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# *Charting A Course: Refining Canada's Approach to Regulating Natural Health Products*

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## **Document Objective**

This document has been developed as a tool to introduce issues and stimulate discussion around the Natural Health Products Regulatory Review (the Review). It is intended to provide the reader with sufficient background and information to understand the context of proposed components of the review. This document is meant to support the initial stages of the discussion.

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## FOREWORD

This document provides background information on the *Natural Health Products Regulations (NHPR)* and the Natural Health Products Regulatory Review Initiative (the Review) for the purposes of stakeholder consultation. The Review is intended to guide the process for the refinement of the regulation of natural health products in Canada.

The purpose of this first step in the process is to provide stakeholders with an opportunity to familiarize themselves with the Review and regulatory policy issues that Health Canada proposes to address in the context of this Review..

This document consists of four chapters: Chapter 1 is intended to contextualize both the operational and the regulatory aspects of the *NHPR*. Chapter 2 describes certain operational improvements which are currently underway. Chapter 3 describes the Review process and those issues which have currently been identified for review. These issues are further elaborated in Appendices A-D at the end of this document. In Chapter 4 can be found an action plan that describes how we are going to deal with policy and regulatory initiatives which Health Products and Food Branch (HPFB) is undertaking in the short term.

The issues that are listed and described in this document (Chapters 3 and 4 and in Appendices A-E), represent an inventory of regulatory policy issues which have been identified over the three years since implementation of the *NHPR*, through both experience and from feedback received from stakeholders.

An online questionnaire will supplement this document to facilitate specific feedback from stakeholders on a listing of issues. The NHPD encourages stakeholders to review this document and provide feedback using this questionnaire, which will be available on the Health Canada website on March 23, 2007. Notification will be sent to stakeholders announcing the availability of this consultation questionnaire.

Because of the regulatory nature of the identified issues, this paper may be of special interest to people in industry, health care practice, academia, non-governmental organization (NGOs), provincial and territorial governments and regulatory bodies, as well as consumers who use NHPs. The feedback received will assist in the development of options and planning for issues resolution.

This document should be read in conjunction with the accompanying Notice to Stakeholders and the relevant sections of the *NHPR* ([http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/index_e.html)).

# CHAPTER 1 - Setting the Stage

## The Context and Background for Refinement of the Natural Health Products Regulatory Regime

### Part 1 – Introduction

The regulatory framework for natural health products (NHPs), the *Natural Health Products Regulation (NHPR)*, came into force January 1, 2004, following extensive legislative and consultative processes. The *NHPR* were a direct response to an expressed need for specific regulatory oversight of NHPs in Canada.

At the time that the regulations came into force, a commitment was made to undertake a review of the regulations within the first three to five years of their implementation. This review has been launched further to that commitment and in consideration of challenges and issues which have been identified in the first three years of regulating NHPs.

These challenges largely flow from one of three sources, operational practices at Natural Health Products Directorate (NHPD) relating to issuing product licences, the interpretation and implementation of compliance and enforcement activities and the regulations themselves. This review will focus on those challenges which flow directly from the regulations. In tandem with this review, operational challenges are being addressed by ongoing business improvement initiatives and compliance and enforcement practices are being refined to best serve the needs of Canadians. (See Chapter 2).

### Broader Context for the NHPR Review

The Natural Health Products Regulatory Review (the Review) is being undertaken as part of the Health Products and Food Branch's (HPFB) Blueprint for Renewal initiative, which aims at modernizing the regulatory system for all health products and food regulated by Health Canada. A number of objectives and initiatives being advanced under the Blueprint umbrella will help inform the action plan to improve the regulatory framework for NHPs. For example, the following Blueprint initiatives will be closely aligned to the Review:

- Strategies to ensure that regulatory interventions are proportional to risk within and across the various regulatory frameworks covering health products and food - for example, Health Canada will consider pursuing administrative or policy approaches to regulate certain low-risk products currently covered under the *NHPR*, such as personal care products.
- Regulatory modernization strategy for food - potential implications for products that are at the border of the NHP and food regulatory frameworks.
- Strengthening safety oversight through the adoption of life cycle approaches to the regulation of pharmaceuticals and biologics (progressive licensing project) - elements of this model could be considered in the context of NHPs.

The HPFB has released a discussion paper on the Blueprint for Renewal plan. Consultations were held from October to December 2006 on this Blueprint plan. Reports from these consultations, as well as the discussion paper, are posted on the Blueprint web site at: <http://www.healthcanada.gc.ca/hpfb-blueprint> .

Complementary activities to the Blueprint for Renewal initiative include a Branch-wide resource review exercise aimed at ensuring that HPFB has adequate capacity and resources to deliver on its mandated activities, as well as the development of a new external charging regime for the various regulatory activities of the Branch. The specific needs of the NHP program will be considered as part of these exercises.

## **Part 2 - Where We Came From: The Regulation of NHPs in Canada**

### ***2.1 Why Regulate NHPs?***

A recent survey shows that 71% of Canadians regularly take vitamins and minerals, herbal products, homeopathic medicines and other products that are now regulated as NHPs. (*Baseline Natural Health Products Survey Among Consumers* (2005) online at [http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/eng\\_cons\\_survey\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/eng_cons_survey_e.html)). Of those surveyed, 38% indicated that they took NHPs daily and a further 38% indicated that they took NHPs daily during certain seasons of the year. The most commonly used types of NHPs were vitamins (57%), Echinacea (15%), herbal remedies and fungal products (11%), Glucosamine (8%), homeopathic medicines (5%), natural organic products (5%) and supplements (5%).

