PHILIP MORRIS PRODUCTS S.A.

To: [redacted]

February 22, 2021

Tobacco Tactics - *Next Generation Products: Philip Morris International* – published on TobaccoTactics.org, accessed on February 17, 2021

Dear Mr. [redacted]

We are aware of an article "Next Generation Products: Philip Morris International"[1] (the **Article**) published on the Tobacco Tactics website (the **Website**), of which you are the Managing Editor. We note that the Website provides the Right of Reply[2] and with this letter, we are putting you on notice that the Article contains significant factual errors and misleading statements. We request that you correct these immediately. To assist you in this matter, a non-exhaustive list of examples of factual errors and misleading statements in the Article is provided in Annex 1.

We note that the Website provides a guide to writing (the **Guide**) and request that you revisit the Article in its totality and implement corrections forthwith, in line with your commitment to provide information that is "*objective, factual and well referenced, not subjective or judgemental*". We believe, and hope you do as well, that readers should not be misinformed or misled by the content of the Article and therefore look forward to seeing an updated version that is in line with your stated editorial principles.

In keeping with Philip Morris International's (PMI) commitment to fostering open and transparent dialogue, we will make our correspondence regarding the Article available to the public via our own website and through our owned media channels.

As our review of the Website continues, we may ask for additional corrections. All of our rights are hereby reserved.

Sincerely,

Dr. Moira Gilchrist

VP Strategic and Scientific Communications

[1] https://tobaccotactics.org/wiki/next-generation-products-philip-morris-international/ accessed February 17, 2021.
[2] https://tobaccotactics.org/wiki/right-of-reply/ accessed February 17, 2021.

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PHILIP MORRIS PRODUCTS S.A.

Annex 1

Non-Exhaustive List of Factual Errors and Misleading Statements in the Article

(1) The Article states *"In conjunction, PMI began making claims of corporate transformation and commitment to social change focussed on a smoke-free future:* [4] *"Society expects us to act responsibly. And we are doing just that by designing a smoke-free future."* [5] *By October 2019, PMI had replaced the word "designing" with "delivering" (a smoke-free future), signposting the central role of the company in the realisation of this future.* [6] [7] ***Despite the promising language, PMI's 2018 annual report revealed that the majority of the company's earnings still came from conventional cigarettes.*** [8] *(emphasis added)* ***At its 2019 Annual General Meeting, PMI CEO André Calantzopoulos further confirmed to shareholders that "Our combustible tobacco portfolio remains the foundation of our business".*** [9] *(emphasis added) Marlboro cigarettes remain key to PMI's business model.* [10]*"*

The referenced points and timeline are misleading: the authors of the Article reference a messaging change in October 2019 before attempting to negate our message with a report published nearly a year earlier and a meeting nearly half a year earlier. Moreover, we have been "delivering" on our commitment: Our full year 2020 results showed that almost one quarter of our net revenues were generated by smoke-free products. And, in just five years, approximately 12.7 million adult smokers around the world have already stopped smoking and switched to *IQOS*. As of December 31, 2020, *IQOS* is available in 64 markets.

Please adopt the following corrections to address this misrepresentation:

(a) Remove the sentences noting the 2018 report and 2019 meeting. OR
(b) Align the referenced timeline so that it is not misleading, and clarify the progress we have made on our commitment.

(2) The Article states *"In May 2017, Vaping Post quoted Calantzopoulos (from an interview with Nikkei Asian Review), saying that in five years' time (i.e. by 2022) "PMI could start talking to governments about phasing out combustible cigarettes entirely".* [11] *However, in 2020 PMI's business is still predominantly focused on the sale of conventional tobacco products. There is evidence of new cigarette brands being launched in low- and middle-income countries, and traditional tobacco products continue to be vigorously promoted.* [12] [13] [14]*"*

Again, the referenced points and timeline are misleading: the authors of the Article downplay the significant growth rate of our smoke-free products. As previously noted, as of December 31, 2020, 24 percent of our net revenues were generated by smoke-free products—up from approximately 13 percent in 2017. This is significant growth, which demonstrates the strength of our commitment to a smoke-free future. In just a few short years since we announced our commitment to a smoke-free future, revenues from products that are key to transitioning adult smokers who would otherwise continue to smoke away from cigarettes have increased from practically zero to almost one quarter of our net revenues. And, in just five years, approximately

12.7 million adult smokers around the world have already stopped smoking and switched to *IQOS*. As of December 31, 2020, *IQOS* is available in 64 markets.

