JOHNS HOPKINS
BLOOMBERG SCHOOL
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Institute for Global
Tobacco Control

INTERNATIONAL REGULATORY LANDSCAPE FOR E-CIGARETTES AND HEATED TOBACCO PRODUCTS

SUBMITTED TO: AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA)

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POLICY SCAN

Available at: https://globaltobaccocontrol.org/e-cigarette_policyscan

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Executive Summary

This report describes the international regulatory landscape for electronic nicotine delivery systems (ENDS) which include electronic cigarettes, or e-cigarettes, and heated tobacco products (HTPs). In Brazil, these devices are jointly referred to as "electronic devices to smoke."

Since 2014, the Institute for Global Tobacco Control (IGTC) at the Johns Hopkins Bloomberg School of Public Health has conducted surveillance (globaltobaccocontrol.org/e-cigarette_policyscan) of national-level policies regulating e-cigarettes in an effort to understand different national-level regulatory approaches. The surveillance system employs media monitoring of e-cigarette policy news using Google and Tobacco Watcher (tobaccowatcher.globaltobaccocontrol.org). Beginning in 2018, the same policy surveillance methods were used to identify policies for regulating HTPs. IGTC conducts outreach to country-specific tobacco control policy experts twice a year to solicit updates or information on the status of e-cigarette and HTP regulations. This surveillance has identified that 101 countries regulate e-cigarettes with a ban or sale/use restrictions. The surveillance has further identified 58 countries that regulate HTPs with a ban or sale/use restrictions.

Thirty countries ban all e-cigarettes, four countries ban nicotine e-cigarettes, 67 countries regulate the sale and/or use of e-cigarettes. E-cigarettes are classified as ENDS or vaping products (70 countries), tobacco products (57 countries), consumer products (18 countries) or medicinal products (23 countries). Of the 67 countries that regulate the sale and/or use of e-cigarettes, 54 countries prohibit or restrict marketing, 48 require marketing authorization before being sold, and 34 require premarket notification. In line with other tobacco products, 43 countries have minimum age of purchase restrictions. Heath warning labels are required for e-cigarettes in 40 countries and 32 countries require child safety packaging. Product regulation includes restrictions to nicotine concentrations in 35 countries, prohibition of some harmful ingredients in 33 countries, and quality control on liquids and flavors in 33 countries. Forty-two countries also prohibit or restrict e-cigarette use in public places and 16 tax e-cigarettes at a national level.

Twelve countries ban HTPs, while 46 countries regulate the sale and/or use of HTPs. Our policy surveillance identified that HTPs are classified as tobacco products (23 countries), novel products (15 countries), and e-cigarettes (5 countries). Out of the 46 countries that regulate the sale and/or use of HTPs, 18 countries prohibit or restrict marketing and have provisions for reporting and notification. Twelve countries have minimum age of purchase restrictions. Packaging policies like heath warning labels are required for HTPs in 25 countries. Product regulation such as restrictions on emissions are in place in four countries. Sixteen countries also prohibit or restrict HTP use in public places and 22 tax HTPs at a national level.

The countries in our examination of pre-market authorizations and regulatory impact assessments (RIAs) included Canada, the European Union (EU), New Zealand, and the United States (US). The examination of the process for pre-market authorization and RIAs highlight that the regulations and their consequences have to be carefully considered. E-cigarettes, in particular, contain a wide range of

product options and using regulatory power on some segments of the e-cigarette market can have the unintended consequence of making other segments more popular.

Countries have adopted different policies to regulate e-cigarettes and HTPs, including completely banning these products. Having a clear picture of the current tobacco epidemic in a country after full implementation of the WHO FCTC guidelines can help governments assess the impact of introducing new tobacco and/or nicotine products to the market. This should include an assessment of resources and regulatory capacity.

Introduction

This report describes the international regulatory landscape for electronic nicotine delivery systems (ENDS) which include electronic cigarettes, or e-cigarettes, and heated tobacco products (HTPs). In Brazil, these devices are jointly referred to as "electronic devices to smoke."

E-cigarettes are devices that heat a liquid, typically propylene glycol (PG) and/or vegetable glycerin (VG), that contains nicotine and usually flavorants. The e-cigarette device heats the e-cigarette liquid to create an inhalable aerosol. There are many different types of e-cigarette devices available on the market that differ in size and battery/power. There are many different e-cigarette liquids with different proportions of VG and PG, different concentrations of nicotine, different nicotine formulations, and literally thousands of different flavors available. There are also e-cigarettes that do not contain nicotine, but those will not be featured here. The term e-cigarettes throughout will refer to nicotine containing e-cigarettes unless otherwise noted.

E-cigarettes were invented in China in 2003 and became commercially available globally, starting in Europe and the United States in 2006.[1,2] The sale/use of e-cigarettes have rapidly increased in high income countries like the United States, Canada, and the United Kingdom. E-cigarettes are now available around the globe, but the same rapid increase has not been experienced in every country. The use of "electronic devices to smoke" among individuals 15 years old and older in Brazil has remained very low (0.6%).[3]

E-cigarettes should be marketed by manufacturers and retailers as means to deliver nicotine to the user as a way to replace combustible smoking.[4] In actuality, several marketing strategies are being used to promote e-cigarettes, with evidence showing that they often target adolescents and young adults.[5,6,7] In August 2019, the US Congress held hearings to examine JUUL role in the youth e-cigarette epidemic[8] and called attention to the use of several marketing practices from the tobacco industry towards youth.[9,10] The high availability of flavored e-cigarettes is one of these practices know to appeal to youth.[11]

The literature on the health impacts of e-cigarettes is nascent, given that they have not been on the market for very long, and that the products are heterogeneous and continue to evolve. Some data indicate that e-cigarettes are less harmful than cigarettes,[12,13,14,15,16] but that does not mean e-cigarettes are harmless. Studies with animals have found that chronic exposure to nicotine-containing vapor from e-cigarettes altered molecular biomarkers associated with lung injury[17] and increased arterial stiffness and impaired normal vascular reactivity responses.[18] The impact of e-cigarettes on public health is still unclear. Some studies show that the majority of adults using e-cigarettes are current smokers;[19,20,21,22,23] there is also evidence that some non-smokers, especially youth, are experimenting with e-cigarettes.[24,25] A recent study found that 29.1% of never smokers and vapers between 16-19 years across Canada, England, and the United States were susceptible to trying e-cigarettes compared to 19.3% to trying cigarettes.[26]

HTPs are a class of tobacco products that heat processed tobacco leaf (similar to a cigarette). Some HTPs heat tobacco products called sticks or plugs or capsules[27], which are heated to a temperature below pyrolysis but sufficiently hot enough to create an aerosol that contains nicotine and other constituents. Some HTPs use processed tobacco sticks (or similar) that include additives that introduce flavors. HTPs were first introduced in the US in the late 1990s, but were discontinued due to a lack of popularity[28] As of 2014, a new generation was reintroduced to the market; first with IQOS – the Philip Morris' flagship HTP – followed by Glo – the British American Tobacco flagship HTP – in 2016. Despite claims that these

products are less harmful, their impact on health is also unclear and independent studies assessing short- and long-term health consequences of their use in humans have not been conducted.[28,29] A recent animal study found that short-term exposure to aerosol from IQOS resulted in similar lung damage and inflammation as found among mice exposed to cigarette smoking,[30] as well as similar cardiovascular effects from acute exposure to IQOS aerosol.[31]

