Minister of Health | Ministre de la Santé

Ottawa, Canada K1A 0K9

December 31, 2022

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

Dear Mr. Williamson,

I would like to begin by again thanking you and the Standing Committee on Public Accounts for undertaking a study of the Commissioner of the Environment and Sustainable Development's audit of Health Canada's regulation of natural health products, and for releasing the report titled "Report 18 – Natural Health Products". The recommendations prepared by the Committee are comprehensive and complement our efforts to modernize the program to better protect Canadians' health and safety.

I am pleased to provide you with the progress updates requested by the Committee on Recommendations 1, 2, 3, and 5.

Sincerely,

The Honourable Jean-Yves Duclos

Response to the Standing Committee on Public Accounts'
Eighteenth Report, Natural Health Products, of the Spring 2021 Report 2, Natural Health Products – Health Canada, of the Commissioner of Environment and Sustainable Development

Theme 1 – Quality (Recommendation 1)

Recommendation 1

That, by December 31 2022, 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.

Background

On the issue of improving the verification of manufacturing facilities and market availability, the 2021 Audit recommended that Health Canada should obtain sufficient evidence to verify that licensed sites follow good manufacturing practices before products are released on the market, and that Health Canada should obtain information about which natural health products are available on the market.

Health Canada agreed with the recommendation, and in its 2021 Management Response and Action Plan, committed to establishing fully costed options for a risk-based approach to quality oversight prior to the issuance or renewal of licenses and determine the full regulatory and operational implications of these options. It also committed to explore mechanisms to obtain information about which products are available on the market, and to take steps to propose user fees to natural health products to offset the costs of licensing and post-market activities.

Progress Report

Following the 2021 Audit, Health Canada has been working diligently to establish a stronger and more robust Natural Health Products Program.

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

The Department has taken steps to adjust the information it collects related to quality. As a first phase, Health Canada has introduced requirements for companies

producing hand sanitizers to provide evidence that they are following Good Manufacturing Practices as part of their submission. This information, coupled with an assessment of the gaps in the review of product quality, has informed the development of a multi-year implementation plan to further strengthen quality oversight to ensure that natural health products are properly made.

The Department has moved forward with implementing operational changes to reduce reliance on company attestations that they meet quality requirements by clarifying industry's responsibility in meeting Good Manufacturing Practices. These clarifications were made by updating online application forms, sharing stakeholder bulletins, publishing updated guidance documents and sending regulatory letters to industry to highlight process requirements. The Department is also requesting that companies provide necessary site information to ensure that quality requirements are met. In addition, there has been an update to the natural health product site license applications for companies who also have approved Drug Establishment Licenses as evidence to support their Good Manufacturing Practices compliance. As noted in the Department response to the audit, in order to fully address quality oversight for natural health products, regulatory amendments to the current regulatory framework will also be required.

Obtaining information about marketed natural health products

Health Canada has taken steps to improve available information on which natural health products are currently marketed in Canada. The Department conducted an assessment of the capacity and tools required to inform operational improvements. These improvements include completing a survey in Spring 2022 to gather baseline information on which products are marketed, and making that information available online in our public-facing product database. The Department is also now requesting that companies indicate whether a product will be marketed following authorization. In July 2022, Health Canada also launched an online form to enable companies to voluntarily update their product's market status.

Theme 2 - Labelling & Advertising (Recommendation 2)

Recommendation 2

That, by December 31 2022, 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.

Background

The 2021 Audit recommended that Health Canada should, for licensed natural health products on the market, including on the internet, take a risk-based approach to ensure that product labels are readable, and monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their licence conditions.

In its response to the Audit, Health Canada agreed with the recommendation and highlighted work already underway to improve the labelling of natural health products, including the development of a regulatory proposal and extensive stakeholder engagement. In its Management Response and Action Plan, the Department committed to continue to pursue regulatory and policy changes to improve labelling for natural health products, and to take steps to complete an analysis of the display format of a Canadian label online to identify recommended options and a critical path forward. It will also take steps to implement a comprehensive proactive monitoring strategy to ensure that advertising of natural health products is consistent with the product licence.

