



CCHA FORMAL NNHPD RESPONSE REGARDING COST RECOVERY

August 1, 2023

The CCHA is responding to the recently proposed Cost Recovery Initiative and proposed changes to the Self Care Framework of Canada's Natural and Non-prescription Health Products Directorate (NNHPD).

The CCHA is reminding the NNHPD that the original *Natural Health Products Regulations* (NHPR) objectives "was to provide reasonable assurance that products offered for sale in Canada are safe, efficacious and of high quality."

The current Canadian NNHPD structure for Natural health products has been viewed as being one of the most modern regulations in the world; yet the proposed changes do not adequately address the needs of Canadians nor is the current changes in line with continued access to safe, effective and affordable products.

Statement in Brief:

- We are concerned about the proposition to exclude traditional use claims for NHPs in favour of scientific research claims only for class III. Traditional use claims are integral to our profession and to the industry and are based on a long history of safe use.
- We are concerned about the proposed regulation's impact on small businesses through policing and exorbitant fees.
- We are concerned about the policing, surveillance and new fines proposed for the natural health product industry.
- We are concerned about the environmental impact when proposed label changes prohibit bottles from being recycled.
- We are concerned about consumer's ability to access affordable, high quality and safe natural health care products.
- We are concerned about the impact of the proposed changes on herbalists' ability to access herbal medicines as permitted by Health Canada's Compounding Policy.
- We are concerned about the NNHPD's lack of communication regarding these recent changes to industry and the public.

CCHA Statement in Detail:

1. We are concerned about the devastating impact that the proposed changes will have to small businesses and cottage industry ventures.

The proposed new cost recovery fees of \$ 50 000 annual fees per business plus an additional 500 per product are exorbitant. This cost structure is unaffordable and will drive many small and medium natural health product producers out of business. With businesses closing, consumers will lose access to many novel products.

Canadians have a right to continued access to high quality and affordable natural health care items available over the counter for the basis of enhancing their health. Without the options available for Canadians to enhance their health and wellbeing – there will be an even greater burden on the already taxed Canadian medical industry.

The new fees will drive the prices of remaining natural products higher as the producers that endure these costs will have to raise prices to stay afloat. Higher prices take away natural products from lower income populations and young families (as they will no longer be able to afford them) and significantly impact a consumer's ability to optimize their health.

The only choice left for Canadians is to purchase their desired Natural Health Products elsewhere- outside of Canada (taking away revenue from Canadian businesses) or pay more money for the reduced selection of products on Canadian retail shelves. The CCHA is calling the NNHPD and government to stop these new fees.

2. The NNHPD speaks of aligning with the new international mandates of other countries including Australia United States and the European Union.

In New Zealand, the Therapeutic Goods Bill has been passed on July 19, 2023, despite many submissions against it. This bill also limits the availability of natural health products and supplements and affecting the way that natural health practitioners can operate. Despite being prohibitive to the industry, New Zealand proposes several points that the Canadian Government may wish to consider adopting. In New Zealand, the government announced an exemption scheme for small scale NHP manufacturers.

The CCHA calls on the NNHPD and Canadian Government to consider a similar exemption clause for small scale businesses and cottage industry manufacturers. In addition, recognizing that professional herbalists are highly trained in product formulation and blending safe herbal medicine products, we also counter that an exception also be granted for herbalists to be able to sell items for retail on a small scale – without prohibitive fees, site licensing and pharmaceutical lab requirements.

3. The CCHA is concerned about the government's recent laws allowing surveillance and enforcement activities within the Natural Health Product Industry. Natural Health Care Products are among the safest products on the market. There is a 14x higher risk of being struck by lightning than being killed from a Natural Health care product.

Allowing for fines in industry is unacceptable for an industry which provides safe and effective products. A field largely focused on enhancing health to the Canadian population does not require policing and huge fines.

Originally when these rules came into effect, the natural health products were found in a separate category away from over the counter prescriptions, cosmetics and toothpaste. Today, many years later, with all the reorganization within the NNHPD- natural health products are included with over the counter pharmaceutical sleep aids, antihistamines, toothpaste, cosmetics, and hand sanitizer.

