

REDUCING YOUTH ACCESS AND APPEAL OF VAPING PRODUCTS

CONSULTATION ON POTENTIAL REGULATORY MEASURES

APRIL 2019





Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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EXECUTIVE SUMMARY

Health Canada shares the concerns of parents, educators, youth and public stakeholders regarding the increase of youth vaping in Canada. Data indicate 15% of students in grades 10–12 (Secondary IV and V in Quebec) used a vaping product in the past 30 days, up from 9% in 2014–15. This represents a 64% increase, or approximately 30% per year.

An Act to Amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other acts became law in May 2018, establishing a new legal framework for regulating vaping products. The Act provides the authority to implement measures to protect youth from health risks that could result from nicotine addiction and tobacco use while at the same time allowing adults access to vaping products as a less harmful alternative to smoking. The legal framework was designed to provide flexibility to respond to changing conditions and new evidence.

Most vaping products are flavoured and contain nicotine. Data show that in addition to playing a role in smoking reduction and cessation for adults, flavours are a key factor influencing youth experimentation and use. Young people who try vaping products containing nicotine are at risk of developing dependence. Nicotine can alter teen brain development and research shows that vaping product use is associated with smoking. Newer products, including the popular pod-based systems, and those containing high concentrations of nicotine, are capable of delivering nicotine on par with smoking tobacco.

Since May 2018, some vaping product brands have been marketed on television, on social media, and in retail locations at point of sale and an increasing number of youth report using vaping products. Given these recent developments, it is incumbent upon Health Canada to examine all regulatory options within existing authorities to better protect young persons. It is critical that a new generation of young people is not enticed to try vaping, risking the development of lifelong addictions to nicotine and potentially reversing Canada's hard-earned gains in tobacco control. At the same time, vaping remains an important opportunity to offer smokers a less harmful alternative.

Earlier this year, Health Canada launched a youth vaping prevention public education campaign with national reach; this was followed by a Notice of Intent (NOI) on February 5, 2019 on potential regulatory measures under the *Tobacco and Vaping Products Act* (TVPA). Health Canada is also working with provincial and territorial partners to address multi-jurisdictional issues and enhance national cooperative and collaborative efforts to reduce youth vaping. In addition to these measures, Health Canada is now seeking advice on additional regulatory measures that would aim to reduce youth use of vaping products. Measures under consideration include: prohibiting the manufacture and sale of vaping products with certain flavours or flavour ingredients and/or prohibiting the promotion of certain flavours; restricting the concentration and/or delivery of nicotine in vaping products; regulating design features; restricting online retail access and restricting product packaging.



INTRODUCTION

WHY WE ARE CONSULTING

Health Canada, like many Canadians and public health stakeholders, is concerned about the rise of youth vaping in Canada. We continue to receive emails, letters, phone calls and messages through our social media channels from parents, educators and others and we agree that the situation must change. Tremendous progress has been made in recent decades to bring smoking rates down to historically low levels. Through a combination of legislation and public education, smoking has been largely denormalized and is no longer perceived by young people as being "cool." Regulatory measures including advertising, promotion and flavour bans have greatly diminished young people's inducements to try smoking.

Reflecting the fact that vaping products are different than tobacco products and present a less harmful alternative for adults who smoke, the TVPA does not regulate them in the same way as tobacco. However, regulatory authorities regarding advertising, promotion, flavours, device attributes and other considerations were built into the TVPA to enable Health Canada to adapt to a changing landscape and to fine-tune restrictions as needed. Legislators also recognized that the rapid evolution of vaping products and their use could potentially require amendments to the Act itself. As such, a legislative review of the provisions and operation of the TVPA is included in the Act. The review is required three years after coming into force, and every two years after that. Further measures that require legislative amendments could be considered through this process.

Indeed, much has changed in very little time. Since the enactment of the TVPA and the creation of a legal market for vaping products without health claims, a new generation of vaping products has emerged, characterized by user-friendly, pod-based devices capable of delivering high concentrations of nicotine on par with traditional cigarettes. Promotional campaigns have been observed on television, on social media, at events, and at retail locations across the country. Canada's important public health achievements are at risk of being eroded if nicotine dependency through vaping becomes normalized among young people, particularly among those who would not otherwise have tried smoking. Nicotine is known to alter teen brain development, the long-term health effects of regular vaping are still unknown, and the potential risk of youth shifting from vaping to smoking exists.

