

**Physicians for a Smoke-Free Canada**

# Response to proposed: *Concentration of Nicotine in Vaping Products Regulations*

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## Introduction

Physicians for a Smoke-Free Canada supports the proposed regulation.

We acknowledge that the primary responsibility for reducing the harms associated with vaping products lies with the manufacturers, and that the duties of these companies are not diminished as a result of the adoption of the federal *Tobacco and Vaping Products Act* (TVPA). Parliament has nonetheless provided the department with the authority and responsibility to develop regulations to intervene where the companies' voluntary actions are insufficient. The department's duties are framed by the purpose of the TVPA and the Minister's responsibilities under the *Department of Health Act*.

Our comments in this brief are centred on three recommendations:

- A. The proposed limit on nicotine concentration (to 20 mg/ml) should be adopted, implemented and enforced as soon as possible.
- B. This measure is necessary but not sufficient to protect the health of Canadians from these products, and additional regulations under the TVPA should be adopted.
- C. The TVPA is in need of revisions, and the department should make public the shortcomings and weaknesses in this act so as to facilitate legislative overhaul.

## **A. The proposed limit on nicotine concentration (to 20 mg/ml) should be implemented and enforced as soon as possible**

### **This regulation is overdue.**

The 20 mg/ml level should have been adopted in December 2019, as part of the *Vaping Products Labelling and Packaging Regulations*, instead of the 66 mg/ml level that was proposed. Health Canada received advice from "most public health organizations, health care professionals, academics and researchers, NGOs and some respondents from the public" to this effect<sup>1</sup>, but did not accept these recommendations. Earlier in the year, Health Canada had sought advice on nicotine concentrations. All but a small percentage (13%) of vapers reported using less than 20 mg/ml, and four times as many respondents supported increased controls on nicotine delivery (50% vs 13%).<sup>2</sup> In March 2019, the provincial and territorial members of the Tobacco Control Liaison Committee (TCLC) wrote in favour of "Limiting the amount of nicotine in vaping liquids"<sup>3</sup>. In September 2019, Canada's major health organizations called for the use of an interim order to reduce nicotine levels to 20 mg/ml.<sup>4</sup> In January 2020, Canada's Chief Medical Officers of Health called for setting the cap at 20 mg/ml to "further decrease the addictive potential for youth".<sup>5</sup>

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### **The current level of 66 mg/ml is based on the wrong risk assessment.**

The logic of initially transferring the levels from pre-existing product standards under the *Consumer Chemicals and Containers Regulations, 2001* and then subsequently revisiting these levels only after the damage of this omission was more apparent was flawed. This maximum nicotine level proposed in the regulation is a result of the overly narrow focus on toxicity by ingestion (and especially the risk of accidental poisoning in children). With vaping products, the harmfulness of a chemical should be measured on the basis of inhalation, not ingestion.

### **The proposed level is consistent with international practices.**

Other jurisdictions have sought to provide some measure of protection by setting maximum levels of nicotine in order to reduce the health consequences of inhalation. As the notice of the proposed regulation observes, the European Union has set a maximum nicotine concentration of 20 mg/ml, as have Israel, Iceland, Moldova, Saudi Arabia and the United Kingdom, with Korea's level being even lower.

### **The proposed level is supported by evidence.**

Researchers have raised concerns that higher levels of nicotine in vaping products can increase the risk of addiction by non-smoking users.<sup>6</sup>

- Analysis of emissions from JUUL electronic cigarettes found that the liquid concentration was 69 mg/ml (higher than the stated 5% level).<sup>7</sup>
- Higher nicotine delivering e-cigarettes have become more popular with young people.<sup>8 9</sup>
- Young people are preferentially drawn to higher delivery nicotine vaping products.<sup>10</sup>
- Higher-delivery products using nicotine salts raise concerns about the potential for earlier and more significant nicotine addiction in teens.<sup>11</sup>

In the absence of restrictions on nicotine concentrations, manufacturers of nicotine products are incentivized to sell products which enhance the bioavailability of nicotine. The marketing of JUUL, with higher concentrations of protonated nicotine, launched a "nicotine arms race" and prompted researchers to call for a cap on the amount of nicotine permissible in e-cigarettes.<sup>12</sup>

This 'nicotine arms race' has also been observed in Canada. A year ago, shortly after the nicotine market was legalized, British American Tobacco announced that it would be offering 3 types of vaping products. None of them contained more than 18 mg/ml of nicotine.<sup>13</sup> Subsequent to the introduction of JUUL in the Canadian market in late summer 2018, BAT launched a fourth product (ePod), which had higher nicotine levels using nicotine salts. It subsequently withdrew from the market those products designed to use lower nicotine levels (the ePen, the eTank and the eStick.)

