E-Cigarette Update: Bill S-5

A New Legislative Framework for E-Cigarettes in Canada

Under current federal legislation, only electronic cigarettes that contain no nicotine and that make no health claims are legal. E-cigarettes that contain nicotine and/or that make a health claim (for example, can help with smoking cessation), are regulated under the *Food and Drugs Act* and require market authorization as drugs. No manufacturer to date has applied for this authorization, yet e-cigarettes with nicotine continue to be widely available across Canada and enforcement by Health Canada has been minimal.

In March 2015 the federal Standing Committee on Health released a report on vaping with 14 recommendations, including the establishment of a new legislative framework for regulating e-cigarettes. Bill S-5, *An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts*, which received first reading in the Senate in November 2016, is the government's response to these recommendations.

According to Health Canada, the proposed legislative framework is based on four key principles:

- Protecting youth and others from development of nicotine addiction and inducement to tobacco use;
- Allowing adults to legally access vaping products as "likely" less harmful alternatives to tobacco use;
- Preserving a path to market for products with therapeutic claims (e.g. smoking cessation); and
- Providing a mechanism to address risks to human health and safety for products without a therapeutic claim.

Two Routes to Market for Vaping Products

	Recreational	Therapeutic
Legislation	Tobacco and Vaping Products Act; Canadian Consumer Product Safety Act	Food and Drugs Act; Canadian Consumer Product Safety Act
Pros	Faster, less expensive route to market; potentially higher product appeal (not all smokers want to be treated as patients with medical problems)	Health claims and relative risk information permitted; potential endorsements from doctors; potential inclusion on provincial drug formularies and coverage under private health insurance
Cons	No relative risk information permitted (no health benefits or comparisons to tobacco)	Expensive and onerous process; risk of product obsolescence upon eventual approval; access could be in theory only

What Bill S-5 accomplishes

Most legislation provides the skeleton onto which the regulations, or meat, can be added. Many specific details in Bill S-5 will be laid out later in the regulations, which cannot be published before the Bill is passed.

As drafted, S-5 will mandate the following measures regarding vaping products:

- A new *Tobacco and Vaping Products Act* which establishes a new regulatory framework for and a definition of vaping products that includes substances with and without nicotine;
- Two distinct classes of vaping products: those regulated by the new *Tobacco and Vaping Products Act* (recreational vaping products), and those regulated by the *Food and Drugs Act* that are manufactured and sold for the treatment of nicotine dependence and for which health claims can be made (therapeutic vaping products);
- Restrictions on certain ingredients, such as vitamins and probiotics, which give an impression of health benefit;
- Restrictions on youth-friendly flavours, such as candy and dessert;
- Youth access restrictions including a ban on the sale and supply to minors under 18 including internet sales, with an exemption for the supply of therapeutic vaping products;
- A ban on advertising, including via the packaging, that could be appealing to young people;
- A ban on cross-branding with tobacco products, as well as sponsorship promotion and promotion that discourages tobacco cessation;
- A ban on false promotion, including making health claims/benefits and comparisons to other tobacco products (therapeutic vaping products exempted);
- A ban on testimonials and endorsements, including by fictional characters;
- A ban on the use of vaping products in federally-regulated workplaces and public places;
- Limitations on sales promotions, such as bonuses, premiums, cash rebates, and contests, to retail establishments where vaping products are ordinarily sold and where minors are not permitted (e.g., vape shops); and
- Product regulation for health and safety.

What will be determined by the regulations

The following measures will be determined by the regulations governing vaping products, after the Bill is passed:

- Product standards including their appearance, shape and sensory attributes, and the amounts and concentrations of substances permitted in the products and their emissions;
- Packaging requirements, including minimum and maximum numbers or quantities of vaping products and warning labels regarding nicotine content and its addictiveness, and the health hazards and health effects of vaping product use and emissions;
- Information required for advertising purposes, including the health hazards and health effects;

- Restrictions on lifestyle advertising;
- Specific information that manufacturers will have to submit to Health Canada about their vaping products, such as ingredients, emissions and health effects;
- Public disclosure, both from manufacturers and Health Canada, of information about vaping products and their emissions;
- Use of dispensing devices for vaping products, such as vending machines;
- Restrictions on point of sale promotions; and
- Details on what constitutes a health benefit.

Bill S-5: Strengths

E-cigarettes have been on the Canadian market for a decade without adequate regulation, causing much public confusion—federal leadership on this issue is welcome and long overdue.

- Bill S-5 will not ban e-cigarettes with nicotine, but rather will legalize and regulate them. This is critical, and reflects the government's desire to balance youth protection with access to less harmful nicotine alternatives;
- All vaping products—both with and without nicotine—will be subject to the same legal framework. This will go a long way toward reducing public confusion, lessening incentives for deception and simplifying enforcement;
- Bill S-5 proposes that vaping products be regulated like other consumer products under the *Canada Consumer Product Safety Act.* This Act has regulation-making authority to address problems such as exploding batteries and will require incident reporting and even recalls where necessary. Other electrical, mechanical and toxicological risks can also be addressed by the *CCPSA* via manufacturing, packaging and labelling standards;
- Youth access restrictions, including a ban on sales to minors, will help to prevent young people from developing addictions to nicotine;
- There will be fewer restrictions on advertising and promotion than with tobacco products, including allowing promotional activities such as coupons and rebates for adults only. These measures are important to help move smokers off combustible tobacco. However, sponsorships, cross-branding with tobacco products, use of endorsements, cartoon characters and other promotional activities will be prohibited;
- Only flavours that overtly target children, including candy and dessert, will be banned. This is important, as research shows that fruit and other flavours are popular among adults, some of who may be vaping to cut down and/or quit smoking cigarettes;
- To a certain degree, Health Canada has "future-proofed" the *Tobacco and Vaping Products Act* by building flexibility into various measures that can be amended by regulation as more evidence emerges and product innovation evolves; and
- Current tobacco users who are also minors will have limited access to therapeutic vaping products for cessation purposes, if any products are approved.

