COUNTRY CASE STUDIES ON ELECTRONIC NICOTINE AND NON-NICOTINE DELIVERY SYSTEMS REGULATION, 2019

BRAZIL, CANADA, THE REPUBLIC OF KOREA AND THE UNITED KINGDOM

World Health Organization
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Abstract

Electronic nicotine and non-nicotine delivery systems (EN&NNDS) are a heterogeneous class of products that use an electrically powered coil to heat and turn a liquid into an aerosol, which is inhaled by the user. Throughout the world, governments use different approaches to regulate EN&NNDS in their marketplace. This brief provides examples of the three more typical regulatory approaches, including banning the sale of EN&NNDS, applying tobacco-control legislation to these products, and creating an elaborate group of specific regulations or recommendations related to the sale, marketing, packaging, product regulation, reporting/notification, taxation and use in workplaces and public places.

Keywords

ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS)

ELECTRONIC NON-NICOTINE DELIVERY SYSTEMS (ENNDS)

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Introduction

Electronic nicotine delivery systems (ENDS) represent a mixed class of products that use an electrically powered coil to heat and turn a liquid into an aerosol, which is inhaled by the user. The liquid generally is made of propylene glycol, glycerol, or a mix of them; it always includes nicotine and may contain flavours. When the liquid does not contain nicotine, they are referred to as electronic non-nicotine delivery systems (ENNDS). Together, ENDS and ENNDS are referred to as EN&NNDS.

Governments use different approaches to regulate EN&NNDS in their marketplace. Four countries have been chosen to depict those different approaches: Brazil, Canada, the Republic of Korea and the United Kingdom.

Canada and the United Kingdom allow the sale of EN&NNDS and regulate these products with specific norms applicable to them, but both have particular features. Canada has a federal system of government by which the national (or federal) level of government regulates some areas of public life through its executive, legislative or judiciary branches. Subnational levels of government can complement federal regulations related to health or regulate on their own. In the United Kingdom, the Government explicitly promotes that smokers switch from conventional tobacco to using ENDS to quit smoking. The Republic of Korea also allows the sale of EN&NNDS but applies existing regulation for conventional tobacco products to ENDS, although not for ENNDS. Brazil bans de facto the sale of both ENDS and ENNDS.

Three of the four countries have a strong tobacco-control environment, indicated by implementation at the highest level of achievement of at least four of the six[1] MPOWER measures *(1)*. In the following sections, the prevalence of EN&NNDS use and the general regulatory approach towards EN&NNDS is described for each country. Annex 1 and Annex 2 present national or federal regulations by policy domain and the specific subnational regulations in the case of Canada.

Fig. 1 compares the prevalence of daily use of ENDS in a sample of combined smokers and ex-smokers in each of the four countries described in this document.

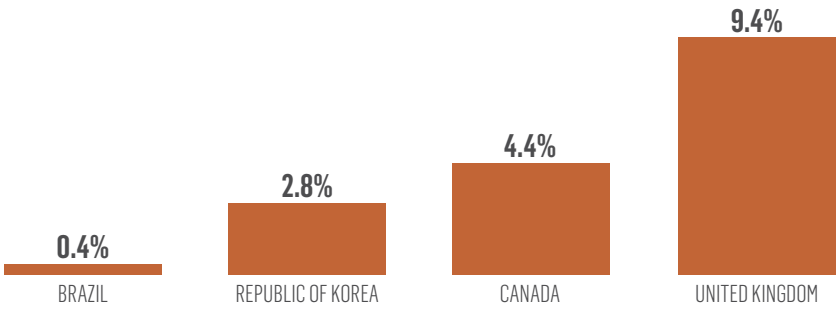

FIG. 1.

Daily use of ENDS among adult (≥ 18 years) smokers and recent ex-smokers in four countries, 2016

Source: modified after Gravely et al. *(2)*

1 The six MPOWER measures are: monitor tobacco use and prevention policies, protect people from tobacco smoke, offer help to quit tobacco use, warn about the dangers of tobacco (health warnings), enforce bans on tobacco advertising, promotion and sponsorship, and raise taxes on tobacco.

Brazil

See Box 1 for a summary of EN&NNDS use in Brazil *(2)*.

BOX 1.
EN&NNDS USE IN BRAZIL

The latest data available from Brazil are from 2016 and cover only the prevalence of ENDS use among a sample of 1340 adult smokers and recent ex-smokers from Rio de Janeiro, São Paulo and Porto Alegre. At the time, 1% of interviewees were using ENDS at least once a month and 0.4% at least daily.

Source: Gravely et al. *(2)*

Effectively, Brazil bans EN&NNDS. The marketing, importation and advertising of "smoking electronic devices" has been prohibited through the Resolution of the Collegiate Board of the National Health Surveillance Agency of Brazil (ANVISA) (RDC) 46/2009 *(3)*. Smoking electronic devices include EN&NNDS and heated tobacco products (HTPs), but manufacturers seeking to market EN&NNDS in Brazil can submit a request for registration of their product if they have the necessary background information proving the efficacy, effectiveness and safety of the devices. In such cases, ANVISA reviews the information provided and decides whether to register the product, and therefore allow its marketing. To date, no request has been submitted for registration of EN&NNDS. If any is registered, the legislation on tobacco control will apply to EN&NNDS and their use will be banned in all indoor public places, workplaces and public transport.

ANVISA's policy for EN&NNDS continues to be to ban them. At the time, the agency's decision was based on the lack of scientific data on the claims of these products, but ANVISA considers its position regularly by reviewing periodically scientific evidence on the potential health risks and benefits of EN&NNDS (in 2016 *(4)*), technical panels (in 2018 *(5)*) and public hearings (in 2019 *(6)*) with participation from the industry and public health organizations (see ANVISA *(7)* for links to all presentations made in the hearings).

Canada

See Box 2 for a summary of EN&NNDS use in Canada *(8)*.