Progress Report

Labelling of natural health products

Since the Audit, the Department has consulted with stakeholders to make important progress to improve the labelling of natural health products. In July 2022, Health Canada published final regulatory amendments to improve natural health product labelling in *Canada Gazette*, Part II.

These amendments introduce new requirements for the labelling of natural health

products in Canada, making labels easier to read, understand, and compare with other similar products. 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 has also published new guidance to help industry comply with the new labelling requirements.

Health Canada's work to ensure natural health products label information is presented in a clear, consistent and legible format continues. The Department is on track to complete an analysis of the display format of a Canadian label online in 2022.

Advertising of natural health products

In June 2021, Health Canada implemented a first pilot to explore the feasibility of using an artificial intelligence tool to support proactive monitoring of the natural health product advertising environment. The approach focused on natural health products making cancer related claims. The proactive monitoring pilot was carried out over a six-month period and led Health Canada to confirm non-compliant advertising incidents involving 1,958 natural health products. This represents a significant increase compared to the number of incidents identified through a complaint-based approach.

In September 2021, Health Canada launched a risk prioritization tool, which classifies advertising incidents based on the level of risk. The tool assigns a level of priority to each advertising incident received under a complaint-based advertising oversight program and provides guidance on whether an incident is deemed low, medium or high risk. Using an alpha grading system, several regulatory criteria have been established to generate a letter grade for each advertising incident, which in turn establishes the corresponding intervention. This shift ensures that the Department focuses on high priority advertising incidents that can potentially pose a significant risk to the health and safety of Canadians.

The Department has recently launched a second pilot to expand the proactive monitoring program to target other potentially high-risk natural health product advertisements. It will proactively monitor the online marketplace for advertisements of natural health products making claims for two targeted high-risk categories: obesity, and a combination of depression and anxiety. These two categories have been identified as the most relevant targets for the second pilot following

consultation with internal and external partners and stakeholders.

Following the second pilot, the Department will evaluate lessons learned to determine the next steps to implement an expanded proactive monitoring of natural health products. A plan for the implementation of a comprehensive, risk-based multi-year expansion of proactive monitoring will be developed.

Theme 3 – Compliance (Recommendation 3 and 5)

Recommendation 3

That, by December 31 2022, 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.

Background

The Audit recommended that Health Canada develop a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risk related to products, sites and problems raised from its follow-up activities.

Health Canada agreed with this recommendation and highlighted that it had completed a number of compliance monitoring projects to gather information on quality oversight of natural health products, but recognized the need to expand its activities into a more robust inspection program. As such, Health Canada committed to implementing a pilot natural health product Good Manufacturing Practices inspection program to promote and verify compliance of the natural health product industry through inspections of site licence holders across Canada, and take further actions based on the outcome of this pilot. The Department also recognized the need to establish fully costed options for a risk-based approach to inspections.

Furthermore, the Department affirmed its intention to take steps towards extending the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) to natural health

products, and proposing the expansion of fees to natural health products. Progress on Vanessa's Law amendments and the implementation of fees are included under recommendation 5 of this report (see following section).

In the Department's 2021 Management Response and Action Plan, specific actions and initiatives were outlined to address this recommendation. This included launching a pilot risk-based inspection program in March 2021, and determining the next steps for establishing a permanent program by April 2023.

Progress Report

Pilot Natural Health Products Good Manufacturing Practices Inspection Program

Between March 2021 and March 2022, the Department conducted a pilot inspection program for natural health products. The objectives of the pilot were to promote and verify industry compliance with all applicable natural health product Good Manufacturing Practices requirements. The pilot was also used to collect data to inform the development of a permanent inspection program, and to signal to stakeholders the Department's intent to move forward with a risk-based inspection program for natural health products. Sites were chosen for inspections using risk-based criteria, including the activities the sites perform, focusing on importing and manufacturing, compliance history, and the type and number of products they handle.

