Voice of the Natural Health Industry
La voix de l'industrie de la santé naturelle

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***Re: Consultation on potential market for cannabis health products that would not require practitioner oversight***

To Whom It May Concern:

On behalf of the Canadian Health Food Association (CHFA), we are submitting feedback on Health Canada's *Consultation on potential market for cannabis health products that would not require practitioner oversight.* The natural health product industry and the organic sector collectively contribute $9 billion to the Canadian economy each year while positively supporting Canada's healthcare system. CHFA Members employ over 55,000 Canadians from coast-to-coast-to-coast, and include manufacturers, retailers, wholesalers, distributors and importers of natural and organic products.

As Canada's largest trade association dedicated to natural health and organic products, we are committed to representing our members and their interests on proposed regulatory changes that directly influence their prospective opportunities for business growth. Our members are particularly interested in this proposal, as its outcome has the potential to broaden the scope of their product offerings or, conversely, shut them out of a major economic opportunity. In Canada alone, Forbes estimates the cannabidiol (CBD) market to generate $1 billion a year by 2023 – representing nearly 20% of Canada's entire cannabis market.

When the government implemented legislation to permit the sale of cannabis for recreational use in October 2018, it overlooked the growing market for non-intoxicating cannabis products used for health and wellness, without the need for practitioner oversight. Specifically, the current cannabis regulatory framework lacks a pathway to bring low-risk CBD-only health products to the Canadian marketplace. Further, the current framework regulates all cannabis products with the same rigor, regardless of the source (i.e. hemp or marijuana), neglecting to reflect the lower risk to consumer in the level of regulatory oversight for these products. Accordingly, CHFA is recommending that the government establish a regulatory pathway to permit the legal sale of CBD in natural health products (NHPs).

Growing consumer interest in, and preference for, non-intoxicating CBD products used for health and wellness highlights the inadequacies in the current cannabis regime; despite broad legalization, an illicit market for CBD health products persists. Within the consultation document, Health Canada

acknowledges that they are "*aware that some Canadians are interested in potential therapeutic uses of cannabis for minor ailments for human use (e.g., sleeplessness, pain relief for sore muscles) and for animals (e.g., pain relief). Cannabis products with unauthorized health claims are also emerging on the market illegally such as cannabidiol (CBD) products claiming to provide relief from muscle aches, joint pain, and inflammation*." Indeed, the document recognizes that the new pathway to market for cannabis health products (CHPs) should displace the illegal market.

While we are pleased to see Health Canada initiate a conversation on CHPs in an effort to address the gap in the cannabis regulatory regime, we are disappointed in, and disagree with, a significant proportion of the key parameters outlined within the consultation document. We are doubtful the proposed framework will enable businesses to fulfill the growing consumer demand for these products. Moreover, CHFA does not believe the scope of the proposed framework will allow this new market to displace the growing illicit market for CBD health products. While we certainly agree there is a problem, we strongly disagree with the proposed solution.

Before providing specific comments on the proposed solution, I would like to note our strong concern with the document distributed for comment. While the purpose of the consultation is to gather information that will inform the development of a regulatory pathway for cannabis health products (CHPs), the consultation document appears to outline a pre-determined regulatory pathway in significant detail. Rather than using the consultation as an opportunity for industry stakeholders and consumers to share their perspectives on an appropriate regulatory pathway for these products, it appears that Health Canada is using this consultation as an opportunity to gather feedback on a predetermined pathway to market for CHPs. This approach may discourage some respondents from submitting alternatives to the regulatory pathway proposed in the document. This also raises doubts regarding Health Canada's willingness to consider alternatives to the existing regime, which prohibits solutions outside of the *Cannabis Act*.

