

Comments on the Proposed Changes to Ontario Regulation under the *Electronic Cigarettes Act* Middlesex-London Health Unit

Linda Stobo, Manager Chronic Disease Prevention and Tobacco Control

Date: Thursday August 27th, 2015

To: Martha Greenburg
Assistant Deputy Minister
Health Promotion Division
Ministry of Health and Long-Term Care

Jackie Wood
Acting Director
Strategic Initiatives Branch
Ministry of Health and Long-Term Care

The following comments are from the Middlesex-London Health Unit concerning the proposed amendments to Ontario Regulation under the *Electronic Cigarettes Act*. Our comments are based on the summary information posted in the absence of actual regulatory language.

Re: Definitions

We would recommend that all terms that provide authority and/or that may be used for compliance and enforcement are defined in the regulations to provide clarity.

Comments Related to “Flavoured Electronic Cigarette” and Nicotine E-Juice

The inaction of Health Canada in enforcing the illegal marketing and sale of nicotine electronic cigarette (e-cigarette) juice (nicotine e-juice) in stores across Ontario 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. By Regulation, define “***flavoured electronic cigarette***” to include electronic cigarettes and its component parts that contain nicotine.

Section of the Act:

Section 8. No person shall sell or offer to sell a flavoured electronic cigarette that has been prescribed as prohibited at retail or for subsequent sale at retail or distribute or offer to distribute it for that purpose.

Based on the current definition of electronic cigarette and the opportunity to regulate nicotine e-juice through the definition of “flavoured” or “flavouring agent”, the need for active enforcement against the illegal sale of e-cigarette juice containing nicotine will be met, protecting children, youth and adult consumers from a product that lacks appropriate manufacturing and quality standards at the present time.

The Middlesex-London Health Unit recommends that Ontario define “flavoured electronic cigarette” to include electronic cigarettes and its component parts that contain nicotine, and to continue to monitor the evidence regarding the use of flavours within e-juice and how flavourings may impact e-cigarette use by young people.

Comments Related to Retailer Registration with the Local Medical Officer of Health

Under Section 5(1)7 of the *E-Cigarette Act*, there exists the opportunity for mandatory registration with the local Medical Officer of Health by those who plan the retail selling of electronic cigarettes and its component parts. The “prescribed place or a place that belongs to a prescribed class” could be defined by Regulation as a place that has not registered with the local Medical Officer of Health as a retail outlet that intends to sell electronic cigarettes and its component parts. Currently, these devices are available for sale in many locations, including convenience stores, specialized vape stores, butcher shops, gift stores, clothing stores and those stores that specialize in the drug culture. Health Units are going to have much difficulty in creating a comprehensive and accurate listing of e-cigarette and e-juice vendors within their jurisdictions. The requirement to register with the local Medical Officer of Health, like the approach taken under the *Skin Cancer Prevention Act* was very helpful to support a smooth implementation of new legislation. By including this requirement, selling electronic cigarettes at retail from a prescribed place would be a chargeable offence; therefore, motivation to register would be high, and enforcement would be more consistent and cost-effective for public health units.

The Middlesex-London Health Unit recommends that Ontario prescribe by way of Regulation that registration with the local Medical Officer of Health as a retail outlet of electronic cigarettes and its components parts become mandatory.

Comments Related to “Owner” and Automatic Prohibitions

“*Commercial*” and “*person*” is the terminology used within the legislation. The Middlesex-London Health Unit would recommend that consideration be given to also define by way of Regulation, the “**owner**” or “**occupier of a place**” that sells electronic cigarettes and its component parts so that there is operator obligation on the appropriate sale and distribution of these devices. This language would strengthen the mandatory registration process, proposed in the above section. Further, the Middlesex-London Health Unit would recommend that re-consideration be given to the inclusion of language that supports the issuing of automatic prohibition orders for those owners or occupiers of a place that routinely contravene Section 2

and 3 of the Act. Those who are selling electronic cigarettes and component parts within a place that contravenes the legislation should be held accountable for their actions.

The Middlesex-London Health Unit recommends that Ontario enact firm language regarding vendor compliance histories, ownership and those who own, occupy or operate the place where electronic cigarettes and component parts are sold to prevent retailers from circumventing obligations and consequences under the Act.

Comments Related to Required Signage

The Middlesex-London Health Unit recommends that only one sign be required for posting within retailers regarding the prohibition on selling or supplying electronic cigarettes to minors. The sign must:

- Be 18 centimetres in height and 35 centimetres in width;
- Have a yellow background with black text;
- Read “it is illegal to sell or supply electronic cigarettes to anyone under 19 years of age” in English, or “il est illégal de vendre ou de fournir des cigarettes électroniques a des personne de moins de 19 ans” in French.

The second prescribed sign proposed within the summary comments would act more as a promotional tool or indirect promotion to youth and young people than its intended use as a tool to help minimize sales to minors. It is with these considerations in mind that New Brunswick adopted new regulations on June 30, 2015 to require a single “sales to minors” sign facing the store employee only.

