PHILIP MORRIS PRODUCTS S.A.

To: STOP: Stopping Tobacco Organizations & Product [redacted]

December 18, 2020

STOP: Stopping Tobacco Organizations and Products factsheet - *The U.S. FDA Ruling on IQOS: Spin vs Truth* - published on ExposeTobacco.org accessed via TobaccoTactics.org

Dear [redacted]

We refer to your factsheet, "*The U.S. FDA Ruling on IQOS: Spin vs Truth*" (the **Article**), and we are writing to put you on notice that it contains significant factual errors and misleading statements. We request that you correct these immediately. Annex 2 includes a non-exhaustive list of examples, while Annex 1 provides important contextual information for your consideration and guidance.

Please revisit the Article in its totality and implement corrections in line with your commitment to *"collecting data and investing in comprehensive research"* and drawing upon the expertise of your *"investigative journalists, epidemiologists, former civil servants, advocates, storytellers and more."*[1] We also note that Vital Strategies "*is committed to conducting itself according to the highest standards of ethical conduct and seeks to avoid even the appearance of impropriety in its actions."*[2] Further, we note Tobacco Tactics'—a program established by the Tobacco Control Research Group (TCRG) at the University of Bath—commitment to provide information that is "*objective, factual and well referenced, not subjective or judgemental."*[3] We look forward to hearing from you and seeing the Article updated in line with your stated commitments.

In keeping with our commitment to foster open and transparent dialogue, we will make our correspondence regarding the erroneous information you have published available on our website and owned media channels.

If you are not the person in your organization who deals with matters of accuracy in published materials, please forward to the most appropriate person as a matter of urgency.

Sincerely,

Dr. Moira Gilchrist
VP Strategic and Scientific Communications

[1] About - STOP (exposetobacco.org) accessed December 9, 2020
[2] Combatting Corruption and Bribery | Vital Strategies accessed December 10, 2020
[3] https://tobaccotactics.org/wiki/guide-to-writing/ accessed December 03, 2020

Philip Morris Products S.A., Avenue de Rhodanie 50, 1007 Lausanne, Switzerland
T:**+41 (58) 242 00 00**, F: **+41 (58) 242 01 01**, W: **www.pmi.com**

PHILIP MORRIS PRODUCTS S.A.

Annex 1

Contextual Information Regarding the Subject Matter of the Article

On July 7, 2020, the U.S. Food and Drug Administration (FDA; the **Agency**) authorized the marketing of Philip Morris Products S.A.'s *IQOS* Tobacco Heating System as modified risk tobacco products (MRTPs)[4]. In their accompanying press release[5], FDA stated that these were *"the first tobacco products to receive "exposure modification" orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population."* FDA's press release also notes that *"There are two types of MRTP orders the FDA may issue: a "risk modification" order or an "exposure modification" order. The company had requested both types of orders for the IQOS Tobacco Heating System. After reviewing the available scientific evidence, public comments and recommendations from the Tobacco Products Scientific Advisory Committee, the FDA determined that the evidence did not support issuing risk modification orders at this time but that it did support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole."*

FDA's authorization[6] states 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 (section 911(g)(2)(A) of the FD&C Act)."* The authorization explains why *IQOS* is fundamentally different from cigarettes. FDA is clear that reduced exposure to harmful chemicals does not render the *IQOS* Tobacco Heating System harmless. Nevertheless, reduced exposure statements are permitted for products authorized under the MRTP pathway and FDA has now allowed use of reduced exposure statements related to our *IQOS* tobacco heating system—the first and only electronic nicotine product to be granted marketing orders through the FDA's MRTP process. With this authorization, FDA has explicitly permitted that exposure reduction information be made available to consumers.

PMI makes clear that *IQOS* is not risk free; it is addictive; it is not a cessation aid and we do not present or market it as such; the best choice any smoker can make is to quit tobacco and nicotine altogether. Those adult smokers who do not quit deserve access to and accurate information about better alternatives, such as *IQOS*. Governments, regulators, scientists and the public health community deserve to hear the truth about U.S. FDA's historic decision in order that they can decide for themselves how best to modernize tobacco regulation and leverage innovations like *IQOS* in the interests of public health.

###

[4] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders accessed December 08, 2020.
[5] https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heatingsystem-reduced-exposure-information accessed December 09, 2020.
[6] https://www.fda.gov/media/139796/download accessed December 09, 2020.