Bill S-5: Shortcomings

1. Prohibits the provision of relative risk information

With respect to vaping products, there are three major flaws with Bill S-5. The first problem is the prohibition against Canadians receiving relative risk information about vaping products compared to other tobacco products, especially cigarettes. S-5 dictates that no health claims/benefits can be communicated about the use of non-therapeutic vaping products and that no comparisons can be made to the health effects of using tobacco products. Despite Health Canada's desire to balance risk with access, Bill S-5 focuses disproportionately on the risks of vaping products without adequate consideration for the potential benefits of shifting large numbers of Canadians *away* from smoking, and certainly without considering the cost of maintaining the status quo. Health Canada has stated that vaping products are "likely" less harmful alternatives to tobacco use. In reality, although the degree is still a topic of spirited discussion among scientists, the evidence to date shows that e-cigarettes ARE less harmful than cigarettes.[1] Research also indicates that believing that vaping is as risky as smoking may impede smokers from trying and regularly using e-cigarettes, choosing to continue smoking instead.[2]

This potentially life-saving information does not have to be withheld until there is absolute scientific clarity regarding the degree of reduced harm; nor should Canadians have to wait until evidence proves that vaping products are effective for cessation. While it is important for people to know that vaping products are not inherently safe to use, it is as important for smokers to know that less harmful choices exist. Smokers desperately need reliable information about vaping products on which to make informed decisions. As it stands, Bill S-5 prevents smokers from receiving relative risk information, which clearly runs counter to the goal of the *Tobacco and Vaping Products Act* to protect the health of Canadians and reduce the incidence of numerous debilitating and fatal diseases caused by tobacco use.

2. Route to market as a therapeutic cessation aid remains overly burdensome

The Bill's second flaw lies in its failure to simplify the route to market for therapeutic vaping products (for which health claims *are* permitted) to be approved as cessation devices. It is estimated to cost a manufacturer millions of dollars, as well as take years, for a vaping product to receive market authorization as a drug. Given that vapour technology is changing rapidly and that it is entirely possible that a product could be outdated by the time it is approved, it seems unlikely that any manufacturer would choose this route to market—indeed, none has to date. The current regulatory framework also favours large manufacturers with deep pockets, effectively shutting small independent players out of the market and concomitantly curbing innovation. While in theory Canadians could have access to therapeutic vapour products to assist with quitting smoking, under the current regulatory framework it seems only a distant possibility.

[1] O'Leary, R, MacDonald, M, Stockwell, T, et al. (2017). Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices. Victoria, BC: Centre for Addictions Research of BC.

[2] Brose LS, Brown J, Hitchman S, et al. Perceived relative harm of electronic cigarettes over time and impact on subsequent use. A survey with 1-year and 2-year follow-ups. Drug Alcohol Depend 2015;157:106–11.

3. Tweaks the *Tobacco Act* rather than creating a nicotine regulatory framework

The third critical problem with Bill S-5 is its failure to look beyond today's issue of vaping products and address nicotine products more broadly. In a fight to retain or indeed grow their markets and profits, tobacco companies are embracing next generation/"reduced risk" products, spending billions to research, manufacture and market what may be less harmful alternatives to cigarettes. For example, Philip Morris International published a smoke-free manifesto in January of this year, and its new tobacco heat-not-burn iQOS product is expected to be available in key Canadian cities in 2017.

Currently, the regulation of nicotine products in Canada is arguably upside down. The most dangerous products—cigarettes—are the least regulated, while the safest ones—nicotine replacement therapies (NRT) including the patch and nicotine gum—are the most regulated. Tobacco manufacturers are relatively free to manipulate taste and other sensory characteristics to enhance the appeal and continued use of their products, whereas making minor changes to NRT products to increase their palatability and acceptance among smokers may require years of testing and regulatory review in order to get approval. There are also different labelling and warning requirements for tobacco and pharmaceutical nicotine products, and differences regarding packaging, ease of access and price all contribute to a confusing, inconsistent and non-strategic regulatory approach. If all nicotine products from the most to the least dangerous, and all the next generation products in between, were regulated under a single nicotine regulatory framework, much could be done through price/ taxation, packaging and warning labels, controls on promotion, and access to educate and encourage smokers who have been unable to quit smoking to choose less harmful alternatives.

The *Tobacco Act* was passed two decades ago, and it could be another 20 years before it is opened up again. Canadians deserve a modernized 21st century approach to tobacco and nicotine regulation that will reduce harm and remain relevant in the face of rapidly changing technology and an ever-increasing spectrum of alternative nicotine products.

Next steps

Senate committee hearings for Bill S-5 are expected to commence in the spring of 2017, at which time Canadians will have an opportunity to make oral and/or written submissions. There will also likely be further opportunities to submit comments when the Bill goes to committee in the House of Commons. Health Canada is also launching a consultation this winter on the renewal of the Federal Tobacco Control Strategy. Now is the time for Canada to take a bold new approach to tobacco and nicotine control—the health of millions of Canadians depends on it.