PAN AMERICAN JOURNAL OF PUBLIC HEALTH 100 YEARS

Opinion and analysis

United States Food and Drug Administration's authorization of reduced exposure claims for IQOS®: implications for regulation in Latin America

Robert Eckford,[1] Gianella Severini,[2] Ernesto M. Sebrié,[1] Monique E. Muggli,[1] Alexandra Beem,[1] Debra Rosen,[1] and Eric Crosbie[3]

Suggested citation Eckford R, Severini G, Sebrié EM, Muggli ME, Beem A, Rosen D, et al. United States Food and Drug Administration's authorization of reduced exposure claims for IQOS: implications for regulation in Latin America. Rev Panam Salud Publica. 2022;46:e155. https://doi.org/10.26633/RPSP.2022.155

ABSTRACT Philip Morris International has used the July 7, 2020 United States Food and Drug Administration's (US FDA) modified risk tobacco product order for IQOS®, which authorized certain reduced exposure marketing claims, as a corporate strategy to promote and normalize its heated tobacco products in Latin America. The modified risk tobacco product orders are based on the US's unique regulatory system that is not, and should not be, replicated anywhere else in the world. Philip Morris International's global public relations campaign largely ignored the FDA's rejection of reduced risk claims for IQOS and other key FDA findings that are important for policy-makers, regulators, and consumers – including tobacco users and Philip Morris International's customers – to understand the risks associated with the product. In Latin America in particular, Philip Morris International has used media outlets to promote this misleading information to the public. This company has also used the FDA ruling to lobby regulators in Latin America to relax regulations on IQOS in the region. As tobacco companies rapidly introduce new tobacco products in low- and middle-income countries, public health advocates and Parties to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) should take measures to prevent the promotion of misleading statements about heated tobacco products, including IQOS. As Latin American countries are at different stages in their regulation of heated tobacco products, governments should adhere to their WHO FCTC obligations and the recommendations of the Conference of the Parties by entirely prohibiting the sale of heated tobacco products or strictly applying to heated tobacco products all the relevant tobacco demand-reduction policies based on the WHO FCTC (making sure to capture both heated cigarettes and heating devices).

Keywords Tobacco products; marketing; policy; United States Food and Drug Administration; Latin America.

In June 2009, the United States (US) Congress enacted the Family Smoking Prevention and Tobacco Control Act. Section 910 of the Act requires that before marketing any new tobacco product (not on the market before February 15 2007) in the US, the Food and Drug Administration (FDA) must approve a premarket tobacco application for the product. To give approval, the FDA has to determine whether the new tobacco product would be appropriate for public health protection which requires the FDA to evaluate the tobacco product's toxicological profile, individual and population health impacts, and labelling, among other things (1). In May 2017, Philip Morris Products S.A. (Philip Morris) submitted premarket tobacco applications

[1] Campaign for Tobacco-Free Kids, Washington, DC, United States of America. ✉ Ernesto M. Sebrié, ESebrie@tobaccofreekids.org
[2] Campaign for Tobacco-Free Kids, Córdoba, Argentina.
[3] School of Public Health, University of Nevada, Reno, United States of America.

seeking to sell the IQOS® heated tobacco product in the US. IQOS is an integrated system that uses an electronic device to heat specifically designed cigarettes (heatsticks), thus generating an inhalable nicotine-containing emission. In April 2019, the FDA issued a premarket tobacco product marketing order that authorized Philip Morris to market IQOS 2.4 in the US with exclusive distribution by the US-based tobacco company, Altria. Separate from the authorization for the sale of IQOS, Philip Morris also applied for permission to advertise and label IQOS as a so-called reduced harm and reduced exposure tobacco product, which requires separate modified risk tobacco product orders. In July 2020, the FDA authorized Philip Morris to use specific reduced exposure claims on the basis that the evidence, overall, showed a substantial reduction in harmful chemicals in the aerosol produced by IQOS compared with conventional cigarette smoke. However, the FDA denied Philip Morris's application to use "reduced risk" marketing claims, stating that Philip Morris "has not demonstrated that [IQOS] will significantly reduce harm and the risk of tobacco-related disease" (2).

