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Global approaches to regulating electronic cigarettes

Ryan David Kennedy, Ayodeji Awopegba, Elaine De León, Joanna E Cohen

Department of Health, Behavior & Society, Institute for Global Tobacco Control, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, USA

Correspondence to
 Professor Ryan David Kennedy, Department of Health, Behavior & Society, Institute for Global Tobacco Control, Johns Hopkins Bloomberg School of Public Health, 2213 McElderry Street, 4th Floor, Baltimore, MD 21205, USA; rdkennedy@jhu.edu

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ABSTRACT

Objectives Classify and describe the policy approaches used by countries to regulate e-cigarettes.

Methods National policies regulating e-cigarettes were identified by (1) conducting web searches on Ministry of Health websites, and (2) broad web searches. The mechanisms used to regulate e-cigarettes were classified as new/amended laws, or existing laws. The policy domains identified include restrictions or prohibitions on product: sale, manufacturing, importation, distribution, use, product design including e-liquid ingredients, advertising/promotion/sponsorship, trademarks, and regulation requiring: taxation, health warning labels and child-safety standards. The classification of the policy was reviewed by a country expert.

Results The search identified 68 countries that regulate e-cigarettes: 22 countries regulate e-cigarettes using existing regulations; 25 countries enacted new policies to regulate e-cigarettes; 7 countries made amendments to existing legislation; 14 countries use a combination of new/amended and existing regulation. Common policies include a minimum-age-of-purchase, indoor-use (vape-free public places) bans and marketing restrictions. Few countries are applying a tax to e-cigarettes.

Conclusions A range of regulatory approaches are being applied to e-cigarettes globally; many countries regulate e-cigarettes using legislation not written for e-cigarettes.

INTRODUCTION

Electronic cigarettes, or e-cigarettes, and other electronic nicotine delivery systems (ENDS), alternative nicotine delivery systems (ANDS) or vapourised nicotine products (VNPs) are devices that heat a liquid, commonly propylene glycol and/or glycerol (glycerin), to create an inhalable aerosol that can contain nicotine.

The modern e-cigarette is often credited to Hon Lik, a Chinese pharmacist who invented the product in 2003;¹ Lik's design was patented internationally in 2007 (Electronic Atomization Cigarette: US 20070267031 A1). E-cigarettes became commercially available in Europe and the USA around 2006.² Reported use of e-cigarettes has increased dramatically in recent years although globally use remains low; countries that report prevalence of adults using e-cigarettes include 0.3% in Indonesia, 1.2% in Italy, 1.9% in Greece and 5.9% in Poland.³ The value of global sales of e-cigarettes was estimated to be 3.5 billion US\$ in 2015,⁴ with the largest three markets being the USA, Russia and Germany (collectively representing 60% of global sales).⁵ E-cigarette products have been marketed by manufacturers as alternative products to combustible tobacco that can be used when cigarettes are not permitted,⁶ or instead of cigarettes.⁷

A number of global tobacco control researchers have stated that e-cigarettes are less harmful than combusted tobacco;⁸⁻¹² however, the impact of e-cigarettes on public health is unclear. This presents specific challenges as jurisdictions determine how to regulate these products.

Studies from around the world suggest that the majority of adults using e-cigarettes are current cigarette users, and some studies suggest that e-cigarette use is often motivated by a desire to quit using combustible cigarettes.¹²⁻¹⁶ However, there is evidence that some non-smokers, including non-smoking youth are also experimenting with e-cigarettes;^{13 17} Some public health advocates have raised the concern that e-cigarettes may be a 'starter' or initiation product for youth who will progress to using combustible tobacco products.¹⁸ It is unclear if non-cigarette smoking youth who report using e-cigarettes would have smoked cigarettes had e-cigarettes not been available, or how long these youth are likely to use e-cigarettes.

