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Re: Consultation on Proposed Fees for Natural Health Products
Email to nnhpd.consultation-dpsnso@hc-sc.gc.ca

Natural and Non-Prescription Health Products Directorate
Health Products and Food Branch
Health Canada
2 Constellation Dr, PL 2607A
Nepean, ON K1A 0K9 August 10, 2023

To the Health Products and Food Branch of Health Canada,

Thank you for the opportunity to participate in the consultation on proposed "cost recovery" fees for natural health products (NHPs).

Health Canada's consultation solicits feedback from stakeholders on the payment regime intended to cover increased regulatory oversight and new labelling standards for NHPs. These fees are an inevitable aspect of protecting consumer safety and conducting business in Canada. However, ***it is important that fees reflect accurate data and the industry's capacity to absorb costs. The current proposal does not achieve either.***

Beyond fees, ***I hope to focus my own comments on the application of Vanessa's Law to NHPs, which significantly contributes to these fees' cost/structure.*** I supported and helped amend *Vanessa's Law* to control and regulate pharmaceuticals in parliament, but the law's implementation has been heavily influenced by the pharmaceutical lobby. The law was intended to require pharmaceutical manufacturers to report and make publicly available all drug trials and to better report side effects. This has not happened. Instead, now the pharmaceutical lobby is succeeding in undermining the NHP sector. ***As a member of Parliament, I strongly object to Vanessa's Law applying to NHPs.*** I call for its immediate repeal for NHPs, at a minimum until it can be subject to robust parliamentary debate.

More broadly, I am concerned about the impact of *Vanessa's Law* and associated fees' roll out for affordability, innovation, competition, sustainability, and cultural inclusion, particularly during times of unprecedented inflation, health system collapse, and costly regulatory changes within the industry. ***I urge Health Canada to re-evaluate its fees***

proposal in the absence of a more holistic impact evaluation and engagement processes.

The following consultation elaborates on these concerns. I begin by outlining the stakes of this issue by evaluating the benefits and risks of NHPs, before diving into the drawbacks of *Vanessa's Law* in this context and of the cost recovery scheme. I end with concrete recommendations for a revised approach.

The Stakes

Benefits of NHPs

Many Canadians rely on NHPs to maintain or restore health. NHPs range from vitamins and minerals, herbal remedies, homoeopathic medicines, probiotics, amino acids, to traditional medicines. In fact, roughly ***70 percent of Canadians report using at least one of these products on a regular basis.*** More than half take vitamins weekly and the market for NHPs is only expected to grow as Canada's population ages.

I have heard from countless constituents, especially small business owners, who testify to NHPs' integral role in their or their customers' proactive health care. They express ***strong concern over the implications of the government levying fees on health and wellness products at a time when the preventative health care system is insufficient.***

We should not discount Canadians' first-hand experiences with these products, especially when they are tied to a broader lineage of cultural practices. Many NHPs have been developed through centuries-old cultural traditions, as in the case of Indigenous medicines as well as Chinese and Ayurvedic medicine. NHPs are generally considered more comprehensive than most pharmaceutical options. Stemming from nature, they offer an environmentally sustainable alternative to other products, supporting greater choice for ecologically conscious consumers.

NHPs also positively contribute to Gross Domestic Product. According to the Canadian Health Food Association (CHFA), the NHP industry has an estimated GDP of 11 billion dollars. This includes the sector's direct activities, supply chain, and increased spending by employees. A database triaging information from Statistics Canada, Industry Canada, and the CHFA, estimates that the industry generated 13.2 billion dollars in sales. Only 3.6 billion of these profits were generated from exports, implying that the majority of items sold directly benefited Canadian consumers.

The health, cultural, environmental, and economic importance of NHPs for a majority of Canadians cannot be understated. Proposed changes will influence their overall living expenses, lifestyle, and wellness. However, Canadians must be wary of industry lobbying and data manipulation, which can overinflate the benefits of these products.

Risks of NHPs

NHPs vary significantly in their effectiveness, credibility, and degree of risk to consumers. Historically, Health Canada has done little to monitor licensed products or check labels to ensure regulations are met.

Just because NHPs usually come from the environment does not mean they are safe. Certain products possess negative side-effects especially when combined with other medications or not used as directed. Hospitals have reported reactions to some NHPs ranging from septic shock, jaundice, disrupted liver function, to allergic reactions. NHPs can prevent access to approved treatments when substituted for, rather than serving as supplements for, scientifically verified procedures/medicines. Some NHPs are mixed with unnatural products, like steroids, which go underreported/assessed.

