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## **Management Response and Action Plan**

### **Audit of the Management of the Natural Health Products Program**

**June 2015**

**Canada**

**Management Response and Action Plan**  
**Audit of the Management of the Natural Health Products Program**  
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| Recommendations   | Management Response and Planned Management Action   | Deliverables   | Expected Completion Date | Responsibility  |
|---|---|--|--------------------------|---|
| <p><b>Recommendation 1</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a program risk profile with mitigating strategies and performance measures, to track the effectiveness of the mitigating actions.</i></p> | Management agrees with the recommendation and will build on the Corporate Risk Profile to enhance its capacity to conduct program risk analysis.  |  |                          |   |
|   | <p>HPFB will develop a Natural Health Products (NHP) Program risk register, in consultation with the Regions and Programs Bureau (RAPB).</p> <p>Building on the departmental Performance Measurement Initiative, indicators will also be developed to assess the effectiveness of the mitigating actions.</p> | <p>Develop a program risk register with appropriate performance measures to assess mitigation actions.</p> | <p>June 30, 2016</p>     | <p>Resource Management and Operations Directorate (RMOD)/Natural and Non-prescription Health Products Directorate (NNHPD)</p> |
| <p><b>Recommendation 2</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, implement an enhanced verification of good manufacturing practices as part of the site licensing model for natural health products.</i></p>       | Management agrees with the recommendation to enhance its good manufacturing practices (GMP) requirements for NHPs.  |  |                          |   |

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|   | Health Canada consulted on a revised approach to site licensing, including a small pilot project to evaluate the feasibility and effectiveness of using third parties for assessing the GMP compliance status of NHP sites. Results of the pilot are being analyzed and will inform the next steps of the site licensing project.   | Develop a formal approach to enhance GMP verification, applying the lessons learned from the pilot. | June 30, 2016            | NNHPD/HPFB Inspectorate                    |
| <p><b>Recommendation 3</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, with support from the Assistant Deputy Minister, Corporate Services Branch, enhance the cross-reference of product licences to site licences.</i></p> | Management agrees with the recommendation and will further enhance and streamline the NHP application process as part of its Investment Plan proposals.   |   |                          |  |
|   | There is value in cross-referencing product and site licence information. The Branch Investment Plan renewal is part of a longer-term technology strategy and solution to address overall program requirements. In that regard, the NHP Program will consult on an approach that strengthens the link between product and site licences and will develop a business case for the NHP Program IT Renewal and Transformation project. | Consult on an approach that strengthens the link between product and site licences.                 | September 30, 2015       | RMOD/Corporate Services Branch (CSB)/NNHPD |
|   |   | Develop a business case for the NNHPP IT Renewal and Transformation project.                        | December 31, 2015        | RMOD/ CSB/ NNHPD                           |

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| <p><b>Recommendation 4</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, in consultation with the A/Senior Director General, Regions and Programs Bureau, strengthen the targeted approach for compliance promotion and monitoring.</i></p>  | Management agrees with the recommendation regarding a review of its approach and oversight of NHPs.  |   |                          |  |
|   | In line with the Inspectorate's <i>Natural Health Products Compliance and Enforcement Policy</i> (POL-0044), the branch (in consultation with the RAPB) will strengthen its approach for compliance promotion and monitoring by shifting to more targeted, proactive activities. The approach will be informed by an increased capacity for trending and monitoring. | Launch a proactive compliance monitoring project for NHPs that will include a compliance promotion component. | September 30, 2015       | Inspectorate/<br>Regions and Programs Bureau (RAPB)              |
|   |  | Electronically post Summary report upon completion of the project.  | March 31, 2016           | Inspectorate/RAPB  |
|   | As well, the branch has implemented a Central Intake and Triage Pilot Project, with an objective of consistent risk-based prioritization of complaints and incidents. The pilot will be evaluated to assess its effectiveness as a model.  | Complete an evaluation report on the central intake and triage pilot project.                                 | December 31, 2015        | Inspectorate   |
| <p><b>Recommendation 5</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, in consultation with the Assistant Deputy Minister, Communications and Public Affairs Branch, develop an outreach strategy with appropriate performance measures, to improve communications on natural health products.</i></p> | Management agrees with the recommendation to strengthen its communications on NHPs and will build on the Departmental Regulatory Transparency and Openness Framework and on the Government of Canada's Open Government Action Plan.  |   |                          |  |
|   | The program currently engages in a number of independent outreach activities. These efforts will be consolidated and formalized into an outreach strategy developed with the support of CPAB.  | Finalize an Outreach strategy.  | November 30, 2015        | NNHPD with support from Communications and Public Affairs Branch |
|   | HPFB will publish information on advertising complaints for both authorized and unauthorized products (including NHPs).  | Update and post the table of advertising complaints on a quarterly basis.                                     | October 31, 2015         | Marketed Health Products Directorate/<br>Inspectorate            |

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|   | As described in the <i>Natural Health Products Compliance and Enforcement Policy</i> (POL-0044), the Inspectorate is shifting to a more proactive approach to generating and monitoring compliance, including the following outreach activities:   |  |                          |                |
|   | <ul style="list-style-type: none"> <li>• A proactive compliance monitoring project for NHPs that will include a compliance promotion component.</li> </ul>   | Electronically post Summary report.  | March 31, 2016           | Inspectorate   |
|   | <ul style="list-style-type: none"> <li>• The development of compliance promotion material, including a document that will communicate the potential risks of buying NHPs online.</li> </ul>  | Electronically post document on the risks of buying NHPs online.                 | November 30, 2015        | Inspectorate   |
| <b>Recommendation 6</b>   | Management agrees with the recommendation to strengthen its performance measurement framework.   |  |                          |                |
| <i>It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a performance management framework to support program objectives.</i> | <p>HPFB has commenced a mapping exercise of its performance measures, indicators and commitments within the departmental Program Activity Architecture and Performance Measurement Framework structure.</p> <p>This work, which will be conducted in consultation with the RAPB, supports the departmental Performance Measurement Initiative in the development of program strategies that would include a more comprehensive suite of both outcome and output measures, to provide a better management tool.</p> | Complete a gap analysis.   | November 30, 2015        | RMOD           |
|   |  | Complete a plan for the development of program performance measurement strategy. | March 31, 2016           | RMOD           |