**Proposed alternative regulatory pathway to market for hemp-derived health products**

Health Canada proposes a unified framework for cannabis health products or CHPs containing any ingredient sourced from cannabis. This approach does not differentiate between ingredients derived from cannabis, containing significant levels of tetrahydrocannabinol (THC), from derivatives of industrial hemp, containing negligible levels of THC. Accordingly, in addition to our comments on the proposal outlined further along in this document, we open our response with a proposal for an alternative regulatory pathway to market for hemp-derived health products that would not require practitioner oversight. This pathway would require targeted amendments to the *Industrial Hemp Regulations* (IHR) to permit ingredients from industrial hemp to be extracted, produced and sold outside of the scope of the *Cannabis Regulations.*

Industrial hemp, as defined in the IHR, is "a cannabis plant— or any part of that plant — in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves." At present, a derivative of industrial hemp, or a product made from that derivative, is exempt from the application of the *Cannabis Act* if the THC concentration of the end product is 10µg/g (i.e. 10 ppm) THC or less. In section 2(2) of the IHR, *derivative* refers to a product made by processing only the grain of industrial hemp. However, we

propose expanding the definition of *derivative* to include products made by processing all parts of industrial hemp. Further, section 3(1) of the IHR should be amended to include, as a licensable activity under the IHR, the possession of flowering heads and leaves for the purpose of processing to create derivatives, including whole hemp extracts, isolates and concentrates.

These amendments would allow for the extraction of ingredients such as CBD from industrial hemp without the need for a licence under the *Cannabis Regulations,* and with the assurance that the concentration of THC in the end product would be negligible. Of note, various jurisdictions differ in their definition of a negligible level of THC. Therefore, we recommend that Health Canada work with the natural health industry to determine an appropriate threshold for THC (e.g. 0.2-0.3% w/w, 10 ppm, etc.) that would address health and safety concerns associated with THC while allowing Canadian businesses to participate in the global markets for these products.

We recommend that these ingredients then be permitted for use in NHPs under the *Natural Health Products Regulations* (NHPR). At present, cannabis and isolated or concentrated phytocannabinoids are listed on Schedule 2 of the NHPR: excluded natural health product substances. In parallel to the aforementioned amendments to the definition of derivative within the IHR, we propose amendment to the NHPR such that isolated and concentrated phytocannabinoids from industrial hemp derivatives are excluded from Schedule 2 of the NHPR. Hemp-derived isolates and extracts, such as CBD extracts, would then naturally be NHPs, since they already fall under Schedule 1 of the NHPR: included natural health product substances. Such revision would capture synthetic phytocannabinoids, identical to naturally derived equivalents, as per Item 6 of Schedule 1 of the NHPR. This approach would be consistent with other substances included in Schedule 1 of the NHPR.

In parallel to the above, we propose amendments to the Prescription Drug List (PDL). The qualifier for phytocannabinoids on the PDL exempts "derivatives of cannabis as defined in subsection 2(1) of the *Cannabis Act* that are exempt from the application of the *Cannabis Act* under the *Industrial Hemp Regulations* and that do not contain an isolated or concentrated phytocannabinoid or a synthetic duplicate of that phytocannabinoids." However, we propose amendments to the PDL to also exclude industrial hemp derivatives including isolated or concentrated phytocannabinoids, such as CBD, and eventually, to remove phytocannabinoids from the list altogether. Certainly, in order to permit the sale of CHPs that would not require practitioner oversight, Health Canada must already be considering similar amendments to the PDL.

Of note, non-intoxicating phytocannabinoids should not have been listed on the PDL in the first place. A body of research supports the safety of these compounds for human consumption without major public health concern. These compounds are already available broadly for recreational use without the need for physician oversight, thereby undermining the justification for inclusion on the PDL.

Through the above regulatory amendments, businesses would have the opportunity to obtain a licence to sell NHPs containing hemp-derived ingredients, such as CBD, as long as they are able to provide sufficient safety and efficacy data supporting their product's intended use. Such amendments would be an efficient way to allow for timely and improved access to non-intoxicating health products containing

hemp-derived phytocannabinoids, while minimizing Health Canada's concerns with respect to the handling or processing of THC within cannabis as a source of CBD in NHPs.

In addition to providing Canadians with improved access to legal hemp-derived CBD products, these amendments would support rapid innovation and growth within Canada's natural health product and agricultural hemp industries by removing barriers to production, processing and marketing of CBD derived from hemp. The hemp sector is projecting significant growth by 2023 (upwards of $1 billion in economic benefits), but a proportion of this economic growth is contingent upon an improved pathway to bring CBD health products to market.

