

December 17, 2024

Tobacco Control Research Group's contributions to recent Royal College of Physicians report, *E-cigarettes and harm reduction, an evidence review* 

Dear

In April 2024, The Royal College of Physicians (RCP) issued a report—*E-cigarettes and harm reduction, an evidence review*—detailing strategies for reducing global combustible cigarette use. Encouragingly, the report concludes that e-cigarettes can be an effective means to help people stop smoking. Real-world evidence demonstrates that innovative nicotine-containing products that do not burn tobacco are already accelerating the decline of cigarette smoking beyond what traditional tobacco control measures can achieve alone.

Despite the well-known risks of cigarette use, the report notes that "tobacco is currently used by an estimated 1.1 billion people," concluding that the role of non-combusted alternatives in reducing smoking-related harms is underutilized due to "lack of awareness of the efficacy of these products for smoking cessation and harm reduction, and public perceptions of the risks of vaping relative to smoking which do not reflect current evidence." Because more than 1 billion people smoke, the RCP concluded that "a risk-based approach to harm reduction is ethically and scientifically sounder than a precautionary approach, especially given the known serious harms of tobacco and the known difficulties in driving tobacco smoking and its associated harms down further without new tools to assist." My company, Philip Morris International (PMI), agrees with that recommendation; moreover, many independent public health experts also share this view.

Though the RCP report provides a thorough set of science-based recommendations to reduce the global health burden of smoking, it takes a sharp and notable detour in chapter nine: *Tobacco industry interests, recent conduct and claims around harm reduction*. This chapter abandons the evidence-based approach to assessing alternatives to continued smoking contained in the rest of the report and instead makes inaccurate, misleading statements, and recycles antiquated criticisms of the tobacco industry and PMI in particular. I am writing to you because you are listed as contributors to the RCP report and, in addition, the Tobacco Control Research Group (TCRG) at the University of Bath is widely referenced throughout chapter nine—in fact, almost half of the total citations supporting this chapter are to sources authored by TCRG members.

I have written to several of you and your colleagues on 13 occasions requesting corrections to false and misleading statements you have made about PMI, our products and science in the media, scientific literature and on your websites. However, almost all these requests were ignored. PMI has, both privately and publicly, asked that you correct at least 22 false and misleading claims (here and here), of which only one erroneous claim has been corrected to date. More disturbing is that your invalid claims have been repeated in chapter nine of the RCP report (as detailed in this letter's conclusion).



Given your collective lack of response over the last years, I had not intended to write to you on this occasion. However, I note the <u>recent letter</u> to Nicotine and Tobacco Research wherein an independent public health researcher also pointed to serious inaccuracies in one of your publications. It seems I am not the only stakeholder questioning the veracity of your communications. Indeed, I also note that in 2021 the BBC upheld a complaint about a radio podcast in which they <u>acknowledged</u> that Professor Gilmore had made false and misleading statements about PMI's corporate practices and removed the interview with her from its website.

The RCP report finds it "*difficult to comprehend why tobacco has been allowed to burden global health so extensively for so long.*" However, it is not that difficult to comprehend at all given the lack of fact-based debate on potential solutions and the companies who bring them to market. The RCP report states that "*[if] potential public health benefits from e-cigarettes are to be realised, it is essential to take account of the conduct of TTCs [Transnational Tobacco Companies*]." Given this, it would appear to be more important than ever that stakeholders with loud and well-funded voices— such as your institution—embrace a complete and factual debate, one free from biases and instead focused on how to effectively deploy smoke-free alternatives to accelerate the decline in smoking, irrespective of who brings them to market.

I invite you to consider a selection of the inaccurate and misleading claims related to PMI that are outlined below. The lack of action to correct factual inaccuracies and biased, misleading claims gives the impression that your work is simply subjective commentary, rather than an objective scientific examination and discussion. A truly serious attempt on your part to reduce and eliminate smoking requires an approach rooted in objectivity—even if the results of such an endeavor do not align with your ideology. Continuing to deploy your playbook of repeating outdated—and often factually inaccurate—grievances against my company will not lead to a single adult stopping smoking.