Concerns have been raised in the United States as well, where recent survey data indicate there has been a significant increase in youth use of vaping products. In response, the US Food and Drug Administration has announced a number of proposals to address the youth appeal and access of flavoured vaping products, including: prioritizing enforcement in retail environments where youth have access (tobacco, mint and menthol flavours exempted); limiting online access by enhancing age verification requirements; working with manufacturers and retailers to remove products targeted at youth from the market; and requiring manufacturers to submit pre-market applications for all flavoured vaping products (other than tobacco, mint, and menthol) by August 8, 2021 (this application date is one year earlier than the agency previously proposed).

The Government of Canada is committed to protecting and advancing the public interest by working with Canadians, stakeholders and other governments to ensure that its regulatory activities are evidence-based, proportionate to risk and result in the greatest overall benefit to current and future generations of Canadians. Vaping and tobacco product control is an issue of shared jurisdiction and success in combatting youth vaping will be maximized when all stakeholders work together towards a common goal. Through Canada's Tobacco Strategy, the Government of Canada is investing to build additional capacity in science, surveillance, and policy, and to provide grants and contributions funding. These resources can be leveraged to aid other jurisdictions in exploring or strengthening their tobacco and vaping policies and programs to protect youth.

PREVALENCE OF VAPING IN CANADA

As of 2017, 4.6 million Canadians aged 15 years and older have tried a vaping product. Daily use remains rare, at less than 1%.¹ The 2016–17 Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) shows 10% of students in grades 7–12 (Secondary I to V in Quebec) have used a vaping product in the past 30 days. However, among older students, 15% of youth in grades 10–12 (Secondary IV and V in Quebec) reported use in the past 30 days, up from 9% in 2014–15. This represents a 64% increase. Of the students in grades 7–12 who did report using a vaping product in the past 30 days, 36% (73,500) had never tried a cigarette. One percent of students reported using a vaping product on a daily basis, which is the same proportion that reported smoking cigarettes daily.² More recent evidence presented to Health Canada suggests that there has been a sizable increase in vaping among 16–19 year old Canadians.³ Similar observations were noted in the United States, where the use of vaping products in the past 30 days rose from 12% in 2017 to 21% in 2018 among high school students.⁴

WHAT YOUTH ARE SAYING ABOUT WHY THEY VAPE

It has been consistently observed in recent studies that youth are most likely to cite reasons associated with friends and social influences or flavours when explaining why they vape. For example, research commissioned by Health Canada⁵ found that the top reasons cited for vaping initiation among Canadians aged 13 to 19 were:

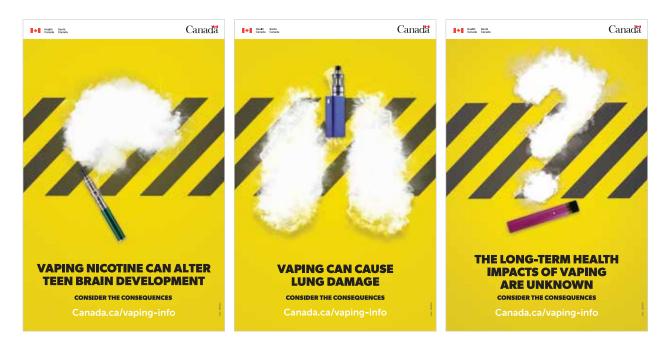
- Friends (58%);
- Flavours (37%);
- "Vaping looking fun and exciting" (22%); and
- Being offered a vape (21%).

A public opinion research study commissioned by Health Canada found that among youth who had ever tried a vaping product, "because e-cigarettes are cool" was the second most cited reason for trying (37%). This same response ranked 6th for young adults and 7th for adults 25 years and older.⁶ In an American population-level study of 4,000 middle and high school students, youth who had tried a vaping product cited a friend or family member first as their reason for trying (39%), followed by flavours (31%) and reduced harm (17%).⁷ Data on American youth recently presented to Health Canada suggest that preference for small-sized, pod-based products over other vaping products is explained by a variety of reasons with the top three being popularity among friends, ease of use and better flavour/taste.³

HEALTH CANADA IS ACTIVELY ADDRESSING THE ISSUE OF YOUTH VAPING

In late 2018 Health Canada launched a youth vaping prevention public education campaign with national reach to youth, their parents and trusted adults. The campaign targets youth through social media as well as with a 30-second ad that is being aired in movie theatres across Canada. Ads were also placed in an in-theatre magazine, along with digital ads and door clings in select theatres. In addition, digital ads are being aired in shopping malls across Canada, with some malls also featuring door clings at main entrances. Two experiential event teams are travelling across Canada, visiting high schools and community venues, offering interactive learning experiences. Vaping Awareness Kits, including bilingual posters, bathroom mirror clings, student activity sheets and a tip sheet for teachers, are available for schools and venues that are not able to host an experiential event or are not covered by the tour schedule. Parents and trusted adults are also being targeted through social media and other marketing, driving them to general information on vaping and a parent tip sheet on how to talk to teens about vaping.

