



## Full Public Policy Position – Cannabis Regulation

Consumer Health Products Canada recognizes that cannabis is being embraced as a health product globally. As the body of evidence for cannabis products continues to grow, patients and consumers are seeking guidance to help interpret the validity of health claims, risks, benefits, contradictions and potential drug interactions associated with these products. Right now, Canada has an opportunity. We can demonstrate to the world how to manage, in an evidence-based manner, the risks associated with recreational cannabis use while creating an environment that encourages research into its potential health benefits. We can implement practices that support patient and consumer interests in health products without categorizing them as recreational drug users.

For the over 800,000 Canadians accessing cannabis for their health without a medical document/prescription seizing this opportunity is important. The current regulatory system is designed to manage access to recreational products and is not adequate to address health products. In fact, what it has done is created a system that has effectively bypassed a very effective regulatory regime that has governed health products in Canada for decades. For example, the current approach to cannabis mingles health-seekers and recreational drug users within retail models designed to sell recreational products. For many health-seeking Canadians this represents an unwelcome introduction, or exposure, to recreational cannabis.

This approach also prevents manufacturers of evidence-based over-the-counter medicines and natural health products from seeking approvals for products that contain cannabis ingredients and is resulting in the saturation of the market with cannabis products that are not designed, tested, labelled or even approved for health uses.

### Recommendations:

- 1. The government should immediately propose changes to the prescription drug list to remove CBD. This change will allow the application of existing non-prescription health product laws to any cannabis-based health products associated with implied health claims, such as cannabidiol (CBD). Any ingredient that has been shown to have no addiction potential should be regulated the same as any other Over-the-Counter (OTC) or Natural Health Product (NHP).*

*As is the case for all other approved medicines, this approach must include separating the sale of products used for health purposes from those used for recreational purposes.*

The pathway for OTCs and NHPs containing cannabis is not new. Existing laws and guidance provide Canadians with the following protections which do not exist for recreational cannabis:<sup>1</sup>

- The use of OTCs and NHPs cannot lead to dependence.
- Every individual product must be approved by Health Canada to ensure that it is safe, effective and of high quality before reaching consumers.



- Among other important information, the labelling must include what the product does, instructions for use, warnings, precautions and what to do if an adverse event takes place.
- The products are sold in locations where other medicines are sold and appropriately direct consumers and patients to contact their health professionals – such as their pharmacist or physician – for support and counselling related to use.

Recommendations:

*2. Health Canada should immediately recognize the World Health Organization's (2018) cannabidiol (CBD) Critical Review Report of their Expert Committee on Drug Dependence.<sup>2</sup>*

We can learn from our experience with hemp and build upon the past. For over 20 years, we have permitted hemp-based products in our market, including in food, cosmetics and NHPs. We have long recognized the science, and reflected in law that tetrahydrocannabinol (THC) is the primary cannabis ingredient (cannabinoid) of concern with respect to addiction and harm. Hemp is simply cannabis with low THC content.

Hemp products may contain CBD or any other number of cannabinoids. However, now after more than 20 years of market use, Health Canada is considering all cannabinoids, even those found in hemp, to be potentially addictive.<sup>3,4</sup>

This unfounded concern has led Health Canada to establish legal barriers to OTC medicines and NHPs that contain cannabis ingredients. This includes CBD, which has been recently studied by the World Health Organization (WHO). The WHO concluded: "In humans, CBD exhibits no effects indicative of any abuse or dependence potential."<sup>2</sup>

Since these products are intended to provide therapeutic benefits, they should be available in health and pharmacy settings – rather than in recreational/adult use retail settings. Cannabis health products should be available to patients and consumers as part of a broader system that can help validate product health claims and, if needed, assess and provide guidance regarding appropriate use.

Health Canada must continue to safeguard the wellbeing of all Canadians, including for the use of cannabis health products.

**Nicotine Vaporizers** – What happens when recreational product manufacturers have exclusivity over a health product market?

The government approach for nicotine vaporizers in Canada provides an unfortunate example of what happens when regulations favour recreational product access over health products.

Nicotine vaporizers are associated with a strong public opinion towards their potential health benefits (for smoking cessation or harm reduction compared to smoking). However, the legal market prevents the sale of Health Canada approved OTC or NHP nicotine vaporizers for these uses.

According to the Statistics Canada *Canadian Tobacco, Alcohol and Drugs Survey (2017)* 32% of current or former cigarette smokers who had ever used vaping products reported using it as a quit-smoking aid.<sup>5</sup>

These Canadians have been given no choice but to use recreational nicotine vaporizers to support their effort to quit smoking. However, unlike health products, the manufacturers of recreational products do not have to prove to Health Canada their products provide any benefit to consumers.

Using recreational laws to achieve consumer benefit can have very real and negative public health outcomes. Recent studies are showing an increase in youth nicotine vape use, renormalization of smoking behaviours and exposure of Canadians trying to quit smoking to unnecessarily high levels of nicotine with unknown impacts on their health or ability to quit smoking.<sup>6</sup>



Conversations with a medical expert, such as a pharmacist, can also play an important role in the safe, effective use of these products and in enabling Canadians to make informed decisions.

*3. The government should conduct a study into the public health implications of using laws designed to control recreational substances in the management of products with potential health benefits.*

For comparison, the United States is also facing a growing black market of cannabis (hemp)-based products, in particular CBD. However, the Food and Drug Administration (FDA) is not proposing to introduce federal regulation to permit the recreational use of CBD products. Rather, they are consulting on the potential regulation of these products under existing food, drug, cosmetic, and veterinary laws. The disparity in regulatory approaches between Health Canada and the FDA are unprecedented for a substance that cannot legally pass through our border. This is particularly concerning given how broadly CBD is being used in both Canada and the US. Confusion for all travellers is likely.

Recommendations:

*4. The government must consider international harmonization, e-commerce and border controls in the establishment of a regulatory approach for non-prescription cannabis-based health products.*

Canada has a long history of regulating OTCs and NHPs. We do not need to reinvent the wheel. We need to work in concert with other jurisdictions facing similar challenges. The strong interest in cannabis-derived health products represents an important opportunity to leverage existing laws. The timing is right for Canada to demonstrate how best to regulate these products while engaging Canadians in their health. Mitigating the public health implications of recreational cannabis use should start with providing Canadians safe and effective cannabis derived health products where other medicines are sold.

1. Health Canada OTC switch/prescription drug listing guidance: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/data-requirements-switching-medicinal-ingredients-prescription-to-non-prescription-status.html>  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/guidance-document.html>
2. WHO critical review cannabidiol: <https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>
3. Prescription Drug Listing cannabinoids: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/notice-prescription-drug-list-2018-10-17.html>
4. Consultation on cannabis health products: <https://www.canada.ca/en/health-canada/programs/consultation-potential-market-cannabis.html>
5. Statistics Canada – Vaporizer use: <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/canada.html>
6. Public health data Ontario <https://www.publichealthontario.ca/-/media/documents/literature-review-ecigarettes.pdf?la=en>