Consultation on Potential Market for Cannabis Health Products that would not require Practitioner Oversight

September 3, 2019

Consumer Health Products Canada | Produits de santé consommateurs du Canada

Advancing evidence-based self-care
Pour l'avancement des autosoins de qualité

1.0 Who we are

Consumer Health Products Canada (CHP Canada) is the industry association that represents the companies that make evidence-based over-the-counter medicines and natural health products.

These are the products you can find in medicine cabinets in every Canadian home. From sunscreens and vitamins to pain relievers and allergy medications, people use self-care products to maintain their health and manage their minor ailments. This is a fundamental part of self-care which is vital to the health of Canadians and the sustainability of our healthcare system.

CHP Canada has been the leading advocate for the self-care products industry for close to 120 years. We have been involved in shaping virtually every piece of legislation, regulation or policy that affects the self-care products that Canadians rely on to manage their personal health. We are committed to working with our members, government, and the broader health care sector to enhance the contribution that self-care with self-care products makes to the health of Canadians and the sustainability of our healthcare system. Our Active Members outlined in the image below are global multi-national manufacturers and marketers of over-the-counter medicines and natural health products.

Together, our industry generates $5.6 billion in sales annually, produces $1.5 billion in exports and sustains over 56,000 jobs.

2.0 Purpose of this submission

The purpose of this submission is to respond to the June 19, 2019 Consultation on Potential Market for Cannabis Health Products that would not Require Practitioner Oversight. The focus of this submission will be on the need for a regulatory approach that is evidence-based and appropriate for self-care.

No portion of this submission is considered confidential. This submission will be made available on our website at the following location: https://www.chpcanada.ca/advocacy/briefs-submissions/

3.0 Responses to Consultation Questions

3.1 Are you interested in manufacturing and selling CHPs on the Canadian market? Why or why not?

Yes, our members are exploring cannabis-based consumer health products, as this aligns with their core business.

3.2 If so, what products are you the most likely to pursue bringing to market in Canada? More specifically, what types of formats, with which cannabis ingredients, and with what health claims?

Most members are focused on cannabidiol (CBD) products, particularly for pain relief, stress relief, and sleep.

3.3 What scientific evidence is currently available that demonstrates the efficacy of cannabis in producing a specific health effect (e.g. relief of headaches, mild muscle pain)?

According to the World Health Organization's 2018 Critical Review Report of CBD, the most advanced science on the efficacy of CBD is for seizure relief in epilepsy patients, which is not a viable consumer health product indication. The report also acknowledges some evidence of efficacy for pain, inflammation, anxiety and other indications that would be suitable for consumer applications.

3.4 Does your organization currently have scientific evidence of safety and efficacy without the oversight of a practitioner to support the approval of a CHP in Canada? Are you working to generate any evidence?

No, CHP Canada has not generated scientific evidence with respect to CBD, and has no plans to do so.

3.5 Are there elements of the proposed approach that would create a particular incentive or disincentive for seeking to bring a CHP to market in Canada? If so, what elements and why?

There are several aspects of the proposed approach that are highly problematic for a manufacturer contemplating the development of a consumer health products containing cannabinoids, particularly CBD. Restricting the sale of any consumer health product to a retail channel that targets recreational drug sales on behalf of recreational drug producers would be a massive disincentive to the existing consumer health products industry. We will elaborate on this in our response to the next question.

The decision to exclude all cannabinoids from the usual pathways for licensing natural health products is also a huge disincentive for most in the consumer health products industry, particularly those considering products

containing CBD. Meeting regulatory requirements under both the *Cannabis Act* (CA) and the *Food and Drugs Act* (FDA) would always be more onerous and limiting for producers because of potential conflicting regulatory objectives, such as labelling requirements under the CA versus the FDA, and the CA exclusion of the under 19 population. This approach particularly fails to take into account the overwhelming evidence indicating that CBD itself is not a contributor to the recreational psychoactive effects of cannabis and has a safety profile that can more than adequately be handled under the FDA, without the overlay of CA requirements.