A federal law, the Tobacco and Vaping Products Act (TVPA) *(9)*, allowed the marketing of ENDS only in 2018: the sale of ENNDS was always permitted. Regulations of ENDS stemming from the TVPA were not wholly developed at federal level when this brief was written. Health Canada nevertheless conducted a public consultation on such regulations *(10)*; the comments received were summarized *(11)* and the Government published the proposed regulations in December 2019. These are now subject to public comment until the end of January 2020 *(12)*. If approved, the regulation will place additional controls to: a) further restrict the promotion of vaping products, including at point of sale and online; b) require health warnings on advertisements; c) prohibit the manufacture of vaping products with certain flavours or flavour ingredients; and d) restrict the concentration and delivery of nicotine in vaping products.

Current federal legislation considers EN&NNDS that make health claims separately from those that do not. If they do, they are governed at federal level by the Food and Drugs Act *(13)* and its regulations, in addition to the TVPA. If EN&NNDS do not make health claims, they are governed by the Canada Consumer Product Safety Act *(14)*, as amended in 2018, and the TVPA of 2018.

The TVPA aims "to prevent vaping product use from leading to the use of tobacco products by young persons and non-users of tobacco products" *(9)*. It establishes a national minimum age of sale for vaping products and significantly restricts their promotion, including bans on lifestyle advertising or promotions that are appealing to young people.

All e-liquids are also subject to the Consumer Chemicals and Containers Regulations of 2001 *(15)*. The Non-smokers' Health Act addresses where to use and where not to use EN&NNDS in federal workplaces *(16)*. Provinces have the authority to expand on the law, including where to use EN&NNDS or not in venues that are not under federal jurisdiction.

EN&NNDS are not treated like tobacco products under Canadian tax legislation. Only the regular general sale tax, which includes a provincial sale tax component, presently applies *(17)*. Two provinces, however, announced in 2019 a tax increase on EN&NNDS for 2020. The Government of British Columbia will increase the provincial sales tax on EN&NNDS from 7% to 20% *(18)*. The tax will apply to all EN&NNDS devices, any substance used in the device, and parts and accessories. The new regulations in British Columbia will also require plain packaging and health warnings for vaping products and restrict public advertising in areas frequented by young people. The Government of Alberta has introduced a fiscal plan *(19)* that includes a 20% tax on the retail sale price of EN&NNDS products in 2020. The tax will

BOX 2.
EN&NNDS USE IN CANADA

In 2017:

- 2.9% and 1.0% of Canadians aged 15 and older had used EN&NNDS in the past 30 days or daily, respectively;
- 12.2% of current smokers and 2.4% of non-smokers were past 30-day EN&NNDS users;
- about 64% of adult EN&NNDS users reported that the last time they used a device, the e-liquid contained nicotine, despite nicotine-containing e-liquids not being approved for sale in Canada at that time; and
- fruit and tobacco were the most commonly cited flavours of the last-used EN&NNDS.

Among young people in school grades 7–9 in 2016–2017:

- 5.4% had used an EN&NNDS product in the past 30 days; and
- two thirds of current smokers had used EN&NNDS in the past 30 days, compared to approximately 5% of non-smokers.

Source: Reid et al. *(8)*.

apply to all vaping liquids, including cannabis liquids and do-it-yourself vaping products sold separately for vaping, such as propylene glycol, vegetable, glycerin, nicotine solutions and flavourings, as well as all vaping devices and related accessories *(20)*. In both provinces, the rationale cited for the tax increase is to curtail the rise of EN&NNDS use among young people.

Health Canada actively monitors TVPA compliance among individuals and corporations. It inspected more than 3000 retail establishments in 2019, while tracking online sales and promotion of EN&NNDS and taking action where necessary. Health Canada is also undertaking a public education campaign through advertising, social media and experiential events in schools to increase awareness about the harms and risks associated with vaping product use targeted at young Canadians aged 13–18 *(21,22)*.

Annex 1 contains a description of the federal regulation that applies to vaping products. Canada is a federal country in which some of its subnational jurisdictions, the provinces, have regulated EN&NNDS within their purview. Eight of the 12 provinces and territories have such laws on EN&NNDS (see Annex 2 for a summary of their provisions).

The Republic of Korea

See Box 3 for a summary of EN&NNDS use in the Republic of Korea *(2,23,24)*.

In 2007, the Government amended the scope of the Tobacco Business Act *(25)* to apply not only to products manufactured using tobacco leaves, but also to those made without using tobacco leaves as the raw materials for inhaling, such as ENDS, except when used as medicines or non-pharmaceutical drugs as covered in the Pharmaceutical Affairs Act *(26)*. Article 27-2 of the enforcement decree *(27)* of the National Health Promotion Act *(28)* in 2017 names ENDS specifically as electronic cigarettes and defines them as products "made to cause the same effect as smoking by inhaling nicotine-containing solution or shredded tobacco into the body through respiratory organ with an electronic device."

ENDS and HTPs are classified in the Republic of Korea as "electronic tobacco" products, so most tobacco-control legislation applies to ENDS and HTPs.

Using ENDS is not allowed where smoking is banned. Smoking is unlawful in all parts of indoor health-care and educational facilities, except universities. Smoking is also prohibited in designated non-smoking areas of workplaces and public places.

Advertising of ENDS is illegal on TV, radio and billboards and other outdoor facilities. Some forms of marketing, such as promotional discounts, are also barred. Enforcement has been challenging, however, typified by the refusal of British American Tobacco Korea to take down an ad in the form of a music video on the grounds that it showcased "an electronic device" and not the container that holds the actual nicotine product. At the same time, British American Tobacco offered an aggressive 50% discount for its vaping devices *(29)*. Other incidents include an ENDS company targeting young people through the promotion of a film in online forums for young people with the option of winning free tickets to watch the movie, the placement of EN&NNDS in films for teenagers and an EN&NNDS company sponsoring a community-based youth orchestra *(30)*.

ENDS must carry pictorial health warnings occupying 50% of the main surfaces of the package *(31)*. ENDS packaging and advertisements should include health-warning text that indicates they contain harmful substances such as tobacco-specific nitrosamines and formaldehyde.

