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Ashley Dalton MP  
Parliamentary Under Secretary State for Health and Social Care  
Department of Health and Social Care  
39 Victoria Street London  
SW1H 0EU

18<sup>th</sup> February 2025

Dear Minister,

**RE: Recent Appointment**

Congratulations on your recent appointment as Parliamentary Under Secretary of State for Health and Social Care. I hope you are settling in well to your new role and I would like to take this opportunity to formally introduce the work we are doing at Philip Morris International (PMI) to create a smoke-free UK.

PMI is committed to accelerating the end of smoking by providing adults who would otherwise continue to smoke with less harmful alternatives to smoking. This includes e-cigarettes, heated tobacco products (HTPs) and nicotine pouches. Our latest figures show that 40% of our total net revenues now come from smoke-free products<sup>i</sup>, and our ambition is to become substantially smoke-free by 2030<sup>ii</sup>.

We have already invested over \$14 billion<sup>iii</sup> to develop, scientifically substantiate and commercialize innovative smoke-free products for those who would otherwise continue to smoke, with the goal of completely ending the sale of cigarettes<sup>iv</sup>. This includes the building of world-class scientific assessment capabilities, notably in the areas of pre-clinical systems toxicology, clinical and behavioural research, as well as post-market studies.

In England, considerable progress has been made in reducing smoking rates as innovative technologies like e-cigarettes have become more prevalent. However, there are still 6 million smokers<sup>v</sup> who need support to either quit smoking or switch to a less harmful alternative. To do so, policies must allow adults who smoke to receive accurate information that is evidence-led and encourages those who do not quit to switch to better alternatives. This is particularly pertinent as smoking is known to be associated with a variety of characteristics, such as education level and socio-economic status<sup>vi</sup>.

As you will be aware, the Tobacco and Vapes Bill has finished its Committee Stage in the House of Commons and is next due back for Report Stage in the coming months. We at PMI have been following the progress of this Bill with great interest and I wanted to draw your attention to some aspects of the Bill that we believe could be improved.

Firstly, we believe that the inclusion of HTPs in the Generational Smoking Ban is a mistake. This is because we believe that equating combustible tobacco products, namely cigarettes, with smoke free products like HTPs, could give the impression to adult smokers that they are just as harmful as one another, which they are not. Our HTP device, IQOS, is up to 95% less harmful than conventional cigarettes, and it would be both misleading and inappropriate to give the impression, via this Bill, that a less-harmful alternative for adult smokers is just as harmful as cigarettes. We would therefore ask that you reconsider the inclusion of HTPs in the Generational Sales Ban and instead include only combustible tobacco products in this.



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Secondly, on Part Six of the Bill, which regards the planned restrictions on advertising and sponsorship of nicotine products, we believe this should be put to further consultation following the Bill being given Royal Assent, so that industry, retailers and consumers can have their voices heard on changes that will no doubt have a deep and far-reaching impact. We would therefore ask that you consider putting Part Six of the Bill up for consultation once the Bill is passed, as other parts of the Bill have provision for this already.

Finally, I wanted to draw your attention to the fact that last week, our Chief Communications Officer wrote to your predecessor regarding comments he made in the Tobacco and Vapes Bill Committee session on 28<sup>th</sup> January 2025. We have attached this letter for your reference. During the session, Andrew Gwynne MP stated:

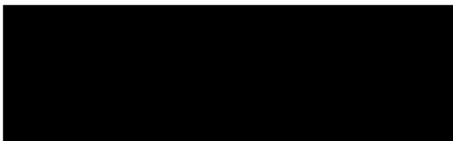
*“Whether it is cigarettes, cigars or heated tobacco, tobacco is tobacco, and tobacco is dangerous. I will not concede to the hon. Member for Windsor on the tobacco industry’s lie that heated tobacco is a smoking cessation tool.”<sup>vii</sup>*

We believe this statement to be misleading and confusing, both in relation to the implication that all tobacco products are equally dangerous and the accusation that the industry is positioning heated tobacco products as a cessation tool. Whilst it is true that tobacco and nicotine products are addictive and not risk free, it is false to imply that all forms of tobacco are equally harmful. It is vital that smokers understand the differences in risk.

