

06 June, 2025

**Health Canada Consultation:**  
**Towards a pathway for health products containing cannabidiol**  
**Health Products Containing Cannabidiol**  
**Canadian Health Food Association (CHFA) Submission**  
**Consultation Questions:**  
**Natural Health Products Containing Cannabidiol (NHPCCs) for Human Use**

1. What are your views regarding the need for a Cannabis Drug License and specific physical and personal security controls required for NHPCCs?

A Cannabis Drug Licence and additional security protocols should not be required for Natural Health Products containing cannabis (NHPCCs). CBD, as a non-intoxicating compound with a low potential for abuse, does not present a meaningful risk for diversion or connection to organized crime. Therefore, applying the same stringent controls used for recreational or medical cannabis is not appropriate. Instead, NHPCCs should be governed under the Natural Health Products Regulations (NHPR), consistent with the approach used for other NHPs.

The NHPR, including site licensing requirements, are already designed to enforce Good Manufacturing Practices (GMPs) for NHPs, provided that there is clear criteria allowing CBD to be transferred between the two systems as a raw material. Introducing a requirement for a Cannabis Drug Licence or mandatory personal security clearances would significantly increase complexity and costs without clear justification.

Where a cannabis licence holder intends to produce and market an NHPCC, they should simply follow the existing process of obtaining a product licence under the NHPR. This would reduce unnecessary regulatory burden while ensuring product quality and safety remain intact. Leveraging the current frameworks avoids duplication and supports an efficient path to market without increasing the risk of misuse.

CHFA maintains that the NHPR already set a high bar for quality assurance, including guidance aligned with Health Canada's expectations for botanical ingredients. These existing standards are more than adequate to ensure the safe manufacture and oversight of NHPs that include CBD.

2. Are additional raw material GMP standards or qualifications necessary for Cannabis Act license holders supplying raw material for NHPCCs to ensure that CBD being used as an ingredient in NHPCCs conforms with established standards for natural health products?

Cannabinoid extracts derived from plants and sourced from cannabis licence holders for use as raw materials in Natural Health Products should conform to Health Canada's *Quality of Natural Health Products Guide: Section Two*, specifically the requirements related to characterization, identification, and quantification. A critical consideration is the control of impurities, particularly tetrahydrocannabinol (THC) in cannabinoid extracts. Acceptable THC impurity limits should be informed by internationally recognized standards, such as the European Pharmacopoeia Monograph 07/2024:3151 for cannabidiol (CBD) or the proposed USP monograph. Both reference documents stipulate that CBD products should meet a purity range of 98% to 102% and set a THC impurity threshold at or below 0.2%. In addition, reporting, identification, and qualification thresholds for cannabinoid actives could be established with reference to the *Substances for Pharmaceutical Use* monograph (2034) of the European Pharmacopoeia, providing a robust international foundation for product quality.

The existing Natural Health Products Regulations (NHPR) and site licensing framework are fully equipped to manage GMP requirements for NHPs, including those that contain CBD as a medicinal ingredient. Requiring a Cannabis Drug Licence or personal security clearances would impose substantial regulatory burden and cost without a proportionate benefit, unless there is clear evidence of diversion risk. CHFA maintains that the NHPR already provide comprehensive oversight for manufacturing standards across a broad range of NHPs. Current Health Canada guidance also reflects expectations for plant-based medicinal ingredients, which are more than adequate to ensure the quality and safety of CBD-containing products under the NHP framework.

3. Please provide any comments related to the need for a Certificate of Analysis for cannabidiol to support the quality of NHPCCs licensed as natural health products.

Products containing CBD should be held to the same quality standards as other Natural Health Products and comply with the *Quality of Natural Health Products Guide* established by the NNHPD. These long-standing requirements have been effective in safeguarding consumer health and are already applied to a wide range of plant-derived ingredients and isolates regulated under the NHPR.

Any cannabinoid-based raw material intended for use in Natural Health Products should be accompanied by a valid certificate of analysis. This documentation should confirm both the quantity of the cannabinoid present and verify that impurity levels from other cannabinoids are within the acceptable thresholds.

4. Given the potential for competing health product and prescription drug use, is there a need for NHPCCs to include a warning statement on the principle display panel to inform the consumer that they contain CBD? Please explain.