Many policy domains can be addressed through e-cigarette regulations. The WHO Tobacco Free Initiative commissioned a report to help countries around the world develop policies to regulate e-cigarettes.^{19 20} This report, published in 2013, provided detailed policy suggestions for countries to regulate e-cigarettes including: banning the use of e-cigarettes anywhere that the use of conventional cigarettes is prohibited, banning the sale of e-cigarettes to anyone who cannot legally buy cigarettes or in any venues where sale of conventional cigarettes is prohibited, apply the same marketing restrictions to e-cigarettes as are applied to conventional cigarettes, ban the practice of cobranding e-cigarette products with cigarettes or marketing in a way that promotes dual use, banning the use of characterising flavours in e-cigarettes, particularly candy and alcohol flavours, banning companies from making claims regarding tobacco-use cessation (until such a time when e-cigarette manufacturers and companies provide sufficient evidence that ENDS products can be used effectively for cessation), and prohibiting e-cigarette companies from making health claims about their products unless approved by appropriate regulatory agencies, and calls for the development of standards for regulating product ingredients and functioning.

In 2014, the WHO Tobacco Free Initiative released a report for the Sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (FCTC) that included findings from a survey sent to all WHO Member States on ENDS and novel tobacco products.²¹ The survey was completed by 90 countries. When considering ENDS products that contain nicotine, 22 countries reported that ENDS were being classified as tobacco products, 12 countries

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classified ENDS as therapeutic products and 14 countries reported that they are classified as consumer products. This report did not provide country-specific policy approaches. The Conference of the Parties Decision recognised that the parties have used a range of strategies to regulate e-cigarettes including bans on their sale, the adoption of regulation similar to that applicable to the marketing of medicines, their control as tobacco products or no regulation at all.²² The WHO report did not address some regulatory issues including nicotine concentrations in products, packaging, including guidance around health warnings.

The authors of the present manuscript sought to identify all country-level policies regulating e-cigarettes and understand how they are being regulated.

METHODS

This study identified countries using policies to regulate e-cigarettes at the national level. Data collection took place between September 2014 and February 2015 and then was regularly updated until October 2016. This involved an iterative method of web-based searching and contacting in-country policy experts, detailed below.

Identifying countries regulating e-cigarettes

The study team used two general strategies to identify countries regulating e-cigarettes. First, the team searched for policies in a subset of countries including the 90 countries that had participated in the 2014 WHO ENDS and novel tobacco products survey.²¹ An additional 12 high-income countries that are members of the Organisation for Economic Co-operation and Development (OECD) but did not contribute to the WHO survey were also included in the targeted search. The study team theorised that higher income countries might be more likely to have an e-cigarette market. Second, we conducted searches to identify other jurisdictions using policy to regulate e-cigarettes at the country level using Google and Tobacco Watcher (tobacowatcher.globaltobaccocontrol.org), a surveillance system for tobacco-focused media stories in 23 languages. Search strategies included variant terms for 'electronic cigarettes' and 'regulation' as keywords. These searches yielded media and non-governmental organization (NGO) reports as well as e-cigarette advocacy websites which revealed possible national level e-cigarette regulation. Through this method, the study team identified an additional 21 countries with potential e-cigarette regulation, for a total of 123 countries included in the policy scan.

Identification of e-cigarette regulation documents

To obtain a copy of each policy, the study team searched the 123 countries' Ministry of Health (MOH) (or similar) websites using variant terms for 'electronic cigarettes' and 'regulation' in English or an official language of the country. Where e-cigarette regulations could not be identified online, the study team contacted in-country tobacco policy experts or MOH staff to enquire about the existence of policies regulating e-cigarettes in their country. This was carried out using a variety of techniques including sending email requests to the email addresses provided on ministry websites, or sending a note using the 'contact us' web page.

Classification of policy approaches, product classification and domains regulating e-cigarettes

Copies of the written policies regulating e-cigarettes were reviewed by the study team to understand how e-cigarettes were being regulated. The study team could review policies written in

English, Spanish or French. The team used Google Translate effectively to review regulations in other languages.