The absence of protective regulations setting a maximum nicotine level has resulted in BAT selling higher-nicotine liquids in Canada than in most other markets. In the European Union, for example, vaping liquids sold by British American Tobacco and Japan Tobacco are considerably lower than those that they sell in Canada. In the case of Canada, the absence of a 20 mg ceiling created a 20 mg/ml floor. The Canadian market consequently became shaped as a high-nicotine market.

### **The proposed exception for exported products cannot be justified.**

While the 20 mg/ml level is justified, there is no reasonable justification for excepting exported products from this limit. If Canadians needed to be protected from high nicotine concentration products, then surely everybody else deserves such protection too. There is no reason to open the door to Canada becoming the

manufacturing centre for high nicotine vaping products to be exported to the rest of the world. Physicians for a Smoke-Free Canada recommends that the provision to except exported products from the proposed 20 mg/ml limit be removed.

**The proposed level will help address the particular risks to Canadians of a high-nicotine market.**

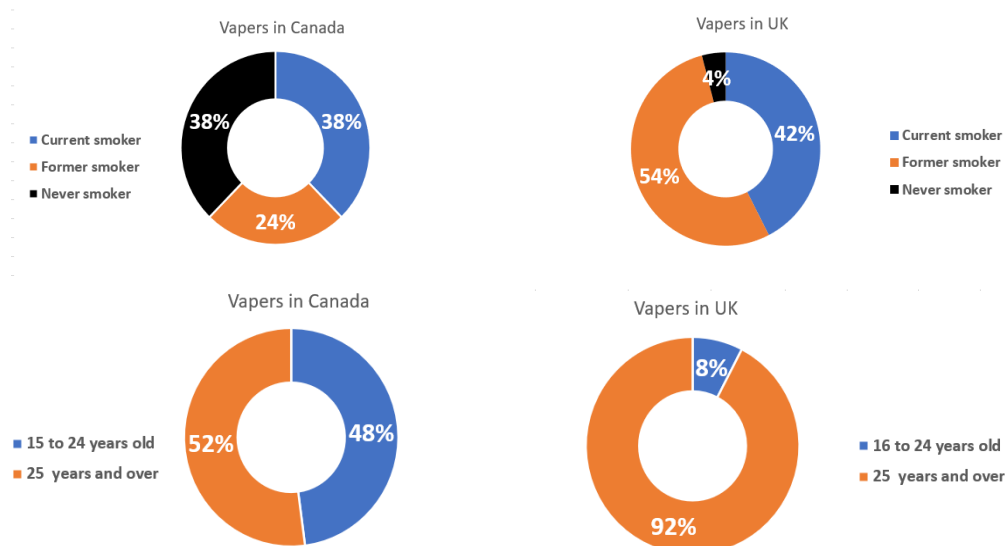
Canada’s relatively lax regulatory environment for e-cigarettes has produced a market where higher nicotine products predominate the market offerings of the leading firms.

**Vaping companies supply higher nicotine products in Canada, and don’t supply lower nicotine products.** In the European Union, for example, vaping liquids sold by British American Tobacco and Japan Tobacco are considerably lower than those that they sell in Canada. In the case of Canada, the absence of a 20 mg ceiling created a 20 mg/ml floor. The Canadian market consequently became shaped as a high-nicotine market.

A recent review of nicotine offerings by British American Tobacco and Japan Tobacco show that these companies have withdrawn (or not introduced) lower nicotine variants in Canada, even though they maintain the sale of very low nicotine products in Europe.