Philip Morris Products S.A., Avenue de Rhodanie 50, 1007 Lausanne, Switzerland
T:**+41 (58) 242 00 00**, F: **+41 (58) 242 01 01**, W: **www.pmi.com**

Annex 2

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

Of the Article's numerous inaccuracies, the most serious and misleading are detailed below. In addition to addressing these points, we respectfully request that the authors of the Article review it in its entirety and correct any additional factual errors or misleading statements.

(1) The Article states: *"Even if only one of these standards (e.g., risk modification or exposure modification) is met, a company might claim MRTP status, which creates confusion as to whether a product actually reduces risk."*

It is unclear what this claim about creating confusion is based on. The Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA") is clear. It 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). A product may be sold or distributed as a "modified risk tobacco product" if it receives FDA authorization through the issuance of an exposure modification or risk modification order. FDA explicitly considered PMI's consumer perception studies and determined that *"consumers generally comprehend the modified risk information in the context of total health."*[7] In particular, the results of PMI's studies *"indicate that consumers understand that the product is not without risks and that it is more harmful than quitting smoking. Consumers also generally perceive the product as less harmful than combusted cigarettes, which is in line with the relative health risks of the product that are reasonably likely."*[8] Thus, FDA determined that PMI's consumer perception studies show that consumers accurately perceived the health risks of the product, which were in line with the risks that were reasonably likely. What is more, FDA stated 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 (section 911(g)(2)(A) of the FD&C Act)."* [9]

Please adopt the following actions:

(a) Clarify that a product may be sold as a modified risk tobacco product (MRTP) if FDA issues an exposure modification or risk modification order.

[7] Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act - Technical Project Lead [hereinafter, the IQOS MRTP TPL], at 50: Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov).
[8] IQOS MRTPA TPL, at 50: Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)
[9] IQOS MRTPA TPL, at 71: Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)

(b) Add a statement clarifying the requisite statutory findings. Specifically, add a statement explaining that the requisite statutory findings under Section 911(g)(2), which include findings that, among other things, issuing a marketing order would be appropriate to promote the public health, that the magnitude of the overall reduction in harmful substances is substantial, and that the scientific evidence that is available, without conducting long term epidemiological studies, demonstrate that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies. 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, the totality of evidence suggests that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely to be established in subsequent studies. To be clear, *IQOS* is not "risk-free," it delivers nicotine, which is addictive. However, the FDA's decision clarifies that *IQOS* is a modified risk tobacco product and that is why the Agency issued an authorization for the product that allows it to be marketed in the United States with reduced exposure information.

(c) Remove the statement that suggests the two standards "create confusion" as a product can be an MRTP if either standard is met.

(2) The Article states: *"SPIN: The FDA "approved" IQOS"*

This is inaccurate and misleading. PMI has been very clear that FDA authorizes, but does not "approve" tobacco products. Any suggestion otherwise contradicts the FDA's MRTP exposure modification order and U.S. law. The FDA press release is very clear: *"Even with this action, these products are not safe nor 'FDA approved.' The exposure modification orders also do not permit the company to make any other modified risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers."*[10]

Please take the following actions:

(a) Clarify that FDA does not "approve" tobacco products and that the FDA issued an exposure modification order authorizing *IQOS* for sale in the United States with reduced exposure information.

(3) The Article states:

[10] FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA

"TRUTH: The FDA ruled that IQOS met its lower "exposure modification" standard, but did not meet its more important "risk modification" standard.
• This means that while IQOS may reduce exposure to harmful substances, it has not been proven to reduce the risk of disease and death compared with smoking cigarettes.
• IQOS did not meet the "risk modification" standard because PMI "…has not demonstrated that… [IQOS]…. will significantly reduce harm and the risk of tobacco-related disease."

(a) *IQOS* received an exposure modification order under FDCA Section 911(g)(2), which authorized *IQOS* 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 that FDA ruling *"means that IQOS* ***may reduce exposure*** *to harmful substances"* (***emphasis added***)**.**

FDA's determination was based on the substantial reductions across the constituents on FDA's Harmful and Potentially Harmful Constituents (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 HPHCs 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 or potentially harmful chemicals."*[11]

(b) The statements (i) that FDA's ruling means that *IQOS "has not been proven to reduce the risk of disease and death compared with smoking cigarettes"* and (ii) that *IQOS* did not meet the "risk modification" standard because PMI *". . . has not demonstrated that . . . [IQOS] . . . will significantly reduce harm and the risk of tobacco-related disease,"* are provided without full context leading to a misrepresentation of the facts.

