

David Cox/BBC Editorial Team BBC Studios 1 Television Centre 101 Wood Lane London W12 7FA

25 April 2025

| By Email:  |  |
|------------|--|
| Copied to: |  |

Dear David, Richard & Zaria

#### **Re: BBC Media Enquiry on Heated Tobacco**

We refer to our letter dated Thursday 17 April 2025 and our exchange of emails on Saturday 19, Monday 21 and Tuesday 22 April 2025.

#### Your conduct to date

As set out in our previous letter, we consider that your conduct to date falls short of the BBC Editorial Guidelines (the "**Guidelines**"), and in particular the specific sections referred to in our previous letter. Rather than providing us with a reasonable opportunity to comment on the numerous, complex and serious allegations put to us in your email timed at 14.28 on Thursday 17 April (the Thursday before the Easter bank holiday weekend), you made it clear in your email timed at 16.17 on 17 April that you expected us to do so over the Easter weekend and provide you with a response by Tuesday 22 April.

As you did not respond to our letter of 17 April, and given the urgency, we wrote to you again at 10.49 on Saturday 19 April, requesting confirmation that you had received our letter. Mr Gray responded at 11.29 that morning, ignoring our extension request, and simply stating: *"I can confirm we have received your five-page, single-spaced letter and note that you appear to be working on the bank holiday weekend"*. This conduct falls far short of the standards of professionalism and responsible journalism that we would expect of the BBC.

As we still had not had a response to our request, we wrote to you again at 4.25pm on Monday 21 April seeking clarification and explaining that PMI's scientists (who are required to input on our responses) are not allowed as a matter of Swiss law to work on a public holiday without filing and receiving authorization with the Local Authority.

Mr Gray did not respond until 10.50am on Tuesday 22 April, indicating the BBC's agreement to the requested extension. This timing was such that we had no choice but to require colleagues outside



Switzerland to begin undertaking substantial work on our response over the bank holiday weekend, as we were not clear whether you would agree to any extension. In this email, Mr Gray suggested that *"four and a half full working days should … be more than enough time to respond"*, despite having previously given us only one working day.

In this email, Mr Gray also referred to Mr Cox's email of 20 February and indicated that you *"had not received your response to these [enquiries]"*. As explained in our previous letter, we were not in a position to respond to the allegations in that email (which differ from the ones put to us on 17 April) not least because it was not clear that Mr Cox had any authority to write the story. Mr Cox had approached us via his Gmail address (not a BBC email address), without copying anyone from the BBC. We reasonably requested a letter of engagement from Mr Cox's commissioning editor on 20 February, as well as confirmation of which BBC outlet he was commissioned by. PMI chased Mr Cox twice for this commissioning letter on 24 and 25 February, stating in an email to Mr Cox on 25 February "it is important to have a fair opportunity to comment noting that your response to our questions [in previous email] is critical for us to assess our response, particularly given the numerous inaccurate and misleading statements cited in the questions you raised."

Despite Mr Cox assuring us on 25 February that we would "definitely get the opportunity to comment" and that he would "reach out to my editor to get a letter confirming that the BBC have commissioned me to write this article and the other details requested", he did not provide the letter of authority until 17 April (and when it did it was unsigned), despite the document properties showing it was created on 4 March. Any delay in PMI responding to Mr Cox's initial enquiries is therefore the fault of the BBC, not PMI.

It seems to us that you have shown a disregard for the Guidelines in your approach to the article you are proposing to write (the "**Proposed Article**"). As set out in our previous letter, and as you ought to be well aware, it is incumbent on you to report on this matter with fairness, accuracy and impartiality in accordance with the Guidelines, and your approach to date shows an unwillingness to reflect PMI's position in the Proposed Article.

#### Sources for the Proposed Article - Maintaining Impartiality

As explained in our previous letter, we are particularly concerned about the Proposed Article because most of the organisations you appear to have spoken to are funded by Bloomberg Philanthropies, a highly partial U.S. organisation with a keen interest in advocating for bans on products like *IQOS*.

