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TOBACCO (K BOLD AND G KONG, SECTION EDITORS)

A Literature Review on International E-cigarette Regulatory Policies

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Abstract

Purpose of Review Jurisdictions around the world have adopted different policies in order to regulate e-cigarette products, to allow for the use of e-cigarettes by cigarette smokers for cessation or harm reduction and to reduce the likelihood of non-smokers initiating e-cigarette use. The purpose of this review is to provide a brief overview of different e-cigarette regulations across the world, focusing on regulations of sales, product standards, nicotine concentrations, flavours and marketing restrictions. This review was conducted between February and April 2020.

Recent Findings There are a large range of policies that countries around the world have chosen in order to regulate vaping products to prevent use and limit harm associated with use of e-cigarettes. Many countries provide avenues for separate regulation of therapeutic and consumer e-cigarette devices.

Summary E-cigarettes have the potential of causing harm among young vapers and reducing harm among adult cigarette smokers. The most effective strategies would balance both of these properties and prevent access to vaping products among adolescents and youths and at the same time increase the availability of the regulated therapeutic products among people trying to quit smoking. Future efforts of research should focus on evaluating the impact of different regulatory policies to achieve these purposes and exploring the use of e-cigarettes as a smoking cessation aid. Our recommendations are based on existing literature on the effectiveness of current e-cigarette regulations.

Keywords E-cigarette · Vaping · International · Regulation · Policy

Overview

There are three key, but contrasting, driving principles behind e-cigarette regulation internationally. The first principle is upholding consumer product standards. Regulations following these principles set out production, manufacturing and retail standards consistent with commercial product regulation common for commercial goods in most countries and are not meant to limit the sales of good but maintain consumer trust in the product. The second is limiting access, addictiveness or attractiveness of e-cigarettes by youths and non-smokers more generally. Finally, countries have also considered regulations that facilitate e-cigarette use for smoking cessation by adults. These regulations are meant to increase sales of the product. We argue that regulatory policies are a key determinant in the uptake of both youth and adult vaping. This review emphasizes the wide range of policy and regulation mechanisms available to governments trying to curb e-cigarette use and harms. There is a clear need for comprehensive regulatory approaches to e-cigarettes that include sales, product standards, nicotine concentrations, flavours and marketing restrictions with separate regulatory streams for medical and recreational products. Isolated regulations that merely target one of these regulatory areas will likely prove ineffective in curbing youth and non-smoker e-cigarette uptake.

This article is part of the Topical Collection on *Tobacco*

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Introduction

Over the past decade, the prevalence of e-cigarette use has increased dramatically. A 2017–2019 cross-country comparison among youths of 16–19 years of age of Canada, England and the US (United States) showed that the prevalence of vaping among American youths increased (e.g. ever vaping

percentage; 31.3 to 43.6% in the US) compared with those of England (e.g. ever vaping percentage; 33.7 to 36.1% and 29.3 to 33.2% in Canada) [1•]. E-cigarettes are known as different names like 'e-cigs', 'e-hookahs', 'mods', 'vape pens', 'vapes', 'tank systems' and 'electronic nicotine delivery systems (ENDS)'. In general, these are battery-operated electronic devices which contain a liquid known as e-liquid and produce an aerosol by heating the e-liquid and may contain nicotine which is then inhaled [2]. As discussed further throughout this paper, these increases in e-cigarette use may indicate distinctly different policy and regulatory environments between the countries. The United States, in particular, has shown a hesitation in e-cigarette regulation.

The National Academics of Sciences, Engineering and Medicine (NASEM) (2018) review of evidence concluded that e-cigarette use results in dependence on e-cigarettes, increased risk of subsequent cigarette smoking initiation and increased frequency and intensity of smoking among youth and young adults [3•]. Nicotine is a highly addictive substance and may affect adolescent brain development, memory and concentration [4]. Furthermore, children and youths may develop nicotine dependence with lower levels of exposure than adults [5•]. In addition to nicotine, e-cigarette aerosol may also contain toxic chemicals like formaldehyde, acrolein and diacetyl which can cause serious lung disease [2]. On the other hand, NASEM also concluded that substituting combustible cigarettes with e-cigarettes could reduce exposure to toxicants and carcinogens present in tobacco smoke and e-cigarette use might increase adult cessation of combustible tobacco products [3•].

