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Final Report

Audit of the Management of the Natural Health Products Program

June 2015

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Executive summary

The focus of this audit was the management of the regulatory program for Natural Health Products (NHP). These products are governed by the *Food and Drugs Act*, and regulated through the *Natural Health Products Regulations*. The regulations were designed to allow market access for these low-risk category products. Health Canada (the Department) regulates the safety and efficacy of all NHPs for use by humans in Canada before and after the products enter the Canadian market place. Since 2004, the Department has authorized over 85,000 natural health products for sale.

The objective of the audit was to assess the effectiveness of the management control framework for regulating NHPs. The audit was conducted in accordance with the Treasury Board *Policy on Internal Audit* and the International Standards for the Professional Practices of Internal Auditing. Sufficient and appropriate procedures were performed and evidence gathered to support the audit conclusion.

The NHP Program has evolved substantially over the last ten years. It is governed by various external and internal committees. The roles and responsibilities among staff at headquarters and in the regions are clear and understood. As well, the NHP Program has a suitable risk management lens that drives its regulatory process; however, the program would benefit from assessing its risks at the program level and identifying associated mitigation strategies. The audit also found strategic and operational plans that are used to allocate limited resources.

Both site and product licensing follow a standardized process that has been designed to be relatively easy and quick. As well, the site licence and product licence are obtained separately and not cross-referenced; however, both are required prior to a product being put on the market. Given the design of the pre-market approach, it would be important to have effective post-market monitoring and compliance activities commensurate with the relative risk of the products. Currently, pre-market expenditures are in the range of \$9 million, while post-market expenditures are approximately \$5 million. While the program has begun to pilot on-site verification of good manufacturing practices for NHPs, it will be important to enhance all post-market activities in order to maintain the integrity of the regulatory system.

The audit found that the branch has an extensive web presence; however, there is an opportunity to better promote the information available to the public. Performance information is collected to track licensing applications against performance standards; however, the performance measures and monitoring should be enhanced to capture other information such as the extent to which its communication efforts are effective.

The audit makes six recommendations to further strengthen the management control framework for the Natural Health Products Program.

A - Introduction

1. Background

Canadians expect natural health products (NHP) to be safe, of good quality and to be effective. Health Canada (the Department) regulates NHPs with a view to satisfying these expectations. These products are governed by the *Food and Drugs Act* (1985) and regulated through the *Natural Health Products Regulations* (2004). The regulations were created after many consultations with Canadian consumers, academics, health care practitioners and industry stakeholders. Since its inception, the regulatory program has evolved significantly in order to address Canadians' concerns about NHP availability and safety. Table 1 presents the key milestones in the evolution of the NHP Program.

Table 1: Milestones in the evolution of Natural Health Products Program

Year	Milestone
1997	Many Canadians express concerns about the regulation and accessibility of herbal remedies. Natural Health Products (NHPs) were subject to the <i>Food and Drugs Act</i> and its regulations.
1998	The Standing Committee on Health released its report, <i>Natural Health Products: A New Vision</i> , which included 53 recommendations on moving forward with the regulation of NHPs.
1999	The Minister of Health announces the creation of the Natural Health Products Directorate (NHPD), now the Natural and Non-Prescription Health Products Directorate (NNHPD).
2000	The Office of Natural Health Products Transition Team released the document "A Fresh Start", which sets the stage for the NHP regulations.
2002	NNHPD holds cross-country consultations with academics and industry stakeholders.
2003	The <i>Natural Health Products Regulations</i> are published. The intent of the regulations is to ensure that Canadians have access to and choice of a wide variety of high-quality, safe and effective NHPs.
2004	The <i>Natural Health Products Regulations</i> come into force, along with a transition period spanning two years for site licensing and six years for products with a Drug Identification Number (DIN).
2010	The Government introduces the <i>Unprocessed Product Licence Applications Regulations</i> , allowing for the legal sale of NHPs that have met specific safety criteria and have provided information supporting their safety, quality and efficacy to Health Canada.
2013	The backlog of unprocessed NHP applications is eliminated. The <i>Unprocessed Product Licence Applications Regulations</i> are repealed.
2014	All products legally available for sale in Canada must carry an eight-digit Natural Product Number (NPN) or Homeopathic Medicine Drug Identification Number (DIN-HM).
2014	The responsibility for the review of non-prescription drugs and disinfectants is formally transferred to NHPD.
2014	A new Consumer Health Products Framework is being developed, with the aim of streamlining and updating the current regulations for certain lower-risk health products, such as cosmetics, that are currently defined as drugs under the <i>Food and Drugs Act</i> , as well as hard-surface disinfectants.

Under the *Natural Health Products Regulations*, NHPs are defined as vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics and other products such as amino acids and essential fatty acids. Since 2004, the Department has authorized over 85,000 natural health products for sale (compared with about 7,000 authorized prescription medications and 5,000 non-prescription medications). Actual expenditures for 2013-14 to administer the program were **\$23.6 million**, with **243** full-time equivalent staff.

The regulations set out the requirements for manufacturing, packaging, labelling, storing, importing for sale, distributing and selling, adverse reaction reporting and conducting clinical trials. The approach to the implementation of the NHP regulations resulted from consultations with Canadian consumers, academics, health care practitioners and industry stakeholders.

To be legally sold in Canada, all NHPs must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have a site licence. As per the regulations, to obtain a licence, specific labelling and packaging requirements must be met, good manufacturing practices must be followed and proper safety, quality and efficacy evidence must be provided. All NHPs licenced for sale in Canada must have an eight-digit Natural Product Number (NPN) located on the label, or a DIN-HM for homeopathic medicines. The number means that the product has been assessed by Health Canada and deemed to be safe, effective and of high quality. The information attached to this number is traceable through the Licenced Natural Health Products Online Database.

Health Products and Food Branch

The Health Products and Food Branch (HPFB) is composed of three directorates, each of which is involved in the administration of the NHP regulations: the Natural and Non-prescription Health Products Directorate, the Marketed Health Products Directorate and the Health Products and Food Branch Inspectorate. The inspection and adverse reaction activities are supported by the Regions and Programs Bureau (RAPB). Additionally, there are two supporting directorates within the branch: the Resource Management and Operations Directorate and the Policy, Planning and International Affairs Directorate, which provide policy and support for all programs within the branch.

2. Audit objective

The objective of the audit is to assess the effectiveness of the management control framework for regulating natural health products.

3. Audit scope

The scope of the audit included program activities that span the lifecycle of NHP management, including pre-market evaluation, post-market monitoring, compliance and enforcement and risk-reduction activities. As such, the audit scope included the activities and resources of the program, as well as the applicable resources of the RAPB. The audit scope

examined program activities for the fiscal years 2013-14 and 2014-15. The audit did not examine the Department's regulatory decisions related to the safety and efficacy of NHPs.

4. Audit approach

The audit procedures included a review of policies, standards, guidelines and frameworks; interviews and enquiries; site observations; testing and analysis. Fieldwork was performed at Health Canada's headquarters in Ottawa and in selected regional offices. Regional field work conducted in Ontario, Quebec and British Columbia pertained to post-market compliance and enforcement activities. These regions were chosen based on materiality, volume of inspections and their coordinating role related to importations.

The audit criteria, outlined in [Appendix A](#), were derived from the *Natural Health Products Regulations* (last amended in 2008); the Office of the Comptroller General Internal – Audit Sector's Audit Criteria Related to the Management Accountability Framework: A Tool for Internal Auditors (March 2011); Action Plan on Open Government; the program's logic model and the program's performance measurement strategy. The audit was conducted in accordance with the Government of Canada's *Policy on Internal Audit* and examined sufficient, relevant, reliable and useful evidence and obtained sufficient information and explanations to provide a reasonable level of assurance in support of the audit conclusion.