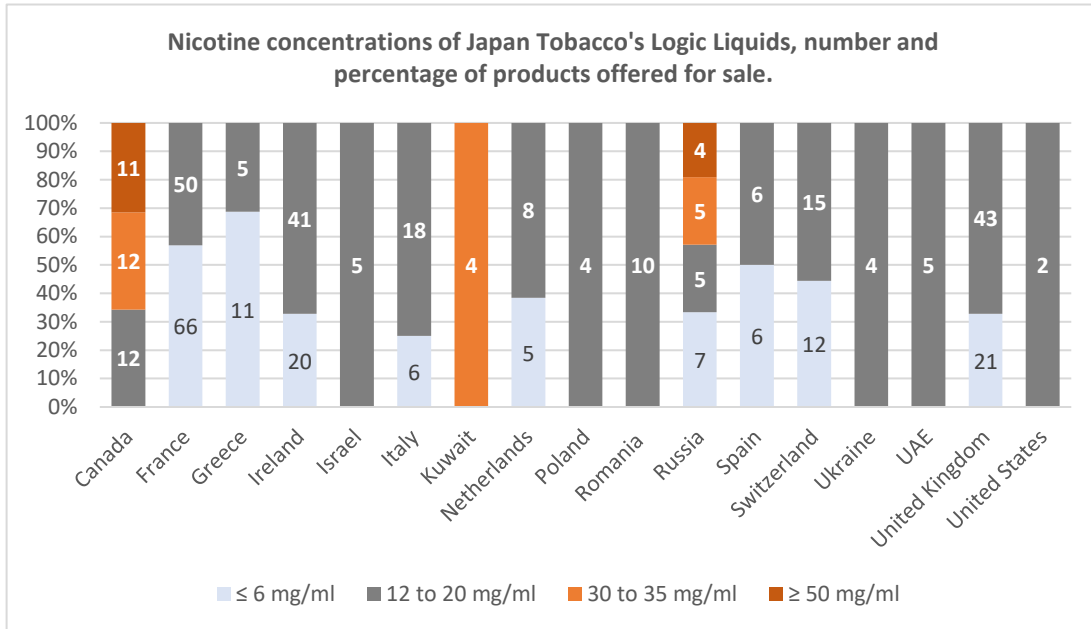
The demand for vaping products in Canada is skewed towards young people and recreational users, unlike other countries. Without establishing a cause-and-effect between the products supplied and the unfortunate demographics of the Canadian vaping market, the government has a responsibility to intervene to address the probability that these two patterns are linked.

In the UK, fewer than 1 in 10 people who identify as current e-cigarette users are under 25, whereas in Canada only about half of those who have vaped in the past 30 days are. (CTNS, 2019). In the UK, about 1 in 20 vapers have never smoked cigarettes, but the proportion is 10 times greater in Canada. In Canada, half as many vapers are former smokers as is the case in the U.K. (The proportion of dual users is about the same.)<sup>14,15</sup>

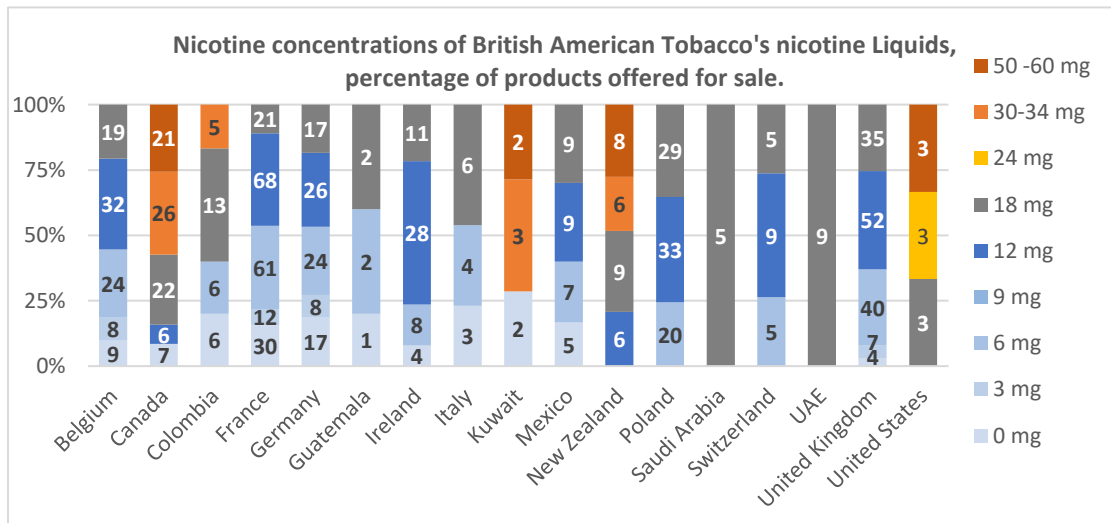


**Figures: Canada has a higher nicotine market than most other countries where vaping products are permitted for sale.**

In France, more than one-half (60%) of JTI's Logic liquids are less than 6 mg/ml nicotine, and 66 flavour variants in this low nicotine range are sold. In Canada it does not sell products less than 18 mg/ml. <sup>16</sup>



In the U.K., 75% of BAT's vaping liquids have 12 mg/ml of nicotine or less. In Canada more than 75% are 18 mg/ml or higher. <sup>17</sup>



## B. The proposed ceiling on nicotine is necessary but not sufficient to protect the health of Canadians from these products.

### Additional regulations under the TVPA should be adopted quickly.

The alarming rise in youth vaping cannot be attributed to a single aspect of the vaping market, and this regulation when implemented is unlikely to reverse the trend on its own.