ENDS are subject to a tobacco consumption tax of 628 Won (approximately US$ 0.5) per mL of nicotine solution *(32)*. They are also subject to other taxes and charges (national health promotion, local education and individual consumption taxes) in addition to a waste charge of 24 Won per 20 cartridges (approximately US$ 0.02) and 10% value added tax (VAT). In total, ENDS are taxed at 1799 Won per mL (approximately US$ 1.5) of nicotine liquid *(33)*.

BOX 3.
EN&NNDS USE IN THE REPUBLIC OF KOREA

The Korea National Health and Nutrition Examination Survey estimated in 2017 that the prevalence of using EN&NNDS at least once a month among adults of 19+ years was 2.3%. Among young people between 13 and 18 years, the figure was 2.7%, according to the Korea Youth Risk Behaviour Web-based Survey in 2018.

A study among adult current smokers indicated that 5.5% used EN&NNDS at least once a month and 2.8% on a daily basis.

Sources: Gravely *(2)*; WHO *(23)*; WHO *(24)*.

The epidemic of lung disease related to the use of adulterated e-liquids for EN&NNDS in the United States of America in 2019 has prompted the Government of the Republic of Korea to initiate specific actions to curb the use of these products among young people. The Government is acting on four fronts: amendments to legislation, enforcement of existing laws, surveillance and education.

The Ministry of Health and Welfare has submitted to the National Assembly changes to the legislation to close some loopholes in the definition of tobacco classes, which would include novel products and ban some flavours. The specifics of these announced changes to the law are not yet clear. Through this legislation, the Government will also require vaping manufacturers to submit more detailed information on the ingredients and additives of their products.

In enforcing existing laws, the Government is focused on reducing illegal sales of e-cigarettes, both online and to minors. At the same time, the Korean Agency for Technology and Standards is preventing the distribution and sale of illegal batteries for safety reasons and local authorities across the country are carrying out inspections to enforce smoke-free regulations in public places, with a particular focus on the use of ENDS and HTPs *(34)*.

The Government is closely monitoring potential cases of lung diseases that may be related to the use of EN&NNDS through the existing consumer risk-monitoring system. The Ministry of Health and Welfare is conducting a health education campaign aimed at providing information on the health risks associated with EN&NNDS and counselling for smokers on how they can quit.

The United Kingdom

See Box 4 for a summary of EN&NNDS use in the United Kingdom *(35,36)*.

As of December 2019, the United Kingdom was still part of the European Union (EU), so was subject to the European Tobacco Product Directive (TPD) *(37)* that came into effect in May 2016 and was transposed into United Kingdom law via the Tobacco and Related Products Regulations of 2016 *(38)*.

The TPD does not regulate ENDS with medicinal purposes. ENDS and refill containers presented as a remedy to get rid of nicotine addiction or restoring, correcting or modifying physiological functions in a significant manner, or otherwise intended for medical purposes, are subject to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 *(39)*.

In the United Kingdom, ENDS under these transposed directives and regulations *(40–42)* fall under the purview of the Medicines and Healthcare Products Regulatory Agency (MHRA).

The TPD does not cover ENNDS, which individual EU Member States can regulate. ENNDS are regulated in the United Kingdom under the General Product Safety Regulations 2005 *(43)*.

The regulation of ENDS with no medicinal purposes in the United Kingdom:

- sets safety standards for e-liquid containers, such as being child- and tamper-proof, being protected against breakage and leakage and having a mechanism that ensures refilling without leakage;
- limits the volume of liquid receptacles in disposable ENDS, single-use cartridges and tanks to less than or equal to (≤) 2 mL;
- limits the volume of dedicated refill e-liquid containers to ≤ 10 mL and the maximum concentration of nicotine per amount of e-liquid to ≤ 20 mg/mL;
- bans the following substances in e-liquids:
  - additives that create the impression that a tobacco product has a health benefit or presents reduced health risks, such as vitamins;
  - additives that are associated with energy and vitality, such as caffeine or taurine;
  - additives having colouring properties for emissions; and
  - ingredients that pose a risk to human health in heated or unheated form (except for nicotine);
- requires devices to deliver a consistent dose of nicotine under normal conditions;
- sets labelling requirements such as carrying information on possible adverse effects or addictiveness and toxicity, including a list of ingredients;

BOX 4.
EN&NNDS USE IN THE UNITED KINGDOM

According to the Eurobarometer, 5.6% of adults used EN&NNDS at least once a month in 2017, which represented close to 3 million users. The United Kingdom has the highest prevalence of current use of EN&NNDS in the European Union. Between 18% and 20% of current smokers in 2017 were also EN&NNDS users, while around 9% of ex-smokers and 0.3–0.6% of never-smokers were EN&NNDS users.

Among adults who had ever tried EN&NNDS more than twice in 2017, 42% indicated that they did it to help stop smoking entirely. The proportion of use of EN&NNDS at least weekly among 11–16-year-olds was 1–3% in 2015–2017, depending on the survey. The proportion of never smokers of that age who used EN&NNDS regularly in 2015–2017 was 0.1–0.5%.

Sources: House of Commons Science and Technology Committee *(35)*; European Commission *(36)*.

- sets warning requirements about the addictiveness of nicotine;
- requires all ENDS and e-liquids to be notified to MHRA before they can be sold; by the end of 2017, almost 400 producers had submitted information about 32 407 e-liquids (90% of notifications) or devices (10% of notifications);
- allows consumers and health-care professionals to report side-effects and safety concerns with ENDS or refill containers to MHRA through the Yellow Card reporting system;
- bans the sale and provision of EN&NNDS and e-liquids to persons under the age of 18; and
- bans advertising of ENDS devices and e-liquids on TV, radio, the Internet and specific printed publications.

The TPD does not regulate whether to tax ENDS or how. It leaves these decisions to individual Member States. EN&NNDS currently are taxed in the United Kingdom as a consumer product with a 20% VAT rate. There are no specific taxes for EN&NNDS in the United Kingdom. Tobacco products are taxed at a higher rate than EN&NNDS, with specific taxes in addition to VAT. In the third quarter of 2019, a 10 mL nicotine-containing e-liquid was 4.3 times more affordable than a 20-cigarette pack of Marlboro *(44)*.