First, the study team identified what kind of legal mechanism was being used to regulate e-cigarettes, such as a law, resolution and decree. Second, the team determined if the policy regulating e-cigarettes was a new or amended law that explicitly regulated e-cigarettes, or if e-cigarettes were being regulated using existing legislation. Third, the team reviewed how e-cigarettes were classified through regulation, that is, whether the devices were considered tobacco products, consumer products or medicinal products. Finally, the study team reviewed the content of regulations and identified what regulatory domains were being applied to e-cigarettes including prohibitions or restrictions. The domains were informed by tobacco control regulations and included sale of products including age-of-purchase, advertising/promotion/sponsorship, distribution, importation, manufacturing, use including vape-free public places, product design including e-liquid ingredients such as flavours and nicotine, taxation, health warning labels (HWLs). We added the categories of, child-safety, and trademarks based on our review of policies.

Verification of regulation

The study team's country classifications were verified by an in-country expert. In most cases, direct contact through phone or email was made with country bureaucrats (generally with the MOH) as well as in-country tobacco policy experts to clarify interpretations of regulation. In many countries, multiple contacts provided guidance and verification.

RESULTS

Countries regulating e-cigarettes and their regulatory approaches

The team identified 68 countries that regulate e-cigarettes at the national level using a range of regulatory mechanisms including laws (new or amended), alerts, circulars, decisions, decrees, notifications, orders, ordinances, rulings and statements. The team identified 22 countries that regulate e-cigarettes using existing regulations; 25 countries that enacted new policies (including laws, rulings, decrees, orders or similar) to regulate e-cigarettes; 7 countries that made amendments to existing legislation and 14 countries that use a combination of new/amended regulations in combination with existing regulation. The identified countries are on six continents and include economies that are classified as high-income, middle-income and low-income. The other 55 countries included in the search did not have national laws regulating e-cigarettes.

The regulatory approaches, product classification and regulatory domains identified for each of the 68 countries are included in [table 1](#).

Product classification(s)

In jurisdictions where new or amended policies regulate e-cigarettes, products are generally being classified as 'e-cigarette', or 'electronic cigarette', or 'electronic smoking device' or 'ENDS'. In jurisdictions that are using existing legislation to regulate e-cigarettes, the devices are classified as a range of products including: tobacco, tobacco derivatives, tobacco imitation products, consumer goods, chemical mixtures, drugs, medicinal products or devices and/or poisons/hazardous substances. Countries classify e-cigarettes based on a variety of characteristics including: nicotine content, reported purpose of use, device components and legal language. E-cigarettes are often classified as medical devices if the product's manufacturer makes a claim associated with health. In four countries, nicotine

Table 1 Global e-cigarette policies: approaches, product classification and regulatory domains addressed (current to October 2016)