Recent investigations have highlighted the need to fortify NHP regulations, given rampant malpractice and false advertising. Misleading claims were particularly pervasive during COVID-19: public health was endangered via the lauding of natural treatments over scientific ones like vaccines. In general, labels across the NHP industry are printed too small. They wrongfully allege to "cure cancer," for example, or state they are safe for children, despite only having received authorization for adults. Under existing law, NHP recalls are voluntary, not forced.

Consumers bear the costs of ineffective products when they purchase NHPs that do not actually produce their touted positive effects. Health benefits are undermined. There is a strong case for increased regulation for these reasons. However, *how* we regulate in a manner that preserves benefits is critical. This is what I urge Health Canada to rethink under the current proposal.

Objection: Use of Vanessa's Law

The decision to define NHPs as a "therapeutic product," without focused debate or study in Parliament, represents a breach of due process. This revision means the powers conferred by *Vanessa's Law* will be applied to NHPs—and they will inherit all of this framework's flaws while distracting from a continued lack of regulatory enforcement for Big Pharma, which heavily influenced the law's implementation.

NHPs will no longer be processed under the Self-Care Framework authorised by Parliament in 2014. They will become subject to the same surveillance—and fee policies—as human drugs and medical devices, including the ability to recall unsafe products and change labels, mandatory adverse reaction reporting by hospitals, and additional pre manufacturing testing requirements. ***The change was slipped into the 2023 Budget Implementation Act (C-47) without meaningful public engagement or, seemingly, nuanced engagement with the many ways NHPs differ from drug products***. The costs of compliance will be significant.

I am concerned that NHPs' designation as a therapeutic product will distract from

enforced regulation of pharmaceuticals, which is proven to be a continued problem. ***Why do we need to crackdown on NHPs, when we are failing to properly regulate pharmaceuticals under Vanessa's Law as it currently stands?*** Why crackdown on NHPs, whose negative impacts are generally not life-threatening, when we are failing to confront Big Pharma's role in causing drug addiction and overdose?

Companies can easily leverage the law's protections for "confidential business data" to the detriment of patients. The Act alleges to increase transparency but imposes a complicated vetting process for physicians and researchers that prevents them from accessing information shared with Health Canada. Individuals "must exhaust all possible sources" before requesting information about the safety of a product from Health Canada. Legal scholars have gone so far as to suggest this carve-out for businesses may violate the Charter of Rights and Freedoms.

I have discussed the collusion between Health Canada's and Big Pharma at length in the Hill Times. ***Health Canada should not be expanding the reach of a Bill that has repeatedly failed in its own outwardly stated aims and been crafted out of subservience to industry.***

Impacts of Law & Proposed Fees

The proposed fee structure for NHPs, as required per *Vanessa's Law*, mimics that of human drugs and medical devices. It encompasses three licensing fees: one-time pre market evaluation ($1,124 to $58,332), annual site licence ($4,784 to $23,071+), and annual right to sell ($542). These fees are intended to shift the burden of administrative costs away from taxpayers and primarily onto the marketplace of businesses/consumers. This is logical. Improved oversight is needed, and it is common practice for regulatory overhead funding to be drawn from the industry itself. However, these fees—and the timing at which they are implemented—are not without consequences.

Affordability

Historically, NHPs have not been subject to cost recovery. The imposition of recovery fees at the same time as costly new labelling/reporting requirements—as well as historic inflation—will likely prove detrimental to small/mid-sized businesses in the industry.

New labelling laws are projected to negatively impact producer and sellers' profit margins, requiring novel machinery for "peel-back labels" and double the packaging to accommodate all of the required text. In one survey, the Canadian Health Foods Association (CFHA) found that 76 percent of brands report a high/very high chance they will need to pull product from the market as a result of these regulations. It is easy to imagine what the impacts of adding licensing fees too will be—and the picture is not pretty.

Inflation is already decreasing Canadians' likelihood to spend on health-related items. ***Even with remissions, small businesses will be forced to push inflated costs onto consumers.*** Increased prices will cause demand to drop. Suppliers will lose customers and customers will lose relied-upon products. ***In contrast, large businesses, corporations, and pharmaceuticals will have greater capacity to absorb start-up costs and retain customers by mitigating inflated product prices***. To summarise, it is not the recovery fees in themselves that put affordability at risk, but their concurrence with other new regulations and rising prices more broadly.

