OVERVIEW OF INDEPENDENT RESEARCH ON IQOS

Over the last few years, numerous independent studies have already confirmed different elements of our research on IQOS.

STUDIES ON IQOS CONDUCTED BY GOVERNMENT BODIES

Many government bodies have conducted literature reviews or performed research on heated tobacco products, finding that they expose users to significantly lower levels of harmful chemicals.

➢ On July 7, 2020, the U.S. Food and Drug Administration (FDA) issued decisions on Modified Risk Tobacco Product (MRTP) applications for IQOS and three HeatSticks variants ("the IQOS tobacco heating system") submitted by Philip Morris International (PMI) in December 2016. In doing so, the agency found that the issuance of the modified risk tobacco product orders with reduced exposure claims would be “appropriate to promote the public health and is expected to benefit the health of the population as a whole.” This decision follows a review of the extensive scientific evidence package PMI submitted to the FDA in December 2016 to support its MRTP applications.

➢ On May 12, 2020 The Dutch National Institute for Public Health and the Environment (RIVM) published the findings of its research on "A Method for Comparing the Impact on Carcinogenicity of Tobacco Products: A Case Study on Heated Tobacco Versus Cigarettes." RIVM research is new and is not a review of PMI’s findings. RIVM developed a method to estimate risk—or assess the potential magnitude of the health impact—between tobacco products. In their publication they assessed eight carcinogens to understand the likely health impact on individuals who switch to IQOS, compared to those who continue smoking. In their conclusions they state that—while IQOS is not risk-free—it is associated with 10 to 25 times lower exposure to these carcinogens, and that this could translate into a substantially improved risk profile.

➢ In April 2020, the Superior Health Council of Belgium ("SHC") published results of its inquiry into heat-not-burn products. The SHC concluded that heat-not-burn products, while not safe, have a more favorable toxicity profile than cigarettes. However, in light of the uncertainty of such products’ short and long-term impacts, the toxic effects of the dual use with cigarettes, and the existence of approved smoking cessation tools, the SHC recommended that current regulations for cigarettes should apply to heat-not-burn products.

➢ Public Health England (PHE) published a review of the evidence on e-cigarettes and heated tobacco products, and stated that heated tobacco products likely reduce users’ and bystanders’ exposure to harmful compounds compared to cigarettes. PHE also stated that the available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes.

➢ The U.S. Food and Drug Administration (FDA), in a briefing document, reviewed PMI’s data supporting IQOS and the available independent literature about IQOS. The briefing document included a section explaining the results of the FDA’s IQOS aerosol chemistry measurements.
On April 30, 2019, following a comprehensive assessment of PMI’s premarket tobacco product applications, the U.S. FDA confirmed that IQOS is appropriate for the protection of public health and has authorized it for sale in the United States. “Appropriate for the protection of public health” means that looking at population as a whole, new products cannot pose the same or greater harm to public health as smoking (i.e., they must pose less harm than combustible cigarettes). The FDA published a detailed report describing their assessment and their conclusions including results on aerosol chemistry, toxicology and unintended use.

The U.K. Committee of Toxicity conducted a review of available evidence on two heated tobacco products, one of which is IQOS, and concluded that there is a “likely reduction in risk for smokers switching to heat-not-burn tobacco products.”

The Dutch National Institute for Public Health and the Environment (RIVM) published a fact sheet on novel tobacco products that are heated and an English-language summary. They concluded that "The use of Heatsticks with the IQOS is harmful to health, but probably less harmful than smoking tobacco cigarettes," based on their aerosol chemistry measurements, which are "of the same order of magnitude as in the data of Philip Morris."

The German Federal Institute for Risk Assessment (BfR), published laboratory studies in Archives of Toxicology, finding that reductions in selected toxicants measured by the institute “are likely to reduce toxicant exposure.”

Two government-commissioned studies were conducted by independent scientists in Russia, confirming that IQOS aerosol contains an average of 90 percent reduced levels of harmful chemicals compared to cigarette smoke, and that IQOS has a minimal effect on biological processes in people compared to smoking. This report is not published yet, though the researchers have made some public statements. (Rossiyskaya Gazeta)

OTHER STUDIES ON IQOS
To date, around 43 studies from independent laboratories have results that are in line with our findings on IQOS. Listed below is a selection of those publications:

- Researchers working for the American Cancer Society (Michal Stoklosa et al., 2019) confirms that the introduction of IQOS is the only likely cause of cigarette sales decline in Japan. A backgrounder, key messages and Q&A can be found here.

- Research by Japanese Department of Environmental Health, National Institute of Public Health, compared selected chemicals in the aerosol generated by IQOS and in smoke from reference cigarettes. The research shows significant reductions in the levels of several chemicals, in line with those found by PMI’s research. (Bekki et al, 2017)
The China National Tobacco Quality Supervision and Test Centre, a member of the WHO Tobacco Laboratory Network, published an independent study comparing the harmful chemicals present in IQOS aerosol and cigarette smoke, which generally agree with PMI’s results. (Li et al, 2018)

One of Ukraine’s leading research institutes conducted a six-month clinical study on IQOS, which was published in prominent national medical periodical Ukrainian Health, showing no significant adverse effect on users of smoke-free products. (Kvasha et al, 2018)

Research by cardiologist and leading e-cigarette researcher Dr. K. Farsalinos on IQOS was published in the journal Addiction, showing that IQOS emits lower levels of carbonyls than a commercial cigarette, but higher levels than an e-cigarette. (Farsalinos et al, 2018)

Researchers at the University of St. Andrews, Scotland calculated that IQOS aerosol has “lower cancer potencies than tobacco smoke by at least one order of magnitude, but higher potencies than ecigarettes.” (Stephens et al, 2018)

The first independent study investigating eCO levels after use of two recently marketed HTPs was conducted by Pasquale Caponnetto, Marilena Maglia, Gaetano Prosperini, Barbara Busà and Riccardo Polosa and was published in Respiratory Research. The aim of this randomized cross-over study was to measure the exposure levels of the combustion marker, carbon monoxide in the exhaled breath (eCO) of subjects after use of two HTPs and to compare these levels with participants’ own brand of cigarettes. The study found no eCO elevations during inhalational testing with HTPs under investigation in any of the study participants.