5. Statement of conformance

In the professional judgment of the Chief Audit Executive, sufficient and appropriate procedures were performed and evidence gathered to support the accuracy of the audit conclusion. The audit findings and conclusion are based on a comparison of the conditions that existed as of the date of the audit, against established criteria that were agreed upon with management. Further, the evidence was gathered in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing. The audit conforms to the Internal Auditing Standards for the Government of Canada, as supported by the results of the quality assurance and improvement program.

B - Findings, recommendations and management responses

1. Governance

1.1 Governance structure

Audit criterion: *The Natural Health Products Program has a governance structure that supports its strategic direction.*

In support of the complex regulatory environment, the audit expected to find a governance structure to support timely and informed strategic decision-making related to the Natural Health Products Program (NHP Program).

External Consultation

The Advisory Council on Traditional Chinese Medicine was established in December 2011 to provide a single window for community members to interact with Health Canada (the Department). The committee meets twice a year. The Natural Non-prescription Health Products Directorate (NNHPD) serves as its secretariat. The mandate of the council is to provide the Minister of Health with advice on current and emerging issues related to traditional Chinese medicine, including the importation, sale and use of products in Canada, the practice of traditional Chinese medicine in Canada and novel products.

In addition, there is a Bilateral Meeting Program, which has the objective of engaging stakeholders in open and transparent communication on issues and risks associated with natural health products (NHP) through an exchange of information, sharing of expertise, discussion and consultation on issues of mutual interest.

Internal Branch Governance

At the branch level, the **Branch Executive Committee (BEC)** is the senior decision-making body responsible for the coherent and strategic overall management of the Health Products and Food Branch's (HPFB) resources and policy, as well as its corporate responsibilities to achieve its objectives. It is chaired by the Assistant Deputy Minister and all directors general and associate directors general within the branch are members. This committee's secretariat function is provided by the Resource Management and Operations Directorate (RMOD). The committee receives dashboards on a regular basis, which provide operational and performance information on activities. While senior management receives dashboard information related to pre-market processing time for licensing, the committee would benefit from additional performance information to support management decision-making (see [Recommendation 6](#)).

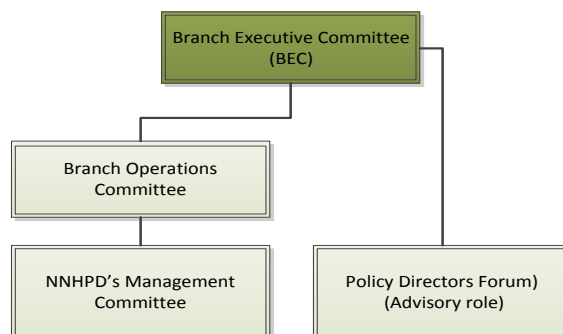
The audit reviewed the terms of reference and agendas for fiscal year 2014-15. The agenda items were typically administrative and operational; however, when required, the NHP Program was discussed.

The **Branch Operations Committee** brings a strategic orientation and an integrated approach to management and operations, with a broad mandate to focus on internal management and operational policies, processes and initiatives, as well as on corporate management matters. It is chaired by the Director General of the RMOD. The other members are a director from each directorate within the branch, one representative from the Human Resources Directorate and the Branch Senior Financial Officer. The audit reviewed the terms of reference, a sample of agendas and records of decisions and found that the NHP Program's operations are routinely discussed.

The **Policy Directors Forum** plays an advisory role to BEC; it is chaired by the Director of the Policy, Planning and International Affairs Directorate. Membership consists of one director from each directorate with a mandate focused on program policy issues, including those related to NHPs. Meetings take place on an ad hoc basis.

Figure 1 sets out the governance structure prior to March 2015.

Figure 1: Governance structure prior to March 2015



New Governance Model

On March 18, 2015, HPFB launched a new governance model with the objective of streamlining and improving decision-making, better aligning with the departmental governance structure and increasing BEC's focus on strategic decision-making. It is supported by three sub-committees.

The Sub-committee on Integrating Policy, Programs and Science is responsible for providing support to various branch initiatives throughout their development and aligning them with other branch priorities. These initiatives include the development of policies, legislations, regulations, programs and international and scientific projects.

The Sub-committee on Transformation, Transparency, Investments and Finance works on improving branch efficiency and effectiveness by addressing financial questions, including the planning and creation of investment plans.

The Sub-committee on Talent and People Management provides solutions for matters affecting HPFB's staff.

Given the magnitude of the regulatory activities within HPFB and the number of existing committees, it is anticipated that the more streamlined committee structure at the branch level will better support strategic decision-making.

Internal Directorate Governance

Directorate-level management committees provide an opportunity to discuss NHP issues as they relate to their directorate's activities.

The **Natural and Non-prescription Health Products Directorate's Management Committee** is led by the Director General. Membership includes the directors of each bureau within the directorate: Licensing Services and Systems, Product Review and Assessment, Program Policy, Risk Management and Stakeholder Engagement and Strategic Planning and Business Services. Its mandate consists of developing objectives, policies, guidelines and standards, priorities and initiatives for decision purposes that are consistent with the directorate's mission statement and guiding principles. Meetings are held weekly. The agendas and records of decisions for 2013-14 and 2014-15 contain program management items. A review of the terms of reference and records of decisions for this committee noted that it provides direction on both pre-market and post-market regulatory activities. However, the terms of reference are seven years old and should be updated to reflect the current structure. The Marketed Health Products Directorate (MHPD) and the Health Products and Food Branch Inspectorate (the Inspectorate) also have equivalent management committees.

Beyond these committees, the three key partners (Natural and non-Prescription Health Products Directorate, Marketed Health Products Directorate and the Inspectorate) meet bilaterally, as required. These meetings provide an opportunity for information exchange regarding any real or potential issues that come to the attention of the NHP Program partners. It is also a vehicle to discuss common program files or upcoming projects.

The audit found that the NHP Program has a governance structure that supports the strategic direction. However, BEC would benefit from receiving additional performance information beyond processing times for licensing (see [Recommendation 6](#)).

1.2 Roles and responsibilities

Audit criterion: *The Natural Health Products Program has documented roles and responsibilities that are clear and understood.*

In order to meet the broad objectives of the regulatory program and to deliver the program efficiently and effectively, it is critical to have clearly defined roles and responsibilities to

support appropriate accountability. Regulating on NHPs is the key responsibility of the Natural and Non-prescription Health Products Directorate, the Marketed Health Products Directorate, the Inspectorate and the Regions and Programs Bureau.

The **Natural and Non-prescription Health Products Directorate (NNHPD)** performs core regulatory responsibilities such as processing and screening submissions for products, sites and clinical trials; evidence assessments; working with partners on enforcement, compliance and adverse reaction surveillance; and policy and guideline development, information dissemination and international cooperation. The directorate works in collaboration with the Inspectorate on matters related to compliance and enforcement. NNHPD has a budget of approximately \$14.1 million.

The **Marketed Health Products Directorate (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. The directorate works to ensure that the programs take a consistent approach to post-approval safety surveillance, assessment of signals and safety trends and risk communications for all regulated marketed health products. It is supported by the Regions and Programs Bureau (RAPB), in that regional coordinators receive, follow-up on and pass along to headquarters any case reports on side effects that are submitted by consumers and healthcare professionals. The MHPD devotes \$2.95 million, or approximately 10% of its budget, to the surveillance of NHPs.

The **HPFB Inspectorate (the Inspectorate)**, in partnership with the RAPB, is responsible for branch-wide compliance and enforcement, allowing for a consistent approach across the spectrum of regulated products. It relies on several policies and guidance documents to conduct its work. The Inspectorate devotes approximately \$0.88 million to natural health products, which represents approximately 6% of its budget.

The **Regions and Programs Bureau (RAPB)** is responsible for compliance promotion and enforcement related to NHPs. It has offices in the Atlantic, Quebec, Ontario, Prairie and British Columbia Regions, as well as an office in the National Capital Region. The RAPB conducts inspections, compliance verifications, investigations and enforcement actions through the regional offices, as well as chemical and microbiological analyses at the laboratories in Ontario and Quebec. The RAPB devotes approximately \$2.3 million to NHPs.

