

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

August 31, 2022

Mr. John Williamson, M.P.
Chair, Standing Committee on Public Accounts
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Williamson,

I am pleased to present you with a progress report on implementing a risk-based monitoring program for natural health products, as requested by the Standing Committee on Public Accounts within its recently tabled *“Report 18 – Natural Health Products”*, which undertook a study of the Commissioner of the Environment and Sustainable Development’s audit of Health Canada’s Natural Health Products Program.

First, I would like to take this opportunity to thank you and the Committee for undertaking this study and for preparing a comprehensive set of recommendations that emphasize the significance of this regulatory program to protect the health and safety of Canadians. Health Canada is closely deliberating on the Committee’s findings and will bring forward a government response pursuant to Standing Order 109.

I want to acknowledge that the Committee has recommended that by August 31, 2022, Health Canada provide the Committee with:

“a progress report about implementing a risk-based monitoring program to A) identify unlicensed natural health products and take appropriate action so that they are not available for sale to consumers in Canada; and B) identify unauthorized activities and take appropriate action so that labelling and advertisements meet product-licence conditions” (Recommendation 4 within the Report).

.../2

Canada

This letter serves to address this specific recommendation. Rest assured that I look forward to comprehensively addressing the remaining recommendations made by the Committee in our forthcoming response.

Canada has a strong regulatory system for natural health products, with some of the most stringent requirements in the world. However, both the audit and the Committee's study identified areas of improvement in our regulatory oversight, such as how Health Canada oversees quality, labelling, advertising, and compliance and enforcement.

One of those areas for improvement relates to how Health Canada monitors and takes action regarding unauthorized products and other prohibited activities under the *Food and Drugs Act* and the *Natural Health Products Regulations*. The audit noted that while Health Canada monitored alerts from international regulators and other organizations to identify suspected cases of non-compliance, the Department undertook limited follow-up to cease or deter activities, given the lower risk posed by some of the products.

I would like to reassure the Committee that Health Canada takes action when health risks are identified. The actions are commensurate with the level of risk. The Department identifies potential non-compliance through consumer or industry complaints, referrals of shipments at the border, international regulatory partners, or proactive monitoring activities such as market surveys. When non-compliance is confirmed, actions are taken based on the potential risk to health posed to the public. This can include directing companies to correct the issue through actions such as stop sales or recalls, public advisories, seizures, and licence suspensions.

Additionally, in our response to the audit, the Department agreed that, while a complaint-based program for regulatory advertising compliance oversight is the current practice, an additional risk-based approach is required. A risk-based approach will ensure unauthorized activities are prevented and/or stopped, which is particularly important given the growing number of natural health products for sale in Canada, particularly online. The Department also acknowledged that natural health products are the only line of health product it regulates for which it lacks the statutory authority to mandate a recall or to impose terms and conditions to mitigate serious safety risks associated with these products.

In response to the Committee's recommendations, the Department has made progress in the following areas, which were identified in our response to the audit and represent the key elements to meeting recommendation 4:

Implement a risk-based approach to the monitoring of advertising

Following the audit, in September 2021, Health Canada implemented a risk-based approach in advertising oversight by launching a risk prioritization tool, which classifies advertising incidents based on the level of risk. This important shift is ensuring that the Department prioritizes high-risk advertising incidents that can potentially pose a significant risk to the health and safety of Canadians.

Furthermore, building on successes noted in the audit with respect to the proactive monitoring of advertising of health products making COVID-19 claims, the Department is piloting the use of Artificial Intelligence to proactively monitor NHP advertising. More information will be provided in future progress reports as requested by the Committee.

The Department has also made progress in collaborating with other federal government departments in taking enforcement actions that support stronger oversight of non-compliant advertising of NHPs. This work includes the development of formal agreements to support joint compliance and enforcement actions, where appropriate.

Taking steps to propose new tools to strengthen its ability to deter and address non-compliance, which include moving forward with a proposal to extend the use of Vanessa's Law powers to natural health products

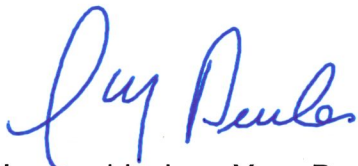
Extending the use of the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) powers to natural health products is key to improving Health Canada's ability to take appropriate action when a serious risk to health is identified. These actions include requiring label changes, package modifications, or to order a recall of natural health products, which the Department currently has no statutory authority to do for NHPs as the powers from Vanessa's Law do not extend to these products.

While the Department had been working diligently to bring this proposal forward last fall to meet the timelines we had identified in our Action Plan, this work is proving to advance more slowly than anticipated given these statutory amendments require support from other government organizations to prepare and introduce legislation. The Department is actively working to pursue the earliest opportunity to bring this proposal forward to Parliament, at which time I look forward to the Committee's support on this important issue.

In closing, I would like to reinforce that in our Departmental response to the audit findings, Health Canada reaffirmed the need for sustainable and predictable funding through fees charged to industry to support increased oversight of these products. Natural health products are the only line of health products for which regulatory activities are fully funded by appropriations. Revenues from fees would support pre- and post-market regulatory activities, including the ones mentioned above. As I have indicated to the Committee, introducing fees is a priority for the Department.

Once again, I thank the Committee for undertaking this important study. I trust that this response is satisfactory in fulfilling the committee's request for a progress report about implementing a risk-based monitoring program and I look forward to providing subsequent progress updates, as requested by the committee.

Yours sincerely,



The Honourable Jean-Yves Duclos, P.C., M.P.