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
K1A 0A6

Dear Mr. Williamson,

On behalf of Health Canada, I am pleased to provide, in both official languages, the final progress reports for recommendations 1, 2, 3, and 5 from the Standing Committee on Public Accounts' Eighteenth Report on Natural Health Products, which was published in June 2022.

The Committee's study of the Commissioner of the Environment and Sustainable Development's 2021 report on natural health products, and corresponding recommendations, were aligned with the Government's ongoing efforts to further strengthen and modernize the natural health products program. Implementing these recommendations will help to ensure that the Canadian population has access to a safe natural health products' marketplace.

I would like to thank the Committee for its thorough examination of these important issues, and I trust that these progress updates are sufficient to satisfy the Committee's request.

Sincerely,

The Honourable Mark Holland

Recommendation 1: Quality

That, by December 31 2023, Health Canada should provide the House of Commons Standing Committee on Public Accounts with a report about A) improving how it verifies that licensed sites follow good manufacturing practices before products are released on the market; and B) obtaining information about which natural health products are available on the market.

Improving how Health Canada verifies that licensed sites follow good manufacturing practices before products are released on the market

As noted in our previous report to the Committee, Health Canada (HC) has made significant progress in enhancing the verification of good manufacturing practices (GMP) compliance for licensed sites producing natural health products. HC initiated a phased approach in 2022, starting with hand sanitizer products during the COVID-19 pandemic, requiring sites to provide evidence of GMP compliance with product submissions.

HC has also taken steps to reduce its reliance on company attestations regarding GMP compliance. This was achieved by clarifying responsibilities of regulated parties through updates to online application forms, stakeholder bulletins, guidance documents, and regulatory letters. Companies are asked to provide detailed GMP and product quality evidence to verify compliance with these clarified quality requirements.

HC is updating two key natural health product guidance documents to further clarify GMP responsibilities and specific quality requirements to meet appropriate standards (such as, purity and contaminants). Early in 2024, these guidance documents will be distributed for consultation with industry stakeholders before they are finalized.

Obtaining information about which natural health products are available on the market

HC has been working to enhance the transparency and accessibility of information related to marketed natural health products in Canada. As stated in its last progress report, HC conducted an analysis to determine the necessary capacity and tools required for these operational improvements. Building on progress made last year, HC has continued its work to further this objective.

In July 2022, HC launched the online Natural Health Products Market Notification

Web Form. This platform enables companies to voluntarily update the market status of their products in the licensed products database. To date, HC has updated the market status of 1848 natural health product numbers in the Licensed Natural Health Products Database, based on market status submissions received through the online web form. This represents less than 13% of all the natural health product numbers issued to-date. HC will continue to encourage companies to notify HC when they market their products through engagement and communication with industry, and may make notification mandatory through a regulatory amendment in the future.

HC's response to the 2021 audit by the Commissioner of the Environment and Sustainable Development (CESD) included the need to seek sustainable and predictable funding through fees charged to industry. Revenues collected through the fees would help strengthen the services HC provides and would enable the Department to have clearer information on which products are marketed. Progress on the Department's expansion of user fees to natural health products are highlighted below under Recommendation 5.

Recommendation 2: Labelling and Advertising

That, by December 31 2023, Health Canada should provide the Committee with a report about implementing a risk-based approach to regulating licensed natural health products on the market, including those available to Canadians through the Internet, to A) ensure that product labels are readable; and B) monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions.

Ensuring that product labels are readable and contain accurate and complete information

Building upon the progress made last year, following the publication of new labelling requirements in July 2022 to make labels easier to read and understand, HC is continuing to work with stakeholders throughout the transition period to support the implementation of the new labelling requirements. The natural health products labelling regulations will come into effect for new products in July 2025 and for existing products on the market in July 2028. These regulatory amendments brought targeted improvements such as:

- the introduction of a standardized Product Facts table that makes information easier to find and compare between products;
- mandatory inclusion of priority food allergens, gluten, added sulphites and

aspartame; and
- the use of modernized manufacturer contact information on product labels.

In the past year, HC also completed an analysis of natural health product labels targeting the Canadian market online. The analysis focused on the display format and representation of natural health products at online point-of-sale, including the presentation of the natural health product number (i.e., NPN), which confirms that the product was authorized by HC. As Health Canada works to expand the proactive monitoring of advertising, consideration will be given on how to similarly monitor online labelling to ensure consumers have access to the same level of detail and information online as they have on physical labels.

Advertising of natural health products

In the past year, HC made important strides in improving the oversight of natural health product advertising by successfully launching a pilot project that used artificial intelligence to monitor advertising related to natural health products claiming to treat cancer. This proactive monitoring resulted in a significant increase in the number of non-compliant advertising incidents compared to HC's complaint-based reactive approach. HC also introduced a prioritization tool to classify advertising incidents based on level of risk, that enables the department to focus on high risk non-compliant advertising that could potentially pose a significant risk to the health and safety of Canadians.