Health Canada dictating that even stricter regulation of natural health products are needed in supposed claims of protecting consumers from harm is dishonest. Health Canada is not balancing the alleged "risk" against the benefits of

natural health products. This is unacceptable. A large number of Canadians are only alive today because of natural health products. A large number of Canadians have quality of life because they successfully manage serious health conditions with natural health products. This is why natural products and natural health practitioners are so popular.

It is wrong for Health Canada bureaucrats to restrict natural health products by regulating them with chemical-drug-style regulations and policing that is becoming stricter and stricter. This legal structure limiting us to Health Canada bureaucrat-approved drugs can make sense for chemical drugs which carry a very high-risk profile; pharmaceuticals cause a large number of deaths a year. This legal structure does not make sense for natural health products which are so safe and effective that the real danger to Canadians is Health Canada restricting them.

In 2008 Health Canada tried to impose the powers and penalties later found in Vanessa's Law (S.C. 2014, c.24) on natural health products. This was defeated by one of the largest citizen rebellions in our history. Health Canada knows the citizens do not want Vanessa's Law to apply to natural products. However in 2023, the Canadian Government snuck into the Budget Bill changes to apply Vanessa's Law to natural products (Bill C-47 sections 500-504). It is now law.

In sections 500- 504 of Bill C-47, the maximum fines just increased from \$5,000 to \$5,000,000. No practitioner or producer can withstand such fines. Censorship will increase and ordinary Canadians will lose access to effective natural products because they cannot be told the truth about them

The CCHA is requesting to have sections 500-504 repealed. These powers and penalties are completely inappropriate for natural health care products. These powers and penalties will be used to destroy and terrify producers and practitioners that are saving lives and alleviating suffering.

If the government feels a need to police over-the-counter pharmaceutical products then the CCHA restates their position that Natural Health Care Products should be in a separate unique category on their own.

The CCHA is requesting a return of natural health care products to its own category as a standalone industry- where safe and effective nutritional supplements remain on our shelves and consumers can access these products at an affordable price. The CCHA is requesting that the policing rules be repositioned to an industry that actually needs policing.

- 4. For many years during the NNHPD consultation process, industry has been attempting to clarify evasive and ambiguous changes to the new third category either limiting statement function claims on labels or requiring clinical trials for novel products including herbal medicine combinations. The CCHA was concerned about the proposition to exclude traditional use claims for NHPs in favour of scientific research claims only. It now appears that Class III: Applications are items that require full assessment (not captured in Class I or II), including products with ingredient combination issues and applications partially referencing monograph information but going beyond the parameters established in the relevant monograph(s).**

Without transparent communication with industry about the Class III, despite regular inquiry, it now appears that Class III is about novel products – meaning when herbs from various paradigms (TCM/ Ayurveda/ Western Herbal Medicine) that have not been previously combined together. It now appears that the NNHPD is requiring a strict fee of up to \$ 58,332 ANNUALLY - for a class III novel product application. This will cripple creativity and new product innovation in Canada. The NNHPD states that they expect this new category to apply to just 1% of applications going forward. That is because no small business will be able to afford putting new innovative products on the market.

Within the current Class I and Class II organization, restricting claims for products to minor conditions only – is not beneficial for the public in any way. Requiring the same levels of evidence for natural health products and chemical drugs is not helping consumers.

Harmonizing the evidence standards will result in the loss of a large number of natural health products. Currently, traditional use evidence can be used to support efficacy claims for natural products. In some traditions, such as the Traditional Chinese Medicine practitioners, there are thousands of years of robust traditional use evidence. When the Standing Committee on Health held extensive consultations to determine how to best regulate natural products they were clear:

1. Natural health products should not be regulated like chemical drugs, and
2. Traditional use evidence needs to be allowed for efficacy claims.

Long standing, documented traditional knowledge should continue to be utilized to assess product safety and be on the same tier as clinical trials.

With the proposed limitation to scientific trials, the bulk of the opportunity lies in the hands of large companies including those from outside of Canada. The process of applying for regulated products requires great expense, not only for scientific trials, but for the administrative costs of the procedure. A stronger, more inclusive system would take into consideration the needs of small businesses. Inclusion of traditional knowledge sets is essential to ensure that we make the best use of the knowledge we share and permit that knowledge to benefit us all, including Canadians with small businesses.