The TPD also does not regulate where ENDS can and cannot be used (ENDS aerosol-free areas), with Member States once again at liberty to decide. The United Kingdom has not legislated to restrict where EN&NNDS can be used. Wales attempted to limit the use of EN&NNDS in some public places, but the bill was voted down. An undetermined number of workplaces, public places and transportation systems nevertheless have voluntarily banned the use of EN&NNDS where smoking is prohibited.

The context of regulatory efforts in the United Kingdom is characterized by an active scientific and technical debate. Discussion has been influenced by several reports, specifically those commissioned by Public Health England,[2] the latest of which was published in 2019 *(45)*, and those from the Royal College of Physicians in 2016 *(46)*, the British Medical Association in 2018 *(47)* and the House of Commons Science and Technology Committee in 2018 *(35)*. All these reports agree that EN&NNDS are substantially less harmful to health than smoking but are not risk-free. They also indicate that evidence on the long-term health impact is lacking. They signify or imply that ENDS have been beneficial to public health in the United Kingdom and that their promotion as a substitute for smoking is therefore likely to generate significant health gains. Similarly, they indicate or imply that concerns about the risk of EN&NNDS potentially providing a gateway into conventional smoking have not materialized in the United Kingdom *(36,48)*.

Several of these reports describe the lack of high-quality research into the effectiveness of ENDS as a cessation aid. They nevertheless agree that most reported studies demonstrate a positive relationship between ENDS use and smoking cessation. The report from the House of Commons Science

2 Public Health England is an independent executive agency of the Department of Health and Social Care responsible for making the public healthier and reducing differences between the health of different groups by promoting healthier lifestyles, advising government and supporting action by local government, the National Health Service and the public.

and Technology Committee *(35)* recommends that the National Health Service (NHS) in England should set a clear central NHS policy on ENDS in mental health facilities, allowing ENDS use by patients as the default policy unless an NHS trust can show evidence-based reasons for not doing so. The Government responded to the report with a command paper which broadly accepted the Committee's recommendations *(49)*. Regarding ENDS as cessation aids, Public Heath England indicated that *(45)*:

> Combining EC [electronic cigarettes] (the most popular source of support used by smokers in the general population), with stop smoking service support (the most effective type of support), should be a recommended option available to all smokers.

The National Institute for Health and Care Excellence (NICE)[3] recommended in March 2018 that health and social services should explain to people who smoke and who are using, or interested in using, an ENDS product to quit smoking that while these products are not licensed medicines, they are regulated, and many people have found them helpful in quitting smoking cigarettes. NICE also recommended that people using ENDS should stop smoking tobacco entirely because any smoking is harmful. The NHS long-term plan for England recommends a new universal smoking cessation offer for long-term users of specialist mental health and learning disability services, which will include the option for smokers to switch to e-cigarettes while in inpatient settings.

The report from the House of Commons Science and Technology Committee *(35)* expressed concerns about some restrictions established by the TPD. The Committee signalled that norms on the size of tanks and refill containers, the maximum nicotine concentration and advertising were holding back their use as a stop-smoking measure, and that these could be changed following the United Kingdom's departure from the EU. The Committee also considered that *(35)*:

> the level of taxation on smoking-related products should directly correspond to the health risks that they present, to encourage less harmful consumption. Applying that logic, e-cigarettes should remain the least-taxed and conventional cigarettes the most, with heat-not-burn products falling between the two.

Following a consultation, the Committee of Advertising Practice and the Broadcast Committee of Advertising Practice announced that they were lifting the blanket ban on making health claims in non-broadcast advertising for ENDS in media not regulated under the TPD (outdoor advertising, posters on public transport, cinemas, leaflets and direct mail). It currently is unclear how the new guidance will be applied in practice.

3 NICE is an independent governmental agency that provides national guidance and advice to improve health and social care.

Conclusions

In 2014, the Conference of the Parties of the WHO Framework Convention on Tobacco Control invited Parties to *(50)*:

> consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health.

The Secretariat of the Convention reported in 2018 that 77 Parties regulated or banned EN&NNDS *(51)*. By the end of 2019, this figure was reported as 98 *(52)*.

This brief provides examples of the three more typical regulatory approaches. The first is banning the sale of EN&NNDS. Brazil is a case in point, with the exception that the existing legislation allows the Government to reconsider the decision as soon as a manufacturer presents convincing evidence to support change. The second is the Republic of Korea. This country applies most of its tobacco-control legislation to EN&NNDS, with some exceptions. Finally, Canada and the United Kingdom (the latter as part of the EU) have created an elaborate group of specific regulations or recommendations related to the sale (including minimum age), advertising, promotion, sponsorship, packaging (child-safety packaging, health-warning labelling and trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavours), reporting/notification, taxation, and use in workplaces and public places of EN&NNDS products. This brief has sought to reflect the regulatory approach of the two countries in this category for a range of reasons, which includes the different role of subnational jurisdictions in regulating EN&NNDS and the fact that Canada tends specifically to regulate some aspects of ENNDS while the United Kingdom does not.

It is hoped that these case studies provide information to regulators and public health advocates seeking to explore what kind of EN&NNDS regulatory options are available in practice, so far.

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Annex 1

National or federal regulation that applies to EN&NNDS

This annex shows specific regulation of electronic nicotine and non-nicotine delivery systems (EN&NNDS) by country and policy domain.