The breadth and variety of these products is immense. It is estimated that some 40,000 products currently on the Canadian market can be classified as NHPs. At the same time, Canadians are taking more responsibility for their own health and, in many cases, this has led to an increased awareness of, and demand for, NHPs. The most often cited reasons for using NHPs include being generally concerned about their health, that they help maintain and promote health, and a belief that they are better for personal health than chemical products/drugs.

NHPs will often be taken to complement conventional medical treatments or address a gap in such treatments. Many of these products have roots in cultural practices and form part of the rich cultural heritage of Canadians. Keeping this in mind, and with so many products falling within the definition of an NHP, it is essential to ensure their safety, efficacy and the accuracy of any health claims that are made concerning their use.

There is a common misconception that all NHPs are 'natural' and therefore safe. In reality the safety of NHPs depends upon the amount or dosage, the characteristics of the user and the context in which they are used. *Indirect harm* may occur when you inappropriately ignore more proven or appropriate care (either complementary or conventional) by taking an NHP. *Direct harm* may occur because the body's organ systems and metabolic processes are complex and interactive and any health product is likely to have side effects. Harm may even occur when taking an NHP as directed, where other factors overlap to make the NHP use dangerous. Effective oversight of the

conditions of use, real world safety and communication between consumers, NHP providers and government is critical in ensuring consumer safety.

## **2.2 The Evolution of the NHPR**

While the debate about regulating NHPs has been going on for some time, the inception of the *NHPR* began in 1997 with an announcement by the Minister of Health of a full public review by the House of Commons Standing Committee on Health (SCOH) of the legal regime governing NHPs in Canada. The SCOH initiated broad consultations to seek input from industry, health care practitioners and consumers regarding a regulatory framework for NHPs. The objective of this consultation was to ensure a balance between Canadians' freedom of choice with respect to NHPs and the assurance of consumer safety.

During these consultations, stakeholders consistently requested a specific regulatory framework for NHPs that would provide Canadians with access to safe, effective and high quality NHPs, and regulate NHPs in a manner commensurate with their level of risk.

In 1998, the Standing Committee tabled in the House of Commons its report called *Natural Health Products: A New Vision*. The Standing Committee report included 53 recommendations which formed the basis of the new regulatory structure for NHPs. Copies of the report are available at [http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2000/2000\\_51bk3\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2000/2000_51bk3_e.html).

In 1999, the Minister of Health announced the creation of the Office of Natural Health Products, now the NHPD, with a mandate to implement the Standing Committee recommendations. (See *NHPD: Progress on the 53 Recommendation of the Standing Committee on Health* at [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/53\\_recommend\\_nhp-cps\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/53_recommend_nhp-cps_tc-tm_e.html)).

In March 2001, the NHPD initiated consultations with representatives from industry, consumer groups, health care practitioners, academics and government and regulatory bodies, and subsequently drafted and released the proposed regulatory framework. Based on stakeholder feedback, and in keeping with the Standing Committee recommendations, the proposed regulatory framework was developed. The proposed regulations were pre-

### **Key Milestones in the Development of the NHPR**

**October 1997** – Minister of Health announces full public review by SCOH of legal regime governing NHPs.

**May 1998** – SCOH tables 53 recommendations for a new regulatory regime governing NHPs.

**March 1999** – The government accepts all 53 recommendations and creates the Office of Natural Health Products, now NHPD.

**June 1999 – May 2000** – Transition team consults and submits report on best way to meet SCOH 53 recommendations.

**June – September 2000** – NHPD consults with stakeholders on best way to implement NHP regulatory regime.

**September 2001** – Draft of Proposed regulations shared with stakeholders.

**December 2001** – NHPR pre-published in Canada Gazette Part I.

**June 2003** – NHPR pre-published in Canada Gazette Part II.

**January 2004** – NHPR came into force with a transitional period for various products.

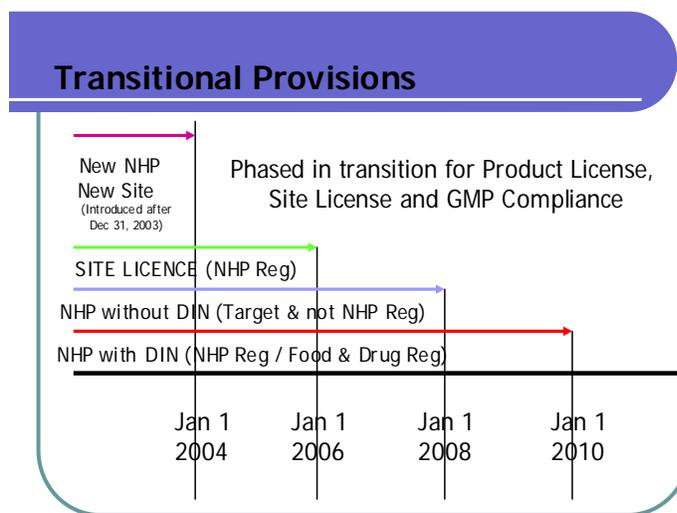
published in the *Canada Gazette*, Part I (CGI), on December 22, 2001. Over 600 comments were received during the CGI comment period. Following analysis and revisions based on this input, the proposed regulations were published in the *Canada Gazette*, Part II on June 18, 2003 and came into force, as noted above, on January 1, 2004.