The National Inspectorate Program, which includes the Inspectorate and RAPB, 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 marketed health products in Canada, including NHPs, provided by Canadian health professionals and consumers on a voluntary basis. These reports are forwarded to the MHPD for post-market surveillance activities.

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.

The **Resource Management and Operations Directorate (RMOD)** 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 NHP Program.

Document reviews and interviews with staff at headquarters and in the regions indicate that roles and responsibilities are clear and understood. Moreover, the roles and responsibilities are also set out on the Department's intranet site.

2. Risk management

2.1 Risk management

Audit criterion: *Risks and opportunities related to the Natural Health Products Program are identified, assessed and managed.*

In regulatory programs, it is expected that management will identify overall program risks; that the risks will be assessed for likelihood of occurrence and magnitude of impact; and that a roll-up of the individual risks will be conducted to form a complete program risk analysis.

Annually, risk issues are captured through the Report on Plans and Priorities, the Corporate Risk Profile and the Branch Operational Plan. The branch reports in its operational plan that risks are discussed by various committees. A review of the records of decisions from various management committees found that risk management and risk communication were discussed. When warranted, directorates develop "issue analysis summaries" that provide additional details and analysis for a risk or issue.

In 2008, the NHP Program completed and documented a risk exercise. It identified risks associated with the need for proactive inspections and additional post-market surveillance in order to manage the potential risk that non-compliant NHPs may be on the market. Also, the NHP Program identified that adverse reactions between NHPs and other drugs are not sufficiently tracked. The mitigating strategy for all the risks identified was to increase communications about the safe use of NHPs. It is difficult to know if the communication strategy was effective, since the audit was unable to find evidence to support the implementation of this measure.

While the audit found risks reported in various documents and at various levels (branch and program), it would be important for the NHP Program to develop and monitor a program-specific risk assessment that includes mitigating strategies, as well as performance measures to assess the effectiveness of the mitigating action. This would also include an enhancement of risk intelligence by investing in systems and analytical capacity to identify trends, prioritize risks and drive program priorities.

Recommendation 1

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a program risk profile with mitigating strategies and performance measures, to track the effectiveness of the mitigating actions.

Management response

Management agrees with the recommendation and will build on the Corporate Risk Profile to enhance its capacity to conduct program risk analysis.

HPFB will develop an NHP Program risk register, in consultation with the Regions and Programs Bureau.

Building on the departmental Performance Measurement Initiative, indicators will also be developed to assess the effectiveness of the mitigating actions.

3. Internal controls

3.1 Program management

Audit criterion: *The Natural Health Products Program's planning includes objectives, timelines and resource allocations.*

Operational plans should be developed at the directorate level, should describe milestones and conditions for success and should explain how and what portion of a strategic plan will be put into operation during the fiscal year. The operational plans should link to both the branch's strategic and operational plans.

The audit examined the operational plans developed at the branch and directorate levels and the documents used to make decisions on resource allocations. The 2014-15 Branch Operational Plan includes priorities, a summary of planned spending and a summary of key investments. The Natural and Non-prescription Health Products Directorate has a strategic plan that includes the program's vision, mandate and outcome priorities statements, along with four three-year program management priorities pertaining to regulatory modernization, operational excellence, people agenda and transparency. In 2013-14, there were eight strategic program priorities and three ongoing activities. Supplementing the program strategic plan is a yearly work plan for 2014-15, which lists 11 deliverables and milestones.

The MHPD also produces an operational plan, which details the surveillance support that it will provide to the NHP Program. The operational plan has seven key priorities and lists the related objectives, deliverables, milestones and performance measures.

The Inspectorate and the RAPB both have work plans. The activities are broken down by product line and may include NHP-related activities such as compliance, verification and

border integrity. NHP direct activities have a specific budget assigned to them, while indirect activities (such as border activities) are attributed to NHP activities by applying a percentage. Each work plan is revised and approved annually. The work plans use a standard template that describes the program, including links to the strategic and operational priorities of both HPFB and the RAPB. Work plans outline the strategic and support activities, but are weaker on providing information on specific deliverables and associated target dates. The regional offices use the national work plans but develop their own budgets to achieve the national plans.

In 2013-14, funding for the NHP Program was \$22.5 million, with expenditures of \$23.6 million. In the past, deficits have been covered by reprofiled branch funds. The directorate reports in its 2015-16 operational plan that an initiative will be undertaken to explore financial options for NHPs. In the interim, the directorate should monitor the financial risk as a part of the program risk registry (see [Recommendation 1](#)).

Overall, program planning includes objectives, timelines and resource allocations and links to the branch's strategic and operational plans.

3.2 *Site licensing*

Audit criterion: *An effective process exists for site licensing applications, amendments, renewals, suspensions and cancellations.*

Before a company can legally manufacture, package, label or import an NHP for sale in Canada, it must obtain a site licence from Health Canada. The Health Canada process requires the applicant to submit documentation proving that the buildings, equipment, practices and procedures used for each activity will comply with the good manufacturing practices (GMP) outlined in Part 3 of the *Natural Health Products Regulations*. GMPs are a set of manufacturing principles and procedures that, when applied by manufacturers, are designed to ensure an effective overall approach to product quality control and risk management. GMPs apply to both Canada and overseas manufacturers.

As a part of its operating procedures, the Department requests that applicants provide evidence of GMPs, such as a Quality Assurance Report (see [Appendix E](#)). The operating procedures also note that on-site compliance verification of GMPs may occur following the paper GMP assessment. However, on-site verification of GMPs is not part of the current site licensing model. In the past, the on-site compliance verifications of NHP facilities were conducted infrequently and generally resulted from complaints. For example, if a product quality issue comes to the NHP Program's attention, the site licence holder is informed and given an opportunity to correct the issue. When the site licence holder communicates corrective actions, the issue is considered resolved without an on-site verification.

Good Manufacturing Practices

- specifications (product);
- premises;
- equipment;
- personnel;
- sanitation program;
- operations;
- quality assurance;
- stability;
- records;
- sterile products;
- lot or batch samples;
- recall reporting.

The branch has committed to improving the framework for site licensing and developed a strategy entitled *A Revised Approach to Site Licensing*, which was published for consultation in January 2014. The approach proposed was risk-based and took into consideration health risk exposure. It also included enhancements to the paper-based self-assessment process, as well as the introduction of a third party on-site GMPs audit component. In the first half of 2014, the directorate conducted a limited pilot test comprising inspections of NHP site licence holders, using four independent third-party on-site auditing organizations and seven volunteer companies to complete the on-site audits.

Management reports that while stakeholders were generally supportive of a voluntary model, there were questions raised through the pilot about the value and consistency of the audits (for example, depth/scope of audit, role of auditors and extent of training). The experience from the limited pilot meant that the proposed approach could not be rolled-out as piloted; some changes would need to be made to the proposed process through consultation. At the same time, the Department has been advancing an aligned approach to consumer health products under the Consumer Health Products Framework; the approach for site licensing therefore needs to be considered in that new context. NNHPD will be developing a plan for the best way to move forward, given the objectives of the Framework and feedback from the limited pilot.

Importers applying for a site licence must also provide evidence that the foreign sites meet GMPs for manufacturing, packaging and labelling. Audit interviews noted concerns about the validity and quality of evidence supplied to support GMPs for importation from third-world countries. Since importers' site licences are linked to foreign manufacturing sites, the NHP Program would benefit from also instituting an inspection strategy for foreign site GMP inspections.

While the regional inspectors do not often visit the manufacturers' premises for GMP inspections, when they have conducted investigative work, they have found site address errors, product specification errors and cases of false or misleading information related to the manufacturing practices. Regional inspectors noted that there are limitations to the current paper-based self-assessment site licencing model and that the most effective means of assessing GMPs is through an on-site audit.