On February 5, 2019 Health Canada issued a Notice of Intent (NOI) on potential regulatory measures to reduce the impact of vaping products advertising on youth. In line with the objectives of the TVPA, the restrictions under consideration are based on limiting advertising that has a high likelihood of being viewed by youth, and preventing inducements to use vaping products. For example, proposed measures include prohibiting advertisements and restricting the display of vaping products at any retail point of sale where young people are permitted access, including online. Comments received on the NOI are being considered in the development of proposed regulations to limit vaping product promotion.



Health Canada also continues to work collaboratively with its provincial and territorial partners to address multi-jurisdictional issues and enhance national cooperative and collaborative efforts to reduce youth vaping.

LEGISLATIVE CONTEXT

There are three separate pieces of federal legislation that govern how vaping products are regulated in Canada:

- The Tobacco and Vaping Products Act;
- The Food and Drugs Act; and,
- The Canada Consumer Product Safety Act.

TOBACCO AND VAPING PRODUCTS ACT (TVPA)

The TVPA, which became law in May 2018, regulates the manufacture, sale, labelling and promotion of tobacco and vaping products. The purpose of the Act is to provide a legislative response to a "national health problem of substantial and pressing concern, and to protect the health of Canadians in light of conclusive evidence implicating tobacco use in the incidence of numerous debilitating and fatal diseases." With respect to vaping products, the purpose of the Act is to prevent vaping product use from leading to the use of tobacco products by young people and non-users of tobacco products while allowing adults access to vaping products as a less harmful alternative to smoking. Among other things, the objectives include the protection of youth from inducements to use vaping products, from exposure to and dependence on nicotine that could result from the use of vaping products, and to restrict access to vaping products.

Youth protection measures under the TVPA relating to vaping products include:

- A ban on furnishing vaping products to young persons (under 18);
- A prohibition on the promotion of vaping products through any indication or illustration of flavour that could be appealing to youth, as well as certain flavours including confectionary, dessert, cannabis, soft drinks and energy drinks;
- A prohibition on the promotion and sale of vaping products with design features that could reasonably be considered appealing to young persons;
- A prohibition on the promotion of vaping products by means of lifestyle advertising, on advertising that could be appealing to young persons, and on promotion by means of testimonials and endorsements, including through the depiction of cartoon characters; and
- Authority to make regulations respecting various aspects of vaping product promotion, including advertising (e.g., content and placement of permitted ads).

FOOD AND DRUGS ACT (FDA)

The Food and Drugs Act (FDA) and its regulations apply to vaping products that make a health claim, including those that contain nicotine (e.g., for smoking cessation) or any other drugs as defined by the FDA. Any vaping products that meet this description and are authorized for sale under the FDA are also subject to the TVPA unless explicitly excluded by regulations (i.e., Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act, such as asthma inhalers and aromatherapy products).

Vaping products seeking to make a health claim must receive market authorization from Health Canada before they can be imported, advertised or sold in Canada. In order to receive market authorization, they must meet the applicable requirements for safety, efficacy and quality established by the FDA and its regulations. Nicotine is present on the Prescription Drug List (PDL), which is a list of medicinal ingredients that when found in a drug, require a prescription. Vaping nicotine is considered a novel route of administration; any nicotine-containing vaping product making a therapeutic claim would be classified as a prescription drug unless specifically exempted from the PDL. This includes nicotine e-liquids for vaping as prescription drugs and the delivery systems as Class II medical devices. A New Drug Submission would be required for market authorization, as per the requirements of the *Food and Drug Regulations*. There are currently no therapeutic vaping products available on the Canadian market. Vaping products that do not make a health claim are not subject to the FDA and therefore do not require a market authorization from Health Canada.

Nicotine is an important component of treatments for smoking cessation. Nicotine replacement therapy (NRT), such as nicotine gum, patches and lozenges, has been available since the 1970s and has proven to be effective and safe to use in comparison to placebo. Nicotine replacement therapy works in part by delivering nicotine, typically in lower amounts and with a slower delivery than cigarettes, to address withdrawal and cravings/motivations to smoke. Nicotine chewing gum, lozenges, transdermal patches and non-active inhalation devices containing 4 mg or less of nicotine have been exempted from the PDL given a review of evidence to support use without practitioner oversight. These products are regulated as natural health products under the *Natural Health Products Regulations* and can be sold "over the counter" without a prescription.

