

Tobacco and Vapes Bill Commons General Committee House of Commons London SW1A OAA

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Friday 10 May 2024

Written evidence in response to Tobacco and Vaping Bill call for evidence

This letter responds to the 17 April 2024 Public Bill Committee "Tobacco and Vaping Bill: call for evidence".1

Philip Morris Limited (PML) is the UK & Ireland affiliate of Philip Morris International (PMI). PMI is a leading international tobacco company working to deliver a smoke-free future and evolving its portfolio for the long-term to include products outside of the tobacco and nicotine sector.

PML is supportive of the government's aim to create a smokefree England by 2030. This can most effectively be achieved by embracing the full range of less harmful alternatives to smoking, alongside further restrictions on combustible tobacco. As such, PML urges the Government to re-assess the position as regards heated tobacco products (HTPs) and to omit them from the current Generational Sales Ban for tobacco products.

HTPs do not involve combustion and hence produce an aerosol (and not smoke) with significantly fewer and lower levels of toxic emissions compared to cigarette smoke. As a less harmful alternative to smoking, their inclusion within the generational sales ban which is principally directed at combustible products will not assist with the goal of further reducing the number of smokers. Conversely, it will be counterproductive and will conflate those combustible products with HTPs, which remain a much less harmful alternative than continued smoking. This may ultimately result in confusion and dissuade adult smokers from switching from cigarettes, impeding progress that has been made over the past decade in that respect.

In context, the reality is that some within the January 2009 birth cohort will still find ways to access tobacco products if they choose. These people will then be prejudiced by the limited selection of less harmful alternatives available to them simply because of their birth date, leading to the absurd situation of people born one day earlier having better choices in support of their efforts to move away from smoking.

Furthermore, conflating combustible tobacco and HTP regulation in the same legislative structure is disproportionate as it does not reflect a fundamental difference between both types of products (i.e., combustion which is involved in smoking cigarettes, but not when consuming HTPs) and the reduced harm potential of HTPs which is similar to that of vaping products. The policy issues which the generational sales ban aims to address are the negative public health outcomes caused by smoking, whereas the Bill goes significantly further - to include products that do not qualify under smoking. HTPs do not combust and hence

¹ See notice dated 17 April 2024 published on the UK Parliament website (<u>Tobacco and Vaping Bill: call for evidence - UK Parliament</u>). This letter supplements PML's response dated 6 December 2023 to the consultation entitled "Creating a smokefree generation and tackling youth vaping" published in October 2023 (PML's consultation response enclosed, for ease of reference).



produce aerosol (and not smoke) with significantly fewer and lower levels of toxic emissions compared to cigarette smoke.

In considering its position, PML urges the Committee to draw the important distinction between the absence of combustion in considering whether HTPs should be included in the Bill, and not to proceed with the over simplistic 'tobacco/non tobacco' distinction.

In support, PML highlights the following reasons why HTPs should be omitted from the generational sales ban. These points relate to both timing and substantive aspects of the measure.

1) The timing for the inclusion of HTPs in the measure is inappropriate. The government has not adequately assessed the evidence regarding HTPs, despite assurances it would do so.

The government peremptorily announced that HTPs would be within scope of the Generational Sales Ban with the publication of the Consultation "Creating a smokefree generation and tackling youth vaping" on 12 October 2023. Less than two weeks beforehand, the 4 October 2023 Command Paper "Stopping the Start" signaled a different stance, explaining that the scope of the restriction "will mirror the existing age of sale legislation" provided for in section 7 of the Children and Young Persons Act 1933. This measure covers cigarettes, products intended for oral or nasal use, and smoking mixtures. Nothing within that definition captures HTPs, and thus PML had a reasonable expectation that those products would not form part of the Generational Sales Ban.