The *Natural Health Products Regulations* require that each production lot be tested in a laboratory for safety. The regulations allow NHP lot testing to be performed by any laboratory as the regulations do not require that a laboratory be licensed in order to be used for testing of NHPs. During interviews, it was noted that it is common for the Department's regional inspectors to be told that the test results required by the regulations do not exist. In those instances where results are provided, they are often difficult to interpret or they may be for the wrong lot altogether. It is anticipated that the new approach to site licensing will be instrumental in strengthening the site licensing model.

The NHP Program should continue its efforts to implement an enhanced verification of GMPs as part of the site licensing model for natural health products.

Recommendation 2

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, implement an enhanced verification of good manufacturing practices as part of the site licensing model for natural health products.

Management response

Management agrees with the recommendation to enhance its good manufacturing practices (GMP) requirements for NHPs.

Health Canada consulted on a revised approach to site licensing, including a small pilot project to evaluate the feasibility and effectiveness of using third parties for assessing the GMP compliance status of NHP sites. Results of the pilot are being analyzed and will inform the next steps of the site licensing project.

3.3 Product licensing

Audit criterion: *An effective process is in place for product licence applications, amendments, suspensions and cancellations.*

All NHPs sold in Canada require a product licence before being marketed. Obtaining a licence requires submitting information to Health Canada on the product, including medicinal ingredients, source, potency, non-medicinal ingredients, recommended use and product risk information. In instances where additional support for the safety and efficacy of a product is required, applicants may conduct clinical trials or obtain results from a previously conducted clinical trial to re-submit with the application. Once a product licence application has been assessed and granted market authorization by the Department, the product label will bear an eight-digit product licence number preceded by the distinct letters NPN (Natural Product Number), or in the case of a homeopathic medicine, by the letters DIN-HM. The product licence number on the label assures consumers that the product has been reviewed and authorized by Health Canada for safety and efficacy (see [Appendix F](#)).

In the early years of the licensing regime, difficulty arose in licensing all products. In 2013, to help eliminate the backlog, the directorate introduced a three-class review system, based on risk/benefit and ingredient certainty. The introduction of this three-class system resulted in a shorter review process for lower risk (class I and II) products. This quicker turnaround was made possible through the Monograph Attestation Form, on which the applicant attests that the ingredients in the product respect and are compliant with one or more of the NHP Program's monographs.

A monograph is a written description of particular elements for an ingredient. The monograph for an ingredient states the proper and common names, the acceptable route of administration, the dosage, the purpose and acceptable health claims, the duration of use, any warnings and known adverse reactions, as well as research references that support the

monograph. The directorate continues to release new monographs for new ingredients. The risk-based process centred on monographs is seen as an improvement on the previous process.

For class III applications, where there are no monographs, the review period is longer and evidence of safety and efficacy of the product must be established by the applicant. The work on this process is guided by documented standard operating procedures. Table 2 provides licensing data since the inception of the program combined with performance data related to processing timelines.

Table 2: Product licence applications and amendments

Product licence applications since program inception	
Licence applications received	86,738
Licences issued	54,990
Refused	22,648
Withdrawn	7,499
In process	1,601
Applications and amendments for Q1 of 2014-15	
In process within 90 days	55%
In process within 91 to 180 days	41%
In process but over 180 days	4%

Source: Natural Health Products Program Quarterly Snapshot – Quarter 1 (Fiscal year 2014-2015).

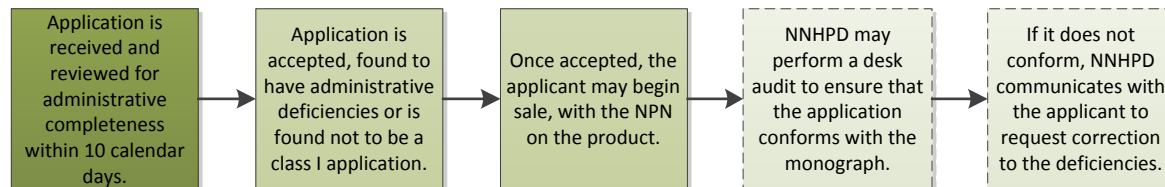
Table 3 presents the expected review times, by class.

Table 3: Expected review times, by class

Class	Description	Safety and efficacy	Review	Expected review time
I	Single monograph	Established	Shortest	10 days
II	Multiple monographs	Supported	Expedited risk-based	30 days
III	Non-monographic	Must be established	Longest	180-210 days

As Table 2 illustrates, monographs allow a more efficient review for class I applications (10 calendar days instead of the previous 60 business days). This accelerated process is made possible through a management assertion rather than an in-depth review. However, once the licence and NPN have been granted and the product is on the market, the NHP Program should perform desk audits on all high-risk applications and should examine an additional 10% of all lower-risk applications to determine if the application matches the monograph. During the interviews, it was acknowledged that approximately 20% of applications are found to be non-compliant. Because labels are not requested as part of the application, the compliance of labels against the wording prescribed in the monograph cannot be ensured.

Figure 2: Class I application process



The regulations require both product and site licences prior to the sale. In order to test that the products on the market also have a site licence, the audit requested a sample of 130 product licence applications and the related site licence. The NHP Program was unable to provide this information because the systems do not have the capability to report on products from a particular site, despite the fact that the online product application has a site licence number field; by regulatory design, the field is not compulsory. The NHP Program was able to determine that there are currently 63,387 active product licences (for domestic use and import), as well as 1,629 site licences. Given these numbers, it seems that on average, each site may be producing about 39 products, but this is only an estimate since site licences and product licences are currently not reconciled.

In addition to the site and product licence systems, there are other systems. They include the Licenced Natural Health Products Database, which contains information about NHPs that have been issued a product licence by the Department; the Natural Health Products Ingredients Database, which lists NHP ingredients; and a compendium of monographs for pre-approved ingredients and related claims that may be made about them.

Overall, it was noted that the directorate is using more than ten different information technology tools to review and process applications. The majority of these systems operate independently. Management recognizes the current challenges. As a result, a detailed gaps analysis was completed to review the directorate's processes and technologies. It identified future-state options, with the associated financial and resource implications and schedules for implementation.

In conclusion, the product licence applications, amendments, suspensions and cancellations are consistently reviewed and issued. However, the directorate would benefit from cross-referencing product and site licence data, to ensure that the NHP Program has accurate information related to the manufacturing sites.

Recommendation 3

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, with support from the Assistant Deputy Minister, Corporate Services Branch, enhance the cross-reference of product licences to site licences.

Management response

Management agrees with the recommendation and will further enhance and streamline the NHP application process as part of its Investment Plan proposals.

There is value in cross-referencing product and site licence information. The Branch Investment Plan renewal is part of a longer-term technology strategy and solution to address overall program requirements. In that regard, the NHP Program will consult on an approach that strengthens the link between product and site licences and will develop a business case for the NHP Program IT Renewal and Transformation project.

3.4 *Post-market surveillance*

***Audit criterion:** Post-market surveillance data, including adverse reactions data, is collected, communicated and used to inform the Natural Health Products Program.*

The Marketed Health Products Directorate (MHPD) is responsible for post-market surveillance. It is expected to track, prioritize and take action on issues and concerns raised nationally and internationally. The directorate monitors the safety, effectiveness and quality of marketed health products in Canada, including natural health products.

In implementing its core responsibilities, the MHPD collects and monitors adverse reaction and medication incident data; reviews and analyzes marketed health product safety data; conducts benefit and risk assessments of marketed health products; communicates product-related risks to health professionals and the public; oversees regulatory advertising activities; develops and implements policies to effectively regulate marketed health products; and actively monitors health product safety and therapeutic effectiveness. The directorate has plans to explore options for obtaining data on NHP utilization.