### 2.3 Transition Period

With the coming into force of the *NHPR*, nearly 40,000 products required review prior to issuing market authorization as an NHP. Some of these products had previously been issued Drug Identification Numbers (DINs) under the *Food and Drug Regulations (FDR)*, some were dealt with as non-compliant foods, while others had not previously been subject to any Canadian regulatory requirements. The *NHPR* provided transition provisions for both products and sites.

The *NHPR* set out a two-year transition period for site licensing beginning on January 1, 2004. Manufacturers, packagers, labelers and importers of NHPs conducting those activities in Canada before the coming into force of the *NHPR* were permitted to continue doing so in accordance with their establishment licence issued under the *FDR* until December 31, 2005. The *NHPR* also contain a six-year transition period for product licensing, from January 1, 2004 to December 31, 2009, with respect to the packaging and sale of NHPs with DINs.

The applicable provisions of the *FDR* continue to apply for products with a DIN until they are licensed under the *NHPR*. These transition guidelines were developed according to the risks associated with a product and the type of evidence needed to assess a product licensing application (i.e. novel products would be assessed before traditional medicines).



As of January 1, 2004, all new products (i.e. products not previously on the market) that meet the NHP definition had to comply with the *NHPR* and with the full licence application process in order to be sold in Canada.

The Health Protection and Food Branch (HPFB), including NHPD and the Inspectorate, put into effect a Compliance Policy which established a process for priority approval of NHPs based on potential risks, while re-enforcing Health Canada's ability to take immediate compliance and enforcement action on any product which poses a risk to the health and safety of Canadians. (The *Priority Approach to Compliance and Enforcement* is presented in the accompanying table, see *Natural Health Products Compliance Guide*

online at [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/compli-conform/compliance-conform\\_guide\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/compli-conform/compliance-conform_guide_e.html)).

Focusing initial licencing efforts on those NHPs which pose the greatest potential harm ensures that Health Canada works efficiently towards its mandate. NHPD continues to strive to meet the deadlines established in the Compliance Policy.

(More information on the assessment and licensing activities of the NHPD is included in Chapter 2.)

<b>Priority Approach to Compliance and Enforcement</b>	
Priority 1 - NHP substances in the TPD's New Drug List	June 1, 2004
Priority 2 - Isolates, amino acids, fatty acids, and concentrated volatile (essential) oils	Jan 1, 2005
Priority 3 - Algal, bacterial, fungal, probiotics and non-human animal materials	June 1, 2005
Priority 4 - Plants, plant materials, extracts and volatile (essential) oils	June 1, 2007
Priority 5 - Vitamins and Minerals	Jan 1, 2008
Priority 6 - Homeopathic Medicines	June 1, 2008

#### ***2.4 International Regulation of NHPs***

The international trend is towards the development of regulations specific to NHPs. The Canadian framework is often cited as a model for good management and law making being considered innovative and forward thinking. While other jurisdictions are still in the early stages of exploring how best to classify these products and ensure appropriate regulatory oversight, the Government of Canada has taken decisive steps to ensure that they are assessed for safety and efficacy.

Many countries lack regulations specific to NHPs as a unique class of therapeutic products. For those countries that do regulate these products, there are vast differences in the definition and categorization of those products which, in Canada, would be considered NHPs with some considering them to be a subset of drugs and some as a subset of foods. For example, while in the United States the vast majority of NHPs are considered as foods (dietary supplements), in certain countries in Europe, herbal medicines are regulated under the drug regulations with vitamins and minerals considered as foods. In other countries, such as Singapore, certain subsets of NHPs (Chinese Proprietary Medicines) are regulated in a very controlled manner with no specific regulations existing for the other types of NHPs on the market. The regulatory situation in each country also impacts which type and extent of claim is permissible. These differences in definition and categorization result in inconsistencies in the approaches to assessing and mitigating risk and thereby creating challenges for both Health Canada and for some stakeholders (e.g., the exportation of NHPs from Canada to countries which categorize NHPs as drugs).

Several countries and the World Health Organization (WHO) have recognized the comprehensive and innovative nature of the *NHPR* and Health Canada's leadership in the regulation of NHPs. They monitor our progress closely. Other jurisdictions are looking to the Canadian model to help ensure the safety of products which do not fall under the conventional definition of either a food or a drug, but are commonly used for medicinal

purposes. Canada is currently acting as Secretariat for the new network for International Regulatory Cooperation on Herbal Medicines, a WHO-facilitated initiative.

### **Part 3 - Where We Are Now: The Present Regulatory Framework for NHPs**

#### ***3.1 At a Glance: A Regulatory Framework for Natural Health Products***

The *NHPR* include provisions on: definitions, product licensing, site licensing, good manufacturing practices, clinical trials, labelling and packaging requirements, and adverse reaction reporting. (These various provisions will be dealt with in greater detail in Chapter 3).

