



Written Submission for the Consultation on Proposed Fees for Natural Health Products

Submitted to: **Health Canada**

Submitted by: **The Direct Sellers Association of Canada**

August 2023

SUBMISSION OVERVIEW

Introduction

The Direct Sellers Association of Canada (DSA Canada) recognizes that a fair and well managed natural health product (NHP) regulatory framework is vital for consumers who purchase and utilize these products, and for companies who market them, including DSA Canada's members.

Having considered Health Canada's proposed cost recovery program for NHPs, DSA Canada has concerns that if implemented as written, it will have negative impacts on both industry and consumers. For this reason, it is imperative that the consultation on this proposal is extended, and implementation delayed, to allow stakeholders to collaborate on a model that works for all.

This submission sets out DSA Canada's rationale for these recommendations.

Summary of Issues

This submission first looks broadly at general industry concerns with Health Canada's cost recovery proposal for NHPs. These have been raised by members of DSA Canada, as well as by other NHP businesses and their representative associations from across the country.

They include:

- The impact on consumer choice and affordability.
- The negative affect on business investment and economic activity in Canada.
- The unrealistic fees proposed by Health Canada for some aspects of cost recovery, particularly considering the lack of a plan to improve existing shortcomings in the regulatory process.
- The rationale used to create the fee structure, specifically as a way to pay for prospective costs.
- The challenge that cost recovery will present to innovation in the NHP market.

The submission then considers important challenges the Health Canada proposal will create for the direct selling industry. These could significantly and specifically harm the channel in Canada.

- Firstly, it will impact the livelihood of the small entrepreneurs who make up the salesforce of DSA Canada's members, and who help to drive economic and social activity in cities and towns across the country.
- Secondly, the introduction of fees, with no commitment to improving product approval times, will lead companies that are currently importing products into Canada, including many in the direct selling space, to increase their use of Canada's personal use (not-for-resale) exemption to sell their NHPs. This risks:
 - Negative consumer health outcomes.
 - The removal of investment and tax revenues from Canada.
 - Placing those businesses who fully commit to the Canadian market and its regulatory regime at a competitive disadvantage.

Recommendations

DSA Canada will recommend the following courses of action, to ensure that Canada moves towards developing a world leading NHP regulatory regime that works for all stakeholders:

- **That the process to implement this proposal is paused, so that further consultation, research, and development can be carried out to inform program improvements.**
- **That detailed economic modelling be completed to measure all the impacts on industry and the Canadian economy resulting from this proposal.**
- **That Health Canada creates a road map clearly setting out how and when, prior to any cost recovery program being introduced, service levels will be substantially improved and other aspects of the Self-Care Framework, such as labeling and product category simplification, will be completed.**
- **That industry and all NHP stakeholders are an integral part of the consultation development process for the cost recovery program and for other changes in NHP regulation.**

Table of Contents

2 Submission Overview

4 Table of Contents

5 Background

6 Submission Body

6 *General Issues*

6 Consumer Choice and Affordability

6 Economic Impacts

7 Inhibiting Innovation

7 Fee Structure

8 Fee Calculations

9 *Direct Selling Focused Issues*

9 Entrepreneurial Impact

9 Personal Use (Not-For-Resale) Exemption

11 DSA Canada Recommendations

12 About DSA Canada

BACKGROUND

DSA Canada's Interest in This Proposal

DSA Canada is a national association, representing companies employing the direct sales model to distribute products and services. This respected and growing sales channel involves independent sales consultants marketing products to their personal networks on behalf of the companies and earning commission income on sales. It is an entrepreneurial business model, particularly popular with women, that has thrived in Canada for over 100 years.

Many of DSA Canada's member companies invest in the development and marketing of self-care products such as cosmetics and NHPs, which are regulated by Health Canada. For this reason, we have a strong interest in Health Canada's cost recovery proposal for NHPs.

Furthermore, most DSA Canada member companies operate in multiple national markets and sell the same or similar products in each of these countries. Certainty and transparency are important market-specific regulatory characteristics that help them to succeed, and predictable timelines make it possible to launch products in each of their markets at around the same time. Without this certainty, individual markets are less attractive for them to participate and invest in.

DSA Canada has worked with Health Canada in a cooperative manner for many years, to assist in the development of all aspects of natural health product regulation, policy, and implementation. While this is done in the best interests of DSA Canada's member companies, their customers and broader Canadian society, it should also be seen as a service of great value to Health Canada themselves.

