



Health Canada and the Public  
Health Agency of Canada

Santé Canada et l'Agence  
de la santé publique du Canada

# **Evaluation of the Natural Health Products Program 2010-2011 to 2014-2015**

Prepared by  
Office of Audit and Evaluation  
Health Canada and the Public Health Agency of Canada

**March 2016**

## **List of Acronyms**

FTE	Full Time Equivalent
HPFB	Health Products and Food Branch
HPFBI	Health Products and Food Branch Inspectorate
MHPD	Marketed Health Products Directorate
NHPP	Natural Health Products Program
NNHPD	Natural and Non-prescription Health Products Directorate
NPN	Natural Product Number
O&M	Operations and Maintenance
RAPB	Regions and Programs Bureau

## Table of Contents

Executive Summary .....	ii
Management Response and Action Plan.....	vii
1.0 Evaluation Purpose .....	1
2.0 Program Description .....	1
2.1 Program Context .....	1
2.2 Program Profile.....	3
2.3 Program Narrative.....	4
2.4 Program Alignment and Resources.....	5
3.0 Evaluation Description.....	6
3.1 Evaluation Scope, Approach and Design.....	6
3.2 Limitations and Mitigation Strategies.....	9
4.0 Findings.....	9
4.1 Relevance: Issue #1 – Continued Need for the Program .....	9
4.2 Relevance: Issue #2 – Alignment with Government Priorities .....	13
4.3 Relevance: Issue #3 – Alignment with Federal Roles and Responsibilities .....	15
4.4 Performance: Issue #4 – Achievement of Expected Outcomes (Effectiveness) .....	17
4.5 Performance: Issue #5 – Demonstration of Economy and Efficiency .....	41
5.0 Conclusions.....	48
5.1 Relevance Conclusions .....	48
5.2 Performance Conclusions .....	49
6.0 Recommendations.....	50
Appendix 1 — Natural Health Products Program Logic Model.....	52
Appendix 2 – Policy and Guidance Documents .....	53
Appendix 3 – Summary of Findings.....	54

### List of Tables

Table 1: Roles and responsibilities of NHPP partners .....	4
Table 2: Program resources (\$).....	5
Table 3: Core Evaluation Issues and Questions.....	7
Table 4: Limitations and Mitigation Strategies.....	9
Table 5: Attestation Audits Results .....	24
Table 6: Domestic Natural Health Product Adverse Reaction Reports Received .....	29
Table 7: MHPD risk assessment activities.....	30
Table 8: Number of incidents and recall actions taken on natural health products - 2010-2015 .....	32
Table 9: Border Integrity .....	33
Table 10: Natural Health Products – Advertising complaints received and actions taken .....	34
Table 11: Natural Health Product Risk Communications Posted on the MedEffect Canada/Healthy Canadians Website by MHPD.....	34
Table 12: Number of Licences Cancelled or Suspended .....	35
Table 13: Variance Between Planned Spending vs Actual Expenditures for NNHPD - 2010-2011 and 2014-2015 .....	42
Table 14: Variance Between Planned Spending vs Actual Expenditures for MHPD - 2010-2011 and 2014-2015 .....	43
Table 15: Variance Between Planned Spending vs Actual Expenditures for HPFBI - 2010-2011 and 2014-2015 .....	43
Table 16: Variance Between Planned Spending vs Actual Expenditures for RAPB - 2010-2011 and 2014-2015 .....	44
Table 17: Number of FTE working on natural health products per directorate* .....	44

## Executive Summary

This evaluation of Health Canada's Natural Health Products Program (NHPP) covered the period from April 2010 to March 2015 and was undertaken in fulfillment of the Treasury Board of Canada's *Policy on Evaluation* (2009).

### Evaluation Purpose and Scope

The purpose of the evaluation was to assess the relevance and performance of the NHPP and included all the activities undertaken by the NHPP. The Natural Health Products Program is carried out by three key groups within Health Canada's Health Products and Food Branch (HPFB), specifically the Natural and Non-prescription Health Products Directorate (NNHPD), the Marketed Health Products Directorate (MHPD) and the Health Products and Food Branch Inspectorate (HPFBI), as well as the Regions and Programs Bureau (RAPB) of Health Canada. The activities carried out by these groups include the implementation of the regulations, conducting pre-market activities such as risk-benefit assessments, post-market safety surveillance, risk communications and regulatory oversight of advertising, compliance and enforcement activities, and laboratory analysis. A number of areas, specifically risk management, governance, and performance measurement, were not fully explored in the evaluation, as they were addressed in a recent (2015) Internal Audit of the NHPP.

### Program Description

The Natural Health Products Program aims to ensure that Canadians have access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity. The Program's main target audiences are the natural health products industry and Canadians. To achieve its objectives, the NHPP carries out the following activities:

- developing, implementing and reviewing the Natural Health Products Regulatory Framework;
- coordinating, collaborating and implementing outreach with stakeholders and partners, including international partners to improve decision-making processes and to share Canadian regulatory knowledge and practices;
- conducting pre-market activities such as benefit-risk assessments of applications for licensing and approval – includes reviewing product and site licence applications; and
- conducting post-market surveillance, benefit-risk assessments, safety monitoring, compliance and enforcement activities including laboratory analysis, oversight of advertising and border activities.

## CONCLUSIONS - RELEVANCE

### Continued Need

Our analysis indicates that there continues to be a need for activities such as those delivered through the Natural Health Product Program to address the increasing use, availability and complexity of natural health products, especially when combined with the various risks that could arise from their potential improper use (e.g., interactions with other medications, self-prescribing without consulting a medical professional) and manufacturing issues that could pose a health risk to Canadians.

### Alignment with Government Priorities

Program activities are aligned with the federal government's priority to protect the health and safety of Canadians by regulating various health products, including natural health products. This commitment is reflected in a variety of Government of Canada and Departmental documents such as Speeches from the Throne, Corporate Risk Profiles, and Operational and Strategic Plans.

### Alignment with Federal Roles and Responsibilities

A clear federal role pertaining to natural health products has been established in a variety of acts and legislation such as the *Department of Health Act*, the *Food and Drugs Act* and the *Natural Health Products Regulations*. Overall, roles and responsibilities between the federal government and other jurisdictions were quite clear and very few gaps were identified.

## CONCLUSIONS – PERFORMANCE

### Achievement of Expected Outcomes (Effectiveness)

To date, the program has made progress in achieving some of its key outcomes; however, some areas require further attention.

Health Canada has been able to adapt to the changing environment by adjusting its administration of the Natural Health Products Regulatory Framework through measures such as developing a product licensing system that links review times for submissions to level of certainty and product risks and benefits, and developing various policy and guidance documents that help clarify information needs for Industry to meet the requirements of the regulations. Challenges such as product classification issues remain and the Department continues to look at ways to refine its regulatory approach.

Many outreach and communication activities have taken place over the past five years, especially those informing industry of regulatory requirements. While the full impact of these activities is unknown, some evidence indicates that these activities have been effective (e.g., significant decline in the number of refused submissions) and industry key informants generally indicate satisfaction with program efforts to engage them and keep them informed of any impending or

potential changes/adjustments to the regulatory environment. In addition, the Program provides industry stakeholders with tools (e.g., monographs, guidance material, fact sheets) which provide further information on their roles as regulated parties. Although NHPP information is made available to the public, primarily through various websites, there is limited evidence to show that Canadians are well informed of the risks and benefits of using natural health products, as well as Health Canada's role and activities in regulating natural health products.

The Program, using a risk-based approach, has contributed to the safety of natural health products. This approach is aided by the development and use of agreed-upon safety standards (e.g., monographs) and other information (e.g., Natural Health Product Ingredient Database). In addition, risk-based and random product licensing audits and any associated follow-up actions help to verify the safety of these products. However, questions remain about the efficacy and quality of some natural health products, and this could have an impact on safety. For example, there is concern that some natural health products make claims that are not supported by scientific evidence and that the lack of an on-site inspection program in conjunction with the current attestation model do not do enough to verify the quality of products manufactured both domestically and outside of Canada, which could have an impact on safety.

A variety of program activities (e.g., surveillance activities, product recalls, risk communications) have taken place to contribute to limiting the exposure of Canadians to health risks associated with the use of natural health products, on a post-market basis (i.e., once on the market). However, it should be noted that challenges remain: product classification issues; accessibility of information technology systems; limited follow up on recalled products; and post-market activities that tend to be generally reactive, and not proactive.

While there are many examples of integration and collaboration within the NHPP, and between the Program and other areas within Health Canada and external stakeholders, there are further opportunities for program activities to be systematically integrated, especially at the working level as most interactions tend to be ad hoc.

## **Demonstration of Economy and Efficiency**

A number of efficiencies have been demonstrated by the various program partners with respect to program design and delivery (e.g., streamlined product licence authorization process; a project to pilot a more consistent approach to the triage, prioritization and follow-up of incidents; and monthly signal assessment meetings to discuss safety issues that have been identified post-market and determine recommended action to address them). The lack of a proper information technology structure and product classification issues represent areas where further efforts are needed to improve efficiencies. Overall, program spending has been in line with allocations.

Even though the backlog of applications has been addressed and service standards have been set and are now generally being met, the NHPP remains one of only a couple of regulatory programs within HPFB that does not contain a cost-recovery element. Furthermore, to date, this option has not been explored in any great detail.

With respect to performance measurement, a logic model (see Appendix 1) exists for the NHPP and a performance measurement strategy is in development. While performance data is collected, it tends to be operational in nature focussing on outputs and performance against service standards rather than focussing on the impacts or outcomes of the activities completed within NHPP.

## RECOMMENDATIONS

### Recommendation 1

**As a science-based regulator, Health Canada may wish to reconsider its current practice of allowing specific health claims on natural health product labels that cannot be supported by scientific evidence.**

One of Health Canada's primary roles is to serve as a regulator that bases its decisions on sound scientific evidence. As such, natural health products present a challenge to the Department's reputation in this area. The efficacy of certain natural health products is challenging to confirm given that there is less scientific evidence that exists to determine their efficacy in treating or preventing conditions or illnesses. Health Canada has made a recent announcement to request licence holders of homeopathic products for symptomatic relief of cough, cold and flu for children 12 and under, and homeopathic nosode products to either remove claims or provide scientific evidence of efficacy.

### Recommendation 2

**Given the reliance on pre-market attestations for natural health products and the general reactive approach to post-market activities, the NHPP should consider expanding its post-market activities such as conducting on-site inspections, conducting more laboratory testing as part of compliance verification, and examining the need for stronger post-market powers in the area of natural health products.**

Currently, quality is verified through industry's attestation to Good Manufacturing Practices under a site license application, with no post market verification, and many of the compliance and enforcement activities carried out within the NHPP are reactive, responding to identified issues. Furthermore, when Inspectorate staff refers suspect natural health products to the laboratories for testing and analysis, the result is a high proportion of unsatisfactory results. For these reasons, it is recommended that the NHPP look at ways to incorporate more proactive compliance and enforcement into the Program. Work is already underway to utilize proactive tools and more could be done in this regard. Specifically, the Program could explore the benefits of an on-site inspection program to verify compliance with the attestation. The Program could also explore sending a higher percentage of samples to the laboratories for testing as results may help identify trends and provide a better appreciation of issues that need to be addressed. In addition, while the NHPP generally takes a cooperative approach with industry when dealing with compliance issues and has various compliance measures at its disposal, there was a perception among some internal and a few external key informants that the Natural Health

Products Regulations are not sufficiently strong enough to persuade industry to address non-compliance (e.g., lacks the tougher penalties available to those areas covered by Vanessa's Law).

### **Recommendation 3**

**Clarify and tighten product classification definitions, specifically those related to natural health products, to help address product classification determination issues.**

While various products can share similar characteristics, they can be subject to different regulatory regimes (e.g., *Natural Health Product Regulations*, *Food and Drug Regulations*, *Cosmetic Regulations*) that impose different requirements. The applicable regulatory regime is generally determined by product ingredients and any claims it may be making. Industry has expressed confusion and frustration with product classification issues and, in some cases, this has led to “regulatory shopping” to find the least onerous and quickest pathway for their products to reach the market. In addition, Health Canada officials both within the NHPP and in other program areas (e.g., Food, Cosmetics) report spending a great deal of time discussing and determining the appropriate regulatory framework that products must follow. Many internal key informants are hopeful that work commenced under the Consumer Health Products Framework to modernize the regulation of “self-care” products (which includes natural health products) will help address this issue.

### **Recommendation 4**

**Explore the feasibility and value of implementing an NHPP licensing cost-recovery framework.**

The Natural Health Products Program is one of only a couple of regulatory programs within HPFB that does not contain a cost-recovery element and to date, this option has not been explored in any great detail. With the product submission backlog now cleared, and service standards having been set and generally being met in this area, it may now be appropriate to explore the extent to which a cost-recovery element can be applied to this Program. Revenues from cost-recovery could be used to address various issues identified in this evaluation (e.g., lack of on-site inspections, conducting more lab testing and more proactive compliance and enforcement activities).



## Management Response and Action Plan

### Evaluation of the Natural Health Products Program

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
1. As a science-based regulator, Health Canada may wish to reconsider its current practice of allowing specific health claims on natural health product labels that cannot be supported by scientific evidence.	Agree	Management will examine its approach to health claims for NHPs and other consumer health products as part of the Consumer Health Products Framework.	<p>Develop an Issue Analysis Summary (IAS) that provides an examination of the current approach to health claims for consumer health products. The IAS will include options to ensure clarity of labels for consumers.</p> <p>Present IAS and recommend options to the Consumer Product Framework DG Steering Committee for approval of an option to move forward.</p>	<p>September 30, 2016</p> <p>October 30, 2016</p>	Director General, Natural and Non-Prescription Health Products Directorate (NNHPD)	Existing resources and budget will be used.
2. Given the reliance on pre-market attestations for natural health products and the general reactive approach to post-market activities, the NHPP should consider expanding its post-market activities such as conducting on-site inspections, conducting more laboratory testing as part of its compliance verification, and examining the need for stronger post-market powers in the area of natural health products.	Agree	<p>Management will continue efforts to increasingly use proactive compliance and enforcement activities in its regulatory oversight of natural health products. This includes ongoing work to meet the commitment made in response to the 2015 audit to "strengthen (the) approach for compliance promotion and monitoring by shifting to more targeted, proactive activities". The approach will increase capacity for trending and monitoring and the Inspectorate will utilize results from the audit program and other sources such as intelligence from NNHPD to inform ongoing targeted compliance and enforcement activities such as compliance monitoring projects and on site inspections.</p>	<p>Plan and implement a pro-active compliance monitoring project (CMP) that pilots on-site inspection of GMP compliance. The CMP will be informed by pre- and post-market risk intelligence to target highest risk regulated parties and will include laboratory testing.</p> <p>As part of the Consumer Health Products Framework, develop an IAS that examines current gaps in post-market powers for NHPs and other consumer health products and proposed options for addressing them. Post-market powers in the areas of natural health products should also apply to surveillance activities conducted by MHPD.</p> <p>Present IAS &amp; options for next steps to relevant RORB and HPFB Executive Committee for approval of and options to move forward.</p>	<p>September 30, 2016</p> <p>March 31, 2017</p>	<p>Director General, Regulatory Operations and Regions Branch (RORB)</p> <p>Director General, Natural and Non-Prescription Health Products Directorate (NNHPD)</p> <p>with support from Director General, Marketed Health Product Directorate (MHPD).</p>	Existing resources and budget will be used.

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
<b>3. Clarify and tighten product classification definitions, specifically those related to natural health products, to help address product classification determination issues.</b>	Management agrees that work can be undertaken to strengthen the NHPP by clarifying product classification issues specific to this class of products. However, classifications issues are much broader and affect an array of products beyond the scope of this evaluation. Furthermore, classification stems from definitions outlined in various regulations, and truly addressing some of these challenges may require regulatory change, actions which are beyond the scope of control of management.	Through the Consumer Health Products Framework, management will work with other regulatory areas within Health Canada to explore ways to address product classification issues at the cosmetic, drug, NHP interface.	As part of the Consumer Health Products Framework: <ul style="list-style-type: none"> <li>Develop a product classification system based on risk of various consumer health products;</li> <li>Develop a definition of a consumer health product, which would include NHPs</li> </ul>	September 30, 2016  March 31, 2017	Director General, Natural and Non-Prescription Health Products Directorate (NNHPD)  with support from Director General, Consumer Product Safety Directorate, Healthy Environments and Consumer Branch (HECSB);	Existing resources and budget will be used.
<b>4. Explore the feasibility and value of implementing an NHPP licencing cost-recovery framework.</b>	Agree	Management will explore the feasibility and value of implementing a cost recovery framework for Natural Health Products (NHPs). This work will be dependent on NHP program policy analysis, and therefore expected completion date is reliant on the completion of that work.	Draft an Issue Analysis Summary (IAS) that includes: <ul style="list-style-type: none"> <li>International comparisons of fees for NHPs</li> <li>Unit costing.</li> </ul> Finalise and present IAS & options for next steps to relevant HPFB and RORB Executive Committee.	March 31, 2017  September 30, 2017	Director General, Resource Management and Operations Directorate (RMOD)  with support from Director General, Natural and Non-Prescription Health Products Directorate (NNHPD), Director General, Marketed Health Product Directorate (MHPD), and Director General, Regulatory Operations and Regions Branch (RORB)	Existing resources and budget will be used.

## 1.0 Evaluation Purpose

The purpose of the evaluation was to assess the relevance and performance of Health Canada's Natural Health Products Program (NHPP) for the period of April 2010 to March 2015.

The evaluation was undertaken in fulfillment of requirements set out in relevant Treasury Board Submissions and the Treasury Board of Canada's *Policy on Evaluation* (2009). The evaluation was designed to assist senior management in program planning and decision making. This evaluation was originally scheduled for completion in 2016-2017; however, to respond to senior management information needs, the start of this evaluation was moved up by a year.

## 2.0 Program Description

### 2.1 Program Context

Natural health products are naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.<sup>1</sup> Under the *Natural Health Products Regulations*, natural health products are defined as: vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids that are manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- restoring or correcting organic functions in humans; or,
- modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Interest in natural health products has grown, and use became more widespread. At the same time, many Canadians began expressing concerns about the regulation, safety and accessibility of natural health products. To respond, Health Canada created an Advisory Panel on Natural Health Products to provide the Department with direction and advice. In October 1997, the Minister announced that the House of Commons Standing Committee on Health would conduct a review of the regulatory framework governing natural health products. The objective of the review was to ensure that Canadians have access to safe, effective and high quality natural health products. In May 1998, Health Canada's Advisory Panel presented its report to the House of Commons Standing Committee on Health, who tabled its own report in November 1998. The Standing Committee report, *Natural Health Products: A New Vision* presented 53 recommendations, all of which were accepted by the Government. Recommendations addressed a variety of issues, including:

- definitions; expertise and regulatory structure;
- safety; quality/good manufacturing practices;
- efficacy;
- product licensing;
- labelling;
- section 3 and schedule A of the *Foods and Drugs Act*;
- importation of human-use drugs for personal use;
- cost recovery;
- appeal process;
- informed choice;
- natural health products practitioners;
- enforcement;
- aboriginal healers;
- plant conservation; and
- transition.<sup>2</sup>

To respond to the Standing Committee recommendations, the Natural Health Products Directorate<sup>i</sup> was formed in 1999 to help set up the Natural Health Products Regulatory Framework. Responsibility for regulating the sale of natural health products falls under the *Food and Drugs Act (1985)* and the *Natural Health Products Regulations (2004)*. The regulations came into effect on January 1, 2004, and set out the parameters for the sale of natural health products in Canada through:

- product licensing;
- site licensing;
- good manufacturing practices;
- adverse reaction reporting;
- clinical trials involving human subjects;
- general issues (e.g., labelling requirements, exemptions, etc.); and
- amendments, transitional provisions. (Note: all original regulatory transitional provisions expired on or prior to December 31, 2009).<sup>3</sup>

Over the years, the NHPP has introduced a number of process, policy and regulatory changes to review the regulations and help clear the backlog of submissions that occurred as a result of the introduction of the regulations and the need to license thousands of products already on the market. For example, in August 2010, the temporary Natural Health Products (Unprocessed Product Licence Applications) Regulations were introduced to allow lower risk products that met safety and efficacy requirements to be legally sold while awaiting full review. At the same time, the Management of Product Licence Applications for Natural Health Products was published. In Fall 2012, the Program introduced the “New Approach to Natural Health Products”, which highlighted a more efficient, flexible regulatory approach that protected health and safety while enabling consumer access and industry innovation and growth, introducing a class system that links review times to the product’s level of certainty, risks and benefits.