Additionally, the false claim *"evidence of new cigarette brands being launched in low- and middle-income countries, and traditional tobacco products continue to be vigorously promoted,"* was in reference to a STOP report citing our brand "Philip Morris Bold" in Indonesia. This was not a brand launch but, in fact, a rebranding of an existing product with 0.3 percent market share. We have been totally transparent about the fact that our leadership position in the cigarette market gives us greater ability to convert smokers to smoke-free products and to finance our transformation to a smoke-free future, as evidenced from the progress noted above. Our business focus on smoke-free products to replace cigarettes as soon as possible is the same world-wide—including in Indonesia where *IQOS* is now present. We have begun introducing *IQOS* to communities of Indonesian adult smokers as part of our commitment. Approximately 95 percent of adult smokers in the country primarily smoke clove cigarettes. This dynamic is unique to Indonesia. Heated tobacco products like *IQOS* are different than cigarettes and as we do not have a clove product in our portfolio, understanding how Indonesian smokers will use and react to *IQOS* with non-clove consumables will be critical in our efforts to successfully convert adult smokers who would otherwise continue smoking.

Please adopt the following corrections to address this misrepresentation:

(a) Clarify that that the information provided is not a complete picture of the data concerning PMI's business and progress made. OR
(b) Include the additional information provided.
(c) Remove the sentence "*There is evidence of new cigarette brands being launched in low- and middle-income countries, and traditional tobacco products continue to be vigorously promoted.* [12] [13] [14]*"* OR
(d) Include the fact that no new brand was introduced.

(3) The Article states *"The year before the snus joint venture came to an end, PMI entered the HTP and e-cigarette (see below) markets. At the time, CEO Calantzopoulos told the Wall Street Journal that he believed the future was in HTPs "because they give uses [sic] a stronger and faster kick of nicotine, more akin to a regular cigarette". [20]"*

Quotes have been selected from the referenced article and taken out of their original context giving a misleading impression. The article actually says, *"André Calantzopoulos, CEO of Malboro-[sic]maker Philip Morris International, calls such new products "heat not burn" — tobacco is heated enough to release flavor and nicotine, but not enough to catch fire and make smoke. The company likes these products more than e-cigarettes because they give uses a stronger and faster kick of nicotine, more akin to a regular cigarette."*

Please adopt the following corrections to address this misrepresentation:

(a) Remove the sentence as it is not a quote from Mr. Calantzopoulos. OR

(b) Clarify that the quote actually came from Wall Street Journal reporter Tom Gara.

(4) The Article states *"IQOS uses a battery-operated device that heats tobacco sticks called HEETS, which are available in several flavours and sold under cigarette brand Marlboro. IQOS heats the tobacco up to 350°C, compared to 600 °C for heating (sic) cigarettes, and therefore, according to PMI there is no "combustion, fire, ash, or smoke" and "the levels of harmful chemicals are significantly reduced compared to cigarette smoke". [22] A subsequent peer reviewed study, using PMI's clinical data, concluded that IQOS was "not detectably different" from cigarettes, in terms of potentially harmful effects. [23]"*

The Article references a 2018 publication by an individual with well-known and strongly held negative opinions about PMI and *IQOS*. However, it fails to mention PMI's public responses and positions on these matters (e.g., PMI's response to the referenced study by Stanton Glantz), and the growing body of other independent studies related to *IQOS*. Additionally, since the 2018 Glantz paper was published, the U.S. FDA has authorized *IQOS* as a Modified Risk Tobacco Product (MRTP) with reduced exposure claims, and in doing so found that issuance of the MRTP Orders "is expected to benefit the health of the population as a whole" and is "appropriate to promote the public health".

Additionally, the Article's claim that *HEETS* (or *HeatSticks*) are "cigarettes" is misleading. In the U.S., FDA classifies *HEETS* as "non-combusted cigarettes," which *"consists of a heating source and tobacco. The tobacco may be wrapped in paper, which makes it a type of cigarette. However, the tobacco is heated to a lower temperature than a combusted cigarette to create an aerosol that the user inhales."*

Please adopt the following corrections:

(a) Remove sentence and/or all information related to the sentence *"A subsequent peer reviewed study, using PMI's clinical data, concluded that IQOS was "not detectably different" from cigarettes, in terms of potentially harmful effects. [23]," including the reference to the cited Stanton Glantz paper. OR
(b) Add that PMI has responded to the Stanton Glantz study [here] and that in the interim the FDA authorized *IQOS* as a Modified Risk Tobacco Product, issuing exposure modification orders. FDA's press release accompanying the Agency's decision can be found [here] while other documents relating to the MRTP authorization can be found [here].
(c) Clarify that *HEETS* are classified in the U.S. as "Non-Combusted Cigarettes".

