

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

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

On behalf of the Government of Canada, I am pleased to present you with the Government Response to the Eighteenth Report of the Standing Committee on Public Accounts (PACP), entitled *Natural Health Products*. This response was developed following PACP's study of the Commissioner of the Environment and Sustainable Development's (CESD) *Report 2 – Natural Health Products*.

To start, I would like to thank you and the Committee for the comprehensive study of this audit, as well as the associated recommendations. These recommendations illustrate the ongoing need to improve Health Canada's regulatory capacity to provide effective oversight over natural health product quality, labelling and advertising, as well as compliance and enforcement to prevent and address potential health and safety risks. I was pleased to provide a first progress report on implementing a risk-based monitoring program for natural health products this past August. I trust that the response was acceptable in fulfilling the Committee's request.

As you are aware, Health Canada accepted the totality of recommendations made in the Commissioner's report (the audit), and in response, prepared a [plan](#) to establish a stronger and more robust natural health products program. As part of the proposed improvements, the Department committed to consider a range of policy, operational, and statutory changes, as well as enhanced compliance and enforcement, such as through the greater use of proactive monitoring and a permanent inspection program. I thank the Committee for inviting officials from Health Canada to speak to the Department's response to the audit.

The Government Response below addresses the themes that have emerged across the Committee's recommendations and highlights key progress to date. The response also reaffirms the Department's intention to explore all possible approaches to address the Commissioner's recommendations at the earliest opportunity.

Theme 1: Quality (Recommendation 1)

The Report recommended that Health Canada provide progress reports on improving how it verifies that licensed sites follow good manufacturing practices before products are released on the market, and on implementing a mechanism to obtain information regarding which natural health products are available on the market. This recommendation is accepted.

The Department is working to establish a stronger and more robust Natural Health Products Program,

including increased oversight in monitoring compliance with good manufacturing practices. In March 2021, the Department implemented a pilot NHP good manufacturing practices inspection program. This pilot included the inspection of 36 manufacturers and importers and concluded in March 2022. The Department is assessing the results of the pilot and planning next steps to implement a permanent risk-based inspection program for natural health products.

Since the audit in 2021, the Department has assessed current capacity and gaps, and has implemented some operational changes to improve the way it regulates the quality of natural health products. However, given the limited extent of the current framework for overseeing quality, the Department is considering further options, which may include regulatory amendments. Health Canada is also using its experience in regulating natural health products during the COVID-19 pandemic to inform current and future practices. For example, the Department has required a demonstration of compliance by hand sanitizer sites to ensure they meet quality requirements before issuing a site license.

The Department has also conducted an industry survey to gather information on marketed natural health products to identify gaps in oversight, and manufacturing site information is now required for most products. Going forward, the Department will develop a multi-year implementation plan, and consider whether regulatory amendments may be required to help obtain information regarding which natural health products are available on the market.

Theme 2: Labelling and Advertising (Recommendation 2 & 4-B)

The Report recommended that Health Canada provide progress reports on ensuring product labels are readable and that there is increased proactive monitoring of labelling and advertising. These recommendations are accepted. A [progress report](#) on recommendation 4 was provided to the Committee on August 31, 2022, and the requested progress reports on recommendation 2 will be provided by the requested dates.

The Department has started to take steps to improve the labelling of natural health products through extensive stakeholder engagement and regulatory amendments to make labels easier to read, understand, and compare with other similar products.

In July 2022, the Department published final regulatory amendments on labelling to the *Natural Health Products Regulations*. The new labelling requirements include a Product Facts table, clearly and prominently displayed label text, labelling of priority food allergens, gluten, added sulphites and aspartame, and use of modernized contact information such as an email address or website instead of a postal address. Health Canada's work to ensure natural health product labels are readable continues, as the Department is also working to complete an analysis on the display format of a standard Canadian label online.

In terms of advertising, the Department has completed a pilot that focused on the proactive monitoring of advertising of natural health products making cancer-related claims. A second pilot will be launched focusing on natural health products making multiple high-risk claims. A plan for the implementation of a comprehensive, risk-based multi-year expansion of proactive monitoring will begin upon completion and evaluation of this latest pilot.

Theme 3: Compliance (Recommendation 3, 4-A, 5 & 6)

The Report recommended that Health Canada provide progress reports on how the Department is developing risk-based activities, including inspections, as part of its compliance and enforcement approach, and is taking appropriate action to remove unlicensed natural health products available for sale to consumers in Canada. The Report also recommended a progress report be provided on how the Department ensures natural health products suspected of causing serious health risk are not on the market. Further, the Report requested that the Department consider the monitoring of NHPs intended for vulnerable sub-populations living with specific health problems, or for which there has been a history of ingredients being substituted, and recommended that the Department review the maximum fines for violations of the *Food and Drugs Act*. These recommendations are accepted. A [progress report](#) on recommendation 4 was provided to the Committee on August 31, 2022, and the requested progress reports on recommendation 3 and 5 will be provided by the requested dates.

Health Canada maintains a complaint-based program for the regulatory compliance oversight of advertising. However, the Department notes that an additional risk-based approach is required to ensure unauthorized advertising activities are prevented or stopped. To date, the Department has developed and launched a tool for monitoring unauthorized natural health product advertising and classifying them based on level of risk. Health Canada is in discussions with another government department to explore a collaborative approach to prevent advertising non-compliance.

The Department is also looking to enhance its oversight of the quality of natural health products and mechanisms to strengthen enforcement to achieve compliance in cases of serious health risks. To do this, the Department recognizes the need to pursue all possible venues to strengthen its ability to deter and address non-compliance. This could include exploring whether the authorities implemented through the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law), can be extended to apply to natural health products under the *Food and Drugs Act*. Doing so would allow the Department to order a recall or compel a label change to a product, and impose tougher fines and penalties.

Conclusion

The government trusts that this response is satisfactory. With what we know about the integral role that natural health products play in helping Canadians care for themselves and their families, we are committed to prioritizing action to ensure that natural health products marketed in Canada meet high thresholds for safety.

Once again, I would like to thank you, Mr. Williamson, and all members of the Standing Committee on Public Accounts for this Report and its recommendations.



Jean-Yves Duclos
Minister of Health