The FDA's decision to issue a reduced-exposure modified risk tobacco product order for IQOS has been criticized by many. Lempert and Glantz argue the law places the burden on the applicant to demonstrate that its product confers public health benefits but the FDA's IQOS decision established a new, weaker de facto standard: a new tobacco product is appropriate for the protection of the public health if the FDA cannot clearly demonstrate, based on the information submitted in the application, that the proposed product is more dangerous than cigarettes (3). In addition, Lempert and Glantz highlight the difference between so-called reduced harm and reduced exposure arguing both are classified as modified risk tobacco product orders and, based on complex US law-making, it is easy to misrepresent the findings to create confusion (3). A deeper analysis into Philip Morris's application by McKelvey and colleagues revealed design flaws and deficiencies with evidence provided to support Philip Morris´ assertions that: the proposed claims will not decrease smokers' intentions to quit; and IQOS users will in fact "switch completely" from smoking cigarettes to using IQOS (4). These authors concluded that consumers will not understand the conditions of the claims of reduced exposure. Gilmore and Braznell, among others, have begun to document how Philip Morris is using a global public relations campaign to promote the FDA's decision and push other governments to open their markets to or relax rules regulating IQOS (5).

Given the US influence in Latin America and the emergence of IQOS in the region, this commentary piece examines how Philip Morris International is using the FDA ruling to lobby for the introduction of IQOS in Latin America. In particular, we document: 1) the obligations of Parties to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) to prevent misleading information to the public; 2) the current regulatory environment on heated tobacco products in Latin America; 3) Philip Morris International's use of the FDA's modified risk tobacco product order in its public relations; and 4) Philip Morris International's lobbying efforts to introduce IQOS in Latin America.

OBLIGATION OF PARTIES TO THE WHO FCTC

In 2018, the WHO FCTC Conference of the Parties, made up of 182 Parties, adopted a formal decision confirming that heated tobacco products are tobacco products and that the WHO FCTC applies to heated tobacco products, reminding Parties to "regulate, including restrict, or prohibit, the manufacture, importation, distribution, presentation, sale and use of novel tobacco products" such as heated tobacco products. This includes "the devices designed for consuming the products" (6). Under the WHO FCTC, Parties to the treaty have obligations that should *prevent them* from adopting a regulatory regime such as in the US – which is a member but has not yet ratified the FCTC – that explicitly permits reduced risk or reduced exposure claims about products as compared to conventional cigarettes.

Parties to the WHO FCTC have recognized that consumption of *any* tobacco product causes death, disease, and disability (Preamble) and have adopted as a guiding principle, "the need to take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products *in any form*" [emphasis added] (Article 4(2)(b)). There are no provisions, recommendations or obligations in the FCTC that allow for a different regulatory approach for some categories of tobacco product.

Second, Article 11.1(a) of the WHO FCTC requires Parties to adopt effective measures to ensure tobacco packaging and labeling do not promote a tobacco product by any means that are "misleading" or "likely to create an erroneous impression about its … health effects" or "give the false impression that a particular tobacco product is less harmful than another tobacco product." Article 11 also prohibits the use of terms such as light, low tar and mild (7), and the Guidelines for Implementation of Article 11 prohibit the use of figures for emission yields such as tar and nicotine because "the marketing of cigarettes with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful" (7). In the WHO FCTC context, these prohibited terms and figures can be viewed as comparable to the claims that have now been authorized for marketing IQOS in the US in that these claims are likely to create an erroneous impression about the products' health effects and whether they actually reduce risk to users. Parties to the WHO FCTC sought to prohibit these terms and statements because no conclusive epidemiological or scientific evidence existed that so-called mild cigarettes were actually less harmful than cigarettes with higher smoke emission yields. Similarly, the FDA found that the current evidence does not demonstrate that IQOS is safer than conventional cigarettes (8).

