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10 HAMMERSMITH GROVE · LONDON ·W6 7AP, TEL: +44 (0) 20 8222 0700 FAX: +44(0) 20 8222 0994

Rt Hon Victoria Atkins MP
Secretary of State for Health and Social Care of the United Kingdom
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU
United Kingdom

19 April 2024

Dear Secretary of State

I am writing to you regarding a social media post from your department (@DHSCgovuk) on Monday 15 April 2024 which makes false and misleading statements about heated tobacco products (HTPs). More details are explained below but in short, HTPs are not intended to be, nor marketed as, smoking cessation aids and the statements made in the social media post distort the scientific evidence base including the Government's own evidential reviews, all of which seriously misleads the public, adults who smoke and those voting on the Bill.

Philip Morris International is leading the development of heated tobacco products and has 91%[1] of global HTP market share. We are committed to responsibly marketing and communicating about these products and that includes ensuring adults have accurate information about them so they can make informed decisions about better alternatives to smoking. We also monitor for false or misleading claims about them as well as our other smoke-free products.

For context, our data show that HTPs have helped 20.8[2] million smokers worldwide leave cigarettes behind and abandon cigarettes altogether. Misleading claims coming from a Government department risk driving some of those consumers back to cigarettes and dissuading current adult smokers from making this switch if they do not quit.

The post in question was part of a content series addressing what it alleged were 'myths' relating to the Tobacco and Vapes Bill. The second post in the series incorrectly stated the following:

> *All forms of tobacco are harmful, and there is no evidence that heated tobacco products are effective for helping people to quit smoking.*

It was accompanied by a graphic, with the following text:

> *Myth – Heated tobacco is safe and effective as a smoking cessation tool.*
>
> *Evidence – Laboratory studies show clear evidence of toxicity from heated tobacco products. Unlike vapes, there is no evidence they are effective for helping people to quit smoking. [Source: Committee on Toxicity, 2017]*

[1] PMI Annual Report 2023
[2] PMI Fourth Quarter Results 2023

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Some facts on IQOS (PMI's leading HTP product):

- **It emits, on average 90-95% lower levels of toxicants** compared to the smoke from a reference cigarette. [3] [4] The lower levels of toxicants result in the *IQOS* **aerosol being significantly less toxic than cigarette smoke**. [5] [6] [7] [8] [9] [10] [11]
- Clinical studies support the risk reduction potential of *IQOS*, with **smokers who switch to it reducing their exposure to toxicants almost as much as those who abstain from smoking**.[12] [13] [14] Our 6-month Exposure Response Study showed improvements in the biological and functional response in smokers who switched to *IQOS* compared to those who continued smoking.[15]

Our message to adult smokers is very clear: HTPs are not risk free, they are a better alternative to smoking cigarettes. This is explicit within our communications to adult smokers. We have never claimed HTPs are 'safe', nor have we claimed a total absence of 'toxicity'. Again, we are clear with adult smokers that HTPs offer a reduction in risk versus smoking cigarettes, and we trust adult smokers to make the choices that are right for them. Although it's true that "*all forms of tobacco are harmful*" it's not true and is misleading to imply that all forms of tobacco are equally harmful. It's important that smokers understand the differences in risk.

There is no doubt that quitting is the best choice for health. HTPs are not cessation devices, nor have we ever claimed such – they are a better alternative for adults compared to continuing to smoke. As you are no doubt aware, all smoking cessation aids in the UK require licensing and we have never

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[3] PMI uses standardized and internally validated methods to analyze more than 50 mainstream aerosol constituents identified by regulators and public health authorities as causes or contributors to smoking-related disease, including respiratory irritants and pulmonary or systemic toxicants. See, e.g., ISO, Routine analytical cigarette-smoking machine – definitions and standard conditions, ISO 3308 (2011); Health Canada 2000. PMI also measures smoke constituents according to analytical methods that we have validated internally according to the guidelines of the International Conference on Harmonization that address investigations of accuracy, precision, quantification and detection limits. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline: Validation of Analytical Procedures: Methodology Q2B (1996).

