



PHILIP MORRIS SERVICES S.A.

8 April 2019

Mavis Lee Yang Boll
Head of Regional Scientific Engagement for Asia Pacific
Philip Morris Services SA

Telephone: +852 2825 1310
Email: Yin.Boll@pmi.com

Hon. KWOK Wai-keung, JP,
Chairman of the LEGCO Bills Committee
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Chairman Kwok,

Submission to the Hong Kong Legislative Council Bills Committee on the Bill to amend the Smoking (Public Health) Ordinance

The goal of Philip Morris International (PMI) is to switch every adult smoker who would otherwise continue to smoke combustible cigarettes to smoke-free products. Smoke-free products are not risk-free and they are not an alternative to quitting. The best choice for anyone who smokes is to quit using tobacco or nicotine products altogether. However, for smokers who don't quit, smoke-free products are a much better choice than continuing to smoke cigarettes.

Research & Development

Our company is committed to play an integral role in the transformation of the tobacco industry. This has been made possible by innovations as well as our investment in research and development (R&D), technology, and manufacturing capacity which exceeds 6 billion USD since 2008. This transformation journey has brought us to building, developing and establishing new infrastructures, systems and resources, including our R&D center in Neuchatel Switzerland, home to over 430 scientists and engineers (established in 2008); in addition our R&D center in Singapore is the home to over 85 scientific and technical personnel (established in 2009); and since June 2018, we have been fostering engineering and supply chain expertise at our **Hong Kong electronics-hub** which quickly expanded and now employs over 70 experts from electronics, engineering and technical background, the majority of which are from Hong Kong.

The Science behind our Tobacco Heating System (THS)

Our Tobacco Heating System (THS), often referred to as a heat not burn (HNB) product, is backed by scientific evidence generated from a highly comprehensive and robust scientific assessment program. PMI is committed to openly and transparently share our research methodologies, results and data. The purpose of this submission is to highlight some of the key scientific results on THS.

When we began our journey into harm reduction arena over 25 years ago, the primary question was: Where does the harm from smoking come from?

The harms caused by smoking primarily come from burning the tobacco and experts agree that nicotine, while addictive and not risk-free, is not the primary cause of smoking-related diseases. The primary cause of smoking-related diseases is the high levels of harmful constituents found in cigarette smoke, the majority of which are emitted when the tobacco is burned (i.e., combusted). By reducing the

temperature of the tobacco from about 800°C during a puff on a cigarette, down to less than 350°C – a temperature well below the temperature required for combustion to occur - we can significantly reduce the number and levels of harmful and potentially harmful constituents (HPHCs) generated and inhaled. It is critically important as these HPHCs are associated with smoking-related diseases .

Our studies demonstrate that no combustion occurs when the THS is used, resulting in a reduction in the levels of HPHCs in the THS aerosol of, on average, about 95% compared to cigarette smoke.

Furthermore, our studies have also shown, that THS aerosol is not smoke. The chemical composition of smoke is very different from the composition of the THS aerosol. For example, smoke contains liquid and solid particles whereas the THS aerosol does not contain any solid particles.

Because, there is no combustion and no smoke is generated with THS, there is also no second hand smoke, no environmental tobacco smoke and no negative impact on indoor air quality considering international standards for indoor air quality and when regulatory norms of ventilation are respected.

The totality of evidence available on THS to-date, comprised of 18 non-clinical and 10 clinical studies on THS, demonstrates that:

1. THS generates no combustion and no smoke.
 - [scientific substantiation of absence of combustion and no smoke formation in ehtp.pdf](#)
 - [scientific substantiation of absence of ETS emission during use of ehts](#)
2. The aerosol contains on average 95% lower levels of toxicants than cigarette smoke.
3. Laboratory studies confirm that these lower levels of toxicants result in the aerosol being significantly less toxic than cigarette smoke.

Schaller, J. P., Keller, D., Poget, L., Pratte, P., Kaelin, E., McHugh, D., & Yerly, M. (2016). Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol. Regulatory Toxicology and Pharmacology, 81, S27-S47. <https://www.sciencedirect.com/science/article/pii/S0273230016302902>
4. Clinical studies show that smokers who completely switch to THS for the duration of the study have a significantly reduced exposure to the harmful compounds, approaching the reductions observed in smokers who abstain from smoking for the duration of the study.
5. Our most recent clinical study, assessing the biological response of smokers who switched to THS for 6 months compared with continued smoking, successfully met its primary objective. The study showed that all eight measures of biological response changed in the same direction observed following smoking cessation, with statistical significance achieved in five of the eight clinically relevant markers. These results show that switching to THS as it is actually used is likely to reduce the risk of smoking-related disease.
 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5896533/>
 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5896432/>
6. Our animal models of disease show that cessation or switching to THS aerosol after cigarette smoke exposure halted progression of atherosclerotic plaque growth compared to continued smoking. Furthermore these studies showed that exposure to cigarette smoke, but not THS aerosol exposure,

led to increased lung inflammation, emphysematous changes, lung function loss and increased lung tumor incidence and multiplicity.

Phillips, B., et al. (2015). "An 8-month systems toxicology inhalation/cessation study in Apoe^{-/-} mice to investigate cardiovascular and respiratory exposure effects of a candidate modified risk tobacco product, THS 2.2, compared with conventional cigarettes." Toxicological Sciences 149(2): 411-432. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4725610/pdf/kfv243.pdf>

Results of an 18-month combined chronic toxicity and carcinogenicity study in A/J mice – implications for the lung disease risk reduction potential of THS. Addendum 2 to Section 2.7 of PMI's Modified Risk Tobacco Application to the US Food and Drug Administration. Available at <https://digitalmedia.hhs.gov/tobacco/static/mrtpa/PMP/August%2030%2C%202018.zip>

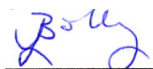
In summary, the totality of the evidence available to date on THS , comprised of 18 non-clinical studies on aerosol chemistry assessments, standard toxicology assessments, studies using animal models of disease combined with systems toxicology approaches, 10 clinical trials, 9 perception and behavioral studies (including approximately 11,000 subjects in USA), as well as a comprehensive post-marketing assessment program, shows that THS is likely to reduce the risks of smoking-related diseases and that switching completely to THS presents less risk of harm than continued smoking.

We hope that the information in this submission has been sufficient in allowing the Committee to better understand the science behind our THS and its role in the harm reduction equation for current adult smokers.

We believe, that if Hong Kong can maximize the number of smokers who stop smoking and switch those who continue to smoke to smoke-free products while at the same time minimizing access to the unintended audiences through science-based regulation and responsible marketing, to which PMI is committed, smoke-free products such as the THS, would have the potential to significantly impact the health of the population.

Thank you once again for the opportunity and please let me know if there are any follow-up questions you would like to address.

Yours sincerely,



Mavis Lee Yang Boll
Head of Regional Scientific Engagement for Asia Pacific
Philip Morris Asia Limited