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<sup>i</sup> Note the Natural Health Products Directorate was renamed the Natural and Non-Prescription Health Products Directorate in 2014.

The Natural Health Products Program was last evaluated in 2010. The 2010 evaluation identified nine recommendations in the following areas: monitoring and surveillance; compliance and enforcement; education and outreach; site inspections; pre-market processes and planning. All nine recommendations have been addressed. During the summer of 2015, an Internal Audit of the Program was concluded as data collection for this evaluation was starting.

## 2.2 Program Profile

### Program Objectives

The Natural Health Products Program aims to ensure that Canadians have access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.<sup>4</sup> The Program's main target audiences are the natural health products industry and Canadians. To achieve its objectives, the NHPP carries out the following activities:

- developing, implementing and reviewing the Natural Health Products Regulatory Framework;
- coordinating, collaborating and implementing outreach with stakeholders and partners, including international partners to improve decision-making processes and to share Canadian regulatory knowledge and practices;
- conducting pre-market activities such as benefit-risk assessments of applications for licensing and approval – includes reviewing product and site licence applications; and
- conducting post-market surveillance, benefit-risk assessments, safety monitoring, compliance and enforcement activities including laboratory analysis, oversight of advertising and border activities.

Within Health Canada, the Health Products and Food Branch (HPFB) is composed of three directorates that are responsible for delivering the NHPP, namely: the Natural and Non-prescription Health Products Directorate (NNHPD); the Marketed Health Products Directorate (MHPD) and the Health Products and Food Branch Inspectorate (HPFBI). The Regions and Programs Bureau (RAPB)<sup>ii</sup> supports both the Health Products and Food Branch Inspectorate and the Marketed Health Products Directorate in their activities. There are two other directorates within the branch that provide policy and support for the branch: the Resource Management and Operations Directorate and the Policy, Planning and International Affairs Directorate (A summary of their roles and responsibilities is provided in Table 1).

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<sup>ii</sup> As of April 4, 2016, RAPB and the Inspectorate will be brought together in a new branch called the Regulatory Operations and Regions Branch.

**Table 1: Roles and responsibilities of NHPP partners**

Directorate	Roles and responsibilities
Natural and Non-prescription Health Products Directorate	NNHPD leads the implementation of the regulations, including pre-market activities such as product licence application reviews and authorizations, review of site applications and authorization of clinical trials. As such, NNHPD processes and screens submissions for products, sites and clinical trials; conducts evidence assessments; works with partners on enforcement, compliance and adverse reaction surveillance and risk communications; and policy and guideline development, information dissemination and international cooperation.
Marketed Health Products Directorate	MHPD undertakes post-market safety surveillance, including health risk evaluation, risk communications and regulatory oversight of advertising, transparency initiatives, outreach, policy and guidance development. More specifically, MHPD is responsible for post-approval safety surveillance, the evaluation of safety signals and the implementation of risk-mitigation activities, including risk communications, the development of policy and regulatory oversight of advertising and education and outreach for adverse reaction reporting. It should be noted that MHPD's natural health product activities are one line of business conducted by the directorate. Financially, this equates to approximately 10% of their expenditures.
Health Products and Food Branch Inspectorate	HPFBI, in collaboration with RAPB, conducts compliance and enforcement activities such as compliance verifications and investigations, compliance monitoring including recall monitoring, border integrity activities and compliance promotions and outreach activities.
Regions and Programs Bureau	<p>RAPB works in partnership with HPFBI in its compliance and enforcement activities. It carries out compliance and enforcement actions through its six regional offices: Atlantic, Quebec, Ontario, Prairie and British Columbia Regions, as well as the National Capital Region.</p> <p>Analyses of natural health product samples are conducted at the RAPB Laboratories in Ontario and Quebec.</p> <p>RAPB also works with other government departments to verify that imported health products meet regulatory requirements and provides admissibility recommendations. As part of the Canada Vigilance Program, the regional offices also collect and assess reports of suspected adverse reactions to natural health products, provided, on a voluntary basis, by Canadian health professionals and consumers. These reports are forwarded to the MHPD for post-market surveillance activities.</p>
Resource Management and Operations Directorate	The Resource Management and Operations Directorate provides branch-wide oversight, coordination and guidance on the consistent, efficient and effective management of operations and resources across all programs led by HPFB, including the NHPP.
Policy, Planning and International Affairs Directorate	The Policy, Planning and International Affairs Directorate provides leadership in developing and advancing HPFB's policy and international agendas. This includes policy development on horizontal issues; legislative and regulatory modernization; activities to increase Canada's influence as a global regulator; and science policy integration.

## 2.3 Program Narrative

The overall goal of the NHPP is to ensure that Canadians have access to natural health products that are safe, effective, and of high quality.<sup>5</sup> According to the NHPP logic model (see Appendix 1), the NHPP has four activity areas: developing, implementing and reviewing the Natural Health Product Regulatory Framework; coordinating, collaborating and implementing outreach with stakeholders, partners and citizens; conducting pre-market activities such as risk/benefit assessments of applications for licensing/approval; and conducting post-market surveillance; risk/benefit assessments, monitoring, compliance and enforcement activities. These activities are expected to lead to the following immediate, intermediate and long-term outcomes.

## Immediate Outcomes

Expected immediate outcomes include: integrated approach for the implementation of the NHPP priorities and activities; Canadians are aware of the regulatory requirements and the risks and benefits of natural health products; safe and effective natural health products are authorized for sale and clinical trial use in Canada while increasing Health Canada’s natural health product knowledge; natural health product risks are identified and appropriately addressed; and mechanisms are in place to observe and maintain adherence to the *Natural Health Products Regulations*.

## Intermediate Outcomes

Achieving immediate outcomes is expected to lead to: a Natural Health Product Framework that evolves to effectively administer natural health products in Canada; Canadians that understand the risks and benefits of natural health products; an industry that understands the regulatory requirements; natural health products that are available to Canadians on the Canadian market that are safe, effective, and of high quality; and reduced exposure of Canadians to health risks.

## Long-term Outcomes

The Natural Health Products Program anticipates that achieving the above outcomes will result in a sustainable, cost-efficient, responsive and evidence-based regulatory system for natural health products and Canadians that make informed decisions, and choose and use natural health products with confidence.

## 2.4 Program Alignment and Resources

The Natural Health Products Program is part of the Health Canada’s Program Alignment Architecture: Program 2.1 Health Products, Sub-Program 2.1.4 Natural Health Products.

The program’s budget for the years 2010-2011 through 2014-2015 for each of the program partners is presented below (Table 2). Overall, the program had a budget of over \$86 million (the majority of which resides in NNHPD) over five years. A summary of the program’s planned versus actual expenditures is reviewed in section 4.5. In 2014-2015, the NHPP had a total of 186 full time equivalents (FTE) (NNHPD: 122, MHPD: 27, HPFBI: 8, and RAPB: 29).

**Table 2: Program resources (\$)**

Year	O&M	Salary	Total
<b>Natural Health Products Program Total</b>			
2010–2011	\$2,798,750	\$14,875,273	\$17,674,023
2011–2012	\$2,932,926	\$16,234,410	\$19,167,336
2012–2013	\$1,092,899	\$17,811,270	\$18,904,169
2013–2014	\$825,734	\$15,681,089	\$16,506,823
2014–2015	\$717,397	\$13,597,040	\$14,314,437

Year	O&M	Salary	Total
<b>Total</b>	<b>\$8,367,706</b>	<b>\$78,199,082</b>	<b>\$86,566,788</b>
<b>NNHPD</b>			
2010–2011	\$2,657,024	\$13,574,529	\$16,231,553
2011–2012	\$2,752,638	\$13,975,673	\$16,728,311
2012–2013	\$912,530	\$14,782,079	\$15,694,609
2013–2014	\$622,653	\$12,340,256	\$12,962,909
2014–2015	\$534,818	\$10,006,661	\$10,541,479
<b>Total</b>	<b>\$7,479,663</b>	<b>\$64,679,198</b>	<b>\$72,158,861</b>
<b>MHPD</b>			
2010–2011	\$141,726	\$1,300,744	\$1,442,470
2011–2012	\$180,288	\$2,258,737	\$2,439,025
2012–2013	\$62,869	\$2,278,739	\$2,341,608
2013–2014	\$121,191	\$2,627,668	\$2,748,859
2014–2015	\$49,642	\$2,826,531	\$2,876,173
<b>Total</b>	<b>\$555,716</b>	<b>\$11,292,419</b>	<b>\$11,848,135</b>
<b>HPFBI</b>			
2012–2013*	\$117,500	\$750,452	\$867,952
2013–2014	\$81,890	\$713,165	\$795,055
2014–2015	\$46,855	\$763,848	\$810,703
<b>Total</b>	<b>\$246,245</b>	<b>\$2,227,465</b>	<b>\$2,473,710</b>
<b>RAPB</b>			
2014–2015*	\$86,082	\$2,422,129	\$2,508,211
<b>Total</b>	<b>\$86,082</b>	<b>\$2,422,129</b>	<b>\$2,508,211</b>

Data Source: Financial data provided by Chief Financial Officer Branch.<sup>iii</sup>

## 3.0 Evaluation Description

### 3.1 Evaluation Scope, Approach and Design

The scope of the evaluation covered the period from April 1, 2010 to March 31, 2015, and included all components of the NHPP.

<sup>iii</sup> Financial data is only available for the past three fiscal years for HPFBI and the last year for RAPB because prior to 2012-2013 and 2014-2015 respectively, HPFBI and RAPB did not report at the sub-program level of the Department's Program Alignment Architecture.



The evaluation issues were aligned with the Treasury Board of Canada’s *Policy on Evaluation* (2009) and considered the five core issues under the two themes of relevance and performance, as shown in Table 3. Corresponding to each of the core issues, specific questions were developed based on program considerations and these guided the evaluation process. An Internal audit of the NHPP was approved in June 2015. A number of areas, specifically, risk management, governance, and performance measurement, were not fully explored through the evaluation, as they were addressed in the Internal Audit.<sup>iv</sup>

**Table 3: Core Evaluation Issues and Questions**

Core Issues		Evaluation Questions
<b>Relevance</b>		
Issue #1:	Continued Need for Program	<ul style="list-style-type: none"> <li>• What are the risks associated with the use of natural health products? Are those risks evolving?</li> <li>• How has the environment changed since the <i>Natural Health Products Regulations</i> came into effect?</li> <li>• How have program activities addressed changes in the environment?</li> </ul>
Issue #2:	Alignment with Government Priorities	<ul style="list-style-type: none"> <li>• What is the federal role related to regulating natural health products? Are current activities aligned with the federal role?</li> <li>• Does the federal role duplicate or complement the role of other stakeholders? Is the federal role appropriate (e.g., gaps or overlaps)?</li> </ul>
Issue #3:	Alignment with Federal Roles and Responsibilities	<ul style="list-style-type: none"> <li>• What are the federal priorities related to regulating natural health products?</li> <li>• What are the Health Canada priorities related to regulating natural health products?</li> <li>• Are current activities aligned with priorities?</li> </ul>
<b>Performance (effectiveness, economy and efficiency)</b>		
Issue #4:	Achievement of Expected Outcomes (Effectiveness)	<ul style="list-style-type: none"> <li>• To what extent have Canadians made informed decisions; chosen and used natural health products with confidence?</li> <li>• How aware is industry of regulatory requirements?</li> <li>• How aware are Canadians of, and how well do they understand, the risks and benefits of natural health products (including regulatory requirements)?</li> <li>• To what extent is the NHPP able to ensure that natural health products available on the market are safe, effective, and of high quality?</li> <li>• Is there reduced exposure of health risks to Canadians?</li> <li>• To what extent is there sustainable, cost-efficient, responsive and evidence-based regulatory system for natural health products?</li> <li>• How integrated is the approach to implement natural health product priorities and activities?</li> <li>• How has the Natural Health Products Regulatory Framework evolved to administer natural health products?</li> </ul>
Issue #5:	Demonstration of Economy and Efficiency	<ul style="list-style-type: none"> <li>• Is the program delivered in an efficient manner? How, and in what ways, can efficiency be improved? Are program resources/capacity aligned appropriately across key activities (pre vs. post-market activities)?</li> <li>• Has the program produced its outputs and achieved its outcomes in the most economical manner? How and in what ways can economy be improved? Are there alternative ways to achieve similar results at a lower cost?</li> <li>• How is performance measurement being used?</li> </ul>

<sup>iv</sup> For further information, the Audit of the Management of the Natural Health Products Program can be found at <http://www.hc-sc.gc.ca/ahc-asc/performance/audit-verif/2015-list/index-eng.php>

An outcome-based evaluation approach was used for the conduct of the evaluation to assess the progress made towards the achievement of the expected outcomes, whether there were any unintended consequences and what lessons were learned.

The Treasury Board's *Policy on Evaluation* (2009) also guided the evaluation design and data collection methods so that the evaluation would meet the objectives and requirements of the policy. A non-experimental design was used based on the evaluation matrix, which detailed the evaluation strategy for this program and provided consistency in the collection of data to support the evaluation.

Data collection started in June 2015 and ended in December 2015. Data for the evaluation was collected using various methods, including:

- **Literature review** – a search for Canadian and international literature from the past five years using search terms such as “natural health products”, “*Natural Health Product Regulations*”, “traditional Chinese medicine”, “herbal remedies” and “self-medicating”. After examining documents to ensure relevance, 35 articles were reviewed.
- **Document review** – approximately 45 documents pertinent to natural health products were reviewed for information regarding the relevance (priorities, roles and responsibilities) of the activities.
- **File review** – approximately 85 files, held by the Directorates responsible for the NHPP, were reviewed to obtain information regarding all aspects of the activities related to NHPP and in particular the performance (achievement of outcomes, economy and efficiency) of activities.
- **Financial data review** – a review of financial data from 2010-2011 to 2014-2015 was conducted, including budgeted and actual expenditures.
- **Key informant interviews** – interviews were conducted with 50 stakeholders: Health Canada (n=28) with the majority being from directorates responsible for the NHPP; other federal government departments or agencies (n=2); and external stakeholders and other organizations (n=20). External stakeholders and other organizations represented industry, healthcare associations, provincial/territorial governments, and subject matter experts. They were selected for their knowledge of and experience with the NHPP and/or issues related to natural health products. Interviews were recorded and transcribed as necessary.
- **International analysis** – a review of natural health product regulations and management was conducted for the United States and Australia. Findings were confirmed through interviews or written feedback with representatives from both countries.
- **Performance data review** – a review of data on performance of program activities between 2010-2011 and 2014-2015 (project-level performance data and evaluation reports).
- **Internal Audit** – the Internal Audit, approved in June 2015, was reviewed and used as a source of information, particularly for areas of activity that were not thoroughly explored during the evaluation as they were addressed in the Audit, specifically outreach activities, risk management, governance, and performance measurement.

Data were analyzed by triangulating information gathered from the different methods listed above. The use of multiple lines of evidence and triangulation were intended to increase the reliability and credibility of the evaluation findings and conclusions.

### 3.2 Limitations and Mitigation Strategies

Most evaluations face constraints that may have implications for the validity and reliability of evaluation findings and conclusions. The following table outlines the limitations encountered during the implementation of the selected methods for this evaluation. Also noted are the mitigation strategies put in place to ensure that the evaluation findings can be used with confidence to guide program planning and decision making.

**Table 4: Limitations and Mitigation Strategies**

<b>Limitation</b>	<b>Impact</b>	<b>Mitigation Strategy</b>
Program activity output and outcome data were either limited or were not always tracked consistently.	In some cases this made it difficult to accurately determine to what extent certain activities had been completed and to assess their subsequent impacts.	Other lines of evidence, such as file review and key informant interviews, were used to help provide as clear a picture as possible as to what activities had been completed. In some cases the program was able to gather the data when requested.
Key informant interviews are retrospective in nature.	Interviews retrospective in nature, providing recent perspective on past events, can impact validity of assessing activities or results relating to improvements in the program area.	Triangulation of other lines of evidence to substantiate or provide further information on data received in interviews.  Document review provided corporate knowledge.
Financial data structure was not linked to outputs or outcomes.	The lack of output- and outcome-specific costing data limited the ability to use cost-comparative approaches to assess efficiency and economy.	Other lines of evidence were used, including key informant interviews and file review, to qualitatively assess efficiency and economy.
A federal election was called during the data collection process.	Interviews with external key informants were suspended for 78 days during the election period.	The data collection timeline was extended to allow for all identified and interested informants to participate.

## 4.0 Findings

### 4.1 Relevance: Issue #1 – Continued Need for the Program

**There is a continued need for the regulation of natural health products given the increasingly widespread availability, both domestic and foreign, complexity of these products and the potential risks associated with their use.**

In Canada, natural health products are defined as vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids.<sup>6</sup> Since 2004, these products have been regulated under the *Natural Health Products Regulations* to ensure that products being sold are safe, effective and of high-quality.

A 2010 Ipsos Reid survey of natural health product use prepared for Health Canada, found that 73% of Canadians had used natural health products, 32% of them on a daily basis. Other research has found that women,<sup>7,8,9,10</sup> those with a higher education,<sup>11,12,13,14</sup> those with a higher income,<sup>15,16,17</sup> certain ethnic groups, such as Chinese Canadians,<sup>18,19</sup> and those who are chronically ill<sup>20,21,22</sup> are more likely than others to use natural health products.

Not only are many Canadians using natural health products, but physicians are also recommending them to their patients. According to a 2012 survey, approximately 38% of Canadian physicians recommend natural health products to their patients; this includes vitamins and minerals such as vitamin D, prenatal vitamins, calcium and iron.<sup>23</sup>

## Changing Environment

Since the 1990s the use of natural health products has been increasing dramatically worldwide.<sup>24</sup> In the United States, the use of herbal products increased 380% between 1990 and 1997,<sup>25</sup> with similar increases being seen throughout North America.<sup>26</sup> In 2012, it was estimated that Canadians spent approximately \$7.84 billion annually on products and services related to natural health.<sup>27</sup> It has also been noted that the worldwide market for traditional Chinese medicine products and services is increasing 10 to 20% annually, with similar increases also reportedly occurring for other natural health products, such as vitamins.<sup>28</sup>

With such a high demand for natural health products, both domestic and foreign products are becoming more readily available. Academic sources, as well as key informants and multiple media sources, report that natural health products are easier than ever to obtain through the internet, in health food stores, grocery stores, and pharmacies.<sup>29,30</sup> The increase in availability of products has been demonstrated by Health Canada's NNHPD, who reported that in March 2015 there were 63,387 active product licenses for domestic use and importation. With the exception of a slight drop in 2011-2012, there has been an increase in the number of product licenses issued or amended each year from 2010-2011 to 2014-2015. In 2010-2011, 8,120 licenses were issued or amended and by 2014-2015, that number had grown to 11,707 licenses.