- The **definitions** include the definition of a natural health product and other terms which are key to the functioning of the *NHPR*. Products that fall within the *NHPR* include herbal remedies, homeopathic medicines, vitamins, minerals, traditional medicines, probiotics, amino acids and essential fatty acids.
- A **product licensing system** requires that all licensed products display an 8-digit product identification number preceded by the prefix NPN, or, in the case of a homeopathic medicine, by the letters DIN-HM on their labels.
- A system of **site licensing** requires that all manufacturers, packagers, labellers, and importers be licensed.
- **Good Manufacturing Practices** (GMPs) are required to ensure product safety and quality, and linked to issuance of a site license.
- **Clinical Trial Procedures** identify those practices which are required for researchers conducting NHP experimental trials involving human subjects.
- Standard **labelling requirements** are established to ensure consumers can make informed choices.
- An **adverse reaction reporting** system for NHPs assists Health Canada in identifying previously unrecognized, rare, or serious adverse reactions, and imparting health product safety knowledge that benefits all Canadians.

The *NHPR* also incorporate by reference a number of provisions from FDR. Some of these are critical for the compliance and enforcement of the *NHPR*.

#### ***3.2 Re-Affirming the Worth of the NHPR***

Following the 2005 Standing Committee on Health (SCOH) hearings on Bill C-420, the value of the current regulatory framework was re-affirmed. In its 2004 report on Bill C-420, the SCOH found that:

*The regulations ensure safety through an appropriate level of oversight, permit a full range of evidence-based health claims, and ensure high quality through outcome-based good manufacturing practices.*

The SCOH also reiterated that:

*The regulations were developed following extensive consultations and thus reflect the desire of Canadians for a regulatory framework appropriate to the level of risk associated with natural health products.*

### **3.3 The Licensing Process**

Generally, NHPD applies a similar process to managing product licensing applications, site licensing applications and clinical trial applications. Assessment of new applications occurs in a four stage process:

**Step 1 Verification** – An NHP application file is created and receipt of the application is acknowledged.

**Step 2 Processing** – The NHP file is reviewed for completeness or basic errors. If the file is incomplete, it will not be processed. If it is found to be complete, it will be presented for assessment.

**Step 3 Assessment** - The application submissions are evaluated, first for the completeness of supporting documentation and then for any missing information. Applications are reviewed and an assessment report is generated based on the evidence provided. Assessment reports are then reviewed and a final recommendation for approval or refusal of the application is made.

**Step 4 Decision** – The NHPD confirms and formally issues the decision to applicants.

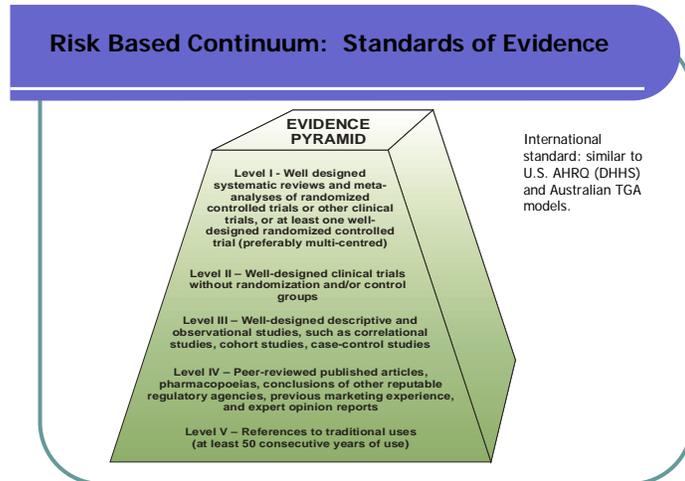
### **3.4 Assessment Proportional to Risk**

In assessing the health and safety risks of NHPs a ‘one size fits all model’ cannot easily be applied. In reviewing the information provided by applicants, the totality of all evidence submitted with the application must be reviewed. Based on the potential risks stemming from particular products, and/or claim(s) being made, a varying continuum of evidential standards needs to be met.

A rigorous and comprehensive review of this data is essential to ensure the health and safety of Canadians and justifying the availability of an NHP in the marketplace. The strength and volume of the presented evidence, the credibility of the sources cited, quality of publications provided, and the overall utility of this data for demonstrating the safety and efficacy of the NHP are all assessed and reviewed in order to reach the final recommendation at Stage 3 ‘Assessment’.

Keeping these points in mind, Health Canada has established an evidence evaluation framework based on categories developed by the United States Agency for Healthcare Research and Quality, and adopted with minor modifications by the WHO, for product evaluations. An important feature of this approach is the recognition that a gradient of evidence can be used to support the claims of safety and effectiveness in a product licensing application.

The risk classification scheme is an evidence-based approach that classifies a product into a level of risk based on relevant information from published and unpublished sources, such as, but not limited to, peer-reviewed or professional journals, textbooks, reports from other regulatory bodies, etc. The evidence will primarily be from experience of the product or ingredient's use by humans, but may also include relevant information, when necessary, from animal studies.



The balance of evidence must support safety and efficacy in such a way that the benefits of allowing the NHP on the market outweigh the risks of doing so. Applicants are expected to provide a summary of all relevant evidence, both favorable and unfavorable.