At this time, there is concern that for the current NHP cost recovery consultation, this assistance is being diminished, with limited opportunity provided for input and meaningful dialogue, particularly with the consultation period being open only over the summer months.

Submission Development

This submission has been developed through discussions across DSA Canada's membership and other stakeholders. A comprehensive study of direct selling companies who market NHPs was carried out in July 2023, to provide crucial data and industry feedback. Along with existing industry research on the impact of direct selling in Canada, this has been used to inform this submission and to help expand on the issues and recommendations that are outlined.

DSA Canada's submission contains selective technical, regulatory and legislative references, to highlight key issues with the Health Canada proposal and to enhance its recommendations. For more in-depth technical analysis, we recommend and endorse the submissions of associations such as the Canadian Health Food Association (CHFA). DSA Canada supports their work and, in this submission, intends to supplement it and highlight specific impacts on the direct sales industry.

SUBMISSION BODY

General Issues

Consumer Choice and Affordability

A majority of DSA Canada's NHP survey respondents indicated that increases in the cost of doing business created by this proposal will lead to retail price rises for Canadian consumers. Several respondents also stated that the cost recovery proposal will result in them reducing their product range in this market and canceling the release of new NHP formulations. At a time when inflation and the cost-of-living are at the forefront for policy makers and consumers, both outcomes will further harm Canadians and the broader Canadian economy.

At this very point in time, running concurrently with the cost recovery consultation, Health Canada has recognized the importance of access to health products for Canadians and is conducting a separate consultation aimed at developing policies and practices that will mitigate shortages, improve access to health products for consumers, and enhance responses to supply and demand challenges. This initiative, titled [Consultation on improving access to drugs and other health products in Canada](#), appears inconsistent with the steps being recommended in the cost recovery proposal and the impacts they will have.

One example of these impacts relates to product availability. Several of the direct selling companies we surveyed stated that up to 30% of the NHPs sold by them would be considered niche products – which do not sell in large quantities or create significant revenue for the business. They are sold as part of a broad product portfolio and as a service to consumers, for whom they perform important health and wellbeing roles. DSA Canada members have made it clear that these are the products most likely to be delisted when cost recovery fees are implemented. As a result, consumers who use these products will no longer have easy access to the NHPs that they depend upon for their personal health.

Economic Impacts

It is estimated that the annual economic impact of NHPs sold through the direct selling channel in Canada is \$2.5 billion (*2022 Canadian Direct Selling Socio-Economic Impact Study*), including via consumer spending, direct and indirect taxes, business investments (such as real estate, product development, manufacturing, etc.) and employment. Direct selling companies also create an entrepreneurial opportunity for their independent sales consultants, which further enhances and multiplies the fiscal impact of the channel. There is a very real risk that Health Canada's cost recovery proposal will diminish each of these impacts in direct selling, but also more broadly for the NHP industry.

DSA Canada was able to attend a Health Canada technical session on July 13, which set out the rationale for the fees being proposed. While informative, the session failed to address and acknowledge the negative economic impacts that this proposal will have on Canadians. It is disappointing and fiscally irresponsible that no formal study of economic impacts was undertaken as part of this planning and consultation period.

From an employment perspective, the potential for job losses is apparent for companies active in the NHP industry and for their associated support networks. There is also a risk to employment for regulators themselves. With the likely reduction in the number of NHP products seeking approval and being sold in Canada, and even a reduction in the number of companies operating here, there will be less need for the services of Health Canada. At some point, in the interests of operating efficiency, Health Canada will require less staff.

Inhibiting Innovation

Innovative products are the lifeblood of the direct selling industry, as companies strive to create value, differentiate themselves and meet evolving consumer and health needs. This is true for companies of all sizes, although small to mid-sized businesses are often the most innovative. Bringing an innovative product to market is inherent with risk, as there are never any guarantees that it will be effective, get approved or find a consumer base.

Through this proposal, the cost of bringing innovative new products to market will rise considerably, particularly if those products are in the Class III or Class III Novel categories. As most NHP formulations cannot be patent protected, which differentiates NHPs from some other categories of Health Canada regulated products, the incentive to develop, license and market innovative NHP products will be diminished due to the increased costs. This incentive is also weakened by the lack of a mechanism to provide refunds for product licence applications that are not approved.

