

TO: Chair and Members of the Board of Health

FROM: Christopher Mackie, Medical Officer of Health

DATE: 2015 June 18

THE NEED FOR ENFORCEMENT AND MANDATORY SAFETY STANDARDS FOR E-CIGARETTE JUICE CONTAINING NICOTINE

Recommendations

It is recommended that the Board of Health:

1. *Endorse Report No. 036-15 re The Need For Enforcement And Mandatory Safety Standards For E-Cigarette Juice Containing Nicotine.*
2. *Recommend that Health Canada actively enforce legislation against the illegal import, advertising and sale of e-cigarette juice containing nicotine, and conduct mandatory inspections of e-cigarette and e-juice manufacturers regarding safety standards, quality controls and packaging requirements, by sending a letter to the Prime Minister of Canada and the federal Minister of Health, copied to local Members of Parliament, and by asking staff to draft a motion to take to the next Association of Local Public Health Agencies Annual General Meeting for consideration.*

Key Points

- Nicotine is a highly addictive and toxic substance which has the potential to cause acute adverse health effects and which can be lethally poisonous at high doses.
- Electronic cigarettes (“e-cigarettes”) containing nicotine and their accompanying nicotine solutions (“e-juice”) fall under the federal *Food and Drugs Act*, requiring authorization prior to importation, advertising and sale.
- To date, no nicotine-containing e-cigarette or e-juice has been approved by Health Canada and therefore persons importing, advertising or selling such products are acting in contravention of the *Food and Drugs Act*.
- Despite the current position of Health Canada, e-juice containing nicotine is increasingly visible and available in the retail market, presenting a number of new public health risks, including nicotine poisoning.

Background

Electronic nicotine delivery devices, known more commonly as e-cigarettes are battery-powered devices that deliver nicotine, flavourings and other chemicals through the inhalation of a vapour. E-cigarette refill liquids, which may or may not contain nicotine, are referred to as “e-juice”. A 2011 survey found that 93% of Canadian e-cigarette users use nicotine e-juice with their devices. Long-term studies on the safety of the devices and their efficacy as a cessation aid are not available. Despite the lack of evidence, e-cigarettes are widely available for sale at pharmacies, grocery stores, convenience stores and gas stations; currently, 70% of Middlesex-London tobacco retailers sell the devices and/or the accompanying e-juice. As global e-cigarette sales are forecasted to reach \$3 billion by the end of 2015, London has seen an increase in the number of e-cigarette specialty stores (“vape stores”) opening for business over the past two years. Such stores exclusively sell electronic smoking equipment and accessories, including e-juice. Worldwide, there are now over 450 brands being marketed in over 7000 flavours.

E-juice is manufactured predominantly in China and bottles are not subject to any legal safety standards for labelling or packaging such as those imposed on the pharmaceutical industry in the production of medication. In 2009, Health Canada issued a Public Notice Advisory to Canadians, attached as [Appendix A](#),

and a notice to stakeholders, attached as [Appendix B](#), instructing persons importing, advertising or selling e-cigarette products in Canada to stop doing so immediately as such activity contravened the *Food and Drugs Act*. The Notice outlined the legal requirement for product market authorization and advised Canadians not to purchase or use the products. Middlesex-London Health Unit Tobacco Enforcement Officers (TEO) distributed this Notice to all tobacco retailers in 2011 due to an increase in calls from tobacco retailers and members of the public. The sale of nicotine e-juice in retail shops in Middlesex-London, primarily flea markets, kiosks in shopping centres and specialty vape stores, were referred by TEOs to Health Canada's Health Products and Food Branch Inspectorate for investigation. A template acknowledgement letter was received by the Health Unit. Every premise reported to Health Canada continues to illegally sell nicotine juice.

Ontario's *Electronic Cigarette Act, 2015* regulates the use of e-cigarettes in places where smoking is prohibited, and imposes sales and advertising restrictions, as described in [Report No. 040-15](#); however, enforcement of the sale of nicotine e-juice lies solely with Health Canada. Failure of Health Canada to actively enforce contraventions of the *Food and Drugs Act* is contributing to the increased availability, marketing and sale of illegal nicotine products.

Public Health Concerns

With an estimated median lethal dose between 1 and 13 mg per kg of body weight, 1 teaspoon (5 ml) of a 1.8% nicotine solution [could be lethal](#) to a 90-kg person. A 20ml bottle of e-juice contains on average 360 mg of nicotine, several times the lethal dose. Incidents of nicotine poisoning have risen substantially, especially in the [United States](#). In Canada, the risks associated with unregulated nicotine e-juice compositions include variable concentrations of chemicals and nicotine, dangerous nicotine dose levels or undisclosed ingredients. According to laboratory testing commissioned by Health Canada, approximately one-half of all products labelled as nicotine-free contained nicotine. In addition, unsealed, leaky or non-child proof bottles containing a potent poison is a concern. The rising prevalence of e-cigarette use is also a concern; use is highest among young people with one in five youth (aged 15-19) and young adults (aged 20-24) having ever tried an e-cigarette. Prevalence varies across provinces; among youth aged 15-19, ever use ranged from 15% in Ontario to twice that (31%) in Quebec. The use of flavourings and lifestyle marketing tactics mimic tobacco industry advertising and promotional practices. All main transnational tobacco companies are now selling e-cigarettes, and are investing hundreds of millions of dollars into product development and manufacturing.

Local Concerns

During recent inspections in London, TEOs found that all nine retail shops which mainly sell drug paraphernalia also sell e-cigarettes and nicotine e-juice. The seven known specialty vape stores in London also sell nicotine e-juice. In addition, TEOs are finding that e-cigarette displays have become more visible and elaborate in tobacco retailer premises. Nicotine e-juice is now prominently displayed on point of sale shelving and countertops of many tobacco retailers in Middlesex-London. Although some still appear to be from "independent" distributors, many are Vapur brand. The Vapur brand e-juice bottles on display are labelled to contain nicotine and participating storeowners have been given a document titled "About Vaporizers and E-Juice", attached as [Appendix C](#). The information sheet is issued by Casa Cubana, the umbrella company of Vapur, who is also an importer and distributor of cigars and tobacco accessories. The document's wording encourages retailers to sell their nicotine juice to customers. The TEOs expressed concern that tobacco retailers may have difficulty understanding the high-literacy language used in the communication, especially for those whom English is a second language. The Casa Cubana document advises retailers that e-cigarettes containing nicotine are "a political and regulatory grey area in Canada" with an "arguable legal status," and retailers are advised to not comply with Health Canada's Advisory Notice.

Next Steps

The inaction of Health Canada in enforcing legislation banning marketing and sale of nicotine juice in stores is contributing to a disregard of the federal law by suppliers, distributors and retailers. The subsequent increased availability of these new commercially-branded, marketed and visibly-displayed nicotine e-juice bottles is misleading retailers and their customers regarding the legal status and safety of the products. There is a need for active enforcement against the illegal import, advertising and sale of e-cigarette juice containing nicotine, and manufacturers need to be subjected to mandatory inspections regarding safety standards, quality controls and packaging requirements to protect children, youth and adult consumers.

This report was prepared by Ms. Leila Davis, Tobacco Enforcement Officer and Ms. Linda Stobo, Chronic Disease Prevention and Tobacco Control Manager.



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<p>This report addresses the following requirement(s) of the Ontario Public Health Standards: Foundations: Principles 1, 2; Comprehensive Tobacco Control: 1, 6, 9, 11 and 13</p>
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