The MHPD also monitors and analyzes emerging safety issues reported in the scientific or medical literature from other countries with a regulatory regime. This information is usually gathered from licensees who flag safety issues, by monitoring domestic adverse reaction reports or when issues are flagged during the pre-market review of products. Issues are detected, prioritized and reviewed accordingly. If a safety issue is determined, appropriate risk mitigation activities are applied on a proportional basis. Since February 2014, the directorate meets monthly with the NNHPD to discuss active and completed post-market reviews and proposed recommendations, in order to gain consensus. Currently, the monitoring of NHP advertising is a shared responsibility between the MHPD and the Inspectorate. Product complaints, advertising complaints and adverse reactions reports are key sources of surveillance data. Consumers, patients and health professionals can report adverse reactions to health products, including natural health products, via the Canada Vigilance Program. A website provides information on how to file an adverse reaction report, as well as information on advisories, recalls, warnings and other data on NHPs.

3.5 *Compliance and enforcement*

Audit criterion: *Compliance and enforcement activities are risk-based and results are used to inform the Natural Health Products Program.*

Compliance and enforcement activities are guided by the Inspectorate and delivered nationally by the six regional offices within the RAPB. The Inspectorate has developed a *Natural Health Products Compliance and Enforcement Policy* (POL-0044). This document reflects a balance between proactive and reactive compliance and enforcement activities.

Compliance promotion activities are focused on generating compliance throughout the supply chain. When conducting compliance promotion activities, the Inspectorate provides regulated parties with the information they need to understand the regulatory requirements, their compliance status or other relevant information needed to maintain compliance. Activities include the publication on the website of standards, policies or guidance; awareness or education campaigns; posting of compliance reports; and issuing compliance letters. There currently are few formal compliance promotion activities undertaken in the field.

Compliance monitoring activities are used as an early warning indicator of situations of non-compliance. The 2008 funding agreement, the 2010 Summative Evaluation and the Compliance and Enforcement policies (2010 and 2014) called for proactive compliance monitoring for NHPs. It was recommended in these documents that a certain percentage of sites be randomly inspected; however, compliance actions are typically reactive, based on complaints and incidents.

Since the fall of 2014, the Inspectorate has been developing a proactive model for compliance promotion and monitoring. To that end, a discussion paper has been drafted on a compliance monitoring project plan to proactively assess the compliance of regulated parties with the *Food and Drugs Act* and its associated regulations. There is also a new Product Safety Program, Central Intake and Triage pilot project. In this pilot project, incident reports are forwarded to headquarters and are sorted, prioritized and sent to the appropriate groups or regions if follow-up is required. Low-priority incidents that represent a low risk are monitored and trends are tracked over time to inform the development of collective compliance activities. In the past, complaints and incidents were managed within each region.

The regional inspectors conduct **compliance verifications** related to domestic advertising, sales and production of NHPs, when potential non-compliance is identified or as a result of complaints from consumers or industry. The inspectors complete incident reports that provide historical information on the issue, the company involved and the actions taken. The regions report on the number of compliance verifications opened, in progress and closed, as well as the number of recalls.

The **National Border Integrity Program** conducts compliance verification of imported NHPs. Products are referred to Health Canada when there are suspicions of violation of import requirements. Referred products undergo an admissibility determination for entry into Canada. The regions take the lead in reviewing import documentation. Importers are responsible for ensuring that any product (other than for personal consumption) is compliant

with the *Food and Drugs Act* and its regulations. The Act provides Health Canada with the power to seize and detain any health product that is believed to be in contravention. For products that do not meet these requirements, the importer may be required to return the products to the country of origin, dispose of them in consultation with and under the direction of Health Canada, or forfeit them to the Department for disposal, in accordance with Subsection 27(1) of the Act.

Referral to laboratories

In the last few years, inspectors working on both domestic and imported products have been actively referring products to the departmental laboratories to assist in making determinations. This referral work has been effective because in 2013-14, more than half of the product samples sent to the laboratory for testing (64/117) were unsatisfactory and required the Department to follow up with manufacturers. Similarly, when Border Integrity Program staff sent samples to the laboratories, they also found products to be unsatisfactory. These findings suggest that the inspectors are able to identify suspect products and that laboratories are readily able to support the inspectors in making determinations in an effort to strengthen compliance. A budget for 2014-15 of \$307,405 was allocated for laboratory work on NHPs.

Enforcement

As per the compliance and enforcement policy, risk mitigating actions will be taken by the Inspectorate to evaluate and mitigate risks posed by identified non-compliance or to achieve compliance with the regulations. The policy notes that the Inspectorate will request corrective actions from the regulated party (such as voluntary stop-sale or recall) or may take enforcement action including regulatory stop-sale, public communications and seizure. The Inspectorate addresses contamination and adulteration situations on a case-by-case basis, since the risk profile of the various contaminants or adulterants that may be found in an NHP may vary. However, staff note that these corrective actions may be insufficient because a site licence or a product licence is not usually suspended when adulterated products are found. They also note that despite ongoing correspondence and phone calls, corrective actions concerning problem NHPs are usually taken only when there is a threat of or an actual stop-sale notice.

While approved NHPs are determined to be safe when used as directed, this is not the case when they are contaminated or adulterated with prescription drugs. This has been shown to be an issue through compliance verification, border and other surveillance activities. In these cases, the NHP is treated as a prescription drug and is subject to the new authorities for compliance provided in Vanessa's Law¹, which include fines.

¹ Vanessa's Law or the *Protecting Canadians from Unsafe Drugs Act*, is named for Vanessa Young, the daughter of the Member of Parliament from Oakville who died from the side-effects of a prescribed drug. It includes new rules that strengthen the regulation of therapeutic products and improve the reporting of adverse reactions by health care institutions. As well, it improves the Department's ability to collect post-market safety information and take appropriate action when a serious health risk is identified.

In a regime where product and site licensing is based on the assertions of producers and importers, there is a need for more post-market activity. Currently, pre-market expenditures are in the range of \$9 million, while post-market expenditures are only about \$5 million. In addition, the NHP Program would benefit from deriving more meaningful performance information related to compliance and enforcement (see [Recommendation 6](#)).

Recommendation 4

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, in consultation with the A/Senior Director General, Regions and Programs Bureau, strengthen the targeted approach for compliance promotion and monitoring.

Management response

Management agrees with the recommendation regarding a review of its approach and oversight of NHPs.

In line with the Inspectorate's *Natural Health Products Compliance and Enforcement Policy* (POL-0044), the branch (in consultation with the Regions and Programs Bureau) will strengthen its approach for compliance promotion and monitoring by shifting to more targeted, proactive activities. The approach will be informed by an increased capacity for trending and monitoring.

As well, the branch has implemented a Central Intake and Triage Pilot Project, with an objective of consistent risk-based prioritization of complaints and incidents. The pilot will be evaluated to assess its effectiveness as a model.

3.6 Open government

Audit criterion: *The guidance documents and website are developed and maintained, and support the achievement of the Natural Health Products Program's objectives.*

Canada's Open Government Action Plan seeks to broaden access to data and information, ensure transparency and accountability and strengthen citizen engagement in the activities of government and in the democratic process. The Treasury Board Secretariat's *Directive on Open Government* was released in October 2014.

The Department has open data initiatives, has an Open Data Working Group and has made numerous datasets available. These include data related to NHPs such as the licenced NHPs database, the NHP ingredients database, the Canada Vigilance Program adverse reaction online database and various recalls and safety alerts.

HPFB's mandate is to take an integrated approach to the management of the risks and benefits of NHPs. This includes promoting conditions that enable Canadians to make healthy choices and providing them with the information needed to make informed decisions about their health. This requires an ability to recognize and understand the risks associated with the

sale, manufacture and importation of non-compliant health products. Since the *Natural Health Products Regulations* came into effect in 2004, the Natural and Non-prescription Health Products Directorate (NNHPD) has been conducting meetings with NHP-related associations through its Stakeholder Bilateral Meeting Program. The objective of the program is to engage in open and transparent communication on issues and risks associated with NHPs through an exchange of information, sharing of expertise, discussion and consultation on issues of mutual interest.