Third, Article 13.2 of the WHO FCTC requires Parties to implement a comprehensive ban on *all* tobacco advertising, promotion, and sponsorship. Importantly, Article 13.4 requires Parties, at a minimum, to ban all forms of tobacco advertising, promotion and sponsorship that "promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions" (7).

In response to the FDA modified risk tobacco product order, WHO issued a statement that reduced exposure to certain chemicals does not "translate to reduced risk to human health" and that "claims that heated tobacco products reduce exposure to harmful chemicals relative to conventional cigarettes may be misleading" (9).

In countries that are Parties to the WHO FCTC, regulatory measures that properly align with the treaty and its implementation guidelines should prevent Philip Morris International

from using the US reduced exposure claims authorized by the FDA. Given the high likelihood that consumers are unfamiliar with the specific provisions of the US FDA regulatory system, it is reasonable for consumers to infer that the rationale of US regulators for providing information about so-called reduced exposure to certain harmful chemicals is to convey that the product is less harmful. Recent research demonstrates how claims of lower exposure to chemicals misleads the public to perceive lower risk even where no lower-risk claim is made (10).

REGULATORY ENVIRONMENT FOR HEATED TOBACCO PRODUCTS IN LATIN AMERICA

The current regulatory environment in Latin America varies, with different and evolving regulatory systems for heated tobacco products in different countries. IQOS, the only heated tobacco product currently in Latin America, is officially available for sale in seven Latin American countries: Aruba, Colombia, Costa Rica, Curacao, Dominican Republic, Guatemala, and Mexico. To date, only three countries ban the commercialization of heated tobacco products: Brazil, under an existing regulation that bans "electronic smoking devices"; Panama, where a health ministry resolution followed by a law declared the commercialization of heated tobacco products inadmissible and banned their use in smoke-free public places; and Mexico through a presidential decree that bans the commercialization of these products. IQOS is officially available in Mexico despite the clear legal ban on heated tobacco products. Specialist IQOS stores established before the ban are still open. This appears to be due to a lack of enforcement by the government and/or injunctions obtained.

Four countries explicitly regulate heated tobacco products as tobacco products (Bolivia (Plurinational State of), Guyana, Paraguay, and Uruguay). Fifteen countries have existing tobacco control legislation that should also apply to heated tobacco products to some extent (Argentina, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Nicaragua, Peru, Suriname, and Venezuela (Bolivarian Republic of)). However, because most countries have not adopted measures to specifically address these new products, tobacco companies are finding loopholes or exploiting a lack of clarity in the existing laws. In particular, the electronic heating devices (used to heat the tobacco sticks or heated cigarettes) do not contain tobacco so may not be classed as tobacco products under a tobacco control law and have therefore often escaped effective regulation in many countries because they are packaged, branded, and sold separately from heated cigarettes (1).

PHILIP MORRIS INTERNATIONAL'S PUBLIC RELATIONS ON IQOS

Within hours of the FDA publishing the modified risk tobacco product order for IQOS, Philip Morris International issued a widely covered press release (8) published online (including videos and other social media posts); incorporated the decision into investor reports; and dispatched company executives at global and regional/country headquarters to conduct interviews and presentations around the world, among other activities (11). Highlighting elements of the decision most useful to its business, Philip Morris International's primary talking points globally have focused on repeating several key messages (Table 1). The company likely used these key messages to confuse policy-makers, regulators, and consumers around the world about the FDA's modified risk tobacco product order for IQOS as they published them without reference to the FDA's denial of the reduced risk claims.

Philip Morris International's global public relations campaign largely ignored the FDA's denial of reduced risk claims for IQOS. The campaign also omitted several other key FDA findings about the risks and characteristics of IQOS that are important for policy-makers, regulators, and consumers – including all tobacco users, even Philip Morris International's customers – to understand the risks and benefits associated with the product (Table 1).