## **Part 4 -Where Are We Going: Identifying and Addressing the Challenges**

### ***4.1 Lessons Learned in the First Three Years of Regulating NHPs***

As part of Health Canada's on-going efforts to consult with Canadians on its regulatory frameworks, the NHPD meets regularly with key stakeholders and its advisory committees (Expert Advisory Committee [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/com/expert/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/com/expert/index_e.html) and Management Advisory Committee [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/com/mgmt-gest/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/activit/com/mgmt-gest/index_e.html)). By meeting with these Committees of representative stakeholders and by listening to additional stakeholders, NHPD has gathered input regarding the functioning of the current regulatory regime under the *NHPR*. The challenges and issues which have arisen during the first three years of the implementation of the *NHPR* point to three aspects: (1) operational/licensing (2) regulatory & policy and (3) compliance and enforcement.

While the focus of this paper is on regulatory review, in response to the operational challenges that the Health Products and Food Branch face related to compliance and enforcement, the Branch has outlined issues of capacity as a priority, and has committed to providing support to address this issue in the upcoming fiscal year.

For example, the Inspectorate has extended its interim policy, which allows NHP companies to make use of the Certificate of Pharmaceutical Product (CPP) program. The CPP program is an internationally recognized WHO document that attests to a product meeting domestic regulatory requirements, and is a prerequisite to have a product imported in many jurisdictions.

In responding to the specific operational issues which have been identified for the Review, efforts have been made to increase operational efficiencies, outlined in more detail in Chapter 2.

## **CHAPTER 2 – NHPD Business Improvement Initiatives**

### **Part 1- Regulation and Sale of NHPs in Canada**

As outlined in Chapter 1, the *Natural Health Products Regulations (NHPR)* came into force on January 1, 2004 following a comprehensive and extensive, multi-sectoral, multi-year consultative process. Under this new regulatory framework, all NHPs must be licenced before they can legally be sold in Canada. Product licences are authorized following a pre-market review and assessment for safety, efficacy and quality conducted by Health Canada. In addition to product licensing, Canadian firms involved in the manufacture, packaging, labeling and/or importation of NHP for commercial sale must have valid site licenses which are obtained by demonstrating that they follow appropriate good manufacturing practices (GMPs).

As with all novel approaches, implementing this ambitious and comprehensive regulatory agenda has not come without its challenges. This is not surprising given the volume, variety and complexity of the products available on the market as well as a developing NHP industry that, for the most part, has not been subject to systematic health regulation.

### **Part 2 - Addressing the Operational Challenges**

As a result, of these initial implementation challenges, Health Canada accumulated a processing delay of several thousand product licence applications within its first three years of operation. Of the estimated 42,000 products currently on the market, approximately 12,400 have been authorized for sale (2,411 since January 1, 2004 and 10,000 as drugs prior to that). Since January 1, 2004, the Department has received a total of 18,017 product and site licence applications and has fully processed 7,003 (either licensed or refused the application due to lack of information or safety concerns).

Acknowledging the situation it found itself in, NHPD launched, in the summer of 2005, its Business Improvement Initiative (BII). Objectives of this initiative are to eliminate the processing delay, streamline the application review process to avoid future delays, and increase operational capacity to permit issuance of 60 product licenses and 12 site licenses per day.

Despite the limited regulatory experience in other jurisdictions, Health Canada nevertheless recognizes the importance of international work in addressing current challenges. For example, use of more international standards to support the implementation of the *NHPR*, when feasible, such as, adoption of the Chinese Pharmacopeia (Canada is the first country outside of Asia to do so), adopting the Australian *Therapeutic Goods Administration (TGA)* approved terminology for naming medicinal ingredients as per their Electronic Listing Facility system, adopting International Conference on the Harmonization (ICH) -M5 Controlled Vocabulary for Dosage forms, adopting Medical Dictionary for Regulatory Activities (MedDRA) medical terminologies for indications and warnings, accepting GMP certificates from international mutual recognition agreements (MRA) and Pharmaceutical Inspection Cooperation Scheme (PIC/S) partner countries and using WHO Monographs.

## **Part 3 - Improvement Efforts**

A first step in the BII was to conduct an in-depth analysis of operating resources and processes to identify strengths and opportunities for improvement. Following this analysis, an action plan was put in place which targets system processes, standard operating procedures and human resources. These BII measures are being progressively phased in and include, specifically:

### ***3.1. Process Reengineering:***

- development of Standard Operating Procedures and process adjustments including: regular, ongoing training for Assessment Officers to ensure consistency, changes to evidence requirements to streamline reviews and reduce review time, and refusal of applications that do not meet minimum screening criteria (eg., for completeness);
- development and ongoing revision of Guidance Documents to ensure clarity, coherence and up-to-date information (see [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index_e.html));
- compendial-like assessment for new types of applications, homeopathic medicines, traditional – pharmacopoeial, food-like NHPs, transitional DINs, etc.;
- development of regulatory focused NHP monographs as tools to increase the number of applications that can be assessed through the compendial stream;
- completion of Category IV Monographs, labeling standards and a monograph policy for multi-ingredient products (e.g., multi-vitamin, multi-mineral);
- focused processing initiatives by product categories (e.g., homeopathic medicine focus); and,
- batch reviews by ingredient and company to increase efficiency and minimize review time via repetitive processing (e.g., Glucosamine and Chondroitin products).