CANADA CONSUMER PRODUCT SAFETY ACT (CCPSA)

Vaping products without health claims are also regulated as consumer products under the *Canada Consumer Product Safety Act (CCPSA)* and the *Consumer Chemicals and Containers Regulations*, 2001 (CCCR, 2001). Under the CCCR, 2001, products that meet the classification of "very toxic" are prohibited from import, advertising or sale. Vaping products with a concentration of nicotine equal to or greater than 66 mg/g (6.6%) meet this definition.¹¹



WHAT WE ARE CONSULTING ON: FURTHER MEASURES TO ADDRESS YOUTH APPEAL AND ACCESS

In addition to further restrictions on promotion in the Notice of Intent described above, Health Canada is seeking input on other possible federal measures under the current legislative authorities that might help to reduce the youth appeal and access of vaping products via this consultation document. Measures under consideration include:

- prohibiting the manufacture and sale of vaping products with certain flavours or flavour ingredients and/or prohibiting the promotion of certain flavours;
- restricting the concentration and/or delivery of nicotine in vaping products;
- regulating design features;
- · restricting online retail access; and,
- restricting product packaging.

Health Canada is also seeking feedback on opportunities to increase openness and transparency to help inform Canadians regarding compliance and enforcement activities with respect to the TVPA.

PROHIBITING THE MANUFACTURE AND SALE OF VAPING PRODUCTS WITH CERTAIN FLAVOURS OR FLAVOUR INGREDIENTS AND/OR PROHIBITING THE PROMOTION OF CERTAIN FLAVOURS

Flavours are an appealing feature of vaping products. Recent public opinion research commissioned by Health Canada found that among youth and young adults who had ever used a vaping product, more than half cited flavour/smell as a primary reason for trying; among adults 25 years and older, flavour/smell ranked third (30%), closely behind smoking reduction (36%) and reduced harm (36%).⁶ Recent research suggests that flavours also play an important role in smoking reduction and cessation in adults. A large, nationally-representative longitudinal study among American young adults found that smokers who used flavoured vaping products (non-tobacco and non-menthol flavours) were significantly more likely to quit or reduce smoking at follow-up, compared with those who did not use vaping products at all.¹²

The vast majority of e-liquids on the Canadian market are flavoured, and flavours are popular among vapers of all ages. Survey data gathered in 2018 before flavour promotional restrictions came into effect found that more than half of vaping liquid brands available in Canada were sold in fruit flavours, more than 30% in confectionary and dessert flavours, and less than 30% in mint, menthol, tobacco and other flavours. Other data from 2017 show that fruit flavours were ranked first among all age groups, being the most common flavour category cited by youth, young adults and adults who had used vaping products in the past 30-days. It is notable that tobacco, mint and menthol flavours were reported by a larger fraction of adults than by youth and young adults, who were more likely to identify candy and dessert flavours. 16

With respect to vaping products, the TVPA seeks to prevent youth uptake by prohibiting the promotion of certain vaping product flavours. At the same time, it permits the sale of flavoured vaping products for adults seeking a significantly less harmful source of nicotine. The Act places no restrictions on additives in vaping products that have flavouring properties or that enhance flavour. A regulatory approach that would restrict the use of specific flavours, for example those that are particularly appealing to youth, in the manufacture of vaping products could be considered. However, flavour additives can impart different properties at different concentrations, and there is a wide range of combinations of flavour additives that can create a particular flavour. For example, strawberry can be created using different recipes to create different strawberry flavours that range from fresh fruit to its candy version. There are a vast number of individual flavouring chemicals and chemical combinations present in e-liquids, and the industry is constantly innovating.

What do you think?

- Should Health Canada consider expanding the list of flavour categories for which promotion is prohibited? If so, what flavour categories should be added to Schedule 3 and why? What evidence can be provided to justify their inclusion?
- Should Health Canada consider prohibitions on the manufacture and sale of vaping products with certain flavours or flavour ingredients? If so:
 - » Which flavours or flavour ingredients should be considered?
 - » What evidence exists to justify their inclusion?
 - » Given the challenges described above regarding concentrations and combinations of different additives, how would you suggest a prohibition on flavour ingredients be designed?
- What evidence exists to support the role that flavours play in youth inducements to use vaping products?
- What are the potential public health risks of expanding the prohibition of flavour promotions or the prohibition of the manufacture and sale of certain attributable flavours?
- What evidence exists to support the role that flavours play in smoking reduction and cessation for adults who use vaping products?
- Is there evidence to help explain why certain flavours are less likely to lead to complete switching from smoking to vaping?