The Article states that *IQOS* did not meet the "risk modification" standard because PMI *". . . has not demonstrated that . . . [IQOS] . . . will significantly reduce harm and the risk of tobacco-related disease,"* referencing the Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act -Technical Project Lead document (the **IQOS MRTP TPL**). Whilst the IQOS MRTP TPL is a factually accurate source, the authors of the Article selected only one phrase ("*has not demonstrated that . . . [IQOS] will significantly reduce harm and the risk of tobacco-related disease*") from a much wider and more complex commentary from FDA.

[11] IQOS MRTP TPL, at 11, 39 and 40 Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)

The FDA determined "*the evidence did not support issuing risk modification orders* ***at this time"*** [12] ***(emphasis added)*** but that "*it did support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders* ***is expected to benefit the health of the population as a whole****." [13]* ***(emphasis added)***

Further, FDA found 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*** *to be established in subsequent studies (section 911(g)(2)(A) of the FD&C Act)."*[14] ***(emphasis added)****.*

Please adopt the following corrections:

(a) 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 statement that FDA's ruling means that *IQOS* "may" reduce exposure to harmful substances and correct the statement referenced under 3(a) above.

(b) Remove the statements noted above under subparagraph 3(b) above; OR

(c) Correct/amend them 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.'"*

(4) The Article states: *"PMI called the decision a "historic public health milestone," even though it included this warning in its MRTP application: "Using the IQOS system can harm your health.""*

FDA clearly recognizes that tobacco products exist on a continuum of risk. The Agency's decision affirms that *IQOS* is fundamentally different from combustible cigarettes. PMI rightly celebrated the decision as a public health milestone because it was, and still is, the first MRTP authorization for an innovative electronic alternative to cigarettes. PMI is clear that *IQOS* is not risk-free, it delivers nicotine which is addictive. However, the quoted statement was one of several potential warning statements tested to ensure that consumers properly understood reduced risk and reduced exposure information that were key parts of the application.

Our findings to date regarding *IQOS* are a matter of public record.[15] Based on these findings, we sought FDA's authorization of *IQOS* as an MRTP with modified risk claims, including exposure

[12] FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA
[13] FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA
[14] IQOS MRTP TPL, at 71 Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)
[15] https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications

modification and risk modification messages. The article takes the above statement completely out of context to create a misleading impression.

The correct context is that statement referenced above was tested in conjunction with PMI's reduced exposure message to demonstrate consumer understanding of the reduced exposure information with a variety of different pieces of contextual information. However, FDA stated in the IQOS MRTP TPL that *"…the currently available evidence suggests that, in general, disclaimers on tobacco products are often limited in their effectiveness. Accordingly, I do not expect that the disclaimer would improve consumer understanding. As noted above, testing of actual consumer perception shows that as the applicant proposes to label and market the product (without a disclaimer), consumers will not be misled about the current state of the evidence regarding the relative health risks of the product. Overall, the available evidence demonstrates that consumers generally understand the relative health risks of the product that are reasonably likely, which would be expected to impact behavior in a way that promotes public health."*[16] As such, the disclaimer was not required in the marketing order.

Please adopt the following correction to address this misrepresentation:

(a) To provide the correct context, clarify that the cited PMI "important warning" was one of several warnings tested in conjunction with the authorized reduced exposure message to demonstrate consumer understanding of the reduced exposure information with a variety of different pieces of contextual information. Please also note in your article that FDA did not require the application of this warning in the Marketing Order for *IQOS*.

(5) The Article states: *"PMI has a history of targeting young people and non-smokers, justifying the FDA's concern about a potential increase in IQOS use among these groups."*

The statement is given without any specific substantiation.

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[17] and Good Conversion Practices.[18]

(a) We are not aware of any studies or data that would lead us to believe that our marketing practices are resulting in worrisome levels of youth uptake of any of our smoke free products and STOP does not produce any data in support of the allegation. STOP claims that PMI has a history of targeting young people and non-smokers. To support this allegation, STOP effectively cites its own opinion by referencing its own report from a February 2020 (the **STOP Report**) as a source. The STOP Report is replete with false claims and speculation. Additionally, whilst it mentions PMI in

[16] IQOS MRTP TPL, at 13.
[17] Marketing Standards | PMI - Philip Morris International
[18] Good conversion practices for PMI's smoke-free products | PMI - Philip Morris International

its title, the STOP Report only deals with PMI in two out of five of its chapters. We have published a brief review of our views on the STOP Report on our corporate website, which we could encourage the Article authors to read.[19]

(b) In terms of the statement about FDA's concerns about a '*potential increase in IQOS use'*, STOP simply references the IQOS MRTP TPL. It is unclear what this statement is based on since FDA clearly states: *"the currently available evidence suggests that youth uptake of IQOS is currently low in countries where it has been measured."*[20] Further, in issuing the MRTP, the FDA found that consumer perception study results did not raise concerns that the proposed MRTP would *"generate a high level of interests among never smokers or former smokers."*[21] More recently, upon authorizing the IQOS 3 device for sale in the U.S. on December 7th 2020, 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.[22]

Please adopt the following corrections:

(a) Provide specific evidence to substantiate your allegations; AND
(b) Provide context that FDA found that *"the currently available evidence suggests that youth uptake of IQOS is currently low in countries where it has been measured."*[23] OR
(c) Remove the statement from the Article.