(5) The Article states *"PMI conducted some user studies (which it submitted to the FDA), [25] but these were run over periods of only 4-6 weeks which limits the ability to generalise the findings as a reflection of **sustained** behavioural change." **(emphasis by Tobacco Tactics).***

The Article fails to identify that, as part of FDA's decision to issue exposure modification orders, PMI is required to conduct postmarket surveillance and studies, including studies expressly

measuring *IQOS* use behavior, as well as consumer understanding and perception (among other things).

Please adopt the following corrections.

(a) Add that PMI has noted that the description in this Article misleadingly portrays the FDA's MRTP decision as well as the rigorous postmarket surveillance and studies required, as part of that authorization. FDA's press release accompanying the Agency's decision to issue exposure modification MRTP marketing orders can be found [here] while other documents relating to the MRTP authorization can be found [here].

(6) The Article states *"PMI also estimates the number of users in the process of "conversion" to using IQOS.[824]. However, PMI defines an IQOS user as an adult who has only used IQOS for a minimum of 5% of their daily tobacco consumption in the previous seven days. It is likely that the actual number of people who use IQOS exclusively, or for most of the time, is lower than PMI's estimates. In addition, its statements on smoking cessation are based on the assumption that current dual users of tobacco and IQOS (of which there are significant numbers, even according to PMI's own research)[25] will* ***all*** *give up smoking cigarettes, and not restart later, and that very few non-tobacco users will take up IQOS.[26] In 2020, PMI claimed that over 10 million smokers had switched to IQOS, with another 4 million "in conversion".[2427] It states that its "aspiration" is for the number of smokers switching to IQOS to exceed 40 million by 2025.[28]"* ***(emphasis by Tobacco Tactics)***

The Authors speculate that the true number of users who use *IQOS* exclusively or for the majority of their tobacco consumption is significantly lower than PMI estimates. They completely fail to provide any facts to back up this assertion. For the sake of clarity, we have transparently published the methodology and basis for our calculations. "Total *IQOS* users" is defined as the estimated number of Legal Age (minimum 18 years) *IQOS* users that used PMI HTUs for at least 5 percent of their daily tobacco consumption over the past seven days. The estimated number of people who have "switched to *IQOS* and stopped smoking" is defined as:

- for markets where there are no heat-not-burn products other than PMI heat-not-burn products: daily individual consumption of PMI HTUs represents the totality of their daily tobacco consumption in the past seven days;
- for markets where PMI heat-not-burn products are among other heat-not-burn products: daily individual consumption of HTUs represents the totality of their daily tobacco consumption in the past seven days, of which at least 70% is PMI HTU.

As of December 31, 2020, PMI estimates that 12.7 million have switched to *IQOS* and stopped smoking.

It is unclear why the Authors claim that *IQOS* is a cessation product when PMI is clear that it is not. This is explained in, for example, PMI's Good Conversion Practices.

Further, in issuing the MRTP exposure modification orders, the FDA found that consumer perception study results did not raise concerns that *IQOS*, if marketed with the proposed reduced exposure claim, would *"generate a high level of interest among never smokers or former smokers."*

More recently, upon authorizing the *IQOS 3* device for sale in the U.S. on December 7th 2020 via the supplemental PMTA pathway, FDA noted that *"use patterns available for IQOS 2.4 within the U.S. have not raised new concerns regarding product use in youth and young adults."*

It should be noted that *IQOS 3* is not yet authorized as an MRTP, although PMI plans to submit a MRTPA for this version of the device.

