

September 3, 2019

Health Canada
Address Locator 0900C2
Ottawa, ON
K1A 0K9

Submitted via Email: publication@hc-sc.gc.ca

Re: Consultation on the Potential Market for Cannabis Health Products

Thank you for providing the opportunity for stakeholders to comment on the Potential Market for Cannabis Health Products (CHP) Consultation posted on June 19, 2019.

Who We Are

Cosmetics Alliance Canada is the leading Canadian industry association and the principal voice of the cosmetics and personal care products industry. Our over 150 member companies include brand owners, manufacturers, importers, distributors and retailers of cosmetics and personal care products, as well as providers of goods and services to the industry.

In addition to cosmetics, the low-risk “cosmetic-like” drugs and natural health products (NHPs) of interest to our members include toothpastes and oral rinses, anti-acne products, anti-dandruff shampoos, diaper rash creams, medicated and antiseptic skin care products, and sunscreens.



The legalization of cannabis has created an exciting dialogue about the potential **opportunity for growth and innovation** in the cosmetics and personal care products sector. **Cosmetics Alliance members have expressed a keen interest in developing products containing cannabidiol (CBD) and other ‘active’ cannabinoids derived from Cannabis sp outside of the authorities provided under the Cannabis Act.**

Cosmetics Alliance recognizes that this consultation is preliminary and focused on identifying the potential types and scope of health and wellness products containing cannabis and cannabis-derived ingredients for non-recreational purposes. Our recommendations are outlined below. We look forward to additional consultations in the future to build a workable framework to approach and develop the details for the regulation of cannabis self-care products.

Cannabis Terms and Current Regulation

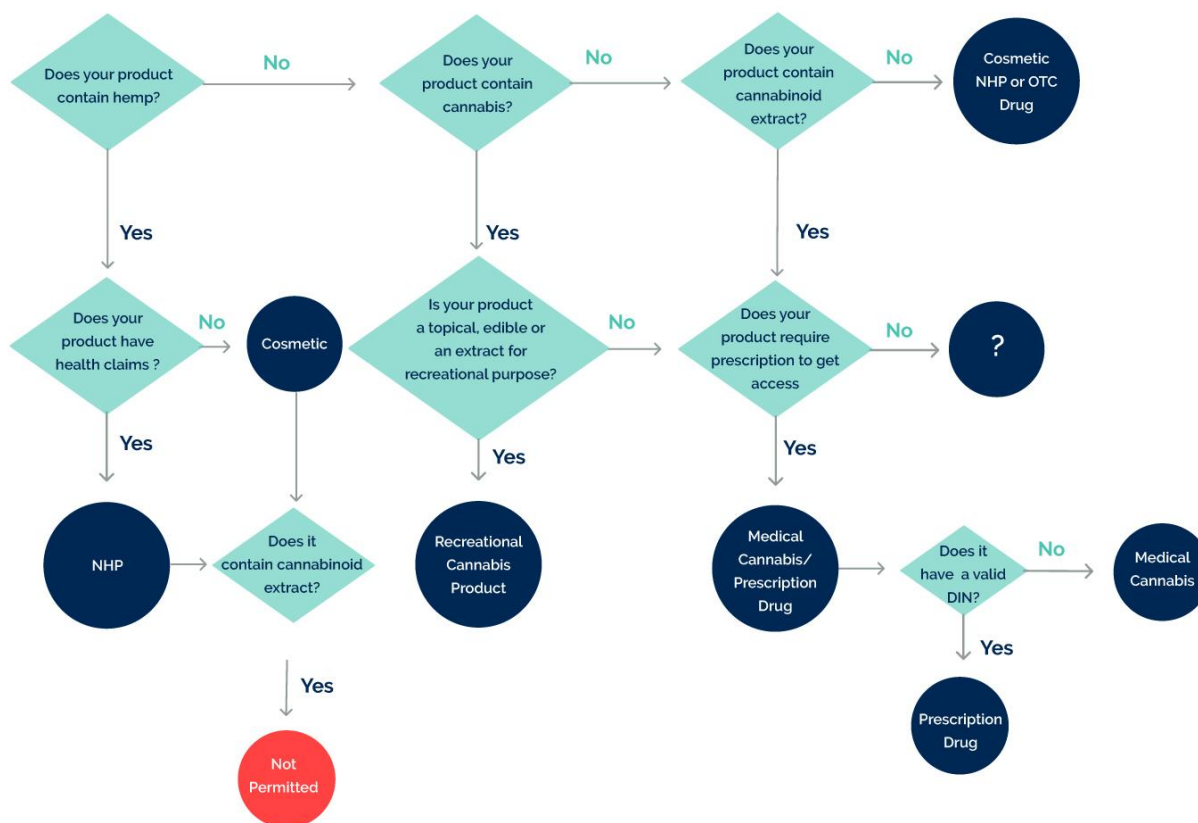
Below is a table summarizing Cosmetics Alliance’s lexicon of cannabis terms used throughout this document. Please note that these do not represent official definitions and was only created for the purpose of this commentary.