HC initiated a second pilot this year to proactively monitor the advertising of natural health products making high-risk claims related to obesity and mental health, including depression and acute anxiety – claims which are not presently allowed for authorized products. A final review of the pilot results is currently underway.

The lessons learned from both pilots will be leveraged to develop a multi-year implementation plan for natural health product advertising oversight. The anticipated outcomes of this oversight is a reduction in non-compliant advertising incidents, to help ensure that Canadians receive accurate information about the natural health products on the market.

Recommendation 3: Compliance

That, by December 31 2023, Health Canada should provide the Committee with a report about implementing a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to natural health products, sites, and problems raised from its follow-up activities, including for natural health

products intended for vulnerable populations living with specific health problems or for which there has been a history of ingredients being substituted.

Implementation of a risk-based monitoring and inspection program

As stated in the department's previous report to the Committee, from April 2021 to March 2022, HC piloted a risk-based inspection program to assess industry compliance with all applicable GMP requirements and to help prevent non-compliance with GMPs. The pilot focused on facilities with either a high number of natural health products or natural health products aimed at vulnerable sub-populations, such as children and pregnant women. During the pilot, 36 natural health product sites across Canada were inspected (representing approximately 4% of Canadian site licence holders), with 42% of them (15 sites) found to be non-compliant.

The results of the pilot are informing the development of a permanent risk-based inspection program, which will take factors, such as site information and compliance history, into account when determining which sites to inspect and how frequently to inspect them. A stakeholder engagement session about the pilot inspection program was held in October 2022, and positive feedback was received, demonstrating the natural health product industry's commitment to safety and regulatory compliance.

Building on last year's progress, HC published an evaluation report of the pilot inspection program in February 2023. This report highlighted the need for strengthened regulatory oversight of the natural health product industry, as well as the need for increased compliance promotion activities. Based on the success of the pilot and feedback received from industry, HC continues to maintain interim risk-based inspection activities to ensure that sites conducting higher risk activities such as manufacturing, packaging/labelling and importation are inspected and remain compliant with natural health product GMPs. Since the pilot, Health Canada has completed approximately 80 inspections of natural health product sites. During the 2024-2025 fiscal year, Health Canada is projecting to complete up to 90 additional inspections.

Going forward, HC is committed to maintaining this interim risk-based inspection program, while developing the necessary infrastructure for a permanent program. However, the ramp up and sustainability of a permanent natural health product inspection program is contingent on funding through fees charged to industry via the implementation of a cost recovery framework, which, as noted above, is currently in the consultation phase.

Recommendation 5: Compliance

That, by December 31 2022, Health Canada should provide the Committee with a report about obtaining the information it needs to ensure that natural health products suspected of causing serious health risk are not available for sale to consumers in Canada.

Extending the use of Vanessa's Law authorities to natural health products

In HC's response to the 2021 CESD audit, it was acknowledged that some actions would require legislative and regulatory changes to provide HC with the tools to strengthen post-market oversight for natural health products and address serious risks to health.

In June 2023, the Government of Canada passed legislation that amended the *Food and Drugs Act* (the Act) by extending the authorities under the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) to natural health products. This allows HC to take assertive action if a serious or imminent risk to health is identified with a natural health product. For example, this legislation allows HC to order a recall of a product or add warnings to labels to support its safe use, if necessary. These actions could not be done prior to amending the Act. The new authorities would be used only if a serious risk to health is identified and if a company refuses to cooperate with voluntary measures.

While natural health products are considered lower-risk, it does not mean they are without risk. The application of Vanessa's Law will provide HC with stronger tools to manage serious health and safety risks should they arise, consistent with all other health products.

Expansion of user fees to natural health products

As stated in its previous report to the Committee and under Recommendation 1, HC is exploring proposed fees for industry to partially fund the natural health products program to create an even safer marketplace for consumers. It is important to note that natural health products are the only health products for which all regulatory activities are funded by taxpayers.

Over the past year, HC has made significant progress to advance the expansion of user fees to natural health products. In May 2023, HC published its fee proposal for consultation, which included fee mitigation measures to minimize the impact of fees on qualifying small businesses. HC held technical briefings and discussions with key industry stakeholders, focusing both on the general framework of the proposal as

well as the specifics of the costing methodology. Since that time, over 4,700 comments have been received on the fee proposal, with many raising concerns about impact on small businesses.

At this time, HC is adjusting its fee proposal to mitigate impacts on the industry including small businesses. HC will continue active dialogue with stakeholders as it considers how best to address concerns raised by industry during the consultations.