Jurisdictions around the world have adopted different policies in order to regulate e-cigarette products. These policies often have dual objectives of allowing for the use of e-cigarettes by cigarette smokers for cessation or harm reduction and reducing the likelihood of non-smokers initiating e-cigarette use, subsequently becoming dependent on e-cigarettes or initiating cigarette smoking. The World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) has provided guidelines for countries to regulate e-cigarette products through the six MPOWER measures [6••]. The WHO recommends that countries adopt legislation that can regulate ENDS effectively and protect people from potential harms of ENDS; apply bans on advertising and flavouring of products; and consider introducing policies to force manufacturers to make products unattractive like plain packaging in order to discourage uptake by young people and non-smokers generally [6••].

Policies have the potential to affect how e-cigarettes are used and how often. The International Tobacco Control Policy Evaluation Project (ITC Project), which conducted surveys in 14 countries between 2013 and 2017 on the use of nicotine vaping products by adult smokers, showed that the prevalence of current use of e-cigarettes was lower in countries with most restrictive policies (Australia, Brazil, Uruguay) relative to restrictive policies (Canada, Malaysia, Mexico, New Zealand) [7]. Yet, there is much more research needed to understand the appropriate policies for e-cigarette regulation. Furthermore, due to the rapidly evolving nature of these policies, regulations are constantly in flux. The purpose of this review is to provide a brief overview of different e-cigarette regulations across the world, focusing on regulations of sales, product standards, nicotine concentrations, flavours and marketing restrictions.

Differentiation of Medical and Consumer Products

The categorization of products has profound implications for the manner in which they are regulated. Policies that regulate e-cigarettes as prescription-only are not possible unless the products are characterized as therapeutic and/or medicinal. As consumer and/or tobacco products, e-cigarettes will continue to be regulated similarly to cigarettes. Categorization policies, however, are often circumvented by companies, with very few bothering to receive official recognition of their products as medicinal or therapeutic. In both the US and Australia, for instance, companies have the option to list e-cigarettes as therapeutic, following the approval of their respective health agencies [8, 9]. Yet, neither of the countries has any officially therapeutic devices on the market to date. This may suggest that the process of therapeutic approval is not worthwhile in the current regulatory climate, in which it is better worth companies' time to simply forego these medicinal messages.

18 countries classify e-cigarettes as consumer products, while 24 countries regulate products that make a health claim and/or contain nicotine as medicinal products [10••]. In Canada, e-cigarettes are regulated under the Tobacco and Vaping Products Act (TVPA), which became law on May 23, 2018. Depending on making a health claim, vaping products are further regulated by either the Canada Consumer Products Safety Act (CCPSA), controlling e-cigarettes without any health claim or the Food and Drugs Act (FDA), regulating nicotine-containing e-cigarettes which claims to help quit smoking. Vaping products which are subjected to the FDA need market authorization from Health Canada, before they can be advertised, sold or commercially imported. But to date, there are no therapeutic vaping devices available in the market [11]. The province of Quebec is planning to require a type of medical authorization in order for an individual to purchase e-cigarettes [12]. Similar policies exist in the EU/UK countries where e-cigarettes may be brought to market either as medicines or consumer products where restrictions on nicotine levels are relaxed for medicinal products [13, 14]. Regardless of nicotine content, in some countries (e.g. South Korea. France), consumer product e-cigarettes cannot be sold

in pharmacies [10, 15]. In the US, the FDA regulates consumer e-cigarettes as tobacco products under the Tobacco Control Act and the Federal Food, Drug and Cosmetic Act (FD&C Act) whereas therapeutic products are regulated by FDA Center for Drug Evaluation and Research (CDER) [8]. South Korea defines nicotine-containing e-cigarettes as tobacco products while non-nicotine e-cigarettes are regulated as consumer products [15].