Policy domain	Brazil	Canada
Product classification	EN&NNDS are referred to in the legislation *(1)* as "smoking electronic devices". They are implicitly classified as tobacco products. "Smoking electronic devices" also include heated tobacco products.	The Tobacco and Vaping Products Act *(2)* defines tobacco products as made in whole or in part of tobacco, including tobacco leaves, as well as devices necessary for the use of such products (such as tobacco-heating devices). However, it defines vaping products very loosely as devices emitting an aerosol for human inhalation and the substances intended for use with those devices, with or without nicotine. Vaping products therefore include zero-nicotine e-liquids.
Pre-marketing notification to government	Pre-marketing notification to the government is not required.	Pre-marketing notification to the government is not required.
Government pre-marketing approval	Government pre-marketing approval (registration) is mandatory. The National Health Surveillance Agency of Brazil (ANVISA) may authorize registration for the marketing of any "smoking electronic devices" based on the submission of toxicological studies and specific scientific tests to substantiate their efficacy, effectiveness and safety.	Government pre-marketing approval is required if a vaping product is marketed for a therapeutic purpose.
Import, sale and distribution	The import, sale and distribution of EN&NNDS are banned unless ANVISA has previously registered the product. Presently, no manufacturer has submitted any product for registration, so none has been registered. Even if registered, the sale, supply (even free of charge) and distribution of any electronic smoking devices to minors is prohibited.	The sale and supply of EN&NNDS (vaping products in the legislation) to persons under 18 or 19 years of age, depending on the province, are banned. One province, Nova Scotia, also bans the possession of vaping products by minors. The manufacture, importation *(9)* or sale of e-liquids with ≥ 66 mg/mL of nicotine is prohibited under section 38 of the Consumer Chemicals and Containers Regulations (CCCR), 2001 *(10)*.

Republic of Korea	United Kingdom
ENNDS are considered consumer products, while ENDS are classified as tobacco products under articles 2 and 3 of the Tobacco Business Act *(3)*. Article 27-2 of the enforcement decree of the National Health Promotion Act *(4)* defines ENDS as products "made to cause the same effect as smoking by inhaling nicotine-contained solution or shredded tobacco into the body through respiratory organ with an electronic device."	Under the European Tobacco Product Directive (TPD) *(5)* regulatory framework, EN&NNDS and ENDS products that do not make any health claim are classified as consumer products, while EN&NNDS that make health claims are considered medicinal products. Although one ENDS product has been licensed as a medicine *(6)*, it is not currently available on the market.
Pre-marketing notification to the government is not required.	Producers of all devices and e-liquids that were on the market before May 2016 had until November 2016 to submit a notification to the Medicines and Healthcare Products Regulatory Agency (MHRA) *(7)*. Producers of new devices and e-liquid products must submit a notification six months before they intend to put their product on the market. Pre-marketing information must notify toxicological data regarding ingredients (including in heated form) and emissions with potential health impact, including addictiveness *(8)*. An "ingredient" is any substance or element present in a finished product or related product, including paper, filter, ink, capsules, adhesives and any additive.
Government pre-marketing approval is not required.	Government pre-marketing approval is only required for EN&NNDS with a therapeutic purpose.
Sale of ENDS is prohibited to minors (under 19 years). Such a ban does not apply to ENNDS.	Purchase of "nicotine inhaling products" (ENDS and conventional cigarettes) by or for persons under the age of 18 has been banned since 1 October 2015 in England and Wales and since 1 April 2017 in Scotland *(11)*. Such a ban does not apply to ENNDS. Retailers in the European Economic Area (EEA) or a Third Country must complete the registration process as required by the TPD before making sales of tobacco or ENDS (or both) into the United Kingdom. Retailers from the United Kingdom only need to register if they are planning to sell directly to consumers in another EEA state.

Policy domain	Brazil	Canada
Advertising, promotion and sponsorship	The advertising, promotion and sponsorship of EN&NNDS are banned unless ANVISA has previously registered the product. If any are registered, it is reasonable to expect that the same regulation will apply than for smoking products, whose advertising and promotion is prohibited, with a sole exemption granted for the display of the products at the point of sale. There are some restrictions on tobacco sponsorship.	The advertising of e-liquids with ≥ 66 mg/mL of nicotine is prohibited under section 38 of the CCCR, 2001 *(10)*. Otherwise, advertising and promotion of vaping products are banned if: - they are appealing to persons under 18 years of age or the product has an appearance or a function that could make the product appealing to said persons; - they are using lifestyle advertising, testimonials or endorsements (including the depiction of a person, character or animal, whether real or fictional), however displayed or communicated, including through the packaging; - it is likely to create an association between the brand element or the name and a person, entity, event, activity or permanent facility (sponsorship) or uses, directly or indirectly, a vaping product-related brand element or the name of a vaping product manufacturer in the promotional material related to a person, entity, event, activity or permanent facility; - they are displaying a vaping product-related brand element or the name of a vaping product manufacturer on a permanent facility, as part of the name of the facility or otherwise, if the facility is used for a sports or cultural event or activity; - they are presented in a manner that is false, misleading or deceptive; - it could cause a person to believe that health benefits may be derived from the use of the product or its emissions; and - it could discourage tobacco cessation or encourage the resumed use of tobacco products.

Republic of Korea	United Kingdom
Advertising of ENDS is illegal on TV, radio and billboards and other outdoor supports. Some forms of marketing, such as promotional discounts, are also barred.	ENNDS are not explicitly regulated. In this case, advertising and promotion are governed by the Consumer Protection from Unfair Trading Regulations, which protect consumers from deception or harassment *(12)*. Advertising and promotion of ENDS with health claims to the general public, if approved by the MHRA, could only be legal if considered over-the-counter medicines *(13)*. The following requirements are only applicable to e-liquids, disposable devices and cartridges containing nicotine that are not medicinal products: - cross-border advertising of ENDS and advertising in broadcast TV and radio is prohibited; and - advertising of ENDS is also banned in newspapers, magazines and periodicals, commercial classified ads, commercial email and text messaging (unless explicitly opted in), marketers' online activities (except factual information), promotional marketing online and online (display) ads in paid-for space, paid-for search listings, preferential listings on price-comparison sites, viral advertisements, paid social media placements, advertisement features and contextually targeted branded content, in-game and in-app advertising, and advertisements that are pushed electronically to devices or distributed through web widgets, affiliate links and product placement. E-liquids, disposable devices and cartridges containing nicotine that are not medicinal products are allowed in: - outdoor advertising, including digital outdoor advertising; - posters on public transport (not leaving the United Kingdom); - cinema, direct mail and leaflets; - private, bespoke correspondence between a marketer and a consumer; - media targeted exclusively to the trade; - advertisements for businesses in non-broadcast media; and - sponsorship of events that are not across borders. Any advertising must: - ensure the ads are socially responsible; - not target, feature or appeal to children; - not confuse e-cigarettes with tobacco products; - not make medicinal claims and take care with health claims; and - not mislead about product ingredients or where they may be used. Public Health England believes that "stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping" *(14)*.