Innovation

Under the proposed fees, Health Canada outlines a new class of NHP called "Novel Class 3," defined as "*a product with novel active ingredients, a novel combination of active ingredient, a novel use or purpose, or a novel physical form.*" This class of product will experience an approval cost of up to $60,000. Once approved, "novelty" is removed, and successive product developers will be subject to a lower fee. If this is indeed the correct interpretation of the ruling, it will negatively impact potential for innovation. Innovation leaders are punished while their competitors will receive unfair market advantages by not paying as high of a cost. It will, again, be particularly challenging for smaller players to innovate due to monstrous start-up costs.

Foreign Competition

The Canadian economy as a whole will suffer by making Canadian NHPs less affordable. Many other countries' regulations on NHPs, supplements, and other products are less strict. The loss of trusted sellers alongside inflated costs may prompt consumers to source their NHPs elsewhere—benefiting foreign, rather than domestic, economies. These products may also not be equally safe for consumption due to less rigorous safety standards. Alternatively, products developed outside of the country that *do* meet Health Canada's standards may enter the Canadian market at lower prices and replace Canadian products. In either case Canadian-owned businesses will be undercut.

Cultural Diversity

Increasingly, traditional Indigenous medicine is being sold commercially. Few have been exhaustively analysed chemically or tested in clinical trials; however, doing so, may constitute a breach of trust or discounting of knowledge that has been passed down for generations. Examples of Indigenous herbal medicines include wild ginger, blue cohosh, goldthread, echinacea, and roseroot—recently highlighted as an adaptogen. ***Reducing access to NHPs and mandating more extensive western, scientific compliance standards may inadvertently infringe of peoples' rights to practise their culture, by limiting access to or affordability of these products.***

Health

The consequences detailed above build towards an obvious point: cost recovery fees will increase barriers to accessing the NHPs that many Canadians rely on to maintain good health. This result ***appears to be in contradiction with this government's other stated goals; namely, its commitment to reduce prescription drug costs***. Our healthcare sector is broken, and we are severely lacking in preventative healthcare options due to the undersupply of Family Doctors. NHPs play a role in proactive healthcare. If there were ever a time to decrease access to these products (which I do not expect there will be), it is not the middle of a care crisis.

Recommendations

It is Health Canada's responsibility to support Canadians' capacities to maintain good health. This involves establishing regulatory schemes to ensure Canadians can access a range of safe and effective wellness products.

Health Canada's new regulations for NHPs, such as labelling requirements, represent an important opportunity to improve Canadians' access to effective products and treatments geared towards improving health. Crafted thoughtfully, the regulations can increase NHPs' accessibility—helping keep Canadians out of hospitals—while improving oversight of high-risk/mislabelled products with proven side-effects.

Developing a fair cost recovery plan requires a holistic evaluation of NHPs' role in the health sector, including their connection to cultural diversity and respect for non western healing traditions. It must account for the financial repercussions of implementing this plan in tandem with other expensive requirements. Health Canada should re-evaluate proposed fees to mitigate projected negative consequences.

Key recommendations are outlined below.

1) Immediately Repeal the Application of Vanessa's Law

As previously stated, the application of Vanessa's law to NHPs should be repealed. At a minimum, reclassifying NHPs as "therapeutics" and subjecting them to the same laws as drugs and medical devices requires a more robust discussion. It should not be decided by fine print in the Budget Implementation Act. An eventual determination will meet less resistance if stakeholders feel they have been meaningfully engaged. Health Canada should encourage separate legislation, or undergo a separate consultation process, to determine whether or not to extend the use of powers under *Vanessa's Law* to NHPs.

As part of this process, a full impact assessment regarding the role NHPs can play in Canada's preventative health care system, as measured in decreased appointments and other medicines, should be conducted. NHPs' positive externalities should be incorporated into final cost offsets and ***pharmaceutical lobbying should be resisted.***

2) Reduce Costs

Canada needs to move in the direction of lowering not raising barriers to health. Creative options should be pursued to ***reduce projected costs and mitigate redundant overhead expenses.*** Repealing *Vanessa's Law* will help. Moreover, as one example, annual product fees could be deferred until the product is sold on the market, lowering barriers to entry.

Health Canada could alternatively opt to become more selective in deciding what qualifies as a "NHP" versus Self-Care product. Not all NHPs need to be held to the same standards for oversight. Canada could learn from Australia, as one model, which regulates "complementary medicines" according to whether they are registered (high risk), assessed listed (lower risk), or listed (lowest risk). Listed goods solely contain low risk ingredients and can only make low-level claims regarding benefit to health. They are not individually monitored or assessed before going to market but can be subject to randomised compliance reviews. This enables quicker access to market, lower overhead costs, and greater risk mitigation than Canada's proposed process that appears to take a more blanket approach.