In the US, prevalence of HTP use has increased. In 2017, 0.7% of adults age ≥18 years reported ever use of HTP[32] compared to 2.4% in 2018.[33] In addition, 1.4% of middle and high-school students reported HTP use in the past 30 days in 2020.[34] Similar prevalence data have been reported in countries such as Italy,[35] and a similar trend was observed in the Republic of Korea, where 3.5% and 5.7% of young adults (18-24 years old) reported current and ever use, respectively, only three months after the introduction of HTP to the market;[36] 2.8% of adolescents (12-18 years old) reported ever use one year later.[37] Japan, where HTPs are widely available, has observed a very rapid increase in HTP use among 15-69 year olds: from 0.2% in 2015 to 11.3% in 2019.[38] This same study found that over 30% of the HTP users were current smokers. Studies have shown that HTP advertising also targets youth.[39,40]

It is important to note that some companies have even developed hybrid devices, combining both e-cigarette and HTP technology. The introduction of new, and rapidly changing, products that can be viewed as possible complements or substitutes for existing tobacco products leaves policies susceptible to creating unintended consequences. While dealing with new products can be challenging for policymakers, governments need to decide how to regulate these products and how those regulations compare to the treatment of existing tobacco products. Considerations given to these new products include the benefit of potentially providing a pathway to reduced exposure to harmful constituents, the risk of introducing young/naïve nicotine users to addictive products, and the unknown health consequences. Regulations for these new products can determine if they will have an advantage or disadvantage compared to existing tobacco products. For example, a study on product prices for 34 countries between 2014-2017 found that some countries are giving tax advantages to HTPs, resulting in lower HTP related costs in relation to cigarettes.[41] Markets for e-cigarettes and HTPs are rapidly changing and growing. With the help of the internet, awareness and availability of these products can outpace local regulations. Evidence that these alternative tobacco products are quite different from each other makes trying to regulate them together challenging.

The WHO Framework Convention on Tobacco Control (FCTC) is an international treaty which delineates several evidence-based policies to reduce tobacco use and exposure to tobacco smoke worldwide. The member parties to the FCTC have not provided recommendations on how to regulate e-cigarettes. A decision from Sixth Conference of the Parties (COP6) in 2014 indicated that Parties should consider banning e-cigarettes or regulating them as tobacco products, medicinal products, consumer products or other, as appropriate; and a decision from COP7 (2016) calls for regulatory measures to prohibit or restrict e-cigarette use, sale, manufacturing, etc.[42] In 2018, a decision from COP8, recognized HTPs as tobacco products indicating they should be subject to the same provisions established for other tobacco products.[43]

The WHO recommends regulatory measures for e-cigarettes appropriate for their context considering the health risks for users and non-users, promotion and initiation by non-smokers, youth, and pregnant women, prohibiting misleading and unproven claims, and protecting tobacco control efforts from tobacco industry interference.[44] The WHO recommends regulating HTPs as tobacco products following all MPOWER measures and FCTC guidelines.[44]

Other tobacco control organizations have shared their considerations and recommendations for the regulation of both e-cigarettes and HTPs. The Campaign for Tobacco-Free Kids proposes a three-step process for governments to follow when thinking about regulation: 1) pursue public health policy goals; 2) assess country circumstances; 3) select regulatory option(s).[45] The International Union Against Tuberculosis and Lung Disease presents arguments for low- and middle-income countries to ban e-cigarettes and HTPs given that these products are advertised to youth, have not been proven to reduce harm given they are usually used in conjunction with cigarettes, might worsen the tobacco epidemic and increase the burden on governments by diverting resources from tobacco control measures and increasing tobacco industry interference.[46]

As the evidence around the health impacts from e-cigarette and HTP use begins to build, more countries will adopt regulatory measures or revise previously adopted ones. The purpose of this report is to provide an overview of current international regulations of these products and to discuss the regulatory processes of select countries where information is available.

Methods

This study uses data from the global surveillance scan (globaltobaccocontrol.org/e-cigarette_policyscan) of e-cigarette and HTP policies that covers over 130 countries and is conducted by the Institute for Global Tobacco Control (IGTC) at the Johns Hopkins Bloomberg School of Public Health. The study also analyzes documents that detail some of the regulatory processes related to adopting or revising tobacco product regulations in Canada, the European Union, New Zealand and the United States.

Global policy surveillance of e-cigarette and HTP regulations

Since 2014, the Institute for Global Tobacco Control (IGTC) at the Johns Hopkins Bloomberg School of Public Health has conducted surveillance of national-level policies regulating e-cigarettes in an effort to understand different national-level regulatory approaches.[47]

IGTC conducts regular media monitoring of e-cigarette policy news using media alerts from Google Alerts and Tobacco Watcher (tobaccowatcher.globaltobaccocontrol.org). Tobacco Watcher is a surveillance system for tobacco-focused media stories in 23 languages. A similar search strategy is employed with both platforms using variants of the terms ‘electronic cigarettes’ and ‘regulation’ as keywords. Beginning in 2018, the same policy surveillance methods were used to identify policies for regulating HTPs. This included expanding the alerts with keyword variants for ‘heated tobacco product’. Articles from Tobacco Watcher are machine translated into English and those identified as relevant are used to prompt in-country experts for details and summaries of any newly implemented regulations. In addition, IGTC conducts outreach to country-specific tobacco control policy experts twice a year to solicit updates or information on the status of e-cigarette and HTP regulations.

The scan is currently conducted with public health and tobacco control experts in over 130 countries. Copies of policies regulating e-cigarettes and/or HTPs are obtained and then reviewed by staff and faculty at IGTC and/or a public health lawyer to characterize how products are being regulated. Policies that are not available in English are machine translated and the details are confirmed by in-country experts. This review process identifies the kind of legal mechanisms used (such as a law or decree), whether this policy is new and specific to e-cigarettes or HTPs, or if existing policies are applied to these products. The team also assesses how e-cigarettes and HTPs are classified (for example, as a tobacco product, a consumer product, and/or a medicinal product). Finally, policies are reviewed to identify what regulatory domains are being applied to e-cigarettes and/or HTPs, including any outright ban of

these products. Regulatory domains include minimum age of purchase, sales restrictions, marketing/advertising restrictions, packaging requirements, product regulations (such as, limiting nicotine concentrations or banning product constituents including flavorants), reporting requirements, clean air provisions, and tax/price requirements.

After policies have been reviewed, IGTC shares the determined legal mechanism, product classification and regulatory domains with at least one in-country expert. In-country experts are often employees of government ministries or members of civil society organizations. In-country experts review the determinations made prior to the scan being updated.

The results of the most recent policy surveillance work are presented here.

