

Canadian Health Food Association

Submission to the House of Commons Standing Committee on Finance

Pre-budget consultations in advance of the 2018 budget

Executive Summary

Every year, \$7 billion is contributed to the Canadian economy by the country's natural health and organic products industries. These sectors continue to grow by fostering innovation and competition, and employ thousands of Canadians across the country. The Canadian Health Food Association (CHFA) represents more than 1,000 member companies within these fields. Seventy-nine per cent of Canadians rely on natural health product (NHPs) for maintaining their health lifestyle, and our members are proud to be a trusted source.

The term NHP includes vitamins and minerals, herbal products, traditional remedies (such as Traditional Chinese Medicines), sports nutrition products, probiotics, and enzymes. The businesses we represent — and the large customer base they serve — remain concerned with the effort to modernize regulations, which may lead to Health Canada limiting their ability to compete in an increasingly challenging global market. Furthermore, these measures will limit the overall productivity of the NHP sector by upsetting the balance that has resulted over the years from government-industry collaboration on the development of guidance and standards.

CHFA worked closely with government officials long before the implementation of the *Natural Health Products Regulations* in 2004. The result of this, which exists today, is an environment in which Canadians can trust that the NHPs they consume are safe, effective and high-quality. Our association recognizes the need for the regulation of all health products, and we have worked with our members to ensure that they abide by these rules. Under this regime, Canadians have shown that access to these products, along with an assurance of quality, are important to them, as demonstrated through continued market growth.

Processes are currently underway to review the self-care products framework. It is vital that these processes and the resulting policy respect the unique qualities of NHPs, the importance of choice and access to consumers, and cultural approaches to wellness. We recommend that government take the following steps to ensure businesses in this growing sector remain competitive and productive.

Strong Regulation Has Supported a Strong NHP Industry

The government is committed to ensuring businesses can succeed and grow in Canada. In the case of our industry, however, the most important issue facing the \$3 billion NHP industry is uncertainty surrounding the proposed self-care products framework, and how it can impede development and innovation.



Since the introduction of the *Natural Health Products Regulations*, over 100,000 products have been licensed, after being subject to pre-market review and approval by Health Canada for safety and efficacy. Because of this system, Canada is seen as a world leader in NHP regulation. This has not only increased consumer confidence in these products, but also helped our industry to grow and create jobs.

Health Canada's review to change these regulations has been ongoing since 2014. At the current stage of the consultation process, the importers, distributors, manufacturers and retailers of NHPs have been left wondering about the future of the products they confidently offer to their customers, after having spent years ensuring compliance with the current *Natural Health Products Regulations*.

Over the course of the consultation sessions, we have seen a number of positive changes to the initial proposal, but more work needs to be done. The self-care products framework must ensure that Canadians from all backgrounds continue to have access to the safe and effective products they use, with consideration for products from around the world that are culturally important and that have been used for centuries.

To ensure competitiveness and productivity for businesses in our sector, government should ensure that impacts on the NHP supply chain are limited, as the existing regulations work well to ensure safety, efficacy and create trust. Under the proposed self-care products framework, businesses may need to once again reformulate their products, relabel their packaging, or invest substantially in additional research on products that are already deemed effective and safe, as indicated by their current sale in Canadian stores and safe use by consumers.

A further concern relates to confusion about labelling that could result from the proposed changes. Consumers can trust products that have been given a Natural Product Number (NPN) by Health Canada. Under the proposed regulatory framework, consumers who have grown accustomed to this may encounter NHPs that have some form of licence number and others that do not. Our members have built their businesses on quality, safety and trust, and the proposed changes challenge each of these pillars.

There are elements of the regulations that Health Canada should modernize, but they ultimately should not dismantle Canada's world-class regulatory system for NHPs in the process. The evidence needed for the approval and marketing of self-care products should reflect the product type and claims made, while traditional sources of evidence must continue to be accepted. If these steps are taken, they would be important strides in preserving the strength of our sector.