Natural Health Product (NHP) labelling already provides clear, science-based information regarding medicinal ingredients, dosage, directions for use, and any relevant risk information, including contraindications. This information is presented in a standardized and accessible manner to help consumers make informed decisions.

Requiring a universal risk statement across all cannabinoid-containing health products is premature. The safety review process carried out by the NNHPD as part of the product licensing application (PLA) already determines when specific risk information is warranted. Additionally, NHPs are subject to post-market surveillance by the Marketed Health Products Directorate (MHPD), which can trigger labelling updates if new safety concerns arise. These existing regulatory mechanisms are sufficient to address risk communication on labels in a responsive and evidence-based manner.

Labelling requirements should also account for practical considerations such as packaging sustainability and cost. Where space is limited, peel-back labels or other expandable formats should be permitted to avoid unnecessary environmental impact. The suggestion by the Science Advisory Committee for Health Products Containing Cannabis to mandate a box and insert for all products is excessive and not supported by market experience. CBD products have been successfully marketed in Canada without such requirements, and international evidence (e.g., from the U.S. or other cannabis markets) does not demonstrate that mandatory boxes and inserts improve consumer safety outcomes.

5. Please describe any barriers or concerns with clinical trials that you are currently facing for products containing cannabidiol or that you anticipate might impact your ability to produce evidence to support the safety/efficacy of NHPCCs?

Health Canada’s assertion that cannabinoid-containing health products (NHPCCs) are “novel” and fall into a “higher risk category for self-care products” presents a misleading characterization. The suggestion that these products should be supported by scientific evidence akin to phase III clinical trials imposes a disproportionate standard that does not align with the historical and current context of CBD use.

The claim of novelty fails to recognize the long-standing traditional use of hemp and cannabis by Indigenous communities in Canada. As noted in a 2017 submission to Parliament by the Indigenous Medical Cannabis Association, cannabis and hemp have been used for medicinal, ceremonial, and utilitarian purposes by various First Nations for thousands of years. This is supported by archaeological records, historical accounts from early European explorers, and the oral histories of Indigenous peoples themselves. As stated in that submission:

*“There have been countless academic studies, archeological findings and reports, archive research and a plethora of journal entries from early European explorers which all corroborates that Indigenous peoples were using cannabis and hemp in its various forms long before any settlers came to North America. Our facts, traditions, culture and oral history demonstrate that First Nations and Indigenous people are connected to the plant in an almost symbiotic nature. We currently practice traditional and modern methods of extracting and utilizing the plants medicinal and hemp qualities”*

Given this historical precedent, the federal government should allow for the possibility of plant-derived CBD to be used and regulated under Health Canada’s Pathway for Licensing Natural Health Products used as Traditional Medicines—such as through the Ethnomedicines of the First Nations framework. While clinical trials may be warranted when a traditional product is used in a non-traditional manner, or where insufficient safety data exists, not all CBD-containing NHPs should automatically be subjected to the rigours of phase III trials.

Evidence requirements for cannabinoid products should be proportional to the claims being made and the risk profile of the ingredient. Like other NHPs, cannabinoid-containing products should follow the existing regulatory process, which includes the option of engaging in a Pre-Clinical Trial Application (Pre-CTA) Consultation Meeting. These meetings offer sponsors a venue to present available evidence, clarify any regulatory uncertainties, and receive early-stage feedback from the NNHPD on trial design and data acceptability. There is no scientific or regulatory rationale for applying an elevated evidence threshold to low-risk cannabinoids such as CBD, especially when the existing NHP framework already provides robust tools for pre-market assessment and evidence-based oversight.

6. Where should NHPCC's be sold? Select all that apply:

Natural Health Products containing cannabinoids (NHPCCs) should be made available for sale in the same retail environments as other Natural Health Products, ensuring consistency in access for consumers.

In alignment with the Science Advisory Committee's recommendations, higher-potency product, specifically those delivering  $\geq 200$  mg of CBD per day, could be restricted to sale behind the pharmacy counter, with pharmacist consultation. This approach reflects a responsible, risk-based model that aligns with Health Canada's regulatory principles.