Country	Regulatory approach (es)	Product classification(s)	Regulatory domain(s)
Argentina	Decree; existing law; ruling	ENDS, tobacco	Advertising/promotion, distribution, importation, sale, vape-free (implicit)
Australia	Existing law; statement	Poison, consumer good	Advertising/promotion, importation, sale
Austria	Amended law; existing law; new law	Tobacco-related product, medicinal, medical device, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
Bahrain	Existing law; decision	ENDS, tobacco	Advertising/promotion, sale, vape-free
Belgium	Existing law	Medicinal, consumer good	Advertising/promotion, distribution, importation, manufacture, sale, vape-free
Brazil	Decree; resolution	E-cigarette, tobacco	Advertising/promotion, distribution, importation, sale, vape-free (implicit)
Brunei Darussalam	Existing law	Tobacco (imitation), poison	Importation, sale, vape-free (implicit)
Cambodia	Circular	E-cigarette	Importation, sale, vape-free
Canada	Existing law; notice	Drug, consumer good	Advertising/promotion, importation, manufacture, sale
Chile	Resolution	Medicinal	Unclear
Colombia	Existing law	Tobacco (imitation)	Advertising/promotion, manufacture, sale, vape-free
Costa Rica	Decree; existing law	ENDS, tobacco (derivative)	Advertising/promotion, minimum age, sale, vape-free
Croatia	Existing law	Consumer good, chemical product, tobacco (imitation)	Advertising/promotion
Czech Republic	Existing law	Medicinal, tobacco (imitation), consumer good, hazardous substance	Advertising/promotion, manufacture, minimum age, sale
Denmark	Existing law; new law	E-cigarette, medicinal	Advertising/promotion/sponsorship, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, sale, vape-free
Ecuador	Decree; existing law	ENDS, tobacco (derivative)	Advertising/promotion, minimum age, sale, vape-free
Estonia	New law	Tobacco-related product, E-cigarette	Advertising/promotion/sponsorship, minimum age, nicotine volume/concentration, sale
Fiji	Amended law/decreed	E-cigarette	Advertising/promotion, distribution, importation, manufacture, minimum age, sale, vape-free
Finland	New law	Medicinal, tobacco (imitation/substitute), tobacco-related product, e-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, importation, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
France	Amended law; decree; existing law	Medicinal, e-cigarette, consumer good	Advertising/promotion, child safety, ingredients/flavours, nicotine volume/concentration, safety/hygiene, sale
Germany	New law	Tobacco-related product, e-cigarette, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
Greece	Amended law	E-cigarette	Advertising/promotion, distribution, manufacture, sale, vape-free
Honduras	Decree; existing law	Tobacco (derivative)	Advertising/promotion, minimum age, vape-free
Hungary	Amended law	Consumer good	Advertising/promotion, distribution, importation, sale
Iceland	Existing law	Medicinal, consumer product	Advertising/promotion, distribution, manufacture, importation, sale
Ireland	Existing law; new law	E-cigarette, medicinal, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/concentration, reporting/notification, safety/hygiene, sale
Italy	Amended law/ ordinance; decree	Tobacco-related product, e-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety and hygiene, tax
Jamaica	Amended law; existing law	ENDS, medicinal	Distribution, importation, manufacture, sale, vape-free
Japan	Existing law; statement	Medicinal	Advertising/promotion, distribution, importation, sale
Jordan	Official letter	E-cigarette	Advertising/promotion, importation, manufacture, sale, vape-free
Kuwait	Decision	E-cigarette	Distribution, sale
Latvia	New law	Tobacco-related product, E-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, tax
Lebanon	Decision	E-cigarette	Distribution, importation, sale
Lithuania	New law	Tobacco-related products, e-cigarette	Minimum age, advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free
Malaysia	Existing law	Poison, electrical appliance	Distribution, importation, minimum age, sale
Malta	Legal notice	Tobacco-related product, e-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, vape-free