RESTRICTING THE CONCENTRATION AND/OR DELIVERY OF NICOTINE

Nicotine is a highly addictive substance, particularly when inhaled, and is the principal basis for tobacco dependence, producing physiological tolerance and withdrawal. Young people are especially vulnerable. Over 80% of current adult daily smokers smoked their first cigarette by the age of 18, 15 and teenagers can develop tobacco addiction with fewer cigarettes and less frequent smoking than adults. In the brain, nicotine directly activates regions that mediate drug reward and long-term addiction to a range of substances and many vaping products, particularly newer models, can deliver nicotine with a speed and concentration equal to or greater than tobacco cigarettes. Speed and quantity of delivery are important factors in producing drug effects and in developing physiological dependence, including for nicotine. The US National Academies of Sciences, Engineering and Medicine (NASEM) recently concluded that "there is substantial evidence that e-cigarette use results in symptoms of dependence on e-cigarettes."

Quitting without the use of any aids or services remains the most common smoking cessation method; however, vaping products have become a popular alternative among smokers. Over the past 2 years, 32% of current and former smokers in Canada who made a quit attempt used a vaping product, second in popularity only to reducing the number of cigarettes smoked.²⁷

The majority of vaping products on the Canadian market contain nicotine, and the two-thirds of Canadians who report having ever tried a vaping product last reported using one with nicotine.¹ A recent Canadian retail survey found that the vast majority of regular e-liquids (92%) contain 0–18 mg/ml of nicotine, while most nicotine salt formulations (68%) contain 18–42 mg/ml.¹³ The nicotine concentration and formulation of a vaping substance are just two of several factors that can influence the amount of nicotine delivered to the user; others include product design and user behaviour.

Evidence of the role of nicotine in the youth appeal of vaping products is very limited and may not reflect current trends. However, available data suggest that youth are not specifically seeking nicotine when making a decision to try a vaping product. Many youth are unaware of the nicotine concentration in the vaping products that they are trying, or that nicotine is even present.²⁶ This may be a function of the fact that the majority of young people are accessing vaping products socially through friends and family and not making purchasing decisions for themselves.

NICOTINE SALT FORMULATIONS

Nicotine salt formulations (nicotine salts) are a relatively recent innovation. Nicotine is combined with an organic acid to create a formulation that is less harsh than regular e-liquid; users can vape higher concentrations of nicotine and consume less e-liquid in the process, achieving high nicotine blood concentrations in relatively short periods of time. Nicotine salts are used in a number of the advanced pod-based systems that appear to be popular among youth. However, nicotine salts are not unique to these systems and can also be purchased for use in refillable, open vaping systems. The emergence of new vaping products that deliver higher nicotine doses than other available products increases the risks of nicotine exposure, including the risk of nicotine dependence, particularly among young non-smokers.

POD-BASED SYSTEMS

Pod-based systems represent the newest generation of vaping products available in Canada. Data recently presented to Health Canada on youth vaping indicate that relatively few survey respondents knew that popular pod-based products always contain nicotine, while the vast majority of this same sample recognized a popular cigarette brand as containing nicotine. These findings are consistent with other data demonstrating low levels of awareness among youth users regarding the nicotine content of popular vaping products.²⁸ Participants in this youth survey who had used pod-based products were asked why they used them instead of other vaping products, and "stronger nicotine hit" was not identified as a leading factor.

Evidence of non-smoking youth becoming dependent on pod-based systems is sparse. The largest study available, involving over 14,000 American youth and young adults, specifically enquired about use of one popular pod-based vaping product brand among young people. It found that for those aged 18–21, experimentation was reported at 11.2% and current use at 7.7%. The report did not provide information on daily use. Across all respondents (ages 15–34), current use was approximately five times higher among current smokers.²⁹ Two other studies compare dependence scores between pod-based systems with other vaping products; neither one observed a difference between users of pod-based systems and other vaping devices.³⁰

The nicotine concentration and formulation of a vaping substance are just two of several factors that can influence the amount of nicotine delivered to the user; others include product design and user behaviour. Many vaping products are highly customizable; in addition to being able to modify the frequency and volume of puffs, users can modify device settings and substitute device components to alter the delivery of aerosol, and consequently, nicotine. For example, a high-powered, earlier model tank device can generate a considerable amount of aerosol and consume relatively more liquid per puff than a pod-based system, resulting in a relatively high blood nicotine concentration that approaches or exceeds that obtained from smoking a cigarette, despite using a low nicotine concentration. 19,20,25

Regulatory authority exists within the TVPA to establish standards on the amounts and concentrations of substances that may be contained in vaping products or their emissions. Note that the TVPA does not currently place limits on the delivery of nicotine in cigarettes and other tobacco products. By way of comparison, the US Food and Drug Administration does not currently limit nicotine concentration for vaping products, and alternatively, the European Union Tobacco Products Directive limits the concentration of nicotine in e-liquid to no more than 20 mg/ml.³¹ The EU Directive asserts that this concentration allows for delivery of nicotine that is comparable to a standard cigarette during the time needed to smoke a cigarette; although as noted above, other factors including user behaviour, device settings, and product design all have influence over the amount of nicotine actually consumed.