In Australia, nicotine is classified as a restricted poison and advertising, promotion, sale and recreational use of ENDS are illegal there. However, under the Therapeutic Goods Administration's (TGA) Personal Importation Scheme, anyone can import up to a three-month supply of nicotine for use in e-cigarettes for therapeutic purposes. Non-nicotine e-cigarettes are allowed to be sold as 'consumer products'. As of March 17, 2020, no e-cigarette has been approved in Australia for sale to help people quit smoking [9].

Sales Regulations

A brief outline of the distribution of countries according to e-cigarette regulation approaches is shown in Table 1. According to The Global Tobacco Control E-cigarette Policy Scan, a policy bank through the Institute of Global Tobacco Control at John Hopkins University Bloomberg School of Public Health, 100 countries currently have national/federal laws regulating e-cigarettes [10••]. Among these countries, selling e-cigarettes (with or without nicotine) is completely banned in 29 countries, including Brazil, Argentina and India. 45 countries including Canada, the United States (US), the European Union (EU) countries, the United Kingdom (UK) and New Zealand have adopted various approaches of regulating sale of e-cigarettes, including minimum age of sale/purchase provisions, restricting/regulating cross-border sale and restricting venues of retailing. Manufacturers and retailers may also have to meet pre-market requirements of their products, provide mandatory annual retailer licensing fees, comply with regular compliance check inspections and pay fines of significant amount or penalties, even face suspension of license for violations. Out of these 45 countries, 33 countries have regulations regarding pre-marketing notification of competent authority before introducing e-cigarettes to the market and submitting annual reports of e-cigarette sales. All 45 countries have regulations on the minimum age of sale and six of these countries do not have any other sale regulations beyond minimum age rules [10••]. Moreover, regulations often vary widely among different jurisdictions within countries. Though the US federal government can place regulations on the manufacturing of tobacco products, states have the ability to regulate how tobacco products are sold and used. Retailers are needed to have a license for selling vaping products in most of the US states, while Mississippi, Tennessee, Illinois and several other states do not have such regulations [16•].

Minimum Legal Sale Age Due to concerns about vaping among adolescents and youths as well as the high risk of developing e-cigarette dependence, cigarette smoking initiation and continuation, different countries have set certain age-limits to prevent youth access to vaping products. 45 countries have legislation of minimum legal sale age (MLSA) for e-cigarette products. The minimum legal sale age is (MLSA) is 18 years in most countries including Canada, the EU and the UK, except 16 years in Belgium, 19 years in South Korea and 21 years in the US, Honduras and Palau [10, 17]. Enforcement of MLSA can include requiring retailers to check identification for all those who look under a certain age and to display point-of-sale signage [17] Sale via vending machines is prohibited in the US unless in an adult-only facility [17].

Product Regulations

32 countries have prohibitions on using harmful ingredients (except nicotine) in e-liquids; 33 regulate the quality of e-liquid, safety and quality of products; and 32 countries have regulations for child-safety packaging [10••]. Besides nicotine, e-liquid may contain several additives, flavours and chemicals which increase toxicity, addictiveness or nicotine uptake. In this respect, countries have provided certain regulations about restricting these harmful ingredients in e-liquid. Banned additives in Canada include amino acids, caffeine, colouring agents, essential fatty acids, glucuronolactone, probiotics, taurine, vitamins and mineral nutrients [11]. Under the EU's Tobacco Products Directives (TPDs) (2014/40/EU), e-liquid should not contain certain additives (vitamins, colourings, caffeine, taurine or other additives and stimulants) and should only use ingredients (except nicotine) that do not pose a risk to human health in heated or unheated form. [13] France and Iceland prohibit additives to e-cigarette products that facilitate inhalation [18, 19]. This may include substances, such as etheric oils, that have local anaesthetic effects that permit the smoker to inhale more deeply. In addition, all EU countries should meet product manufacturing standards, e.g. e-cigarettes should be child-resistant and tamper-proof, protected against breakage and leakage and have a mechanism that ensures filling without leakage [13]. Canada and the Philippines, meanwhile, do not permit the use of ingredients, aside from nicotine, that pose a risk to human health in nicotine-containing liquid [10••].

