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Exploring a Canadian regulatory framework for cannabidiol (CBD)

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Health Canada is seeking stakeholder consultation for a proposed framework that would allow Canadians to access cannabidiol (CBD) containing health products without a prescription. The newly-published discussion paper, *Towards a pathway for health products containing cannabidiol*, sets out the organization's preliminary suggestions for regulatory amendments affecting both humans and animals.

What you need to know

- For human use, Health Canada proposes amending the existing *Natural Health Products Regulations* to include CBD as a medicinal ingredient.
- For animal use, Health Canada proposes regulating CBD health products under the *Food and Drug Regulations* as non-prescription veterinary drugs.
- Stakeholders and consumers are encouraged to provide feedback until the consultation period closes on June 5, 2025.

Current state

In 2018, Canada's *Cannabis Act* came into force, creating a legal framework for the production and sale of cannabis for recreational and medical purposes. Although cannabis can meet the definition of a "drug", it is only regulated under the *Food and Drugs Act* in certain circumstances. Currently, products containing cannabis, including CBD, can either be sold:

1. Under the *Cannabis Act* for medical or non-medical (recreational) use, with strict restrictions on promotion and without any health claims. No pre-market review for safety and efficacy is required. These products can only be sold from provincially licensed cannabis retailers.
2. Under the *Food and Drugs Act* and *Cannabis Act* as a prescription drug where the product must undergo pre-market review for safety and efficacy, and health care practitioner oversight is required. These prescription products are sold through pharmacies and can make health claims. Both the *Food and Drugs Act* and *Cannabis Act* apply to these products.

There is currently no legal pathway to market a non-prescription natural health product (i.e., a product making health claims) containing CBD in Canada. Currently, cannabis is expressly excluded from the application of the *Natural Health Products Regulations.*

Why regulate non-prescription CBD?

In 2018, the Government of Canada committed to exploring appropriate regulatory pathways for health products containing cannabinoids. A Scientific Advisory Committee was established to provide consensus on important factors about cannabinoids, including possible risks of harm and the degree of supervision required by physicians[1]. The Committee concluded that healthy adults can safely tolerate low doses of CBD, though a practitioner or pharmacist should be consulted about potential interactions with other medications. Evidence also showed that CBD can improve pain associated with conditions like osteoarthritis, though its efficacy for treating minor ailments requires further research[2].

If passed, new regulations for non-prescription CBD products could allow users to access these products without visiting a licensed recreational cannabis retail store. Instead, consumers could purchase the non-prescription CBD products, labelled with health claims, alongside vitamins and nutritional supplements in a variety of retail settings such as pharmacies, health food stores and online platforms.

A proposed framework for humans

Natural Health Products (NHPs) are a category of over-the-counter drugs in Canada; the term refers to a group of health products including vitamin and mineral supplements, herbal remedies and other plant-based health products, and traditional medicines. The current legislation governing NHPs is the *Natural Health Products Regulations* under the *Food and Drugs Act.* Currently, cannabis is expressly excluded from the application of the *Natural Health Products Regulations.*

In order to regulate non-prescription CBD products, Health Canada proposes to amend CBD's classifications in the *Natural Health Products Regulations and Pharmaceutical Drug List*. CBD would be re-introduced into the *Natural Health Products Regulations* as a medicinal ingredient. As with other natural health products, full safety and efficacy assessments would be required to obtain market authorization for marketing claims associated with the products.

The *Cannabis Act* currently requires all manufacturers of cannabis products to obtain a Cannabis Drug Licence, which mandates additional physical and personal security requirements at manufacturing sites. In its discussion paper, the Committee suggests foregoing this licensing requirement due to the low risk of diversion of products solely containing CBD. Instead, a site license under the *Natural Health Product Regulations* would be required, as is the case with all other NHPs.

The Committee also suggests removing the Cannabis Research Licence requirement set out by the *Cannabis Act* when conducting clinical trials involving non-prescription CBD products. Instead, clinical trial requirements for non-prescription CBD products would align with those applicable to other NHPs.

A proposed framework for animals

Canada's current regulatory regime supports two potential regulatory pathways for veterinary products containing cannabis derivatives:

1. Regulation as a prescription drug under the *Cannabis Act* and *Food and Drugs Act*. This pathway applies to any veterinary drug containing phytocannabinoids (e.g., CBD), and requires veterinary supervision. Currently, there are no authorized veterinary drugs containing cannabis.

2. Regulation as a hemp-based veterinary health product (VHP) under the *Food and Drugs Act*. This pathway is only available to products containing parts of cannabis and hemp plants that are not considered cannabis under the *Cannabis Act*. Thus, CBD products could not be regulated as VHPs.

For ease of access, Health Canada is currently exploring a novel non-prescription pathway for veterinary drugs containing CBD (VDCC). The first step towards this regulatory shift would be amending the Prescription Drug List to exclude or otherwise open alternate regulatory pathways for CBD. Given the limited research on veterinary applications of CBD, a new pathway would be limited to the use of CBD as a medicinal ingredient (as opposed to a non-medicinal ingredient).

From its review of existing literature, the Committee found that dogs and cats may benefit from very low doses of CBD to treat specific conditions; however, evidence is extremely limited at this time. Based on Health Canada's discussion paper, the only VDCC that Health Canada would currently consider granting is an oral dose of CBD (0.2-2 mg/kg twice a day) to treat pain from osteoarthritis in dogs. The approval process is proposed to involve a thorough pre-market safety and efficacy review.

The Committee recommended limiting the sale of VDCCs to veterinary clinics, since veterinarian oversight is crucial until more safety and efficacy data is available.

Food-producing animals like livestock would be excluded from the upcoming regulatory scheme, as CBD's impact on the food chain is unknown.

Deadline to comment

Stakeholders and consumers can provide feedback on the discussion paper until the consultation period closes on June 5, 2025. Proposed regulations are expected to be published for comment in late 2025.

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