Electronic cigarettes: A comparison of national regulatory approaches

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ABSTRACT

E-cigarettes have been readily available to global markets since 2004. However, regulations have lagged behind popular use and availability. As policies emerging from national health agencies have an important role to play in shaping consumer health, we examined the existing and upcoming national regulations surrounding e-cigarette availability and use in a convenience sample of English- and French-speaking countries, including Canada, the United States, the United Kingdom, France, Australia and New Zealand. There is substantial international variation in regulatory policies and the extent to which these are enforced. Of the countries considered in this review, the US has regulations that remain the most permissive, whereas those in Canada and New Zealand are the most conservative. However, regulations in Canada, Australia and New Zealand are easily bypassed through Internet imports and lenient enforcement. European health agencies are paving the way for Member States to take appropriate steps to regulate e-cigarettes according to their own jurisdictions. Currently, national regulations of e-cigarettes appear to be ill-defined in terms of shaping the future of e-cigarette availability and use. National regulations should be strengthened to reflect the public health implications of e-cigarettes and to emphasize their difference from consumer products.

KEY WORDS: E-cigarettes; regulation; health policy

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Since their introduction to global markets in 2004, electronic cigarettes (e-cigarettes) have dramatically increased in use and availability. However, policies governing their manufacture, distribution and sale have not kept pace with product use. Given the inconclusive evidence regarding the safety of e-cigarettes and the unclear public health implications resulting from their use, there is an ongoing debate surrounding the appropriate mechanisms that must be put in place to oversee their production, distribution and sale. As the future of e-cigarettes and consumer health is likely to be influenced by the regulatory policies governing their availability, we reviewed the existing and upcoming national regulatory policies governing the classification, distribution and use of e-cigarettes in a convenience sample of English- and French-speaking countries. Specifically, we searched government websites to examine the national policies implemented in Canada, the United States (US), the United Kingdom (UK), France, Australia and New Zealand (NZ).

Product classification

Most global legislation overseeing the availability of e-cigarettes has been formulated according to whether these products are considered medicinal or non-medicinal devices (Table 1). In 2009, Health Canada ruled that nicotine e-cigarettes are medicinal devices requiring market authorization prior to importation, advertisement or sale in Canada.¹ Authorization is granted on the basis of scientific evidence demonstrating the safety and efficacy of the product's therapeutic claims. To date, no nicotine e-cigarette has obtained market authorization in Canada. In contrast, e-cigarettes are widely available in the US with or without nicotine and are currently unregulated by the Food and Drug Administration (FDA). However, in April 2014, the FDA issued a proposal to impose further controls on e-cigarettes.²

With their inclusion in the *Tobacco Control Act*, e-cigarettes would become subject to general tobacco controls. A final decision is expected to be reached in 2015.

Australian classifications are similar to Canada's insofar as nicotine e-cigarettes are therapeutic goods subject to approval by the Therapeutic Goods Administration.³ Currently, no nicotine e-cigarette is approved for sale in Australia. However, the country's health agency has stated that its position will ultimately be informed by the World Health Organization's (WHO) Framework Convention on Tobacco Control.⁴ In NZ, the Medicines and Medical Devices Authority has ruled that nicotine e-cigarettes and those non-nicotine e-cigarettes making therapeutic claims remain illegal, while non-nicotine e-cigarettes that do not make therapeutic claims can be purchased in the same way as tobacco cigarettes.⁵

European Union (EU) Member States have taken varied approaches, including complete prohibition (e.g., Greece, Lithuania), regulation as tobacco products (e.g., Malta), regulation as medicinal products (e.g., France, Netherlands, Denmark) and regulation as consumer products (e.g., UK, Spain, Italy).⁶ In France, e-cigarettes are regulated as medical devices if 1) they

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Table 1. Federal approaches to e-cigarette regulation

