



Questions and Answers

Developments in the regulation of CBD as a Health Product:

Update on cannabidiol regulation in Canada

Current Canadian regulations for cannabidiol (CBD)

Check out this previous ISURA online article from August 2019 for additional information – *Q&A: Is CBD a Natural Health Product?* Here's a recap:

- In recent years a constituent of the cannabis plant, cannabidiol or CBD, has gained a great deal of popularity both in Canada and globally for a number of health care uses;
- Unlike other constituents found in cannabis such as delta-9-tetrahydrocannabinol or THC, CBD does not produce a “high” or intoxication;
- In 2018 the *Cannabis Act* was passed in Canada which regulated CBDs as recreational cannabis products rather than as health products;
- In response to concerns voiced by Canadians wanting to access CBD for its potential healing properties, in 2019, Health Canada launched a consultation titled *Potential Market for Cannabis Health Products (CHPs) that would not require practitioner oversight*;
- While the consultation process was held, global pandemic meant that Health Canada was delayed in responding to the consultation: Health Canada published *What we heard* report in September 2020 capturing comments from the consultation with Canadians.

What did Health Canada propose?

The aim of the Health Canada proposal is to create a new regulatory category of health products called Cannabis Health Products (CHPs) which would include CBD as well as other active ingredients found in cannabis. CHPs would be suitable for use where practitioner supervision was not required. This new regulatory framework would combine elements found in the *Cannabis Act* with those for health products found in the *Foods and Drugs Act*. The result would be a range of regulatory approaches for cannabis products including CHPs, recreational cannabis products and those regulated as prescription drugs.

Some of the main points of the proposal are:

- CHPs would be subject to certain controls under the *Cannabis Act* as well as provisions to allow for approval of health claims supported by scientific evidence;
- CHPs would be allowed for both human and veterinary uses;
- While general health claims would not be permitted, specific health claims supported by robust scientific evidence, for minor ailments and those appropriate for self-care, would be permitted; in this case “traditional medicine” evidence is not considered “robust” evidence;
- CHPs could contain non-cannabis-related ingredients both medicinal and non-medicinal with cannabis-based components to be listed as active ingredients and be directly linked to the claim being made;
- Before a CHP could be brought to market, the application would undergo a pre-market review (including that of the label);
- CHPs could only be sold by provincially, territorially or federally licenced retailers or sellers of cannabis products. While in most places this would mean recreational cannabis stores, individual

provinces or territories could extend this to include other retailers such as pharmacies, vet clinics and pet stores; and

- Steps would be taken to protect young persons, as is currently required for recreational and medicinal cannabis products, including ensuring that labelling does not appeal to youth.

To reflect the different needs of various parts of the community, specific sets of questions were developed for three general stakeholder groups: consumers, industry and others (practitioners, academics, provincial/territorial government organizations, etc.).

The complete Health Canada proposal is located online at <https://www.canada.ca/en/health-canada/programs/consultation-potential-market-cannabis/document.html>.

What did Canadians say?

A summary of the response to Health Canada's proposed "way forward" was published in September 2020. The report is quite detailed but does contain some very useful charts and diagrams including direct comments and issues raised by participants in the consultation process. You can access the report at <https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/summary-report-consultation-potential-market-health-products-cannabis.html>.

Here are some of the main points:

- **Consumers:** This was the largest group of respondents and they were interested in CHPs for both human and animal use. The vast majority (92%) were in favour of access to CHPs with a number of potential therapeutic uses particularly for pain/inflammation, anxiety/stress/depression and sleep. Though a majority of respondents favoured oral dosage forms, a significant number also identified topical use as well as via vape or smoke. There was a general feeling that the current situation was not appropriate and that consumers were looking for a system that did not require supervision and better supported informed choice.
- **Industry:** Many of the respondents from the industry group, notably the Natural Health Product (NHP) and cannabis sectors, voiced general support for the ability to market a "new range" of cannabis products. A significant number of respondents thought that CHPs should be regulated distinctly from other cannabis products to "ensure consumer choice and better access to safe, effective, and quality products". Some concerns were raised as to where CHPs should be sold – respondents indicated that CHPs should be sold through pharmacies (seen as #1 option) and health food stores rather than through approved recreational cannabis outlets. Concerns were also raised regarding the proposed packaging – a preferred approach was a system similar to that used for NHPs or non-prescription drugs. Many wanted to see CBD considered specifically with a number of the cannabis industry respondents proposing a two-system approach distinguishing between CHPs with THC and CHPs with CBD. Many industry respondents also raised concerns about the fact that generalised claims would not be allowed.