Understanding government regulatory strategies in selected countries

Our team identified documents outlining the guidelines for pre-market authorization, a process that e-cigarette and/or HTP manufacturers undergo before introducing their products to the market. In addition, we identified and reviewed regulatory impact assessments (RIAs) that modeled effects of e-cigarette and/or HTP regulations.

Purposive sampling was employed to identify documents through government websites. The selected countries were: Australia, Canada, Ecuador, the European Union, Japan, New Zealand, and the United States. These countries were selected because they either recently implemented new policies regulating e-cigarettes and/or HTPs, revised existing policies, or, in the case of Japan, had a unique scenario in which nicotine-containing e-cigarettes are banned, but HTPs are allowed.

When pre-market authorization and/or RIA documents were not located, input was requested from in-country experts who support our policy surveillance work. Identified documents were reviewed and content analyzed by the study team. The following information was extracted into Microsoft Excel: a) citation; b) government body responsible for the regulatory process; c) steps/approaches taken during the process(es); d) key definitions; e) key criteria; f) key evidence; g) reason for conducting the assessment; and h) other relevant information.

Results

National-level policies regulating e-cigarettes and HTPs

IGTC's surveillance of national-level regulations of e-cigarettes and HTPs has identified 101 countries that regulate e-cigarettes with a ban or sale/use restrictions. The surveillance has further identified 58 countries that regulate HTPs with a ban or sale/use restrictions.

E-cigarette policy regulation

Based on the policy surveillance work, e-cigarette regulation can be classified into one of the following categories: 1) countries that ban the sale of all e-cigarettes or ban the sale of only e-cigarettes containing nicotine, 2) countries that regulate the sale and/or use of e-cigarettes, 3) countries that report they do not have regulations for e-cigarettes, and 4) countries that report that the current e-cigarette regulatory environment is unclear.

The sale of all e-cigarettes or only e-cigarettes that contain nicotine is banned (category 1) in 34 countries. The sale of all e-cigarettes is banned in 30 countries (Argentina, Brazil, Brunei Darussalam, Cambodia, Colombia, Egypt, Gambia, India, Iran, Kuwait, Laos, Lebanon, Mauritius, Mexico, Nepal,

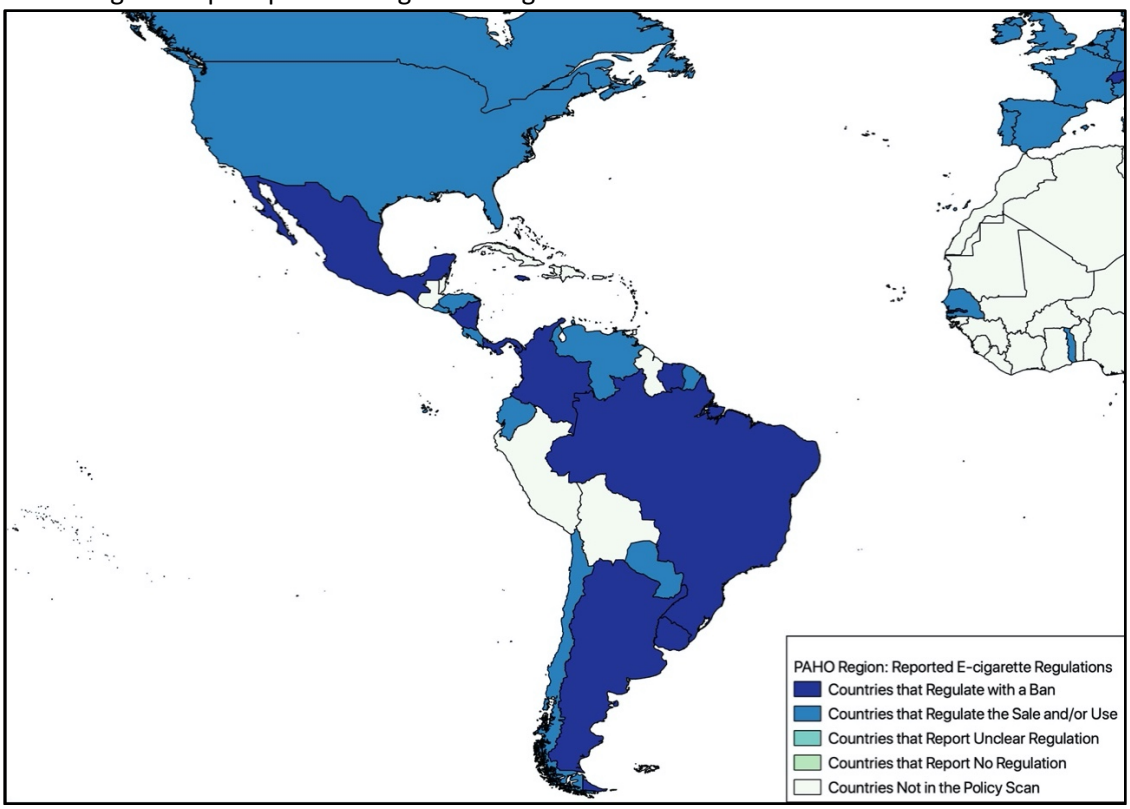
Nicaragua, Oman, Panama, Qatar, Seychelles, Singapore, Sri Lanka, Suriname, Syrian Arab Republic, Thailand, Timor-Leste, Turkey, Turkmenistan, Uganda, and Uruguay). Four countries (Australia, Jamaica, Japan, and Switzerland) make the distinction in their policies between e-cigarettes that have and do not have nicotine. These four countries ban the sale of nicotine-containing e-cigarettes.

The sale and/or use of e-cigarettes is allowed with regulations (category 2) in 67 countries (Austria, Azerbaijan, Bahrain, Barbados, Belgium, Bulgaria, Canada, Chile, China, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, El Salvador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Honduras, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Jordan, Latvia, Lithuania, Luxembourg, Malaysia, Maldives, Malta, Moldova, Netherlands, New Zealand, Norway, Palau, Paraguay, Philippines, Poland, Portugal, Romania, Saudi Arabia, Senegal, Serbia, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Tajikistan, Togo, Ukraine, United Arab Emirates, United Kingdom (including England. Scotland, Northern Ireland, Wales) United States, Venezuela, and Vietnam).