In the context of the National Border Integrity Program, the Inspectorate is responsible for delivering compliance promotion activities and material to inform the general public and trade-chain partners, including importers, brokers and freight-forwarders, about the requirements to legally import health products into Canada. The RAPB is responsible for the delivery of educational material and sessions to other government departments regarding importation requirements for health products. In addition to the compliance promotion activities and the information published on the website or social media for guidance on the regulatory requirements related to NHPs, the NHP Program partners meet regularly with key stakeholders as part of ongoing bilateral meetings with industry associations or when attending tradeshows and industry conferences. When time is available, the regions also engage in education and outreach activities with external stakeholders. The Department serves the information needs of a broad and diverse set of audiences with a highly varied understanding of NHPs, their associated regulations and potential risks. These audiences include, but are not limited to, manufacturers, distributors, sellers, health professionals and the Canadian public. The Marketed Health Products Directorate provides presentations to health professionals on their responsibilities.

Website and social media

Increased awareness and public education were part of the 2013-14 consolidated priorities and recommendations from the regional offices. This included the development of a national approach to communications, the development of brochures and website information and standard communications to respond to questions at call centres. Of particular note was the need to prepare and share information with the public on the risks related to purchasing products on the Internet and while abroad.

In support of these strategies, the Department has undertaken a variety of initiatives, including an extensive Web presence. For consumers, there is information available on topics such as what NHPs are; their associated regulations and the departmental approach; the various databases on products and their associated risks; how to use NHPs safely; and how and where to report side effects. There is a Licenced Natural Health Products Database, which includes information on licenced NHPs: product name, ingredients, dosage, recommended use and risk information.

Consumers, patients and health professionals can report adverse reactions to health products (also known as side effects), including prescription and non-prescription medications, biologics, NHPs and radiopharmaceuticals, to the Canada Vigilance Program. Licensees are required to submit all serious domestic adverse reactions and all serious unexpected adverse reactions to the Department; additionally, they are required to prepare, on an annual basis, a

summary of all adverse reaction reports (serious and non-serious). If a safety issue occurs, the Department may request licensees to submit these reports. The departmental website also has a link to the Healthy Canadians and MedEffect websites, which provide extensive information on NHPs, their ingredients, public warnings, advisories and communications for health professionals. The Recalls and Alerts page provides information on product recalls and other safety alerts related to NHPs. This includes the Canadian Adverse Reaction Newsletter and access to the Canada Vigilance Adverse Reaction Online Database, which contains information about suspected adverse reactions to health products. The Department is also disseminating its messaging through the use of external association websites.

The Marketed Health Products Directorate (MHPD) electronically publishes a wide variety of public warnings and advisories, communications with health professionals, an adverse reaction newsletter, guidelines and other fact sheets. It is also distributing its information by collaborating with external stakeholders and by making use of association websites.

For industry, there is guidance on all aspects of the regulatory requirements related to NHPs. This includes information on how to apply online for licences and authorizations, as well as related application forms, guidelines and templates. Departmental staff also communicate with the public and industry through emails, phone calls and by mail.

The Inspectorate's *Natural Health Products Compliance and Enforcement Policy* (POL-0044) is published on the Department's website. As well, there are a variety of ways for individuals to be connected to the Department via social media (Facebook, Twitter, Pinterest and YouTube). These tools could be used more frequently to direct consumers to important web content about NHPs. The Department states online that it "assures/ensures that all Canadians have ready access to a wide range of natural health products that are safe, effective and of high quality." It also notes that all NHPs are assessed before being sold in Canada, that they are properly manufactured (without contamination or incorrect ingredients). The Healthy Canadians website notes that the regulations provide assurance to consumers that the label clearly reflects the actual product content.

To the public, this gives the impression that the Department is actually assessing products and manufacturing facilities. However, on-site verification of good manufacturing practices is not occurring as planned and the licensing process is a paper exercise comprised of reviewing assertions by applicants (see [Recommendation 4](#)).

Outreach and monitoring

Despite the stakeholder engagement activities and extensive web presence, the NHP Program would benefit from knowing the extent to which its communication efforts are effective. For example, the audit requested statistical information on visits (or hits) to the NHP website. While this information was available, the NHP Program does not request or analyze this information to inform decision-making.

There is also a need to develop an outreach strategy aimed at users and health professionals, including the promotion of the Canada Vigilance Program, to encourage the reporting of adverse reactions to NHPs. Through interviews, staff reported that they believe only a small percentage of adverse reactions are being reported by consumers and health practitioners. To

mitigate this risk, the MHPD has been working with various Canadian poison control centres. As well, there is a dedicated Health Portfolio Working Group, which is exploring the development of a national adverse reaction reporting network with these centres. The MHPD is also researching other sources of data on adverse reactions.

The NHP Program has guidance documents and a Web presence that is maintained and helps to regulate NHPs. However, the NHP Program would benefit from developing an outreach strategy and method of measuring and monitoring (beyond the anecdotal) the full extent of its communication activities and resources used.

Recommendation 5

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, in consultation with the Assistant Deputy Minister, Communications and Public Affairs Branch, develop an outreach strategy with appropriate performance measures, to improve communications on natural health products.

Management response

Management agrees with the recommendation to strengthen its communications on NHPs and will build on the Departmental Regulatory Transparency and Openness Framework and on the Government of Canada's Open Government Action Plan.

The program currently engages in a number of independent outreach activities. These efforts will be consolidated and formalized into an outreach strategy developed with the support of CPAB.

HPFB will publish information on advertising complaints for both authorized and unauthorized products (including NHPs).

As described in the *Natural Health Products Compliance and Enforcement Policy* (POL-0044), the Inspectorate is shifting to a more proactive approach to generating and monitoring compliance, including the following outreach activities:

- A proactive compliance monitoring project for NHPs that will include a compliance promotion component.
- The development of compliance promotion material, including a document that will communicate the potential risks of buying NHPs online.

3.7 Performance management

Audit criterion: *Management has identified performance measures linked to planned results, and performance is monitored against these planned results.*

Performance information is central to supporting effective management decision-making. Management and external stakeholders require performance information to determine the extent to which expected results have been achieved. This in turn requires appropriate and comprehensive performance measures linked to planned results, which are regularly monitored and used to support management decision-making.

Performance framework and reporting

The NHP Program and the RAPB have developed various elements of a performance measurement framework to support the management of NHPs. They have defined a series of performance indicators. Performance reports for key program areas are developed from a variety of internal online databases and dashboards are produced.

The specific dashboard for NHPs provides historical comparative information on the status of product licence applications, post-market surveillance activities and the extent to which staff time is tracked. Licensing applications are tracked against performance standards for each class of applications. They show that standards are consistently met for each class.

Information is gathered during concentrated regional border inspections, compliance verifications and border integrity work. Border integrity statistics are shared internally on a quarterly and annual basis; they provide information by region on both personal and commercial shipments refused and released, import alerts, communications and outreach activities. They also provide information on ongoing compliance verifications dealing with such issues as cases opened or closed and active workload by quarter and by region. The Inspectorate has mid-year and year-end reports that present information on both the Border Integrity Unit and the Drug Compliance Verification and Investigation Unit, as well as on other programs.

The Marketed Health Products Directorate (MHPD) also has internal dashboards that report on all safety reviews completed on NHPs. There is also a Post-market Review Table, which contains all safety review work and recommendations.

Information is available on the number of adverse reaction reports received. The online portion of the database is updated on a quarterly basis. In 2014, 66,989 domestic adverse reactions were reported to Health Canada. Of these, 678 involved NHPs as a suspected product. The Healthy Canadians site is updated regularly with content from the MedEffect Canada website on adverse reactions, where there is continual reporting of recalls and advisories, including those on NHPs. A search showed that there were 9,029 recalls or advisories on the site. Advisories may be issued to communicate a safety issue arising from a completed safety review by the MHPD or non-compliance identified by the Inspectorate. Sources of these advisories include compliance verifications, journal reviews by the MHPD and adverse reaction reports and advisories from other jurisdictions. In addition, trends can be

identified regarding adverse reactions by looking at the type of reporter and the seriousness of the reaction. Search reports include trending information and the monthly signal meetings also provide data on trends.