Nicotine Regulations

Higher nicotine concentrations (e-cigarettes containing at least 4% nicotine) comprise more than 75% of the e-cigarette market [20]. While the EU restricts nicotine concentrations in e-cigarettes to 2%, there are no current restrictions in the United

Table 1 Distribution of countries according to e-cigarette regulatory policies [10••]

Domain	Policy	Country
Sales regulations	Ban e-cigarette sales	Argentina, Brazil, Brunei Darussalam, Cambodia, Colombia, Egypt, Gambia, India, Iran, Kuwait, Lebanon, Mexico, Mauritius, Nepal, Nicaragua, Oman, Panama, Qatar, Seychelles, Singapore, Sri Lanka, Suriname, Syrian Arab Republic, Thailand, Timor-Leste, Turkey, Turkmenistan, Uganda and Uruguay
	Regulations via marketing authorizations	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malaysia, Maldives, Malta, Moldova, Netherlands, New Zealand, Northern Ireland, Norway, Palau, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, Spain, Sweden, Tajikistan, United States, Venezuela and Wales
	Ban on all nicotine-containing e-cigarettes	Australia, Jamaica, Japan, Mexico, Sri Lanka and Switzerland
	Legislations on minimum legal sale age (MLSA)	Belgium, Bulgaria, Canada, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Honduras, Iceland, Israel, Italy, Lithuania, Luxembourg, Malaysia, Maldives, Moldova, Netherlands, New Zealand, Norway, Poland, Portugal, Scotland, Slovenia, Sweden, Tajikistan, Togo, United States and Viet Nam, South Korea, Honduras and Palau
Nicotine regulations	Limit nicotine concentration or volume in e-liquids	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Northern Ireland, Poland, Portugal, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Sweden and Wales
Product regulations	Ban ingredients (other than nicotine) that pose a risk to human health in heated or unheated form in e-liquids	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Northern Ireland, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, Spain, Sweden and Wales
	Regulations on quality of e-liquid, safety and quality of products	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Moldova, Netherlands, Northern Ireland, Poland, Portugal, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Sweden and Wales
	Regulations for child-safety packaging	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, England, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Philippines, Poland, Portugal, Romania, Scotland, Slovakia, Slovenia, Spain, Sweden, United States and Wales
Flavour regulations	Ban all flavours including menthol	Finland, Moldova, Bermuda
	Restrict subsets of flavours	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Poland, Portugal, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Sweden and Wales
Marketing regulations	Prohibit or regulate marketing	Argentina, Australia, Austria, Bahrain, Belgium, Brazil, Bulgaria, Canada, Colombia, Costa Rica, Croatia, Cyprus, Denmark, Ecuador, England, Estonia, Fiji, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, Hungary, Iceland, Iran, Ireland, Israel, Italy, Japan, Jordan, Latvia, Lithuania, Luxembourg, Maldives, Malta, Mexico, Moldova, Nepal, Netherlands, New Zealand, Northern Ireland, Norway, Palau, Panama, Poland, Portugal, Qatar, Republic of Korea, Romania, Scotland, Senegal, Serbia, Seychelles, Slovakia, Slovenia, Spain, Sweden, Timor-Leste, Togo, Turkmenistan, United Arab Emirates, United States, Uruguay, Venezuela, Viet Nam and Wales
	Restrict marketing of only nicotine-containing e-cigarettes	Costa Rica, Ecuador, Georgia, Japan, Mexico, Moldova, New Zealand and Palau
	Mandatory health warnings on packaging	Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Finland, France, Georgia, Germany,

Table 1 (continued)

Domain	Policy	Country
		Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Maldives, Malta, Moldova, Netherlands, New Zealand, Northern Ireland, Poland, Portugal, Republic of Korea, Romania, Saudi Arabia, Scotland, Slovakia, Slovenia, Spain, Sweden, Tajikistan, United States and Wales
Differentiating medicinal vs consumer products	Regulate as consumer products	Australia, Canada, England, France, Germany, Greece, Hungary, Iceland, Indonesia, Ireland, Moldova, Northern Ireland, Republic of Korea, Scotland, Switzerland, United States, Venezuela and Wales
	Regulate as 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

States. While older e-cigarettes used free-base nicotine, newer e-cigarettes (including pods and refillable systems) use nicotine salts, allowing for far higher nicotine concentrations [20]. Nicotine salts lower the pH of e-liquids, allowing for higher concentrations of nicotine delivery with less irritation to the user [2].