Another component of the self-care products framework is the introduction of cost recovery for sites, applications and right to sell for NHPs. Cost recovery was expected to eventually be incorporated into our sector, as it was part of the original recommendations set forth by former Health Minister Hon. Allan Rock. As a maturing industry, we accept the purpose of cost recovery but, nonetheless, are concerned as a small sector that fees will have a significant impact. Recent consultations on updates to cost recovery for other consumer health and drug products show



fees as high as \$30,000 for site licensing, \$600,000 for product licensing and \$4,500 for the right to sell. The NHP industry wants to accept the responsibility for the oversight applied to our products, but we have concerns with how a large-sum fee or fees could be detrimental to some small- or medium-sized businesses. To help NHP companies ease into the anticipated cost-recovery regime, we propose that the government consider phasing in the cost-recovery model over four years, following the coming-into-force of updates to the existing regulations. We also request additional funding for the Natural and Non-prescription Health Products Directorate (NNHPD) to assist them with the implementation of tools to transition into a fully cost-recovered sector. The proposed regulations will put significant added pressure on that department, which may result in long-term pressures including increased costs for NHP manufacturers and distributors. Additional funding will help NNHPD to alleviate the pressure of these changes and ensure a smooth transition for the directorate and the businesses that rely on it. These steps will respect the extensive costs that will be taken on by these businesses and help develop a process that industry can fund moving forward.

Maintaining the *De Minimis* Threshold

CHFA represents more than 1,000 businesses across Canada that compete on a daily basis with companies around the world, especially with those headquartered in the United States. Many of our member businesses are small- and medium-sized enterprises that offer niche products to Canadian consumers with very small profit margins. U.S.-based online retailers have lobbied Canada to increase its *de minimis* threshold substantially, and they have pushed for the U.S. to adopt a similar bargaining position in the coming NAFTA negotiations. Our sector welcomes competition, but it is crucial that this competition happens on a level playing field. Canada needs a stricter *de minimis* threshold, as our online purchases more regularly come from outside of the country, sending Canadian money abroad while decreasing the tax revenues collected by government. This great expense comes with no benefit to the small- and medium-sized businesses that fuel the Canadian economy.

NHP retailers, wholesalers and distributors are already concerned that consumers exploit an existing personal importation loophole that allows them to bring products into our country that have not been regulated by Health Canada. We have a world-class regulatory system that features pre-market approvals to ensure consumers have access to safe and effective products. It is therefore very concerning that, if incentives continue to tilt in favour of international online sales, more consumers will start taking advantage of this loophole, which could jeopardize their safety and create challenges for regulatory enforcement. We strongly recommend the continuation of the current *de minimis* threshold to ensure Canadians continue to have an opportunity to succeed and grow, and that incentive structures point consumers in the direction of effectively regulated products from those in the Canadian marketplace.



Support for Natural Health Products Research Funding

New standards for scientific proof may arise from what is currently being proposed through the proposed self-care products framework. This could present a huge challenge for NHPs. While many products are rigorously supported by scientific evidence, the evidence requirements for NHPs reflect the fact that they have been used traditionally for thousands of years and are generally considered lower-risk. Additionally, since patentability of a natural substance is not widely available, this deters an NHP manufacturer from investing heavily into expensive clinical research.

Innovators in the Canadian NHP sector are constantly looking for ways to improve their products. Developing new and patentable processes for extracting natural ingredients is one way they can create products that help Canadians achieve better health outcomes through self-care. Clinical research improves the reputation of Canadian businesses distributing their products domestically but also abroad, which brings more money to our shores.

The lower patentability of NHPs makes it less desirable for many smaller producers to undertake more research. This issue could be remedied through funding for research that businesses would be able to apply for. The primary mechanism for health research funding in Canada is the Canadian Institutes of Health Research (CIHR). CIHR divides over \$1 billion annually in research funding to investigator-driven research and priority-driven research. The latter “refers to initiatives created by the Government of Canada to investigate pressing health issues that are of strategic importance to our country,” and receives approximately 25 per cent of the funding distributed each year. While individual researchers can submit proposals to this stream, we propose that a small portion of priority-driven research funding be allocated annually to support NHP research. In 2018–2019, we propose that pilot funding of \$10 million be contributed toward this initiative. This funding would create a strong foundation for improved products that will lead to lasting improvements in our sector, increasing the productivity and competitiveness of Canadian businesses in the global NHP market.

Recommendations:

- To help NHP companies ease into the anticipated cost-recovery regime, we propose that the government consider phasing in the cost-recovery model over four years, following the coming-into-force of updates to the existing regulations.
- We also request additional funding for the Natural and Non-prescription Health Products Directorate (NNHPD) to assist them with the implementation of tools to transition into a fully cost-recovered sector.
- We strongly recommend the continuation of the current *de minimis* threshold to ensure Canadians continue to have an opportunity to succeed and grow, and that incentive structures point consumers in the direction of effectively regulated products from those in the Canadian marketplace.



- We recommend that \$10 million in pilot funding be made available in 2018-2019 to support priority driven research, within the Canadian Institutes of Health Research, be allocated annually to support research geared toward NHPs.