The Middlesex-London Health Unit recommends that the only signage that should be required in retail premises selling e-cigarettes is ID signage located behind the counter that faces the retail clerks, along with the other signage required for prohibition of use of e-cigarettes within enclosed public places, workplaces and other locations as prescribed.

Comments Related to Packaging Requirements

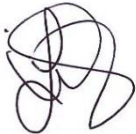
Under Section 7 of the *Electronic Cigarette Act*, “no person shall sell or offer to sell electronic cigarettes at retail or for subsequent sale at retail or distribute or offer to distribute electronic cigarettes for that purpose unless the electronic cigarettes are packaged in accordance with the regulations.” Currently, there are no federal manufacturing and packaging requirements for electronic cigarettes and e-juice; therefore, the Middlesex-London Health Unit recommends that Ontario prescribe by way of Regulations packaging requirements. Additional information that supports this recommendation is being provided by way of including [Report No. 036-15](#) “The Need for Enforcement and Mandatory Safety Standards for E-Cigarette Juice Containing Nicotine” that was presented to the Middlesex-London Board of Health in June. After a full

discussion, it was moved by Mr. Studenny, seconded by Ms. Poole, and carried, 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, and further
3. Send a letter to the Advisory Committee on Health Delivery and Human Resources (with a copy sent to all local Members of Provincial Parliament) to seek its support in advocating to the federal Government on the E-Cigarette Juice Containing Nicotine.

Given the lack of federal action on this important consumer safety issue, the Middlesex London Health Unit recommends that Ontario prescribe by way of Regulations under the *Electronic Cigarette Act* strict packaging requirements that would currently fill the void that exists for the manufacturing and distribution of electronic cigarettes and component parts.

If you wish to discuss further any of the considerations provided, please do not hesitate to contact us.



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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.



Christopher Mackie, MD, MHSc, CCFP, FRCPC
Medical Officer of Health

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



Health Canada Advises Canadians Not to Use Electronic Cigarettes

Advisory

2009-53

March 27, 2009

For immediate release

OTTAWA - Health Canada is advising Canadians not to purchase or use electronic smoking products, as these products may pose health risks and have not been fully evaluated for safety, quality and efficacy by Health Canada.

These products come as electronic cigarettes, cigars, cigarillos and pipes, as well as cartridges of nicotine solutions and related products. These products fall within the scope of the *Food and Drugs Act*, and under the *Act*, require market authorization before they can be imported, advertised or sold. The sale of these health products is currently not compliant with the *Food and Drugs Act* since no electronic smoking products have been granted a market authorization in Canada.

In recent months, a number of electronic cigarettes, cigars and pipes as well as cartridges of nicotine solutions and related products have been marketed in Canada, and through the Internet. Most of these products are shaped and look like their conventional counterparts. They produce a vapour that resembles smoke and a glow that resembles the tip of a cigarette. They consist of a battery-powered delivery system that vapourizes and delivers a liquid chemical mixture that may be composed of various amounts of nicotine, propylene glycol, and other chemicals.

Nicotine is a highly addictive and toxic substance, and the inhalation of propylene glycol is a known irritant. Although these electronic smoking products may be marketed as a safer alternative to conventional tobacco products and, in some cases, as an aid to quitting smoking, electronic smoking products may pose risks such as nicotine poisoning and addiction. Please visit the Health Canada website for further information about [nicotine and addiction](#).*cont'd on reverse*)

While no electronic smoking product has yet been authorized for sale in Canada, Health Canada has authorized the sale of a number of smoking cessation aids, including nicotine gum, nicotine patches, nicotine inhaler, and nicotine lozenges.

Electronic smoking products, including their nicotine cartridges, must be kept out of the reach of children at all times, given the risk of choking or nicotine poisoning. Nicotine is hazardous to the health and safety of certain segments of the population such as children, youth, pregnant women, nursing mothers, people with heart conditions, and the elderly.

Persons importing, advertising or selling electronic cigarette products in Canada must stop doing so immediately. Health Canada is providing information to interested stakeholders on how to apply for the appropriate market authorizations and establishment licences.

Canadians who have used e-cigarette products and are concerned about their health should consult with a health care practitioner.

Complaints involving electronic smoking products can be reported to the Health Products and Food Branch Inspectorate by calling the toll-free hotline at 1-800-267-9675, or by writing to:

Health Products and Food Branch Inspectorate
Health Canada
Address Locator: 2003C
Ottawa, Ontario K1A 0K9

You can also contact a [Health Products and Food Branch Inspectorate Regional Operational Centre](#):

ONTARIO OPERATIONAL CENTRE
Health Products and Food Branch Inspectorate
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7
Tel: (416) 973-1600
Fax: (416) 973-1954
E-mail: insp_onoc-coon@hc-sc.gc.ca

Please see the attached Health Canada [Notice to Stakeholders](#) regarding E-Cigarettes.