- Others: Responses from the “Others” category (practitioners, academics and provincial/territorial government organizations) often differed from those above. They raised a number of concerns around safety, the lack of scientific evidence supporting claims re: CBD and the potential for addiction. This group also voiced support for practitioner sale or supervision and thought any regulatory framework should be distinct from that for drugs and NHPs – i.e. CHPs should not carry Drug Identification Numbers (DINs) or Natural Product Numbers (NPNs).
- The question of evidence in support of the use of CBD as a health product was raised by many respondents in all categories as a significant issue to be addressed. While many consumers thought that historical evidence was sufficient, a number of industry respondents and the vast majority of responses from the academic and research community voiced the need for more scientific evidence and support for research in this area. Health Canada has already identified the need for advice here and will establish an external expert advisory committee to provide guidance on questions related to evidence and the science behind CHPs.

What will the Scientific Advisory Committee look like?

Recognising the many outstanding scientific questions about CHPs, Health Canada committed to creating an external scientific advisory committee as part of its proposed regulation and consultation about CHPs. This committee would have 8 to 12 core members with the option of consulting with additional experts in specific disciplines if needed. Members of the committee need to be familiar with the health products sector and should come from a range of disciplines including but not limited to cannabis and drug research, health law and policy, pediatric medicine, geriatric medicine and toxicology.

Though the call for nominations to the Scientific Advisory Committee went out in 2019, other priorities delayed the announcement of members until late in 2020. You can find more information about the request for nominations and the members of the committee at <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/nomination-call-for-members.html> and <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/membership-list-biographies.html> respectively.

What about the economic impact of regulating CBD as a health product?

In addition to the important potential therapeutic uses of CBD is the positive impact that regulating it as a health product could have on the Canadian economy. A report titled *Assessing the Economic Impact of Regulating CBD Products as Health Products* was recently published by the prestigious Institute of Fiscal Studies and Democracy at the University of Ottawa. Commissioned by the Canadian Health Food Association, this report estimated that the regulation of CBD as a health product could have an economic impact of as much as \$2.45 billion annually with the addition of over 20,000 Full Time Equivalent (FTEs) by 2023.

Though it should never take priority over the question of safe and appropriate use, the economic impact of regulating CBD as a health product rather than as a recreational cannabis product is an important one to

consider. This report is an important step in answering this question but as identified by the report's authors, more Canada focused economic and market research is sorely needed.

The report is very detailed and contains information about what a future CBD sector could look like. It can be found at:

https://chfa.ca/Portals/30/RegAffairs/Cannabis/2020/IFSD_CBD_ECON_IMPACT.pdf?ver=2020-09-13-212538-793

Some final thoughts:

Health Canada has taken the positive step of asking Canadians for their opinions about CBD and other cannabis phytocannabinoids which could be used as health products in self-care. That being said, if they are truly open to making regulatory changes, there are some very basic points which need to be thought through in more detail.

While several phytocannabinoids may have therapeutic properties for use in self-care, the focus today amongst consumers, in Canada and globally, is almost entirely around CBD. In fact, most of the safety concerns focus on THC including its potential for abuse. Recognising that most of the safety concerns and potential for abuse rest with other phytocannabinoids in CHPs such as THC, as a first step, why not simply focus on CBD?

For all CHPs including CBD, the question of whether or not there is science-based evidence to support health claims, dosage and long-term safety in a self-care setting is a very valid one to ask.

The vast majority of consumers already have access to CBD products through recreational cannabis outlets and increasingly use it to address health care issues. What they don't have are the tools to make informed decisions about its use for health and self-care. Nor do consumers have access to people who have training and experience in counselling consumers in the responsible use of such health products. Recognising that more evidence is often needed, and that Canada is home to many of the world's leading cannabis researchers, now is the time for the Canadian government to support and fund a focussed research agenda.

The hope is that working with industry, academics and, most importantly, consumers the Canadian government will follow through with a strong commitment to develop and implement a regulatory framework for CHPs which provide consumers with access to safe and high quality products supported together with evidence based information and advice to help them decide whether or not to include a CHP in their health care options.

About the author: Michael Smith is trained as a pharmacist and a naturopathic doctor and is recognized internationally as an expert in NHPs and Complementary and Alternative Medicine. For more than 10 years, he worked in senior regulatory positions at the then Natural Health Products Directorate, Health Canada and the Therapeutic Goods Administration in Australia. In addition to his work as a consultant, he is an Adjunct Professor at the National Center for Natural Products Research at the University of Mississippi in the USA and an Adjunct Fellow at the National Institute of Complementary Medicine at Western Sydney University in Australia. Michael is a member of ISURA's Scientific Advisory Committee.