### ***3.2. Human Resource (HR) Capacity:***

- increasing HR capacity and shifting role and responsibility areas, including shifting administrative tasks to free scientists to concentrate on assessment activities and reallocating resources to priority areas such as monograph development.

### ***3.3 System Development:***

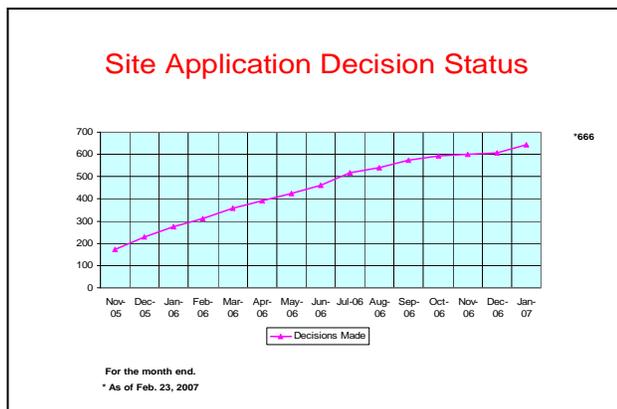
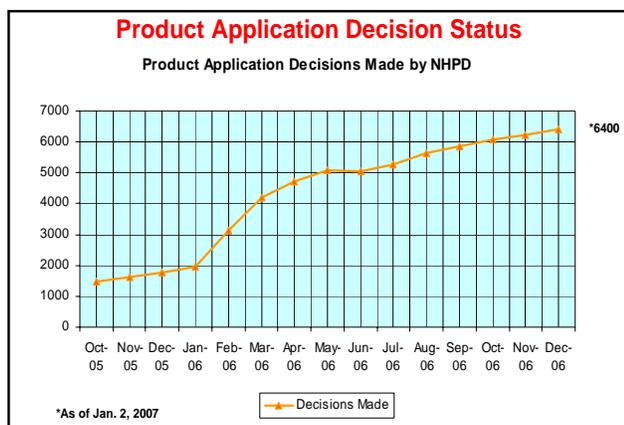
- implementation of an online information system - to support the NHP licensing program - for filing and processing submissions under the *NHPR*. The solution will maintain a database of pre-qualified acceptable known NHP ingredients as well as manage the submission and handling of license applications through the entire lifecycle. This solution will also:
  - collapse processing delays and work effort related to errors and/or omissions in applications;
  - reduce manual entry by enabling electronic submission of applications; and

- development of a world-class ingredient database that is the first of its kind, which will greatly enhance future productivity when posted and will be subsequently integrated into the Online System. The aim of this database is to consolidate all approved ingredient related information (medicinal and non-medicinal) specific to NHPD. 'Stage 1' (non-medicinal ingredients, and classified medicinal ingredients) is now complete, with 4,000 ingredients now available. The system has been recommended for production by our technical authorities and is available internally at Health Canada as of late January 2007.

#### **Part 4 - Positive Results thus Far**

Since the coming into force of the regulations in January 2004, the NHPD has addressed operational challenges related to implementing the new regulatory framework through ongoing adjustments. The BII was designed to build on results achieved during this initial implementation period. Since the launch of the BII in late 2005, a number of positive results have been achieved, including:

- decisions on licence applications are being made 6 times faster than in 2005 prior to the launch of the BII, representing a 400% decrease in the time it takes for decisions;
- Health Canada is now actively assessing an average 40 licence applications per day;
- 40% of the applications received are complete in site licensing, product licence acknowledgment and screening, and compendial product licence application assessment; and
- The majority of clinical trials have been assessed
- assessment of site licence applications is meeting the 30 day service standard.



#### **Part 5 - Next Steps**

The NHPD has made significant progress since the Summer 2005 implementation of the BII. That being said, a sizeable number of product licence applications remain unprocessed and improvement efforts are ongoing that will focus on this last area of processing delay. Key to this will be the launch within the next fiscal year of the on-line product assessment system, which will allow for a fully automated and speedier review of

incoming licence applications. This new tool will also go a long way in facilitating industry's ability to submit complete and high quality product and site licence applications. If the achievements of the past year and a half serve as any indication, Health Canada will be able to reach its goal of processing the majority of the remaining processing delays within the new fiscal year. Health Canada will continue to work with international partners on systems development issues, in particular with Australia which has implemented its very successful "Electronic Listing Facility" system for all listed complementary medicines.

The Review occurring in tandem with the BII, as outlined in Chapter 3, is designed to address regulatory issues which have been identified since the coming into force of the *NHPR*. It is anticipated that solutions to these issues will include regulatory amendment, policy development and operational adjustments. Issues identified during the Review that require operational solutions will be referred to the BII for further analysis and implementation.

### ***Part 6 - Conclusions***

The BII is designed to address the high demand for product licence approvals and will allow Health Canada to move forward to meet the challenges resulting from the coming into force of the new regulatory framework for NHPs. Health Canada will continue to keep Canadians informed of progress within this initiative via the Health Canada website.

# CHAPTER 3 – The Natural Health Products Regulatory Review

## Part 1 – Review Objectives, Challenges and Guiding Principles

### 1.1 Objectives

As noted in Chapter 1, the review of the *Natural Health Products Regulations (NHPR)* is being undertaken to respond to Health Canada’s commitment to conduct a review of the regulations with three to five years of coming into force. Revisiting/reevaluating new regulations is standard practice and an essential element of good governance. A key objective for the Review is to improve regulatory performance and ensure the sustainability of the NHP regulatory program. Additional objectives of equal importance are that the Review aligns with regulatory modernization initiatives within Health Canada and Health Product and Food Branch.