In a July 2020 virtual press conference for Latin American journalists, Mario Masseroli, President of Philip Morris International for Latin America and Canada, and Dr Andrea

TABLE 1. Comparing the United States FDA MRTP order with Philip Morris International's statements

FDA MRTP order	Philip Morris International talking points/statements to press	Key omissions in Philip Morris International's statements about the FDA MRTP order for IQOS
The FDA categorizes IQOS as a "non-combusted cigarette" not an "electronic nicotine product" which could be confused with products categorized as "electronic nicotine delivery systems," which contain no tobacco leaf (2).	"IQOS is the first and only electronic nicotine product to be granted marketing orders through the FDA's MRTP process" (11, 12).	The FDA acknowledged IQOS is not safe (2). Users are still exposed to many harmful chemicals, and long-term use is likely to produce significant health risks when compared with not using any tobacco products (15).
The FDA specifically prohibited messages that referred to IQOS as "safer" or "less harmful." (2)	"IQOS is a fundamentally different tobacco product and a better choice for adults who would otherwise continue smoking" (12).	The FDA did not find that the use of IQOS reduced the user's risk of disease or that the product was less harmful than smoking cigarettes (15).
The FDA did not find that the use of IQOS reduced the risk of disease in users, or that the product was less harmful than smoking conventional cigarettes. In addition, according to the FDA, Philip Morris is not allowed to make any statements in the US that "convey or could mislead consumers into believing" that IQOS is endorsed or approved by the FDA, or that the FDA deems the products to be safe for use by consumers (2).	Reference to IQOS as a "lower risk" (13) or "reduced risk" product (14).	The FDA did not find that IQOS could help smokers to quit (15).

FDA, Food and Drug Administration; MRTP, modified risk tobacco product.
Source: Prepared by the authors based on information and data from the July 7, 2020 FDA modified risk tobacco product order for heatsticks and IQOS system holder and charger, and press releases and media statements by Philip Morris International and its subsidiaries.

Constantini, Scientific Affairs Leader, stated, "Products such as IQOS are prohibited in Latin America, but conventional cigarettes, which we know for sure cause more harm, are approved" (13).

There are also numerous examples of in-country media outlets within Latin American countries misconstruing the FDA's modified risk tobacco product order, including with direct quotes attributed to Philip Morris International executives, which contain highly misleading information about IQOS being a "better choice" or even being "a safer product" (Table 1). Latin American media coverage has focused on the US being a precedent for other governments to follow. In Uruguay, in July 2020, an article in a leading newspaper emphasizing "the importance of the FDA decision", stated that "despite the fact that the FDA decision has no direct impact on the decisions made by Latin American governments, it sets prestigious precedent regarding the system" (16). Some months later, in March 2021, Uruguay lifted the ban on heated tobacco products through Decree 87/21 and now regulates them as tobacco products (17). A Uruguayan national legislator requested information from the health ministry on the evidence used to lift the Uruguayan ban on heated tobacco products and the ministry responded highlighting the FDA's modified risk tobacco product order.

In February 2020, Mexico issued a decree that prohibited the import and export of electronic nicotine delivery systems (ENDS), e.g. electronic cigarettes and heated tobacco products. In July 2020, media articles raised the question of whether the FDA decision was a "precedent for Mexico" and stated that FDA authorization for the marketing of IQOS in the US "could set a precedent in countries that maintain strong regulations for alternative tobacco products" (Figure 1) (14). In July 2021, the import/export decree was amended to keep the ban on ENDS but exclude heated tobacco products from the ban. However, the President publicly mentioned that he would reverse this decree and, on October 22, 2021, a new presidential decree banning the import and exports of heated tobacco products was adopted (18). The ban on imports and exports was later reinforced by law in June 2022, and the President issued a decree to ban the commercialization of these products in May 2022 (18).