Campaign for Tobacco Free Kids, Vital Strategies and the Tobacco Control Research Group at the University of Bath ("**TCRG**"), are all significant beneficiaries of Bloomberg Philanthropies who have awarded grants of hundreds of millions of dollars over the past 10 years in funding these groups to advocate and lobby for bans on smoke-free products (like heated tobacco and e-cigarettes), which are widely acknowledged by independent science to be far less harmful than traditional cigarettes. These groups are often active in countries that need smoke-free products the most due to disproportionately high numbers of smokers. The effect of this lobbying means that there are many



countries such as Turkey, Thailand, Vietnam, Argentina, Brazil and India where cigarettes and other combustible tobacco products can legally be sold, however, better alternatives for adult smokers are banned.

We also previously explained to you that the TCRG is an unreliable and inaccurate source of information (based on previous encounters we have had with them) and that a previous BBC podcast with Professor Anna Gilmore, Director of the TCRG, was removed from the BBC website following our editorial complaint that it lacked accuracy, fairness and impartiality. It is not clear to us whether you have taken any of these points on board, as you have not substantively responded to our previous letter. You have also not confirmed whether the Proposed Article falls within commercially funded content or not. We note that the TCRG has a long history of sponsoring investigative journalism to carry their messages. **Please now do so as a matter of urgency.** 

Professor Anna Gilmore and Dr. Sophie Braznell—in addition to their work at the TCRG —are spokespeople for STOP, an anti-tobacco lobbying and public relations group with no legal entity status.

STOP is neither unbiased nor objective and since 2018 the TCRG claims to have <u>received over</u> <u>\$17million</u> from Bloomberg Philanthropies with a focus on publishing often inaccurate and misleading "research" aimed at discrediting the industry and its science. The TCRG is one of the partners of STOP and their role as researchers at the University of Bath is therefore not independent of their role as a spokespeople for STOP. In this regard, we refer you to paragraph 4.3.12 of Section 4 of the Guidelines (Impartiality), which states that the BBC "should not automatically assume that contributors from other organisations (such as academics, journalists, researchers and representatives of charities and think-tanks) are unbiased. Appropriate information about their affiliations, funding and particular viewpoints should be made available to the audience, when relevant to the context".

We are concerned that the BBC appears willing to act as a mouthpiece repeating false and/or misleading allegations made by sources with a clear axe to grind against Philip Morris International and its businesses ("**PMI**"). We are aware that Dr Braznell, the TCRG and STOP are holding a media briefing next week on exactly these topics titled: "<u>Media Advisory: Big Tobacco vs. the Evidence –</u> <u>What We Really Know About Heated Tobacco Products</u>". The timing and themes seem too similar to be coincidence.

It would not be responsible journalism, nor in the public interest to simply repeat inaccuracies (and thereby mislead the public) on matters of public health, especially now you are on notice of the true factual position (see below). As outlined above, the BBC has a responsibility to ensure impartiality, fairness and accuracy.

The BBC ought to be aware of the conflicts of interests and highly partial agenda (outlined above) in relying on these sources in its reporting.



### PMI's Position & General Background

Notwithstanding our serious concerns with your approach to date, we set out below PMI's position in relation to the specific matters put to us on Thursday 17 April. As set out below, we expect the BBC will thoroughly and completely reflect of our position in its reporting. We also provide an on the record statement at the end of this letter.

Please be aware that should you proceed with the Proposed Article, our full response, which follows, will be published on our corporate website on a <u>page</u> used to catalogue some of the more significant detailed responses we have sent to organizations that have made inaccurate and misleading allegations.

As an overarching point, everyone knows that smoking is harmful and addictive and despite the known health risks there are still around one billion people who smoke according to the WHO. We all agree the best choice for health is not to start smoking, or to quit, but the reality is that many people do not quit, and they deserve better choices than continuing to smoke. This is why PMI has invested over \$14 billion in the development and responsible commercialization of smoke-free products such as *IQOS* since 2008, and as of the end of 2024, smoke-free products accounted for almost 40% of our global net revenues. Our ambition is to be a predominantly smoke-free business by 2030 with over two thirds of our revenues coming from smoke-free business. We are committed to delivering a smoke-free future and our CEO has said cigarettes belong in a museum.

