HEALTH CANADA MANAGEMENT RESPONSE AND ACTION PLAN (MRAP)

In response to the recommendations of the Natural Health Product Program
of the Spring 2021 Report of the Commissioner of the Environment and Sustainable Development to the Parliament of Canada

Note: The MRAP has certain dependencies on undertaking legislative and/or regulatory changes. In recognition of these dependencies, the key milestones have been divided into two parts to reflect milestones that fall within and outside the existing NHP program's framework. Actions listed as within the existing framework would not require legislative and/or regulatory changes to implement.

Report Ref. No.	OAG Recommendation	Departmental Response	Description of Final Expected Outcome/Result	Expected Final Completion Date	Key Interim Milestones (Description/Dates)	Responsible Organization/ Point of Contact (Name, Position, Tel #)	*Indicator of Achievement* (For Committee Use Only)
Para 24	Health Canada should obtain • Sufficient evidence to verify that licensed sites followed GMPs before products were released on the market. • Information about which NHPs are available on the market.	Agreed. Health Canada notes its limited regulatory authorities to compel companies to provide information on quality as part of the product license submission process. Applicants are only required to provide an attestation that their product will meet the prescribed quality requirements. To improve its pre-market quality oversight of NHPs, the Department has been using information gathered through two Compliance Monitoring Projects and a paper-based audit of Good Manufacturing Practices (GMP) at a number of manufacturing sites. The Department also acknowledges that NHPs are the only line of health products for which all regulatory activities are funded by the public. The absence of a stable funding framework combined with the limited regulatory authorities for quality has placed significant pressure on the Department to perform its regulatory activities and efficiently respond to the increasingly high number and scientific complexity of product submissions. In response to this recommendation, Health Canada will: • Establish 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; • Explore mechanisms to obtain information about which products are available on the market; and • Take steps to propose user fees to NHPs to offset the costs of licensing and post-market activities.	Health Canada has appropriate requirements in place to ensure oversight of quality prior to the issuance or renewal of licences, which includes information about which NHPs are available on the Canadian market.	November 2024 for improved quality oversight (if regulatory change is advanced as part of the approved recommendation(s))	**<u>Within existing framework</u>** Assess the capacity and tools required in the pre-market functions associated with quality review to effectively deliver mandated program activities, identify gaps, and develop an options analysis report with recommendations, which are expected to include proposed regulatory amendments. (January 2022) Based on the approved recommendation(s), develop a multi-year implementation plan, to improve the pre-market oversight of the quality of NHPs. (September 2022) Signal to industry the Department's intention to implement fees for NHPs to provide stable funding for key regulatory activities and develop a fee proposal for consultation (October 2021) Consult on a cost recovery proposal (April 2022) Amend the Fees Order to include NHPs (October 2023). **<u>Outside existing framework</u>** Dependent on the approved recommendation(s), seek regulatory amendments to improve the oversight of the quality of NHPs (Timelines will be based on the implementation plan)	Natalie Page, Director General, NNHPD, HPFB (quality) Etienne Ouimette, Director General, RMOD, HPFB (fees)	

Para 33	Health Canada should, for licensed natural health products on the market, including the internet, take a risk-based approach to: • ensure that product labels are readable • monitor product label and advertisement information to ensure that they contain accurate and complete product information, consistent with their license conditions	Agreed. The department has started to take steps through extensive stakeholder engagement and the development of a regulatory proposal to improve the labelling of NHPs, to make them easier to read, understand and compare with other similar products. Health Canada will: • Continue to pursue regulatory and policy changes to improve labelling of NHPs; • Explore options to require licence holders to display a Canadian label, including an NPN, in advertisements targeted to Canadians; • Take steps to implement a comprehensive proactive monitoring strategy to ensure that labels and advertising of NHPs are consistent with the product licence.	Health Canada has a regulatory framework in place to ensure clear labelling of NHPs. Health Canada has implemented proactive monitoring of labelling and advertising information of NHPs to ensure information is consistent with licensing conditions.	June 2022 for improved labelling in Canada Gazette Part II; October 2022 to implement proactive monitoring of NHP advertising	**<u>Within existing framework</u>** Pilot an approach, analyze the pilot and develop a multi-year implementation plan to expand proactive monitoring of advertising to NHPs, including full costing and the identification of Artificial Intelligence tools needed for the expanded approach (February 2022) Conduct a feasibility study to expand proactive monitoring oversight to online monitoring of NHP labels (June 2022) Begin implementation of the approved approach for the expansion of proactive monitoring of advertising of NHPs (October 2022) Complete an analysis on the display format of a Canadian label online, including presentation of the NPN, to identify recommended options and a critical path forward (December 2022) Evaluate lessons learned to determine feasibility of expanded proactive monitoring of NHPs and make necessary modifications as per an internal proactive monitoring process review (September 2023) **<u>Outside existing framework</u>** Publish proposed amendments to the Natural Health Products Regulations (NHPR) in Canada Gazette I to improve the labelling of NHPs with a product facts table and minimum font size, for formal consultation (targeting June 2021) Dependent on the above, publish final regulatory amendments to the NHPR in Canada Gazette II to improve the labelling of NHPs (targeting June 2022)	Kelly Robinson, Director General MHPD, HPFB (monitoring) Natalie Page, Director General, NNHPD, HPFB (labelling)	
Para 45	Health Canada should develop a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to	Agreed. Health Canada recognizes that NHPs are the only line of health products for which there is no ability to mandate a recall or to impose terms and conditions to mitigate safety risks associated with these products. The Department has completed a number	Health Canada has an effective risk-based approach to monitoring and inspection to manage the post market	April 2023 for risk-based monitoring plan; November 2022 for Vanessa Law powers	**<u>Within existing framework</u>** Launch a pilot NHP GMP inspection program (March 2021)	Linsey Hollett, Director General, HPCD, ROEB (inspection)	