**Comments on the key parameters of a proposed regulatory framework for CHPs**

Herein, please find our comments on the key parameters of a proposed regulatory framework for CHPs:

**3.1 Legal Oversight**

CHFA agrees that measures under the *Food and Drugs Act* (FDA) should be applied, allowing for health claim approvals on these products. We continue to agree that these health claims should be supported by appropriate levels of scientific evidence to ensure that they are safe, effective and of high quality. We maintain that the NHPR offers the most fitting framework that allows businesses to develop quality health products from naturally derived substances such as the cannabis constituents under discussion. The NHPR's pre-market approval process gives Health Canada the power to require sufficient evidence to demonstrate that the product, its ingredients and their intended use, are safe and effective. Accordingly, an NHP would not be approved for sale unless applicants are able to provide appropriate safety and efficacy data, which provides assurance that the product is fit for self-selection.

Should Health Canada pursue the proposed CHP framework, a novel product category, to bring these products to market, CHFA suggests that the level of oversight for a given product should reflect its risk to the consumer. The varying cannabis ingredients present unique levels of risk to consumers. For example, due to the respective intoxicating and non-intoxicating natures of THC and CBD, respectively, the risks associated with THC consumption is inherently much higher than the risks associated with the use of CBD. Accordingly, risk-based oversight should be a key component of a regulatory framework for CHPs, as not all cannabis ingredients require the same regulatory rigor. The level of oversight should be determined based on the cannabis ingredient(s) in the product, the dose of the ingredient(s), the intended use of the product and its associated health claims. For example, CBD products containing THC at concentrations below 10 ppm should be subject to lower levels of oversight than products containing levels of THC above this threshold.

Finally, if Health Canada pursues a novel regulatory framework for CHPs, we stress the importance of maintaining medical access to cannabis. The CHP self-care market should not replace the existing access to cannabis for medicinal purposes that requires physician oversight, nor should it impact patients' supply of medicinal cannabis. The legalization of cannabis for recreational use has already had detrimental effects on 1 in 4 medical cannabis users, who claim that it has been more difficult to access the cannabis they need since legalization in October 2018. Further, due to a number of factors, the

present cost of CBD-only products in recreational stores is unmanageable for many Canadians who use medium to high doses of CBD to address certain health issues. It is our hope that a pathway to create non-intoxicating health products derived from hemp would allow more of these products to be readily available to Canadians in a variety of retail locations and at a much lower cost. This anticipated decrease in cost would stem from lower overhead licensing costs under the *Cannabis Regulations,* in addition to lower production costs to create derivatives from industrial hemp with high concentrations of cannabinoids like CBD.

**3.2 Health Claims**

CHFA agrees that health claims should depend on what evidence exists to support the claim. While more research is needed, it is our understanding that CBD has potential to be used as an anxiolytic, analgesic, anti-oxidant, anti-inflammatory agent, as well as potential to be used as a sleep aid. Our members remain interested in creating and selling products with scientifically supported therapeutic properties, as they currently do under the NHPR. In addition, as emerging evidence uncovers the role of phytocannabinoids in supporting the human body's endocannabinoid system, other more general health claims should be permitted in the future. For example: CBD supports the immune system through its influence on the endocannabinoid system.

Evidence requirements must be appropriate and based on the products intended use and/or purpose. We have concerns that the process for obtaining a research licence under the *Cannabis Act* to assess the safety and efficacy of cannabis constituents as they relate to human health is a time-consuming and cumbersome process for any business, especially small and medium-sized players. Thus, we stress the need to address the compliance hurdles within the cannabis research licensing regime that act as barriers to innovative research projects in Canada. Health Canada's role in this research process should uphold a light-touch compliance and enforcement approach that works in coordination with, and does not duplicate, other processes already in place that ensure safe and ethical research is conducted in Canada. As well, the Government of Canada should play a more significant role in funding research related to cannabis and its impact on human health. Each research grant should be awarded for research projects with a clear plan for knowledge translation and transfer; all Canadians would benefit from a clearer understanding of the health impacts of cannabis consumption.