What do you think?

- What are the potential public health benefits and consequences of placing restrictions on the concentration and/or delivery of nicotine in vaping products?
- How could nicotine delivery be effectively restricted, given the multiple factors that contribute to it?
- Could a limit on nicotine delivery (or concentration) be expected to impact:
 - » Vaping initiation rates among Canadian youth?
 - » Smoking initiation rates among Canadian youth?
 - » Smoking reduction and cessation rates among Canadian adults?
 - » The illegal market?

REGULATING DESIGN FEATURES

The vaping product industry continues to evolve rapidly, with new and innovative products constantly coming onto the market, offering increasingly improved nicotine delivery and increasingly appealing product designs and flavours. Batteries have become smaller and more powerful, enabling devices to be lighter and more discreet, and allowing for longer lengths of time between re-charging. Bluetooth technology is enabling communication between similar devices, and to connect devices to apps and websites for usage and nicotine intake tracking, social networking, and to receive personalized information based on user data. Other features can restrict device access to registered users. There are now hundreds of vaping products on the market in thousands of variations. As previously mentioned, the newest products, popular among youth, are small and standardized pod-based systems. However, the specific factors or combination of factors driving adolescent appeal are not well understood.

SIZE

Much like electronic devices in general, vaping products are being designed smaller and smaller as battery technology improves. Media attention has recently focused on the small size of pod-based systems, and the ability of youth to covertly vape ("stealth vape") in school washrooms and even classrooms. There is limited data on the role of device size and vapour emissions in youth appeal. In one recent study,³² researchers analysed the stated importance of product features from a sample of more than 1,500 young people (aged 15–17). The most common features cited for choosing a product/device were:

- Quality;
- Price;
- Flavours;
- Sensation of inhaling;
- Size of cloud; and
- Ability to hide the device.

Data presented to Health Canada on vaping product preferences among youth indicated that "easier to hide" did not rank highly; "popularity among friends," "easier to use," flavour/taste and "easier to get" were all identified as more important attributes.³ Although evidence is limited, when product design features (other than flavour) are among the reasons for vaping cited by young people, they tend to rank behind social influences, flavours, harm reduction, and features like price and quality.

APPEARANCE, SHAPE AND SENSORY ATTRIBUTES

One of the new popular pod-based vaping products available in Canada is described as sleek and resembling a USB stick—high tech attributes that are appealing to all consumers, including young people. The TVPA provides regulatory authority that could be used to establish standards respecting characteristics of vaping products and their emissions, including sensory attributes such as appearance and shape. Health Canada is interested in identifying specific device or product attributes that are clearly youth-oriented.

What do you think?

- Are there specific design features that are attractive to youth that Health Canada should consider regulating?
- What evidence exists to support the assertion that a specific design feature is appealing to youth?
- In striving to make vaping products less attractive and appealing to youth, are there possible unintended consequences regarding adults switching from smoking to vaping that should be considered?
- What evidence exists regarding the potential benefits and risks of Bluetooth-enabled vaping devices? Are there relevant lessons that can be learned from wearable technology?

RESTRICTING ONLINE RETAIL ACCESS

Online vaping product retailers typically ask website visitors if they are of legal age in their province or territory to purchase vaping products by simply clicking "yes" or "no" before permitting entry to the site. Shoppers are often warned that they will need to provide identification to verify age upon delivery. However, vaping products are also commonly available through online resellers that do not employ age verification measures, presenting additional challenges. Based on the most recent data available to Health Canada, online sales represent a minority of the market in Canada. In 2016, before the enactment of the TVPA, less than one quarter of all vaping product sales in Canada were online.³³ The most recent national survey¹ from 2017 indicates that:

- More than three-quarters of youth aged 15–19 who tried a vaping product usually borrowed, shared or bought it from a friend or relative (note that this data includes individuals of legal age to purchase vaping products in their jurisdiction);
- One in ten bought from a vape shop;
- One in ten bought from a convenience store; and
- Online sales were too low to report.