	products, sites and problems raised from its follow-up activities.	compliance monitoring projects to gather information on quality oversight of NHPs and recognizes the need to expand its activities into a more robust inspection program. Health Canada will: • Implement a pilot NHP Good Manufacturing Practices (GMP) inspection program to promote and verify compliance of the NHP industry through inspections of licence holders across Canada, and take further actions based on the outcome of this pilot; • Take steps to propose new tools to strengthen Health Canada's ability to deter and address non-compliance which include moving forward with a proposal to extend the use of Vanessa's Law powers to NHPs; • Establish fully costed options for a risk-based approach to inspections; and • Take steps to propose the expansion of user fees to NHPs to offset the costs of post-market activities.	risks related to products and sites		Assess the results of the pilot and identify options for a risk-based NHP inspection program, which includes full costing (April 2022) Complete consultations with stakeholders on a recommendation for a future risk-based NHP inspection program (August 2022) See interim milestones for recommendation 24 regarding fees Based on the approved recommendation(s) and existing resources, determine next steps to implement an effective risk-based approach to monitoring compliance and inspections (April 2023) **<u>Outside existing framework</u>** Seek authority to introduce legislative amendments to the *Food and Drugs Act* with a view to expand the Vanessa's Law powers to NHPs (October 2021) Dependent on obtaining authority, consult stakeholders on the policy and implementation to extend the use of Vanessa's Law powers to NHPs (January 2022) Dependent on obtaining authority, start to develop regulations to extend the full suite of Vanessa's Law authorities to NHPs (November 2022)	Natalie Page, Director General, NNHPD, HPFB (Vanessa Law)	
Para 49	Health Canada should develop a risk-based monitoring program to: • Identify unlicensed products and take appropriate action so that they are not available for sale to consumers in Canada • Identify unauthorized activities and take appropriate action so that advertisements meet product license conditions	Agreed. Health Canada does maintain a complaint-based program for regulatory advertising compliance oversight but recognizes that an additional risk-based approach is required to ensure unauthorized activities are prevented and/or stopped. Health Canada will: • Implement a risk-based approach to monitoring of advertising; and • Take 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 NHPs.	Health Canada has a comprehensive risk-based approach applied to NHP advertising incidents	January 2022 for risk-based monitoring of advertising; November 2022 for Vanessa's Law powers	**<u>Within existing framework</u>** Develop and launch a risk-based approach for monitoring NHP advertising incidents, via a tool which will classify advertising incidents based on level of risk (January 2022) Assess the feasibility of partnering with other government departments (OGDs) to address non-compliance in NHP advertising. This will also include the development of costing assumptions (January 2022) Subject to approval, implement a collaboration approach jointly with OGDs and	Kelly Robinson, Director General MHPD, HPFB (monitoring)	

					the Department to allow OGDs to use existing enforcement powers for serious non-compliance incidents in advertising of NHPs (April 2022) **<u>Outside existing framework</u>** See interim milestones for recommendation 45 regarding Vanessa's Law	Natalie Page, Director General, NNHPD, HPFB (Vanessa Law)	
Para 54	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	Agreed. In addition to the immediate steps Health Canada already takes to protect the health and safety of Canadians when a serious risk to health is identified, Health Canada will: • Take 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 NHPs; and • Take steps to propose the expansion of user fees to NHPs to offset the costs of licensing and post-market activities.	Health Canada has strengthened tools to, in cases of products suspected of causing serious health risk, obtain information and ensure the products are not available to consumers.	November 2022 for Vanessa's Law powers	**<u>Within existing framework</u>** See interim milestones for recommendation 24 regarding fees **<u>Outside existing framework</u>** See interim milestones for recommendation 45 regarding Vanessa's Law	Etienne Ouimette, Director General, RMOD, HPFB (fees) Natalie Page, Director General, NNHPD, HPFB (Vanessa Law)	