Continued

Table 1 Continued

Country	Regulatory approach (es)	Product classification(s)	Regulatory domain(s)
Mauritius	Existing law	Tobacco (imitation)	Distribution, sale
Mexico	Existing law	Tobacco (imitation)	Advertising/promotion, distribution, manufacture, sale
Nepal	Notification	ENDS	Advertising/promotion, vape-free
Netherlands	Existing law; decree; order	E-cigarette, medicine, tobacco-related product, consumer good	Advertising/promotion/sponsorship, child-safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety and hygiene, sale
New Zealand	Existing law	Medicinal, tobacco, consumer good	Advertising/promotion, distribution, importation, sale
Nicaragua	Existing law	Tobacco (imitation)	Importation, manufacture, sale
Norway	Existing law	Medicinal, tobacco surrogate, e-cigarette	Advertising/promotion, importation, minimum age, sale
Oman	Decision	E-cigarette	Distribution, sale
Panama	Decree	ENDS, tobacco (imitation)	Advertising/promotion, distribution, importation, sale, vape-free
Philippines	Order	Medicinal, medical device	Child-safety, sale, vape-free
Poland	New law	Chemical mixture, Consumer good	Unclear
Portugal	Existing law	E-cigarette	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety/hygiene, sale, tax, vape-free
Qatar	Circular; decision	E-cigarette	Advertising/promotion, distribution, importation, sale
Republic of Korea	Amended Law; existing law	Tobacco, consumer good	Advertising/promotion, health warning labelling, minimum age, tax, vape-free
Saudi Arabia	Decision	E-cigarette	Advertising/promotion, sale
Seychelles	Existing law	Tobacco (imitation)	Advertising/promotion, distribution, importation, manufacture, sale
Singapore	Existing law	Tobacco (imitation)	Distribution, importation, sale
Slovakia	Amended law	Tobacco/tobacco-free product intended to smoked	Advertising/promotion, minimum age, vape-free
South Africa	Ruling	Medicinal	Sale
Spain	Amended law	ENDS	Advertising/promotion, minimum age, vape-free
Suriname	New law	ENDS	Distribution, importation, sale
Switzerland	Existing law; statement	E-cigarette, consumer good	Importation, sale
Thailand	Existing law; notification; order	'Modern' medicinal, tobacco (imitation), e-cigarette	Importation, manufacture, sale
Togo	New law	Tobacco (derivative)	Advertising/promotion, minimum age, tax, vape-free
Turkey	Amended law; circular; notice	Tobacco, e-cigarette	Sale, advertising/promotion, importation, vape-free
Ukraine	Amended Law	E-cigarette	Sale, vape-free
United Arab Emirates	Decision	E-cigarette	Advertising/promotion, importation, sale
UK	Existing law; new law; statement	E-cigarette, medicinal, consumer good	Advertising/promotion/sponsorship, child safety, health warning labelling, ingredients/flavours, minimum age, nicotine volume/concentration, reporting/notification, safety and hygiene, tax
USA	New law	Tobacco product	Advertising/promotion, child-safety, health warning labelling, minimum age, reporting/notification
Uruguay	Amendment/decreed	Electronic smoking device	Advertising/promotion, importation, sale, trademarks
Venezuela	Alert, existing law	Medicinal, tobacco (derivative), consumer good	Advertising/promotion, sale, vape-free
Vietnam	Existing law	Tobacco	Advertising/promotion, minimum age, vape-free

ENDS, electronic nicotine delivery systems.

is classified as a controlled poison or hazardous substances (Australia, Brunei Darussalam Czech Republic and Malaysia). Brunei Darussalam classifies nicotine liquid as a poison if the nicotine concentration is above 7.5%.

In 37 countries, e-cigarettes could meet multiple product classifications. For example, in Thailand, these products could be classified as e-cigarettes, medicinal products or products that imitate tobacco depending on which regulation is applied.

E-cigarette regulation policy domain(s)

The study team identified the following domains of regulation including product prohibitions or restrictions related to e-

cigarette: manufacturing, distribution, importation, sale including where sales are allowed and minimum age of purchase, use restrictions including vape-free public places, advertising, promotion, and sponsorship, taxation, trademark, health warning labelling, ingredients/flavors, safety/hygiene, reporting/notification, nicotine volume/concentration and child-safety packaging (table 1).

The sale of e-cigarettes is banned in 25 countries; market authorisation is required in 17 other countries. In countries permitting the sale of e-cigarettes, minimum age-of-purchase policies are common. There are 23 countries with policies that are consistent with the age of purchase for combustible cigarettes

which is 18 years in; 19 years in the Republic of Korea and 21 years in Honduras.

E-cigarette use is banned in enclosed public spaces such as bars, restaurants and other workplaces in 25 countries. Advertising and promotion of e-cigarettes are banned in 35 countries; some countries did not have explicit advertising and promotion bans, but contend that such bans are inherent within their bans on sale, including Argentina and Australia.