Cannabis	refers to hemp or marijuana (the term marijuana is interchangeable with cannabis)
Marijuana	is a cannabis plant specifically cultivated with 0.3% or higher THC content with high or low amounts of CBD (depending on the strain)
Hemp	is a cannabis plant specifically cultivated with only 0.3% THC or less and has trace amounts of CBD
Cannabinoids	active compounds found in hemp and cannabis. Two major ones are THC and CBD
THC	is a cannabinoid found in cannabis and hemp and is responsible for psychoactive effects of cannabis
CBD	is a cannabinoid found in cannabis and hemp. Does not contribute to a psychoactive effect but believed to be largely responsible for cosmetic and medicinal benefits

With the legalization of cannabis in Canada, recreational cannabis delivering a psychoactive sensation is now permitted for sale under the *Cannabis Act*. Medicinal cannabis is also regulated under the *Cannabis Act* while prescription drugs containing cannabis are regulated by both the *Cannabis Act* and the *Food & Drugs Act*.

Currently, cosmetics and NHPs containing hemp with a maximum concentration of 10 µg/g of THC are permitted for sale in Canada and are governed under the *Food & Drugs Act* and associated *Cosmetics and NHP Regulations*. Cosmetics and NHPs containing cannabinoids (outside of the *Industrial Hemp Regulations*) are currently NOT allowed to be introduced to market, despite the fact that hemp, naturally contains CBD and is permitted.

Our understanding of the current regulatory landscape is illustrated in the diagram below. **This illustration is important as it conveys the issue with “isolating” cannabis and cannabis-derived ingredients from any other therapeutic ingredient used in a non-recreational cosmetic, non-prescription drug, or NHP.**



Our Recommendations

1. Cannabis Health Products should be regulated under the *Food & Drugs Act*

Health Canada's "Proposed CHP Category" as outlined in the Consultation Document suggests that CHPs could fall under the *Cannabis Act* with the same regulatory requirements as recreational and medicinal cannabis products, i.e. no access to young persons, sold in provincially or territorially licensed stores, labelled with plain packaging, etc. If Health Canada's proposal is that CHPs will treat minor health ailments, then they should not be regulated alongside recreational and medicinal cannabis products.

Health and personal care products containing cannabis - whether they be cosmetics, non-prescription drugs, or NHPs - should be **regulated under the *Food & Drugs Act* ONLY and NOT the *Cannabis Act***. The intended purpose of CHPs is health and wellness related just like any other cosmetic, non-prescription drug, or NHP on the market today. They are NOT intended for recreational use nor are they intended to deliver any psychoactive benefits. The objective here is to gain access to functional ingredients in cannabis – just like any other sources of ingredients - that offer therapeutic benefits to treat minor health ailments or cosmetic benefits!

Furthermore, regulating health and personal care products containing cannabis and cannabis-derived ingredients for non-recreational purposes under the *Food & Drugs Act* only would meet the government's imperative to regulate under the *Best Place Act* principle (i.e. Guide to Making Federal Acts and Regulations, Privy Council Office, 2002).

While we understand the need to control the supply of cannabis (as a raw material), this could be handled through an incorporation by reference to the appropriate sections of the *Cannabis Act* to ensure quality supply of raw materials. Furthermore, GMP regulations under the *Food & Drugs Act* provide for such controls. Provisions for packaging and labelling, protecting young persons, evidence-based claims, and so on could also reside under the *Food & Drugs Act and Regulations*. This precedent already exists with respect to alcohol and other ingredients.

We recognize that to bring CHPs to market, the *Cannabis Act* will likely need to be amended to carve out health and wellness products containing CBD or other cannabinoids. An exemption could be implemented under the *Cannabis Act* to ensure these products are regulated under the *Food & Drugs Act*, similar to the exemption that already exists for prescription drugs containing cannabis or cannabis-derived ingredients.