Currently, 35 countries across the world have regulations regarding nicotine concentration and volume in e-liquids; however, the level of nicotine concentrations and volumes allowed vary [10••]. For example, the Tobacco Products Directives (TPDs) in the EU/UK mandates that nicotine concentration in consumer product e-liquids should not be more than 20 mg/ml, e-cigarette tanks must not exceed 2 ml and the volume of refill bottles should not exceed 10 ml. In addition, e-cigarettes must deliver a dose of nicotine at a consistent level [13]. On the other hand, Health Canada has determined the maximum concentration of nicotine allowed in e-liquids at 66 mg/g (6.6%). It has based the current limit on 'a peer-reviewed toxicity evaluation of the ingestion of pure nicotine' [11]. While there is no regulation regarding nicotine concentration in South Korea, from an analysis of sample of e-liquid collected from South Korea, the nicotine concentration in the products found from 6.4 to as high as 150.3 mg/ml [21].

Flavour Regulations

Flavour regulations must strike a balance between reducing appeal to youth while encouraging smokers find e-cigarettes appealing enough to switch over. Jurisdictions have a variety of options around flavour restrictions, including banning all flavours and banning all characterizing flavours excluding menthol (e.g. chocolate, cherry). For example, the US FDA has already banned characterizing flavours for cigarettes (except for menthol), but there are no current federal flavour bans for other tobacco products in the US [22]. 33 countries regulate flavours in e-cigarettes, either by banning all flavours or restricting to a subset of flavours (including menthol and tobacco) [10••].

Varying levels of flavours restrictions in e-cigarettes by jurisdictions in the US and Canada are outlined in Tables 2 and 3. These two countries' regulations have been split by province/state, thus providing useful points of comparison of varying regulations within the countries themselves.

Ban Flavours in E-liquids Finland first banned flavours in both nicotine and non-nicotine e-liquids in 2016 [23]. In addition, Moldova and Bermuda have banned flavours [10, 24]. A number of countries, including Estonia and Denmark, have tabled legislation to ban flavoured e-liquids [25, 26].

In the US, the Food and Drug Administration (FDA) released its enforcement policy in early 2020 declaring that

Table 2 Levels of flavour restrictions by jurisdictions in the US and Canada [12, 16]

Level of Restriction	Jurisdiction
Minor restrictions	British Columbia, Canada North Dakota, US Northwest Territories, Canada Ontario, Canada Saskatchewan, Canada Yukon, Canada
Major restrictions	Michigan, US New York, US Rhode Island, US Washington, US
Comprehensive restrictions	EU Member States Massachusetts, US New Jersey, US Nova Scotia, Canada

N.B.: Banning sales of all types of flavours including menthol in e-cigarettes is indicated as comprehensive restrictions, restricting most of the flavours as major restrictions and restricting the sale of flavoured e-cigarettes in adult-only facilities is indicated as minor restrictions

Table 3 Flavour bans in US states [16•]

State	Law
Massachusetts	The sale of flavoured e-cigarettes is prohibited.
Michigan	The sale of flavoured nicotine-containing e-cigarettes is prohibited.
Montana	A ban on sale of all flavoured e-cigarettes including menthol containing products has been proposed.
New Jersey	The sale of all flavoured e-cigarettes is banned.
New York	The possession, manufacturing, distribution and sale of all flavoured e-cigarettes is banned.
North Dakota	The sale and distribution of flavoured e-cigarettes to individuals under the age of 21 is prohibited.
Rhode Island	The sale of flavoured e-cigarettes is prohibited.
Washington	The sale of e-cigarettes that contain vitamin E acetate, flavours and products reasonably known to be used to flavour vapour products is prohibited.

N.B.: Banning flavoured e-cigarettes means banning all sorts of flavours except tobacco flavours

manufacturing, distributing and selling unauthorized flavoured cartridge-based e-cigarettes that appeal to youth, including fruit and mint flavours should be ceased. This enforcement policy is not an actual ban and it does not apply to menthol and tobacco flavours as well as tank-based and other non-cartridge-based vaping devices [27]. Currently, in the US, sale of flavoured e-cigarettes is banned in 3 states (Massachusetts, New York and Rhode Island).