If Canada is not seen as a supporter of innovation, companies will invest their time and expertise in other countries, where they see a better chance of a positive return on investment.

Fee Structure

Across industry, it is generally accepted that some level of cost recovery charges are a core part of Health Canada's Self-Care Framework. Most businesses are prepared to pay for services that are of a high quality and completed in a timely, transparent, and customer-focused manner. DSA Canada member companies have stated that they will commit to a fee-for-service model if the charges are reasonable and there are significant service standard improvements. This will create a level of certainty and predictability for both their Canadian and global operations.

From the proposal, three possible fees and fee types stand out as creating a challenge to direct selling companies. Firstly, a Class III novel application at \$58,332 is unnecessarily restrictive, particularly as the nature and scope of such products has not been clearly defined by Health Canada. The review time service standard for such products is proposed to be longer than current, moving from 210 days to 300 days. This is the exact opposite of something that is reasonable, timely and a service standard improvement.

Secondly, site licence costs for an importer of goods are set at over \$20,000 – this will create a barrier to entry for companies considering launching their products in the Canadian market. It will also have a detrimental impact on those businesses who are endeavouring to maintain their own high customer standards (and create employment), by having multiple licensed sites across Canada.

Finally, charging an annual right-to-sell fee of \$542 is inhibiting to businesses with a large product range or with products that have a small number of customers. Once again, this could lead to the delisting of important products and the loss of investment and jobs.

Fee Calculations

One aspect of the calculations presented by Health Canada for developing the fee structure was that part of the charges will be allocated as a tool to fund prospective costs. That is, to pay for future infrastructure required for Health Canada's NHP regulatory role.

It is DSA Canada's understanding that the portion of the fees that relate to prospective costs would in fact be classed as a tax, as they would be an obligation on current market participants to fund future regulatory infrastructure, rather than reimbursement for the operation of the existing infrastructure on a per use basis. Health Canada alone does not have the authority to impose taxes (which need to be approved via Parliament).

If it was determined that these charges are not a tax, the statutory authority that allows for cost recovery expressly limits such charges to actual costs. Prospective costs would inherently exceed actual costs, so it would still be outside Health Canada's authority, as it is not reasonable cost recovery.

Charging for prospective costs may also be in contravention of Canada's commitments to the CUSMA Trade Agreement. CUSMA limits permissible fees for certain activities, including "conformity assessments", to the recovery of the approximate costs of services rendered – i.e., the actual services that are completed, not prospective services that might be or were not completed. Based on the information available to date, CUSMA arguably requires a direct link between the amount of a fee and the activities of Health Canada in the period during which the fee is collected.

Direct Selling Focused Issues

Entrepreneurial Impact

Over 1.1 million Canadians are active as independent sales consultants (ISCs) in the direct selling channel. These entrepreneurs, 84% of whom identify as women, typically use the incremental income generated through their part-time direct selling business to help support themselves and their families. In Canada, \$1.57 billion is annually created in personal revenue for direct selling ISCs (*2022 Canadian Direct Selling Socio-Economic Impact Study*). This “side hustle” income opportunity helps individuals pay down mortgages, support their children’s extracurricular activities and strive for financial security.

Direct selling is a simple and inexpensive way for an individual to get a start in the world of entrepreneurship. It is a training ground for economic activity – many people who begin their journey in the direct selling world move on to take on larger entrepreneurial pursuits, such as developing their own products and launching their own retail operations.

DSA Canada estimates that approximately 45% of current ISCs who participate in direct selling gain at least some of their income from selling NHPs (*2022 Canadian Direct Selling Socio-Economic Impact Study*). A proposal such as this one from Health Canada, which is likely to lower available products, reduce innovation and even lead to companies leaving the Canadian market, will have a detrimental impact on each of these people and the economic impact they create and gain from.

ISCs are also important to the social fabric of communities, particularly for rural and remote areas. They often hold sales events for friends, family, and broader connections, bringing people together, and providing crucial access to NHPs in regions that don’t have bricks and mortar retail (such as drugstores and nutritional outlets) that are easily accessible. While this is difficult to measure in economic terms, it provides great value to these communities.