The CCHA feels strongly that 50 year traditional use claims for NHPs continue to be held on the same tier as clinical trials and allowed for efficacy.

- 5. NNHPD label decisions are made with the consideration for transparency to the consumer and the environment in mind where bottles can continue to be recycled.**

One of the changes that the NNHPD has adopted is labeling changes including font size to fit additional information onto the label. Industry argued that the font would be too small to be readable by the population and for a brief time the NNHPD recommended moving non medicinal ingredients in products to a website rather than being listed on the label.

Consider the impact of non medicinal ingredients found in lower quality products including sugar, lactose, poly ethylene glycol, and FD & c colorings, being visually removed from labels of products and hidden away on a website – confusing the public. Hardly a safe solution when many Canadians are sensitive or suffer allergies from these unnecessary ingredients. A proposed solution to this was the 2 level label where a flap could be opened and additional information would be found on the inside label panel. A seemingly good solution however – this label required heavy glue to affix to the glass bottle, renders the labels impossible to remove and subsequently the bottles are unable to be recycled.

At a time in history where environmental concerns are essential and recycling of glass is an expected part of doing our duty to preserve our environment. It is unacceptable for the government to propose rules that make it impossible to recycle raw materials. Better solutions are needed.

- 6. In 2004-2006 the NHPD, recognized the need to develop a policy for the compounding of products by practitioners, created a working group and then created a policy for holistic health care providers who compound at the request of a patient. The CCHA is concerned about the impact of the proposed changes on the Compounding Policy.**

Herbalists have been operating within the compounding policy, which Health Canada created in response to overwhelming public opinion and consultation with industry. Over the past couple of years – NNHPD documentation has changed the wording of the compounding policy – inserting the word INTERIM compounding policy. This is worrisome.

We recognize that health care occupations are regulated provincially- however with the rapid bills and government laws being introduced without adequate government official or public consultation (such as Bill 36 in British Columbia)- the CCHA is requesting that the federal government formularize the compounding clause – making it law- which will provides continued assurance for natural health care practitioners that they can access, blend and formulate for their clients without a site license and good manufacturing policy regardless of provincial changing rules. This action will go a long way for building public rapport within these changing policies.

7. The NNHPD has cited regular consultation and communication with industry and vested interest groups.

During online focus group meetings, the NNHPD met with the various public and vested interest groups. These meetings were highly censored and prohibited attendees in voicing concerns or raising questions to the whole group. The meeting chat box lacked the space to pose lengthy questions or share comments- leaving attendees frustrated and concerns unaddressed. If this is truly consumer consultation, then we urge you to please return to in person meetings immediately. Thus we acknowledge gratitude in posting the word count allowance (20 000 characters) for this particular consultation.

Summary

The CCHA has a longstanding relationship with the NHPD/NNHPD. Over the course of 18 years representatives from the CCHA have acted as consultants to share expertise about herbal products that are included in the NNHPD. Our members were heavily engaged during the creation of the original regulations and offered expertise to guide the appropriate management of herbal products.

On the first page of the Cost Recovery consultation form it states that “Health Canada is the federal department responsible for helping people in Canada maintain and improve their health.” <https://www.canada.ca/en/health-canada/programs/consultation-proposed-fees-natural-health-products/overview.html>

The CCHA is clear that the NNHPD is not about safe and effective natural health care products nor is the NNHPD about assisting Canadian citizens in improving their health, but instead about regulating and enforcing rules which are becoming more and more prohibitive.

As paid government officials, you all represent the voices of Canadian citizens, you have a duty to protect all Canadians. The most fundamental right and issue for Canadians is for us to decide what to do with our own bodies.

We call on the NNHPD to reinstate a separate category for Natural Health care Products, abolish the policing and impossible cost recovery fee structure and look at ways of supporting the small business while also considering environmental impact.

We are not only interested in the impact of the proposed changes on practitioners and small businesses while also ensuring quality products are available for the health of the Canadian people.

The CCHA

www.herbalccha.org