For the benefit of Canadians, Health Canada and provincial governments have introduced other important controls on nicotine manufacturers to recruit new customers and harm additional people. Among these are the federal Vaping Products Promotion Regulations (SOR/2020-143) which came into force in the summer of 2020.

Among the additional measure needed are those recommended by Canada's Chief Medical Officers of Health. These include the following legislative, regulatory and administrative actions:

- Ban all flavoured products (with potential for regulatory exemption).
- Adopt other appropriate standards regarding nicotine delivery (e.g. temperature, use of organic acids and nicotine salts, voltage, permissible amount of nicotine per device, pH, particle size).
- Tax vaping products in a manner consistent with maximizing youth protection while providing some degree of preferential pricing as compared to tobacco products.
- Consider making the age of 21 the minimum sales age for both tobacco and vaping products.
- Create requirements for age-verification of internet purchases of vaping products that are the same as those required for cannabis.
- Enhance surveillance and reporting of vaping product use and population health impacts.
- Require product manufacturers to disclose all ingredients of vaping devices and all constituents of vaping product aerosol to Health Canada as a condition of being marketed, including establishing consistency in reporting nicotine levels, pH levels, particle size in all inhalable products, including smoked or inhaled tobacco products and both open and closed vaping systems.
- Require plain and standardized packaging along with health risk warnings for all vaping products.
- Include vaping as part of smoke-free restrictions for locations under federal jurisdiction.
- Enhance public awareness and educational initiatives on the risks of vaping products targeted at youth, parents, educators and health care professionals.
- Establish comprehensive cessation initiatives for people with nicotine addiction, especially for youth
- Monitor and research the short and long-term health effects of vaping products.
- Research the effectiveness of policy approaches to address youth vaping.
- Research the effectiveness of vaping products in supporting smokers to **end or reduce their use of all nicotine-containing products.** (emphasis added)
- Develop a broad regulatory approach to all alternative methods of nicotine delivery (i.e. other than tobacco products) that offers strong youth protection while allowing appropriate access for adult smokers to products **if, as a condition of permission to sell, they are proven effective in decreasing or stopping the use of all nicotine-containing products.** (emphasis added). Currently, vaping products do not meet that test. At a population level, they are neither safe nor effective for reducing tobacco and nicotine use. They have also spawned an epidemic of youth vaping.<sup>18</sup>
- Require manufacturers to provide enough evidence to satisfy the regulator that allowing any new product on the market is in the public interest before that product can be legally sold.

To this list we would add the following additional urgent need:

- Additional and enhanced warnings on vaping products using pictorial, graphic and text elements, along the lines of those on tobacco products.

### C. Revisions to the TVPA

The third regulatory action that we recommend to government is to plan to improve the *Tobacco and Vaping Products Act* in order to address systemic and structural barriers to protecting young people, non-users, smokers and vapers from the health consequences of using tobacco and vaping products.

#### **Health Canada is moving (too) slowly to implement the advice of public health officials**

The proposed regulation demonstrates the need for these additional measures. By addressing the foundational problems that the regulation is seeking to redress, Health Canada can move from a series of time-consuming 'band-aid' and reactive regulations to implementing a coherent system of health protection.

These barriers include:

- The conflict between the obligations of suppliers (under the *Canada Business Corporations Act, CBCA*) to generate revenues and profits and the needs of public health to minimize the sale and use of these products. One way that federal law addresses similar conflicts is to exempt certain business activities from the CBCA.<sup>a</sup>
- Lengthy delays that are inherent in regulation-making. The government needs clear authority to rapidly implement interim regulations to address emerging problems.
- The privileged status of vaping promotions. Under the TVPA, all tobacco promotions are banned unless specifically allowed. All vaping promotions are allowed unless specifically permitted. This has created widespread advertising and promotion for vaping products. Enforcement actions have done little to correct this problem. While some advertising has been curtailed by the Vaping Products Promotion Regulations, advertising and promotion on websites and social media continues with impunity.<sup>19</sup>
- Align rules for vaping products with those of tobacco products by including vaping products in the definition of tobacco products, thereby applying the tobacco provisions of the act and many regulations, such as reporting of sales and promotional expenditures, to vaping products.
- Replace the Vaping Products Promotion Regulations, which allow for an excessive amount of advertising and promotion for vaping products,<sup>19</sup> with legislative provisions that would prohibit vaping product advertising with few exceptions, thereby aligning advertising and promotion controls to those that apply to tobacco.
- Inability to enforce in a timely way. Following the TVPA a number of promotions were launched (many of which continue). Health Canada's enforcement mechanism proved unable to protect Canadians from non-compliant television advertising and digital promotions.<sup>20</sup> Health Canada was

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a Banks, co-operative, insurance companies, post secondary educational institutions, hospitals and other institutions are not governed by the CBCA.

unable to protect Canadians from non-compliant marketing of vaping products.<sup>b</sup> The TVPA needs to be changed to provide more effective options, such as creating ticketing offences, for monitoring and enforcement personnel to use.