Please adopt the following corrections:

(a) Remove the sentences, *"However, PMI defines an IQOS user as an adult who has only used IQOS for a minimum of 5% of their daily tobacco consumption in the previous seven days. It is likely that the actual number of people who use IQOS exclusively, or for most of the time, is lower than PMI's estimates."* OR
(b) Provide an accurate explanation aligned with the facts clearly noted in our reports.
(c) Add a clarifying statement that *IQOS* is not a cessation product, is not marketed as such, and is not intended to help smokers quit tobacco and nicotine altogether – the best choice any smoker can make.
(d) Provide context that FDA found in issuing exposure modification orders for *IQOS* that *"the currently available evidence suggests that youth uptake of IQOS is currently low in countries where it has been measured."*
(e) Update the numbers of estimated *IQOS* users to align with the latest available data.

(7) The Article states *"The Australian government also continued to reject the product."* This claim is a misleading statement, as it implies that the "rejection" relates specifically to *IQOS*. In fact, the legislation bans all nicotine containing products other than the most harmful form—combustible cigarettes.

Please adopt the following corrections:

(a) Remove the sentence *"The Australian government also continued to reject the product."* OR
(b) Clarify the Australian government's ban prohibits all nicotine containing products except for combustible cigarettes.

(8) The Article states "*This followed approval from the US Food and Drug Administration (FDA) to launch the product on the US market (albeit without the desired "Modified Risk" status).* [31] [32] [33] *On 7 July 2020, the FDA partially approved PMI's Modified Risk Tobacco Product application. While it concluded that the data PMI submitted showed that IQOS may reduce exposure to harmful*

substances, it did not agree that IQOS reduces the risk of disease and death, compared to smoking cigarettes, and so had failed to meet the higher standard of "risk modification"."

The sentence "*This followed approval from the US Food and Drug Administration (FDA) to launch the product on the US market (albeit without the desired "Modified Risk" status),"* is misleading as it implies that PMI sought and failed to secure modified risk orders for *IQOS* through the premarket tobacco pathway. The 2019 decision concerned the PMTA application—of which a modified risk order was not at issue—but did concern FDA's decision authorizing commercialization of *IQOS* as "appropriate for the protection of public health".

FDA does not approve tobacco products. FDA authorizes tobacco products if they meet the standard outlined in U.S. Federal Food, Drug, and Cosmetic Act ("FDCA"). It does not recognize the concept of partial authorization.

FDA does not have two standards for assessing modified risk. Rather, the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA") provides that a tobacco product may be authorized as a Modified Risk Tobacco Product under FDCA Section 911(g)(1) or FDCA Section 911(g)(2). A product authorized under either section is a Modified Risk Tobacco Product by virtue of the application, as well as the definition of the term in FDCA Section 911(b)(1). Further, under Section 911(g)(2), to issue an exposure modification order, FDA must find, among other things, that the applicant has demonstrated that issuance of an order with respect to the application is "appropriate to promote the public health" and "is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." [FDCA Section 911(g)(2)(A)(i), (B)(iv)]. Note, the distinction between "expected," which dictionaries define as "to consider probable or certain," and "potential," which dictionaries define as "existing in possibility." Accordingly, the article suggests that FDA could have issued its authorization on the basis of mere possibility, as opposed to probability.

Additionally, FDA did not disagree with the statement *"that IQOS reduces the risk of disease and death, compared to smoking cigarettes."*

IQOS received exposure modification orders under FDCA Section 911(g)(2), which authorized the *IQOS* system to be sold in the United States with the following information: *"the IQOS system heats tobacco but does not burn it," "this significantly reduces the production of harmful and potentially harmful chemicals,"* and *"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."* Thus, it is simply inaccurate to state "*While [FDA] concluded that the data PMI submitted showed that IQOS may reduce exposure to harmful substances, it did not agree that IQOS reduces the risk of disease and death, compared to smoking cigarettes, and so had failed to meet the higher standard of "risk modification"*." FDA's determination was based on the substantial reductions across the constituents on FDA's HPHC list, which demonstrates that, on the whole, as compared to cigarette smoke, the process used to heat tobacco in the *IQOS* system significantly reduces the production of harmful and potentially harmful chemicals

compared to cigarette smoke. Indeed, this is why FDA authorized the claim that *"scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful and potentially harmful chemicals."* While the FDA concluded that the evidence did not support issuing risk modification orders at this time, FDA did conclude that the evidence supported issuing exposure modification orders. This determination included a finding that issuance of the exposure modifications orders is appropriate to promote public health and is expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products. Further, FDA found that the 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 to be established in subsequent studies.