Moreover, an alternative pathway and/or research licence should be developed for the study of hemp-derived phytocannabinoids as they relate to human health. Analogous with an alternative regulatory pathway for hemp-derived health products, the regulatory oversight for hemp research should be less stringent than that for cannabis research. This process should be less burdensome and more efficient than the pathway developed for cannabis research, taking into account the fundamental lower risk of hemp to human health.

Health Canada is currently working to evaluate the evolving health product landscape to understand what regulatory changes might be needed in order to efficiently and effectively bring novel health products to market. Within their discussion paper on *Agile regulations for advanced therapeutic products and clinical trials,* Health Canada notes that they will focus regulatory modernization initiatives on using a risk-based approach for regulating clinical trials and creating a flexible approach for

authorizing complex and novel health products. We suggest that Health Canada mirror this approach and regulate in proportion to risk while addressing a pathway that removes barriers to approving clinical trials that are needed for industry to create low-risk hemp-derived health products.

Under the NHPR, businesses have the opportunity to submit evidence to Health Canada during the required pre-market approval of an NHP. If Health Canada were to indicate that this pathway is available to businesses in the natural health sector for CBD and hemp-derived materials as ingredients in NHPs, businesses would follow this same approval process for natural health products containing these ingredients. However, in order for businesses to invest significant time, resources and funding into clinical trials substantiating the use of CBD for a specific health effect, they first require a signal from the government that there will be an appropriate regulatory pathway for them to bring CBD health products using these claims to market. Otherwise, most businesses in our sector are not willing to risk investing in research and product development without a clear end benefit.

In addition to stimulating future research into the therapeutic properties of cannabis constituents, we encourage Health Canada to reflect on existing evidence of the safety of CBD for consumption in otherwise healthy adults. The World Health Organization recognized CBD to be "generally well tolerated with a good safety profile". They have stated, "To date, there is no evidence of public health-related problems associated with the use of CBD". Further, the McMaster University Michael G. DeGroote Centre for Medicinal Cannabis Research recently released a knowledge synthesis, funded by our Association, assessing the safety of CBD for human consumption. Amongst the key findings in this report was the notion that CBD has a wide margin of safety with use, and with no reports of serious adverse events. It also noted that CBD appears to have no abuse or dependence potential, and is non-intoxicating. The most common side effects associated with CBD are drowsiness, fatigue, insomnia and gastrointestinal disturbances, and these side effects are primarily observed following the consumption of high-doses. Moreover, in lower doses of CBD, side effects are not often observed. CBD does interact with a number of drugs, warranting further research into a variety of drug interactions with CBD at high doses. In summary, low doses of CBD (e.g., <200 mg/day) are associated with minimal risk in otherwise healthy adults.

**3.3 Ingredients**

CHFA supports the inclusion of other medicinal and non-medicinal ingredients in products that contain CBD and other phytocannabinoids from the cannabis and hemp plants. We believe the inclusion of other medicinal and non-medicinal ingredients gives Canadians access to a broader range of innovative products, and allows businesses to create unique and useful products sought after by Canadians and abroad. Once again, CHFA believes non-intoxicating cannabinoids, especially when derived from hemp, belong under the NHPR framework in NHPs. Accordingly, if the government is interested in including all cannabis constituents in this potential new market, they should consider risk based oversight based on products above and below the current standard for negligible levels of THC, such as 10 ppm.

Our members are interested in bringing NHPs containing naturally occurring substances from hemp, including extracts and derivatives, to market in Canada. These products would be available in a variety of formats, including: liquids, capsules, soft gels, creams, tinctures, patches, powders, topical creams,

oils, gummies, protein powders, drink mixes, and oral spray. The primary cannabis ingredient in these products would be CBD, though full spectrum hemp extracts should be included in the scope of products permitted on the market.

**3.4 Retail Environment**

Government-licensed recreational stores are not appropriate as the only retail outlet for low-risk health products containing negligible THC, and the proposal to maintain the use of these retail outlets to control the sale of all health products containing derivative from hemp and cannabis would present unique challenges for customers. Many Canadians are not interested in visiting a government-licensed recreational cannabis store to purchase CBD products they intend to use to benefit their health. These same Canadians are much more comfortable purchasing CBD products online, and are often unaware that these products are illegal in Canada and that there are significant risks in purchasing unregulated health products online. The continued success of the illicit market for therapeutic CBD products is, in part, attributed to this lack of consumer desire or ability to enter a recreational cannabis store to obtain non-intoxicating products – this is especially true in certain populations and in rural areas where there are no licenced stores and delivery can be challenging. If one of the primary objectives of this proposed framework for health products derived from cannabis is to displace the illegal market, Health Canada needs to consider retail environments outside the scope of the *Cannabis Act* as maintaining the status quo will not dispel the illegal market.

