

What exactly is CBD?

CBD, or cannabidiol, is one of a group of chemical substances called cannabinoids and are found in the flowers and leaves of the cannabis plant, *Cannabis sativa*. Unlike the more widely known cannabinoid, delta-9-tetrahydrocannabinol or THC, CBD does not produce the classic “high” or intoxication.

Why is CBD so popular / in the news?

CBD is popular and used for a number of conditions and illnesses such as anxiety, pain relief, as an inflammatory and smoking cessation just to mention a few. In 2018, the US Federal Drug Administration approved the use a specific CBD product for certain types of childhood epilepsy. Though CBD is used therapeutically, with the exception of specific CBD products for epilepsy, there much debate about the evidence supporting these claims.¹

How are CBD products regulated in Canada?

Until relatively recently, like other cannabis containing products, those containing CBD were regulated as controlled substances. This changed with the passing of the *Cannabis Act* in 2018, with its availability dependent on a number of factors such as whether or not a health claim is being made and the form/state of the CBD itself.

Under the *Cannabis Act*, CBD oil is available and can be purchased dependent on provincial and territorial legislation. In these cases, the CBD is largely unchanged from that found in the plant and the product itself cannot make any therapeutic claim.

When the *Cannabis Act* came into force, the Prescription Drugs list (PDL) was amended to include phytocannabinoids (including CBD) produced by or found in the cannabis plant, including any product containing an isolated or concentrated phytocannabinoid or synthetic duplicate. In addition, health products both containing CBD and making a therapeutic claim are considered to be prescriptions drugs in Canada.

Do some dietary supplements in the USA contain CBD?

While it is true that some CBD products available in the US are marketed as dietary supplements, the US Food and Drug Administration has been pretty clear is saying that “anyone who thinks it is lawful is mistaken.”²

¹ www.medicalnewstoday.com

² <https://www.nutraingredients-usa.com/Article/2018/11/06/Top-FDA-official-Anyone-who-thinks-CBD-is-lawful-is-mistaken#>

That being said, as in Canada, there is a significant push by many groups both inside and outside the dietary supplement sector demanding that CBD be considered as an appropriate dietary supplement ingredient. The US Food and Drug Administration recently held a workshop in Washington DC to hear opinions from academics, industry, consumers and practitioners. More information can be found about this workshop at <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds#event-materials>.

Why did Health Canada not regulate CBD products as NHPs?

This is a good question especially considering CBD as a NHP was one of the recommendations made by the Expert Committee created to advise the government on how cannabis products should be regulated. The reason cited by Health Canada for not following this advice was a lack of clinical evidence regarding safety and efficacy in a self-care situation. More information can be obtained at <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html>

Could CBD become a NHP in the future?

Yes, of course it could but likely only after a long and complicated process.

To better understand this, it is important to know that the NHP regulations contain two lists or schedules of substances. Schedule 1 lists substances such as herbs, vitamins, essential fatty acids that are considered appropriate as ingredients in NHPs. Schedule 2 lists situations when substances are not permissible in NHPs such as controlled substances, tobacco, injectable products etc. So, NHPs can contain substances captured by schedule 1 and not captured by Schedule 2.

In this case, in addition to the change to the PDL, the *Cannabis Act* contains provisions adding phytocannabinoids (including CBD) that are isolated, concentrated or a synthetic duplicate to schedule 2 (the exclusion list) of the NHP regulations. This change specifically prevents health products containing CBD and making a claim from legally being regulated in Canada as a NHP.

As it stands at the moment, before CBD could be considered in an NHP, not only would the PDL need to be amended but the NHP regulations would have to be amended as well. This could happen in the light of new evidence acceptable to Health Canada supporting its safe use in a self-care setting but would also require a great deal of political will.

Many in the NHP sector are pushing strongly for CBD to be considered an ingredient in NHPs. Leaders in the field have published a white paper on the subject as well as launching a grass root campaign called "Get well not high". More information about this can be found at <https://www.getwellnohigh.ca>

Will CBDs be regulated as NHPs?

In June 2019, Health Canada published a draft proposal and launched an on-line consultation seeking feedback on a regulatory approach that would allow what they referred to as Cannabis Health Products (CHP) to be available with health claims without the need for supervision by a practitioner. Though not specifically focused on CBD, given that this product is used for therapeutic reasons, it is likely to be a key part of what Health Canada hears.

Though this new consultation is a very welcome development, it does not specifically propose that CBD products used for self care should be regulated as NHPs. Instead they propose that any regulatory framework for these “Cannabis Health Products” would “be subject to the evidence-based approach of the *Food and Drugs Act* while respecting the objectives of the *Cannabis Act*”. Again, these CHPs capture not only CBD products but also potentially products containing THC.

More about the proposal and access to the online consultation can be found at <https://www.canada.ca/en/health-canada/programs/consultation-potential-market-cannabis.html>.

Does this apply to cannabis edible products?

Health Canada consulted on cannabis in edible products and released its draft regulation in December 2018 with final regulations published in June 2019. More information can be found at <https://www.canada.ca/en/health-canada/news/2019/06/health-canada-finalizes-regulations-for-the-production-and-sale-of-edible-cannabis-cannabis-extracts-and-cannabis-topicals.html>

These new food-based regulations do not consider or discuss CBD as a NHP.

About the author: Dr. 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.