PHILIP MORRIS INTERNATIONAL'S LOBBYING OF IQOS IN LATIN AMERICA

Philip Morris International's lobbying is also visible in the language used for draft legislation regulating heated tobacco products in Latin America. Draft bills contain references to the supposed harm reduction attributes of these products. For example, in Panama, while the commercialization of heated tobacco products and ENDS is banned, draft bills have been introduced to the Congress intended to soften this ban in order "… to provide current adult smokers with a smoke-free and lower-risk alternative" (19). In Colombia, a draft bill that was approved in its first debate in the Chamber of Deputies on June 16, 2021, established as an objective to "implement harm reduction and reduced risks public policies" and refers to purported evidence that supports ENDS, heated tobacco products, and other products as "reduced risk products" (20). In Chile, a draft bill at the Congress states that "public institutions have published several studies at the international level and with international recognition, which refer to the effectiveness of these devices in anti-smoking therapies and are used as part of their public policies for risk reduction" (21). Statements such as these attempt to introduce the idea that these products are less harmful than traditional tobacco products and they use industry-funded research, which has a clear conflict of interest.

CONCLUSIONS

As misleading and even erroneous claims about the FDA's modified risk tobacco product order for IQOS continue in the international media and are pushed forward in legislative bills, public health advocates should contact media outlets that are reporting on such claims to request corrections and consider reaching out to decision-makers, regulators, and journalists to offer critical and accurate facts about the FDA's modified risk tobacco product order. Indeed, consumer protection laws and regulations in some countries could be relied on to demand correct information and to publicly denounce any misleading information.

Governments and civil society in Latin America should anticipate that Philip Morris International will continue to misrepresent the FDA-authorized claims about IQOS, which are specific to the complex US regulatory structure, in its global lobbying efforts to weaken regulation of heated tobacco products. As the global tobacco companies rapidly introduce new tobacco and nicotine products into more markets, WHO FCTC Parties must adhere to their obligations under the treaty and the recommendations of the Conference of the Parties, including the obligation to prevent misleading information to the public (5). Parties can best meet their WHO FCTC obligations by prohibiting entirely the sale of heated tobacco products such as IQOS, or strictly applying all the relevant tobacco demand-reduction policies to heated tobacco products (ensuring that relevant legislation applies to both heated cigarettes and devices) including: comprehensively prohibiting all tobacco advertising, promotion, and sponsorship; banning non-tobacco flavors in products; ensuring smoke-free laws include use of heated tobacco products in covered places; applying all packaging and labeling requirements including pictorial health warnings; prohibiting misleading claims and adopting plain packaging; and taxing the tobacco sticks at the same rate as conventional cigarettes.

Author contributions. GS conceived the original idea and all authors contributed data and analysis tools and wrote the paper. All authors reviewed and approved the final version.

Conflicts of interests. None declared.

Funding. RE, GS, AB, EMS and MEM received funding from the Bloomberg Initiative to Reduce Tobacco Use. EC was supported by the University of Nevada, Reno. Neither the university nor the Bloomberg Initiative played a role in the conduct of the research or the preparation of this article.

Disclaimer. The authors hold sole responsibility for the views expressed in the manuscript, which may not necessarily reflect the opinion or policy of the RPSP/PAJPH or the Pan American Health Organization (PAHO).

FIGURE 1. Mexican newspaper headline on the precedent set by the United States Food and Drug Administration in issuing the modified risk tobacco product order for IQOS

Note: Translation – FDA says yes to Philip Morris's IQOS.
Source: Expansión (14).