While we understand Health Canada's responsibility to maintain the sale of intoxicating cannabis products under strict retail environments, we do not understand why all non-intoxicating cannabis health products, including hemp-derived CBD products, would be subject to the same restrictions and retail regime. Non-intoxicating health products do not belong in recreational cannabis stores. Health products should be presented and sold based on the risk to consumer, their intended use and intended benefit. Allowing non-intoxicating products containing hemp-derived cannabinoids to be sold broadly in a variety of retail locations such as health food stores and pharmacies will contribute to an accurate public perception of these products. Conversely, selling non-intoxicating products in recreational cannabis stores has the potential to skew the public's perception of the intended use of these products.

Canadians should be able to visit their local health food store or pharmacy where they can purchase products from experienced staff in a familiar place. This is especially the case with seniors, who are less likely to enter a recreational cannabis store, but would likely benefit from CBD health products sold alongside other non-prescription drugs and natural health products. The health food store environment offers unique benefits for consumers in addition to acting as an alternative to recreational cannabis stores. Health food store employees are accustomed to interacting with customers looking to purchase NHPs to support their health. CBD health products share similarities with other products already on health food store shelves, including products used for mild pain management or products used to reduce inflammation. Accordingly, customers would have the ability to visit a health food store or retail location of their choice and compare CBD health products with other NHPs of similar indication. Customers are also accustomed to health food store environments and their staff, and have shared that they are much more inclined to visit a health food store than to seek CBD products from a recreational

cannabis retailer. Once again, for those unwilling to enter a recreational cannabis store, the present alternative is to seek out unregulated CBD health products online.

**3.6 Packaging and Labelling**

Non-intoxicating health products derived from hemp should reflect the packaging requirements set out under the NHPR for all NHPs. Under the NHPR, all licence applications must show that the label text meets the requirements outlined in sections 93-94. These requirements are appropriate for naturally derived substances used to support or maintain health. These labels would include all proper information, including use and purpose of the product, as well as warnings and instructions to consult a healthcare practitioner prior to use with other medications.

To reiterate, NHPs are already required to be labelled with important information supporting their intended use, such as warnings, contraindications, medical ingredients and directions for use. Accordingly, NHPs containing hemp-derived constituents such as CBD would be required to meet the packaging and labelling requirements outlined in the NHPR.

**Final remarks**

The proposal to create a new category of health products called "cannabis health products" and the processing licensing requirements under the *Cannabis Act* and its regulations would be a major deterrent for businesses seeking to bring a CBD health product to market in Canada. Legal oversight of health products containing cannabis ingredients should reflect a risk-based approach, based on the ingredient(s) used in the product, dose of the ingredient, intended use and health claim.

Many Canadian businesses are interested in providing low-risk health products using CBD to Canadians, but simply do not have the resources to apply for a processing license under the *Cannabis Act.* Further, the requirement to obtain a retail licence from the government and/or have a storefront that only sells CBD health products would also be a major disincentive to participate in the Canadian market for CBD products.

We are encouraged to see Health Canada address this significant gap in the cannabis regulatory regime. However, we are not convinced that the key parameters outlined within the consultation document will adequately fulfill the growing market demand for non-intoxicating cannabis health products, nor will it dispel the growing illicit market for CBD. We will continue to advocate on behalf of our members for an appropriate regulatory pathway that allows CBD's use in NHPs. This pathway offers a viable option to bring regulated products to market. It would protect the health of Canadians and reduce the illegal market for CBD health products while promoting growth and economic success in the natural health industry.

Thank you for considering our feedback on the proposed approach to regulating cannabis health products in Canada, and please do not hesitate to contact me if you wish to discuss our comments in further detail.

chfa
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Sincerely,

Helen Long
President