(6) The Article states: *"if taken up in large numbers, especially by those who otherwise wouldn't have smoked, HTPs could harm public health."*

Although we cannot speak to the entire category of HTPs, with respect to *IQOS*, FDA specifically found that issuing an exposure modification order for *IQOS* is *"appropriate to promote the public health"* and *"is expected to benefit the health of the population as a whole"*[24] considering both users and nonusers of tobacco products. In doing so, the Agency had to take into account the "…increased or decreased likelihood that persons who do not use tobacco products will start using the modified risk tobacco product…"[25] and specifically found that there was an expected benefit to the U.S. population as a whole. In any event, PMI is clear that those who do not smoke, should not start using any nicotine or tobacco containing product. *IQOS* is only for adult smokers who would otherwise continue to smoke.

Please adopt the following corrections:

[19] STOP report| PMI - Philip Morris International
[20] IQOS MRTP TPL, at 75. Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)
[21] *Ibid*., at 63-64.
[22] IQOS 3 PMTA TPL, at 3. Technical Project Lead (TPL) Review: PM0000634 (fda.gov)
[23] IQOS MRTP TPL, at 13.
[24] IQOS MRTP TPL, at 13.
[25] IQOS MRTP TPL, at 10.

(a) Provide context that FDA found that authorizing IQOS as an MRTP with reduced exposure messages is *"appropriate to promote the public health"* and *"is expected to benefit the health of the population as a whole"* considering both users and nonusers of tobacco products. In doing so, the Agency had to take into account the "…increased or decreased likelihood that persons who do not use tobacco products will start using the modified risk tobacco product…".

(7) The Article states: *"PMI showed reduced exposure to only 40 of the 93 potentially harmful substances recognized by the FDA; yet 56 other substances are higher in IQOS aerosol than cigarette smoke."*

STOP appears to be referencing the Tobacco Control article, *"IQOS: examination of Philip Morris International's claim of reduced exposure"* by Gideon St. Helen *et al*.[26] However, STOP fails to reference PMI's public response to the referenced article where the above statement is sourced. Further, it fails to reference that, at the time the article was written, well-established analytical protocols to measure these HPHCs were not available, leading to the FDA recommendation of the abbreviated list of 18 HPHCs. In addition, since the time of publication, validated analytical protocols have been developed, which allowed PMI to test for all HPHCs listed in the extended FDA list. These data were submitted to FDA in September 2018.[27] The total reduction of the levels of HPHCs was found to be fully aligned with the previous measurement made using the PMI-58 list. Both PMI's and independent assessments of the *IQOS* aerosol have consistently found that the product emits levels of HPHCs that are on average more than 90 percent reduced compared with the levels emitted in cigarette smoke.

Further, the Article omits important contextual information and misleadingly suggests that FDA did not consider the above-referenced data. In the IQOS MRTP TPL, FDA stated "*In the non-targeted differential screening study, the applicant identified 53-61 compounds across Heatstick variants (80 unique compounds) that are either present exclusively or are found in higher quantities in the aerosol of the IQOS system with Heatsticks compared to the mainstream smoke in the 3R4F reference cigarette."*[28] As background, PMI submitted two different aerosol assessments (1) the targeted assessment which included the quantification of the known harmful and potentially harmful constituents (HPHCs) and (2) the non-targeted assessment which is an extensive evaluation of the aerosol of *IQOS* and the smoke of a 3R4F reference cigarette to identify compounds that might be unique or in higher concentration in the aerosol of *IQOS*. As a result of the non-targeted assessment, PMI identified and assessed 80 compounds in the *IQOS* aerosol that are unique or are present in higher concentrations than in cigarette smoke. From this, PMI identified four of the 80 compounds as potentially carcinogenic to humans during PMI's toxicology evaluation, but determined that the levels