There are concerns with the way importation issues are reported internally for decision-making. When personal shipments are refused due to quantities over 90 days, they are reported in the incident reporting system as commercial shipments. In addition, NHPs that are found to be adulterated with a drug are reported as 'drugs'. As a result, while the personal importation of NHPs continues to be a risk, the availability of information to support decision-making on this issue remains limited.

The audit found that the majority of performance information is quantitative: incident reports opened and closed, active workload, items returned or retained for both drugs and NHPs. However, data is not collected and reported regarding the number of NHPs refused at the border and the associated trends in imports of specific products. The exception is when joint international projects are conducted and imported products are inspected; in these cases, a detailed report is produced on the number of packages seized and refused and their estimated retail value. As well, there is no reporting of trends on compliance verifications or adverse reactions. There is also very limited data available on the Internet sales of NHPs or their purchase online by Canadians, a significant source of NHPs. In addition, no reporting is done on the monitoring of activities related to advertising of NHPs or complaints about advertising. However, as part of Openness and Transparency Initiatives, the Department is planning to post a summary of advertising complaints (including NHP advertising complaints) in spring of 2015. Lastly, performance statistics related to NHPs are not reported in the Inspectorate Annual Report.

Despite all the performance indicators, the 2013-14 Department Performance Report highlighted only one expected result: the Natural Health Products industry understands regulatory requirements. The performance indicator was the percentage of natural health product submissions that meet regulatory requirements, with a target of 80% by March 31, 2014 and actual results of 94%. However, the previous year's performance report provided significantly more information. There were performance indicators, targets and results for increased availability of safe, effective and high quality NHPs, timely regulatory decisions for NHPs and a timely regulatory response for NHP-related risks. By expanding the current performance measurement methods and tools into a broader framework that supports more comprehensive measurement of program inputs, activities, outputs and results would assist in moving from output-oriented reporting to more outcome-related expanded results and measures for NHPs.

Enhancement of the current performance measurement framework would support management in its evaluation of program operations (pre-market and post-market activities) and decision-making to better enable the NHP Program to tell its performance story.

Recommendation 6

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a performance management framework to support program objectives.

Management response

Management agrees with the recommendation to strengthen its performance measurement framework.

HPFB has commenced a mapping exercise of its performance measures, indicators and commitments within the departmental Program Activity Architecture and Performance Measurement Framework structure.

This work, which will be conducted in consultation with the Regions and Program Bureau, supports the departmental Performance Measurement Initiative in the development of program strategies that would include a more comprehensive suite of both outcome and output measures, to provide a better management tool.

C - Conclusion

Health Canada (the Department) aims to ensure market access for Canadians to natural health products (NHP) that are safe and effective, based on the *Natural Health Products Regulations*.

Since the establishment of the *Natural Health Products Regulations* in 2004, the NHP Program has evolved and includes standard operating procedures for licensing and the creation of ingredient monographs, thereby reducing the overall evaluation time for a product licence. Since the NHP Program's inception, the Department has authorized over 85,000 natural health products for sale.

The NHP Program is led by the Natural and Non-prescription Health Products Directorate. Post-market activities are led by the Marketed Health Products Directorate and the Inspectorate. Post-market compliance and enforcement activities are delivered by Health Canada's regional offices.

The current governance framework for the NHP Program provides for strategic direction and oversight. Roles and responsibilities are clear and balanced among directorates at headquarters and in the regions. The NHP Program has operational plans to manage its resources and there are processes in place for the registration and assessment of product and site licences prior to sales. However, in a regime where product and site licensing is primarily based on the assertions by manufacturers and importers of products, there is a need for a more proactive post-market effort.

The audit makes six recommendations to further aid in strengthening the internal controls related to risk management, site and product licensing, compliance and enforcement, communication and performance management.

Appendix A – Lines of enquiry and criteria

Audit of the Management of the Natural Health Products Program		
Criteria Title		Audit Criteria
Line of Enquiry 1: Governance		
1.1	Governance structure ²	The Natural Health Products Program has a governance structure that supports its strategic direction.
1.2	Roles and responsibilities ²	The Natural Health Products Program has documented roles and responsibilities that are clear and understood.
Line of Enquiry 2: Risk management		
2.1	Risk management ²	Risks and opportunities related to the Natural Health Products Program are identified, assessed and managed.
Line of Enquiry 3: Internal controls		
3.1	Program management ²	The Natural Health Products Program's planning includes objectives, timelines and resource allocations.
3.2	Site licensing ³	An effective process exists for site licensing applications, amendments, renewals, suspensions and cancellations.
3.3	Product licensing ³	An effective process is in place for product licence applications, amendments, suspensions and cancellations.
3.4	Post-market surveillance ³	Post-market surveillance data, including adverse reactions data, is collected, communicated and used to inform the Natural Health Products Program.
3.5	Compliance and enforcement ³	Compliance and enforcement activities are risk-based and results are used to inform the Natural Health Products Program.
3.6	Open government ⁴	The guidance documents and website are developed and maintained, and support the achievement of the Natural Health Products Program's objectives.
3.7	Performance management ²	Management has identified performance measures linked to planned results, and performance is monitored against these planned results.

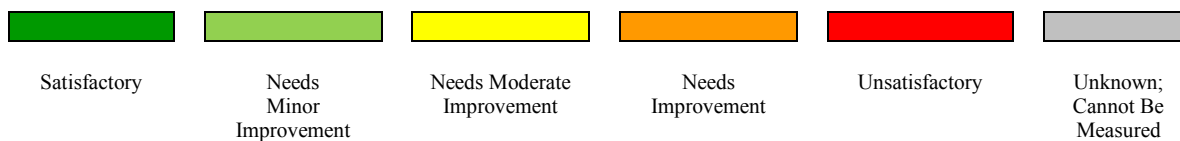
² Office of the Controller General – Core Controls

³ *Natural Health Products Regulations* (2003)

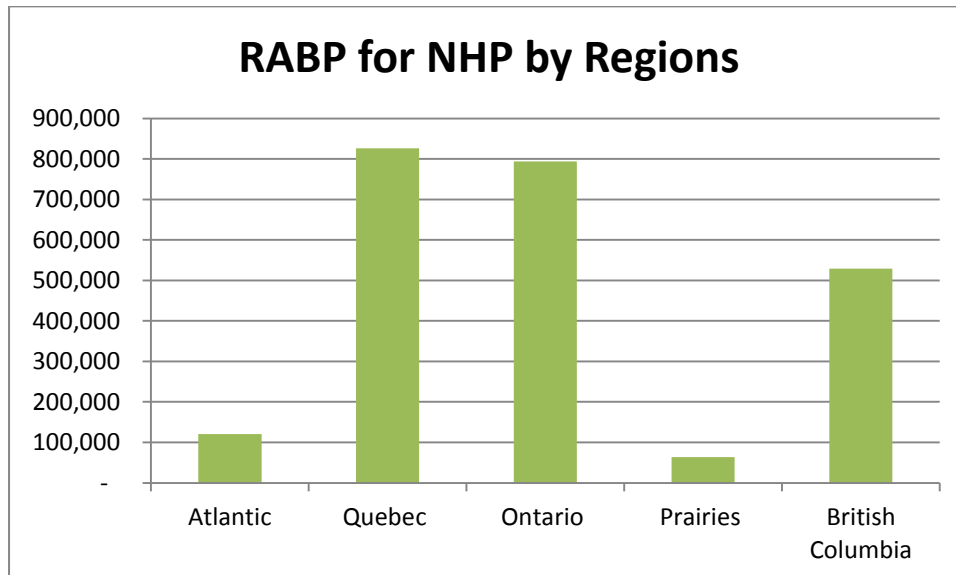
⁴ Canada's Action Plan on Open Government