However, Health Canada is closely monitoring the vaping product market as the online market is dynamic and there is a need to be ready to respond to any new data or evidence in this area.

The TVPA prohibits the furnishingⁱ of a tobacco or vaping product to a young person in a public place or in a place to which the public has access. This includes online retailing. The Act does not specify how age verification is to be done, but it does specify that a person, including a retailer, who verifies the age of a person by asking for and being shown prescribed documentation for the purpose of verifying age shall not be found guilty of having contravened the prohibition on furnishing a vaping product to a young person. The TVPA also prohibits the sending and delivering of a tobacco or vaping product to a young person. A sender who has instructed the delivery person to verify age, and the delivery person who verifies the age of the person taking delivery by asking for and examining a piece of government-issued photo identification, shall not be found guilty of having contravened the prohibition on the sending and delivering of a tobacco or vaping product to a young person.

The TVPA contains amendments not yet in force that could be brought into force to replace the current provisions of the Act relating to the verification of the age of a person seeking to purchase or take delivery of a tobacco or vaping product. These provisions would refer to the process for verifying age and identity established in the regulations. Once these provisions are brought into force, regulations could be made respecting verifications of age and identity of persons purchasing or taking delivery of a tobacco or vaping product. Future regulatory measures could include:

- Requiring that online retailers post information advising prospective customers that the sale of vaping and tobacco products are restricted to persons of legal age;
- Requiring two-step age verification for online retailing. (Two-step verification is a process that
 involves two authentication methods performed one after the other to verify that someone is who
 or what they are declared to be. Note that two-step age verification is not generally required for
 online sales of alcohol or cannabis);
- Requiring that packages containing vaping or tobacco products bear a prescribed label that reads "Age verification required at delivery";
- Requiring a signature upon delivery and prohibiting packages from being left on doorsteps;
- Restricting delivery to prescribed carriers; and
- Restricting online retailing to retailers that utilize third-party age verification services.

What do you think?

- Are some or all of these additional measures to restrict youth access to vaping products online warranted? If yes, which options hold the most promise?
- Are you aware of other options not listed? What do you propose?
- What best practices in age and identity verification measures or technologies can you suggest that are currently being used in Canada or other jurisdictions?

Furnish means to sell, lend, assign, give or send, with or without consideration, or to barter or deposit with another person for the performance of a service.

RESTRICTING PACKAGING

Packages are powerful promotional vehicles to communicate positive brand imagery and attract new consumers, including young people. Plain and standardized packaging refers to packages without any distinctive or attractive features, which are similar in appearance and of the same ordinary colour. The TVPA places certain limits on what can appear on vaping products, including prohibitions of the following:

- Testimonials or endorsements:
- Promotions that could cause a person to have false impressions about the vaping product or its emissions or believe that it is contributing to health benefits;
- Comparisons to a tobacco product;
- Content (including an illustration or brand element) related to flavours that could be appealing to youth; and
- Tobacco brand elements.

In 2017 Health Canada published a **consultation document** with proposals for the regulation of vaping products, including packaging and labelling, information reporting requirements, the use of relative health risk statements and advertising restrictions. A **report** was published that provides a summary of the feedback received during the consultation period, and regulations are currently being developed. The TVPA also provides authority to regulate the packaging of vaping products, including by prohibiting the display of terms, expressions, logos, symbols or illustrations on the package that could be appealing to young persons. Similar to concerns related to product design features described above, Health Canada could consider new restrictions on such packaging elements for vaping products to make them less appealing to young people.

Health Canada has also consulted on regulatory proposals to standardize the appearance of tobacco products and their packaging for retail sale in Canada, which will be finalized in the near future. The objectives of these regulations are to protect youth and others from inducements to use tobacco products and to prevent Canadians from being deceived or misled with respect to the health hazards of using tobacco products. These regulations will apply to all tobacco packages and products and include removing distinctive and attractive features from packaging and products, requiring all packages to be of the same drab brown colour and bearing only permitted text, which must be displayed in a standard location, font, colour and size. Cigarette packaging will be standardized to a slide and shell format, and the appearance of cigarettes and other tobacco products will be standardized as well. Implementing PSA measures will strengthen the Government's efforts to protect Canadians from the health hazards of using tobacco products.

The Government has also implemented plain packaging and labelling requirements for cannabis packages, including limits on the use of colour, branding and logos. The packaging of cannabis products must be a single uniform colour, the colour cannot be fluorescent or metallic, and it must contrast with the colour of the health warning messages and the standardized cannabis symbol (a red stop sign with the cannabis leaf and the letters THC). Cannabis product labels must include the brand name and may include one other brand element. Cannabis packages are also subject to other restrictions that are not applicable to tobacco but are relevant to vaping products. For example, cannabis product packaging must be child-resistant and tamper-evident. Together these restrictions aim to protect young Canadians from accessing cannabis products and from inducements to use cannabis.

