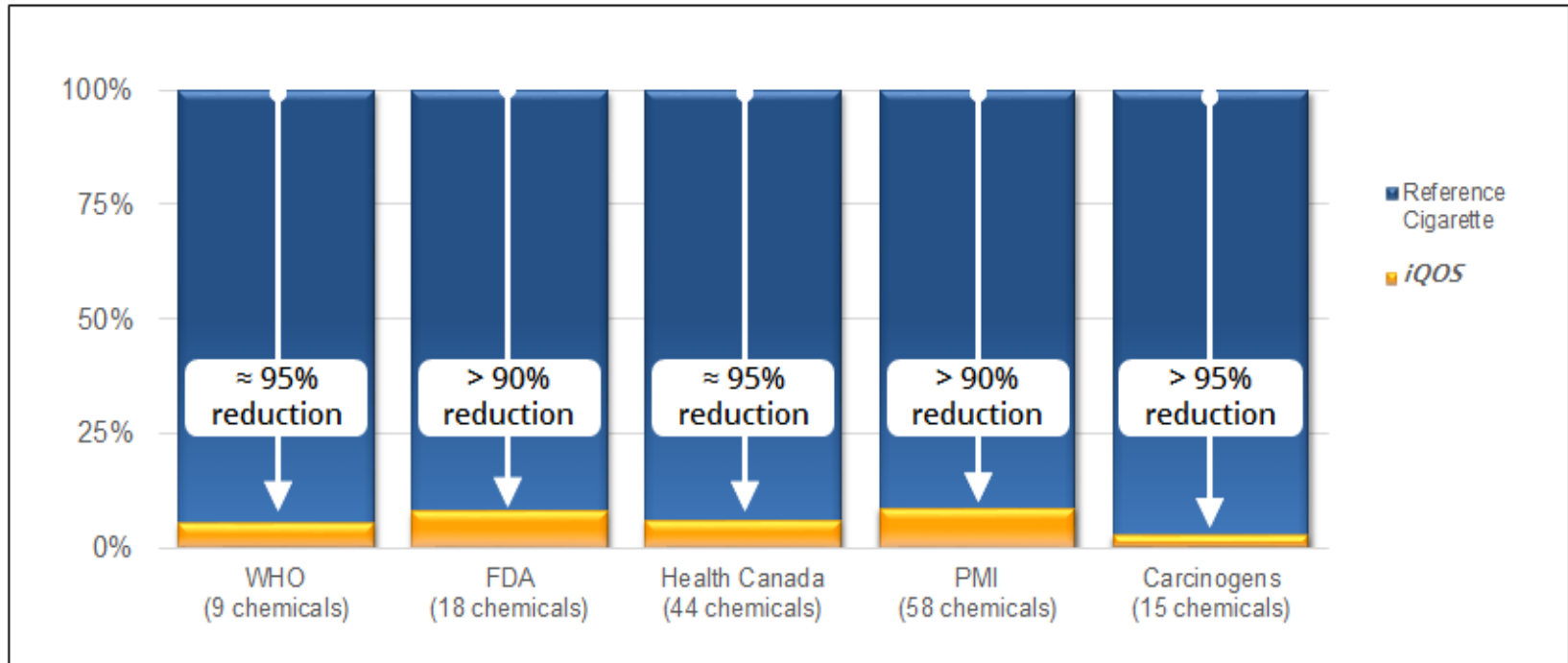


Reduced Formation



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Average reductions in formation of harmful or potentially harmful constituents for *iQOS* compared to levels measured in smoke from the 3R4F reference cigarette*