The "Stopping the Start" proposal refers extensively to the 2022 independent review "Making Smoking Obsolete" led by Dr. Javed Khan OBE as a foundation for the current policy. In that paper, Dr Khan recommended that the Government support further independent research into heated products, tracking their use and population effects, stating "The government should track the patterns of HTP use and population effects. Based on this research, the government should ensure the regulatory framework is appropriate for these products." Dr. Khan's report underscored that smoked tobacco is by far the most harmful form of consumption and that there is "differing evidence on the health harms" relating to other forms.

Dr. Khan's recommendation for further evidence followed an overwhelming number of earlier calls for the impact of HTPs to be examined, all leading to a reasonable expectation by PML that such would be the case. These calls included: i) the Committee on Toxicity in 2017², ii) the December 2018 Government Response to the Science and Technology Committee's Seventh Report³, iii) the July 2019 report from the Department of Health and Social Care "Advancing our health: prevention in the 2020s – consultation document"⁴ iv) the Cochrane Group's 2022 review on heated tobacco products⁵, and v) the Tobacco and Related Products Regulations consultation of March 2022⁶.

² "Further information on the population impact of availability of these products should be collected, including uptake of these products by smokers and nonsmokers and their age profile, whether product switching or dual use occurs including with e-cigarettes, uptake of smoking as a result of use of these products by non-smokers, and overall population exposure, including bystanders, to compounds of concern."

³ "The Government will review and consider where there are gaps in evidence for further independent research, and continues to collaborate and share knowledge both in the UK and internationally to help develop the research base and understanding of these products."

⁴ "The Government was committed to assessing further ways to deliver nicotine with less harm than smoking tobacco and that it would "run a call for independent evidence to assess further how effective heated tobacco products are, or are not, in helping people quit smoking and reducing health harms from smoking."

⁵ "To clarify the impact of rising heated tobacco use on smoking prevalence, there is a need for time-series studies that examine this association."

⁶ The government stated that it "continues to monitor developing evidence on these [heated tobacco] products".



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Despite the appeals for a review of the evidence, no governmental assessment in this regard has taken place, with HTPs fast-forwarded into the Generational Sales Ban. Compounding this omission, the Government's response to the Consultation "Creating a smokefree generation and tackling youth vaping" provides no detailed explanation as to why HTPs have been included, and neither the modelling compiled in support of the restriction, nor the Impact Assessment of 20 March 2024 included HTPs in their estimates.

PML submits that given this failure to follow up on promises of further enquiry, the matter is not yet ready for legislation, particularly – as explained below – given that HTPs are (1) significantly less harmful than traditional combustible tobacco products, and (2) form an important alternative, helping smokers to switch.

2) The evidence is that HTPs are significantly less harmful than combustible tobacco products.

As far back as 2017, the UK Committee on Toxicity conducted a review of available evidence on two HTPs, one of which was Philip Morris's IQOS, concluding that there was a "likely reduction in risk for smokers switching to heat-not-burn tobacco products" (i.e. HTPs). Then, in 2018, Public Health England published a review of evidence on e-cigarettes and HTPs, its conclusion as regards the latter being they were "likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds". On that basis, it concluded that "heated tobacco products may be considerably less harmful than tobacco cigarettes ..."

In July 2020⁷ and March 2022⁸ the U.S. Food and Drug Administration (the FDA) authorised the marketing of two HTP (IQOS brand) variants in the US as modified risk tobacco products (MRTPs). These are the first tobacco products to receive "exposure modification" orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of a population.

The FDA authorised Philip Morris to market these products with the following information:

"AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.,
- This significantly reduces the production of harmful and potentially harmful chemicals,
- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals".

The FDA further determined that the issue of the MRTP 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 review by the FDA was the most thorough and scrupulous assessment by any regulator worldwide to date with regard to HTPs and it is entirely appropriate for the Government to factor this development into its own policy decision.

New Zealand, upon whose initiative the government based its plans, took the decision to base the concept of a Generational Sales Ban to only smoked tobacco products.