Not only are natural health products more widely available, but they are becoming increasingly complex. Several internal and external key informants reported that manufacturers are becoming more innovative with natural health products. For example, they reported that certain products that were once standalone are now being combined, such as vitamins with dietary products like Omega-3 fatty acids. Similarly, both internal and external key informants are now seeing natural health products combined with products typically from other industries, such as foods and cosmetics.

Since there have been changes to the natural health products environment, in particular the increase in the number of products and their complexity and availability, as well as the number of people using them, the risks associated with these products, while still low, may increase in frequency.

## Risks Associated with the Use of Natural Health Products

Overall, natural health products are safe and low risk. Much of the literature reviewed, while discussing potential risks, also pointed to the fact that natural health products can be beneficial and are generally safe, when they are manufactured in accordance with good manufacturing practices and used in accordance with the recommended directions for use.<sup>31,32,33,34,35</sup>

### Direct Health Risks

While natural health products are generally low risk, there are a number of health risks that can occur when they are improperly used. In particular, pharmaceutical drugs and natural health products can interact with each other reducing the effectiveness of a medication and/or causing an adverse reaction.<sup>36,37,38,39,40</sup> For example, St. John's Wort is a common natural health product used to treat depression that is well known to interact with certain pharmaceutical medications.<sup>41,42</sup> Similarly, ingredients such as garlic, ginkgo biloba, and ginseng can increase the risk of bleeding during surgery.<sup>43,44</sup> Pharmaceutical-natural health product interactions are of particular concern for patients with chronic diseases who are more likely to be taking multiple medications, increasing their chance of potentially harmful interactions.<sup>45,46</sup>

Improper use of natural health products can occur, causing health risks, when individuals self-prescribe without consulting medical professionals.<sup>47,48,49,50</sup> With self-diagnosis and self-prescription a delay in consulting with a medical professional may lead to a worsening of symptoms, progression of the disease, or lack of protection from potentially fatal illnesses.<sup>51,52,53</sup>

Health risks can also be associated with self-prescription because certain natural health products, which would be well known to relevant health care practitioners (e.g., naturopathic doctors), are intrinsically toxic and can cause unwanted side effects or serious illness.<sup>54,55,56</sup> For example, ingredients such as *Aristolochia* (commonly known as bithwort or pipevine), *Aconitum* (commonly known as monkshood or wolf's bane), and pyridoxine (commonly known as vitamin B-6) can cause kidney, cardiac, neurologic and gastrointestinal issues, as well, they can be carcinogenic, or cancer causing in certain dosages.<sup>57</sup> Without consulting the appropriate practitioner before using natural health products, consumers risk taking dangerous substances or taking a dangerous or potentially fatal dose of a substance.<sup>58</sup>

Even natural health products that are not intrinsically toxic can contain toxic substances that may have an adverse effect on a person's health. A study by Genuis et al. (2012) conducted toxic element testing on 121 natural health products and 49 routinely prescribed pharmaceuticals. They found that toxic element contamination of natural health products is common, but that only a few exceeded established daily limits for contamination when taken on their own.<sup>59</sup> Despite being safe at the recommended dose, there are increased risks of contamination because many people consume multiple different natural health products and/or pharmaceuticals each day and

the cumulative impact of these toxic substances could result in individuals exceeding the established daily limits.<sup>60</sup>

### **Production and Manufacturing Issues**

As discussed, natural health products contain ingredients that are generally recognized as being safe and of low risk, however, the risk of using natural health products increases when there are issues with production and manufacturing. For example, production and manufacturing issues can lead to contamination and adulteration in products, which can raise the risk to health as a result of using natural health products.<sup>61,62,63</sup>

Contamination with toxins including lead, mercury, and arsenic, has been documented in a variety of natural health products from various parts of the world, but particularly in products with raw materials originating from some parts of Asia.<sup>64,65</sup> Raw materials used to make natural health products often come from international sources, which have less stringent controls over agricultural practices including the use of pesticides and fungicides, as well as different regulations on acceptable levels of pollution for water, air, and soil.<sup>66,67,68</sup> These practices can all increase the toxicity of raw plant materials used to make natural health products. At the manufacturing and processing stage, storage, additives, microorganisms, and human adulteration can all impact the level of contamination of natural health products.<sup>69,70,71,72,73,74</sup>

Adulteration is another way in which production and manufacturing can increase the risk resulting from the use of natural health products. Adulterated products contain substances that are not declared on the label but were intentionally added during the manufacturing process. This can include prescription medications or other potentially dangerous ingredients. A study by Newmaster et al. (2013), which looked at the ingredients of 44 natural health products, found that adulteration of products and ingredient substitution is not uncommon as ingredients of lower quality replace those of higher quality and typically higher cost.<sup>75</sup> Products are also adulterated when fillers are added that are not included on the product's label. Newmaster et al. (2013) found that 21% of the products they tested had added fillers, often composed of common allergens such as wheat and soy, which were not included on the label.<sup>76</sup>

When an individual uses an adulterated product, they are ingesting substances without their knowledge, which can present serious risks to their health such as allergic reactions and drug interactions.<sup>77</sup> In some circumstances the undeclared drug may even be one not regulated by Health Canada, or not previously determined to be safe.<sup>78</sup> Products that have often been found to be adulterated include products for weight loss, body building, erectile dysfunction, sleep problems, inflammatory conditions and diabetes.<sup>79</sup>

## 4.2 Relevance: Issue #2 – Alignment with Government Priorities

**Protecting the health and safety of Canadians by regulating health products, including natural health products, is a priority for the Government of Canada as well as Health Canada, and there is alignment between the Government, Department and Branch priorities and the activities of the NHPP.**

As mentioned earlier, the Minister of Health announced the creation of the Natural Health Products Directorate in 1999. This announcement was part of the response to the 53 recommendations from the House of Commons Standing Committee on Health's examination of the regulatory framework for natural health products.

In 2003, the Natural Health Products Regulations were published. The purpose of the regulations was to ensure that Canadians have access to a wide variety of high-quality, safe and effective natural health products. The regulations came into force on January 1, 2004.

While the regulation of natural health products is not specifically mentioned in recent Speeches from the Throne and Budget Plans, these documents note that protecting the health and safety of Canadians is a priority for the Government. The Government of Canada has demonstrated that the regulation of natural health products is a priority through the following commitments with regards to natural health products:

- While out of scope of this evaluation, the 2007 Speech from the Throne noted that Canadians should expect the same standards of quality from imported goods as they do from products made at home, stating that the Government will introduce measures on product safety to ensure that families have confidence in the quality and safety of what they buy.
- Budget 2008 set aside funds for initiatives to protect the health and safety of Canadians such as ensuring greater safety of natural health products.
- In the 2010 Speech from the Throne, the Government committed to reintroduce legislation to protect Canadian families from unsafe food, drug and consumer products.

Health Canada identifies ensuring the safety of Canadians by regulating health products, and providing Canadians and other stakeholders with evidence-based knowledge to make informed decisions regarding their health, as key priorities. These priorities are outlined in Health Canada's Corporate Risk Profile; Health Canada's Report on Plans and Priorities; and Branch and Directorate strategic and operational plans. For example:

Corporate Risk Profiles from 2012-2013 to 2015-2016 identify the following priorities:

- Modernize health protection legislation and programs.
- Increase transparency, communications and engagement with Canadians.
- Strengthen openness and transparency by implementing Health Canada's Regulatory Transparency and Openness Framework. Health Canada's Regulatory Openness and

Transparency Framework Action Plan , outlines steps Health Canada is taking to improve access to timely, useful and relevant health and safety information for products including natural health products

- Recent Reports on Plans and Priorities confirm Health Canada's commitment to modernizing its regulatory frameworks, increasing transparency and providing information about health products, including natural health products.

While natural health products are not specifically mentioned, HPFB's 2012-2015 Strategic Plan highlights their commitment to modernizing the regulatory framework through the development of the HPFB Regulatory Roadmap for various health products that would include natural health products. The Regulatory Roadmap for Health Products and Food plans to deliver more efficient and transparent food and health product regulations to increase the health and safety of Canadians.

The Consumer Health Products Framework, launched for consultation on June 9, 2014 as part of the Health Products and Food Regulatory Roadmap, proposed to advance a new approach to the regulation of consumer health products (non-prescription drugs, natural health products, cosmetics and disinfectants) that would establish a consistent and aligned approach for these products while continuing to ensure that Canadians have access to safe and effective products. This included proposed new regulations for non-prescription drugs as well as policy changes and operational improvements to better balance the oversight for consumer health products.

The Corporate Overview of Operational Plans supports the four departmental priorities including the following HPFB priorities for health products such as natural health products:

- regulatory modernization;
- openness and transparency, including clear communications with the general public and other stakeholders;
- plain language labelling; and
- reduction in regulatory burden and increased cooperation with major trading partners.

The above mentioned departmental and branch plans are aligned with the NHPP Strategic and Operational Plans that highlight the following Program priorities: regulatory modernization, operational excellence, people agenda and transparency of program activities with key stakeholders. While an NHPP-specific Strategic Plan was developed for 2010-2012; there is no current strategic plan. Even though there is no current NHPP-specific strategic plan, previous NHPP strategic and current operational plans are aligned with Branch plans and priorities. Further, Branch strategies and plans reflect the priorities set out by Health Canada and the Government of Canada and are aligned with current activities.



### 4.3 Relevance: Issue #3 – Alignment with Federal Roles and Responsibilities

**Health Canada has a clear federal regulatory role for health products including natural health products. The activities carried out by the NHPP are consistent with federal responsibilities under the *Department of Health Act*, the *Food and Drugs Act* and the *Natural Health Products Regulations*.**

Health Canada is responsible for helping Canadians maintain and improve their health. This includes its role as a regulator for the safety of natural health products. While the provinces and territories are responsible for delivering health care to the majority of Canadians, the federal government also has a number of key roles and responsibilities in areas that affect health.<sup>80</sup>

- As a partner in health, Health Canada:
  - endeavours to protect Canadians from unsafe health and consumer products
  - informs Canadians to make healthy choices
- Before a drug or a natural health product can be sold in this country, Health Canada must receive evidence demonstrating the safety, efficacy and quality of the product, and must assess its benefits and risks before taking a decision on whether it should be made available to Canadians.
- Health Canada ensures that Canadians and key stakeholders (e.g., health professionals and natural health practitioners) have access to evidence-based information needed to make informed decisions regarding their health and safety.

The *Department of Health Act*, the *Food and Drugs Act* and *Natural Health Products Regulations* provide Health Canada with the authority to develop, maintain, and implement a regulatory framework associated with a broad range of health products, including natural health products. The *Department of Health Act*<sup>81</sup> gives Parliament jurisdiction related to the promotion and preservation of the health of Canadians whereas the *Food and Drugs Act*<sup>82</sup> sets out the requirements for the production, importation, exportation, and sale of food, drugs, medical devices including contraceptive devices, and cosmetics. The *Food and Drugs Act* also gives the Minister the power to develop regulations such as the *Natural Health Products Regulations* in order to carry out provisions in the Act.

- The *Natural Health Products Regulations*<sup>83</sup> outline the Government of Canada's responsibility with regards to:
  - the sale of natural health products;
  - the manufacturing, packaging, labelling and importation for sale of natural health products;
  - the distribution of natural health products; and
  - the storage of natural health products for the purposes of manufacture, packaging, labelling, importation for sale or distribution.

At the time the Standing Committee report was released, Health Canada's HPFB was mandated to produce a regulatory framework for natural health products to protect the health of consumers, respect consumers' access to products and guarantee product safety and quality. As such, the NHPP was responsible for all regulatory functions within the lifecycle of natural health products.

More recent policy and program authorities for the NHPP outline the implementation of a new risk-based approach with the following activities for the Program:

- pre-market reviews, regulatory cooperation and outreach, regulatory, policy and standards development, and program management and support;
- post-market surveillance; and
- compliance verification and enforcement activities.

The Health Product and Food Branch's mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by: minimizing health risk factors to Canadians, while maximizing the safety provided by the regulatory system for health products and food; and, promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

The 2015 Internal Audit of the NHPP found that the roles and responsibilities among staff are clear and well understood. The majority of internal and external key informants for this evaluation noted that Health Canada's role in regulating the sale, manufacturing, packaging, labelling, importation, distribution and storage of natural health products is clear and does not duplicate that of the provinces and territories who are responsible for regulating the practice of health care professionals. However, some external key informants felt that natural health products shouldn't be regulated at all; if they have to be regulated it should be under a separate category and not under the *Food and Drugs Act*.

The activities conducted by the NHPP align with the Department's regulatory role in providing pre-market assessments, product and site licensing, safety (adverse reaction), monitoring, compliance and enforcement. The Department has a clear role in implementing and maintaining a regulatory program which includes pre-market review, post-market surveillance and compliance verification and enforcement activities.

Further, the majority of internal and external key informants who were probed about potential gaps in the regulation of natural health products did not see any; however, given that certain provincial and territorial governments regulate the practice of naturopathic doctors, some interviewees thought that this could lead to potential gaps especially as naturopathic doctors prepare tinctures, which are essentially compounds of natural ingredients. There is a potential gap since Health Canada does not regulate those products and it is unclear whether the provinces and territories, who are responsible for regulating the practice of health care professionals, have filled this gap.

## 4.4 Performance: Issue #4 – Achievement of Expected Outcomes (Effectiveness)

In this section, we outline the extent to which key program outcomes have been achieved. Given the difficulty in assessing long-term outcomes, our focus for this evaluation has been on the key immediate and intermediate outcomes that will lead to these long-term outcomes. Therefore, with respect to the long-term goal of having Canadians make informed decisions and choose and use natural health products with confidence, we have examined Health Canada's performance in making industry aware of regulatory requirements; making Canadians aware of and understand, the risks and benefits of natural health products; the extent to which NHPP is able to ensure that natural health products available on the market are safe, effective and of high quality; and reducing exposure of health risks to Canadians. Similarly, for the long-term goal of having a sustainable, cost-efficient, responsive and evidence-based regulatory framework for natural health products, we have examined the Department's performance of the extent to which it has an integrated approach for implementation of NHPP priorities and activities and a natural health products framework that evolves to effectively administer natural health products in Canada.

### 4.4.1 To what extent have the outcomes been achieved?

#### **Outcome #1: Canadians are Aware of Regulatory Requirements and Understand the Risks and Benefits of Natural Health Products**

**Although NHPP information is made available to the public by the program, there is limited evidence to show that Canadians are well informed of the risks and benefits of using natural health products, as well as Health Canada's role and activities in regulating natural health products.**

#### **Communications to Canadians**

The evaluation found that communications to Canadians on the subject of natural health products are conducted primarily through the Healthy Canadians and the Health Canada websites, including the Health Product InfoWatch. A content review of these communication sources reveals a focus on product recalls, foreign product alerts and describing regulatory requirements.

A review of the Healthy Canadians Recalls and Alerts database<sup>84</sup> was conducted for the time period between January 1, 2014 and May 30, 2015. During that period a total of 104 announcements were made regarding natural health products. Of those, 14 were advisories, 43 were recalls, 43 were foreign product alerts and four were information updates and covered issues such as product safety, undeclared substances, important safety information, unauthorized products, contamination and/or labelling and packaging.

The most popular NHPP page directed towards Canadian consumers was Health Canada's "About Natural Health Product Regulations in Canada"<sup>85</sup> webpage, with 166,623 page views between March 1, 2011 and March 31, 2015. The webpage provides a basic overview of the types of products that fall under the regulations, as well as links to further information on the Health Canada website. By contrast, during the same time period, Health Canada's Drug Products index page received 551,818 page views.

A 2015 Internal Audit<sup>86</sup> also found that the Program has an extensive web presence with a great deal of information available for consumers, such as: a definition of natural health products; their associated regulations and the departmental approach to natural health product licensing and regulation; databases on products and their associated risks; how to use natural health products safely; and how and where to report adverse side effects.

Both internal and external key informants reported that Health Canada could be clearer in communicating its role in regulating natural health products, particularly with regard to safety, efficacy and quality. Internal interviewees reported that despite departmental initiatives aimed at strengthening and improving communications, the Program has not communicated effectively to the public and that many Canadians do not appear to know what the presence of a Natural Product Number (NPN) on a product signifies. Efforts to inform Canadians to look for an NPN or a Homeopathic Medicine Number (DIN-HM) when buying a natural health product were deemed appropriate, but insufficient to address consumer information needs such as awareness of potential drug interactions between natural health products and prescription or over-the-counter drugs.

In addition, the scope of recent departmental initiatives to strengthen and improve communications to the public, such as the Plain Language Labelling Initiative and the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, have not included the NHPP. Some internal and external key informants felt that excluding natural health products from these initiatives that apply to drugs and other health products, impacts Health Canada's ability to communicate important issues to both industry and Canadians at large in a clear and consistent manner.

### **Canadians' Awareness of What Constitutes a Natural Health Product and Who Regulates Natural Health Products**

The evaluation did not find recent public opinion research on natural health products. The most recent data is from a survey published in 2010 that was conducted by Ipsos Reid<sup>87</sup> on behalf of Health Canada. It found that Canadians at that time were uncertain who regulates natural health products. Health Canada is named most often as the regulator of natural health products in Canada (27%) and nearly two in five (17%) believe it is the federal government. Thus, less than half the Canadian population recognized that natural health products' regulation is the responsibility of the Government of Canada.

The survey<sup>88</sup> also found that, while knowledge of specific products that qualify as natural health products in Canada is high in some respects, there is also evidence of confusion regarding which products fall under the natural health products regulations. High proportions of respondents accurately categorize vitamins or minerals (72%) and homeopathic medicines (60%) as natural health products, yet Canadians are less clear with respect to traditional medicines as 43% say they are not natural health products. There is also significant confusion regarding organic food/biologics, as seven in ten respondents (69%) think they are natural health products.

Some internal key informants, particularly those who worked on post-market issues, commented on the lack of recent public opinion data for use in decision making. Other key informants, both internal and external, stated that without having baseline information on what consumers do and do not know about the products and regulations, it will be difficult for the Program to identify and target any information gaps.

### **Canadians Making Informed Decisions – Awareness of the Risks and Benefits of Natural Health Products**

Many internal and external key informants stated that they were unsure of the extent to which Canadians are aware of the risks and benefits of natural health products. The 2010 Ipsos Reid survey found that fewer than half of those surveyed (42%) agreed that natural health products are safe because they are made from natural substances. Moreover, only one in five agreed that if a natural health product is made of natural substances, there is no risk associated with its use.

The survey also found that a significant proportion of Canadians question the safety and quality of natural health products. Only 20% of respondents believed that there are no risks associated with product use if a natural health product is made of natural substances, while 39% indicated that they are concerned with the safety of natural health products and about a third (34%) agreed with the statement ‘I think natural health products can be harmful to use’. Further, 42% indicated that they question the quality of natural health products, and a third (32%) indicated that they do not trust the information on natural health product labels. Canadians in general do not appear too complacent regarding their use of these products, as 72% agree with the statement that it is important to talk to a medical doctor before using a natural health product.

The 2015 Internal Audit<sup>89</sup> noted that much of the material available to the public gives the impression that the Department is assessing product and manufacturing facilities even though on-site verification of good manufacturing practices is not occurring.

The evaluation did not find evidence of a NHPP strategic communications strategy and both internal and external key informants stated that the program could enhance the promotion of information currently available to the public. For example, using social media tools such as Facebook, Twitter, Pinterest and YouTube could connect consumers to the available information. The Program is aware of the need to consolidate outreach activities and committed in the Internal Audit Management Response and Action Plan to formalizing an outreach strategy, with appropriate performance measures, by March 4, 2016.