Respectfully, I request that you communicate to the RCP report's author group that many of your resources cited in the report do not reflect the substantial correction requests you have received from PMI over the last years.

In the interest of full disclosure, I will write publicly to RCP and provide PMI's perspective on their complete report and will draw their attention to your continued inaction on correspondence sent to you by PMI. Additionally, please be aware that this letter will also be made public.

I of course would welcome the opportunity to discuss this matter with you at any time. An absence of dialogue yields only the absence of a complete, reality-based plan to end smoking.

Sincerely,

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Dr. Moira Gilchrist Chief Communications Officer Philip Morris International



#### A SELECTION OF FACTUAL ERRORS AND CONTEXTUAL MISDIRECTIONS CONTAINED IN CHAPTER NINE OF THE ROYAL COLLEGE OF PHYSICIANS REPORT "E-CIGARETTES AND HARM REDUCTION, AN EVIDENCE REVIEW"

Below is a selection of specific claims in chapter nine (marked in **bold**) that appear to be derived, in whole or in part, from references authored by the Tobacco Control Research Group at the University of Bath. Over the last several years we have repeatedly asked for these to be corrected.

### "TTCs made very public claims of commitment to what they called 'harm reduction','<sup>3,4</sup> despite continuing to heavily invest in and market their tobacco product lines."<sup>5-7</sup>

PMI is clear on our commitment to tobacco harm reduction and mission to end smoking. We are proud to be fulfilling this commitment, and our progress is undisputedly demonstrated and supported by the facts. Publicly available data from our Securities and Exchange Commission filings bears this out:

- 37% of PMI's total net revenues came from our smoke-free business as of year-end 2023.
- 33 million estimated total adult users of PMI's smoke-free products.
- 20.8 million adults are estimated to have switched to *IQOS*, our heated tobacco system, and stopped smoking.
- 84 markets where our smoke-free products are available.
- IQOS net revenues surpassed Marlboro to become the number one international nicotine brand on this measure in Q4 2023.

We are proud to have reached 25 markets where smoke-free products exceed 50% of our top-line revenue for both Q4 2023 and the full year. We aim to reach 60 markets by 2030, driving our ambition for smoke-free revenues to exceed two-thirds of group net revenues. In markets where PMI smoke-free products were available for sale as of the end of 2023, the company's combustible tobacco product shipment volume decreased by more than 33% versus 2015. If this trajectory continues, PMI expects that the growth of smoke-free products and consequent replacement of cigarettes will translate into a more than 50% decline of the company's combustible tobacco product shipment volume in these markets by 2030.

We have also progressed on our 2025 aspiration to have low- and middle-income markets represent at least half of the markets where we commercialize our smoke-free products—which, as of the end of 2023, represent 47% of the markets where we commercialize them globally.

A smoke-free future—for our consumers and for our company—is attainable. The benefits this can bring to adults who would otherwise continue to smoke, and hence to global public health, are enormous. Accelerating progress requires all stakeholders to take an evidence-based approach that encourages proper government oversight and regulation of smoke-free alternatives in order that they can play their part in contemporary tobacco control policy.



## "[Weakens tobacco control] Promotes harm reduction policies that focus on minimising harm at the individual level, rather than evidence based, population-level measures."

In relation to PMI, this is false. Take, for instance, what the U.S. Food and Drug Administration (FDA) concluded: On July 7, 2020, FDA issued modified risk tobacco product (MRTP) authorizations for the *IQOS* tobacco heating system. In doing so, the agency found that issuing reduced exposure modification orders for *IQOS* is "appropriate to promote the public health" and "is expected to benefit the health of the population as a whole."

Furthermore, an improvement at the population level cannot be achieved without reducing harm at the individual level. To that end, FDA <u>concluded</u> in its *IQOS* MRTP authorizations that "[t]he scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies."

#### "PMI's 'harm reduction equation' misleadingly equates individual smokers switching to lower-risk products to population harm reduction, regardless of whether any smokers quit, the extent of dual use, or what happens in the wider population. The latter, of course, includes the children who it targets with its new product marketing."