Appendix B – Scorecard

Scorecard – Audit of the Management of the Natural Health Products Program			
Criterion	Rating	Conclusion	Rec #
Governance			
1.1 Governance structure		The NHP Program has a governance structure that supports the strategic direction; however, performance and emerging risk-related analysis will further support decision-making.	
1.2 Roles and responsibilities		The NHP Program has documented roles and responsibilities that are clear and understood.	
Risk Management			
2.1 Risk management		Risks and opportunities related to the delivery of the NHP Program should be more formally identified, assessed and managed.	1
Internal Controls			
3.1 Program management		Program planning includes objectives, timelines and resource allocations. However, reliance on reserve funding should be monitored.	
3.2 Site licensing		A process is in place for site licensing applications, amendments, renewals, suspensions and cancellations. However, verification of good manufacturing practices should be conducted.	2
3.3 Product licensing		A process exists for product licence applications, amendments, suspensions and cancellations. However, site licence and product licence applications should be cross-referenced to ensure that all licenced products are traceable to licenced sites.	3
3.4 Post-market surveillance		Post-market surveillance data is used to inform the NHP Program. However, the promotion of the adverse reaction reporting system would assist surveillance.	
3.5 Compliance and enforcement		More proactive compliance monitoring is required. The use of post-market surveillance data, including information on adverse reactions, should be strengthened.	4
3.6 Open government		There is guidance and a web presence. However, this information needs to be promoted and its effectiveness measured, to ensure that statements on Health Canada’s role concerning NHPs match the work performed.	5
3.7 Performance management		Management would benefit from having performance measures that are linked to planned results, with performance monitored against these planned results.	6



Appendix C – Natural Health Products Program regional expenditures



Expenditures, by region	
Region	Expenditure
Atlantic Region	\$120,494
Quebec Region	\$826,335
Ontario Region	\$793,899
Prairies Region	\$63,358
British Columbia Region	\$528,924
Total regional expenditures	\$2,333,010

Appendix D – Product licensing: A three-class system

The three-class system sets out the review targets, from Class I products that attest fully to an Natural and Non-prescription Health Products Directorate (NNHPD) monograph, to the more complex Class III products, which require more review. Applicants are encouraged to use the NNHPD monographs to ensure the fastest review. As more monographs become available and as further process improvements are implemented, NNHPD will continue redefining and expanding the three-class system criteria. As of the writing of this report, the following rules have been established to allow for shorter review times, where possible.

Class I: High level of certainty – Lowest level of pre-market review

Class I comprises products that can be indexed against an individual monograph. The level of certainty is higher, as the product has been licenced repeatedly due to its well-established safety and efficacy profile. Applications submitted using the electronic Product Licence Application form (ePLA) and meeting all the parameters of the monograph will have the opportunity to attest using the embedded form and receive a licence within 10 days. NNHPD will continue to explore the expansion of this application stream.

Class II: Medium level of certainty – Medium level of pre-market review

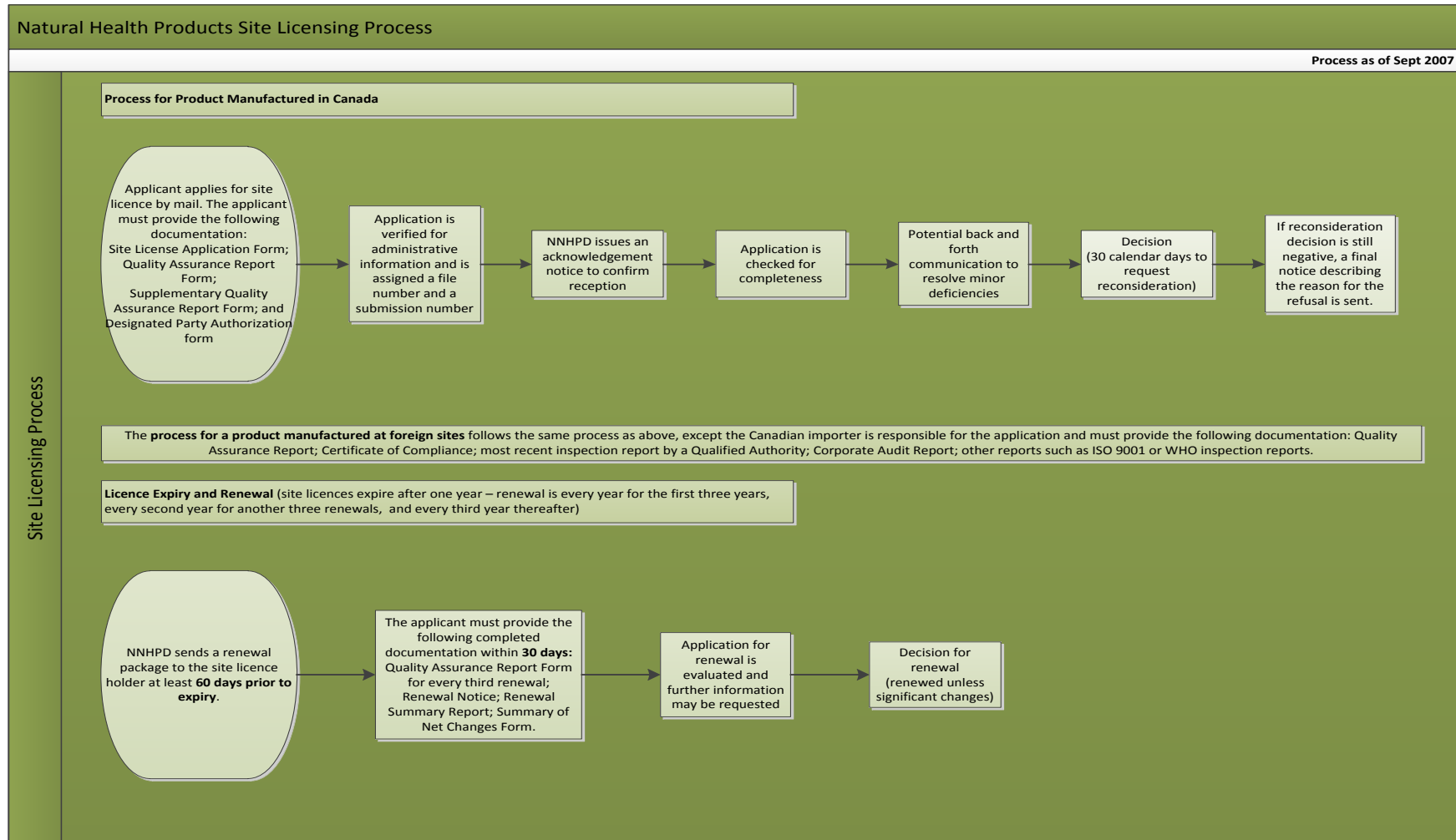
Class II comprises applications with safety and efficacy profiles of medium certainty. This includes multi-ingredient products supported by a combination of NNHPD monographs. For applications in this class, applicants are required to submit an attestation confirming that their product meets the individual monograph parameters. These products are subject to an expedited risk-based review, with a target of 30 days. Combinations with lower certainty may be subject to a Class III review, or additional information may be requested if a potential risk to safety is identified.

Class III: Low level of certainty – Higher level of pre-market review

Class III is composed of applications with safety and efficacy profiles of higher uncertainty. Examples belonging to this class are products with previously unlicensed claims for serious conditions, never before seen ingredients or combinations and products with potentially significant safety concerns. For the portions of these applications that are supported by NNHPD monographs, applicants are required to attest, in a stand-alone form, that the product meets the parameters of the relevant monographs. For the portions of these applications pertaining to new ingredients, applicants are required to submit supporting evidence. NNHPD aims to complete the review of these applications within 180 days. When possible, NNHPD will capitalize on previous licensing decisions and complete reviews in less than 180 days.

As the certainty on the safety and efficacy profiles of new natural health products increases, NNHPD will develop or update monographs in order to facilitate movement from Class III to Class II and Class I. The performance rate of each class of review will be communicated in the NNHPD Quarterly Snapshot.

Appendix E – Site licensing process map



Appendix F – Product licensing process map