#### **Detailed Responses**

1. To begin with, the researchers who the BBC interviewed from the above organisations, say while heated tobacco products pose less of a risk than traditional cigarettes, they are still harmful to human health and urge users to give up tobacco altogether. They also say that the long-term effects of such products have also yet to emerge, but some early research is raising concerns, particularly surrounding the levels of toxins that are found in the emissions of heated tobacco products.

#### Does PMI have a general response to this?

It's encouraging that all these groups agree with us that heated tobacco products pose less of a risk than traditional cigarettes. PMI has never claimed heated tobacco products are safe or risk-free. As we have made consistently clear publicly (including on our website), we agree the best choice for any adult smoker is to quit altogether and those not already using tobacco products should not start. However, we are clear that switching completely to a smoke-free alternative is the better choice for any adults than continuing to smoke. Numerous independent studies, including extensive review leading to authorization by the U.S. Food and Drug Administration ("**U.S. FDA**"; as to which see further below) confirm that our heated tobacco product *IQOS* provides a significant reduction of the



harmful and potentially harmful compounds ("**HPHCs**") found in cigarette smoke, emitting on average 95% lower levels of harmful chemicals compared with cigarettes. This conclusion is further supported by the U.S. FDA following extensive scientific review of PMI's *IQOS* Modified Risk Tobacco Product ("**MRTP**") application.

While the reduction in harmful and potentially harmful constituents in *IQOS* aerosol compared to cigarette smoke has been clearly established, a small number of constituents are found to be higher in *IQOS* aerosol, due to fundamental differences in product design. The differences in these constituents are detected at thresholds below 100 nanograms/item and the low total concentration was not considered to be a risk in authorizing the products as "modified risk" by the FDA. Furthermore, analysis on the aerosol has demonstrated a significantly lower toxic potential overall, compared to cigarette smoke. The toxicological risk of any of the constituents found at low levels in *IQOS* aerosol is significantly outweighed by the reduction in exposure to known HPHCs which cause smoking related diseases in cigarette smoke.

2. Silvano Gallus, an epidemiologist at the Mario Negri Institute for Pharmacological Research in Milan, claims that despite the messaging from tobacco firms, existing smokers do not appear to be the main audience for these products. Gallus accuses the industry of cynically targeting young people, commenting, "When you look at the users of heated tobacco products, they're young. They aren't 60-year-old hardcore smokers looking for an alternative to cigarettes."

Gallus says that to date, marketing for IQOS has appeared at music festivals, sporting events and film festivals in Europe, Asia and South America. According to the non-profit organisation Campaign for Tobacco-Free Kids, influencer-driven campaigns on social media platforms such as Instagram, Facebook, X (formerly Twitter), TikTok and YouTube have also played a key role in raising the visibility of IQOS and other heated tobacco brands. The below study of social media marketing of heated tobacco products by researchers at the University of Rochester concluded that the devices tend to be positioned as lifestyle products.

#### https://pmc.ncbi.nlm.nih.gov/articles/PMC10131776

#### What is PMI's response to this?

This question includes demonstrably false claims. It is simply not true that our heated tobacco products are being marketed to young people. For example, *IQOS* is not used in the sponsorship of any sporting events, PMI does not have official accounts on TikTok for marketing or otherwise, and X (formerly Twitter) is only used by *IQOS* for customer care. Any third-party event we sponsor has a clear requirement for at least 75% of the audience to meet the legal age for purchasing tobacco products within the country and digital marketing is directed at legal age adults on platforms with age verification measures in place. Additionally, PMI's <u>robust marketing code</u> does not allow marketing that appeals to minors (e.g., we don't use cartoons, youth-oriented celebrities, or models who are or appear to be under the age of 25 nor engage in product placement in movies or on television – and we decline every request we receive in relation to the same). These false allegations show the lack of research and rigor of Dr Gallus' claims.



In the U.S., when reviewing the available data, the FDA, as part of its scientific review process to grant Premarket Tobacco Product Application authorization ("**PMTA**") of *IQOS* for commercialization ("**the PMTA Review**"), noted: "available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using *IQOS*, including youth."