The fortieth report[i] of the WHO Expert Committee on Drug Dependence included the following recommendation:

> "CBD is one of the naturally occurring cannabinoids found in cannabis plants. There are no case reports of abuse or dependence relating to the use of pure CBD. No public health problems have been associated with CBD use.
> CBD has been found to be generally well tolerated and to have a good safety profile. Adverse effects of CBD use include loss of appetite, diarrhoea and fatigue.
> Therapeutic applications of CBD are being researched for a variety of clinical uses. Research in this area is most advanced in the treatment of epilepsy. In clinical trials, one pure CBD product has demonstrated effectiveness for treating some forms of epilepsy, such as Lennox-Gastaut syndrome and Dravet syndrome, which are often resistant to other forms of medication.
> CBD is not specifically listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions. However, if prepared as an extract or tincture, it is controlled under Schedule I of the 1961 Single Convention on Narcotic Drugs.
> There is no evidence that CBD as a substance is liable to similar abuse or leads to similar ill-effects to substances controlled under the 1961 or 1971 Conventions such as cannabis or Δ9 -THC, respectively.
> The Committee recommended that preparations considered to be pure CBD should not be scheduled."

CHP Canada believes that Health Canada should immediately recognize the Expert Committee's report and findings with respect to CBD. CBD as a compound has been the subject of a significant and growing body of research on its potential medicinal uses for a number of years. Though sourced from the cannabis plant, the form of purified CBD most suitable for this type of research and product development has no recreational use or abuse potential. As this was the basis for adding all phtyocannabinoids to the prescription drug list (PDL), Health Canada should immediately launch a process to amend the PDL to exclude CBD, in line with the Expert Committee's recommendation.

With the PDL impediment to NHP status removed, we believe the standard pathways to NHP licensing are more than adequate to evaluate potential CBD products. In light of the evidence dissociating purified CBD from the recreational psychoactive effects of cannabis, and especially recalling that the latter has been sanctioned by Health Canada for ad libidum recreational use, we see no reason to pre-impose additional restrictions on any approvable uses. Any age restriction should be established under the normal standards of evidence for NHP licensing under the FDA, not on the basis of the CA's recreational use restrictions. We see no reason to exclude the traditional evidence pathway categorically, though this is likely a hypothetical issue since cultural/traditional use of *purified* CBD would seem improbable.

3.6 Are there any other specific elements of the retail environment for cannabis that would present unique benefits or challenges to the sale of CHPs?

The consumer health products industry is structured do deliver products that address the health concerns of Canadians. The business model is to develop products that consumers trust to treat or prevent their common ailments. Brand loyalty is built out of positive health outcomes. Part of this model involves partnering with retailers who are also focused on health care, such as pharmacies, grocery stores and health food stores. These businesses are structured to collaborate on providing consumers who are seeking self-care solutions with a wide array of options, in an information-rich environment. Excluding CBD health products with no recreational potential from these traditional self-care channels, in favour of provincial models built around the sale of recreational products, makes no sense.

In addition to the disincentive it would create for the consumer health products industry, the proposed approach would be a massive disservice to Canadians practicing self-care. The new product selection process that Canadians most often rely on in the practice of self-care involves visiting pharmacies or health food stores and evaluating their available options. These consumers might be looking for a new pain reliever or sleep aid, perhaps considering seeking out the advice of a pharmacist or other decision support. These conditions would not generally be met under the provincial regimes developed for recreational cannabis.

Finally, we note that the issue of conditions of sale for consumer health products is well within the authorities of the FDA. The Government of Canada and the provincial and territorial governments have all made a commitment under the Canadian Free Trade Agreement to resolve the drug scheduling issue. Once that commitment is fulfilled, any concerns related to the conditions of sale for CBD health products could be addressed in a far more effective and evidence-based way.

3.7 Is there any additional feedback that you'd like to share on the potential market for cannabis health products?

CBD is an ingredient that has attracted a great deal of attention for its health product potential, generating a significant amount of clinical research. While Canada is some ways in a potential leadership position for advancing this potential by creating a pathway for authorizing CBD health products, there are underlying gaps in the current regulatory frameworks for consumer health products that stand in the way. The lack of regulatory data protection vastly diminishes the incentive to invest in research for a non-patentable product. Further, the lack of enforcement against unauthorized cannabis health products in retail establishments and the widespread availability of such products online also means that companies investing in regulated CBD health product development face diminished returns by having some of their sales potential cannibalized by non-compliant products. This makes it all that more important to ensure that the regulatory environment for CBD health products imposes no artificial barriers to the compliant industry. Such barriers would have the effect of leaving the market to non-compliant actors, to the detriment of consumers.

[i] 40th Report, WHO Expert Committee on Drug Dependence, WHO Technical Report Series, No. 1013, Geneva 2018