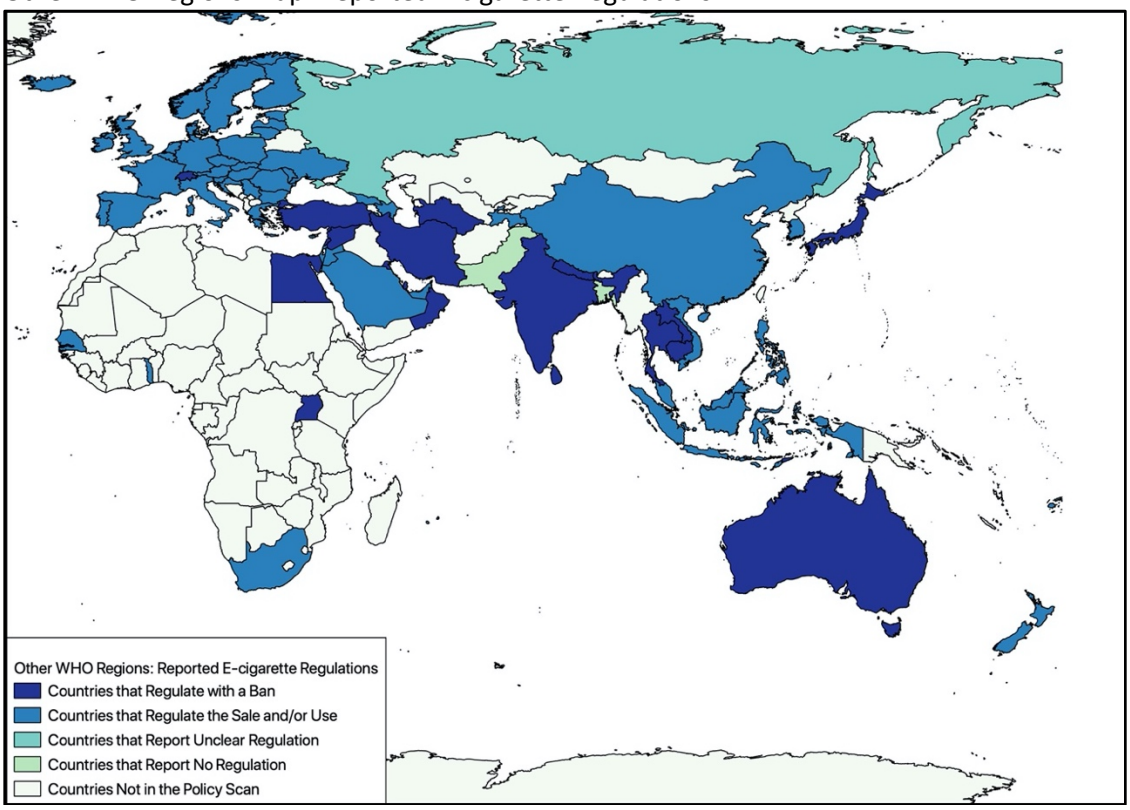
Two countries (Bangladesh, Pakistan) have reported that they have no regulations on e-cigarettes (category 3), and it was reported that the regulatory environment is unclear (category 4) in Russia. According to in-country experts in Russia a law passed in 2019 sets the definition for e-cigarettes, but further regulations on their use are unclear.

The e-cigarette policy scan has no reported information for 91 countries/jurisdictions; these countries have no data in the policy scan because they do not have any stated regulations on e-cigarettes or a lack of in-country experts available to confirm information.

PAHO Region Map: Reported E-cigarette Regulations



Other WHO Regions Map: Reported E-cigarette Regulations



Classification of e-cigarettes

E-cigarettes are classified as ENDS or vaping products (70 countries), tobacco products (57 countries), consumer products (18 countries) or medicinal products (23 countries). In some instances, e-cigarettes can be classified as multiple types of products. For example, the United Kingdom allows e-cigarettes on their market as consumer products and medicinal products, the latter requiring approval and licensing. The classification of e-cigarettes is particularly important for countries that classify them as a tobacco product and have ratified the FCTC, which has specific guidelines on how to regulate tobacco products (such as, clean air and advertising restrictions).

Twenty-three countries provide a pathway for products that make a cessation claim and/or contain a specific threshold of nicotine to be medicinal products (Austria, Belgium, Canada, Chile, Denmark, England, Estonia, Finland, France, Iceland, Ireland, Jamaica, Japan, Northern Ireland, Norway, Philippines, Scotland, South Africa, Sweden, Thailand, United States, Venezuela and Wales).

Regulatory mechanisms of e-cigarettes

The mechanisms by which countries regulate e-cigarettes can vary. Many countries adopted new or specific regulations to include e-cigarettes. For members of the European Union, this meant harmonizing the Tobacco Products Directive (TPD) and regulating e-cigarettes as a novel product. However, some countries (e.g., Laos, Turkmenistan, Uruguay, Jamaica) have amended current tobacco control regulations to include e-cigarettes and other countries (e.g., Brunei, Colombia, Honduras, Iceland, Malaysia) indicate that existing regulations broadly define tobacco products and thus they also apply to e-cigarettes.

Policy domains for e-cigarettes
All of the 67 countries that regulate the sale and/or use of e-cigarettes also regulate these products in one or more of the following domains. Fifty-four countries prohibit or restrict marketing, 48 require marketing authorization before being sold, and 34 require premarket notification. In line with other tobacco products, 43 countries have minimum age of purchase restrictions. Heath warning labels are required for e-cigarettes in 40 countries and 32 countries require child safety packaging. Product regulation includes restrictions to nicotine concentrations in 35 countries, prohibition of some harmful ingredients in 33 countries, and quality control on liquids and flavors in 33 countries. Forty-two countries also prohibit or restrict e-cigarette use in public places and 16 tax e-cigarettes at a national level.

HTP policy regulation
Based on the policy surveillance work, HTP regulation can be classified into one of the following categories: 1) countries that ban the sale and/or use of HTPs, 2) countries that regulate the sale and/or use of HTPs, 3) countries that report not having HTP regulations, and 4) countries that report that HTP regulations are unclear.

The sale and/or use of HTPs is banned (category 1) in 12 countries (Australia, Brazil, India, Iran, Malta, Mexico, Norway, Oman, Panama, Singapore, Thailand, Uruguay).