The Department notes, and supports, PACP's emphasis on incorporating consideration of natural health products intended for vulnerable populations, such as children and individuals who are pregnant or breastfeeding, as a risk factor when establishing risk-based approaches to monitoring and inspections. These target populations were part of the risk-based criteria used by inspectors when selecting a representative sample of natural health products for review during the pilot inspections. In total 36 sites were inspected, representing approximately 4% of Canadian site licence holders at that time. The pilot was completed in March 2022 and found 15 sites (42%) to be non-compliant. The main objectives for the pilot were met based on an internal assessment of the pilot and feedback received from the industry.

The results of the pilot inspection program support the need to improve industry compliance with natural health products regulatory requirements. The Department recognizes that more resources are needed for risk-based monitoring and inspection activities to become permanent and cover an appropriate portion of the

natural health products industry.

The Department is currently developing a plan to implement a permanent risk-based Good Manufacturing Practices inspection program for natural health products. Data collected during the pilot is important in this process, including real time information on how long inspections take, training requirements, quality system requirements, and the use of remote and in-person inspections. A permanent program would be established drawing on the experience from the pilot. Sites would be chosen for inspections using a risk-based approach that would include an assessment of available information such as site information (e.g., licensable activities conducted) and compliance history.

Health Canada held a stakeholder consultation in October 2022 with key natural health product industry association groups to communicate the results of the pilot, discuss next steps for the natural health product inspection program, and consult on communications strategies and training needs in advance of implementation of a permanent program. The session was well received by all stakeholders.

Recommendation 5

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.

Background

The Audit recommended that Health Canada should, in cases of products suspected of causing serious health risk, obtain the information it needs to verify and ensure that these products are not available for sale to consumers in Canada.

In response, Health Canada recognized that an additional risk-based approach is required to ensure unauthorized activities are prevented or stopped. The Department acknowledged the need to pursue all possible venues to strengthen its ability to deter and address non-compliance, including by exploring whether the post-market authorities implemented through Vanessa's Law can be extended to natural health products. The Department further highlighted the importance of taking steps to propose the expansion of user fees to natural health products to offset the costs of post-market activities.

Progress Report

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

In its response to the audit, Health Canada is taking steps to strengthen its monitoring, compliance and enforcement authorities to deter and to address non-compliance. This could include, for example, extending authorities provided by the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) to natural health products. These authorities have been in place since 2014 for all other categories of health products regulated by Health Canada, and would better enable the Department to take action when significant health or safety risks are identified, such as mandating a recall of unsafe products or compelling a label change, and imposing tougher fines and penalties. The Department has been working diligently to advance this proposal.

Expansion of user fees to natural health products

Charging fees to industry for regulatory services provided for natural health products remains a key priority to offset the additional costs of enhanced licensing and post-market activities. Natural health products are the only line of health products for which regulatory activities are fully funded by taxpayers, despite the private benefits industry derives from these activities (e.g., approval to sell their products on the Canadian market). Revenues from fees would support pre- and post-market regulatory activities and help fund many of the measures needed to respond properly to the audit. This would in turn help ensure the health and safety of Canadians while providing a more robust, reliable and predictable regulatory framework to the natural health product industry.

Since the Audit, Health Canada has engaged with industry and signaled that the Department is exploring the possibility of implementing fees for natural health products, in line with the types of fees charged for the regulation of other health products. This includes fees for the scientific review of products before marketing authorization, the review of site licences, and annual fees to maintain the right to sell products in Canada.

Conclusion

I would like to reiterate that we at Health Canada are strongly committed to improving the oversight of natural health products and to addressing the health and safety risks identified in the Commissioner of the Environment and Sustainable Development's audit and the Standing Committee of Public Account's report.

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.