Furthermore, <u>available evidence</u> shows that unintended use among youth is very low in the 70 markets where *IQOS* is currently available. For example, in Japan (our biggest and most mature market for heated tobacco products where independent data shows that cigarette sales have declined 5 times <u>faster</u> since the introduction of IQOS in 2014), the <u>2022 Lifestyle Survey of</u> <u>Adolescents</u>, a nationwide cross-sectional survey of Japanese youth conducted for comprehensive research on lifestyle-related diseases by the Ministry of Health, Labour and Welfare, Health Science Research Fund, found 0.3% of junior and senior high-school students report current use of HTPs.

Dr Gallus' comments on the demographics of *IQOS* users are plainly wrong and not supported by data. In fact, the data shows (see p. <u>46 of our investor information</u>) that 82 percent of IQOS consumers are over the age of 29, illustrating that *IQOS* is being adopted by its intended audience – legal age adults who were formerly smoking.

Please also note the study you refer to above incorrectly refers to *IQOS* as an acronym for "I Quit Ordinary Smoking" which is a false statement and urban myth created by certain tobacco control researchers – it has no basis in fact and PMI has never designed or denoted *IQOS* as an acronym for anything.

3. Gallus describes heated tobacco products as a "gateway to conventional cigarettes." Last year, Gallus and colleagues in Italy published a study based on data from more than 3,000 Italians aged between 18 and 74. Gallus and his colleagues tracked the participants for six months during 2020. They found that non-smokers who began using heated tobacco products were 5.8 times as likely to subsequently transition to smoking as people who never used heated tobacco products.

#### https://pubmed.ncbi.nlm.nih.gov/36207129/

#### What is PMI's response to this?

Dr Gallus' study has severe limitations and is unreliable. Real life observations in Japan show that smoking rates and cigarette sales are decreasing, not increasing. The data from millions of consumers around the world consistently show that *IQOS* is a gateway out of smoking (the opposite of what you suggest) with over 70% of legal age users of *IQOS* having switched completely away from cigarettes. In our biggest market for *IQOS*, Japan, <u>data also shows</u> that *IQOS* has accelerated a decline in cigarette sales and total tobacco consumption has not increased. In short: it is not causing people to start smoking.

Furthermore, in the U.S., the FDA, as part of the PMTA Review, noted: "available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using *IQOS*, including youth."



It is notable that, you have failed to reference an important point from the conclusion of Dr Gallus' study, which are available in the link you sent. The authors concede that their study had "limited sample size within specific strata". Indeed, out of 2122 never smokers sampled at baseline, less than 1 percent (21 people) met the criteria of using Heated Tobacco Products ("**HTP**") and had smoked cigarettes at follow-up.

4. Last year, Luciano Ruggia of the Swiss Association for Tobacco Control, published the below report entitled, "Benzopyrene, smoke and money."

#### https://www.at-

schweiz.ch/documents/35/2024\_02\_08\_Ruggia\_L\_Benzopyrene\_smoking\_and\_money\_AT\_Re search\_Series\_No2.pdf

In the report, he claims that the tobacco industry has repeatedly sought to obstruct the truth surrounding some of the possible risks of heated tobacco products, and cites benzopyrene, a known carcinogen – or cancer-causing substance – found in tobacco smoke, as a key example. "Benzopyrene provokes changes in DNA which are linked to a certain kind of lung cancer," Ruggia told the BBC.

He also highlights a study published in 2017 by a group of Swiss scientists, which analysed emissions from IQOS devices, which concluded that despite PMI's statements that the devices give users, "the true taste of tobacco, with no smoke, no ash and less smell", the product did indeed release smoke. The study also found that emissions from the product also contained many of the same harmful chemicals emitted by conventional cigarettes

#### https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2628970

Ruggia claims that this elicited a furious response from PMI, who attempted unsuccessfully to force the retraction of the publication.