Alternatively, Canada may consider increasing the interval for site licensing by at least one year, and conducting more randomised assessments, to again lower overhead costs while still increasing the pressure to comply. At a minimum, ***I strongly urge Health Canada to extend the roll-out of cost reduction fees and/or labelling requirements, to give businesses more time to absorb multiple increased costs and to allow inflation to simmer.***

3) Support Small Businesses

There is a significant difference between a small business making 30,000 CAD per year versus 5 million. Health Canada should consider supporting small business owners by ***distinguishing between 'small' and 'micro' businesses, when considering its fee remissions.*** The United Kingdom differentiates in this way.

As a starting point, Health Canada can consider expanding remissions for small businesses earning under $1 million per year. This may include increasing fee remissions for "annual right to sell fees" from 25 to 50 percent (or more) or increasing fee remissions from 50 to 100 percent for all subsequent product submissions. Such changes would be consistent with international standards.

In addition to remissions, Health Canada can support small businesses by educating them on their rights as per the "small business mitigation" program. Many have expressed confusion and concern over proposed changes, and a strong communications outreach strategy could help decrease businesses' concerns and assist them in adapting their business models to prepare for expected costs.

4) Incentivize Effectiveness and Innovation

Health Canada can incentivize the sale of evidence-based NHPs by conferring clearer benefits (such as certain labelling/marketing rights) to NHPs, which can offer scientific validation of their efficacy in achieving whatever benefits they claim. Such changes can potentially increase sales in the industry by improving consumer confidence. To mitigate concerns around potential loss of innovation, as mentioned previously, Health Canada needs to clarify the rights to data exclusivity of Novel Class Three products. Last, ***a broader public health campaign related to the benefits and risks of NHPs should be conducted***. Consumers deserve to know their rights and the high cost of purchases based on misinformation ought to be reduced.

5) Respect Cultural Diversity

Cultural awareness should be an important lens for all decision-making when finalising fee recovery regimes and is one of the strongest arguments for delaying the implementation of *Vanessa's Law* for NHPs. For example, medicines with a strong cultural tradition should be considered for remissions, especially to help with start-up costs. It is important the intellectual property of these traditional medicines is also protected, and the culture with ownership over these ideas are the ones who benefit directly. A broader discussion is required.

6) Expand Access

Health Canada should consider expanding insurance options for "medically necessary" prescribed supplements and alternative health care services, such as Chinese medicines and other products proven to be effective in treating conditions. This will promote continued, accessible access to the supplements upon which many people rely, especially if the average cost of NHPs is expected to increase. It will also affirm the importance of other non-western healing practices in our national culture.

7) Sustainability

While not directly related to the cost recovery proposal, the new labelling regime ought to prioritise a sustainable approach, which could reduce business costs and overall stress on the industry. Plastics cause severe environmental damage due to the hundreds of years they take to break down, the wildlife deaths they cause, and the pollution it takes to make plastic in the first place. To remove the negative environmental results of new labelling, which will likely require a larger surface area, Health Canada should promote modern labelling practices, such as electronic labelling. This could be achieved through a fee-reduction program for environmentally sustainable products. Electronic labelling would alleviate concerns of information hidden behind the non-recyclable peel back labels, or the increased cost and waste of larger containers for NHPs.

The Path Forward

Vanessa's Law should not apply to NHPs. I strongly object to this change. In fact, Vanessa's Law has not been fully implemented to meet its intended objective to protect Canadians of the negative side effects of prescription drugs. Our health priority must be about properly implementing *Vanessa's Law* to deal with pharmaceuticals. NHPs are unique products with unique regulatory needs. They should not be automatically regulated the same way as pharmaceuticals and medical devices. Instead, new labelling requirements and cost recovery fees should work to the health benefit of consumers, supporting the broader vision of a society that prioritises wellness, respects diversity, and cares for the environment.

Thank you again for the opportunity to contribute to the decision on the changes to natural health product regulations. I would be happy to meet with the Health Products and Food Branch of Health Canada to discuss how we can provide Canadians with safe, affordable natural health products and protect small businesses.

Sincerely,

Elizabeth May, O.C.
Member of Parliament
Saanich—Gulf Islands
Leader of the Green Party of Canada