Please adopt the following corrections:

(a) Please change "approval" and "approved" to "authorization" and "authorized", respectively. FDA does not "approve" tobacco products.
(b) Clarify that FDCA (as opposed to FDA) provides for authorization of modified risk tobacco products under two different statutory provisions (i.e., Section 911(g)(1) and Section 911(g)(2)).
(c) Clarify that PMI's MRTP application for *IQOS* requested authorization under both g(1) and g(2) and that to issue an exposure modification order PMI had to demonstrate that issuing an exposure modification order for *IQOS* would be *"appropriate to promote the public health"* and *"is expected the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products."* [FDCA Section 911(g)(2)(A)(i), (B)(iv)].
(d) Clarify that the FDA authorized the reduced exposure claim *"switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."* Thus, FDA found that switching completely to *IQOS* does, in fact, reduce exposure to harmful (or potentially harmful) substances. Note, the distinction between the Article's false statement that *IQOS* "may" reduce exposure to harmful substances.
(e) Remove the sentence that suggests FDA agreed that *IQOS* does not reduce risk of disease and death when compared to cigarette smoking. AND/OR
(f) Correct the sentence to state, *"FDA concluded evidence did not support issuing risk modification orders at this time. However, FDA also found that 'the 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 to be established in subsequent studies.'"*

(9) The Article states *"In October, PMI also announced that it had launched in Jordan, although the precise timing and nature of the launch was unclear.[3942] In 2020, Jordan had the world's highest smoking rates, and experienced a large amount of tobacco industry interference, including by PMI.[43] For more information see the Eastern Mediterranean Region page."*

The authors fail to include our response to the allegation, which is actually included in the cited article. The article made allegations in relation to the following actions: 1) *"PMI attended a series of meetings last year to discuss standards for e-cigarettes and heated tobacco products,"* 2) *"Philip Morris paid to refurbish 10 schools in the Amman neighbourhood where its factory is located, and provided children in 25 schools with bags and stationery,"* and 3) *"Philip Morris has also run careers training programmes…"*

PMI's response to these statements were included in the article and were, respectively:

- *"Our interactions with government officials in Jordan – like elsewhere – comply with all applicable laws," PMI said. "In addition, we abide to our own international standards and practices which are stricter than many national laws. In any democratic society, the central objective of regulatory policy – ensuring that regulations are designed and implemented in the public interest – can only be achieved with full participation of those concerned."*
- *"PMI said its factory was located in an underprivileged area "where the local community has often requested much needed in-kind support and aid". "It is saddening that even actions to improve the living conditions of people around our factory might be seen as a reason to attack us," the company said."*

Please adopt the following correction to address this misrepresentation:

(a) Include specifics to show that the alleged "interference" was, in fact, a lawful charitable contribution and lawful discussions with regulators.

(10) The Article states *"Although it does not disclose its marketing spend, PMI has allocated a large amount to advertising and promoting IQOS.[826] As well as retail websites and distribution deals, it has established dedicated 'concept' stores around the world to promote its products direct to its customers, with multiple stores in some cities (see below). It has developed sophisticated, multi-platform advertising campaigns, using traditional and social media.(For examples see images from Stanford University's research into the impact of tobacco advertising and work by the Campaign for Tobacco Free Kids). It has also promoted its products at music festivals and cultural events in glamourous locations around the world.[263749] PMI has been accused of marketing IQOS and other NGPs to youth, including through the use of paid social media influencers. [2637495051]"*

At PMI, we have a clear and unambiguous position on youth use and access to tobacco and nicotine products: Youth should not use tobacco and nicotine products in any form. We do not market our products to youth. Our actions are governed by marketing standards and Good Conversion Practices.

Additionally, the referenced Stanford University research includes many images for which PMI was not responsible. The referenced Campaign for Tobacco-Free Kids report includes similar

pictures, such as a "Marlboro Originals" clothing store in South America that is not connected to PMI.

We use age-verification to control access to our Social Media Brand Activation Accounts. We utilize best practices from various countries and industries to reduce the likelihood of youth being exposed to our brand communications through our Social Media Brand Activation Accounts. Additionally, PMI has ended the digital influencer program. The authors repeat unfounded allegations regarding digital influencers for *IQOS*, despite the fact that this program ended in 2019. No laws were broken, as implied by the Authors—the program was ended due to an internal company decision.