Country	Regulatory agency	Product classification	Product standards	Sale to minors	Use in public places	Advertising regulations
AUS	TGA	Nicotine e-cigs are therapeutic goods not currently approved for sale. No legislation for nicotine-free e-cigs, except for their prohibition in the state of Western Australia.	None.	No national legislation. Prohibited in the state of Queensland.	No national legislation. Prohibited in the state of Queensland as of 2015.	No national or state legislation.
CAN	Health Canada	Nicotine e-cigs are medical devices, not currently approved for sale. No legislation for nicotine-free e-cigs.	None.	No national or provincial legislation. Prohibited in select municipalities.	No national legislation. Prohibited in the province of Nova Scotia and various municipalities.	No national or provincial legislation.
FRA	ANSM (Subject to EU laws)	Products not considered medical devices are available for general sale. By 2016, nicotine-containing products not licensed as medicines will be subject to EU regulations.	None currently. Manufacturing guidelines to be enforced EU-wide in 2016.	Prohibited sale to youth under 18 years.	Prohibited use in establishments for minors, public transport facilities and public workplaces.	No advertisements allowed outside select retail locations. In 2016, packaging will list ingredients, nicotine content, delivery per dose, batch number, warning to keep product away from children and potential for addiction.
NZ	Medsafe	Nicotine e-cigs are medical devices, not currently approved for sale. No legislation for nicotine-free e-cigs.	None.	Prohibited sale to youth under 18 years.	No national or regional legislation.	No national or regional legislation.
UK	MHRA (Subject to EU laws)	Currently regulated as consumer products. By 2016, nicotine-containing products not licensed as medicines will be subject to EU regulations.	None currently. Manufacturing guidelines to be enforced EU-wide in 2016.	No national or regional legislation.	No national or regional legislation.	TV restrictions for misleading or youth-appealing advertisements. In 2016, packaging will list ingredients, nicotine content, delivery per dose, batch number, warning to keep product away from children and potential for addiction.
US	FDA	Currently unregulated. Proposed rule to regulate e-cigarettes as tobacco products under the <i>Tobacco Control Act</i> .	None.	No national legislation. 22 states restrict youth access.	No national legislation. 12 states have smoke-free air legislation mentioning e-cigs.	Product listing, ingredient listing.

AUS = Australia; TGA = Therapeutic Goods Administration; e-cigs = e-cigarettes; CAN = Canada; FRA = France; ANSM = Agence nationale de sécurité du médicament et des produits de santé; EU = European Union; NZ = New Zealand; Medsafe = NZ Medicines and Medical Devices Authority; UK = United Kingdom; MHRA = Medicines and Healthcare Products Regulatory Agency; TV = television; US = United States; FDA = Food and Drug Administration.

make therapeutic claims for smoking cessation, 2) the nicotine content in a cartridge is ≥ 10 mg or 3) the rechargeable liquid has a nicotine content ≥ 20 mg/mL.⁷ Similarly in the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) announced in 2013 that all nicotine-containing products would be regulated as medicines.⁸ However, this report was issued before the European Commission's 2014 revision of its Tobacco Products Directive,⁹ which, contrary to the MHRA, does not consider all nicotine products as medicines. Rather, nicotine-containing products not licensed as medicines are subject to EU-wide restrictions regulating product contents, advertisement and distribution. Member States will be expected to comply with these directives by May 2016.

By and large, countries included in this review acknowledge that nicotine is a drug that warrants targeted controls. However, neither the US nor the UK currently consider nicotine e-cigarettes to be health-related products, as they are subject only to consumer controls. Furthermore, despite Canada, Australia and NZ's regulations prohibiting the sale of nicotine e-cigarettes, these are weakly enforced, and nicotine e-cigarettes and e-liquids are easily purchased locally or through Internet imports. Such lack of enforcement necessarily entails the absence of quality controls for e-liquids and e-cigarette devices. This is surprising, as even cosmetics fall under the purview of national health agencies, including Health Canada and the FDA, which are mandated to ensure that products with potentially harmful effects are safe. The variability observed in national approaches towards e-cigarette classification in particular reflects the high degree of uncertainty surrounding a product that is reminiscent of yet fundamentally different from either conventional cigarettes or existing nicotine replacement therapies.

Access to minors

In 2014, the WHO issued a warning concerning the use of electronic nicotine delivery systems (including e-cigarettes) among children, adolescents, pregnant women and women of reproductive age on the basis of the potential long-term consequences resulting from fetal and adolescent nicotine exposure.¹⁰ Of the countries considered in this review, only NZ¹¹ and France¹² have produced national legislation prohibiting the sale of e-cigarettes to minors, although the UK is considering similar restrictions. While the 2014 European Commission Tobacco Directive⁹ does not set an age limit for e-cigarette purchase or use, additional EU rulings include child-proof mechanisms for e-cigarettes and refill containers.¹³ In the US, the FDA suggested restricting e-cigarette sales to minors as part of its proposed rule,² although no final ruling has been issued. Currently, there are no national restrictions prohibiting minors from purchasing e-cigarettes in either Canada or Australia.

At present, the evidence in support of a gateway hypothesis, in which youth turn from e-cigarettes to tobacco, remains inconclusive. While cross-sectional evidence has shown that e-cigarette use among youth is associated with higher odds of ever or current cigarette smoking,¹⁴ neither causal nor directional relationships can be established from these data. However, given the unknown health effects of long-term nicotine use¹⁵ and of frequent inhalation of propylene glycol,¹⁶ public health interests dictate that youth access to e-cigarettes

should be regulated and product use among youth should be monitored to better inform future policy developments.