What do you think?

- Given that the TVPA already places limits on what can appear on the packaging of vaping products, are there additional elements that Health Canada should consider regulating?
- Could additional requirements or restrictions on vaping product packaging be expected to impact smoking reduction and cessation rates among Canadian adults who may consider accessing vaping products as a significantly less harmful alternative?

INCREASING REGULATORY TRANSPARENCY AND OPENNESS

As a regulator, Health Canada plays an important **role** in protecting the health and safety of Canadians and is committed to greater transparency and openness to further strengthen trust in regulatory decisions. Health Canada regularly conducts consultations with the public and other interested stakeholders which provide the department with an opportunity to hear what Canadians are thinking on a particular issue. The department already produces an **Annual Report on Compliance and Enforcement Activities** for tobacco control and is looking to be more proactive and to enhance information so that Canadians can see on a more dynamic and regular basis how the tobacco and vaping industries follow the rules. This is particularly important as it relates to new regulatory regimes, emerging issues and rapid evolution within industry.

Health Canada could consider releasing more information regarding industry non-compliance, as well as entities (retailers, broadcasters, etc.) that are found to be in contravention of the TVPA for furnishing products to youth and/or advertising and promotions that are in contravention of the Act and its regulations.

What do you think?

- What kind of regulatory or compliance information would be of interest?
- What mechanisms could Health Canada put in place to allow for intake of complaints and/ or sharing of information related to potential instances of non-compliance with the TVPA?



CONCLUSION

Like parents, educators, public health stakeholders and other Canadians, Health Canada is concerned about the rise of youth vaping. Through the youth vaping prevention public education campaign, collaborative efforts with provinces and territories, and a consultation on the Notice of Intent to further regulate the advertising and promotion of vaping products, the problem is being actively addressed. However, it is recognized that more can be done. The TVPA was designed to permit flexibility to respond to a changing environment and Health Canada is now seeking additional input on further measures. The regulatory measures included in this consultation aim to reduce the youth appeal and access of vaping products. These include prohibiting the manufacture and sale of vaping products with certain flavours or flavour ingredients and/or prohibiting the promotion of certain flavours; restricting the concentration and/or delivery of nicotine in vaping products; regulating design features; restricting online retail access; restricting product packaging and increasing openness and transparency regarding compliance and enforcement activities. However, any proposed measures would also need to consider potential impacts for adults who use, or may be considering using, vaping products as a significantly less harmful alternative to smoking.

Health Canada, together with its partners, has worked hard to bring down smoking rates in Canada. Through a combination of legislation and public education, smoking has become denormalized and is no longer seen by young people as being "cool." However, this public health success is at risk of being eroded if a new generation of youth become dependent on nicotine through vaping. The long-term health consequences of regular vaping remain unknown, nicotine is known to alter teen brain development, and regular vaping is associated with smoking.

Canadians are encouraged to submit their thoughts and ideas, as well as to share high quality evidence demonstrating support for or against the regulatory measures proposed.

SUBMITTING COMMENTS

Comments received in response to this consultation will be used to inform the development of proposed regulations to further reduce youth access and appeal of vaping products. You must declare any perceived or actual conflicts of interest with the tobacco industry when providing input to this consultation. If you are part of the tobacco industry, an affiliated organization or an individual acting on its behalf, you must clearly state so in your submission.

Health Canada is also interested in being made aware of perceived or actual conflicts of interest with the vaping and/or pharmaceutical industry. Therefore, please declare this, if applicable, when providing input. If you are a member of the vaping and/or pharmaceutical industry, an affiliated organization or an individual acting on their behalf, you are asked to clearly state so in your submission.

Please do not include any personal information when providing feedback to Health Canada. The Department will not be retaining your email address or contact information when receiving your feedback and will only retain the comments you provide.

The comment period to provide feedback on this consultation ends on May 25, 2019. There will be further opportunities to provide comments throughout the federal regulatory process. Please provide your comments to: Manager, Regulations Division, Tobacco Products Regulatory Office, Tobacco Control Directorate, Controlled Substances and Cannabis Branch, Health Canada, Address Locator: 0301A, 150 Tunney's Pasture Driveway, Ottawa, Ontario K1A 0K9 or in electronic format (Microsoft Word or Adobe Acrobat) to hc.pregs.sc@canada.ca.

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