#### What is PMI's response to this?

The FDA has identified a list of toxicants ("**HPHCs**") that are linked to the most serious smoking related diseases. Regarding benzo[a]pyrene, analysis done by PMI as part of our *IQOS* PMTA submission to the U.S. FDA shows a 93-95 percent reduction of the quantity of the compound in the *IQOS* aerosol compared to reference cigarette smoke (https://doi.org/10.1016/j.yrtph.2016.10.001).

Regarding Carbon Monoxide, analysis shows a reduction by over 99 percent compared to reference cigarette smoke, with the remaining <1.0 percent likely to be due to environmental background. This is because *IQOS* does not combust tobacco and does not produce carbon monoxide (https://doi.org/10.1016/j.yrtph.2016.10.001). The U.S. FDA recognized this when they decided to remove the requirement to include the Surgeon General Warning on Carbon Monoxide exposure in *IQOS* labeling requirements, stating that it would be misleading:

"Removal of the warning: "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide." from the required warnings to be displayed on the product package labels and



advertisements under FCLAA. Based on a fair evaluation of all material facts, the warning is misleading with respect to these products which, although categorized as cigarettes, **do not produce carbon monoxide above environmental levels and do not increase CO-related health risks [emphasis added].** "https://www.fda.gov/media/124247/download (see page 98)

They also noted this decision in their press release:

https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heatingsystem-through-premarket-tobacco-product-application-pathway

The significant reductions in HPHCs like benzo[a]pyrene and carbon monoxide are due to *IQOS* heating tobacco rather than burning it. This has been confirmed by both PMI's science and numerous independent studies, including:

- https://doi.org/10.1016/j.yrtph.2016.10.001
- <u>https://doi.org/10.1016/j.tca.2019.178475</u>
- <u>https://doi.org/10.3390/toxics11120947</u>

These findings are further supported by the U.S. FDA, who concluded in granting a modified risk tobacco product order with reduced exposure claims in July 2020 that available evidence demonstrates *IQOS* "heats tobacco but does not burn it".

The research letter by Dr Auer from 2017 that you refer to has a number of methodological flaws and its reliability has been questioned by highly respected institutions, including the U.S. FDA. However, the TCRG and others continue to falsely rely on it to support their misleading narrative on heated tobacco products. The weight of scientific evidence (including numerous scientific studies as outlined above) supports the view that the *IQOS* system does not produce smoke.

It is misleading to highlight this 2017 study without placing due prominence on the U.S. FDA's 2020 conclusions about it. Their review of the Research Letter from Auer and his colleagues concluded that:

"Auer et al conducted the analysis over two consecutive days and some of the data included too few replicates. Data published in the article lack the appropriate number of replicates, and do not include testing of some compounds in cigarettes, such as acenaphthene. In addition, the identity of some of the compounds, such as acenaphthene, cannot be confirmed since the method used is not selective. The data published is not considered adequate for comparing the levels of HPHCs between the IQOS products and combusted cigarettes. There are significant analytical issues in the Auer study, such as lack of testing reference samples, low number of replicates, lack of selectivity on some analytical methods. In comparison, we have not identified specific issues added]." with the applicant's [PMI's] methods [emphasis https://www.fda.gov/media/110387/download (see page 13).

And:



"...the [FDA] chemists concluded the data published by Auer et al. are not considered adequate for comparing the levels of [harmful and potentially harmful constituents] between the IQOS products and [conventional cigarettes] due to analytical issues [emphasis added]– specifically lack of testing reference samples, low number of replicates, and a lack of sensitivity on some analytical methods. <u>https://www.fda.gov/media/124247/download</u> (see page 21).

PMI's response to the authors of the research letter was in no way a "furious response", but instead was an invitation to discuss its findings, which were entirely at odds with our own science – see our letter attached, which we published on our website quite some time ago in response to public health groups misrepresenting its content to journalists. Mr Ruggia's obvious misrepresentation of PMI's response is a clear indicator that he is biased and an unreliable source.