⁷ FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA

⁸ Philip Morris Products S.A. Modified Risk Tobacco Product (MRTP) Applications | FDA



The proposed legislation ignores the growing body of evidence that HTPs can assist in encouraging adult smokers to move to less harmful alternatives. A study⁹ relating to smoking in Japan by researchers at the American Cancer Society, published in the British 'Tobacco Control Journal' concluded: "Cigarette sales begin to substantially decline at the time of the introduction of IQOS [heat-not-burn system] in each of 11 Japanese regions (...) The introduction of IQOS likely reduced cigarette sales in Japan." Philip Morris' own estimates are that approximately 28.6 million¹⁰ adults around the world have switched to their HTPs and stopped smoking.

Most recently, a study¹¹ published in 19 December 2023 by prominent international tobacco control researchers stated that effects and attitudes reported after vape and HTP use may indicate that *both* of those products are viable cigarette substitutes that could promote switching. Echoing the call for more research, the authors concluded, "Nonetheless, given the comparable psychopharmacological profile and perceived acceptability of both products, taken together with the now established effectiveness of NVP [nicotine vaping products] for smoking cessation, this would suggest that HTP may play a useful role in combustible tobacco harm reduction."

3) HTPs' position alongside other alternatives to smoking

Philip Morris views the 'tobacco / non-tobacco' distinction as a basis for inclusion of products within the measure as an over-simplification that fails to address the key parameter of relative harmfulness. The government must instead draw the important distinction between absence of combustion in considering any proposed measures.

HTPs exist within a range of less harmful smoke-free alternatives. It is clear that adult smokers who wish to use a less harmful alternative will benefit from having a broader rather than narrower choice of products. For example, in Sweden where snus is permitted (otherwise banned in the EU), daily smoking prevalence as of 2022 declined to 5.8%¹² - notably, Sweden has the lowest smoking prevalence across the EU¹³.

HTPs have features in common with vaping, which is the most frequently used less harmful alternative for smokers. Both products produce a nicotine vapour for inhalation through use of an electronic device. Neither produces smoke, ash, or fire, or has an impact on indoor air quality. For an important section of smokers, however, HTPs offer the distinct advantage over vaping in that they use real tobacco and thus can provide similarities as regards – for them – the factors of taste, addressing their cravings, and satisfaction as compared to cigarettes. Recent evidence¹⁴ illustrates this point, suggesting that in a sample of UK smokers naïve to HTPs, those products were perceived as more satisfying than vape products, though still less satisfying than cigarettes.

⁹ Stoklosa, M. et al., 2020. Effect of IQOS introduction on cigarette sales: Evidence of decline and replacement. Tob. Control. 29, 381–387

¹⁰ Philip Morris International, Fifth Integrated Report (2023), Page 4, pmi-integrated-report-2023.pdf

¹¹ Kale, D. et al, Examining acute psychopharmacological effects of nicotine vaping versus heated tobacco products in a randomised crossover study of product naïve adult smokers. Sci Rep. 2023 Dec 19;13(1):22676

¹² http://fohm-

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 $^{{\}tt ^{13}}\, \underline{\sf https://health.ec.europa.eu/publications/attitudes-europeans-towards-tobacco-and-electronic-cigarettes-1}\,\,\underline{\sf en}$

Supra fn 7.



Equally, a recent study from Italian researchers¹⁵ who compared quit rates for smoking between groups using HTPs or vapes, and found a marked reduction in cigarette consumption that was comparable for both types of products, summarising, "HTPs may be a useful addition to the arsenal of reduced-risk alternatives for tobacco cigarettes and may contribute to smoking cessation."

Conclusion

This response includes three convincing reasons why the government should act now to remove HTPs from the proposed Generational Sales Ban. There are no good arguments to the contrary, and the public deserves better from its legislators than to proceed with a measure for which there is simply no persuasive evidence.

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PML's response dated 6 December 2023 to the consultation entitled "Creating a smokefree generation and tackling youth vaping" published in October 2023.

¹⁵ Caponnetto et al, Comparing the Effectiveness, Tolerability, and Acceptability of Heated Tobacco Products and Refillable Electronic Cigarettes for Cigarette Substitution Public Health Surveill. 2023 here.