## Outcome #2: Industry is Aware of and Understands the Natural Health Products Regulatory Requirements

The Program engaged in many outreach and communication activities to inform the natural health products industry of regulatory requirements. External key informants agreed that the Program has been effective in these areas. Efforts were also undertaken to inform health care professionals of adverse reaction reporting. While the full impact of all of the outreach and communications activities is not yet known, some evidence indicates that these activities have been effective.

### Engagement with Industry

There is evidence that a number of stakeholder consultations, information sharing and engagement activities took place during the evaluation time frame. The Natural and Non-prescription Health Products Directorate publishes a semi-annual calendar of activities in the form of a newsletter on Health Canada's Drugs and Health Products webpage<sup>90</sup> that details upcoming consultations, publications, stakeholder workshops and meetings, as well as any updates or revisions from the previous newsletter.

Key informants from other Directorates, including MHPD, HPFBI and the Food Directorate, reported being part of NNHPD-led consultations with industry, when appropriate. For example, in 2011, two cross-country stakeholder information and consultation sessions were held regarding the natural health product Compliance and Enforcement Policy.

In addition to attendance at industry conferences and events, NNHPD held webinars and ongoing bilateral meetings with the following stakeholder groups and associations: Consumer Health Products Canada, Canadian Health Food Association, Canadian Homeopathic Pharmaceutical Association, Canadian Natural Products Association, Canadian Cosmetic, Toiletry and Fragrance Association, Canadian Consumer Specialty Products Association, Direct Sellers Association, Traditional Chinese Medicines Community. Furthermore, MHPD has conducted outreach such as participating in the Canadian Pharmacovigilance and Risk Management Meeting with Develop Innovate Advance, a global company that brings health care product development professionals together. For example, on May 21, 2015 the following issues were discussed: Consumer Health Products Framework, pharmacovigilance approaches and new post-market activities. Both internal and external key informants were very satisfied with program outreach activities and reported that a Health Canada presence at industry events was beneficial to all parties as it provided opportunities for information sharing. As appropriate, NHPP Directorates were able to consult industry on some of the initiatives undertaken by their group. For example, both NNHPD and HPFBI informed industry of the implications of the end of the *Natural Health Products (Unprocessed Product Licence Applications) Regulations*.

Many internal and external key informants highlighted how effective NNHPD has been in engaging stakeholders by keeping them informed of all changes affecting the regulatory framework. Informing stakeholders of changes to the regulatory framework was deemed an area of focus by NNHPD given the transition period from temporary regulations to the full implementation of the natural health products regulations. Health Canada held in-person consultations with stakeholders during this transition period to ensure transparency and openness, take into account the potential range of existing business practices, and support a successful transition towards regulatory compliance. In addition to in-person consultations, NNHPD sent emails to stakeholder groups requesting feedback on issues under consideration.

In addition to organizing or participating in industry and associations events, NNHPD developed guidance material, including brochures, fact sheets and Frequently Asked Questions for industry and retailers, aimed at informing industry of changes to the regulatory framework, as well as the development of a Compliance and Enforcement Policy for natural health products, and to provide further information on their roles as regulated parties.

The majority of external key informants agreed that the Program has been effective in engaging regularly with industry through participation at industry events and scheduling ongoing bilateral meetings with stakeholder groups. In addition, many praised the now defunct Program Advisory Committee, which was set up to ensure consistent communication and feedback between industry and the program during the transition to full regulatory implementation and was active from September 2009 to November 2011. More recently, a number of external interviewees noted that communication between the program and stakeholders has decreased after the dissolution of the Program Advisory Committee and, while bilateral communications between the program and stakeholder groups are ongoing, according to external key informants, a venue comparable to the Program Advisory Committee would be beneficial to help facilitate engagement opportunities.

Information on a wide variety of NHPP topics such as regulations, licensing requirements, and adverse reaction reporting is available on the Health Canada website. Web analytics show that the most popular industry directed page was Health Canada's Compendium of Monographs, with 146,270 page views between March 1, 2011 and March 31, 2015.

A significant decrease in the number of refused submissions within the evaluation timeframe may be due in part to an improved understanding of natural health products regulatory requirements by industry. While 153 refusals were issued in 2010-2011, that number decreased each year, and by 2014-2015 only 13 submissions were refused. However, the decrease in refusals could also be due to open communications and application assistance between NNHPD and the natural health products industry. On the other hand, some internal key informants felt that the three-class system may have diminished the thoroughness of application reviews. This could also explain the lower number of refusals.

Some internal interviewees felt that the exclusion of natural health products from departmental initiatives such as the Plain Labelling Initiative and *Vanessa's Law* causes confusion for industry. Similar products can fall under different regulatory regimes and have very different approval processes depending on whether they are a food, a natural health product, a cosmetic or a non-prescription drug. This can result in significant time spent on back-and-forth communications between program personnel and industry representatives in an attempt to clarify which regulatory regime a product should fall under. Industry has expressed confusion and frustration with product classification issues and, in some cases, this has led to “regulatory shopping” to find the least onerous and quickest pathway for their products to reach market. However, there is hope among both internal and some external interviewees that the work commenced under the Consumer Health Products Framework to modernize the regulation of self-care products, including natural health products, will help address this issue.

## Engagement with Health Care Professionals

A variety of educational and outreach activities, including annual presentations to students of naturopathic medicine, were conducted to inform health professionals of their role in the area of natural health products safety and adverse reaction reporting. The potential for interactions between natural health products and prescription or over-the-counter drugs was mentioned as an area of particular concern. Some interviewees noted that the primary focus has been on communications to health care professionals within the natural health community and not medical professionals, such as family doctors, who regularly interact with Canadians who may be consuming natural health products.

Various presentations took place over the years to provide stakeholders with information on adverse reaction reporting and MHPD's activities in that area. Post-market information and outreach activities by MHPD included two presentations per year, one to each of the November and March intake classes of the Canadian College of Naturopathic Medicine. An annual presentation is also given to fourth-year students of the Boucher Institute of Naturopathic Medicine. The Natural and Non-prescription Health Products Directorate also meets twice yearly with the Canadian Association of Naturopathic Doctors.

An online survey of naturopathic doctors conducted in 2012<sup>91</sup> found that despite Health Canada's outreach activities, there were ongoing barriers that may impact adverse reaction reporting. The majority (75%) of respondents indicated that an easier, clearer reporting process, as well as an increased awareness of the adverse reaction reporting process, would make it more likely that naturopathic doctors would submit adverse reaction reports to Health Canada.

## Challenges and the Way Forward

While it is clear that a number of activities took place during the evaluation time frame, there is no indication that those activities were tracked in a systematic manner and the evaluation did not find any centralized year-on-year data listing of the number and type of activities conducted. For example, it was unclear how many stakeholder meetings occurred in a given fiscal year or the average number of interactions between the Program and industry for each license application.



The evaluation was also unable to determine the extent of the NHPP's impact on regulatory awareness for either the natural health products industry or Canadians at large.

A more thorough and consistent approach to tracking and monitoring program activities is needed in order to show the impact of these efforts. The Program has committed to consolidating and formalizing an outreach strategy as part of the 2015 Internal Audit,<sup>92</sup> however, it is not clear whether tracking of all communications activities between the Program and industry stakeholders will be included as part of the strategy.

### **Outcome #3: Natural Health Products available to Canadians on the Canadian market are safe, effective and of high quality**

**The Program, using a risk-based approach, has contributed to the safety of natural health products. However, questions remain about the efficacy and quality of some natural health products, and this could have an impact on safety.**

The objective of the NHPP is that natural health products available on the Canadian market are safe, effective and of high quality. This objective stems from the *Food and Drugs Act*. Safety, efficacy and quality refer mainly to the pre-market authorization activities conducted by NNHPD. It also refers to some post-market activities conducted by MHPD, HPFBI and RAPB such as surveillance and compliance verifications. This information is then used by NNHPD to take actions to licenses not meeting these requirements (e.g., issuing stop sale and suspension letters, updating labels and/or product monographs). Safety is mainly ensured by companies adhering to ingredient monographs and/or through labelling that describes how a product should be used. Efficacy means the ability of the product to impact the condition it is expected to address, improve and/or treat. As outlined in the *Pathway for Licensing Natural Health Products Making Modern Health Claims*, it is assessed by NNHPD via standards of efficacy, which depend on ingredient risk, product type and health claims, with evidence ranging from clinical trial data to references in pharmacopeia. Finally, quality of products is how a product is manufactured/packaged/labelled. The Natural and Non-prescription Health Products Directorate assesses this through a site licence application system which is a company's adherence to Good Manufacturing Practices.

#### **Safety**

The Natural and Non-prescription Health Products Directorate has conducted activities to contribute to the safety of natural health products by developing agreed-upon safety standards (i.e., monographs) that can be used in the product licensing applications. These applications are then reviewed by NNHPD and the level of review is dependent on whether the product adheres to a monograph or not, and how many monographs are applicable, ensuring that products with less certainty of safety and efficacy (i.e., new formulations; Class III) receive a more thorough review.

The Natural and Non-prescription Health Products Directorate shares information on agreed-upon safety standards and information through the Natural Health Product Ingredient Database. This database, developed in 2009, is an electronic tool that allows the public to access information on acceptable medicinal and non-medicinal ingredients used in natural health

products, standard terminology referring to quality test methods, dosage forms, and the purpose of non-medicinal ingredients, and other pre-approved sources of information such as single ingredient monographs, product monographs, and abbreviated labelling standards.<sup>93</sup> From July 2010 until March 31, 2015, there were 3,231 ingredients added to the database.

Monographs are a key component of the Natural Health Product Ingredient Database. To facilitate the review of their product application, companies are encouraged to refer to monographs. Monographs describe the particular elements for an ingredient/product, including: proper and common names; acceptable route of administration; dosage; purpose and acceptable health claims; duration of use; warnings; known adverse reactions, and research reference that support the monograph. New monographs continue to be developed every year. There are over 250 natural health product monographs available online representing hundreds of ingredients.

While adherence to monographs is required for Class I (one individual monograph) and Class II (multiple monographs), further evidence of safety is required (along with efficacy) for applications that fall under the Class III applications. Using Standard Operating Procedures, NNHPD assesses the safety of Class III applications. Along with an attestation to a particular monograph or monographs if they are applicable, applicants are required to submit supporting evidence that safety and efficacy has been established. During 2014-2015, 2,914 Class III applications were reviewed by NNHPD. Of these, 2,585 applications were granted an NPN.

Within two weeks of granting an NPN, to further verify the safety of approved products, NNHPD has been carrying out risk-based audits on 100% of Class I applications containing ingredients of higher risk (e.g., caffeine). Risk-based audits are not required for Class II and Class III products as higher risk ingredients are routinely audited prior to receiving a licence. Additionally, NNHPD conducts random audits of Class I, II and III product applications. These audits verify whether or not the monograph parameters against which applicants have attested are met.

In 2014-2015, there were a total of 2,442 audits conducted, with a failure rate of 18%. As per Table 5 below, a considerable proportion of random audits resulted in failures (43% in 2014-2015, up slightly from 37% in the first three months of 2014). The issues identified were not linked to the safety of ingredients per se, but related more to risk statements and the quantity of medicinal ingredients. The risk-based audits are yielding better results, with only a 9% failure rate from 1,782 applications. In this case, failures were mostly linked to the proper identification of information (e.g., risk statements, source not per monograph, claims, quantity of medicinal ingredient), which, however, could result in potential health risks from consumers not using the products appropriately.

**Table 5: Attestation Audits Results**

Type	January 2014-March 2014			April 2014-March 2015		
	# of audits	# of failures	% of failure	# of audits	# of failures	% of failure
Random	173	64	37	680	293	43
Risk-based	n/a	n/a	n/a	1,782	153	9
Total	173	64	37%	2,442	446	18

Data Source: NNHPD

The Natural and Non-prescription Health Products Directorate reports that most issues identified in the audits have been resolved; however, as of October 2015, 43 issues remained open (19 issues from the random audits, 24 from the risk-based audits). The Natural and Non-prescription Health Products Directorate has met with industry representatives regarding those results, and as of November 9, 2015, has begun issuing suspension notices in response to all audit failures, where licence recipients have 90 days to demonstrate that the situation giving rise to the suspension did not exist or has been corrected. If a response to the licence suspension is not received within 90 days, NNHPD issues a cancellation notice for the associated NPN.

As discussed in the next section (Reduced Exposure of Canadians to Health Risks), MHPD conducts a variety of surveillance activities to contribute to the safety of natural health products. These activities include monitoring adverse reaction data, signal assessment research, and conducting product or ingredient safety reviews. These surveillance activities have had an impact on the approval of products. For example, MHPD activities found that ginkgo biloba, an ingredient in some natural health products, interferes with anticoagulant medication, which can be a safety issue for individuals that are recovering from a surgery. The Natural and Non-prescription Health Products Directorate changed the product monograph for ginkgo biloba, which then led to products now including a warning statement (i.e.: “do not use if you are taking health products that affect blood coagulation (e.g. blood thinners, clotting factor replacements, acetylsalicylic acid, ibuprofen, fish oils, vitamin E) as this may increase the risk of spontaneous bleeding”).

While MHPD conducts risk-based post-market surveillance activities to verify safety, the bulk of the efforts to assess product safety is done pre-market. This is in contrast to the United States whose activities are largely post-market, with exception to a requirement for manufacturers to register any new dietary ingredients (i.e., ingredients that had not been used prior to their legislation being enacted in October 1994) being used in their products. In this case the United States Food and Drug Administration would conduct a review of the manufacturer’s application to ensure there are no concerns with the product. Similarly to Canada, Australia conducts both pre-market and post-market activities that are dependent on the level of risk of products. Pre-market efforts are reserved for products that have been determined to be of higher risk to the Australian public. These products undergo comprehensive assessments of safety, quality and efficacy prior to entering the market, whereas low risk products are not evaluated pre-market, but subject to random and targeted reviews post-market.

Overall, internal key informants stated that the NHPP was better prepared to verify the safety of products than the efficacy or quality given the presence of agreed-upon safety standards (i.e., monographs). However, some internal key informants reported that safety becomes compromised by the lack of quality when products are adulterated and/or contaminated (see Quality sub-section below). While external key informants generally agreed that the NHPP is able to assess safety, a few key informants had concerns regarding products that have not been licenced but are still available for purchase in Canada or through importation.

## Efficacy

The efficacy of certain natural health products is challenging to confirm given that there is less scientific evidence or conflicting scientific evidence that exists to determine the efficacy of certain natural health products in treating or preventing conditions or illnesses. Additionally, activities carried out by Health Canada in assessing the efficacy of natural health products especially for Class I product applications appear to be limited. As with quality, efficacy is assessed against the *Pathways for Licensing Natural Health Products* via the use of monograph claims and through attestation only.

There are different standards of evidence requirements for natural health products based on the health claims and risk profile of a product or ingredient.<sup>v</sup> In December of 2012, NNHPD released the *Pathway for Licensing Natural Health Products Making Modern Health Claims*,<sup>vi</sup> the *Pathway for Licensing Natural Health Products used as Traditional Medicines*, and the *Evidence for Homeopathic Medicines Guidance Document* to confirm the Department's approach to assessing the efficacy of natural health products. The guidance documents stipulate that the "level of evidence (type and amount) that can be provided to support the safety and efficacy of a natural health product varies depending on the proposed health claims of the product and the overall risk profile of the product or its ingredients".<sup>94</sup> For instance:

- non-traditional products – based on seriousness of claim, such as a reference to a monograph or clinic trial;
- traditional products (e.g., Traditional Chinese Medicine, Ayurvedic Medicine) – two independent traditional references which use the same method of preparation; and
- homeopathic medicines – acceptable homeopathic reference or non-traditional reference.

The types of health claims allowed on a product differ according to products that make modern<sup>vii</sup> health claims, and products used as traditional medicines and homeopathic medicines. For instance, a Traditional Chinese Medicine product will have a claim that is prefaced with qualifiers indicating the specific traditional system of medicine.

The efficacy of natural health products generated a lot of discussion during internal and external key informant interviews. The majority of internal key informants and some external key informants agreed that the Department should be careful when it comes to allowing health claims on products that are regulated with less stringent standards of evidence, such as homeopathic products. Many internal key informants felt that the limited evidence required for products to receive an NPN was not clear, especially to the public, and is not aligned with Health Canada's science-based mandate.

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<sup>v</sup> A health claim is the statement found on a product label that identifies the effect produced by a product when it is used as per the recommended conditions of use (*Pathway*, 2012, p. 4).

<sup>vi</sup> 'Products making modern health claims' are all natural health products except traditional and homeopathic products.

<sup>vii</sup> Modern is used to describe natural health products that are not used in traditional medicines.

There have been recent changes made by the Department in the area of efficacy of natural health products. Internal informants thought that the July 2015 departmental announcement related to certain homeopathic products was a step in the right direction. The Department's decision was as follows:

- “The Department will no longer approve health claims on homeopathic products for symptomatic relief of cough, cold, and flu for children 12 and under, unless they are supported by scientific evidence”. Companies have been requested to remove health claims from these products by July 2016.
- “Homeopathic nosode products will include two statements to make it clear that they are neither vaccines nor alternatives to vaccines (i.e., “this product is neither a vaccine nor an alternative to vaccination, and this product has not been proven to prevent infection. Health Canada does not recommend its use in children and advises that your child receive all routine vaccinations”).<sup>95</sup> Companies have been requested to change their product labels by January 2016.

The July 2015 announcement, while more targeted, is similar to the approach taken by the United States, where all natural health products<sup>viii</sup> (with exception to homeopathics which are regulated as drugs in the United States) using a health claim are required to include a disclaimer on their label that reads “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease”.<sup>96</sup>

As reported in the NHPP program authority and as noted by a few internal key informants, the Branch was mandated to produce a regulatory framework for natural health products that includes respect for consumers' access to products; hence, the general health claims allowed on those products. Natural health products have been found to be generally low risk, however, as described under the Continued Need section, the risk is relative as long as individuals are not foregoing potentially needed medical treatment, and as long as products are manufactured properly.

## Quality

According to internal key informants, verifying the quality of health products is a key aspect of regulatory activities given that most health issues are due to the improper manufacturing of products. On the pre-market side there is the *Quality of Natural Health Products Guide* which sets standards companies are expected to meet prior to releasing their product for sale. Currently, quality is verified through industry's attestation to Good Manufacturing Practices under a site licence application.

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<sup>viii</sup> The scope of the *Dietary Supplement Health and Education Act* is not identical to the scope of the *Natural Health Products Regulations*.

An on-site inspection program is typically a key component of Good Manufacturing Practices. For natural health products, a mandatory on-site inspection program has yet to be implemented for both domestic sites and those outside of Canada; however, key informants have indicated that discussions about such an inspection program have begun. This is in contrast to both the United States and Australia who rely on formalized inspection programs with ongoing and reoccurring inspections, to verify the quality of products on the market.

Both internal and external key informants were unsure if NHPP-conducted activities were sufficient enough to verify the quality of natural health products. Further, key informants pointed out that the quality of natural health products is currently based on attestation through a paper-based exercise which is not verified by an on-site inspection program.

The 2015 Internal Audit also raised concerns about the lack of on-site inspections. In response to one of the 2015 Internal Audit recommendations, HPFB agreed to implement an enhanced verification of good manufacturing practices by reviewing options with program partners by June 2016. This consultation will be based on results from a previous on-site inspection pilot project, which was conducted by third party on-site auditing organizations between April and May 2014 with seven companies. Overall, the companies that took part in the pilot project felt that the model was not an appropriate model to implement given concerns raised about the value and consistency of the audits (e.g., depth and/or scope of audit, role of auditors, and lack of training).