PMI’s HTPs have undergone rigorous independent scientific assessments which support the conclusion that these products, while not risk-free, are significantly less harmful for adults than continuing to smoke cigarettes<sup>viii ix</sup>. To this end, it is recommended that the Government support access to, and information about, all the scientifically substantiated alternatives for adult smokers.

We know that prevention is crucial to eradicating health inequalities and strengthening our National Health Service. By supporting smokers to switch from cigarettes by providing accurate and evidence-based information, we believe the UK can finally achieve its ambition of becoming a smoke-free society. Government and industry can and should work together to achieve this and we would welcome the opportunity to meet with you and your team to discuss this further.

I would like to congratulate you again on your new role and look forward to hearing from you.



<sup>i</sup> Earnings Slides - Q4 2024

<sup>ii</sup> Our progress | Philip Morris International | Delivering a smoke-free future

<sup>iii</sup> PMI's smoke-free products | PMI - Philip Morris International

<sup>iv</sup> Our progress | Philip Morris International | Delivering a smoke-free future

<sup>v</sup> Adult smoking habits in the UK - Office for National Statistics

<sup>vi</sup> Adult smoking habits in the UK - Office for National Statistics

<sup>vii</sup> Tobacco and Vapes Bill (Fourteenth sitting) - Hansard - UK Parliament



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<sup>viii</sup> Evaluation of the Tobacco Heating System 2.2. Part 2: Chemical composition, genotoxicity, cytotoxicity, and physical properties of the aerosol - ScienceDirect

<sup>ix</sup> Effects of Switching to the Menthol Tobacco Heating System 2.2, Smoking Abstinence, or Continued Cigarette Smoking on Clinically Relevant Risk Markers: A Randomized, Controlled, Open-Label, Multicenter Study in Sequential Confinement and Ambulatory Settings (Part 2) | Nicotine & Tobacco Research | Oxford Academic



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Rt Hon Andrew Gwynne MP  
Parliamentary Under-Secretary of State for Public Health and Prevention  
Department of Health and Social Care  
39 Victoria Street  
London  
SW1H 0EU  
United Kingdom

CC: Members of the Tobacco and Vapes Bill Committee

05 February 2025

Dear Minister,

I am writing to you regarding comments you made during the Tobacco and Vapes Bill Debate on Tuesday 28<sup>th</sup> January 2025, about heated tobacco products (HTPs) and tobacco, which are incorrect.

During the debate you stated:

*“Whether it is cigarettes, cigars or heated tobacco, tobacco is tobacco, and tobacco is dangerous. I will not concede to the hon. Member for Windsor on the tobacco industry’s lie that heated tobacco is a smoking cessation tool.”<sup>1</sup>*

We believe this statement to be misleading and confusing, both in relation to the implication that all tobacco products are equally dangerous and the accusation that the industry is positioning heated tobacco products as a cessation tool.

More details are explained below but in short, HTPs are not intended to be, nor marketed as, smoking cessation aids – they are a better alternative for adults who would otherwise continue to smoke. Further, tobacco itself is not the primary danger –the smoke from the burning of tobacco is. It is important that smokers are offered a choice of reduced risk products as any single smoke-free alternative is not suitable for all. The statements made in the Debate fail to reflect the scientific evidence base including the Government’s own evidential reviews, all of which seriously misleads the public, adults who smoke and those contributing to the legislative progress of the Tobacco and Vapes Bill.

Misleading claims equating HTPs with cigarettes, risks driving some of those consumers who have switched, back to cigarettes and dissuading current adult smokers from making this switch if they do not quit.