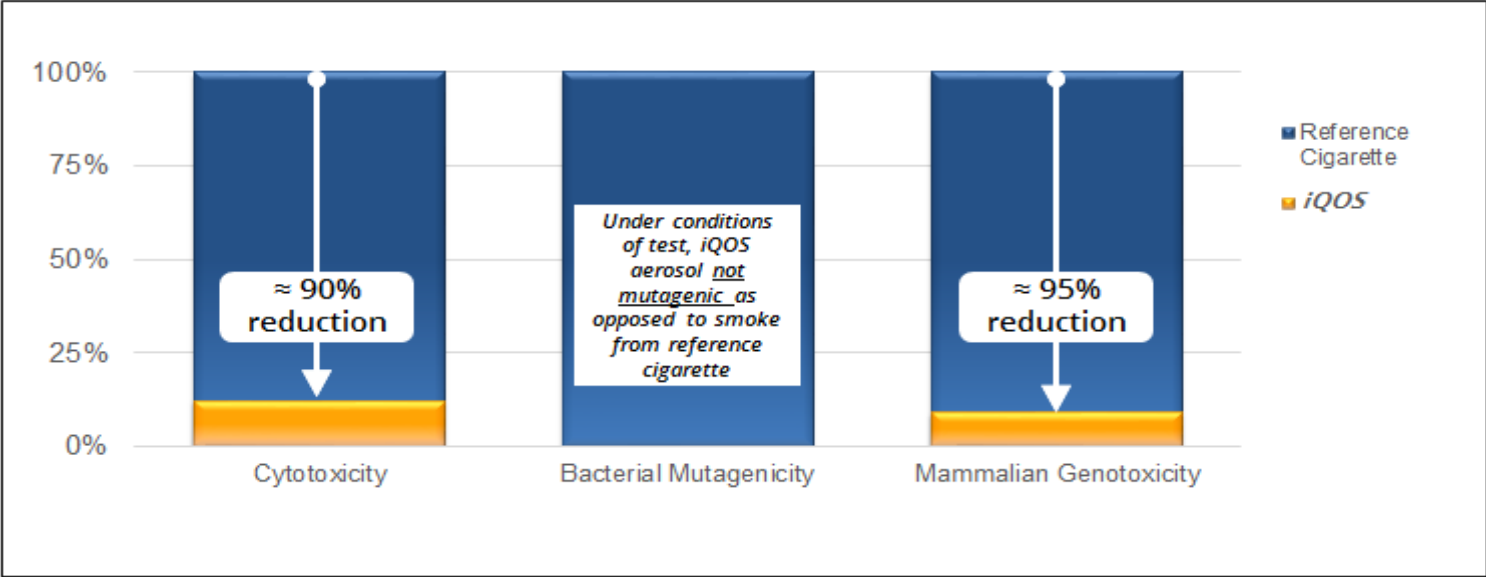


*Aerosol collection with Intense Health Canada's Smoking Regime (55 mL puff volume, 2 second puff duration, 30 second interval puff); Comparison on a per-stick basis
Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter
Note: These data alone do not represent a claim of reduced exposure or reduced risk.

Reduced Toxicity



Average reductions in toxicity compared to levels measured for the 3R4F reference cigarette. Measured using Neutral Red Uptake, AMES and Mouse Lymphoma Assays



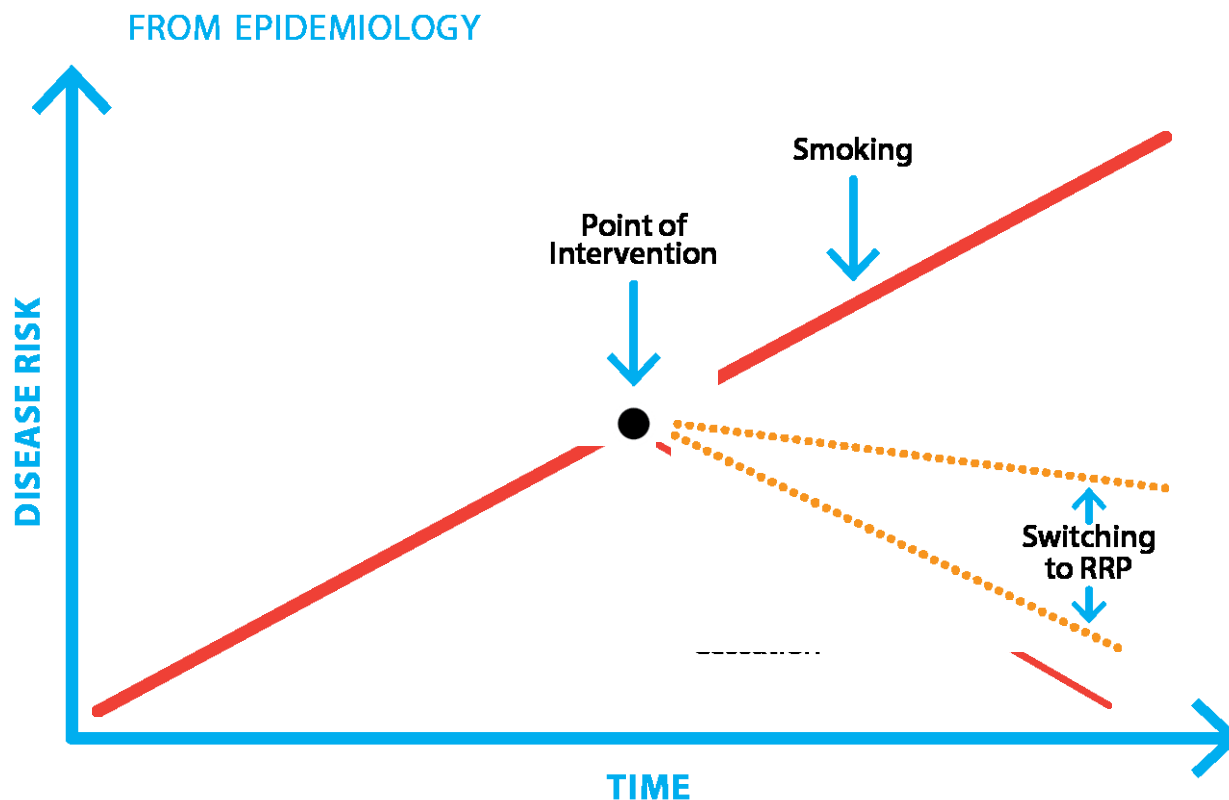
Comparison on a per-nicotine basis
Note: These data alone do not represent a claim of reduced exposure or reduced risk.