Policy domain	Brazil	Canada
Packaging and labelling	**Packaging** Specific legislation or regulation of the packaging of EN&NNDS does not exist at present.	**Packaging** Canada is considering Vaping Products Labelling and Packaging Regulations *(15)*. Until the proposed regulations are approved and come into force, the following requirements apply: - e-liquids with ≥ 66 mg/mL of nicotine meet the classification of "very toxic" under the CCCR, 2001 and are prohibited from manufacture, import, advertising or sale under section 38 of the CCCR, 2001; and - e-liquids with 10–65 mg/mL of nicotine meet the classification of "toxic" and are subject to all applicable requirements under the CCCR, 2001 for toxic chemicals; stand-alone containers of vaping substances intended for sale at retail are required to be sold in child-resistant containers and to be labelled per the applicable CCCR, 2001 requirements, including a toxic-hazard symbol on the container's main display panel. Health Canada considers that e-liquids with 0.1–9 mg/mL of nicotine are potentially toxic when ingested so therefore must adhere to all requirements of the CCCR, 2001 for "toxic" products, including the requirements for a child-resistant container.
	Labelling requirements Specific legislation or regulation of the labelling of EN&NNDS does not exist at present. However, if any EN&NNDS is registered, it is reasonable to assume that the tobacco product regulation for labelling would apply, including mandatory pictorial health warning occupying 50% of the main surfaces of the packaging.	**Labelling requirements** Vaping products must carry the following warning: "Nicotine is highly addictive" *(16)*.

Republic of Korea	United Kingdom
Packaging No specific legal norm applies to the regulation of packaging of EN&NNDS so far.	**Packaging** All nicotine-containing receptacles (disposable devices, cartridges and e-liquids boles) must have: child-resistant and tamper-evident packaging; protection against breakage and leakage; and a mechanism for ensuring refilling without leakage. The nicotine-containing liquid must be in: a dedicated refill container not exceeding a volume of 10 mL; a disposable electronic cigarette; or a single-use cartridge or tank that does not exceed a volume of 2 mL.
Labelling requirements ENDS must carry pictorial health warnings occupying 50% of the main surfaces of the package.	**Labelling requirements** The pack must have: - a health warning: "This product contains nicotine which is a highly addictive substance"; the text must be prominent in black on a white background covering 30% of the area on the front and back of the unit packet and any container pack; - a list of ingredients in the liquid where they are used in quantities of 0.1% or more; - nicotine content and delivery per dose; - batch number; and - recommendation to keep the product out of reach of children. The accompanying leaflet (unless included on the pack) must have instructions for use and storage, including instructions for refilling where appropriate. The MHRA advises that the information should include appropriate advice on product storage, particularly on how to ensure the battery does not malfunction, contraindications, warnings for specific risk groups and possible adverse effects, addictiveness and toxicity, and contact details of the producer, including a contact within the European Union (EU).

Policy domain	Brazil	Canada
Product regulation of contents and emissions	No specific legal norm applies to the regulation of the contents and emissions of EN&NNDS so far, but no EN&NNDS have yet been registered for marketing. All additives that enhance the flavour and taste of tobacco products to make them more attractive are banned *(17)*. It is likely that such a ban would apply to EN&NNDS if any such products are registered. All characterizing flavours are banned for tobacco products *(17)*. It is likely that such a ban would apply to EN&NNDS, if any such products are registered.	Manufacturers of vaping devices are strongly encouraged (but not legally required) to certify their products to standard ANSI/CAN/UL 8139 on Electrical Systems of Electronic Cigarettes and Vaping Devices and to use lithium-ion batteries that meet standard CAN/CSA-E62133 or equivalent. Chargers provided with the product should be certified to the applicable Canadian national standard by a certification body accredited by the Standards Council of Canada. The diluents used in vaping liquids should be within the specifications of an accepted pharmacopoeia, so solvents of known human toxicity, such as ethylene glycol or diethylene glycol, should not be used. "Ingredient" means any substance used in the manufacture of a tobacco product, vaping product or their components, including any substance used in the manufacture of that substance, and, in respect of a tobacco product, also includes tobacco leaves. Additives prohibited are: amino acids, caffeine, colouring agents, essential fatty acids glucuronolactone, probiotics, taurine, vitamins and mineral nutrients. Emissions are not explicitly regulated. However, Health Canada recommends that the generation of harmful emissions due to thermal decomposition of e-liquids should be as low as reasonably achievable. It is recommended, but not legally required, that all flavourings added to vaping liquids should be of food-grade or higher purity and that substances with known inhalation risks (such as diacetyl and 2,3-pentanedione) should not be used in flavourings. The following flavours are legally banned: confectionery, dessert, cannabis, soft drink and energy drink.
Taxation	No specific legal norm applies to the regulation of the taxation of EN&NNDS so far, but no EN&NNDS have yet been registered for marketing.	Only the regular general sale tax applies to EN&NNDS.