Further to that, NNHPD is unable to match/cross-reference product applications to site licence applications which, in turn, limit the evaluation's ability to confirm that NNHPD can attest to the quality of products. The 2015 Internal Audit noted this weakness and recommended that the Department should "enhance the cross-reference of product licences to site licences".<sup>97</sup>

Studies, such as the one conducted in 2013 by Newmaster and colleagues at the University of Guelph, show that the adulteration of natural health products can be significant. The study tested 44 herbal supplements purchased in Canada or the United States and found that nearly 60% of the products were adulterated, with the products containing ingredients not listed on the label. Adulteration, such as that found by Newmaster et al., leads to safety concerns – making products once on the market potentially unsafe to consumers, which then leads to potential health risks.

## **Outcome #4: Reduced exposure of Canadians to health risks**

**Overall, various program activities have contributed to limiting exposure to health risks; however, important challenges remain.**

The outcome of reduced exposure of Canadians to health risks was defined, through key informant interviews, as the activities carried out by Health Canada once products are available on the market (i.e., post-market activities). As a few internal key informants put it, health risks especially for some natural health products are mostly known after products are used by consumers, given the limited clinical trial data and research in the area. The logic model (see Appendix 1) illustrates that the majority of the activities conducted to limit exposure to health risks are post-market activities; however there are a few pre-market activities such as the three

class application review system and attestation audits that also contribute to reducing exposure to health risks. These activities are discussed in more detail in the section on Safety, Efficacy and Quality, particularly under Safety.

Even though natural health products are considered low risk, especially in comparison to prescription drugs, a variety of activities still take place to minimize health risks associated with the use of natural health products.

## Surveillance

The Marketed Health Products Directorate has conducted a variety of monitoring activities to help minimize health risks posed by natural health products, including surveillance of adverse reactions, signal assessment research, and product or ingredient safety reviews.

### Adverse reaction data

One of the key activities carried out by MHPD is the monitoring of adverse reactions to health products through the Canada Vigilance Program System – a system where licence holders, consumers, patients and/or health professionals report adverse reactions. The reporting of adverse reactions suspected of being associated with natural health products, although very low in comparison to prescription pharmaceuticals (between one to two percent of all reports), has slightly increased over the years. It is difficult to know whether this increase is due to an actual increase in adverse reactions or whether it is due to an increased number of licence holders, health care professionals and individuals reporting reactions. Table 6 below illustrates the fluctuation in reports received.

**Table 6: Domestic Natural Health Product Adverse Reaction Reports Received**

2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	Total
678	680	683	1,122	722	<b>3,885</b>

Data Source: MHPD

The Marketed Health Products Directorate continues to explore options to improve access to adverse reactions data sources. Phase three of a 3-year pilot project, completed over a period of five months (November 2012 to April 2013) with only two of the Canadian Poison Control Centres resulted in a considerable increase in reporting – approximately 300 reports were filled during the five-month period, and for only a subset of pre-identified products/ingredients. During that short period, MHPD was successful in identifying a serious health risk and taking appropriate action. Specifically, one Poison Control Centre reported a serious adverse reaction linked to an unlicensed product (Compound Danshen Dripping Pills) that was sold in Canadian stores. A public alert was then issued.<sup>ix</sup>

<sup>ix</sup> <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36157a-eng.php>

Health Canada, in collaboration with other health portfolio members (e.g., the Public Health Agency of Canada) and other stakeholders such as the Canadian Institute for Health Information, is participating in a broader pilot project with Poison Control Centres to further investigate the data they collect by establishing a Canadian Surveillance System for Poison Information. This system would create a centralised database of all Canadian poison control data, including information on adverse reactions. The planning phase of the project was launched in 2014 and is expected to result in ongoing access to the Centres’ data. Both a Task Force and a Steering Committee have been formed to lead this project. Two face-to-face meetings with the Canadian poison centres have been held to move the project forward, and four additional meetings are planned for 2016-2017. A pilot of a database for pan-Canadian poison data is planned for late fiscal year 2015-2016 and into 2016-2017. As noted by internal key informants, the increased and ongoing availability of adverse reaction data is a key component in determining the health risks posed by natural health products, especially given that these consumer health products are ones that are usually taken without individuals being monitored by healthcare professionals.

### Signal assessments

To identify a health risk before it becomes an issue in the broader population, MHPD monitors and analyzes emerging safety issues from international scientific and medical literature through a variety of activities such as signal assessments, causality assessments, Annual Summary Report Reviews (in Periodic Safety Update Report format), ad-hoc reviews and reviews of product alerts issued by other countries. Between 2010-2011 and 2014-2015, a total of 563 different risk assessment activities took place, with the majority of these being reviews of product alerts issued by other countries. A breakdown of the number and type of review activities conducted can be found in Table 7. These risk assessment activities can result in a variety of actions, including standard monitoring, enhanced monitoring, labelling recommendations, and risk communications.

**Table 7: MHPD risk assessment activities**

Year	Risk Assessment Activity						Total
	Signal Assessment	Causality Assessment	Periodic Safety Update Report – Level 1	Periodic Safety Update Report - Level 2	Ad-Hoc Review	Reviews of Product Alerts Issued by Other Countries	
2010-2011	10	29	10	0	20	52	<b>121</b>
2011-2012	9	16	10	2	14	37	<b>88</b>
2012-2013	9	6	10	2	14	37	<b>78</b>
2013-2014	10	0	16	6	15	82	<b>129</b>
2014-2015	6	7	24	1	5	104	<b>147</b>
<b>TOTAL</b>	<b>44</b>	<b>58</b>	<b>70</b>	<b>11</b>	<b>68</b>	<b>312</b>	<b>563</b>

Data Source: MHPD



The Marketed Health Products Directorate-led signal assessment meetings and the MHPD-NNHPD Post-Market Recommendations spreadsheet are the mechanisms through which MHPD ensures that appropriate follow-up action is undertaken by NNHPD to address the findings and recommendations stemming from signal assessments and ad-hoc reviews. The key findings, recommendations and actions taken to address these issues are identified and tracked in that spreadsheet. From November 2014 to May 2015, 21 issues were addressed, seven were open, and research was ongoing for three issues.

This structure allowed both parties to deal with outstanding issues. Of the 21 issues that were resolved by MHPD and NNHPD, health risks were most frequently minimized by considering and/or making changes to labelling requirements. For example, labelled warnings for an ingredient (greater celandine or Chelidonium majus) found to cause acute hepatitis was implemented and indicated potential liver problems and informing consumers that the product should be used under the supervision of a healthcare practitioner.

At the time of the evaluation, one of the seven issues that is in the process of being addressed by NNHPD includes a signal assessment review where hypersensitivity and/or anaphylactic reactions were identified with the use of salicylic acid. The review was shared with NNHPD in February 2015 and included various recommendations, such as updating product labels and issuing a risk communication item. The Natural and Non-prescription Health Products Directorate and MHPD collaborated on the revision of the labels and accompanying Acne Monograph. This monograph was posted for comment on January 12, 2016, it is a 60 day consultation after which the monograph will be finalised.

### **Product Safety Reviews**

In April 2015, MHPD posted its first natural health product Summary Safety Review online for goldenseal, an herbal ingredient. The review led to an Infowatch article to raise awareness and to encourage the reporting of related adverse reactions with goldenseal used in conjunction with conventional medications. The online posting of natural health product-specific reviews should further assist the Department in minimizing health risks by making this information available to consumers and healthcare professionals.

### **Compliance and enforcement**

Over the past five years, a variety of compliance and enforcement actions were taken by the NHPP to minimize health risks. These actions included: conducting compliance verifications; requesting and monitoring product recalls; monitoring at the border and recommending refusal of shipments of unsafe products referred to Health Canada by the Canada Border Services Agency; communicating risks to the public and/or healthcare professionals to inform them of product risks and/or unsafe products; and cancelling or suspending product/site licences.

## Compliance verification

When HPFBI becomes aware of potential non-compliance with the *Natural Health Products Regulations*, it takes steps to verify whether non-compliance has occurred and takes appropriate compliance and enforcement action as necessary and proportional to the risk posed to the public. Incidents of non-compliance can be identified via a variety of sources, including; complaints, foreign alerts, laboratory analysis, referrals from other government departments, and media articles.

To date, the majority of incidents received have been complaints-based with internal key informants reporting that most of those are coming from industry. As presented in Table 8 below, over the period of 2010-2011 to 2014-2015, HPFBI opened 1,948 incidents involving natural health products and closed 2,194 of them.<sup>x</sup> Over the past five years 265 non-compliant products have been removed from the market via a product recall; approximately 128 of those posing a risk that could result in death, also known as a Type 1 risk. There were also recalls on 70 natural health products posing a Type II risk (i.e., products that may cause temporary adverse health consequences or where the likelihood of severe adverse reactions are not high) and 67 natural health products posing a Type III risk (i.e., an adverse health consequence is unlikely). Natural health products represent approximately one out of three of all compliance verifications conducted by HPFBI. This is down from the 2010 NHPP Evaluation which found that 40% of all compliance verification activities were for natural health products.

**Table 8: Number of incidents and recall actions taken on natural health products - 2010-2015**

Category Type		2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	TOTAL
Incidents	Opened	432	403	340	380	393	<b>1,948</b>
	Closed	508	420	545	357	364	<b>2,194</b>
Recalls	Type I	37	5	7	74	5	<b>128</b>
	Type II	25	3	18	13	11	<b>70</b>
	Type III	21	6	10	19	11	<b>67</b>
	<b>Total</b>	<b>83</b>	<b>14</b>	<b>35</b>	<b>106</b>	<b>27</b>	<b>265</b>

Data Source: HPFBI Yearly Project Reports

It should be noted that the product recall numbers may not be an accurate depiction of all natural health product-related recalls given that, up until early 2015, natural health products that were tested and found to be adulterated with a prescription drug substance were reported and counted as prescription drugs.

<sup>x</sup> There are more incidents closed between 2010-2011 and 2014-2015 than were opened due to carry-over from ongoing incidents that had been opened in previous years.

To assist in compliance verification activities, laboratory testing of natural health products was conducted at the request of RAPB inspectors working on both domestic and imported products. The 2015 Internal Audit found that in 2013-2014, more than half of the samples sent to the laboratory for testing (64 of 117) were unsatisfactory.<sup>xi</sup> Most of these unsatisfactory samples were natural health products adulterated with a prescription drug.

## Border integrity

The Canada Border Services Agency refers shipments of potentially non-compliant natural health products to RAPB inspectors, who conduct an admissibility determination and recommendation for entry, or refusal of entry, into Canada. In the past five years, there have been 61,231 admissibility determinations conducted for natural health products. Of these, 13,758 unlicensed natural health products were recommended for refusal at the border.<sup>xii</sup> Almost all of these refusals were for natural health products for commercial use. As presented in the table below, there are a considerable number of personal shipments that result in releases as opposed to refusals, likely due to personal shipments involving a much smaller quantity of product (i.e., no more than 90 days' worth of doses).

**Table 9: Border Integrity**

Shipment Type	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	Total
<b>Commercial</b>						
Releases	397	354	497	750	671	2,669
Refusals	6,636	1,533	2,139	1,729	1,611	13,648
<b>Personal</b>						
Releases	4,450	5,124	16,855	10,103	8,272	40,804
Refusals*	110	0	0	0	0	110

Data Source: HPFBI

\* A decision was made that starting in 2011-2012, personal imports which contained more than a 90 day supply of natural health products were to be reported as commercial shipments.

## Advertising complaints

As presented in Table 10, over the period of 2010-2011 to 2014-2015, there were 134 advertising complaints related to natural health products. This represents approximately 35% of all advertising complaints received by MHPD. A variety of actions were taken to address

<sup>xi</sup> In the case of an unsatisfactory result, at least one of the following situations applies: the sample did not meet specifications; the sample did not meet regulatory requirements; a method-related problem was encountered; the laboratory does not have information on the regulatory limits for an analyte suspected to be a health hazard; validation data has not been received within a reasonable time frame; validation for the method is not confirmed and testing was not completed as required materials were not received within a reasonable time frame.

<sup>xii</sup> It should be noted that on April 1, 2011 a change was made to the tracking and reporting of personal importation refusals, whereby shipments to individuals of a greater than 90 day supply of a health product were subsequently recorded as commercial importation refusals rather than personal importation refusals. This was to ensure consistency in reporting and alignment with HPFBI's "Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations" (GUI-0084) as to the type of importation activity occurring (commercial vs personal).

advertising complaints including referring to advertising preclearance agencies, referring to HPFBI for compliance verification, and issuing letters to Market Authorization Holders. As is evident in Table 10, not all complaints were addressed from 2010-2011 to 2012-2013 to 2014-2015.

**Table 10: Natural Health Products – Advertising complaints received and actions taken**

Advertising complaints received and actions taken	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	Total
Natural health product complaints received	16	19	31	20	48	134
<b>Actions Taken</b>						
Referral to Advertising preclearance agency**	0	1	7	6	16	30
Referral to HPFBI for compliance verification	8	10	17	11	18	64
Regulatory letters issued	2	5	3	3	14	27
Other***	6	3	4	0	0	13
<b>Total Actions Taken</b>	<b>16</b>	<b>19</b>	<b>31</b>	<b>20</b>	<b>48</b>	<b>134</b>

Data Source: MHPD

\*\* Advertising Preclearance Agency refers to advertising preclearance agencies (e.g., Advertising Standards Canada, Pharmaceutical Advertising Advisory Board, MIJO – Extreme Reach).

\*\*\* Other refers to other forms of action taken besides referral to APA or HPFBI (e.g., referral to another directorate, further information required from complainant, assessment completed and no violations found).

### Risk communications

There have been continued efforts to communicate health risks associated with using natural health products through risk communication activities such as public advisories, foreign product alerts, information updates, and Health Product InfoWatch (formerly the Canadian Adverse Reaction Newsletter). Between 2010-2011 and 2014-2015, 297 natural health product risk communications were posted on the MedEffect Canada and the Healthy Canadians websites. Of those, 63%, or 186, were Foreign Product Alerts issued by MHPD, with another 26%, or 77, being Public Advisories. The high rate of Foreign Product Alerts may be explained by globalisation of online consumer purchasing, and the ease of access to those products for which safety, efficacy and quality has not been evaluated by Health Canada if originating from other countries.

**Table 11: Natural Health Product Risk Communications Posted on the MedEffect Canada/Healthy Canadians Website by MHPD**

Risk Communications Posted on the MedEffect Canada/Healthy Canadians Website	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	Total
Public Advisory	22	16	11	15	13	77
Foreign Product Alert	52	33	23	35	43	186
Information Update	9	5	8	6	2	30
Canadian Adverse Reaction Newsletter/Health Product InfoWatch*	3	0	0	0	1	4
<b>Total</b>	<b>86</b>	<b>54</b>	<b>42</b>	<b>56</b>	<b>59</b>	<b>297</b>

Data Source: MHPD

\* As of January 2015, the quarterly Canadian Adverse Reaction Newsletter has been replaced with the monthly Health Product InfoWatch.

## Product licence actions

There are a variety of product licence actions that can be taken to address health risks posed by a licensed natural health product. Regulatory letters can be sent to licence holders to request changes to the product licence, request safety information, direct a stop sale of a product, suspend the licence, or cancel the licence. Out of all of these actions, the cancellation of a licence is the final step taken to address product issues. In the past five years, 67 licences have been cancelled.

**Table 12: Number of Licences Cancelled**

Licence Type	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015	Total
Cancelled	5	2	46*	3	11	67

Data Source: NNHPD

\* These cancellations were all part of a transition in the classification system of certain natural health products related to food which were transferred to the Food Directorate and the licenses were cancelled.

## Challenges

There are various factors impacting whether health risks are minimized. Although improvements to monitoring, compliance and enforcement activities have taken place, and more activities are planned for the future, outstanding issues remain.

- To date, the majority of the activities carried out by HPFBI and RAPB have been reactive – when an issue is identified, HPFBI and RAPB, following prioritization of the issue, verify a product’s compliance with the regulations. The transition period for compliance and enforcement activities related to the program. The Health Products and Food Branch Inspectorate launched a framework in 2015 which highlights a shift toward a more proactive compliance program where Compliance Monitoring Projects would be planned regularly and informed by trending and analysis of risk information.
- Information technology systems are not comprehensive and are not fully accessible to every NHPP partner. For example, HPFBI does not have full access to NNHPD’s databases. Further, there is not one system or list that exists on all issues identified, tracked, and addressed by product and/or site.
- As noted by internal key informants, there is limited follow-up action to verify that recalled products have been removed from the market. The hope going forward is that the Health Product and Food Branch Inspectorate’s new case management system, RADAR, will help identify if recalled products have been removed.<sup>xiii</sup>

<sup>xiii</sup> The RADAR system was implemented in October 2014, and at the time of the evaluation, there was no information available about its implementation.

- The *Natural Health Products Regulations* are not perceived to be sufficiently strong by some internal and a few external key informants to persuade industry to address non-compliance. For example, natural health products were not included in Vanessa's Law, which imposes tougher penalties, including jail time and fines up to \$5 million per day, for unsafe prescription drugs, over the counter drugs, vaccines, gene therapies, cells, tissues and organs, and medical devices.

## Outcome #5: Integration of program activities

**While there are current and past examples of integration (e.g., NHPP Director General Steering Committee, Central Intake and Triage Pilot, Signal Assessment meetings, Program Advisory Committee), there are further opportunities for program activities to be systematically integrated, especially at the working level.**

There are many examples of integration such as: integration within the NHPP, integration within Health Canada and integration with external stakeholders, but despite this, there remain areas for improvement.

### Integration within the NHPP

There have been efforts to integrate activities within the NHPP. For example, the former NHPP Director General Steering Committee consisted of representatives from the Program directorates and was chaired by the Director General of Natural Health Products Directorate. Its purpose was to guide and monitor the implementation of the activities and program performance as a whole. This committee involved all program partners and had a terms of reference (membership, mandate, and scope); a secretariat; and clear and aligned decision-making authority and accountability; however, it is no longer active because the Branch moved to a new governance model.

A recent Internal Audit of the program found that in March 2015, a new governance model was introduced to streamline and improve decision making while increasing the Branch Executive Committee's focus on strategic decision making. The new governance model is supported by three subcommittees: Integrating Policy, Programs and Science; Transformation, Transparency, Investments and Finance; and Talent and People Management. Within NNHPD, MHPD and HPFBI, there are Management Committee meetings, and all three directorates meet bilaterally as needed.

Another example of integration is the Central Intake and Triage Pilot Project. Initiated in November 2014, this HPFBI's project enables integration across HPFBI and RAPB. The Central Intake and Triage Pilot Project's main objective is to implement a central intake and triage model such that:

- incidents are received centrally in HPFB (national capital region);
- incidents are triaged in HPFB (national capital region), prioritized and forwarded to the appropriate groups/regions if follow-up is required; and
- low risk incidents are monitored by HPFBI to inform the development of collective compliance activities and any trend data.

Many internal key informants working on this project noted that the Central Intake and Triage Pilot Project is well structured and has made processes more efficient and consistent because it provided a central area to send all incidents and has the potential to provide a national picture, picking up on trends quicker than was possible under the old system.

A further example of integration is the MHPD-led signal assessment meetings where MHPD and NNHPD convene through a natural health product-specific forum. The purpose of these meetings is to jointly discuss the signals that have emerged post-market for which MHPD is carrying out an assessment, and reach consensus on the appropriate risk management activities that should be taken, if applicable. This forum is also useful for NNHPD to bring items forward that may be of interest to MHPD e.g., high priority files, or pre-market safety issues that are of high priority (i.e., those reaching Director General or Assistant Deputy Minister level). However, the signal assessment meetings are mostly focussed on MHPD safety reviews and actions for follow-up, which are done in collaboration with NNHPD.