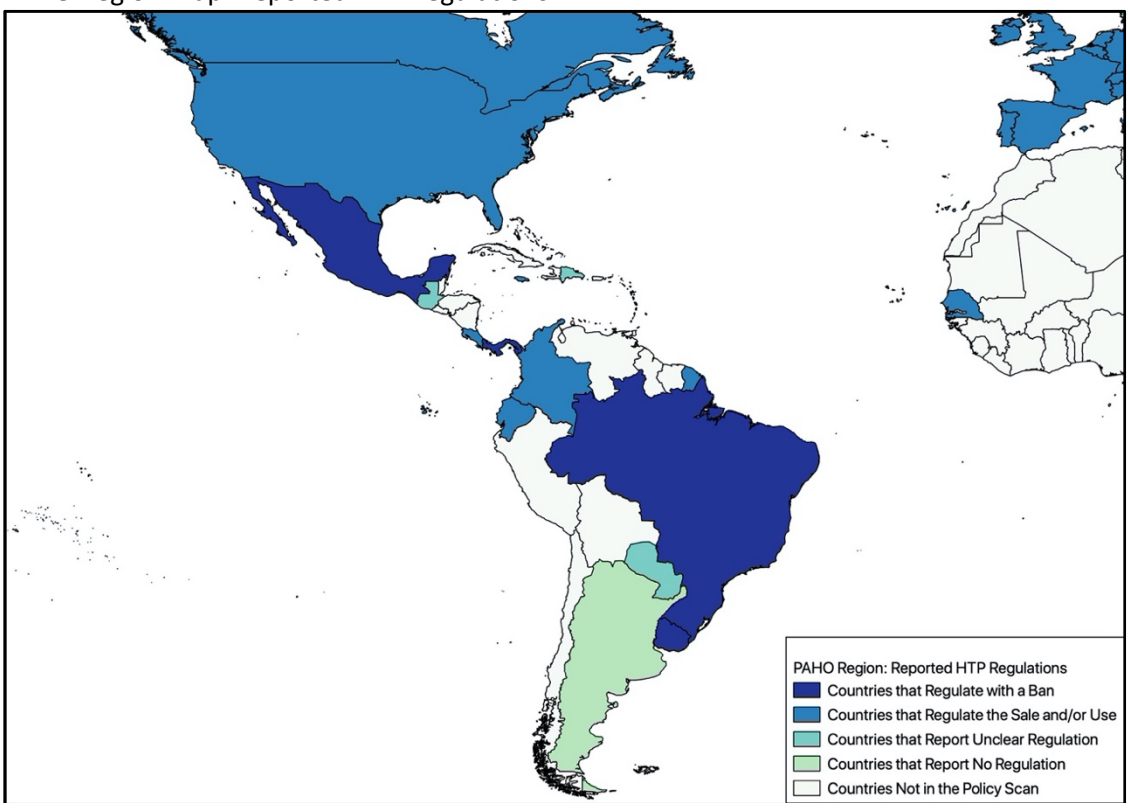
The sale and/or use of HTPs is allowed with regulations (category 2) in 46 countries (Belgium, Brunei, Canada, Colombia, Costa Rica, Cyprus, Czech Republic, Ecuador, Estonia, Fiji, France, Georgia, Germany, Ireland, Israel, Italy, Jamaica, Japan, Luxembourg, Malaysia, Maldives, Moldova, Nepal, Netherlands, New Zealand, Philippines, Poland, Portugal, Romania, Saudi Arabia, Senegal, Seychelles, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Tajikistan, Timor-Leste, Turkey, Turkmenistan, United States, United Kingdom (including England. Scotland, Wales)).

There is no regulation for HTPs (category 3) reported in six countries (Argentina, Azerbaijan, Bahrain, Cambodia, Iceland, Finland). This category includes countries with tobacco control policies that do not specifically apply to HTPs.

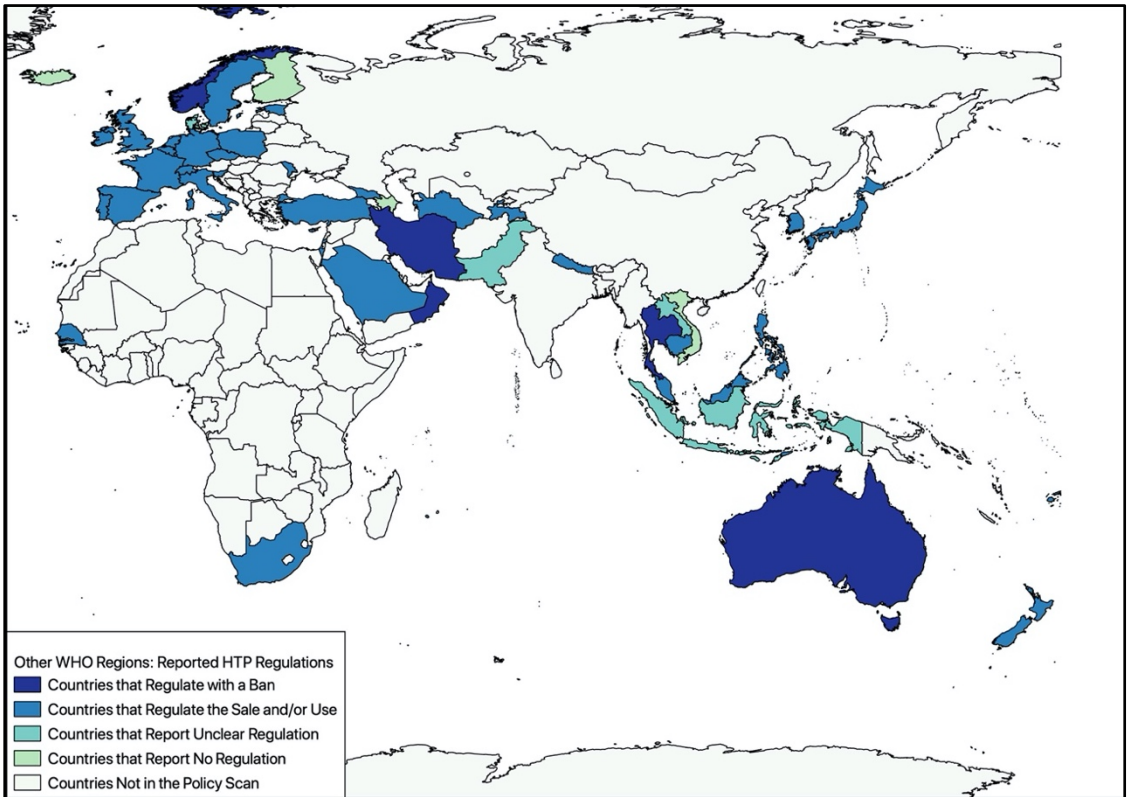
The regulatory environment is reported to be unclear (category 4) for HTPs in nine countries (Denmark. Dominican Republic, Guatemala, Indonesia, Laos, Pakistan, Palau, Paraguay, Vietnam). An unclear regulatory environment can be due to poorly written tobacco control laws that do not define or specify if HTPs are included, or the language is ambiguous.

The HTP policy scan has no reported information for 122 countries/jurisdictions. HTPs are a newer product where regulations may not have been adopted to cover these products. Additionally, these remaining countries/jurisdictions have no data in the policy scan due to a lack of confirmation of such policies by in-country experts.

PAHO Region Map: Reported HTP Regulations



Other WHO Regions Map: Reported HTP Regulations



Classification and policy domains of HTPs
Our policy surveillance identified that HTPs are classified as tobacco products (23 countries), novel products (15 countries), and e-cigarettes (five countries).

Out of the 46 countries that regulate the sale and/or use of HTPs, 18 countries prohibit or restrict marketing and have provisions for reporting and notification. Twelve countries have minimum age of purchase restrictions. Packaging policies like health warning labels are required for HTPs in 25 countries. Product regulation like restrictions on emissions are in place in four countries. Sixteen countries also prohibit or restrict HTP use in public places and 22 tax HTPs at a national level.

Country-specific regulatory processes: pre-market authorization and RIAs
The selected countries in our examination of pre-market authorization and RIAs included Australia, Canada, Ecuador, the European Union (EU), Japan, New Zealand, and the United States (US). We could not identify relevant documents for Australia and Japan, and key informants from Ecuador confirmed that their decision to regulate e-cigarettes followed recommendations from the FCTC and experience from other countries. Canada, the EU, and New Zealand conducted RIAs to review their legislation regarding e-cigarettes and HTPs; the US already offered a pathway for marketing approval for HTPs. See table 1 for more details. Appendix 1 compares the legislation for each jurisdiction by product.