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<sup>1</sup> [Tobacco and Vapes Bill \(Fourteenth sitting\) - Hansard - UK Parliament](#) Column 550



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### Scientific-substantiation

Although it's true that tobacco and nicotine products are addictive and not risk free, it is untrue and misleading to imply that all forms of tobacco are equally harmful. It's important that smokers understand the differences in risk. PMI's HTPs have undergone rigorous independent scientific assessments which support the conclusion that these products, while not risk-free, are significantly less harmful for adults than continuing to smoke cigarettes. 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.<sup>2 3</sup> The lower levels of toxicants result in the *IQOS* aerosol being significantly less toxic than cigarette smoke.<sup>4 5 6 7 8 9 10</sup>
- 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.<sup>11 12 13</sup> 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.<sup>14</sup>

<sup>2</sup> 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).

<sup>3</sup> 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>

<sup>4</sup> PMI's non-clinical studies are planned, performed, monitored, recorded, reported and archived following Good Laboratory Practices (GLP) (OECD, 1998).

<sup>5</sup> 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>

<sup>6</sup> 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>

<sup>7</sup> 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>

<sup>8</sup> 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>

<sup>9</sup> 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>

<sup>10</sup> 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>

<sup>11</sup> 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](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)

<sup>12</sup> 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.

<sup>13</sup> 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).

<sup>14</sup> 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%2Fnt%2Fntx028>

<sup>15</sup> 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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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.”<sup>15</sup>
- 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.”<sup>16</sup>

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”.

### Cessation

With regard to your comments about cessation – there is no doubt that quitting is the best choice for health. Cessation in relation to cigarettes is widely accepted to mean stopping all tobacco and nicotine products entirely. 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 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.

While we don’t market these products as cessation devices, they are effective at helping people switch away from smoking. For context, our data shows that HTPs have helped 22.1<sup>17</sup> million smokers worldwide leave cigarettes behind and abandon cigarettes altogether. With the introduction of heated tobacco products, Japan has reduced smoking rates from almost 20% of adults in 2014 to 13% in 2019.

Indeed, recent research from UCL, funded by Cancer Research UK<sup>18</sup>, has shown that “Quit success rates could be improved by encouraging people to use more effective methods,” including non-combustible nicotine products. The results of this important publication have an important bearing on public health, and show that the three aids most associated with quit

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<sup>15</sup> 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](#)

<sup>16</sup> 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 \(www.gov.uk\)](#)

<sup>17</sup> PMI Second Quarter Results 2024

<sup>18</sup> Prevalence of Popular Smoking Cessation Aids in England and Associations With Quit Success, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2829358?resultClick=1>

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success were e-cigarettes, varenicline, and heated tobacco products (the latter having the highest odds of quit success, albeit with a smaller number of participants using this aid).

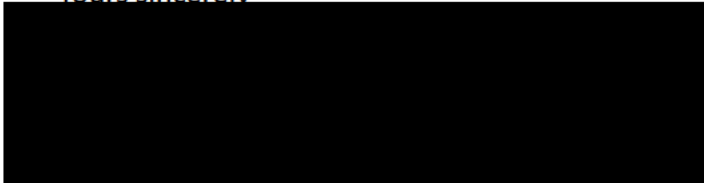
### **Better regulation**

PMI backs the previous Government's ambition to see England smoke-free by 2030, and we support better regulation and enforcement that protects consumers and the environment from products that don't meet the highest standards of scientific scrutiny. At the same time laws must allow adults who smoke to 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 believe those making policy and law should be basing their statements in debates, and indeed their decisions, on the latest scientific evidence, and so we felt compelled to write to you to share the information we have set out above.

We hope that this information will assist you in correcting the record and would welcome the opportunity to discuss this important issue with you further. We look forward to hearing from you.

Yours sincerely



Dr. Moira Gilchrist

Chief Communications Officer

Philip Morris International

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