Federal legislation in Canada bans the promotion or labelling of confectionary, dessert, cannabis, soft drink and energy drink flavours for e-cigarettes. Under Canada's Tobacco and Vaping Products Act (TVPA) it is illegal to advertise vaping products' flavours that could appeal to youth [11]. On the contrary, several provinces and territories in Canada have suggested or imposed stricter regulations on flavoured e-cigarettes. For example, selling flavoured vaping products is banned in Nova Scotia, while British Columbia and other provinces are considering more strictly regulating flavours in e-cigarettes [12]. States and territories in New Zealand banned fruit and confectionary flavoured e-cigarettes. Moreover, New Zealand is developing regulations that would only allow 3 flavours (tobacco, menthol and mint) in e-cigarettes and regulates use of the names of flavours (Honey Bear, tropical Bomb, Good Morning Sunshine) attracting youths [28].

Restrict Flavours to Adult-Only Stores Restricting the sale of flavoured e-cigarettes to adult-only stores is a policy option being put forward in the Ontario province of Canada [29]. This option holds some promise in allowing access to flavours for adult smokers seeking e-cigarettes for cessation and harm reduction while keeping them out of the hands of young non-smokers. The policy will go into effect on July 1, 2020, where most flavoured e-cigarettes will be sold in specialty vape stores and cannabis retail stores, and not in convenience stores, gas stations, grocery stores and other such stores. However, e-cigarettes with tobacco, mint and menthol flavours will still be available in stores other than specialty vape stores [29].

Marketing Regulations

E-cigarette marketing can take a variety of forms, including advertising, promotion and sponsorship. It includes both point-of-sale marketing and broader online, broadcast and outdoor advertising. E-cigarette marketing is prohibited or regulated in 68 countries and 8 of these countries regulate marketing of only nicotine-containing e-cigarettes [10••]. All advertisements, promotion and sponsorships of e-cigarettes are prohibited in Gambia, Honduras and Israel [10••]. A brief list of jurisdictions with various marketing regulatory policies is presented in Table 4.

Prohibit Broadcast Advertising and Outdoor Signs The EU and England regulate most tobacco (both e-cigarette and cigarette) advertisements, including direct tobacco advertising on national TV and radio, in local magazines and newspapers and on billboards (96%, 89% and 83% of countries regulating these forms of tobacco advertisements respectively). In contrast, the least regulated forms of advertisements include tobacco point-of-sale display and indirect promotion through the appearance of tobacco products in TV and/or films (regulated in 19% and 15% of countries respectively) [30•]. The European regional office of the WHO aims to adopt a comprehensive ban on all tobacco and e-cigarette advertising, promotion and sponsorship by 2025 [31•]. On the other hand, in the US, there is no federal regulation and e-cigarette advertisements are allowed on TV, radio and online [20]. And as a 'balanced approach', weighing the importance of e-cigarettes for helping adults quit tobacco with the problems of youth vaping uptake, New Zealand allows product display and vaping information provision in retail stores and online [32].

Table 4 Regulation of selected examples of e-cigarette advertising [10, 16, 32, 33]

Type of regulation	Jurisdiction
Prohibits advertising e-cigarettes through websites and mobile applications that are directed at minors, as well as prohibits advertising tobacco on outdoor billboards that within 1000 feet of a school or public playground.	California
Prohibits marketing or advertising tobacco substitutes on online or mobile applications directed to children.	Delaware
Prohibits advertising that is misleading, such as claiming e-cigarettes to be 'safe' or 'harmless'	Michigan
Prohibits advertising of e-cigarettes on transit	New Jersey
Prohibits advertising of e-cigarettes on certain campuses of higher education.	Washington
Prohibits advertising tobacco products in retail tobacco stores that they cannot sell, use fraudulent and misleading statements or display advertisements with celebrities, cartoons or other endorsements	Massachusetts
Prohibits e-cigarette advertising on billboards and outdoor signs	Saskatchewan, Manitoba, Quebec, Nova Scotia and Prince Edward Island
Prohibits broadcast advertising	Manitoba, Quebec, Nova Scotia, New Brunswick, Prince Edward Island and Newfoundland
Prohibits ads in stores and on display	British Columbia, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland
Restricts advertising, promotion and sponsorship of e-cigarettes to adult-only venues and events or through direct communications	Costa Rica
Prohibits all domestic and cross-border tobacco advertising, promotion and sponsorship	The Gambia
Prohibits the advertising, promotion and sponsorship of e-cigarettes in public displays; however, it explicitly enables all retailers to display e-cigarette products in-store, in contrast to regulations that require other tobacco products be out of the public's sight.	New Zealand