Table 1. Overview of regulatory processes

	RIA	*Pre-market authorization*	*Responsible for the process*	*Specific to a product?*	*FCTC party*	*Public consultation available*	*Target stakeholder engagement*	*Cost-benefit analysis*
Canada	Yes	No	Health Canada	No	Yes	Yes	Yes	Yes
EU	Yes	No	European Commission	No	Yes	Yes	Yes	Yes
New Zealand	Yes	No	Ministry of Health	No	Yes	Yes	Yes	Yes
US	No	Yes	FDA	Yes	No	Yes	No	NA*

*information not available

Canada - the Tobacco and Vaping Products Act (TVPA)[48,49]

> *"Vaping products are harmful, particularly to the health of youth and non-users of tobacco products. For adult tobacco users (e.g. smokers) who completely switch to vaping, these products offer a less harmful alternative to tobacco use."*

Before the implementation of the TVPA in May 2018, e-cigarettes[a] were not regulated in Canada, and the country observed a dramatic rise in youth use of e-cigarettes driven mostly by promotional activities. The overall aims of the TVPA include protecting youth and non-tobacco users from vaping

[a] In Canada, e-cigarettes are classified as vaping products, which are defined as "a) a device that produces emissions in the form of an aerosol and is intended to be brought to the mouth for inhalation of the aerosol; b) device that is designated to be a vaping product by the regulations; c) a part that may be used with those devices; and d) substance or mixture of substances, whether or not it contains nicotine, that is intended for use with those devices to produce emissions." (Vaping Products Labelling and Packaging Regulations: SOR/2019-353)

products and enhancing public awareness of vaping products, especially about their health hazards. The TVPA and associated regulations set out e-cigarette regulations in relation to 1) warning labels, 2) product specifications (nicotine concentration, additives, child safety packaging), and 3) marketing.

Under the general rulemaking of Canada, an RIA is required. As the Canadian department overseeing national health policy, Health Canada is responsible for proposing and creating regulations and conducting RIAs. Part of this process includes public consultation regarding the proposal to then draft regulations/guidelines, which are published again for a consultation period. In some cases, Health Canada invited specific stakeholders to submit comments on the proposal. Health Canada also commissioned a public opinion research study on nicotine-related health warnings to test different warning statements. Overall, the RIA of e-cigarettes was based on two criteria: 1) cost-benefit analysis, which outlined the financial impact to manufacturers, government, and consumers; 2) any potential impacts to small-businesses due to increased regulations. As part of the RIA, a "Gender-bases analysis plus (GBA+)" was conducted to identify potential impacts based on sex, gender, race, and ethnicity. Different policy options were also delineated with indication of the preferred one by Health Canada.

In its RIA, Health Canada recognized the lack of evidence regarding the long-term effects of vaping and their intentions to establish a regulation to prevent youth initiation of e-cigarettes and other tobacco products; yet, it recognized that e-cigarettes offer a less harmful alternative to adult smokers if they switch completely.

European Union – the Tobacco Products Directive (TPD)[50]

"The overall objective of the revision is to improve the functioning of the internal market, while ensuring a high level of health protection."

The TPD was adopted by the Member States in 2001; ten years later, a revision was initiated to update the TPD considering the developments in the market, science, and global scenario and also to ensure implementation of the FCTC, which is the underlying pillar of the RIA. One of the main points for revision accounted for the fact that e-cigarettes or other nicotine containing products (NCPs)[b] were not available when the TPD was adopted. The RIA highlights how NCPs were primarily marked as consumer/leisure products and also as alternatives to cigarettes, but not as devices to support cessation. In addition, the RIA recognizes the growing interest of the tobacco industry in getting involved with e-cigarettes.

The European Commission was the organization responsible for the review process, which included an analysis of economic, social and health impact of all the proposed policy options accounting for socioeconomic, legal, and scientific considerations. Specific concerns around e-cigarettes were related to: ingredients, packaging safety, market, marketing, use in smoke-free places, and competition with nicotine replacement therapies. All policy options were evaluated in terms of their effectiveness (can

[b] The RIA defines NCP as "a product usable for consumption by final consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption". Novel tobacco products as defined as "a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of the Directive." Finally, smokeless tobacco products (STP) are defined as "a tobacco product not involving a combustion process, including tobacco for oral use."

they achieve their objectives), efficiency (can they be achieved considering certain level of resources or at least cost), and coherence (are they aligned with overarching objectives of EU policy).

The process included the following steps:

- **Reports** assessing the application of the TPD, of which the second one addressed the regulation of STP and new tobacco and nicotine products.
- **Public consultation** on the proposed revision of the TPD.
- **Target discussions** over a 3-year period with stakeholders, including consumers, representatives of the industry, NGOs and who were able to submit **written contributions** as well.
- **Regular meetings** of the TPD Regulatory Committee over a 3-year period.
- Establishing the **Inter Service Steering Group (ISSG)** to support the Directorate-General for Health and Consumers (DG SANCO).
- Commission of **external studies**.
- **Two opinions** presented by the European Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).
- **Eurobarometer surveys**.
- **Impact Assessment Board (IAB).**

New Zealand - the Smoke-free Environments Act (SFEA)[51]

> *"The literature on vaping products is growing, but at this stage the evidence is not conclusive. However, it is clear that vaping is significantly less harmful than smoking and it appears likely that vaping can help people to stop smoking."*

Based on a rapid increase in e-cigarette use in New Zealand combined with a regulatory framework (SFEA) that did not regulate products considered less harmful to users (i.e., e-cigarettes and smokeless[c]), the Ministry of Health (MOH) commanded the RIA process, setting forth recommendations for reviewing the framework with the following criteria for policy development: harm reduction; harm prevention; risk proportionality; cost and ease of implementation. To assess product safety, the RIA process included a review of guidelines established by regulatory agencies in other countries.

The following steps were taken as part of the process:

[c] We decided to use e-cigarettes for consistency; however, throughout the RIA, the terminology used is *vaping products* defined as: "(…) electrical devices that produce a vapour, rather than smoke, by heating a solution (vaping liquid) which the user inhales. Vaping liquids are available with or without nicotine and are usually flavoured. The liquids and devices can be sold separately." E-cigarettes making a therapeutic claim (e.g., support cigarette cessation) are regulated under the Medicines Act 1981 and are not part of the scope of this RIA. HTPs are considered smokeless products and are defined as "devices that heat, rather than burn, manufactured tobacco sticks." Prior to a Court decision in a lawsuit of Philip Morris vs MOH that established as lawful the sale, import, and distribution of HEETS (tobacco sticks used with HTPs), only nasal tobacco was lawfully sold in the country. *(Supporting smokers to switch to significantly less harmful alternatives – Regulatory Impact Statement)*

- **Public consultation** on regulating e-cigarettes and e-cigarette liquids with nicotine as consumer products; establishing regulatory controls on product safety; and establishing excise duty on e-cigarette liquids with nicotine.
- **Target stakeholder engagement**, which included health sector agencies, practitioners, and researchers; e-cigarette and/or cigarette users; e-cigarette and cigarette manufacturers, importers, and retailers.
- Development of **policy options** for specific domains (e.g., use in smoke-free areas and regulation of promotion, advertising and sponsorship).
- **Impact analysis** of each policy option considering the criteria for policy development (i.e., harm reduction; harm prevention; risk proportionality; cost and ease of implementation) in comparison with the status quo (no changes to SFEA).
- **MOH policy recommendation/preference**, including **costs** and **benefits** to each of them.

