



September 8th, 2020

## ***International Tobacco Company Distorts Decision Made by the U.S. Food and Drugs Administration (FDA) in order to Promote its New Products in Latin America***

On July 7th 2020, the U.S. Food and Drug Administration (FDA) authorized IQOS, a Philip Morris International (PMI) heated tobacco product, to be marketed as a “modified risk product” in the United States.<sup>1 2</sup>

However, the FDA only allowed PMI to **make claims of reduced exposure**. What is the difference between the concepts of **reduced risk** and **reduced exposure**, used in the U.S.?

- a. A claim of “Reduced risk” suggests that a product is less harmful or presents a lower risk of disease than other tobacco products;
- b. A claim of “Reduced exposure” suggests that the product presents reduced exposure to harmful chemicals, which doesn’t necessarily mean there is reduced risk or less harm. That is to say, the **FDA only allowed Philip Morris to make this claim, which states that switching completely from conventional cigarettes to the IQOS system reduces exposure to harmful chemicals.**

Additionally, the FDA specified that PMI isn’t allowed to make any other claims<sup>3</sup>, given that:

- The overall body of evidence **was no sufficient to demonstrate that completely switching from combusted cigarettes to the IQOS system reduces the risk of tobacco-related disease or harm;**
- Heated tobacco products, including IQOS, **are just as addictive as cigarettes** and can sustain addiction in nicotine dependent populations;
- **IQOS wasn’t found to be “safe” or even “safer” than other tobacco products**, nor can it help smokers quit.

Unlike the U.S., the majority of Latin American countries are parties to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) and are obligated to adopt public policies and tobacco control regulating measures in line with this framework which aim to protect populations from the devastating consequences of tobacco consumption.

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<sup>1</sup> L. Wheeler, Tobacco giant asks the FDA to approve ‘less risky’ cigarette, thehill.com, 23 August 2017, accessed August 2020

<sup>2</sup> L.K. Lempert, S. Glantz, Heated tobacco product regulation under US law and the FCTC, Tobacco Control, 2018;27(Suppl 1):s118-s125, doi:10.1136/tobaccocontrol-2018-054560

<sup>3</sup> <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>

Despite this, **PMI has taken advantage of the confusion and has distorted the decision made by the FDA**, in order to promote a highly addictive product and pressure other countries' governments to authorize the marketing of IQOS<sup>4</sup>.

For this reason, it is crucial for all governments to understand the FDA's scope of communication. **Heated tobacco products fall under the category of "tobacco product" according to the FCTC and all regulating measures that apply to conventional tobacco products also apply to them.** In addition, even though the FDA is one of the most influencing regulatory agencies worldwide, countries are not obligated to follow in its decisions.

Mexico has already taken a big step in that direction, by means of a statement from the Secretary of Health, through the National Commission Against Addictions and the Federal Commission for the Protection against Sanitary Risk, which declares that *"FDA's decision only applies to the United States, a country which is not party to the WHO FCTC, an international treaty binding in terms of tobacco control, which Mexico is party to."*<sup>5</sup>

For its part, in Australia, the Department of Health's Therapeutic Goods Administration (TGA) has refused to modify its guideline to allow the marketing of heated tobacco products. Australian's guideline states that new nicotine products are prohibited due to nicotine being classified as a "dangerous poison". On December 2019, PMI sought authorization to sell IQOS in Australia. TGA declined and showed "big security concerns", mentioning the lack of "convincing evidence to suggest the existence of any public health benefit" concerning heated tobacco products.<sup>6</sup>

Likewise, and in response to FDA's statement and the marketing campaign of tobacco companies, WHO and the FCTC Secretariat have issued statements on the topic. Among these, the following stand out: **"WHO reiterates that reducing exposure to harmful chemicals in Heated Tobacco Products (HTPs) does not render them harmless, nor does it translate to reduced risk to human health. [...]"**<sup>7</sup> While the FCTC Secretariat, apart from reaffirming WHO's statement, reminds that investigations suggest that the public is confused and perceives the claims of "reduced exposure" as the equivalent of the claims of "reduced risk".<sup>8</sup>

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<sup>4</sup> Examples: Colombia: <https://www.dinero.com/internacional/articulo/philip-morris-pide-regulacion-diferenciada-a-productos-como-igqos/292419>

Argentina: <https://www.baenegocios.com/negocios/Decision-de-EE.UU.-abre-una-puerta-para-la-llegada-del-sistema-de-tabaco-calentado-20200716-0054.html>

Mexico: <https://www.forbes.com.mx/negocios-philip-morris-venta-igqos-mexico/>

Uruguay: <https://www.elpais.com.uy/vida-actual/igqos-aval-fda-ilegal-uruguay.html>

Brasil: <https://www.prnewswire.com/news-releases/fda-autoriza-comercializacao-do-igqos-como-um-produto-de-tabaco-de-risco-modificado-886090080.html>

Panama: Entrevista radial con Edna Jaramillo 28 de julio-Andrea Constantini-Head of Regional Scientific Engagement LA&C Philip Morris International

<sup>5</sup> <https://www.gob.mx/cofepris/articulos/a-la-opinion-publica?idiom=es>

<sup>6</sup> <https://www.tga.gov.au/sites/default/files/public-notice-final-decisions-acms29-accs27-joint-acms-accs24-march-2020.pdf>.

<sup>7</sup> <https://www.who.int/es/news-room/detail/27-07-2020-who-statement-on-heated-tobacco-products-and-the-us-fda-decision-regarding-igqos>

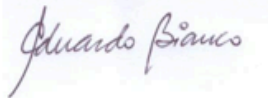
<sup>8</sup> Linda L. Pederson, David E. Nelson, M.P.H., Literature Review and Summary of Perceptions, Attitudes, Beliefs, and Marketing of Potentially Reduced Exposure Products: Communication Implications, Nicotine & Tobacco Research, Volume 9, Issue 5, may 2007, pages 525-534, <https://doi.org/10.1080/14622200701239548>

**On the basis of the above, the signatory organizations present:**

- *Call all countries to sustain and strengthen the commitment to the protection of public health, through the implementation of tobacco control policies based on evidence. Even more within the context of the COVID-19 pandemic.*
- *Urge the authorities of countries in which the marketing of new tobacco products is already prohibited, especially Uruguay and Panama, to sustain the prohibition.*
- *Urge governments to acknowledge that, due to its high addictive qualities and its potential to bring about new generations of addicts, IQOS is “part of the problem, not part of the solution” and that the only way to reduce the risk for smokers is to apply effective national smoking cessation programmes based on evidence.*
- *Urge the enforcement of the obligations established by the FCTC, and other international human rights treaties, the 2030 Agenda, among others, that insist on better policies that allow the gradual increase of the right to health and the protection of the most vulnerable; and support the states in the process.*



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