One of the essential elements driving the Review is the safety of Canadians. In making the recommendations that eventually established the *NHPR*, the SCOH asserted that “All members of the Committee share the same objective – that the health of Canadians must remain as the most vital criterion underlying any regulatory analysis”.<sup>1</sup> Similarly, Health Canada recognizes that its role must include, “minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products.”<sup>2</sup>

While the consultation process which is underway will provide the NHPD with feedback, the NHPD will consider the level of health risks as well as work being done concurrently on other regulatory frameworks in determining the appropriate regulatory changes to be made.

On the whole, the desired outcome is a regulatory framework for NHPs that (1) protects the health of consumers, (2) respects consumers’ access to products, (3) guarantees product safety and quality, and (4) ensures consumers can make an informed choice.

### 1.2 Challenges

The review process itself is not without its challenges. There were several key considerations in designing the approach to the Review: primarily scoping and the complexity of the process.

As has already been mentioned in Chapter 1, it is very important that the Review recognize and encompass the initial identification of a variety of issues by both external and internal stakeholders, some of which are operational issues rather than fundamental regulatory problems (discussed to in Chapter 2). As well as the concept of exceptions and outlying products which do not easily fit within the NHP regulatory model. For example, in some cases, lower risk products

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<sup>1</sup> Report of the Standing Committee on Health, *Natural health Products: A New Vision*, (November 1998), chapter 2, paragraph 2.

<sup>2</sup> See Health Canada; About Mission, Values, Activities on line at : [http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/activit/about-apropos/index_e.html).

may be over regulated currently while some higher risk products may more properly fit under other existing regulations.

### ***1.3 Guiding Principles***

In looking then at these objectives and challenges for the Review, the following guiding principles have been developed for the process.

#### ***The Review will:***

- Respect the underlying principles/logic of the *Food and Drug Act* regarding the pre- and post-market review of product classes based on level of risk.
- Identify and attempt to address regulatory lessons learned from parallel models of regulatory health risk assessment from within Health Canada

#### ***The Review will NOT:***

- Revisit and make direct changes to the core definition of what is a natural health product. We will however consider reviewing the exclusions and inclusion criteria contained in Schedule 1 and Schedule 2.
- Fully revisit all of the original recommendations of the Standing Committee on Health (SCOH). We will however continue to build on the recommendations.

The purpose of the Review therefore is not to reassess the fundamental framework of the *NHPR*. The purpose of the Review is to address the specific regulatory policy issues that have been identified over the three years following implementation of the *NHPR*. It will seek to target specific regulatory issues for refinement. While adjustments to operational procedures are occurring in tandem with this Review (see Chapter 2), those operational challenges that do not flow directly from the regulations are outside of the scope of the Review.

### **Part 2 – Why is it Time for a Regulatory Review?**

Regardless of how precise or exhaustive they may appear on implementation, no set of regulations can anticipate every eventuality or eliminate the need for interpretation, clarification or amendment. The *NHPR* and their implementation are no exception.

There are several reasons why now is the appropriate time to initiate a review of the regulatory process for NHPs as is summarized in the following listing.

#### ***(1) A 3-5 Year Commitment for Review***

As of January 1<sup>st</sup>, 2007 the regulations have been in operation for three years. Reviewing the regulations at this early stage allows us to meet the commitment that was made by Health Canada to review the operation of the regulations within the first 3 to 5 years of their coming into force and to ensure that the *NHPR* is on the right course.

#### ***(2) Lessons Learned***

Over the past three years, NHPD has been listening to the concerns of its stakeholders regarding the regulations. The implementation of the *NHPR* has allowed the identification of issues that could only become apparent in translating the regulations into action.

*(3) Housekeeping Amendments and the Continuity of the Regulations*

NHPD has heard from the Standing Joint Committee for the Scrutiny of Regulations (SJCSR) regarding a collection of technical housekeeping amendments that are required to maintain the consistency of the *NHPR*. In responding to the recommendations of the SJCSR, NHPD will strive to ensure the continuity and clarity of the regulations.

*(4) Harmonizing with Blueprint for Renewal*

Health Canada has initiated processes to modernize its regulatory practices. As part of the *Blueprint for Renewal* Health Canada as a whole is striving to reorient the health product and food regulatory system to better align with modern realities. The Review represents an opportunity to strive to meet the broader goals as articulated in the *Blueprint*.

*(5) Keeping Pace with other Branch Initiatives*

There is an opportunity to ensure coherence and synergy with the other regulators in Health Canada's Health Protection and Foods Branch (HPFB), as well as other Government partners, such as the Canadian Food Inspection Agency (CFIA). Other regulatory program areas of the HPFB have recently, or are currently, reviewing many of their own regulations. The *Blueprint for Renewal*, Progressive Licensing Framework and the Regulatory Review of Division 5 of the *Food and Drug Act* are just a few examples. There is a unique opportunity to look at overlaps between these various regulatory regimes and harmonize.