We also acknowledge that amendments to the Prescription Drug List (PDL) may also be necessary to allow these products to be assessable without healthcare practitioner oversight and sold in mass retail. Additionally, the Cosmetic Ingredient Hotlist and Natural Health Products Ingredient Database would need to be updated to accommodate restrictions or prohibitions as appropriate (including thresholds/limits on use concentrations). Finally, as cannabinoids are currently identified under the *Controlled Substances Act* domestically and are subject to corresponding controls internationally, an amendment may need to be pursued.

With respect to supporting the safety and efficacy of cannabis ingredients and products, we understand the need to develop evidence supporting the non-recreational benefits and/or risks associated with these products. Industry is committed to working with Health Canada to address these data gaps and build the science behind this category of products treating minor health ailments.

2. Leveraging Health Canada's new Self-Care Products Framework

The outdated and overly complex legislative, regulatory, and administrative environment that is currently applicable to cosmetics and personal care products in Canada has led to a major regulatory reform initiative by Health Canada. The **Self-Care Products Framework (SCF) proposes a modernized approach** to regulating all self-care products (including cosmetics, NHPs, and non-prescription drugs) under one set of regulations administered by one branch of Health Canada.

Unlike the current system which includes three different and inconsistent sets of regulations administered under two different branches of Health Canada, the SCF aims to regulate products with similar risk profiles in a similar fashion so that requirements for bringing them to market will be consistent and easier to understand for both consumers and industry. This will ultimately eliminate unnecessary regulatory burden, minimize cost, simplify processes, and eliminate the regulatory issues which hinder getting products to market for Canadians.

Health Canada is currently completing the structural details of the Framework which include how these products will be classified, how health claims will be approved, and what will be the right set of tools for oversight. Importantly, the SCF will ensure that legitimate cosmetics, non-prescription drugs, and NHPs containing cannabis or cannabis-derived ingredients are managed in a similar and consistent manner – in line with current practices that are already adequately in place under the *Food & Drugs Act*.

As previously stated, these products should not be treated as high-risk products nor regulated like recreational, medicinal, or prescription cannabis products under the *Cannabis Act* as their intended use and resulting risk factors are completely different. Once the SCF is implemented, these products would fall under the new Framework just like any other self-care product treating minor health ailments or

providing cosmetic benefits.

Summary

By legalizing cannabis in Canada, the government has implicitly acknowledged the potential behind the functional ingredients within the cannabis plant. This creates significant opportunities for **growth and innovation** in the cosmetics and personal care products sector, of which industry is eager to participate.

The current restrictions on the use of cannabinoids in products other than prescription drugs or medicinal marijuana needs to be revised – which we believe this consultation is intending as a first step.

Cosmetics Alliance believes that cannabis self-care products (including cosmetics, non-prescription drugs, and NHPs) should be **regulated under the Food & Drugs Act ONLY** and **NOT the Cannabis Act**. **In future, once the Self-Care Products Framework is implemented, these products would then be regulated under the Framework just like any other self-care product treating minor health ailments.**

Finally, we wish to point out the time sensitivity of this matter. A long delay in moving forward will reduce the opportunities for new product development and innovation. As such, we urge Health Canada to move forward with the framework development as quickly as possible. We also ask Health Canada to consider some type of interim process to enable low-risk products to get to market sooner while longer term legislative reforms are underway. Cosmetics Alliance is eager to explore this with you in greater detail.

Thank you for the opportunity to provide feedback. We look forward to engaging in further consultations as Health Canada moves forward. If you have any questions or wish to discuss our comments in further detail, please contact me at 905-890-5161 ext. 249 or lganesh@cosmeticsalliance.ca

Regards,



Linitha Ganesh
Regulatory Coordinator
Cosmetics Alliance Canada

cc:

Ed Morgan, Director General, Policy, Planning and International Affairs Directorate, Health Canada

Manon Bombardier, Director General, Natural and Non-prescription Health Products Directorate, Health Canada

Amanda Moir, Director, Natural and Non-prescription Health Products Directorate, Health Canada

Matthew Bown, Senior Analyst, Consumer Health Product Modernization, Natural and Non-prescription Health Products Directorate, Health Canada

Patricia Pelletier, Director General, Consumer and Hazardous Products Safety Directorate, Health Canada

Geoff Barrett, Director, Consumer and Hazardous Product Safety Directorate, Health Canada