Personal Use (Not-For-Resale) Exemption

Based on the Health Canada proposal, there is risk that small and medium-sized businesses may not be able to afford the planned fees, and that larger businesses may choose not to operate in a Canadian market that has created this added expense.

It remains to be seen how companies will manage these costs, but one option that is appealing to internationally based businesses is to ship from non-Canadian warehouses to consumers, utilizing Canada’s [personal use exemption](#) (sometimes called not-for-resale/NFR). This exemption allows Canadian consumers to order up to 90 days of product supply from a business located outside Canada; products which do not have to meet Health Canada’s ingredient, dosage, or labeling requirements.

Currently, there are some non-resident and non-DSA Canada member direct sellers who operate wholly via this model in Canada, i.e., simply shipping US products to Canadian consumers. There are other direct selling companies who utilize the exemption for a small part of their range and/or for a limited time, for example if they wish to have a product available in Canada at the same time as other markets and the Canadian licensing process is taking longer than expected.

DSA Canada fears, and is backed up by feedback from industry, that this proposal will result in Canadian consumers ordering more non-compliant products from outside of Canada, and international companies choosing this method as the way to do business in Canada. This places those businesses who fully commit to the Canadian market and its regulatory regime at a competitive disadvantage.

The outcomes of these moves are an increase in risk to consumers, based on a growth in consumption of unregulated products, and the removal of investment and tax revenues from Canada. It will also lead to a reduction in income opportunities for independent sales consultants in the direct selling channel, as products sold via the personal use exemption cannot be marketed and commercialized in Canada or create commission revenue for these entrepreneurs.

DSA CANADA RECOMMENDATIONS

Based on the issues raised in this submission and the specific and real concerns of DSA Canada's member companies, we strongly recommend that the following courses of action be considered and followed. These will help ensure that Canada moves towards developing a world leading NHP regulatory regime that works for all stakeholders:

- **That the process to implement this proposal is paused, so that further consultation, research, and development can be carried out to inform program improvements.**
 - Discussions since the release of this proposal have clearly shown that there is uncertainty, fear and questions across the NHP community. There is also a conviction that industry has not had the appropriate level of input or consultation on an issue that is a potentially existential threat to many of its participants.
 - Companies from other Health Canada-regulated categories, such as cosmetics, who may be impacted in the future by current cost recovery program development decisions, should also be consulted.
 - It is important that all aspects of the proposal be deliberated, including fee structure and rates, service standards, mitigations, and timelines.
- **That detailed economic modelling be completed to measure all the impacts on industry and the Canadian economy resulting from this proposal.**
 - Many of the questions raised about this proposal are centred on how it will impact the economy, at a macro and micro level. The proactive way to answer these questions, to either inform adjustments to the proposal or alleviate industry concerns, is to carry out a detailed economic impact study.
- **That Health Canada creates a road map clearly setting out how and when, prior to any cost recovery program being introduced, service levels will be substantially improved and other aspects of the Self-Care Framework, such as labeling and product category simplification, will be completed.**
 - It is difficult for industry to accept being asked to pay for a system that is currently operating at a sub-optimal level. To have a clear road map in place that lays out a path towards improved service levels, reductions of fees over time and enhanced processes is an important step in creating long-term trust and success.
 - Implementation of cost recovery should only occur as part of the final phase of an optimized Self-Care Framework.
- **That industry and all NHP stakeholders are an integral part of the consultation development process for the cost recovery program and for other changes in NHP regulation.**
 - Successful implementation of a proposal relies on buy-in from all stakeholders. Along with a broad alliance of industry colleagues, DSA Canada offers up its time and expertise to help build an NHP program that works for government, consumers, and industry.
 - We welcome the opportunity for true two-way conversations in the best interests of Canada.

About DSA Canada

Since 1954, the Direct Sellers Association of Canada has established and upheld rigorous standards, ethics and good business practices, as the recognized voice of our industry. We are a family of competitors, using our combined strength to ensure fairness in regulations and to gain credibility and respect with Canadians.

As an industry that connects 1.1 million Canadians to entrepreneurial opportunity and enrichment, we provide assurance of member company integrity and a foundation of trust for independent sales consultants (ISCs) and consumers.

For more information, please contact:

Peter Maddox

President

Direct Sellers Association of Canada

180 Attwell Drive, Suite 250, Toronto, Ontario, M9W 6A9

E: peter@dsa.ca

C: 416.903.8518