In issuing the MRTP, the FDA found that consumer perception study results did not raise concerns that *IQOS*, if marketed with the proposed reduced exposure would *"generate a high level of interests among never smokers or former smokers."* More recently, upon authorizing the *IQOS 3* device for sale in the U.S. on December 7th 2020 via the PMTA process, FDA noted that *"use patterns available for IQOS 2.4 within the U.S. have not raised new concerns regarding product use in youth and young adults." IQOS 3* is not yet authorized for sale as an MRTP, although PMI plans to submit a MRTPA for this version of the device.

The available evidence demonstrates that there is no significant issue with youth uptake of *IQOS*. In Japan, the largest *IQOS* market and the first country where the product was commercialized, we are encouraged by the results of a recent study conducted under a Japanese Ministry of Health research grant, which showed that 0.1% of high-school students were daily users of heated tobacco products.[3] Further, the most current study on youth smoking behavior by the Federal Center for Health Education (BZgA), Germany's highest smoking-prevention authority, clearly shows that heated tobacco products are products that smokers switch to and are not an initiation mechanism for minors.

Please adopt the following corrections to address this misrepresentation:

(a) Clarify that the referenced Stanford University and Campaign for Tobacco-Free Kids reports include pictures for which PMI was not responsible.
(b) Amend your statements with clarifying content that we have provided above including FDA's statement that *"the currently available evidence suggests that youth uptake of IQOS is currently low in countries where it has been measured."* OR
(c) Remove the statement from the Article.

(11) The Article states, *"PMI's promotion of IQOS is inextricably linked to its "Smoke-Free" public relations strategy, and campaigns such as "Hold My Light" and "UnSmoke Your World". Research published in February 2020 by Stanford University shows how PMI's promotional activities not only*

[3] *Osaki Y, et al. "Field survey on drinking and smoking and the development of effective alcohol reduction intervention approaches for the prevention of lifestyle-related diseases." Annual Report of MHLW Research Committee, May 2018.*

replicate advertising strategies used in the past to promote cigarettes, but also help to "normalize" the company and its heated tobacco products in the eyes of the consumer. [264952] *This normalization increases pressure on policy makers to regulate these products in ways that benefit the industry, particularly in lower income countries."*

The advertising allegations conveyed are false and misleading.

"UnSmoke Your World" is not a marketing campaign and it does not promote or advertise any PMI or third-party tobacco or nicotine containing product brands.

The purpose of the "Hold My Light" campaign was to provide information to adult smokers (and their supporters) about the wide range of choices to help them quit completely (such as NHS services) or for those who don't quit, to provide factual information on switching to better alternatives to continued smoking. It also asked smokers to make an initial commitment to going smoke free for 30 days with the support of friends and family who could make a simple gesture of support of their choosing (such as buying them a meal) to reward them for successfully going smoke free. The campaign did not and was never intended to promote any PMI products. It was about getting smokers to begin their smoke free journey.

Please adopt the following corrections to address this misrepresentation:

(a) Substantiate claims such as, "*This normalization increases pressure on policy makers to regulate these products in ways that benefit the industry, particularly in lower income countries,"* with facts and data. OR
(b) Remove the sentence.
(c) Clarify that neither campaign was used to promote our products.

(12) The Article states *"The most recent addition was developed in-house: IQOS Mesh (see image 3), the only PMI e-cigarette labelled under the IQOS brand. CEO Calantzopoulos informed investors in December 2019 that Mesh was ready for further commercialisation, but that a global roll-out had been postponed due to the backlash against e-cigarettes following the sudden deaths of a number of vapers in the US.*[19] *In January 2020, the roll-out appeared to be going ahead, with Calantzopoulo (sic) announcing "a launch in the coming months".*[54] *However it was delayed further by the Covid-19 pandemic and finally launched under the Veev brand name in September 2020.*[3955]*"*

The Article references the "sudden deaths of a number of vapers in the US[,]" but fails to provide proper context for the "e-cigarette, or vaping, product use-associated lung injury" ("EVALI") outbreak sharply increasing in August 2019. Specifically, it fails to mention that the U.S. Centers for Disease Control ("CDC") stated that "tetrahydrocannabinol (THC)-containing e-cigarette, or vaping products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak." CDC also stated that "Vitamin E acetate is strongly linked to the EVALI outbreak."