[26] St Helen G., Jacob Iii P, Nardone N, Benowitz NL. IQOS: examination of Philip Morris International's claim of reduced exposure. Tob Control. 2018;27(Suppl 1):s30-s6.
[27] https://digitalmedia.hhs.gov/tobacco/static/mrtpa/PMP/September%2021%2C%202018.zip
[28] IQOS MRTPA TPL, at 24; Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)

were below the levels of toxicological concern. In the IQOS PMTA Technical Project Lead Review (TPL) [the "IQOS PMTA TPL"], FDA stated in their toxicological risk assessment of *IQOS* that *"the levels of exposure to these possible carcinogens appear low and when considered with other data does not preclude a conclusion the products are appropriate for the protection of public health."*[29] FDA also stated in the IQOS MRTPA TPL that, *"[d]espite the increase in some constituents of concern, the substantial reduction across constituents on FDA's HPHC list demonstrates that, on the whole, the process used to heat tobacco in the IQOS system significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke."*[30] FDA reviewed this data as part of its review of the *IQOS* application and requested additional information be submitted as part of the postmarket surveillance and studies program that FDA required PMI to submit as a condition of its issuance of an exposure modification order.

Please adopt the following corrections:

a) **Remove all information and references derived from the Gideon St. Helen et al. Tobacco Control paper. OR**
b) **Include the following statement from PMI: *"With respect to the referenced findings, PMI has prepared a point-by-point assessment of the cited paper, which can be found here."* AND**
c) **Clarify that FDA stated that PMI's non-targeted differential screening *"identified 53-61 compounds across Heatstick variants (80 unique compounds) that are either present exclusively or are found in higher quantities in the aerosol of the IQOS system with Heatsticks compared to the mainstream smoke in the 3R4F reference cigarette.*" AND**
d) **Include discussion of contextual information that only four of the 80 unique compounds were identified by PMI as potentially carcinogenic. Further, clarify that FDA stated in their toxicological risk assessment of *IQOS* that *"the levels of exposure to these possible carcinogens appear low and when considered with other data does not preclude a conclusion the products are appropriate for the protection of public health."* [IQOS PMTA TPL , at 32]. FDA also stated in the *IQOS* MRTPA TPL that, *"[d]espite the increase in some constituents of concern, the substantial reduction across constituents on FDA's HPHC list demonstrates that, on the whole, the process used to heat tobacco in the IQOS system significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke."* [IQOS MRTP TPL, at 26].**

(8) The Article states: *"IQOS has not been shown to help smokers quit and does not carry significantly less risk than smoking."*

(a) It is unclear, including in terms of relevance, why STOP makes the claim, since PMI is clear that *IQOS* is not a cessation product. See for example PMI's Good Conversion Practices.

[29] IQOS PMTA TPL, at 32; https://www.fda.gov/media/124247/download.
[30] IQOS MRTP TPL, at 26; Technical Project Lead (TPL) Review: MR0000059-MR0000061, MR0000133 (fda.gov)

(b) At this time, the FDA acknowledges that a reduction in risk is reasonably likely based on the studies submitted including those demonstrating the reduction in exposure but requires subsequent studies. The FDA's conclusion in this regard is not solely a function of the science and the totality of evidence PMI submitted, but also of FDA's interpretation of U.S. statutory provisions that set a standard specific to the U.S. and not applicable elsewhere.

Please adopt the following correction:

(a) Please 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.
(b) Please add a clarifying statement that in the U.S., consumer communication about IQOS may include exposure modification information and that FDA determined that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(9) The Article states: "*PMI markets IQOS heavily on social media platforms that have a strong youth audience, causing concern for increased youth uptake. PMI has been found to use influencers and celebrities to push IQOS, attempting to portray the device as an upscale lifestyle product associated with glamor, hearkening back to decades-old cigarette ads.*"

STOP's claims are false. In addition to the below notes under subparagraphs (a) and (b), please see point 5 above, especially with respect to FDA's statements in the IQOS MRTP TPL.

(a) We age control 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.[31] [32]

(b) PMI has ended the digital influencer program. STOP reference digital influencers for IQOS, despite the fact that this program ended in 2019. [33]

Please adopt the following correction:

(a) Please amend your statements with clarifying content that we have provided above including FDA statements from the IQOS MRTP TPL; OR
(b) Remove the statements from the Article altogether.

###

[31] *"Social Media Brand Activation Accounts" are accounts focused on marketing our smoke-free products to adult nicotine users, and are distinct from customer care accounts, which provide customer support to existing adult users of our smoke-free products.*
[32] Responsible Marketing Practices, December 2019, p. 11: https://www.pmi.com/resources/docs/default-source/default-document-library/responsible-marketing-practices-at-pmi.pdf?sfvrsn=496446b4_4
[33] *Ibid.*