[4] JP Schaller, et al., Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol. Regul Toxicol Pharmacol 81 Suppl2: S27-S47 (2016), available at https://doi.org/10.1016/j.yrtph.2016.10.001

[5] PMI's non-clinical studies are planned, performed, monitored, recorded, reported and archived following Good Laboratory Practices (GLP) (OECD, 1998).

[6] JP Schaller, et al., Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol. Regul Toxicol Pharmacol 81 Suppl2: S27-S47 (2016), available at https://doi.org/10.1016/j.yrtph.2016.10.001

[7] JP Schaller, et al., Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol. Regul Toxicol Pharmacol 81 Suppl2: S27-S47 (2016), available at https://doi.org/10.1016/j.yrtph.2016.10.001

[8] DJ Smart, et al., Mode of action analysis of the effects induced by nicotine in the in vitro micronucleus assay. Environ. Mol. Mutagen. 60(9), 778-791 (2019), available at https://doi.org/10.1002/em.22314

[9] ET Wong, et al., Evaluation of THS 2.2 Part 4: 90-day OECD 413 rat inhalation study with systems toxicology endpoints demonstrates reduced exposure effects compared with cigarette smoke. Regul. Toxicol. Pharmacol. 81. Supple 2, S59-S81 (2016), available at https://doi.org/10.1016/j.yrtph.2016.10.015

[10] B Phillips, et al., 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. Toxicol Sci 149(2): 411-432 (2016), available at https://doi.org/10.1093/toxsci/kfv243

[11] ET Wong, et al., Reduced chronic toxicity and carcinogenicity in A/J mice in response to life-time exposure to aerosol from a heated tobacco product compared with cigarette smoke, Toxicol Sci 178(1): 44-70 (2020), available at https://doi.org/10.1093/toxsci/kfaa131
B Titz, et al., Respiratory effects of exposure to aerosol from the candidate modified-risk tobacco product THS 2.2 in an 18-month systems toxicology study with A/J mice, Toxicol Sci 178(1): 138-158 (2020), available at https://www.academia.edu/69740483/Respiratory_effects_of_exposure_to_aerosol_from_the_candidate_modified_risk_tobacco_product_THS_2_2_in_an_18_month_systems_toxicology_study_ with_A_J_mice

[12] Biomarkers of exposure to selected HPHCs were selected based on criteria that included HPHCs linked to known disease risk, measurable outcomes, and guidance from the FDA and WHO. Biomarkers of exposure were measured in blood and urine and collected once daily for the first 5 days and at day 30, 60 and 90 during the ambulatory period.

[13] ClinicalTrials.gov ID: NCT01959932. Brief title: Reduced exposure study in smokers using Tobacco Heating System 2.2 (THS 2.2) with 5 days in a confinement setting (EU); ClinicalTrials.gov ID: NCT01970982. Brief title: Reduced Exposure Study in Smokers Using the Tobacco Heating System 2.2 (THS 2.2) for 5 Days in a Confinement Setting (Japan); ClinicalTrials.gov ID: NCT01970995. Reduced Exposure Study Using the Tobacco Heating System 2.2 (THS 2.2) Menthol for 90 Days in Confinement and Ambulatory (Japan); ClinicalTrials.gov ID: NCT01989156. Reduced exposure study using THS 2.2 Menthol with 5 days in a confinement setting followed by 86 days in an ambulatory setting (US).

[14] F Lüdicke et al., Effects of switching to the Tobacco Heating System 2.2 menthol, smoking abstinence, or continued cigarette smoking on biomarkers of exposure: a randomized, controlled, open-label, multicenter study in sequential confinement and ambulatory settings (Part 1). Nicotine Tob Res 20(2): 161-172 (2018), available at https://doi.org/10.1093%2Fntr%2Fntx028

[15] Biomarkers of harm were chosen based on known epidemiologic link to smoking-related disease, biomarkers that are affected by smoking status and are reversible upon smoking cessation. These included biomarkers linked to lipid metabolism, blood clotting, endothelial function, oxygen delivery, inflammation, oxidative stress, lung function and genotoxicity.

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sought such a license. The same is also true of the vast majority of e-cigarettes on the market which are neither licensed as medicines nor risk-free, and which also contain toxins in their aerosol, albeit at significantly lower levels than cigarette smoke.