## **Integration within Health Canada**

The Natural Health Products Program engages regularly with both the Healthy Environments and Consumer Safety Branch and the Food Directorate within HPFB. Historically, food products could not make a health claim. When the *Natural Health Products Regulations* came into force, industry started applying for an NPN, resulting in hundreds of products moving over to Natural Health Products Directorate between 2006 and 2009. In fall 2009, the Minister announced the intention to transition all products in food format back to the food regulatory framework. During this transition phase, internal key informants noted that the Food Directorate worked collaboratively with the Natural Health Products Directorate, which helped develop relationships with the stakeholders affected by the transition. At the peak of the transition, there were daily interactions at the working level. This engagement further intensified around the time that the Natural Health Products (Unprocessed Product Licence Applications) Regulations was introduced and continued until this regulation was repealed.

These good working relationships continue today, the Food Directorate and the NHPP still interact regularly through bilateral meetings, the Product Classification Committee meets regularly in person or by phone, and also participate in meetings regarding the Consumer Health Products Framework. Staff from the Healthy Environment and Consumer Safety Branch mainly works with the NHPP on classification issues to determine the regulatory regime that applies to products that straddle the line between different regimes.

## **Integration with external stakeholders**

As previously mentioned in the discussion of Industry awareness, the NHPP holds joint outreach activities for external stakeholders. Key informants from other Directorates, including MHPD, HPFBI and the Food Directorate, reported being part of NNHPD-led consultations/bilats with industry and industry associations. Ongoing bilateral meetings are held with the following stakeholder associations: Consumer Health Products Canada, Canadian Health Food Association, Canadian Homeopathic Pharmaceutical Association, Canadian Natural Products Association,

Canadian Cosmetic, Toiletry and Fragrance Association, Canadian Consumer Specialty Products Association, Direct Sellers Association, Traditional Chinese Medicines Community.

Following public consultations to develop the *Natural Health Products Regulations*, the NHPP Advisory Committee became the key forum for ongoing consultation. As previously mentioned, the Program Advisory Committee meetings were held between 2009 and 2011 and were set up to ensure consistent communications and feedback between the industry and the program during the transition to full regulatory implementation.

Further, RAPB conducts information sessions with the Canada Border Services Agency, conducts training and provides the Canada Border Services Agency with online tools such as alerts, in addition to having a 1-800 line available for the Canada Border Services Agency inspectors.

Internationally, since there are a lot of products that cross the borders, the United States Food and Drug Administration and Health Canada work together to share information on scientific collaboration when reviews are ongoing. For example, MHPD has quarterly international pharmacovigilance teleconferences where items are brought forwards that are of international interest. The Marketed Health Products Directorate also regularly follows up with the European Medicines Agency and United States Food and Drug Administration about safety reviews, and they receive monthly updates from the European Medicines Agency's Pharmacovigilance Risk Assessment Committee on safety reviews, including those on natural health products. Health Canada also works with the Therapeutic Goods Administration in Australia, both formally and informally, to share information about safety of products, regulatory approaches, and compliance actions for manufacturers.

## Areas for improvement

While there have been many attempts to integrate the activities of the NHPP, work remains. Some internal key informants felt that the level of integration in the NHPP was appropriate; however, just over half of the internal key informants confirmed that the majority of interactions are on an ad-hoc basis, and although staff knows who to talk to at the appropriate time, half of the interviewees noted that, overall, there could be better integration. As previously mentioned, the MHPD-led signal assessments meetings are useful and a number of internal key informants confirmed that the signal assessment meetings are a good forum to share information and discuss issues; however, they also noted that there would be value in having HPFBI included in those discussions given its role in post-market activities. It would also be beneficial to have a terms of reference for the meetings to confirm membership, committee objectives, priorities, and roles and responsibilities. Even though there are mechanisms in place at the Branch level, for example, natural health products-specific issues can be brought forward at the Branch Executive Committee's sub-committees to help ensure integration of activities; there do not appear to be the same systematic opportunities at the working level where interactions are mostly ad hoc.

Many internal key informants noted that a lot of staff time is spent on classifying products. While the majority of the products can be classified easily, there will always be challenges with those products that straddle the definition between natural health products, food products and



cosmetics. Product classification is an ongoing challenge, but there is hope that moving forward, the Consumer Health Products Framework will help. Some internal key informants felt that the Consumer Health Products Framework governance structure could assist in integrating activities better as it includes representatives from related program areas at the senior and staff level, and is addressing cross-cutting policy issues.

External key informants appear to have quite varied experiences with respect to their interactions with Health Canada: a number seem to be in constant communication with the Program, others are engaged through the bilateral meetings and a few have no contact whatsoever. Many external key informants noted that engagement with Health Canada has diminished in the last few years and several expressed disappointment that there is no longer a committee similar to the Program Advisory Committee since this was seen as a useful venue to get together, discuss issues and be advised of new developments.

Internationally, the United States Food and Drug Administration and Health Canada work together to share information. A key informant from the United States Food and Drug Administration noted that these interactions are very good but are mostly ad hoc, with staff making calls and getting in touch as needed. More recently, there have been discussions about holding more formal/regular calls to discuss issues such as online sales of those products that eventually cross the border.

## **Outcome #6: Evolving Natural Health Product Framework**

**Health Canada has been able to adapt to the changing environment by adjusting the Natural Health Products Regulatory Framework; however, some challenges still remain that impede Health Canada's ability to respond to the changing environment.**

At the time the regulations came into force in 2004, there were already approximately 42,000 products on the market which were then required to obtain a product licence. As a result, this created a backlog of applications. To help clear the backlog, the NHPP adapted by introducing the temporary *Natural Health Products (Unprocessed Product Licence Applications) Regulations* to allow these natural health products to be sold pending approval of their product licences. At the same time, the NHPP published the following policy: *Management of Product Licence Applications for Natural Health Products*.

In fall 2012, the Program further adapted by implementing a new approach to regulating natural health products. This approach included changes to how product licensing, site licensing, compliance and enforcement were conducted by the Program. With regards to product licences, the NHPP proposed to introduce a Class Approach that linked review times to the Program's level of certainty with the product's risks and benefits.<sup>98</sup> This system meant that products with the greatest level of certainty (i.e., those that are in line with over 250 monographs that have been published by Health Canada) are subject to the shortest review time. As of February 2013, a licensing decision had been issued for all applications received prior to the implementation of UPLAR, clearing up the backlog of unprocessed applications. To further shorten product review times, the Management of Product Licence Applications for Natural Health Products was updated in 2014 and introduced product licence application review service standards based on

the new Class Approach to product review. Current service standards are as follows: 10 business days for Class I products, 30 calendar days for Class II products and 180 calendar days for Class III products.<sup>99</sup>

As previously mentioned, consultations were launched on a new Consumer Health Products Framework which proposed to further streamline and update the current regulations for lower-risk health products.

As noted, and supported by internal key informants, not only is there a vast amount of natural health products readily available, but they are also becoming increasingly complex. As a result, a number of policy and guidance documents were developed to help strengthen the regulations by supporting implementation of the regulations and providing Canadians and industry with the information needed to meet the requirements of the regulations.

Policy and guidance documents set out Health Canada's approach to pre-market and post-market activities under the regulations. These documents describe adverse reaction reporting requirements, compliance activities and Health Canada's approach to reviewing natural health products, as well as the requirements for quality products so that Canadians have access to safe, effective and high quality natural health products. (see Appendix 1 for a list of policy and guidance documents).

Although much has been done to adapt to the changing environment, challenges remain. For example even though the three-class system and Natural Health Product (Unprocessed Product Licence Applications) Regulations were perceived to be a success by many internal and external key informants, others felt that they had resulted in Health Canada reducing the thoroughness of application reviews.

Health products are becoming more innovative and as a result, the Department has struggled to address product classification issues. According to some internal key informants, clearly determining under which regulatory regime products fall continues to represent one of the key challenges facing the program – over 1,620 product classification requests were addressed by NNHPD in the past five years.<sup>xiv</sup>

Despite these challenges, there are opportunities moving forward. Some internal and external key informants were optimistic that current outreach activities (industry bilats, participation on various industry association conferences) were effective in informing the program of upcoming shifts in the industry. Work started under the Consumer Health Products Framework may also assist in addressing some of these issues by trying to ensure that consumer health products regulations are more consistent since the objective is to treat similar products with similar risks the same.

Overall, many internal and external key informants agree that Health Canada has adapted to the changing environment through implementation of the regulations, elimination of the backlog, introduction of monographs, service standards and the three-class system. Looking forward,

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<sup>xiv</sup> Note: this number was only fully tracked starting in 2012 and therefore is likely an under-representation of activities.

many external key informants observed that Health Canada is well positioned to adapt to future changes because of its regulatory framework, and improvements to the system such as the monographs database and the addition of performance standards that are predictable and reliable. While a few internal key informants noted that the language used in the *Natural Health Products Regulations* is considered modern and therefore easier to adapt in comparison to other regulations, other internal key informants felt that Health Canada would not be able to adapt quickly to future changes in the environment, given that it takes a long time to adjust regulations.

## 4.5 Performance: Issue #5 – Demonstration of Economy and Efficiency

The Treasury Board of Canada's *Policy on Evaluation* (2009) and guidance document titled *Assessing Program Resource Utilization When Evaluating Federal Programs* (2013), define the demonstration of economy and efficiency as an assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes. This assessment is based on the assumption that departments have standardized performance measurement systems and that financial systems link information about program costs to specific inputs, activities, outputs, and expected results.

The data structure of the detailed financial information provided for the program did not facilitate the assessment of whether program outputs were produced efficiently, or whether expected outcomes were produced economically. Specifically, the lack of output- and outcome-specific costing data limited the ability to use cost-comparative approaches. In terms of assessing economy, challenges in tracking funding within the broader program envelope limited the assessment. Considering these issues, the evaluation provided observations on economy and efficiency based on findings from internal key informant interviews and available relevant financial data.

In addition, the findings below provide observations on the adequacy and use of performance measurement information to support economical and efficient program delivery and evaluation.

### Observations on Economy

**For most of the last five years, the program has spent the majority of its planned allocations. In the last few years there have been significant reductions to NNHPD's financial and human resources.**

Directorates were not required to report at the sub-program level of the Department's Program Alignment Architecture until 2012-2013; therefore, the program has not been able to report on its planned and actual allocations for the whole timeframe of the evaluation. Natural Health Products Program-specific financial data is fully available for NNHPD and MHPD, while it is only available for the past three fiscal years for HPFBI and for one fiscal year (2014-2015) for RAPB.

## Planned versus actual expenditures

While the full picture of planned versus actual expenditures for the NHPP as a whole is unavailable due to reporting differences among responsible directorates, data is available from three of the four groups (with RAPB the exception) for 2012-2013 to 2014-2015. Available data indicates that the program is spending approximately 99% of its planned allocations during this timeframe. While there is an overall balance in program spending, this is achieved through overspending in salaries (\$5.3 M over three years), while underspending on operations and maintenance (O&M) (\$5.7M).

NNHPD's planned budget was reduced by \$8.2M – close to 45% of its initial budget – in the past four years (from almost \$18M in 2011-2012 to \$9.8M in 2014-2015). As presented in Table 13 below, NNHPD has slightly overspent its allocated budget, from 2012-2013 to 2014-2015, the years following the decision to reduce the Directorate's budget. The percentage by which NNHPD is overspending has been increasing. Similarly to the above picture of the program as a whole, it appears that, while NNHPD has been spending its entire allotment (or more in recent years), this overall balance is represented by overspending on salary (\$14.7M over five years) and is similarly underspending on O&M (\$15.6M over five years).

Of note, to offset an ongoing deficit, NNHPD regularly received funding from the Deputy Minister's reserve (this funding is represented in planned spending) ranging from a high of \$7.2M in 2010-2011 to a low of \$4M in 2014-2015. Funding in the amount of \$6.4M was made a permanent part of the program's budget in 2014-2015.

**Table 13: Variance Between Planned Spending vs Actual Expenditures for NNHPD - 2010-2011 and 2014-2015**

Year	Planned Spending (\$)			Expenditures (\$)			Variance (\$)	% planned budget spent
	O&M	Salary	TOTAL	O&M	Salary	TOTAL		
2010-2011	9,599,277	7,690,820	<b>17,290,097</b>	2,657,024	13,574,529	<b>16,231,553</b>	1,058,544	93.88
2011-2012	7,250,913	10,734,999	<b>17,985,912</b>	2,752,638	13,975,673	<b>16,728,311</b>	1,257,601	93.01
2012-2013	30,448	15,270,690	<b>15,301,138</b>	912,530	14,782,079	<b>15,694,609</b>	-393,471	102.57
2013-2014	4,483,320	8,143,099	<b>12,626,419</b>	622,653	12,340,256	<b>12,962,909</b>	-336,490	102.66
2014-2015	1,692,618	8,065,962	<b>9,758,580</b>	534,818	10,006,661	<b>10,541,479</b>	-782,899	108.02
<b>TOTAL</b>	<b>23,056,756</b>	<b>49,905,570</b>	<b>72,902,146</b>	<b>7,479,663</b>	<b>64,679,198</b>	<b>72,158,861</b>	<b>782,899</b>	<b>98.9</b>

Data Source: Financial data provided by the Chief Financial Officer Branch

The two tables below present MHPD's (Table 14) and HPFBI's (Table 15) planned spending and actual expenditures. Both directorates have had limited budgetary reductions in the past five years. Although budgets have remained somewhat stable for both groups, expenditures have fluctuated slightly over the years.

As is demonstrated in Table 14, over the last five years MHPD has reported spending approximately 83% of its planned allocations. The vast majority of the surplus is the result of O&M funds that appear not to have been spent. However, the data for MHPD should be interpreted with caution due to the fact that three of the four bureaus in receipt of natural health product funding are also funded by other product line allocations. Expenditures against those

three bureaus have been viewed and tracked as ‘horizontal’ expenditures and not by the area that may have provided the funds. This horizontal tracking has led to a less accurate account of the totality of natural health product expenditures within the directorate. This has been rectified and will be properly reported in the future. The Health Products and Food Branch Inspectorate has generally spent its allotment, with the percentage spent increasing steadily from 91% in 2012-2013 to 98% in 2014-2015.

**Table 14: Variance Between Planned Spending vs Actual Expenditures for MHPD - 2010-2011 and 2014-2015**

Year	Planned Spending (\$)			Expenditures (\$)			Variance (\$)	% planned budget spent
	O&M	Salary	TOTAL	O&M	Salary	TOTAL		
2010-2011	482,000	1,362,000	<b>1,844,000</b>	141,726	1,300,744	<b>1,442,470</b>	401,530	78.23
2011-2012	577,999	2,013,000	<b>2,590,999</b>	180,288	2,258,737	<b>2,439,025</b>	151,974	91.13
2012-2013	612,945	2,540,193	<b>3,153,138</b>	62,869	2,278,739	<b>2,341,608</b>	811,530	74.26
2013-2014	620,360	2,972,654	<b>3,593,014</b>	121,191	2,627,668	<b>2,748,859</b>	844,155	76.51
2014-2015	499,290	2,548,671	<b>3,047,961</b>	49,642	2,826,531	<b>2,876,173</b>	171,788	94.36
<b>TOTAL</b>	<b>2,792,594</b>	<b>11,436,518</b>	<b>14,229,112</b>	<b>555,716</b>	<b>11,292,419</b>	<b>11,848,135</b>	<b>2,380,977</b>	<b>83.27</b>

Data Source: Financial data provided by the Chief Financial Officer Branch

**Table 15: Variance Between Planned Spending vs Actual Expenditures for HPFBI - 2010-2011 and 2014-2015**

Year	Planned Spending (\$)			Expenditures (\$)			Variance (\$)	% planned budget spent
	O&M	Salary	TOTAL	O&M	Salary	TOTAL		
2012-2013	122,258	829,000	<b>951,258</b>	117,500	750,452	<b>867,952</b>	83,306	91.24
2013-2014	102,447	728,166	<b>830,613</b>	81,890	713,165	<b>795,055</b>	35,558	95.72
2014-2015	134,682	691,770	<b>826,452</b>	46,855	763,848	<b>810,703</b>	15,749	98.09
<b>TOTAL</b>	<b>359,387</b>	<b>2,248,936</b>	<b>2,608,323</b>	<b>246,245</b>	<b>2,227,465</b>	<b>2,473,710</b>	<b>134,613</b>	<b>94.84</b>

Data Source: Financial data provided by the Chief Financial Officer Branch

While both planned and expenditure data for RAPB is only available for 2014-2015, as the program did not previously breakdown their planned spending at the level required to report on NHPP activities, the Bureau appears to have spent approximately 93% of their planned allocations for that year. As demonstrated in Table 16, a large proportion of the unspent funding was O&M. Budget allocations were not reflective of the activities between the four sub-activities within Program 2.1 - Health Products in RAPB. This resulted in overstatements in certain activities and understatements in others. A review is currently underway to ensure budgets are reflective of business requirements. This indicates that the numbers reported do not accurately represent the variance for that year.

**Table 16: Variance Between Planned Spending vs Actual Expenditures for RAPB - 2010-2011 and 2014-2015**

Year	Planned Spending (\$)			Expenditures (\$)			Variance (\$)	% planned budget spent
	O&M	Salary	TOTAL	O&M	Salary	TOTAL		
2014-2015	408,290	2,275,466	<b>2,683,756</b>	86,082	2,422,129	<b>2,508,211</b>	175,545	93.46%

Data Source: Financial data provided by the Chief Financial Officer Branch

## Human resources

Budgetary cuts have resulted in fewer human resources for NNHPD. As illustrated in Table 17 below, in two fiscal years, NNHPD lost approximately 58 FTEs, from 180 FTEs in 2012-2013 to 122 FTEs in 2014-2015, while FTEs remained relatively stable for MHPD, HPFBI and RAPB.

**Table 17: Number of FTEs working on natural health products per directorate\***

Year	NNHPD	MHPD	HPFBI	RAPB	TOTAL
2010-2011	158	14	1	n/a	<b>173</b>
2011-2012	185	26	10	18	<b>239</b>
2012-2013	180	25	9	20	<b>234</b>
2013-2014	151	26	8	30	<b>215</b>
2014-2015	122	27	8	29	<b>186</b>

Data Source: Financial data provided by Chief Financial Officer Branch

\* Numbers are rounded and do not include temporary employees.

The Natural and Non-prescription Health Products Directorate addressed staff reductions and backlog issues created by the regulations coming into effect, by streamlining its review processes as mentioned in section 4.4.1.

Internal key informants were divided when asked to comment on the allocation of resources along the continuum of the regulatory lifecycle. Some informants were of the opinion that pre-market activities need to be strong to verify whether products are safe and of high quality, before entering the market. Other informants stated that the post-market activities should be strengthened as a result of pre-market activities using a risk-based approach to product and site licence submission review, and therefore, needing to have a strong post-market presence to effectively monitor products, and address potential issues.

The Natural Health Products Program and the Food Program are the only HPFB regulatory programs that are not cost-recovered. Now that NNHPD has cleared the product submissions backlog and has maintained its product review service standards (from July 2014 to March 2015, 90.7% of licence application reviews were completed on time), a few internal key informants suggested that it may be appropriate to review the extent to which a cost-recovery approach might be applied to NHPP. An international analysis of natural health product regulation in the United States and Australia indicated that both countries have some form of cost-recovery as part of their models. In the United States, regulations indicate that manufacturers may be required to pay a fee if they are introducing a new ingredient and/or if their site requires re-inspection;

however, in discussion with the responsible program area it was clear that while the ability to cost-recover some expenses exists, in practice it is not used. In Australia there is an initial application fee and an ongoing charge to maintain the product on the Australian Register of Therapeutic Goods, in order for the product to be supplied in Australia.