March 27, 2009

NOTICE

Our file number: 09-108446-55

To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada

Electronic smoking products (i.e., electronic products for the vaporization and administration of inhaled doses of nicotine including electronic cigarettes, cigars, cigarillos and pipes, as well as cartridges of nicotine solutions and related products) fall within the scope of the *Food and Drugs Act*. All of these products require market authorization prior to being imported, advertised or sold in Canada. Market authorization is granted by Health Canada following successful review of scientific evidence demonstrating safety, quality and efficacy with respect to the intended purpose of the health product. This evidence is provided by the sponsor seeking market authorization. To date, no electronic smoking product has been authorized for sale by Health Canada.

In the absence of evidence provided by the sponsor establishing otherwise, an electronic smoking product delivering nicotine is regulated as a New Drug under Division 8, Part C of the *Food and Drug Regulations*. In addition, the delivery system within an electronic smoking kit that contains nicotine must meet the requirements of the *Medical Devices Regulations*. Appropriate establishment licences issued by Health Canada are also needed prior to importing, and manufacturing electronic cigarettes.

Health Canada is aware that some electronic smoking products have been advertised and sold in Canada without market authorization from Health Canada. Persons who may be importing, advertising or selling electronic smoking products without the appropriate authorizations are asked to stop doing so immediately. Products that are found to pose a risk to health and/or are in violation of the *Food and Drugs Act* and related *Regulations* may be subject to compliance and enforcement actions in accordance with the Health Products and Food Branch Inspectorate's Compliance and Enforcement Policy (POL-0001).

If you wish to submit a complaint about the advertising or sale of a health product without market authorization, please contact the Health Products and Food Branch Inspectorate.

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The following Web links are provided for your information:

"How to Submit a Trade Complaint":

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui_38_trade-industrie_cp-pc-eng.php

For information pertaining to applications and submissions for drugs and health products:

<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index-eng.php>

Information about establishment licensing requirements may be found at:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php>

Sponsors interested in seeking market authorisation for electronic smoking products may contact Health Canada's Therapeutic Products Directorate for information about the drug submission process at: SIPDMail@hc-sc.gc.ca.



April 2015

ABOUT VAPORIZERS & E-JUICE

What is the current situation?

The vaping market in Canada has evolved over the last several years – from standard disposable E-cigarettes, to now include vape tanks and liquids (with/without nicotine).

In Canada, most e-cigarettes users are smokers aiming to cut back on cigarettes (or quit them altogether) and searching for alternative nicotine free and nicotine delivery products. Consequently, thousands of vape shops have opened up across the country in the last several years – all offering e-cigarette/liquids consumers a nicotine alternative.

Through its established VAPUR® brand, Casa Cubana has decided to introduce a range of nicotine delivering liquids specifically designed for the Convenience & Gas Channel.

Are liquids with nicotine legal in Canada?

Health Canada has long stated that all products containing nicotine are regulated under Canada's Food and Drugs Act (FDA) – effectively requiring subsequent approval or certification before being sold in Canada. But everyone knows that tobacco products, as one example, although containing much larger amounts of nicotine than typical E-juices found in our marketplace – are not regulated under the FDA.

Despite some general public positioning and subsequent Cease and Desist letters since issued to shop owners across the country, Health Canada has yet to seize any product or stop any retail outlet from selling any branded E-Juices (with nicotine) in Canada over the last 3 years.

Because the nicotine ingredient in VAPUR® liquids is dispensed in/at such low levels – it is the longstanding position of the E-Juice industry in Canada that this type of product is effectively exempted from regulation (as a drug) under Canada's Food and Drugs Act.

Because the VAPUR® liquids (with or without nicotine) are not marketed as health products (i.e. for medicinal use) or sold as healthier alternatives to smoking or as smoking cessation devices – the product is also not regulated as a Natural Health Product under the Federal Government's Natural Products Regulations.

Consequently, it remains the industry's position that no specific government approval or certification (at this time) is required for selling these (low-level nicotine) products in Canada.



April 2015

ABOUT VAPORIZERS & E-JUICE

Are Casa Cubana clients doing anything illegal by distributing VAPUR® liquids with nicotine?

Casa Cubana takes its commitments and responsibilities to its commercial partners quite seriously. We are confident that if ever challenged in any way, our activities and products would be well argued and defended.

That being said, Governments and government inspectors have the authority to interpret legislation (or review their interpretations) whenever and however they see fit – and on any consumer product.

Know that Casa Cubana stands 100% behind the quality and legality of all of our products.

Are electronic cigarettes containing nicotine still illegal in Canada?

Electronic cigarettes containing nicotine remain a political and regulatory grey area in Canada. While the devices do not make any health claims and deliver (exempted) low-levels of nicotine to consumers – existing Canadian laws should arguably not impact these products.

Despite the arguable legal status of these products, Health Canada remains steadfast in its position that they do require market authorization before being imported and sold in Canada. Their enforcement activities to date have led to the continued refusal of imported product into Canada (refusal at Customs). Because no E-cigarette product is actually manufactured in Canada, these products are consequently seldom found in the marketplace.

Does Casa Cubana **guarantee its products?**

We stand behind everything that we sell. Period.



Should any issue ever arise as to the quality or legality of any of our VAPUR® products or for more information regarding the content of this document, please do not hesitate in contacting us.