For the sake of completeness, in your original enquiry from February you also mentioned:

The Swiss Association for Tobacco Control claims that they have obtained contracts showing that PMI paid ETH Zurich more than 1.2 million CHF (equivalent to 804,000 GBP) in 2017 for work which ultimately led to this publication indicating that heated tobacco products do not produce any benzopyrene: <a href="https://pubs.acs.org/doi/10.1021/acscentsci.3c01597">https://pubs.acs.org/doi/10.1021/acscentsci.3c01597</a>

They gave this comment: "Benzopyrene provokes changes in DNA which are linked to a certain kind of lung cancer. So it's in the interests of PMI to have a good study by one of the most prestigious universities in the world saying that there's no benzopyrene and so IQOS is safe, and apparently that's worth one million francs."

This statement is untrue and defamatory and seems to deliberately misrepresent information which is already in the public domain.

The contract referred to was disclosed by ETH Zurich to Swiss media last year under transparency rules (similar to Freedom of Information Act laws in the UK). The contract did not involve *IQOS* and was designed to research quantitative models linking DNA adduct patterns with the formation of mutations in vitro (i.e. it aimed to develop research techniques for better assessing disease risk factors and could be used broadly across industries). An extract from the contract providing the full background purpose of the research is copied below for ease of reference:



#### Summary of the research plan

Exposure to DNA-reactive chemicals can lead to accumulation of mutations in critical cellular genes initiated by the formation of DNA adducts. DNA adducts involve the covalent binding of a reactive chemical to DNA. Their formation is one of the earliest events in a genotoxic mode of carcinogenesis. Levels of DNA adducts represent not only exposure, but account for differences in metabolic activation vs. detoxification as well as repair. Therefore, DNA adducts are candidate biomarkers for *bridging the gap between markers of exposure and markers for risk* of developing critical mutations and initiating carcinogenesis. Limitations in using DNA adducts as biomarkers for risk include the technical difficulty in measuring adducts, which occur at extremely low abundance, and the availability of predictive models for how adduct formation is associated with mutation frequency.

The broad objectives of this research are to establish a quantitative model linking DNA adduct patterns (levels and genomic location) with the formation of mutations in vitro. The goals of this project are to establish new analytical approaches for detecting DNA adducts in the genome of cells exposed to chemicals in vitro. The planned work will center on three specific aims:

- 1. Detection of total genomic burden of DNA damage in vitro
- 2. Detection of DNA damage in highly mutated cancer genes
- 3. Localization of DNA damage in Genomic Regions

The foundational approach laid out in these three aims with an initial focus on N2-BaP-G will be expanded to include additional structures such as 8-oxo-G, O6-Me-G, 7-NNK-G, N2-(4-hy-droxyphenyl)-2'-deoxyguanosine-3'-phosphate, other harmful and potentially harmful compounds (HPHCs) and their mixtures (e.g. TPM). The expected outcome will be quantitative in vitro strategies for evaluating mutation risk associated with chemical exposures.

ETH Zurich had full independent control over the study and results and are not limited in how they use the research. You will note there is not a single reference in the published research to *IQOS* or PMI's products – and the link you provided includes a full disclosure acknowledging both the funding and the independent nature of the research:

"We acknowledge funding from Philip Morris International and funding from the Swiss National Science Foundation (185020,186332), which funded independent research projects."

A reasonable reader of this can only draw the conclusion that the spokesperson for the Swiss Association for Tobacco Control is knowingly and falsely claiming that PMI paid a university to create a study to promote *IQOS* and that this cost one million Swiss Francs. There is no basis in which the Swiss Association for Tobacco Control can stand up this comment, which is untrue and defamatory, as shown by both the contract and the published research itself.

5. The European Respiratory Society Tobacco Control Committee published a position paper (see link below) in February 2024 stating that while the tobacco industry claims a 90-95% reduction in harmful and potentially harmful substances and toxicity for heated tobacco products, this is not the full picture.



### https://www.ersnet.org/news-and-features/news/ers-position-paper-on-heated-tobaccoproducts

The paper states that independent research shows these products actually emit substantial levels of carcinogenic, tobacco-specific nitrosamines, irritants and potential carcinogens, as well as similar nicotine and tar levels to a standard cigarette. In 2022, a systematic review by the University of Bath's Tobacco Control Research Group also concluded that PMI's clinical trials of its heated tobacco products were of poor quality and at high risk of bias.