REFERENCES

1. Lempert LK, Glantz SA. Heated tobacco product regulation under US law and the FCTC. Tob Control. 2018; 27(Suppl 1):s118–s125. https://doi.org/10.1136/tobaccocontrol-2018-054560
2. Modified Risk Orders for Philip Morris Products SA for Marlboro heatsticks, Marlboro Smooth menthol heatsticks, Marlboro fresh menthol heatsticks, and IQOS system holder and charger [Internet]. Silver Spring, MD: US Food and Drug Administration; 2020 [cited 2020 Dec 22]. Available from: https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders
3. Lempert LK, Glantz S. Analysis of FDA's IQOS marketing authorisation and its policy impacts Tob Control. 2020 Jun 29:tobaccocontrol-2019-055585.https://doi.org/10.1136/tobaccocontrol-2019-055585
4. McKelvey K, Popova L, Kim M, Lempert LK, Chaffee BW, Vijayaraghavan M, et al. IQOS labelling will mislead consumers. Tob Control. 2018;27(Suppl 1):s48–s54. https://doi.org/10.1136/tobaccocontrol-2018-054333
5. Gilmore AB, Braznell S. US regulator adds to confusion around heated tobacco products BMJ. 2020; 370:m3528. https://doi.org/10.1136/bmj.m3528
6. WHO FCTC 8th Conference of the Parties. Decision. FCTC/COP8(22). Novel and emerging tobacco products [Internet]. Geneva: WHO Framework Convention on Tobacco Control; 2018 [cited 2020 Dec 12]. Availablefrom:https://fctc.who.int/who-fctc/governance/conference-of-the-parties/eight-session-of-the-conference-of-the-parties/decisions/fctc-cop8(22)-novel-and-emerging-tobacco-products
7. WHO Framework Convention on Tobacco Control. Geneva: World Health Organization; 2003 [cited 2020 Dec 12]. Available at: http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf?ua=1; and the Guidelines for Implementation. Available at: https://fctc.who.int/who-fctc/overview/treaty-instruments.
8. Press statement. FDA authorizes marketing of IQOS as a modified risk tobacco product. Business Wire. July 7, 2020 [cited 2020 Dec 22]. Available from: https://www.businesswire.com/news/home/20200707005847/en/FDA-Authorizes-Marketing-IQOS-Modified-Risk-Tobacco
9. WHO statement on heated tobacco products and the US FDA decision regarding IQOS [Internet]. Geneva: World Health Organization; 2020 [cited 2021 Dec 2]. Available from: https://www.who.int/news/item/27-07-2020-who-statement-on-heated-tobacco-products-and-the-us-fda-decision-regarding-iqos
10. El-Toukhy S, Baig SA, Jeong M, Byron MJ, Ribisl KM, Brewer NT. Impact of modified risk tobacco product claims on beliefs of US adults and adolescents. Tob Control. 2018;27(Suppl 1):s62–s69. https://doi.org/10.1136/tobaccocontrol-2018-054315
11. Ansorena TR. FDA authorizes Philip Morris to sell IQOS devices as a better alternative to smoking. Forbes Argentina, July 7, 2020 [cited 2020 Dec 17]. Available from: https://www.forbesargentina.com/negocios/la-fda-autoriza-philip-morris-vender-sus-dispositivos-iqos-como-una-mejor-alternativa-cigarrillo-n3343
12. FDA authorizes marketing of IQOS as a modified risk tobacco product [Press release]. New York, NY: Philip Morris International; 2020 [cited 2021 Dec 2]. Available from: https://www.pmi.com/media-center/press-releases/press-details?newsId=22631