This is a misleading characterization of the harm reduction equation, a model developed by wellknown health experts. As explained <u>here</u>, the harm reduction equation describes the criteria for making a significant impact on public health by converting the greatest number of existing adult smokers who would otherwise continue smoking to less-harmful alternatives and further reducing initiation of combustible cigarettes.

A few important steps are needed to make this commonsense approach a reality for millions of adults who smoke. First, less harmful alternatives to cigarettes must be developed. Second, these alternatives must be appealing to those adults—in other words, they should deliver a taste and sensory experience that leads adults who would otherwise continue to smoke to change completely to the better alternative. When this occurs a population-level health benefit can be realized.

PMI is clear that minors should not use any tobacco or nicotine products. We design and market our products for adults who currently consume nicotine and wish to continue doing so. Suggestions otherwise are baseless.

# "PMI offered the NHS £1 billion to help smokers switch to alternatives, under the condition that the U.K. relax regulation on e-cigarettes and HTPs following Brexit, an offer that the U.K. government rejected."<sup>8,38</sup>

This claim is inaccurate and misleading. As we explained when we <u>wrote</u> to you in February 2021, PMI had proposed a comprehensive approach to establish a regulatory framework with the objective of enabling adults who smoke to have access to, and accurate information about, smoke-free alternatives. Simultaneously, the framework would have pushed tobacco companies to phase out cigarettes through a tobacco transition fund paid for by the industry—not £1 billion from PMI but apportioned based on the tobacco companies' respective market share of combustible tobacco sales.



The United Kingdom's government has repeatedly endorsed the principle of tobacco harm reduction and encouraged men and women who smoke to switch to less harmful alternatives, such as ecigarettes, if they do not quit altogether. Unfortunately, the regulations governing tobacco and nicotine products are outdated and inconsistent, with improvements needed to achieve the government's goals as quickly as possible. We supported the creation of a new product category that is future-proofed and for which any communication of the products would be restricted to specifically targeting adults who smoke.

## "PMI has also misrepresented the science on smoke and aerosol, claiming that IQOS is smoke-free, safer than conventional cigarettes and even less harmful than e-cigarettes."<sup>47, 155</sup>

As we have told you on numerous occasions, this statement is misleading and inaccurate. Multiple <u>independent studies</u> have concluded that *IQOS* does not produce smoke because it does not burn tobacco. For example, the FDA <u>determined</u> that PMI has "demonstrated that because the *IQOS* Tobacco Heating System heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke."

We have sound scientific <u>data</u> demonstrating that *IQOS* operates without combustion (neither incomplete, nor complete), including temperature measurements, experiments demonstrating the absence of net exothermic processes, the exclusion of oxygen (a catalyzer of a combustion reaction) during the heating process, and measurements of constituents that represent typical markers of combustion.

Aerosol chemistry <u>studies</u> show the level of emissions of harmful and potentially harmful constituents (HPHCs) generated by *IQOS* are on average 90 to 95% lower than those found in cigarette smoke. Furthermore, our untargeted screening of the *IQOS* aerosol demonstrated that the it is significantly less complex than cigarette smoke, and that exposure to the four compounds of potential toxicological concern elevated in the *IQOS* aerosol compared with cigarette smoke are below the level of toxicological concern. Moreover, and in contrast to cigarette smoke, we have demonstrated that *IQOS* aerosol does not contain solid particles originating from a combustion process as described by <u>Pratte et al. 2017</u>.

All of this evidence was reviewed by FDA who concluded in their 2020 MRTP decision that "The low temperature in the IQOS system, the lack of an exothermic process, the similar levels of HPHCs in the presence and absence of oxygen, and the low level of nitrogen oxides in the aerosol of the IQOS system with Heatsticks suggest that combustion does not occur in the IQOS system with Heatsticks when it is used as intended. There is sufficient evidence to support the following statement: The IQOS system heats tobacco but does not burn it."

Please also take note that PMI has never marketed our smoke-free products as "*safe*." While *IQOS* is less harmful than combustible cigarettes, it is not risk free and is not a cessation device—and has never been marketed as such.