#### https://tobaccocontrol.bmj.com/content/33/3/383

#### What is PMI's response to this?

Your representation of the European Respiratory Society's position paper is selective and misleading. Their conclusion states that "Even though heated tobacco products may perhaps be less harmful for smokers they nevertheless remain both harmful and highly addictive, and there may be a risk that smokers will switch to heated tobacco products instead of quitting. ERS cannot recommend any product damaging the lungs and human health." Further, in relation to *IQOS*, we refer you to the U.S. FDA's conclusions in granting modified risk status with reduced exposure claims, which are outlined above.

A systematic review conducted by independent researchers based in the UK evaluated clinical trials that could demonstrate the effectiveness and safety of Heated Tobacco Products ("HTPs") in quitting smoking. Comparing tobacco specific nitrosamines levels (NNAL) among HTP users compared to smokers, the authors concluded there was "moderate certainty evidence" that NNAL levels were lower among HTP users compared to smokers. It is important to note that the moderate certainty grade was downgraded from "high certainty" because of a perception of high risk of bias suggesting that a 'worst-case scenario' still shows evidence of a reduction in exposure to nitrosamines. (Heated tobacco products for smoking cessation and reducing smoking prevalence - Tattan-Birch, H - 2022 | Cochrane Library).

Furthermore, the U.S. FDA, German Federal Institute for Risk Assessment (BfR) and many others have conducted actual emissions test that consistently support reductions in toxicants from heated tobacco products compared to cigarettes. The BfR concludes "that levels of major carcinogens are markedly reduced in the emissions of the analyzed HNB [Heated Tobacco] product in relation to the conventional tobacco cigarettes and that monitoring these emissions using standardized machine smoking procedures generates reliable and reproducible data which provide a useful basis to assess exposure and human health risks."

6. Efthimios Zervas of the National Technical University of Athens says that as with cigarettes, heated tobacco products release fine particles, capable of penetrating deep into the body, along with toxic gaseous emissions.

https://pmc.ncbi.nlm.nih.gov/articles/PMC10986040

What is PMI's response to this?



The term "fine particles" refers only to particle size, without consideration of other important characteristics such as whether the particles are solid or liquid or their chemical composition. The generation of smoke from tobacco combustion leads to the formation of solid particles, with a median diameter below 100 nm. Conversely, the *IQOS* aerosol contains liquid droplets comprised of mainly water and glycerin. *IQOS* does not generate solid particles (see also Investigation of solid particles in the mainstream aerosol of the Tobacco Heating System THS2.2 and mainstream smoke of a 3R4F reference cigarette - P Pratte, S Cosandey, C Goujon Ginglinger, 2017).

PMI has never claimed heated tobacco products are safe or risk-free but numerous independent studies and reviews, including by the FDA, confirm our science that there is significant reduction in harmful and potentially harmful compounds compared to cigarette smoke. *IQOS* emits on average 90-95 percent lower levels of harmful chemicals compared with cigarettes.

While the reduction in HPHCs in *IQOS* aerosol compared to cigarette smoke has been clearly established, a small number of constituents may be higher in *IQOS* aerosol, due to fundamental differences in product design and blend. However, analysis on the whole aerosol has demonstrated a significantly lower toxic potential, compared to cigarette smoke. The toxicological risk of any of the constituents found at low levels in *IQOS* aerosol is significantly outweighed by the reduction in exposure to known HPHCs in cigarette smoke.

7. Silvano Gallus, the University of Bath's Tobacco Control Research Group, and the Campaign for Tobacco-Free Kids say that heated tobacco products may encourage people to consume more tobacco, citing studies such as the below 2023 paper detailing the results of various studies explains that a large proportion of users are so-called "dual users", which means that they both smoke and use heated tobacco products. Gallus says that dual users have a significantly higher risk of disease and premature death compared with smokers.

#### https://pmc.ncbi.nlm.nih.gov/articles/PMC9975263/

"Despite what Philip Morris says, we're seeing that a substantial proportion, if not the vast majority of users of heated tobacco products, are not using them exclusively," Sophie Braznell, a researcher in the University of Bath's Tobacco Control Research Group told the BBC. "And so then, what's the point? If you're not actually reducing tobacco consumption, it undoes any potential reduced harm effects, and the industry's just making money from people twice over."