PMI's HTPs have undergone rigorous scientific assessments which support the conclusion that these products, whilst not risk-free, are significantly less harmful for adults than continuing to smoke cigarettes.

There is evidence from independent bodies—here and abroad—on HTPs:

- Overseas, the US FDA concluded that ''*…[US FDA] found that the aerosol produced by the IQOS Tobacco Heating System" [EHTP with THD] "contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke."*[16]
- With the introduction of heated tobacco products, Japan has reduced smoking rates from almost 20% of adults in 2014 to 13% in 2019.[17]
- Closer to home, in 2018, a Public Health England report stated, "*The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes."*[18]
- The social media post in question selectively references The UK Committee on Toxicity who in addition to highlighting that HTPs are not without risk —also in 2017—stated: ''… [HTPs] *are likely to be less risky than smoking conventional cigarettes… There would likely be a reduction in risk for conventional smokers deciding to use heat-not-burn tobacco products instead of smoking cigarettes. Investigations on both products that were assessed by the Committees, showed a decrease in the harmful and potentially harmful compounds (HPHCs) to which the user would be exposed, compared to the HPHCs from a conventional cigarette. For both products, there were some HPHCs where the reduction was approximately 50%, and the reduction in other HPHCs was greater than 90%."*[19]

On the latter point, the selectivity of the social media post in question is extremely concerning from both a scientific and communications perspective. No-one is suggesting that HTPs are risk-free, but if the question is whether they are better for adults than continuing to smoke cigarettes, the answer based on the totality of scientific evidence, including the Government's own evidential reviews, is undoubtedly "yes".

16 FDA Authorization of IQOS Heated Tobacco Product with 'reduced exposure' information (2020) FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA

17 Association between the introduction of heated tobacco products and declines in cigarette smoking | PMI - Philip Morris International

18 Evidence Review of e-cigarettes and heated tobacco products (March 2018) Evidence review of e-cigarettes and heated tobacco products 2018: executive summary - GOV.UK (www.gov.uk)

19 UK Committee on Toxicology, Statement on the toxicological evaluation of novel heat-not-burn tobacco products (2017) heat_not_burn_tobacco_statement.pdf (food.gov.uk)

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We need more independent research on HTPs

We have repeatedly heard independent voices calling for research into HTPs – from a report to the Science and Technology Committee in 2018[20] [21] [22] to the Khan Review into Making Smoking Obsolete[23]

PMI continues to support this – as did your Government, who responded saying that it accepted the Committee's recommendation on the need for more research.[24] Yet, nothing has been forthcoming from either the Committee on Toxicology (COT) or the Office for Health Improvement and Disparities (OHID).

PMI backs the Government's ambition to see England smoke-free by 2030. However, in order to achieve this, we believe the Government needs to confidently embrace the full range of less harmful alternatives to smoking and play their part in ensuring that adults who smoke receive accurate information regarding smoke-free products that is consistent and evidence-led and avoids dissuading those who do not quit from switching to better alternatives at all costs.

We request that a correction is issued regarding the social post in question, or that it is removed. There was widespread criticism of the government's recent Online Safety Bill adequately seeking to curb the risks of misinformation online, particularly on social media. Whether erroneous or deliberate on this occasion, it is the government's responsibility to lead by example.

Yours sincerely

Dr. Moira Gilchrist

Chief Communications Officer

Philip Morris International

[20] Science and Technology Committee, E-Cigarettes Report (2018) E-cigarettes (parliament.uk)

[21] Science and Technology Committee, E-Cigarettes Report, Page 40 (2018) E-cigarettes (parliament.uk)

[22] Science and Technology Committee, E-Cigarettes Report, Page 40 (2018) E-cigarettes (parliament.uk)

[23] Khan Review: Making Smoking Obsolete (June 2022) Making smoking obsolete (publishing.service.gov.uk)

[24] The Government Response to the Science and Technology Committee's Seventh Report of the Session 2017-19 on E-cigarettes, Page 5 (December 2018) The governments response to the scientific and technology committee's seventh report of the session 2017-19 on E-cigarettes (publishing.service.gov.uk)