June 16, 2023

Hon. Jean-Yves Duclos, P.C., M.P.
Minister of Health
Health Canada
Address Locator 1801B
Ottawa, Ontario K1A 0K9
By email: jean-yves.duclos@hc-sc.gc.ca

Re: Self-Care Framework & NHP Cost Recovery

Dear Honourable Minister:

We, the undersigned associations, represent the manufacturers of the vast majority of natural health products (NHPs), non-prescription drugs (OTCs) and cosmetics that Canadians use every day. For more than eight years, we have been working with your officials on the development of a sound, risk-based regulatory framework for these products, known since 2016 as the Self-Care Framework (the Framework). We are writing to express our frustration with the slow progress on this Framework and our alarm at the decision to propose an NHP cost recovery scheme when the Framework is still far from complete and the overall state of the NHP program can only be described as dysfunctional. Both the timelines and sequencing of the Framework are highly problematic and we would like to meet with you to resolve these issues.

Cost recovery was always logically positioned as part of the final phase of the Framework, so that it could be advanced in concert with the new regulations, much as is being done with the new biocides regulations and accompanying cost recovery proposal. Doing cost recovery first is a clear instance of putting the "cart before the horse," as the whole exercise will have to be repeated once the Framework is actually finalized.

The Department's rationale for this approach is that it is required in order to respond to the recent report of the Commissioner of the Environment and Sustainable Development (CESD) which, as you know, found the NHP program lacking. In fact, had the Self-Care Framework been completed by 2019 as projected, the concerns raised in the CESD report would already have all been addressed. Cost recovery, on its own, will not address them. Instead, the Department has now stated (in their most recent meeting to stakeholders on May 11th) that the regulatory reforms will not be completed until some time in "2025 or beyond." After an eight-year delay, this new, ambiguous timeline is unacceptable and will have a significant impact on the operations of companies in Canada and the availability of products on store shelves.

The lack of progress on the Framework means that backlogs and delays on product authorization and site licence submissions for NHP manufacturers have grown so severe that they have been threatening product availability, product launches and even major expansions into export markets. We are all increasingly being called upon by our respective members to help overcome these challenges, and we know that companies have also had to seek direct support from officials in your office. This crisis environment in our industries is a direct result of the lack of progress on the Framework.

While your officials have recognized the need for the "simplified product authorization pathways and operational improvements," that will address these issues, the lack of progress so far and the lack of a firm commitment on their substance and the timing of their implementation amounts to a "just trust us" approach. That is not a risk that we can take as longstanding regulatory obstacles compound the challenges of the post-pandemic business environment. This also comes on top of the recently approved NHP labelling regulations, modelled on the OTC Plain Language Labelling (OTC PLL) regulations, that together will cost our members $400-500 million to implement over the period 2016-2028, and have already resulted in the disappearance of more than one in six of the OTCs that were on the market when OTC PLL began being implemented in 2016.

The "cart before the horse" approach to cost recovery will not only add to industry's challenges, it also provides no guarantee of the stable, sustainable funding the Department says it needs. The data and assumptions Health Canada used to prospectively calculate service fees are necessarily suspect, since they are based on as yet incomplete reforms for which little to no detail has been provided. Even the number of products on the market, a figure absolutely critical to calculating the Right to Sell (RTS) fees that account for most of the revenue in the proposal, is an educated guess at 50,000. The actual number could be as little as 20,000, which would profoundly reduce the revenues for this program.

Finally, the whole intent of the Self-Care Framework was to recognize the need for a consistent, risk-based approach to these products separate from the prescription drug requirements. The fact that the fee ratios (the proportion of program costs to be charged to industry in services fees) proposed for NHPs and those currently in place for OTCs and prescription drugs are all identical defies logic. We've been told that, consistent with Treasury Board policy on service fees, the main factor in calculating these ratios is the public/private benefit. It cannot be possible for this approach to result in the same ratios for all three product classes when OTCs and NHPs generate $400-500 million in GST revenues, while prescription drugs are exempt.

We are appealing to you to reconsider this proposal and its place in the development of the Self-Care Framework, and would like to meet with you to discuss the following revised approach:

1) Suspend this consultation and accelerate the development of the remaining elements of the Self-Care Framework, including the long-promised simplified product authorization pathways, operational efficiencies and postmarket compliance and enforcement improvements, so that a complete regulatory package can be consulted on in tandem with a corresponding cost recovery proposal; and,
2) Work with industry to revisit the fee ratio setting calculation, more realistically reflecting the public vs private financial benefits of the regulatory programs for self-care products relative to prescription drugs and other tax-exempt therapeutic products.

We want to underline that all of our associations recognize and support the fair application of cost recovery to the NHP program. All three associations have also invested heavily in supporting the work of your officials on the Framework and will continue to do so. But the current status and direction of these intertwined initiatives is in no way aligned with the oft-stated objectives of the Self-Care Framework or the findings of the CESD report and are instead creating a crisis environment for our industries. We urgently request a meeting with you to address these concerns.

Respectfully,

Michael Graydon
Chief Executive Officer
Food, Health & Consumer Products of Canada

Aaron Skelton
President and Chief Executive Officer
Canadian Health Food Association

Darren Praznik
President and Chief Executive Officer
Cosmetics Alliance Canada