Republic of Korea	United Kingdom
No specific legal norm applies to the regulation of the contents and emissions of EN&NNDS so far. Additives are not explicitly regulated. Flavourings can be used but not advertised according to article 9-3 of the National Health Promotion Act *(4)*.	E-liquids without nicotine, whether in disposable devices or separate containers, are regulated under General Product Safety Regulations *(18)*. A product is considered safe if it conforms to: a) a specific health and safety rule of part of the United Kingdom, in the absence of a United Kingdom law; b) a voluntary national standard of the United Kingdom giving effect to an official European standard; or c) otherwise conforms to other specified standards or recommendations, including product safety codes of good practice in the sector concerned, and reasonable consumer expectations concerning safety. The assessment of safety is made regarding the risks and categories of risk covered by the specified requirements of conformity. Nicotine e-liquid ingredients: - must be of high purity - may not pose a risk to human health in a heated or unheated form. The maximum nicotine concentration in e-liquid is 20 mg/mL. Additives prohibited are: vitamins or other additives that create the impression that they have a health benefit or present reduced health risks; caffeine, taurine or other additives and stimulant compounds that are associated with energy and vitality; and additives that have colouring effects on emissions. All other additives are restricted to quantities that do not increase, to a significant or measurable degree, the toxicity, addictiveness or carcinogenic, mutagenic or reprotoxic properties of the product when it is consumed. Emissions are not specifically regulated. Flavours are not specifically regulated.
ENDS are subject to several taxes and charges (national health promotion, tobacco consumption, local education and individual consumption taxes) proportional to 1 799 Won/mL (≈ US$ 1.5) nicotine liquid; also there is a waste charge of 24 won/20 cartridges (≈ US$ 0.02) and a 10% value added tax (VAT) *(19)*.	EN&NNDS are taxed with a VAT rate of 20%.

Policy domain	Brazil	Canada
Use in indoor places	The use of EN&NNDS is banned in all enclosed common areas, including aircraft and public transportation. An enclosed common area is defined as a public or private place, accessible to the general public or for common use, totally or partially enclosed on any of its sides by a wall, partition, roof, awning or covering, whether of a permanent or temporary nature *(20)*.	The Non-smokers' Health Act *(21)* bans indoor use of EN&NNDS in federally regulated workplaces, such as banks, ferries, passenger aircraft and federal government offices. Most provinces have banned their use where tobacco use is banned.
Protection from commercial interests	The protection of public health from commercial interest from the EN&NNDS industry is not explicitly regulated.	The protection of public health from commercial interest from the EN&NNDS industry is not explicitly regulated.
Surveillance and monitoring	No specific legal norm applies to the regulation of the surveillance and monitoring of EN&NNDS so far, but no EN&NNDS have yet been registered for marketing. In case of irregularities, such as the commercialization, advertising and illegal importation of these products, complaints may be lodged through ANVISA's service channels.	Under the Canada Consumer Product Safety Act (CCPSA), sellers, distributors, importers, manufacturers and suppliers in general of vaping products for commercial purposes must report any health or safety incidents involving one such product to Health Canada and the supplier of said product *(24)*. Depending on the type, the incident must be reported within two or 10 days after the day on which those required to report become aware of the incident. Any person who manufactures, imports, advertises, sells or tests a vaping product for commercial purposes must prepare and maintain documents indicating whom they obtained the product from or to whom they sold it, among other data. They are required to submit records upon request of the Government. The purpose of this requirement is to help improve the traceability of noncompliant products through the supply chain if dangers must be addressed *(25)*. Under the CCPSA, Health Canada has the power to order recalls and other measures and order tests or studies on a product. Enforcement actions taken by Health Canada on noncompliant products depend on the degree of risk associated with noncompliance.

Republic of Korea	United Kingdom
The use of ENDS, but not ENNDS, is banned where smoking is banned, and is completely banned in health-care facilities and educational facilities except universities. In all other public places and workplaces, smoking and ENDS use is banned only in designated no-smoking areas.	There is no blanket legal requirement regulating the use of ENDS or ENNDS in workplaces and public spaces. The owner or manager of each venue may decide to apply restrictions on a private basis. Although there are no official statistics, it seems that most hospitals and transportation have banned vaping indoors. Vaping on a plane is strictly not allowed by the companies as per International Air Transport Association recommendations *(22)*. Public Health England issued guidance on the use of EN&NNDS in public places and workplaces that emphasizes the distinction between smoking and vaping. The guidance states that "a more enabling approach to vaping may be appropriate to make it an easier choice than smoking" *(23)*. It also recommends that policies be based on evidence of harm to bystanders and risk assessments be informed by evidence. The guidance indicates that the risk to the health of bystanders from second-hand aerosol is extremely low and insufficient to justify prohibiting EN&NNDS use indoors based on international peer-reviewed evidence.
The protection of public health from commercial interest from the EN&NNDS industry is not explicitly regulated.	The protection of public health from commercial interest from the EN&NNDS industry is not explicitly regulated.
No legal norm applies to the regulation of the surveillance and monitoring of EN&NNDS specifically, but the Government is closely monitoring cases of lung diseases potentially related to the use of EN&NNDS through the existing consumer risk-monitoring system *(26)*.	Consumers and health-care professionals can report both side-effects and product safety concerns to the MHRA through the Yellow Card scheme. This scheme records suspected adverse reactions to medicines from health professionals, manufacturers or members of the public. It includes ENDS and e-liquids. A total of 37 reports were received with a suspected adverse reaction to electronic cigarettes between 1 January 2015 and 20 October 2017, and 263 reports associated with a suspected adverse drug reaction to nicotine replacement therapy were received during the same reporting period. The most commonly reported adverse reaction related to gastrointestinal disturbance and respiratory problems.

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Annex 2

Additional regulatory requirements by the provincial jurisdictions of Canada

This annex shows the specific regulation of electronic nicotine and non-nicotine delivery systems (EN&NNDS), by Canadian province.