- Absence of barriers to launching new products. There are no requirements for manufacturers to demonstrate any public health or public benefits before introducing novel product designs. Since 2000 we have seen increases in youth nicotine use through flavoured little cigars, salted nicotine, closed vaping systems, etc. There were no barriers to the introduction of these products, not even requirements for notification. This put a significant burden on Health Canada to establish the need to regulate and then to put regulations in place. When it comes to harmful drugs, the burden should be on the manufacturer to prove a benefit, not on the regulator to prove a harm.

The CCMOH has recommended that such measures be put in place:

*It is important that the regulatory and policy approaches for vaping products be reviewed as the evidence of health risks and benefits evolve. For example, if it becomes clear that vaping products are effective in helping people stop or reduce their use of all nicotine-containing products, then it may then be appropriate to approve, license and regulate vaping products in the same way as other tobacco cessation products.<sup>21</sup>*

### **Tobacco companies are moving (too) quickly to exploit weaknesses in current laws.**

The Current *Tobacco and Vaping Products Act* reflects the mindset that there are a small number of tobacco products of public health concern and that there should be different levels of regulation on some products than on others. Tobacco companies can introduce products and benefit from relatively lax regulations.

For example:

- Heated tobacco products were introduced to Canada in 2017. Four years later, they are still regulated as “other tobacco products”, and therefore have reduced regulatory requirements, including for labelling and reporting. (They are also taxed at a lower rate).
- Tobacco companies demonstrated that they were able to exploit flaws in regulatory drafting when they launched flavoured little cigarillos in the early 2000s. Provincial laws (which treated products more generically as “tobacco products”, some of which also regulate e-cigarettes as tobacco products, have shown the benefits of a less fragmented regulatory approach.
- Tobacco companies are now developing hybrid vaping-tobacco products (eg. Philip Morris LIL Hybrid and BAT glo-sens), and tobacco-free oral tobacco. The TVPA is not structured to manage these products.

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b On March 27, 2009, Health Canada issued an advisory on e-cigarettes cautioning that anyone selling, importing or advertising electronic cigarette products in Canada “must stop doing so immediately”. Despite this vape shops continued to operate.

## The Minister has an obligation to identify the regulatory weaknesses of the federal law and to report them to Parliament

The *Tobacco and Vaping Products Act* contains obligations on the Minister of Health to prepare and table a review of the “provisions and operation” of the TVPA and to provide both the Senate and the House of Commons of her findings. (s. 60.1) This review must commence no later than May 23, 2021.

The law does not give the minister the option on reporting on only a section of the law, or to restrict the review to only certain operational elements. It does not oblige her to recommend to parliament ways in which the act could be improved or that public health could be better protected. It does not prohibit such advice from being offered.

## ENDNOTES

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- 3 Letter from Andrew Loughead and Robert Strang to Mathew Cooke, March 22, 2019.
- 4 CBC News. Vapes need same restrictions as tobacco, medical groups tell federal parties.
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- 6 Boykin, R et al. Evidence of Nicotine Dependence in Adolescents Who Use Juul and Similar Pod Devices. *International Journal of Environmental Research and Public Health*. 2019.
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- 16 Physicians for a Smoke-Free Canada. Japan Tobacco marketing of Logic Vaping Devices . February 2021.
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- 19 Physicians for a Smoke-Free Canada. BAT's new trademarks hint at new vaping promotion, 12 January 2021 <http://smoke-free-canada.blogspot.com/2021/01/bats-new-trademarks-hint-at-new-vaping.html>
- 20 See submission by PSC, March 2019: Enforcing the Tobacco and Vaping Products Act to protect young people from the current marketing practices of the vaping industry in Canada. <http://smoke-free.ca/wp-content/uploads/2020/04/2019-05-Vape-ads-1.pdf>Reference to complaints
- 21 Statement from the Council of Chief Medical Officers of Health on Nicotine Vaping in Canada. January 22, 2020. <https://www.canada.ca/en/public-health/news/2020/01/statement-from-the-council-of-chief-medical-officers-of-health-on-nicotine-vaping-in-canada.html>