Restrict Youth Exposure to Advertisements Canada's TVPA restricts advertising and promotion of vaping products that appeal to youth in how they look or work [11, 33]. 11 out of 13 Canadian provinces and territories ban visible product display and e-cigarette advertising at retail stores, but exceptions are made for adult-only specialty vape stores [33]. While California, Delaware and New Mexico have prohibited self-service displays, 21 states have restricted self-service displays to adult-only specialty tobacco or vape shops [16•]. In addition, Costa Rica and Ecuador have restricted advertisements in venues accessed only by adults [10••].

Health Warnings on Packaging 39 countries have made regulations of mandatory placement of health warnings on e-cigarette packaging including the EU/UK countries, Canada and the US [10••]. In addition, making false health claims or misleading or appealing information is also prohibited. Health warnings are generally text-based and focus on the negative health effects of vaping. There is little precedent for image warnings (similar to cigarettes) for e-cigarettes.

Restricting Discounts and Free Samples Offering free samples of e-cigarettes are prohibited in the US and both discounts and free samples are prohibited in the EU countries [13, 17].

Discussion

There is an inherent tension in policies that attempt to restrict the availability and attractiveness of products with policies that attempt to facilitate use by a segment of the population. A number of countries such as Canada, the US and South Korea, the EU/UK and Australia have dual regulatory frameworks meant to distinguish between appropriate (smoking cessation) and inappropriate (youth e-cigarette use) behaviours, but currently, there has been a very limited market presence of therapeutic devices. Some countries like New Zealand have decided that vaping is less harmful than smoking and an important part of a 'balanced approach' to help smokers quit cigarettes, specifically noting this in their recently amended 'smoke-free bill' [32]. On the other hand, though youths can obtain their e-cigarettes from social sources like friends, families and older peers who can purchase the products from retail stores [34, 35], raising the bar of minimum legal sales age (MLSA) has been adopted in some jurisdictions to reduce adolescents and youths access to vaping products from older friends and prevent initiation of vaping at early age [36].

Notwithstanding some limited attempts to model e-cigarette regulations, the nascent nature of the field

has resulted in limited data on the effectiveness of these regulations. This discussion section attempts to outline policies available to legislators. Regardless of precise policy, a combination of regulations across these fields will be necessary to properly reduce and prevent e-cigarette use. We suggest that, similarly to lessons learned in combustible cigarette regulations, siloed approaches to e-cigarette regulation will not be effective.

Product Classification Policymakers should consider the implications of classifying e-cigarettes as therapeutic or consumer products. Efforts to regulate e-cigarettes as prescriptions will likely prove difficult if e-cigarettes are considered as mere consumer products. Despite this, consideration should be given to the likelihood of companies to take up these regulations. Despite the option to classify products as therapeutic, there is been little uptake in the US or Canada. The promotion of e-cigarettes as a therapeutic product rather than a commercial consumer product may attract more adults to therapeutic use. This implies that certain regulatory environments that do not permit and/or encourage e-cigarettes as therapeutic devices will inevitably find themselves unable to properly strike a balance between avoiding youth e-cigarette uptake and improving harm reduction efforts for adult cigarette smokers.