Province	Applicable law	Main provisions
British Columbia	Tobacco and Vapour Products Control Act. Date in effect: 1 September 2016 *(1)*	Under this law, the following are banned: - EN&NNDS use in all enclosed public spaces, including all public and private school grounds, workplaces and health-care facilities other than in designated areas; - sale and supply to minors (under 19); - sales wherever tobacco sales are banned; - any promotion in stores except at point of sale (POS) showing availability and price, including duty-free shops; - all POS displays except at POS where minors are not permitted to enter; and - vending machines in adult-only venues, including duty-free shops.
Manitoba	The Non-Smokers Health Protection and Vapour Products Act. Royal assent received: 5 November 2015 *(2)*	Under this law, the following are banned: - EN&NNDS use in enclosed public places and other places where smoking is presently prohibited, including workplaces, and work vehicles with more than one occupant (the following places are exempted from the ban to use EN&NNDS: where EN&NNDS are predominately sold and in designated smoking/vaping rooms in hotels and group living facilities); - EN&NNDS advertising and promotion as applicable to tobacco products; and - sale and supply to minors (under 18).
New Brunswick	Smoke-free Places Act, 2011. Tobacco and Electronic Cigarette Sales Act. As amended, date in effect: 10 November 2018 *(3)*	Provisions of the Act include the following bans: - EN&NNDS use where smoking is prohibited, including enclosed public spaces, workplaces, restaurants and bars, and vehicles when an individual under the age of 16 is present (there are exemptions for some hotel rooms and private residences); - sale and supply to minors (under 19); - sales of EN&NNDS wherever tobacco sales are banned; and - indoor and outdoor advertising and promotional materials, even within vape shops.
Newfoundland and Labrador	Smoke-Free Environment Act (as amended) *(4)*, Tobacco and Vapour Products Control Act (as amended) *(5)*. Date in effect: 17 October 2018	The following are banned: - sale to minors; - sale wherever tobacco sales are banned; - POS promotion, products and promotional materials (cannot be visible inside or outside the shop); - restrictions on signage inside shops; and - vape shops are allowed to operate if the only business conducted is the sale of vaping products. Treatment: treats EN&NNDS the same as combustible tobacco cigarettes, prohibiting the use of EN&NNDS in any place to which the public customarily has access, including workplaces, private clubs, licensed restaurants, bus shelters, and health-care and educational facilities. Young people: prohibits the use of EN&NNDS in motor vehicles when occupied by a person under the age of 16 and prohibits the sale of EN&NNDS and other vaping products to persons under the age of 19. Communications and advertising: there currently are no restrictions on EN&NNDS advertising. Vape shops can provide consumers with testimonials and health information regarding vaping.

Province	Applicable law	Main provisions
Nova Scotia	Smoke-free Places Act (amended) *(6)* and Tobacco Access Act (amended) *(7)*. Date in effect: 31 May 2015	The following are banned: - EN&NNDS use where smoking is prohibited, including enclosed public spaces, workplaces, education and recreation facilities, restaurants and bars, and vehicles when an individual under the age of 19 is present; - sale and supply to minors (under 19 years); - possession by minors; - sale in pharmacies; - requirement to display age-restriction signage; and - POS promotion, except inside vape shops.
Ontario	Electronic Cigarettes Act, 2015, replaced by Smoke-Free Ontario Act, 2017 (last amended 2019) *(8)*	The following are banned: - EN&NNDS use where smoking is prohibited, including enclosed public place and workplaces, group living facilities, public vehicles or vehicles used in the course of employment while carrying two or more employees (there are exceptions for guest rooms in hotels and designated areas in residential facilities); - sale and supply to minors (under 19); - supply or offer to supply health-care facilities and pharmacies; - sale wherever tobacco sales are banned (regulatory authority to make some exemptions); - promotion outdoors, at POS (only signage showing price and availability allowed), and premises to which children are permitted access; and - display visible to children in any place or premises in which tobacco or tobacco-related products are sold.
Quebec	Tobacco Control Act. Date in effect: 26 November 2015 *(9)*	Under the law, the following are banned: - EN&NNDS use where smoking is prohibited, including enclosed public spaces, workplaces, educational and recreational facilities, restaurants and bars, and vehicles when an individual under the age of 16 is present; - sale and supply to minors; - sale wherever tobacco sales are banned; and - outdoor signage restricted, shops are only allowed to show availability and price. All prohibitions that apply to tobacco promotion also apply to EN&NNDS. The ban on flavours in cigarettes does not apply to e-liquids.
Prince Edward Island	Tobacco and Electronic Smoking Device Sales and Access Act *(10)* and regulations *(11)*; in effect 1 October 2015	The following are banned: - EN&NNDS use where smoking is prohibited, including enclosed public spaces, workplaces, education and recreation facilities, restaurants and bars, and vehicles when an individual under the age of 19 is present; - sale and supply to minors and purchase by minors under the age of 19; - sale where tobacco sale is banned; - POS promotion and promotion visible from outside retail premises; - vape shops can only display e-cigarettes if individuals under the age of 19 are not permitted; and - any advertising that is misleading regarding the characteristics, health effects and health hazards of these devices.

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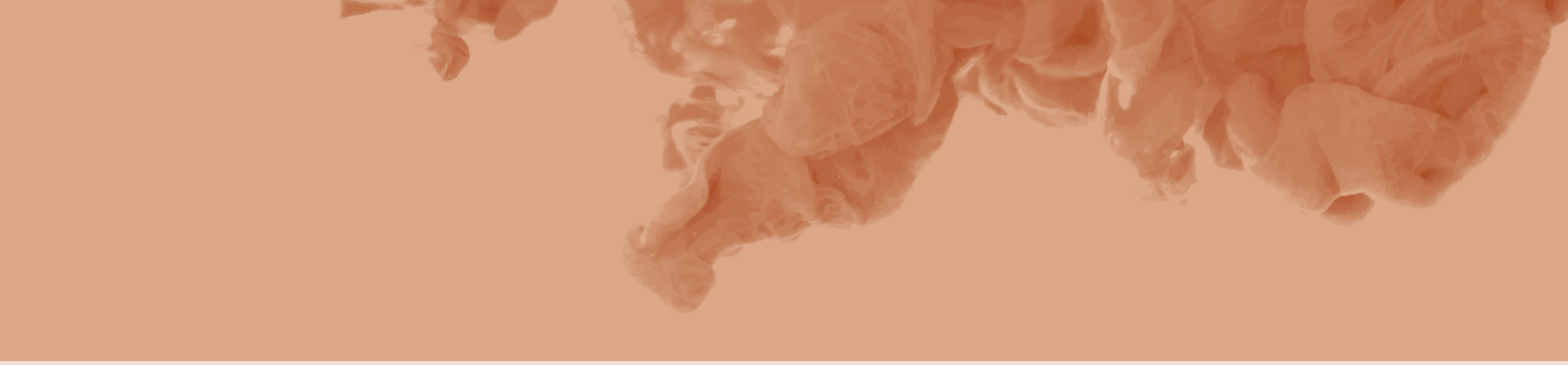

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