13. "En América Latina se prohíben los productos como IQOS, pero sí están aprobados los cigarrillos tradicionales que se sabe causan más daño": Mario Masseroli, presidente de PMI en América Latina y Canadá [In Latin America products such as IQOS are prohibited, but traditional cigarettes that are known to cause more damage are approved: Mario Masseroli, President of PMI in Latin America and Canada]. Despejando Dudas. July 18, 2020 [cited 2020 Dec 17]. Available from: https://www.despejandodudas.co/index.php/especiales/marcas/2064-en-america-latina-se-prohiben-los-productos-como-iqos-pero-si-estan-aprobados-los-cigarrillos-tradicionales-que-se-sabe-causan-mas-dano-mario-masseroli-presidente-de-pmi-en-america-latina-y-canada
14. La FDA le da el sí a IQOS de Philip Morris [The FDA says yes to IQOS from Philip Morris]. Expansión. July 7, 2020 [cited 2020 Dec 17]. Available from: https://expansion. mx/empresas/2020/07/07/la-fda-la-de-el-si-a-iqos-de-philip-morris
15. Scientific review of modified risk tobacco product application under Section 911(d) of the FD&C Act – technical project lead. Silver Spring, MD: Food and Drug Administration; 2020 [cited 2021 Dec 2]. Available from https://www.fda.gov/media/139796/download
16. Malek M. IQOS tiene aval de FDA, pero es ilegal en Uruguay [IQOS is endorsed by the FDA, but it is illegal in Uruguay]. El País. July 19, 2020 [cited 2020 Nov 21]. Available from: https://www.elpais.com.uy/vida-actual/iqos-aval-fda-ilegal-uruguay.html
17. Uruguay Decree No. 87/2021. Montevideo: Presidency of the Oriental Republic of Uruguay; 2021 [unofficial translation] [cited 2021 Dec 2]. Available from: https://www.tobaccocontrollaws.org/files/live/Uruguay/Uruguay%20-%20Decree%20No.%2087_2021.pdf
18. Tobacco control laws. Legislation by country. Mexico. Washington, DC: Tobacco-Free Kids; 2022 [cited 2022 Jul 31]. Available from: https://www.tobaccocontrollaws.org/legislation/country/mexico/laws
19. Panamá trámite legislativo 2020–2021 anteproyecto de ley: 209 [Panama legislative process 2020-2021 preliminary bill: 209]. Panama City: 2021 [cited 2021 Dec 2]. Available from : https://www.asamblea.gob.pa/APPS/SEG_LEGIS/PDF_SEG/PDF_SEG_2020/PDF_SEG_2020/2020_A_209.pdf
20. Texto definitivo aprobado en primer debate del proyecto de ley no. 493 de 2020 cámara "por medio de la cual se regulan los productos de administración de nicotina y sin nicotina y se dictan otras disposiciones [Final text approved in first debate – Bill No. 493 of 2020 "Through which nicotine and nicotine-free delivery products are regulated, and other provisions are issued]. Bogota: Chamber of Deputies of Colombia; 2021 [cited 2021 Dec 2]. Available from: https://www.camara.gov.co/camara/visor?doc=/sites/default/files/2021-06/Texto%20Definitivo%20Proyecto%20No.%20493%20de%202020%20C%C3%A1mara.docx
21. Proyecto de ley: Regula el consumo, publicidad, comercialización, calidad y seguridad de los cigarrillos electrónicos, vaporizadores u otros, que operen como sistemas electrónicos de administración de nicotina, o sistemas similares sin nicotina [Provisions regulates the consumption, advertising, marketing, quality and safety of electronic cigarettes, vaporizers or others, which operate as electronic nicotine administration systems, or similar systems without nicotine]. Santiago: Chamber of Deputies of Chile 2019 [cited 2021 Dec 2]. Available from: https://www.camara.cl/legislacion/ProyectosDeLey/tramitacion.aspx?prmID=13231&prmBOLETIN=12694-11