United States - Modified Risk Tobacco Products (MRTP)[52]

> *"Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."*

The Federal Food and Drug Administration (FDA) in the United States has established a regulatory framework that allows for new tobacco products to apply to be lawfully sold in the country through a premarket tobacco application (PMTA). Here we review the process for a specific HTP, IQOS, which applied for a PMTA, granted in April 2019, and to be considered under the Modified Risk Tobacco Products (MRTP). Any other product applying to a MRTP would be subject to the same process delineated here.

While the FDA is the overall responsible party for the pre-market authorization process, all applications are available for public consultation and, if deferred, are reviewed by the Tobacco Products Scientific Advisory Committee (TPSAC)[d] (except for the MRTP, then all are reviewed by TPSAC). In its review, the FDA assesses: relative health risk; likelihood of smokers who would have quit tobacco use to switch; initiation of use by non-smokers; risks and benefits compared to nicotine replacement therapy; and, comments, data, information shared by interested individuals. Applicants should provide information on how the product is expected to benefit the health of the whole population.

The review process is comprised of the following phases:

- Phase 0 – **Pre-submission meetings** between the applicant and the FDA (not mandatory).
- Phase 1 – **Acceptance review** to ensure that the product falls under the authority of the FDA's Center for Tobacco Products (CTP).
- Phase 2 – **Filing review** to ensure the application includes all the required items.

[d] TPSAC is comprised of 12 individuals with knowledge in diverse areas regarding the manufacture, evaluation, and use of tobacco products. Members are selected by the FDA Commissioner and can serve for up to four years. Out of 12 members, nine are considered voting members with specific technical qualifications (e.g., physician in a relevant area) while the other three are non-voting members, who represent the industry interests (e.g., tobacco growers and manufacturers).

- Phase 3 – **Substantive review** of the available evidence in the application and FDA's evaluation of the TPSAC recommendations, public comments, and any other information shared with it. As part of this process, the FDA might request additional information. The result of this review is a **Final Action** taken by the FDA to either grant a modified risk order or not.
- Phase 4 – **Postmarket Reporting** (applicable only if the product was granted a modified risk order) requires that the applicant conducts and submits for review surveillance and postmarket studies to assess consumers' perceptions, behaviors and health.

Granted authorizations are not permanent, and the applicant must renew after the established period (e.g., IQOS authorization is valid for four years).

IQOS has been authorized under the MRTP with an *exposure modification order*, and not a *risk modification order*, since there was not enough evidence that the product would significantly reduce harm and the risk of diseases related to tobacco to users and would not benefit the health of population as whole.[48] With the exposure modification order, the product is allowed to be marked "as containing reduced level of or presenting a reduced exposure to a substance or as being free of a substance."

Discussion

National-level regulation for e-cigarettes and HTPs span from product sales bans, to open markets with minimal regulations. There exists ambiguity in some countries about whether or how these products are being regulated. These ambiguities can be the result of multiple product classifications within a country and/or banning these new products as part of one regulation, but recognizing these products in separate regulation. At present, the results of our policy surveillance indicate that fewer countries have taken a regulatory stance on HTPs compared to e-cigarettes.

While some research indicates that e-cigarettes can be less harmful than cigarettes, the evidence for HTPs is not supportive of that. The FDA decision about the HTP IQOS allowed a reduced exposure claim, but denied a reduced risk claim. Although they are both electronic devices that can introduce and addict consumers to nicotine, HTPs seems to be more similar to cigarettes than e-cigarettes. Additionally, the FCTC classifies both HTPs and cigarettes as tobacco products, implying that any policy applied to cigarettes should be applied to HTPs. However, some countries that allow their sale and are parties to the FCTC have adopted different policies to regulate cigarettes and HTPs. For example, France, the United Kingdom, Saudi Arabia, and Slovenia exclude HTPs from their plain packaging policy. Also, in Germany, HTPs do not have to bear a graphic health warning like cigarettes and are taxed as pipe tobacco and not cigarettes, bearing lower taxes, which might result in a competitive advantage.[54]

While most countries that regulate e-cigarettes classify them as vaping products, some countries classify e-cigarettes as tobacco products, consumer products and/or medicinal products. There are also instances of countries using multiple product types depending on nicotine levels or health claims. For example, the countries of the United Kingdom allow e-cigarettes on their market as consumer products and have a pathway for products to be licensed as medicinal. In countries where e-cigarettes are allowed and regulated, they sometimes face similar restrictions to cigarettes regarding minimum purchase age, health warning labels, use in public places, and taxation. It is important to consider the strength of e-cigarette policies relative to cigarette policies in the same policy domain.

The examination of the process for pre-market authorization and RIAs highlights that the regulations and their consequences have to be carefully considered. E-cigarettes, in particular, contain a wide range of product options and using regulatory power on some segments of the e-cigarette market can have the unintended consequence of making other segments more popular. While the RIAs generally appeared to be a response to a growing popularity of new products, it should be noted that they were conducted within specific political and socioeconomic contexts which were not part of the scope of this work but certainly influenced the overall regulatory decision. Further, tobacco industry lobbying activities influenced the revision of the EU-TPD.[55]

The introduction of "electronic devices to smoke" to consumers has potential positives and negatives. There is the possible benefit of these products being used to replace cigarette smoking for established smokers. On the other hand, there is the potential cost of creating a pathway to nicotine addiction and to cigarette smoking among individuals who would not otherwise smoke. The potential benefits of these two products appear to be greater for e-cigarettes. Any introduction of such products needs to carefully regulate the products to maximize the benefits and minimize the costs. The introduction of e-cigarettes in a country that has a strong regulatory capacity and where the prevalence of cigarette use is high could be a long-term net positive. But any country deciding to introduce any alternative tobacco products should do so carefully and after fully implementing and enforcing MPOWER measures and FCTC guidelines to curb cigarette smoking. For countries that do not ban e-cigarettes, the WHO recommends regulatory measures appropriate for their context considering the health risks for users and non-users, promotion and initiation by non-smokers, youth, and pregnant women, prohibiting misleading and unproven claims, and protecting tobacco control efforts from tobacco industry interference.[44]

Strengths and Limitations

This report has focused on describing the current policy approaches taken by countries/jurisdictions on regulating e-cigarettes and HTPs. The current policy scan does not conduct surveillance in some countries, and therefore is missing a complete global perspective. Also, it is common for countries to implement policies at a subnational level, which is not captured in the current policy scan.