Please adopt the following corrections to address this misrepresentation:

(a) Please clarify that the EVALI related vaping deaths which occurred in 2019 were traced back to the inclusion of vitamin-E acetate in THC-containing vaping cartridges and were not associated with traditional e-cigarette products.
(b) In addition, as a technical matter, please ensure that the spelling of PMI's CEO's name is accurately reflected as "Calantzopoulos"

(13) The Article states, *"Although PMI has been promoting a "smoke-free" narrative, including funding the Foundation for a Smoke-Free World and its "Unsmoke" marketing campaign, it has also been working to undermine smoking bans and enable the use of IQOS in smoke-free areas.[37]"*

With respect to The Foundation for a Smoke-Free World ("Foundation"): The foundation holds U.S. nonprofit status and is an independent body governed by its own independent board of directors. The Foundation's role, as set out in its corporate charter, includes funding research into the field of tobacco harm reduction, encouraging measures that reduce the harm caused by smoking, and assessing the effect of reduced cigarette consumption on the industry value chain. The Foundation is an independent entity and makes its own decisions.

With respect to the "Unsmoke" campaign please see (11) above.

PMI agrees that tobacco products should be appropriately regulated. At times, we have objected forcefully to measures that would do nothing to dissuade people from starting to smoke or encourage cessation. But it's equally clear that millions of men and women will continue to smoke, and they should have the opportunity to switch to better alternatives.

Please adopt the following corrections to address this misrepresentation:

(a) Remove the cited sentence.
(b) Provide background on the Foundation as well as the purpose of the Unsmoke campaign.
(c) Clarify that PMI agrees that tobacco products should be subject to strict rules and enforcement and link to our webpage providing our principles and position on regulation.

(14) The Article states, "*Just two months after the public smoking ban was introduced in the Czechia (then the Czech Republic) in 2017, PMI promoted IQOS on Radio Praha to Czech smokers, which according to the radio station "might allow them [smokers] to 'smoke' in public places once again". [61]"*

The Article quotes an inaccurate statement made by the above-referenced radio station and insinuates that PMI was the entity making the inaccurate claim to entice smokers to switch to *IQOS*. In fact, the radio station was the entity that made the claim.

Please adopt the following correction to address the misrepresentation:

(a) Clarify that PMI did not endorse, encourage, or entice Radio Praha's inaccurate statement.

(15) The Article states, "*In February 2020, an investigation by The Guardian newspaper revealed that, in the UK, PMI lobbied for lighter regulation of IQOS, as a "considerably less harmful novel smokeless tobacco product" (CLHTP). PMI also proposed setting up a UK£1 billion fund for cessation services in exchange for the relaxation of advertising regulations for e-cigarettes and HTPs.* [65] *It also tried to get IQOS adopted as a cessation product in New Zealand.*"

PMI supports the government's commitment to make England smoke-free by 2030. To realize this ambition, millions of current smokers need to be persuaded to quit altogether or switch to less harmful alternatives. A regulatory framework that ensures smokers have the facts about alternatives and that tobacco companies are pushed to phase out cigarettes will be critical to this effort. We have made this point time and time again to MPs, civil servants, local councillors, journalists and the broader public. What this story really shows is that Philip Morris International has been consistent in its efforts to make smoke-free 2030 a reality.

Additionally, and as stated in point six above, PMI is clear that *IQOS* is not a cessation product. See for example PMI's Good Conversion Practices.

Please adopt the following corrections to address the misrepresentation:

(a) Include our response to The Guardian's claims.
(b) Substantiate and cite the accusation that "[PMI] tried to get *IQOS* adopted as a cessation product in New Zealand." OR
(c) Remove the sentence.

(16) The Article states, *"PMI has also taken advantage of tobacco control measures being implemented in the UK in order to promote its HTPs. In January 2019, PMI announced that it would be selling IQOS and menthol HEETS sticks in the UK, ahead of the deferred EU Tobacco Products Directive ban on menthol cigarettes (due to come into effect in May 2020).*[66676869]"

This statement is factually wrong and implies that we introduced menthol *HEETS* in the UK to circumvent the menthol ban. We launched *IQOS* in the UK on November 30, 2016—almost three years before the EU Tobacco Products Directive ban on menthol cigarettes came into effect in May of 2020. The UK launch included the "Turquoise *HEETS*" menthol variant.

Please adopt the following correction to address the misrepresentation:

(a) Clarify that PMI began selling menthol *HEETS* in the UK in 2019. OR
(b) Remove both sentences.

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