Manuscript submitted on 4 December 2021. Revised version accepted for publication 22 April 2022.

Autorización de la Administración de Alimentos y Medicamentos de Estados Unidos de declaraciones sobre exposición reducida respecto de IQOS: implicaciones para la regulación en América Latina

RESUMEN Philip Morris International ha empleado el dictamen que la Administración de Alimentos y Medicamentos (FDA) de Estados Unidos emitió el 7 de julio del 2020 sobre IQOS como producto de tabaco de riesgo modificado —que la autorizó a usar ciertas declaraciones relativas a una exposición reducida al comercializar el producto— como estrategia corporativa para promover y normalizar sus productos de tabaco calentado en América Latina. Los dictámenes sobre productos de tabaco de riesgo modificado se fundamentan en el sistema regulatorio único de Estados Unidos, que no se replica ni debería ser replicado en ningún otro lugar del mundo. La campaña mundial de relaciones públicas de Philip Morris International omitió en gran medida que la FDA rechazó los argumentos de que IQOS implica un riesgo reducido y otros hallazgos clave de la FDA que son importantes para que los responsables de las políticas, los reguladores y los consumidores, incluidos los consumidores de tabaco y los clientes de Philip Morris International, comprendan los riesgos asociados con el producto. En América Latina en particular, Philip Morris International ha utilizado los medios de comunicación para difundir esta información engañosa. Esta compañía también ha utilizado el fallo de la FDA para presionar a los reguladores en América Latina con el objetivo de que flexibilicen las regulaciones sobre IQOS en la Región. A medida que las compañías tabacaleras introducen con celeridad nuevos productos de tabaco en países de ingresos bajos y medianos, los defensores de la salud pública y los Estados Parte del Convenio Marco para el Control del Tabaco de la Organización Mundial de la Salud (CMCT de la OMS) deben tomar medidas para evitar la difusión de declaraciones engañosas sobre los productos de tabaco calentado, como IQOS. Dado que los países latinoamericanos se encuentran en diferentes etapas en la regulación de los productos de tabaco calentado, los gobiernos deben cumplir con sus obligaciones estipuladas en el CMCT de la OMS y las recomendaciones de la Conferencia de las Partes mediante la prohibición total de la venta de productos de tabaco calentado o la aplicación estricta a los productos de tabaco calentado de todas las políticas pertinentes sobre la reducción de la demanda de tabaco basadas en el CMCT de la OMS (y asegurarse de abarcar tanto los cigarrillos calentados como los dispositivos de calentamiento).

Palabras clave Productos de tabaco; mercadotecnía; políticas; United States Food and Drug Administration; América Latina.

Autorização pela Administração de Alimentos e Fármacos dos Estados Unidos de alegações de exposição reduzida para os produtos IQOS: implicações para a regulamentação na América Latina

RESUMO A Philip Morris International utilizou a decisão de 7 de julho de 2020 da Administração de Alimentos e Fármacos dos Estados Unidos (*United States Food and Drug Administration*, FDA), que caracterizou o IQOS como produto de tabaco com risco modificado e que permitiu o uso de determinadas alegações de exposição reduzida no marketing do produto, como estratégia corporativa para promover e normalizar seus produtos de tabaco aquecido na América Latina. As decisões relativas aos produtos de tabaco com risco modificado se baseiam no singular sistema regulatório dos EUA, que não é e não deve ser reproduzido em nenhum outro lugar do mundo. A campanha global de relações públicas da Philip Morris International ignorou em grande parte a rejeição da FDA às afirmações de risco reduzido do IQOS e outros achados fundamentais da FDA, que são informações importantes para formuladores de políticas, órgãos regulamentadores e consumidores – incluindo usuários de tabaco e clientes da Philip Morris International – entenderem os riscos associados ao produto. A Philip Morris International tem usado a mídia para veicular essa informação enganosa ao público, principalmente na América Latina. A empresa também usou a decisão da FDA para pressionar órgãos regulamentadores na América Latina a flexibilizarem a regulamentação do IQOS na região. Conforme as empresas de tabaco introduzem rapidamente novos produtos em países de baixa e média renda, os ativistas de saúde pública e as Partes da Convenção-Quadro para Controle do Tabaco (CQCT) da Organização Mundial da Saúde (OMS) devem tomar providências para prevenir a promoção de alegações enganosas sobre produtos de tabaco aquecido, incluindo o IQOS. Como os países da América Latina estão em diferentes estágios da regulamentação de produtos de tabaco aquecido, os governos devem cumprir suas obrigações com a CQCT da OMS e seguir as recomendações da Conferência das Partes, proibindo totalmente a venda de produtos de tabaco aquecido ou aplicando rigorosamente aos produtos de tabaco aquecido todas as políticas relevantes de redução da demanda por tabaco, com base na CQCT da OMS (certificando-se de abranger tanto os cigarros aquecidos quanto os dispositivos de aquecimento).

Palavras-chave Produtos do tabaco; marketing; políticas; United States Food and Drug Administration; América Latina.