Despite these limitations, the scan is updated twice a year in order to survey the fast-changing regulatory landscape. The scan relies on in-country experts to identify new policies, changes to existing policies, and/or confirm our policy categorizations, taking care to avoid misinterpretations due to the use of machine translation. The scan reports what policies are enacted and does not incorporate or report the extent to which policies have been implemented. Future studies should explore to the extent that these policies regulating e-cigarettes and HTPs have been implemented. Future studies could also identify subnational policies and explore its implications and potential unexpected consequences within the same country, which offers a somewhat more similar context for policy evaluation.

In order to describe specific regulatory processes for e-cigarette and HTP policy making, we selected countries based on our previous experience and knowledge of the literature and the availability of documents through government websites. Therefore, our work may have missed other country-specific processes that could have further elucidated the decision-making process in other settings. Despite some commonalities among these processes, these findings are not necessarily generalizable to other countries. Moreover, regulation of e-cigarettes and HTPs was not discussed in the broader context of tobacco control and the tobacco epidemic stage of each country. Future studies should consider key informant interviews with different members involved in the process to further contextualize the

available information. Notwithstanding its descriptive character, this report may offer several insights to decision-makers, advocates, and researchers focusing on e-cigarette and HTP regulation.

Conclusion

Countries have adopted different policies to regulate e-cigarettes and HTPs, including completely banning these products. The number of countries adopting or adapting regulations has increased in recent years. Some countries have introduced processes whereby e-cigarette devices could be classified as medicinal devices; to date no jurisdiction has a product for sale that has entered the marketplace via one of these processes.

The FCTC offers evidence-based policies to reduce the tobacco epidemic both at the country-level and worldwide; therefore, it is fundamental that countries prioritize the implementation of the FCTC at its highest level and are able to monitor their progress.

Having a clear picture of the current tobacco epidemic in a country after full implementation of the WHO FCTC guidelines can help governments assess the impact of introducing new tobacco and/or nicotine products to the market. This should include an assessment of resources and regulatory capacity. Moreover, the tobacco industry has a well-documented history of interfering in science and policy and marketing their products to specific groups (such as youth and low-income populations) resulting in tobacco-related disparities. Governments should assure that a new or revisited policy will not create, maintain or exacerbate these disparities even if they could reduce tobacco use as a whole and that they are not influenced by the commercial interests of the tobacco industry.[56]

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Appendix 1: Overview of national policies adopted by Canada, European Union, New Zealand, and United States, by product

CANADA

DOMAIN	**E-cigarettes**	**HTPs**	**Cigarettes**
CLASSIFICATION	Vaping products	Tobacco products	Tobacco products
USAGE	Clean air regulated by provinces/lower-tiered	Near-complete prohibition of use in federal government workplaces	Banned in all public places
MARKETING	Advertising that can be seen or heard by young persons is prohibited (including POS display)	Prohibition of promotion, advertising, and sponsorship except in adult-only venues	Prohibition of promotion, advertising, and sponsorship except in adult-only venues
RETAIL	Sales prohibited to < 18 No restrictions on what type of retailers can sell	Sales prohibited to < 18 No restrictions on what type of retailers can sell	Sales prohibited to < 18 Retailers that have pharmacies cannot sell
PRICING	Fed excise tax: none Province excise tax: varies	Fed excise tax: none Province excise tax: varies	Fed excise tax: CAD 2.40/20 sticks Province excise tax: varies
PRODUCT STANDARDS	Text HWL and nicotine concentration label Child-resistant container for e-liquid with nicotine Nicotine limit < 66 mg/ml Flavors are allowed	Plain packaging with graphic health warning labels Misleading descriptors, such as “light” and “mild” prohibited Flavors are banned*	Plain packaging with graphic health warning labels Misleading descriptors, such as “light” and “mild” prohibited Flavors are banned

*Information hast not yet been confirmed with an in-country expert.

EUROPEAN UNION

DOMAIN	**E-cigarettes**	**HTPs**	**Cigarettes**
CLASSIFICATION	Electronic cigarette*	Novel tobacco products May vary by country	Tobacco products
USAGE	Country-level	Country-level	Country-level

MARKETING	Prohibition on cross-border advertising and sponsorship Country-level: advertising without cross-border effects	Prohibition on cross-border advertising and sponsorship	Prohibition on cross-border advertising and sponsorship
RETAIL	Country-level: age-limit Countries can prohibit cross-border sale	Countries can prohibit internet sales Countries can prohibit cross-border sale	Countries can prohibit internet sales Countries can prohibit cross-border sale
PRICING	Country-level	Country-level	Country-level
PRODUCT STANDARDS	Maximum volume (10 ml) and nicotine concentration (20 mg/ml) Safety and quality requirement Child-resistant container Health warnings and ingredient lists are required Promotional and misleading elements are banned Country-level: flavor restrictions		Text and graphic HWL required (65% front and back of pack) Characterizing flavors are banned (including menthol) Promotional and misleading elements are banned

*If they make a claim to help quitting smoking, then they must seek medicinal license.

NEW ZEALAND

DOMAIN	**E-cigarettes**	**HTPs**	**Cigarettes**
CLASSIFICATION	Tobacco products	Tobacco products	Tobacco products
USAGE	Banned in all public places	Restrictions at the workplace	Banned in all public places
MARKETING	Prohibition of promotion, advertising, and sponsorship, including at the point-of-sale, except for vape shops	Restrictions on promotion, advertising, and sponsorship	Prohibition of promotion, advertising, and sponsorship, including at the point-of-sale

RETAIL	Sales prohibited to < 18 General retailers only carry tobacco, mint/menthol flavors	Sales prohibited to < 18	Sales prohibited to < 18
PRICING	Not subject to excise taxes	NZD 1,370.19/kilo tobacco content (KTC) Taxed as other manufactured tobacco products	Excise tax: NZD 18.50/20 sticks
PRODUCT STANDARDS	Do not require HWLs or nicotine concentration label	Plain packaging with graphic health warning labels	Plain packaging with graphic health warning labels

UNITED STATES

DOMAIN	**E-cigarettes**	**HTPs**	**Cigarettes**
CLASSIFICATION	Tobacco products*	Tobacco products	Tobacco products
USAGE	No federal ban State smoke-free legislation: varies	No federal ban State smoke-free legislation: varies	No federal ban State smoke-free legislation: varies
MARKETING	Must not be marketed as safer than cigarettes without MRTP designation	No TV or Radio ads Should not target youth	No TV or Radio ads Should not target youth
RETAIL	Sales prohibited to < 21	Sales prohibited to < 21	Sales prohibited to < 21
PRICING	Fed Excise: None State Excise: Varying levels vs. cigarettes	Taxed as a cigarette	Fed Excise: USD 1.01/20 sticks State Excise: Varies
PRODUCT STANDARDS	Text health warning label E-liquid container must be child-resistant Flavors partially limited to tobacco and menthol	Text health warning label Flavors limited to tobacco or menthol	Text health warning label Flavors limited to tobacco or menthol

*If marketed as therapeutic product to help quitting smoking, then they are classified as drugs, devices, or a combination of both.

Institute for Global
Tobacco Control

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