Substantiating Reduced Risk



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We apply the US Institute of Medicine’s “gold standard” for assessing risk reduction: comparability to cessation



Note: Reduced-Risk Products (RRPs) is the term we use to refer to products that have the potential to reduce individual risk and population harm

The descriptions in the chart are for illustrative purposes only

Source: IOM (Institute of Medicine), 2012, Scientific Standards for Studies on Modified Risk Tobacco Products. Washington, DC: The National Academies Press

Reduced Exposure - 3 months



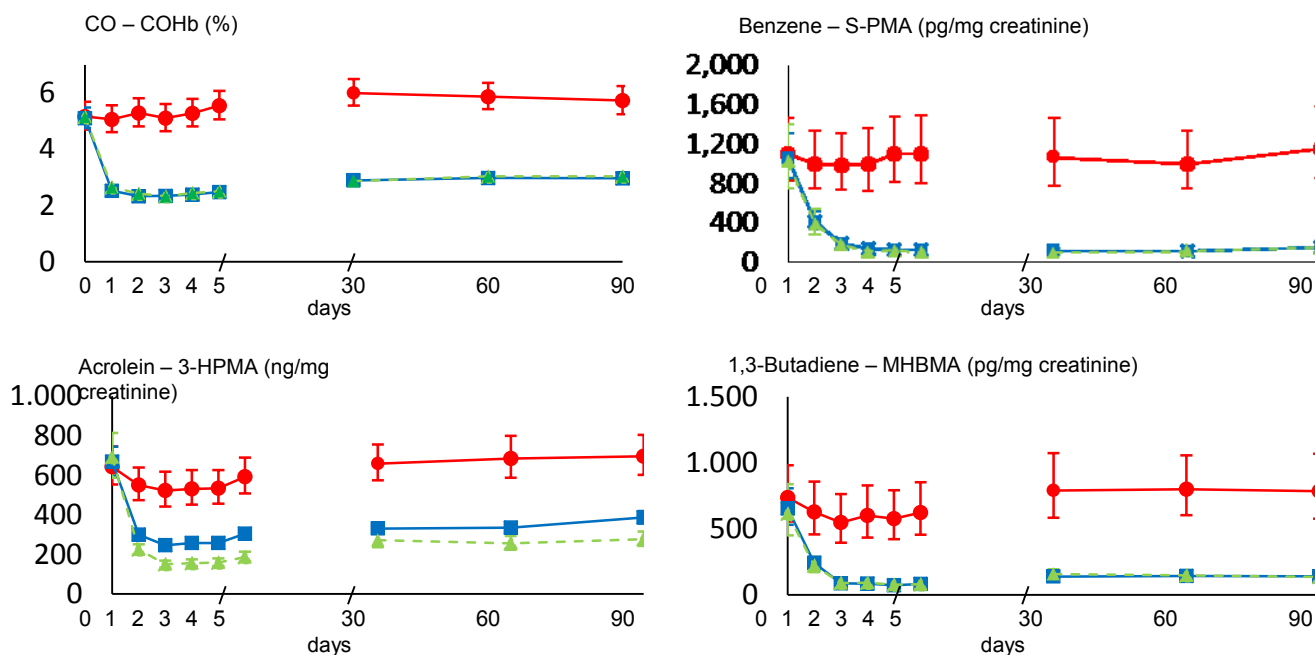
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Smokers used the products *ad libitum*
Smokers