We identified 14 countries that require e-cigarettes to have a HWL, and 13 that regulate ingredients and flavours that can be used in e-cigarettes. Nicotine concentrations cannot exceed 20 mg/mL of e-liquid in 14 countries. Child-safety standards for e-cigarettes and/or e-liquid bottles are required in 11 countries. Manufacturing standards for e-cigarettes marketed as medicines are required in 13 countries. Regulations on importation of e-cigarettes are in place in 14 countries. The distribution of e-cigarettes marketed as medicines is regulated in 21 countries. Italy, Latvia, Portugal, Republic of Korea, Togo and the UK apply a tax to e-cigarettes. Manufacturers/retailers are required to notify the appropriate authority prior to marketing e-cigarettes in 13 countries. Certain safety standards (eg, using materials/chemicals of high quality) are required for e-cigarettes or e-liquids in 26 countries. Venezuela prohibits the registration of e-cigarettes as a brand/patent.

DISCUSSION

Our scan identified 68 countries that regulate e-cigarettes through a variety of legal mechanisms. Generally, countries regulate e-cigarettes based on their classification as tobacco, medicinal or consumer products. Some countries are using more than one classification for e-cigarettes resulting in multiple regulatory approaches for these products. Policies that were common included banning the sale of e-cigarettes, and expanding tobacco control laws to e-cigarettes including vape-free public places and age of purchase laws that mirror laws for cigarettes. Of the countries identified regulating e-cigarettes, about a third do not have regulations specifically written for e-cigarettes, rather they apply existing tobacco control regulations to these products. This may or may not be consistent with the intent of the original laws.

Some policies that have been adopted for tobacco products, such as HWLs, present interesting challenges for e-cigarettes given that there is a wide variety of devices and packaging. Further, there is little understanding about what health warnings should be included on e-cigarettes. We identified very few examples of policies that are regulating e-cigarette sponsorship outside the European Union. Very few countries are applying taxes to e-cigarettes or the liquids. There were no policies regulating e-liquid ingredients beyond nicotine. Some countries, all in Europe, have introduced policies to address flavourings; this is important given that there is evidence that some chemicals used to flavour e-liquids, including diacetyl, are associated with lung disease.²³

This study did not review government websites for every country in the world; however, based on the findings from our general search strategy it appears that most of the countries in the world are not regulating e-cigarettes using national regulatory approaches.

In May 2016, the European Union's Tobacco Products Directive addressed the regulation of e-cigarettes across the 28 member states. This directive includes a range of policy domains, including that nicotine-containing liquid can only be sold if the nicotine concentration does not exceed 20 mg/mL.²⁴ Countries in the EU are at different stages of policy

implementation and in some jurisdictions aspects of the directive are being challenged.

This study has several limitations including the fact that some national policies may not have been identified using our search strategy. Further, policies to regulate e-cigarettes may be implemented at a subnational level including clean air laws (vape-free) and age-of-purchase requirements, so this specific policy scan does not fully represent the scale or scope of e-cigarette regulation around the world. Although we confirmed countries' policies with government bureaucrats in the respective country, there could still be misinterpretations about how the policies are being applied. Further, this policy scan focuses on the policies that are 'on the books'; it is important to note that there might not be full implementation and/or compliance with these policies 'on the ground'.

In tobacco control, and other areas of public health, we have seen the benefit of learning from natural experiments comparing jurisdictions with different policy environments. This policy scan may support the identification of jurisdictions to further study and understand how policies impact e-cigarette use, tobacco use and public health.

The evidence on the harms and benefits of e-cigarettes has not yet been clearly established. As the evidence base grows, we expect additional activity in the regulatory arena.

The state of global e-cigarette regulation will be updated and reported at globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes.

What this paper adds

- ▶ This study scanned the globe to identify which countries are regulating e-cigarettes, what regulatory mechanisms are being used and what regulatory domains are being applied.
- ▶ We identified 68 countries regulating e-cigarettes—the most common forms of regulation included sale bans, use restrictions (vape-free public places), age-of-purchase requirements and advertising and promotion bans.
- ▶ Few countries are applying a tax to e-cigarettes.
- ▶ Many countries are regulating e-cigarette products with legislation that was written before e-cigarettes were on the market.

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