## **Observations on Efficiency**

**During the last five years a number of efficiencies have been gained through initiatives implemented by the NHPP. Efforts are required to gain further efficiencies.**

### **Efficiencies**

Over the last five years, efficiencies have been gained by all program partners. The efficiencies implemented include a streamlined approval process and monthly signal assessment meetings, as well as the development of a more consistent approach to the triage, prioritization, and follow-up of incidents, which was piloted and is currently being reviewed.

#### **Three-class review system**

The three-class review system developed and implemented by NNHPD was identified by the majority of internal key informants as an important efficiency for the program. The three-class system has allowed NNHPD to clear the backlog of product licence applications and sustain its activities amidst budgetary cuts. Product applications that meet agreed-upon standards are licensed within the appropriate service standard (i.e., 10 days for Class I products). Applications that meet a product monograph are submitted with an attestation that monograph parameters are met and that non-medicinal ingredients fully comply with the Natural Health Products Ingredients Database and are safe.

Although this system is very efficient, there are issues related to the quality of the applications received by NNHPD. As reported under the section on Safety, Quality and Efficacy, a considerable proportion of applications failed the attestation audits carried out by NNHPD.

#### **Central Intake and Triage Pilot Project**

Prior to the launch of the Pilot, all complaints were received in the region where the complainant was located and would then be referred to the region in which the regulated party was located, if different. Complaints were triaged/prioritised using a prioritization table. The Health Product and Food Branch Inspectorate helps manage incidents determined to pose a high risk, are national in scope or require input from other program partners. The Central Intake and Triage Pilot Project was initiated following a recommendation that came out of an internal Compliance Verification Review to test a central model for the consistent risk-based prioritization of incidents, including early identification of high risk and sensitive incidents. Incidents assessed as high or medium priority are referred to the Regions where the regulated party is located for action while low priority incidents are tracked and monitored by HPFBI.

In order to address this inefficiency, HPFBI initiated the Central Intake and Triage Pilot Project in November 2014. The pilot project includes the following activities/steps:

- Incidents are received centrally;
- Incidents are triaged, prioritized and forwarded to the appropriate groups/regional offices if follow-up is required; and
- Low risk incidents are monitored and trends are established to inform the development of collective compliance activities.

To date, internal key informants from HPFBI and RAPB are satisfied with how the pilot project has assisted in ensuring a more streamlined and consistent approach to the triage, prioritization and follow-up of incidents. The pilot, which is in the process of being evaluated, is expected to result in the efficient, effective and consistent triage of incidents based on risk.

### **Monthly signal assessment meetings**

As highlighted under previous sections of the report, MHPD's monthly signal assessment meetings with NNHPD established a process to systematically track post-market safety review recommendations and actions taken which allows for safety issues (e.g., recommended changes to product labels or monograph updates) to be addressed in a more proactive way and has increased communication between the Directorates before the finalisation of the review or actions are implemented. The evaluation found that this increased communication allows MHPD to share safety issues that they have identified and their potential recommendations with NNHPD. NNHPD then actions the recommendations, where applicable. This process helps to ensure that NNHPD is aware of safety issues that have been identified and whether or not they are in agreement with the recommendations being proposed by MHPD. Internal key informants have indicated that these meetings and the tracking of the recommendations have improved the efficiency by which appropriate risk mitigation actions are agreed and acted upon.

### **Areas of potential inefficiencies**

#### **Product classification**

Product classification issues arise because there are a number of products that share similar characteristics, yet are subject to three separate regulatory regimes (i.e., *Food and Drug Regulations*, *Natural Health Product Regulations*, *Cosmetic Regulations*) that impose different types of requirements. The regulations that a product is ultimately required to adhere to depend on what the product contains, and how it is represented for use, based on advertising or label claims. The overall issues with similar products being regulated using different regulatory requirements is that the requirements can be disproportionate to the level of risk, there are inconsistent requirements for evidence standards for efficacy, and the regulatory approach is not necessarily aligned with how the products are seen by consumers.

Internal key informants reported that classification issues were causing staff from NNHPD and other Health Canada directorates to spend a lot of time discussing and determining under which regulatory framework products should fall. As noted earlier, well over 1,620 product



classification requests were addressed by NNHPD in the past five years (this number began to be fully tracked in 2012 prior to which it was only partially tracked). Internal key informants reported that some of these issues have taken the Department years to clarify and confirm (e.g., energy drinks), with the most challenging being discussed at the Department's Product Classification Committee. Some external key informants noted that the different possibilities for regulation of similar, if not identical, products were confusing and inefficient for the industry and consumers, who may not understand that different versions of the same product have had very different levels of review, especially with respect to efficacy.

Although there have been efforts made to clarify which regulatory framework products should fall under, innovation in natural health products is significant and product lines are becoming more and more blurred. Many internal key informants noted that the work commenced under the Consumer Health Products Framework may help to address this issue as it seeks to establish a consistent and aligned approach to the regulation of self-care products that are deemed low-risk.

### **Information technology structure**

The lack of a proper information technology structure has resulted in inefficiencies. As identified by internal informants and as reported in the 2015 Internal Audit, information technology improvements, such as the ability to cross-reference product licences to site licences but also the streamlining of many other product application-related systems, are needed. The impact of not having the ability to cross-reference between systems could be experienced at various levels and for different matters.

- There is currently no way for the program to confirm if approved products are being produced and sold. This could be of concern in the event that issues are found with one particular manufacturing plant because the program would not be able to confirm, in a timely manner, how many licenced products may be affected. There is no database that links approved products to the sites that manufacture/import/package/label them.
- Some internal informants reported that the Licensed Natural Health Products Database, Natural Health Products Ingredients Database, and the Compendium of Monographs were not linked, and were difficult to search, this database also does not indicate when products are suspended or subject to a stop sale order. This can lead to inefficiencies when partners, such as RAPB Inspectors, are unable to find information on products that are brought to their attention. As opposed to finding the information on their own, Inspectors are left with consulting HPFBI who then may need to consult NNHPD.

### **Observations on the Adequacy and Use of Performance Measurement Data**

**Considerable output data is collected and a logic model exists for NHPP. In addition, a performance measurement strategy is in development. However, many key indicators are output rather than outcome focussed.**

A logic model for the NHPP was developed for the 2010 evaluation and is currently still in use. In September 2014, NNHPD developed a program performance measurement strategy. However, the current evaluation found that the strategy was not approved by program partners such as

MHPD and HPFBI. In response to a 2015 Internal Audit<sup>100</sup> recommendation, the program has committed to completing the draft strategy by March 31, 2016.

Dashboards, presented to the HPFB Branch Executive Committee on a monthly basis and Health Canada's Executive Committee on a quarterly basis, ensure that ongoing data collection and reporting of selected NHPP activities take place at the directorate level. However, this data is primarily operational in nature, with a focus on output indicators, such as files received and reviewed within specified service standards. Each directorate collects data on specific performance metrics.<sup>xv</sup> The information collected is then reported up to senior management and may also be used to revise workflow policies and practices.

Other output measures, such as the number of site licences issued, renewed or amended and number of letters sent to product license holders, are also tracked. However, while records are kept of the total number of letters sent each year, further detail, such as tracking the number of letters by issue or by licensee, is not kept. In addition, it is currently not possible to track all communications from the pre-market to post-market phases by license number.

Many internal key informants agreed that performance measurement could be strengthened to be more outcome focused at the program level. Several key informants were not aware that NNHPD had drafted a program level performance measurement strategy and knew only of their directorate's performance measurement and reporting activities. Further, there was consensus that outcome-level indicators could be better tracked and analyzed. These views are supported by the 2015 Audit,<sup>101</sup> that found there are a number of program areas that could benefit from enhanced performance measurement and data collection, specifically measures of whether communication efforts are effective, numbers of natural health products refused at the border and other importation related data, information about internet sales and purchases of natural health products, and trend information on adverse reactions.

## 5.0 Conclusions

### 5.1 Relevance Conclusions

Our analysis indicates that there continues to be a need for activities such as those delivered through the Natural Health Product Program to address the increasing use, availability and complexity of natural health products, especially when combined with the various risks that could arise from their potential improper use (e.g., interactions with other medications, self-prescribing without consulting a medical professional) and manufacturing issues that could pose a health risk to Canadians.

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<sup>xv</sup> The Compliance Verification data reported by HPFBI combines natural health products with drugs and veterinary drugs.

Program activities are aligned with the federal government's priority to protect the health and safety of Canadians by regulating various health products, including natural health products. These commitments are reflected in a variety of Government of Canada and Departmental documents such as Speeches from the Throne, Corporate Risk Profiles, and Operational and Strategic Plans.

A clear federal role pertaining to natural health products has been established in a variety of acts and legislation such as the *Department of Health Act*, the *Food and Drugs Act* and the *Natural Health Products Regulations*. Overall, roles and responsibilities between the federal government and other jurisdictions were quite clear and very few gaps were identified.

## 5.2 Performance Conclusions

### 5.2.1 Achievement of Expected Outcomes (Effectiveness)

Health Canada has been able to adapt to the changing environment by adjusting its administration of the Natural Health Products Regulatory Framework through measures such as developing a product licensing system that links review times for submissions to level of certainty and product risks and benefits, and developing various policy and guidance documents that help clarify information needs to meet the requirements of the regulations. Challenges such as product classification issues remain and the Department continues to look at ways to refine its regulatory approach.

Many outreach and communication activities have taken place over the past five years, especially those informing industry of regulatory requirements. While the full impact of these activities is unknown, some evidence indicates that these activities have been effective (e.g., significant decline in the number of refused submissions) and industry key informants generally indicate satisfaction with program efforts to engage them and keep them informed of any impending or potential changes/adjustments to the regulatory environment. In addition, the Program provides industry stakeholders with tools (e.g., monographs, guidance material, fact sheets) which provide further information on their roles as regulated parties. Although NHPP information is made available to the public, primarily through various websites, there is limited evidence to show that Canadians are well informed of the risks and benefits of using natural health products, as well as Health Canada's role and activities in regulating natural health products.

The Program, using a risk-based approach, has contributed to ensuring the safety of natural health products. This approach is aided by the development and use of agreed-upon safety standards (e.g., monographs) and other information (e.g., Natural Health Product Ingredient Database). In addition, risk-based and random audits and any associated follow-up actions help to verify the safety of these products. However, questions remain about the efficacy and quality of some natural health products, and this could have an impact on safety. For example, there is concern that some natural health products make claims that are not supported by scientific evidence and that the lack of an on-site inspection program and the current attestation model are insufficient to verify quality.

A variety of program activities (e.g., surveillance activities, product recalls, risk communications) have taken place to contribute to limiting the exposure of Canadians to health risks associated with the use of natural health products, on a post-market basis (i.e., once on the market). However, it should be noted that challenges remain: activities tend to be generally reactive, and not proactive; product classification issues; accessibility of information technology systems; limited follow up on recalled products and regulations that are not sufficiently strong to enforce compliance.

While there are many examples of integration and collaboration within the NHPP, and between the Program and other areas within Health Canada and external stakeholders, there are further opportunities for program activities to be systematically integrated, especially at the working level as most interactions tend to be ad hoc.

## 5.2.2 Demonstration of Economy and Efficiency

A number of efficiencies have been demonstrated by the various program partners with respect to program design and delivery (e.g., streamlined product approval process; more consistent approach to the triage, prioritization and follow-up of incidents; and monthly signal assessment meetings to discuss safety issues that have been identified and determine recommended action to address them). The lack of a proper information technology structure and product classification issues represent areas where further efforts are needed to improve efficiencies. Overall, program spending has been in line with allocations.

Even though the backlog of applications has been addressed and service standards have been set and are generally being met, the NHPP remains one of only a couple of regulatory programs within HPFB that does not contain a cost-recovery element. Furthermore, to date, this option has not been explored in any great detail.

With respect to performance measurement, a logic model exists for the NHPP and a performance measurement strategy is in development. While performance data is collected, it tends to be operational in nature focussing on outputs and performance against service standards rather than focussing on the impacts or outcomes of the activities completed within NHPP.

# 6.0 Recommendations

## Recommendation 1

**As a science-based regulator, Health Canada may wish to reconsider its current practice of allowing specific health claims on natural health product labels that cannot be supported by scientific evidence.**

One of Health Canada's primary roles is to serve as a regulator that bases its decisions on sound scientific evidence. As such, natural health products present a challenge to the Department's reputation in this area. The efficacy of certain natural health products is challenging to confirm

given that there is less scientific evidence that exists to determine their efficacy in treating or preventing conditions or illnesses. Health Canada has made a recent announcement to request licence holders of homeopathic products for symptomatic relief of cough, cold and flu for children 12 and under, and homeopathic nosode products to either remove claims or provide scientific evidence of efficacy.

## Recommendation 2

**Given the reliance on pre-market attestations for natural health products and the general reactive approach to post-market activities, the NHPP should consider expanding its post-market activities such as conducting on-site inspections, conducting more laboratory testing as part of compliance verification, and examining the need for stronger post-market powers in the area of natural health products.**

Currently, quality is verified through industry's attestation to Good Manufacturing Practices under a site license application, with no post market verification, and many of the compliance and enforcement activities carried out within the NHPP are reactive, responding to identified issues. Furthermore, when Inspectorate staff refers suspect natural health products to the laboratories for testing and analysis, the result is a high proportion of unsatisfactory results. For these reasons, it is recommended that the NHPP look at ways to incorporate more proactive compliance and enforcement into the Program. Work is already underway to utilize proactive tools and more could be done in this regard. Specifically, the Program could explore the benefits of an on-site inspection program to verify compliance with the attestation. The Program could also explore sending a higher percentage of samples to the laboratories for testing as results may help identify trends and provide a better appreciation of issues that need to be addressed. In addition, while the NHPP generally takes a cooperative approach with industry when dealing with compliance issues and has various compliance measures at its disposal, there was a perception among some internal and a few external key informants that the Natural Health Products Regulations are not sufficiently strong enough to persuade industry to address non-compliance (e.g., lacks the tougher penalties available to those areas covered by Vanessa's Law).

## Recommendation 3

**Clarify and tighten product classification definitions, specifically those related to natural health products, to help address product classification determination issues.**

While various products can share similar characteristics, they can be subject to different regulatory regimes (e.g., *Natural Health Product Regulations*, *Food and Drug Regulations*, *Cosmetic Regulations*) that impose different requirements. The applicable regulatory regime is generally determined by product ingredients and any claims it may be making. Industry has expressed confusion and frustration with product classification issues and, in some cases, this has led to “regulatory shopping” to find the least onerous and quickest pathway for their products to reach the market. In addition, Health Canada officials both within the NHPP and in other program areas (e.g., Food, Cosmetics) report spending a great deal of time discussing and determining the appropriate regulatory framework that products must follow. Many internal key informants are hopeful that work commenced under the Consumer Health Products Framework

to modernize the regulation of “self-care” products (which includes natural health products) will help address this issue.

#### **Recommendation 4**

**Explore the feasibility and value of implementing an NHPP licensing cost-recovery framework.**

The Natural Health Products Program is one of only a couple of regulatory programs within HPFB that does not contain a cost-recovery element and to date, this option has not been explored in any great detail. With the product submission backlog now cleared, and service standards having been set and generally being met in this area, it may now be appropriate to explore the extent to which a cost-recovery element can be applied to this Program. Revenues from cost-recovery could be used to address various issues identified in this evaluation (e.g., lack of on-site inspections, conducting more lab testing and more proactive compliance and enforcement activities).

## **Appendix 1 — Natural Health Products Program Logic Model**

[Natural Health Products Program Logic Model](#)

## **Appendix 2 – Policy and Guidance Documents**

Policy documents include:

- POL-0044 – Health Products and Food Branch Inspectorate Natural Health Products Compliance and Enforcement Policy (August 29, 2014). This policy is to be used in conjunction with POL-0001.
- POL-0001 – Compliance and Enforcement Policy
- POL-0093 – Natural Health Products (Unprocessed Product Licence Applications) Regulations (now repealed)
- POL-0016 – Health Products and Food Branch Inspectorate Recall Policy

Guidance documents include:

- Guidance Document: Schedule A and Section 3 to the Food and Drugs Act
- Guidance Document: Data Requirements for Switching Medicinal Ingredients from Prescription to Non-prescription Status
- Guidance Document: Classification of Products at the Food-Natural Health Product Interface: Products in Food Format
- Guidance Document: Pathway for Licensing Natural Health Products Used as a Traditional Medicine
- Guidance Document: Pathway for Licensing Natural Health Products Making Modern Health Claims
- Guidance Document: Quality of Natural Health Products
- Guidance Document: Disinfectant Drugs
- Guidance Document: Management of Disinfectant Drug Applications
- Guidance Document: Safety and Efficacy Requirements for Contact Lens Disinfectants
- Guidance Document: Reporting Adverse Reactions to Marketed Health Products

## Appendix 3 – Summary of Findings

### Rating of Findings

Ratings have been provided to indicate the degree to which each evaluation issue and question has been addressed.

### Relevance Rating Symbols and Significance:

A summary of Relevance Ratings is presented in Table 1 below. A description of the Relevance Ratings Symbols and Significance can be found in the Legend.

**Table 1: Relevance Rating Symbols and Significance**

Evaluation Issue	Indicators	Overall Rating	Summary
<b>Continued need for the program</b>			
What are the risks associated with the use of natural health products? Are those risks evolving?	<ul style="list-style-type: none"> <li>Evidence of current and emerging health risks</li> <li>Perception of current and emerging health risks</li> </ul>	<b>High</b>	<p>There is a continued need for the regulation of natural health products given the increasingly widespread availability, both domestic and foreign, complexity of these products and the potential risks associated with their use.</p> <p>Overall, natural health products are safe and low risk. Much of the literature reviewed, while discussing potential risks, also pointed to the fact that natural health products can be beneficial and are generally safe, when they are manufactured in accordance with good manufacturing practices and used in accordance with the recommended directions for use. Between 2010 and 2011, there were 3,885 adverse reaction reports suspected of being associated with natural health products that were received by the Canada Vigilance Program System. This number is lower than for other health products; however, it is well known that there is significant under-reporting for natural health products.</p> <p>While natural health products are generally low risk, there are a number of health risks that can occur when they are improperly used. In particular, pharmaceutical drugs and natural health products can interact with each other reducing the effectiveness of a medication and/or causing an adverse reaction</p>

### Legend - Performance Rating Symbols and Significance:

- High** There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.
- Partial** There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.
- Low** There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.



Evaluation Issue	Indicators	Overall Rating	Summary
			<p>As discussed, natural health products contain ingredients that are generally recognized as being safe and of low risk, however, the risk of using natural health products increases when there are issues with production and manufacturing. For example, production and manufacturing issues can lead to contamination and adulteration in products, which can raise the risk to health as a result of using natural health products.</p> <p>Since there have been changes to the natural health products environment, in particular the increase in the number of products and their complexity and availability, as well as the number of people using them, the risks associated with these products, while still low, may increase in frequency.</p>
<p>How has the environment changed since the <i>Natural Health Products Regulations</i> came into effect?</p>	<ul style="list-style-type: none"> <li>• Description of environment prior to 2004</li> <li>• Identification of social, economic and other changes in the environment since 2004</li> <li>• Trends in the number of pre-market site and product licences submissions submitted, post-market submissions received for natural health products, and adverse reaction reporting</li> <li>• Identification of emerging trends in the environment</li> </ul>	<p><b>High</b></p>	<p>Since the 1990s the use of natural health products has been increasing dramatically worldwide. The increase in availability of products has been demonstrated by Health Canada’s NNHPD, who reported that in March 2015 there were 63,387 active product licenses for domestic use and importation. Not only are natural health products more widely available, but they are becoming increasingly complex. Manufacturers are becoming more innovative with natural health products and certain products that were once standalone are now being combined with each other as well as with products typically from other industries, such as foods and cosmetics.</p>
<p><b>Alignment with Federal Roles and Responsibilities</b></p>			
<p>What is the federal role related to regulating natural health products? Are current activities aligned with the federal role?</p>	<ul style="list-style-type: none"> <li>• Identification of the federal role</li> <li>• Evidence of alignment between activities and departmental mandate, role and commitments</li> </ul>	<p><b>High</b></p>	<p>Health Canada is responsible for helping Canadians maintain and improve their health. This includes its role as a regulator for the safety of natural health products. The <i>Department of Health Act</i>, the <i>Food and Drugs Act</i> and <i>Natural Health Products Regulations</i> provide Health Canada with the authority to develop, maintain, and implement a regulatory framework associated with a broad range of health products, including natural health products.</p>

**Legend - Performance Rating Symbols and Significance:**

- High There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.
- Partial There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.
- Low There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.