Adult smokers in cigarette or IQOS arms free to use as often as wished, in the clinic (5 days) then ambulatory (85 days)



■ Continued smoking ■ Quit during study ■ Switched to Platform 1



These data alone do not represent the full study. Source: PMI Research & Development

Levels of reduced exposure approached those observed in people who stopped smoking for the duration of the studies

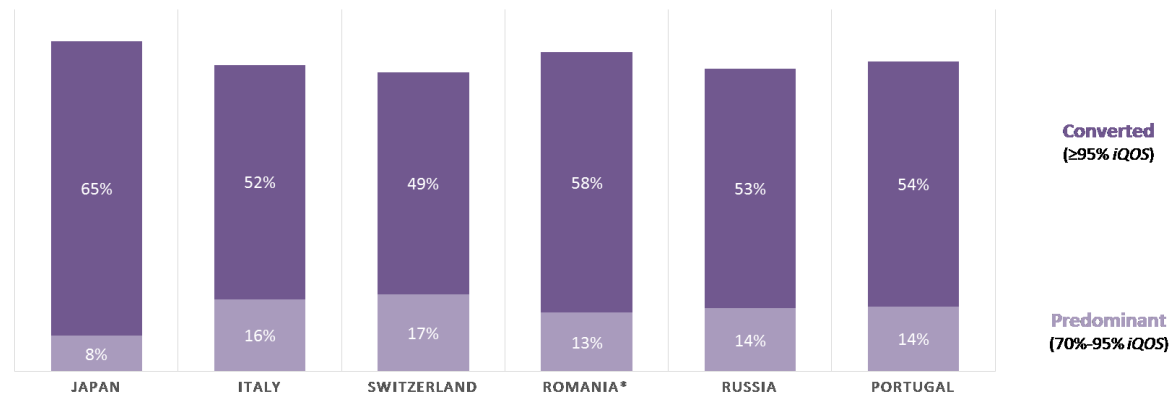
Encouraging smokers to switch



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Our stated ambition is to **convince all current adult smokers who intend to continue smoking to fully switch** to non-combustible products as soon as possible to improve public health

Converted and Predominant User Share (July 2016)



* For Romania, data relates to August User Panel

Combined full and predominant conversion levels of circa 70% in Portugal (December 2016)

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Philip Morris International (PMI) Announces Filing of Application for Its Electronically Heated Tobacco Product with the US Food and Drug Administration (FDA)

LAUSANNE, Switzerland--(BUSINESS WIRE)--Dec. 6, 2016-- Philip Morris International Inc. ("PMI") (NYSE / Euronext Paris: PM) on Dec. 5 submitted a Modified Risk Tobacco Product (MRTP) application for its electronically heated tobacco product with the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products. This is consistent with the company's stated goal of submitting its MRTP application in 2016. PMI anticipates the FDA taking a minimum of 60 days to complete an administrative review to determine whether to accept the application for substantive review.

Study conducted with analytical methods and facilities that are accredited under ISO17025 simulating real life situations in a controlled environment

Category
ISO Environmental Tobacco Smoke Markers 6 substances
Carbonyls 4 substances
Volatile Organic Compounds 5 substances
Inorganics 3 substances
Total of 18 substances measured



We have demonstrated that the operation of *iQOS* indoors **does not have a negative impact on air quality**

- *iQOS* is not a source of Environmental Tobacco Smoke
- Levels of 16 substances are the same as background measurements
- Nicotine is detectable ($1.8 \mu\text{g}/\text{m}^3$) → but at levels **275 fold lower** than EU occupational exposure limits¹
- Acetaldehyde is detectable ($5 \mu\text{g}/\text{m}^3$) → but at levels **40 fold lower** than EU indoor exposure limits²



¹ European Agency for Safety and Health at Work: Directive 2006/15/EC

² The Index Project, Critical Appraisal of the Setting and Implementation of Indoor Exposure Limits in the EU, EC, Joint Research Center, Institute for Health and Consumer Protection, January 2005

Note: These data alone do not represent a claim of reduced exposure or reduced risk.



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Thank you!

<https://www.pmiscience.com/pt>

<http://iqossience.com/pt-pt>