Together, these measures support a balanced framework that prioritizes public safety while enabling access to legal, high-quality CBD products. Such a system would enhance consumer protection and provide a credible alternative to unregulated black-market sources.

7. What retail considerations for NHPCC's would optimize consumer safety and prevent misuse of products? Select all that apply:

For a licensed Natural Health Product containing CBD, an ingredient that is non-psychoactive, the potential for diversion to recreational use is not a concern. Like all NHPs, these products are required to carry clear labelling that outlines recommended use, dosage, and any relevant risk information, ensuring consumers have the necessary guidance to use the product safely and appropriately.

8. Are there any further considerations on advertising and promotion that Health Canada should consider? Please explain.

The rules governing advertising and promotion of CBD-containing Natural Health Products should align with the existing standards applied to all Natural Health Products.

9. Are there any further considerations on vigilance that Health Canada should contemplate?

All health products inherently carry potential risks and benefits. Therefore, any Natural Health Product containing cannabinoids (NHPCC) should be subject to the same post-market safety surveillance as other NHPs. This includes the mandatory submission of any suspected adverse reactions to Canada Vigilance, which can also be reported by consumers via phone to regional Canada Vigilance offices. Consequently, any new regulatory framework for cannabinoid health products (CHPs) should require manufacturers to actively monitor and report all adverse events related to their products. CHP license holders must promptly report serious adverse reactions to Health Canada.

Existing systems that enable Canadian consumers to report unwanted side effects, whether through healthcare providers or directly to Health Canada via online platforms, email, or phone, should be fully utilized.

10. Are there additional comments or suggestions you would like to share that could help in developing the NHPCC pathway for human use?

**Potency Issue & Lack of Consistency**

The proposed THC threshold of 10 ppm is excessively restrictive, being 300 times lower than the 0.3% THC limit recommended by Health Canada’s Scientific Advisory Committee on Health Products Containing Cannabis (SAC-HCC). The SAC concluded that oral consumption of CBD at doses up to 200 mg per day for up to 30 days is safe and well tolerated by healthy adults. At these levels, the amount of THC absorbed into the bloodstream is negligible and unlikely to cause any psychotropic effects in most individuals. This evidence supports allowing a higher THC threshold than the proposed 10 ppm, while still maintaining consumer safety.

**International Standards**

This 10 ppm limit is also far below international standards, such as the draft United States Pharmacopeia (USP) monograph, which proposes a THC impurity limit of 0.1% (1,000 ppm) in CBD isolates, along with a total impurity ceiling of 2%. The significant discrepancy between Canada’s proposed limit and these global benchmarks could create considerable challenges for Canadian manufacturers and exporters aiming to meet international quality and regulatory requirements.

**UN Treaties**

We strongly recommend that:

1. Natural Health Products containing cannabinoids (NHPCCs) be allowed to be exported without requiring a Health Canada export permit or other similar authorizations.
2. Health Canada update its interpretation of United Nations treaties (last revised July 30, 2020) that currently classify CBD as a controlled substance. This update should reflect the 2020 WHO Expert Committee on Drug Dependence (ECDD) guidance, which clarifies that CBD products containing  $\leq 0.2\%$  THC are not internationally controlled substances. Without such clarity, Canada risks lagging behind global regulatory trends and imposing unnecessary trade restrictions on domestic companies wishing to access international markets for NHPCC and vaporized cannabinoid-containing products (VDCCs).

**Industry Implications:**

*Manufacturing Difficulties:* Enforcing a THC limit as low as 10 ppm would require extensive additional refinement processes, increasing production complexity and costs.

*Trade Limitations:* The stark contrast between Canada’s stringent THC limit and international thresholds could impair the competitiveness of Canadian CBD products in export markets that allow higher THC levels.

Additionally, an overly strict THC limit risks pushing consumers toward unregulated or illicit CBD products, which are unlikely to comply with such stringent requirements and lack adequate safety or quality controls. This outcome would undermine public safety objectives and erode consumer confidence.

**Recommendation:** We recommend revisiting the THC threshold to adopt a more practical, evidence-based limit such as 0.3%, which ensures products remain non-intoxicating while accommodating a wider range of product types and fostering participation in the legal market. We also suggest referencing the draft USP monograph as a key scientific resource to help avoid future regulatory misalignment.