#### What is PMI's response to this?

This is demonstrably false and once again these contributors are making unsubstantiated claims that they have not backed with data (nor could they as the data does not support these points).

It is not correct to state that "a large proportion of *IQOS* users are 'dual users'". Our data clearly demonstrates a conversion rate of 72% (see slide 42), where legal age smokers have fully switched to *IQOS* and stopped smoking. The remaining percentage of users are dual users, normally in various phases of switching fully away from cigarettes. Clearly, this is not the "vast majority of users", or even the majority. As set out above, data from our biggest *IQOS* market in Japan clearly



demonstrates that cigarette sales are in rapid decline with the Japanese Ministry of Health data showing exclusive smoking at a record low of around 10% of the adult population. Additionally, total tobacco sales (cigarettes and heated tobacco products combined) are not increasing, illustrating that those using heated tobacco are not using them in addition to cigarettes in large numbers. To give some sense of perspective, there were over 32 million *IQOS* legal age users in the world at the end of 2024, a large proportion in Japan alone, which shows there is more than enough real-world data to demonstrate that this claim by the authors is false.

We are clear that products like *IQOS* are addictive, and they are not risk-free, but switching completely to a smoke-free alternative is the better choice for any adult smoker than continuing to smoke cigarettes. This is also reflected in our U.S. FDA authorized MRTP claim for *IQOS*: "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 false statements put to us clearly show that your source is biased and unreliable, and indicate they represent the interest of their funder, Bloomberg Philanthropies.

8. According to this Reuters report from last year, PMI wants to get a 10% share of total U.S. cigarette and heated tobacco volumes within around five years of it launching the latest version of IQOS.

https://www.reuters.com/business/healthcare-pharmaceuticals/philip-morris-faces-keytest-with-us-heated-tobacco-push-2024-04-29/

#### Is this still correct?

As we said during our Q1 earnings call on April 23 2025:

"In the U.S., as planned, we commenced direct sales of *IQOS 3* devices and heated tobacco units in Austin, Texas at the end of March, following targeted engagement with legal-age nicotine consumers over recent months. While intentionally small-scale, we have received strong interest with further *IQOS 3* pilots planned in the coming months as we prepare for the at-scale launch of *IQOS ILUMA*. As a reminder, we are not assuming any significant HTU volumes from the U.S. in our full-year forecast."

Our marketing application for our more advanced *IQOS ILUMA* product in the United States remains under FDA review.

It should also be noted that PMI has never, and will never, sell traditional cigarettes in the United States and PMI has been separate from Altria and Philip Morris USA (who are quoted in the Reuters article) since 2008. Any suggestion to the contrary in the Proposed Article would not be accurate.

#### Conclusion

For the reasons outlined above, it is our view that the Proposed Article is based on the accounts of biased and inaccurate sources of information, which, if repeated wholesale, would produce an



article littered with inaccurate and/or defamatory allegations about PMI that will mislead the public on matters of public health.

If you nevertheless intend to proceed with publication of an article based on these sources, we encourage you to carefully consider our position above and ensure that it is fully reflected in the article in a fair, accurate and impartial manner in accordance with the Guidelines. Please also include this on the record statement in full:

### Statement for attribution to PMI Global Chief Communications Officer, Dr. Moira Gilchrist:

--Starts--

"We should all take a moment to celebrate that many public health experts contacted by the BBC have concluded that heated tobacco products are less harmful than combustible cigarettes. This fundamental principle underpins the promise that smoke-free products like IQOS hold for advancing global health and further validates PMI's commitment to a smoke-free future. We encourage the BBC to speak with one of the many millions of adults around the world who have switched to IQOS and stopped smoking to understand why they made that choice."

--Ends--

If any article that you may publish contains false allegations (particularly where we have corrected these above) and/or is not fair, accurate and impartial in compliance with the Guidelines, we reserve our rights in full.

Yours faithfully, Philip Morris International - Press Office

Avenue de Rhodanie 50 1007 Lausanne Switzerland