Sales At a minimum, we suggest restrictions on locations of sale of e-cigarettes. Furthermore, given the frequently poor uptake of minimum age requirements for e-cigarette sales, we suggest that manufacturers and retailers also meet premarket requirements of their products, provide mandatory annual retailer licensing fees, comply with regular compliance check inspections and pay significant penalties for poor uptake. A recent modelling study of Singapore, where e-cigarettes have been recently prohibited, found that the most effective theoretical combination of policies to simultaneously lower risk among current cigarette users while limiting initiation of e-cigarette use among non-smokers was minimum legal age requirements plus moderate tax raises and requiring a prescription for e-cigarettes [37•]. This approach tries to balance reducing access to nicotine by young non-smokers and providing access to e-cigarettes to adults trying to quit smoking. We may speculate on why e-cigarette manufacturers have made minimal attempts to sell e-cigarettes as therapeutic devices but this comparison suggests that barriers to entry into the therapeutic market are too high and the barriers to entry into the consumer market are much too low.

Product Policy options should include regulations banning using harmful ingredients (except nicotine) in e-liquids; ensuring quality of e-liquid, safety and quality of products; and child-safety packaging.

Nicotine If the objectives of e-cigarettes are for a 'harm reduction' approach to help cigarette smokers switch, nicotine salts and/or excessive nicotine concentrations are not required in e-cigarettes.

Flavour Flavoured e-cigarettes are very popular among adolescents and youths, and a recent systematic review found that flavour is the most important factor behind trying and initiating vaping among adolescents [38•]. Among the flavours, fruit, sweet and menthol/mint are most popular among adolescents and young adults, while coffee and menthol flavours are particularly preferred by non-smokers [38, 39]. Adolescents also tend to prefer sweet flavours compared with adults [40]. For this reason, restricting flavours could reduce the appeal of e-cigarettes and prevent initiation and continuation of vaping among youth. There are some policies which can be enacted for both therapeutic and consumer e-cigarettes. A systematic review did not find any conclusive evidence of flavoured e-cigarettes contributing to smoking cessation [38•]. This suggests that restricting flavours for both therapeutic and consumer products is an appropriate aim. While some people who use e-cigarettes to attempt to quit smoking appreciate flavours, that is a secondary reason for use of e-cigarettes for people trying to quit cigarettes and there are other ways of motivating therapeutic use.

Marketing Commercial marketing for cigarettes has been successful at attracting youth to vaping, but less successful in attracting smokers to quit. In Canada, 36% of teenagers aged 15 to 19 and 48% of young adults aged 20–24 have tried e-cigarettes, compared with 12% of adults older than 25 [41]. Given that commercial marketing has largely not attracted adult smokers to use e-cigarettes for cessation, restrictions on marketing will be effective at reducing youth use without necessarily impacting therapeutic use. There is a considerable body of evidence including Cochrane literature review and the US Surgeon General Report 2012 concluding that exposure to tobacco advertising and promotion increases the likelihood of smoking initiation among adolescents and youths and the same would be expected for e-cigarettes [5, 42, 43]. Studies on tobacco regulatory policies found that a comprehensive marketing ban is much more impactful than partial advertising bans in reducing tobacco consumption [44, 45]. Partial bans often exclude sports, arts and cultural sponsorship distribution of promotional merchandise and tobacco samples; music events; and covert uses of the internet. Thus, a fully effective advertising, promotion and sponsorship ban must address all of these activities [46•]. Higher restriction on advertisements and marketing in England have been suggested as contributing in the lower prevalence of vaping among youths in a recent study [1•].

Conclusion

E-cigarettes have the potential of causing harm among young people who are otherwise naïve to tobacco products and also reducing harm among adult cigarette smokers. The most effective strategies would balance both of these properties and prevent access to vaping products among adolescents and youths and at the same time increase the availability of the regulated therapeutic products among people trying to quit smoking. Future efforts of research should focus on evaluating the impact of different regulatory policies to achieve these purposes and exploring the use of e-cigarettes as a smoking cessation aid. Finally, national-level comprehensive regulations are recommended over scattered or partial restrictions placed at the provincial or state level and countries should be prepared for strong opposition from the e-cigarette industries while enacting legislations by developing more policies that take into account evidence of both the effectiveness of e-cigarettes on curbing cigarette use and the risks of another generation that may take up a new form of tobacco use.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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- • Of importance
- •• Of major importance

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