Advertising regulations

E-cigarettes are marketed to consumers through multiple platforms, including television, social media, celebrity endorsement, online advertising and point-of-sale displays. In 2009, Health Canada issued a notice warning against advertising for nicotine-containing e-cigarettes.¹ However, businesses routinely selling nicotine e-liquid with e-cigarette hardware may advertise products if these do not explicitly mention nicotine. Similarly in the US, because e-cigarettes are not currently regulated as tobacco products, they are not subject to advertising restrictions similar to those for conventional tobacco products. In contrast, the French Health Minister announced in 2014 that France would eventually prohibit the advertisement of e-cigarettes outside of select retail locations.¹⁷ In the UK, the Advertising Standards Authority has previously banned televised e-cigarette advertisements, which it deemed either misleading or appealing to children.¹⁸ More generally, the European Commission has stated that, while Member States will be free to regulate the specifics of advertising restrictions within their own jurisdictions, advertisements should not encourage tobacco consumption or conflate e-cigarettes with tobacco products.⁹ Neither the Australian nor NZ health authorities comment on the permissibility of advertising e-cigarettes with or without nicotine.

As e-cigarettes are thought to have similar toxicity to existing nicotine replacement therapies,¹⁹ regulations should allow for targeted advertising to smokers seeking to reduce the harms associated with cigarette smoking, without encouraging product use among non-smokers or minors. However, because tobacco advertisements in print and other media have long been prohibited, today's youth have never experienced similar marketing strategies prior to those employed by e-cigarettes brands. It is unknown whether such marketing may have the unintended effect of encouraging the consumption of tobacco cigarettes. As marketing and advertisements stand to influence the demographic picture of e-cigarette users, advertising regulations should be carefully considered as an extension of youth and non-smoker protection.

Product use in public places

Many jurisdictions regulate the use of e-cigarettes in public places at a subnational level. Such policy is increasingly common in light of the WHO's 2014 statement on the unknown health consequences for bystanders and second-hand e-smokers.¹⁰ Of the countries considered in this review, only France has enacted federal legislation prohibiting e-cigarette use in public places: in May 2016, "vaping" will be banned in all establishments geared to minors, in all public transport facilities and all public workplaces.²⁰ Other countries have introduced smoke-free air legislation at the provincial, regional or state levels, including Canada (e.g., Nova Scotia²¹), Australia (e.g., Queensland²²) and the US (12 US states as of April 2014²³).

The discussion surrounding e-cigarette use in public places is rooted in several key issues. First, despite evidence supporting their short-term safety for both users and bystanders,¹⁶ the long-term health effects resulting from exposure to e-cigarettes

remain uncertain. Second, although the likelihood of this potential risk is difficult to assess, it is possible that the ubiquity of e-cigarettes and the production of smoke-like vapour may contribute to the renormalization of a smoking culture. Last, there is a strong ethical argument to be made for e-cigarette exposure not to be imposed upon non-users. Consequently, the inclusion of e-cigarettes in smoke-free air policies is likely to be scaled up as products become increasingly regulated.

CONCLUSION

With the advent of new EU directives and the promise of increased FDA controls, Europe and the US appear to be leading the way towards e-cigarette policy that acknowledges governments' responsibility to impose public health regulatory controls. In contrast, restrictive policies juxtaposed with a lack of enforcement, as seen in Canadian, Australian and NZ e-cigarette policy, sends an unclear message to both consumers and health practitioners concerning the safety and appropriate use of these devices. E-cigarettes are increasingly used by consumers who may be regularly exposed to nicotine, as well as by smokers attempting to quit. Consequently, e-cigarettes are health-related products whose oversight should ultimately be informed by public health interests and governed by standards imposed by national health agencies.

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RÉSUMÉ

Les cigarettes électroniques sont aisément accessibles sur le marché mondial depuis 2004. Cependant, la réglementation est en décalage par rapport à leur consommation et à leur disponibilité. Les politiques des administrations nationales de la santé ont un rôle important à jouer dans la santé des consommateurs; c'est pourquoi nous avons examiné les règlements en vigueur et en préparation portant sur la disponibilité et la consommation des cigarettes électroniques dans un échantillon de commodité de pays anglophones et francophones : le Canada, les États-Unis, le Royaume-Uni, la France, l'Australie et la Nouvelle-Zélande. Les politiques de réglementation et la mesure dans laquelle elles sont appliquées varient beaucoup à l'échelle internationale. Parmi les pays à l'étude, les É.-U. avaient les règlements les plus permissifs, tandis que le Canada et la Nouvelle-Zélande avaient les plus stricts. Toutefois, les règlements au Canada, en Australie et en Nouvelle-Zélande sont facilement contournés par les importations sur Internet, d'autant plus que l'application des règlements laisse à désirer. Les administrations européennes de la santé préparent la voie aux États membres pour qu'ils puissent prendre les mesures qui s'imposent pour réglementer la cigarette électronique selon leur compétence. À l'heure actuelle, les règlements nationaux semblent mal définis pour ce qui est de préparer l'avenir de la disponibilité et de la consommation des cigarettes électroniques. Il faudrait les renforcer pour tenir compte des répercussions pour la santé publique de la cigarette électronique et pour mieux définir leurs différences par rapport aux biens de consommation.

MOTS CLÉS : cigarette électronique; réglementation gouvernementale; politique sanitaire