Evaluation Issue	Indicators	Overall Rating	Summary
Does the federal role duplicate or complement the role of other stakeholders? Is the federal role appropriate (e.g., gaps or overlaps)?	<ul style="list-style-type: none"> <li>• Presence/absence of other programs that complement or duplicate program activities, including P/T role</li> <li>• Views on programs that complement, overlap or duplicate Health Canada involvement</li> </ul>	High	Roles and responsibilities among staff are clear and well understood. The majority of internal and external key informants for this evaluation noted that Health Canada's role in regulating the sale, manufacturing, packaging, labelling, importation, distribution and storage of natural health products is clear and does not duplicate that of the provinces and territories who are responsible for regulating the practice of health care professionals.
<b>Alignment with Government Priorities</b>			
What are the federal priorities related to regulating natural health products?	<ul style="list-style-type: none"> <li>• Evidence of recent/current federal priorities</li> </ul>	High	<p>Protecting the health and safety of Canadians by regulating health products, including natural health products, is a priority for the Government of Canada as well as Health Canada, and there is alignment between the Government, Department and Branch priorities and the activities of the NHPP.</p> <p>While the regulation of natural health products is not specifically mentioned in recent Speeches from the Throne and Budget Plans, these documents note that protecting the health and safety of Canadians is a priority for the Government.</p>
What are the Health Canada priorities related to regulating natural health products?	<ul style="list-style-type: none"> <li>• Evidence of recent/current departmental priorities</li> </ul>	High	Health Canada identifies protecting the health and safety of Canadians by regulating health products, and providing Canadians and other stakeholders with evidence-based knowledge to make informed decisions regarding their health, as key priorities. These priorities are outlined in Health Canada's Corporate Risk Profile; Health Canada's Report on Plans and Priorities; and Branch and Directorate strategic and operational plans.
Are current activities aligned with priorities?	<ul style="list-style-type: none"> <li>• Evidence of alignment between activities and government and departmental priorities</li> </ul>	High	While an NHPP-specific Strategic Plan was developed for 2010-2012; there is no current strategic plan. Even though there isn't a current NHPP-specific strategic plan, previous NHPP strategic and current operational plans are aligned with Branch plans and priorities. Further, Branch strategies and plans reflect the priorities set out by Health Canada and the Government of Canada and are aligned with current activities.

**Legend - Performance Rating Symbols and Significance:**

- High There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.
- Partial There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.
- Low There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.

**Performance Rating Symbols and Significance:**

A summary of Performance Ratings is presented in Table 2 below. A description of the Performance Ratings Symbols and Significance can be found in the Legend.

**Table 2: Performance Rating Symbols and Significance**

Issues	Indicators	Overall Rating	Summary
<b>Achievement of Expected Outcomes (Effectiveness)</b>			
To what extent have Canadians made informed decisions; chosen and used natural health products with confidence:			
To what extent is industry aware of and understands regulatory requirements?	<ul style="list-style-type: none"> <li>Views on achievement of this outcome, including challenges/barriers</li> <li>Number, percentage and trends of visits on natural health product pages directed towards industry</li> <li>Number and type of outreach activities and materials directed toward industry, including bilateral meetings, web communication/presence, including reach/outreach to stakeholders</li> <li>Performance data on rate of refusals (product, site, clinical trial), information request notices sent to applicants, pre-submission meetings held with industry, client service time, application audit results, licence suspensions/cancellations</li> </ul>	<b>Progress Made; Further Work Warranted</b>	<p>There is evidence that a number of stakeholder consultations, information sharing and engagement activities took place during the evaluation time frame. In addition to organizing or participating in industry and associations events, NNHPD developed guidance material, including brochures, fact sheets and Frequently Asked Questions for industry, retailers and practitioners, aimed at informing industry of any changes to the regulatory framework and to provide further information on their roles as regulated parties.</p> <p>The significant decrease in the number of refused submissions within the evaluation timeframe may be due in part to an improved understanding of natural health products regulatory requirements by industry. However, the decrease in refusals could also be due to open communications and application assistance between NNHPD and the natural health products industry. On the other hand, other internal key informants felt that the three-class system may have diminished the thoroughness of application reviews. This could also explain the lower number of refusals.</p>
To what extent are Canadians aware of and understand the risks and benefits of natural health products (including regulatory requirements)?	<ul style="list-style-type: none"> <li>Views on achievement of this outcome, including challenges/barriers</li> <li>Public opinion research (POR)/media reports</li> <li>Evidence of outreach activities and materials, including web communication/presence, personal goods importation information</li> <li>Number, percentage and trends of visits on natural health product pages directed towards</li> </ul>	<b>Unable to Assess</b>	<p>The evaluation did not find recent public opinion research on natural health products. The most recent data is from a survey published in 2010 that was conducted by Ipsos Reid on behalf of Health Canada. Communications to Canadians on the subject of natural health products are conducted primarily through the Healthy Canadians and the Health Canada websites, including the Health Product InfoWatch. The Program has an extensive web presence with a great deal of information available for consumers, such as: a definition of natural health products; their associated regulations and the departmental approach to natural health product licensing and regulation; databases on products and their</p>

**Legend - Performance Rating Symbols and Significance:**

- Achieved The intended outcomes or goals have been achieved or met.
- Progress Made; Further Work Warranted Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
- Little Progress; Priority for Attention Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
	<p>Canadians</p> <ul style="list-style-type: none"> <li>• Performance data on trends re. availability and access to regulated natural health products/companies, information requests from Canadians</li> </ul>		<p>associated risks; how to use natural health products safely; and how and where to report adverse side effects. Both internal and external key informants reported that Health Canada could be clearer in communicating its role in regulating natural health products, particularly with regard to safety, efficacy and quality. Internal interviewees reported that despite departmental initiatives aimed at strengthening and improving communications, the Program has not communicated effectively to the public and that many Canadians do not appear to know what the presence of an NPN on a product signifies.</p> <p>The evaluation did not find evidence of an NHPP strategic communications strategy and both internal and external key informants stated that the program could do a better job of promoting the information that is currently available to the public. The evaluation was unable to determine the extent of the NHPP's impact on regulatory awareness for Canadians at large.</p>
<p>To what extent is NHPP able to ensure that natural health products available on the market are safe, effective and of high quality?</p>	<ul style="list-style-type: none"> <li>• Mapping of activities carried out by HC to ensure a) safety, b) efficacy, and c) quality of natural health products</li> <li>• Views on whether activities are ensuring the safety, efficacy and quality of natural health products</li> <li>• Identification of challenges/barriers</li> <li>• Performance data on information request notices sent to applicants, rate of refusals (product, site, clinical trial), application audit results, licence suspensions/cancellations</li> <li>• Number of post-market reviews and recommendations made</li> </ul>	<p><b>Little Progress; Priority for Attention</b></p>	<p>The Program, using a risk-based approach, has contributed to the safety of natural health products. This approach is aided by the development and use of agreed-upon safety standards (e.g., monographs) and other information (e.g., Natural Health Product Ingredient Database). In addition, risk-based and random product licensing audits and any associated follow-up actions help to verify the safety of these products. However, questions remain about the efficacy and quality of some natural health products, and this could have an impact on safety.</p> <p>The Natural and Non-prescription Health Products Directorate has conducted activities to verify the safety of natural health products by developing agreed-upon safety standards that can be used to review product licence applications. The level of review is dependent on whether the product adheres to a monograph or not, and how many monographs are applicable, ensuring that products where there is less certainty of safety and efficacy receive a more thorough review.</p> <p>The efficacy of certain natural health products is challenging to confirm given that, there is less scientific evidence or conflicting scientific evidence that exists to determine the efficacy of certain natural health products in treating or preventing conditions or illnesses. Additionally, activities carried out by Health Canada in assessing the efficacy of natural health products especially for Class I product applications appear to be limited. As with quality, efficacy is assessed against the Pathways for Licensing Natural Health Products via the use of</p>

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			<p>monograph claims and through attestation only.</p> <p>According to internal key informants, verifying the quality of health products is a key aspect of regulatory activities given that most health issues are due to the improper manufacturing of products. An on-site inspection program is typically a key component of Good Manufacturing Practices. For natural health products, a mandatory on-site inspection program has yet to be implemented; however, key informants have indicated that discussions about such an inspection program have begun.</p> <p>Overall, internal key informants felt the NHPP was better prepared to assess the safety of products than the efficacy or quality given the presence of agreed-upon safety standards. However, some internal key informants reported that safety becomes compromised by the lack of quality when products are adulterated and/or contaminated.</p>
<p>Is there reduced exposure of health risks to Canadians?</p>	<ul style="list-style-type: none"> <li>• Views on achievement of this outcome, including challenges/barriers</li> <li>• Number and type of monitoring, compliance and enforcement activities conducted (e.g., frequency of desk audits)</li> <li>• Evidence that recommendations from monitoring, compliance and enforcement activities are tracked and addressed</li> <li>• Performance on data/trends on adverse reactions, product recalls/advisories, classification requests</li> <li>• Number of safety summary reviews and risk communications posted on HC website</li> </ul>	<p><b>Progress Made; Further Work Warranted</b></p>	<p>Overall, various program activities have contributed to limiting exposure to health risks; however, important challenges remain.</p> <p>This outcome was defined, through key informant interviews, as the activities carried out by Health Canada once products are available on the market. Over the past five years, a variety of compliance and enforcement actions were taken by the NHPP to minimize health risks. These actions included: conducting compliance verifications; requesting and monitoring product recalls; monitoring at the border and recommending refusal of shipments of unsafe products referred to Health Canada by the Canada Border Services Agency; communicating risks to the public and/or healthcare professionals to inform them of product risks and/or unsafe products; and cancelling or suspending product/site licences.</p> <p>The reporting of adverse reactions suspected of being associated with natural health products, although very low in comparison to prescription pharmaceuticals, has slightly increased over the years. It is difficult to know whether this increase is due to an actual increase in adverse reactions or whether it is due to an increased number of health care professionals and individuals reporting reactions. To identify a health risk before it becomes an issue in the broader population, MHPD monitors and analyzes emerging safety issues from international scientific and medical literature through a variety of activities such</p>

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Issues	Indicators	Overall Rating	Summary
			<p>as signal assessments, causality assessments, Annual Summary Report Reviews (in Periodic Safety Update Report format), ad-hoc reviews and risk communications including product alerts issued by other countries. Between 2010-2011 and 2014-2015, a total of 563 different risk assessment activities took place, with the majority of these being reviews of product alerts issued by other countries. A breakdown of the number and type of review activities conducted can be found in Table 7. These risk assessment activities can result in a variety of actions, including standard monitoring, enhanced monitoring, labelling recommendations, and risk communications.</p> <p>Challenges include: the majority of activities have been reactive; information technology systems are not comprehensive and are not fully accessible to every NHPP partner; and there is limited follow-up action to verify that recalled products have been removed from market.</p>
<p>To what extent is there a sustainable, cost-efficient, responsive and evidence-based regulatory system for natural health products:</p>			
<p>How integrated is the approach to implement natural health products priorities and activities?</p>	<ul style="list-style-type: none"> <li>• Identification of integrated approach and rationale for integration (e.g., pre-market and post-market activities inform each other and improve processes/framework components as appropriate)</li> <li>• Views on achievement of this outcome, including challenges/barriers to integrating</li> <li>• Evidence of program approach to natural health products, including setting joint priorities, work plans, meetings, presentations, agreements (internally and externally (nationally and internationally)) (e.g., MHPD-NNHPD monthly signal meetings, post-market recommendations tracking document)</li> <li>• Views on, and evidence of, integration between Health Canada Directorates/Branches to resolve product classification issues</li> </ul>	<p><b>Progress Made; Further Work Warranted</b></p>	<p>While there are current and past examples of integration (e.g., NHPP Director General Steering Committee, Central Intake and Triage Pilot, Signal Assessment meetings, Program Advisory Committee), there are further opportunities for program activities to be systematically integrated, especially at the working level.</p> <p>A recent Internal Audit of the program found that in March 2015, a new governance model was introduced to streamline and improve decision making while increasing the Branch Executive Committee’s focus on strategic decision making. Another example of integration is the Central Intake and Triage Pilot Project. Initiated in November 2014, which enables integration across HPFBI and RAPB. A further example of integration is the MHPD-led signal assessment meetings where MHPD and NNHPD convene through a natural health product-specific forum.</p> <p>The Natural Health Products Program engages regularly with both the Healthy Environment and Consumer Safety Branch and the Food Directorate within HPFB on classification issues determining under which regulatory regime</p>

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			<p>products fall.</p> <p>The Natural Health Products Program holds joint outreach activities for external stakeholders. Key informants from other Directorates, including MHPD, HPFBI and the Food Directorate, reported being part of NNHPD-led consultations/bilats with industry/associations.</p> <p>While there have been many attempts to integrate the activities of the NHPP, work remains. Just over half of the internal key informants confirmed that the majority of interactions are on an ad-hoc basis, and, although staff know who to talk to at the appropriate time, overall there could be better integration.</p>
<p>How has the Natural Health Products Regulatory Framework evolved to administer natural health products?</p>	<ul style="list-style-type: none"> <li>• Views on achievement of this outcome, including challenges/barriers</li> <li>• Evidence of actions taken to improve the Natural Health Products Regulatory Framework (e.g., site inspection pilot project)</li> <li>• Evidence of additions/revisions to the Natural Health Products Regulatory Framework</li> <li>• Evidence of research and/or consultation taking place to address changes in the environment</li> </ul>	<p><b>Progress Made; Further Work Warranted</b></p>	<p>At the time the regulations came into force in 2004, there were already approximately 42,000 products on the market which were then required to obtain a product licence. As a result, this created a backlog of applications. To help clear the backlog, the NHPP adapted by introducing the temporary <i>Natural Health Products (Unprocessed Product Licence Applications) Regulations</i> to allow these natural health products to be sold pending approval of their product licences. In fall 2012, the Program further adapted by implementing a new approach to regulating natural health products. This approach included changes to how product licensing, site licensing, compliance and enforcement were conducted by the Program. With regards to product licences, the NHPP proposed to introduce a Class Approach that linked review times to the Program's level of certainty with the product's risks and benefits. This system meant that products with the greatest level of certainty (i.e., those that are in line with over 250 monographs that have been published by Health Canada) are subject to the shortest review time. As a result of the increasing numbers and complexity of natural health products, a number of policy and guidance documents were developed to help strengthen the regulations by supporting implementation of the regulations and providing Canadians and industry with the information needed to meet the requirements of the regulations.</p> <p>Health products are becoming more innovative and as a result, the Department has struggled to address product classification issues. According to some internal key informants, clearly determining under which regulatory regime products fall continues to represent one of the key challenges facing the program – over 1,620 product classification requests were addressed by NNHPD in the past five years.</p>

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			Despite these challenges, there are opportunities moving forward. Work commenced under the Consumer Health Products Framework to modernize the regulation of “self-care” products (which includes natural health products) could help address this issue
<b>Demonstration of Economy and Efficiency</b>			
Is the program delivered in an efficient manner? How, and in what ways, can efficiency be improved? Are program resources/capacity aligned appropriately across key activities (pre vs. post- market activities)?	<ul style="list-style-type: none"> <li>Qualitative evidence that Health Canada has structure/mechanisms in place to ensure that the most efficient means are being used to administer/deliver the program.</li> </ul>	<b>Progress Made; Further Work Warranted</b>	<p>Over the last five years, efficiencies have been gained by all program partners. The efficiencies implemented include a streamlined approval process and monthly signal assessment meetings, as well as the development of a more consistent approach to the triage, prioritization, and follow-up of incidents, which was piloted and is currently being reviewed.</p> <p>Internal key informants were divided when asked to comment on the allocation of resources along the continuum of the regulatory lifecycle. Some were of the opinion that pre-market activities need to be strong to verify whether products are safe and of high quality, before entering the market. Others stated that the post-market activities should be strengthened as a result of pre-market activities using a risk-based approach to product and site licence submission review.</p> <p>The lack of a proper information technology structure and product classification issues represent areas where further efforts are needed to improve efficiencies.</p>
Has the program produced its outputs and achieved its outcomes in the most economical manner? How and in what ways can economy be improved? Are there alternative ways to achieve similar results at a lower cost?	<ul style="list-style-type: none"> <li>Variance between planned and actual expenditures, and implications</li> <li>Delivery cost per activity or output</li> <li>Identification of budgetary decisions</li> <li>Views on whether funds are appropriately targeted</li> <li>Views on whether costs of producing outputs is as low as possible and value is being obtained</li> <li>Evidence of, and views on, examination of alternative program models that would assist in achieving outcomes at lower cost</li> </ul>	<b>Progress Made; Further Work Warranted</b>	<p>While the full picture of planned versus actual expenditures for the NHPP as a whole is unavailable due to reporting differences among responsible directorates, data is available from three of the four groups for 2012-2013 to 2014-2015. Available data indicates that the program is spending approximately 99% of its planned allocations during this timeframe. While there is an overall balance in program spending this is achieved through overspending in salaries while underspending on O&amp;M.</p> <p>NNHPD’s planned budget was reduced by close to 45% of its initial budget in the past four years. The Natural and Non-prescription Health Products Directorate has slightly overspent its allocated budget, from 2012-2013 to 2014-2015, the years following the decision to reduce the Directorate’s budget. The percentage by which the program is overspending has been increasing. To offset an ongoing deficit, NNHPD regularly received funding from the Deputy Minister’s reserve. This funding was made a permanent part of the program’s budget in 2014-2015.</p>

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			<p>The Natural and Non-prescription Health Products Directorate addressed staff reductions and backlog issues created by the regulations coming into effect, by streamlining its review processes. The program implemented an attestation approach based on a three-class review system where lower risk product applications that adhere to a specific monograph receive a less thorough review than higher risk products.</p>
<p>How is performance measurement being used?</p>	<ul style="list-style-type: none"> <li>• Existence of logic model, performance measurement framework or strategy</li> <li>• Evidence of implementation of performance measurement framework or strategy</li> <li>• Evidence of, and views on, use of performance information in decision making</li> </ul>	<p><b>Progress Made; Further Work Warranted</b></p>	<p>A logic model for the NHPP was developed for the 2010 evaluation and is currently still in use. In September 2014, NNHPD developed a program performance measurement strategy. However, the current evaluation found that the strategy was not approved by program partners such as MHPD and HPFBI. Dashboards, presented to the HPFB Branch Executive Committee on a monthly basis and Health Canada’s Executive Committee on a quarterly basis, ensure that ongoing data collection and reporting of selected NHPP activities take place at the directorate level. However, this data is primarily operational in nature, with a focus on output indicators, such as files received and reviewed within specified service standards. Many internal key informants agreed that performance measurement could be strengthened to be more outcome focused at the program level.</p>

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## Endnotes

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