### **Part 3 – What do We Want to Be?**

Health Canada is committed to serving Canadians both now and into the future, by continuing to strengthen its position as a regulator. This means ensuring the *NHPR* meets the evolving needs of Canadians and adjust to the challenges of diverse social, economic, scientific and technological developments. To that end, NHPD continues to strive to be:

- **A World Class Regulator** – Health Canada has taken the international lead in establishing a regulatory regime that deals comprehensively with NHPs as a distinct class of products (see Section 2.4, Chapter 1). NHPs are increasingly being used within a global context, yet international standards, being fluid, vary extensively. Canadian regulations have garnered a great deal of interest internationally, generally being regarded as innovative and forward thinking. Health Canada will continue to take the lead in regulating NHPs.
- **Allow Access while Ensuring the Safety, Efficacy and Quality of NHPs** – NHPD will continue to provide clear government oversight by applying appropriate levels of scrutiny to new products. This includes ensuring health

claims not be allowed without ensuring the existence of some form of supporting evidence.

- **Regulate Proportional to Risk** – Measures in place to oversee the regulation of NHPs, must be proportional to risk. The SCOH originally recommended that “the level of regulation should be consistent with the level of safety associated with a particular product.” NHPD must concentrate its evaluation efforts on those products which pose the greatest risks. The pre-market evaluation of an NHP must be based on an analysis of the benefits and risks associated with each product: the higher the risk, the greater the level of evidence required. Conversely, where the risk is low, evidential standards should be less onerous. The regulation of risk must also be adjusted in light of new facts that emerge from post-market surveillance.

- **Recognize the Cultural Component of NHP Use** – While NHPs are taken for medicinal purposes, their roots often play an integral element of cultural practices. For example, traditional forms of Asian medicine and Aboriginal healing practices draw heavily upon the use of NHPs. As such, NHPD will continue to be respectful and remain sensitive, allowing for NHPs cultural uses as well as their role in non- conventional western medicine.

- **Reflect the Broad Range of NHPs** – NHPs by their very nature are a wide class of products, with many variations in formulation and use. The broad difference in NHPs means that no simple rules can easily be placed on all NHPs as a class of products. Regulatory solutions must be sufficiently flexible to allow for the accommodation of these variations.

## **Part 4 – Background to the *Natural Health Products Regulations (NHPR)***

### ***4.1 Scope of the NHPR***

The *NHPR* were created under the authority of the *Food and Drug Act* to regulate NHPs. As noted briefly in Chapter 1, the *NHPR* contain requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of NHPs.

These Regulations place requirements on persons who produce NHPs for sale, namely manufacturers, distributors, importers, packagers and labelers. The NHPD considers that growers, who handle and/or treat a product in order to preserve the integrity of the raw material, are not considered manufacturers. Health care practitioners (for example, pharmacists, Traditional Chinese Medicine (TCM) practitioners, herbalists, naturopathic doctors, homeopathic practitioners, etc.) who prepare or compound products at the request of a patient are not included within the manufacturer definition. The NHP Regulations are not aimed at regulating the practice of complementary and alternative health care practitioners or the practice of traditional Aboriginal medicine.

### ***4.2 Content of the NHPR***

The *NHPR* are divided into 6 sections, each dealing with a different aspect of the regulation of NHPs.

The regulations are fronted by two sections (s.1 & s.2) that provide definitions to key terms in the regulations, including ‘natural health products’, and specify the application of the regulations. The regulations have an additional 2 schedules: Schedule 1 sets out those substances included in the definition of an NHP; Schedule 2 those substances which are excluded from the definition of an NHP.

**Part 1 of the *NHPR*** deals with product licensing (PL). Before any NHP can be sold in Canada, it must be issued a product identification number (NPN, DIN-HM for homeopathics) based on a product monograph or submission of other evidence of safety and health claims. Part 1 covers such topics as what is required in a license application, conditions of issuance of a licence, licence contents and records keeping and other sections required for the effective establishment of a product licence.

**Part 2 of the *NHPR*** deals with Site Licenses (SL). All NHP manufactures, packagers, labelers and importers must demonstrate they meet appropriate standards and practices regarding NHP manufacturing, storage, handling and distribution. Part 2 covers such topics as SL application, SL contents, renewal of SL and suspension and cancellation of SL and other sections required for effective regulation of the sites in which NHPs are handled.

**Part 3 of the *NHPR*** deals with good manufacturing practices (GMP). GMPs are to be employed to assist in providing product safety and quality. Part 3 covers such topics as GMP for premises, GMPs for equipment, GMP for personnel, Quality Assurance, directions for packagers, labelers, importers and distributors and other topics assuring the good manufacture of NHPs.

**Part 4 of the *NHPR*** deals with the requirements for clinical trials (CT) involving human subjects. Scientific trials conducted using NHPs must be conducted in such a way as to assure the safety of participants and adhere to recognized good clinical practices. Part 4 covers such topics as the procedure for applying to conduct a CT, sponsor’s obligations in conducting a CT, good clinical practices, record keeping, adverse reaction reporting and other measures designed to ensure an effective NHP clinical trial.

**Part 5 of the *NHPR*** provides several general provisions related to the regulation of NHPs. Part 5 covers such topics as labeling and packaging, small package labeling, security packaging, imported NHPs, export certificates, and tablet disintegration times and other general sections related to the effective regulation of NHPs.

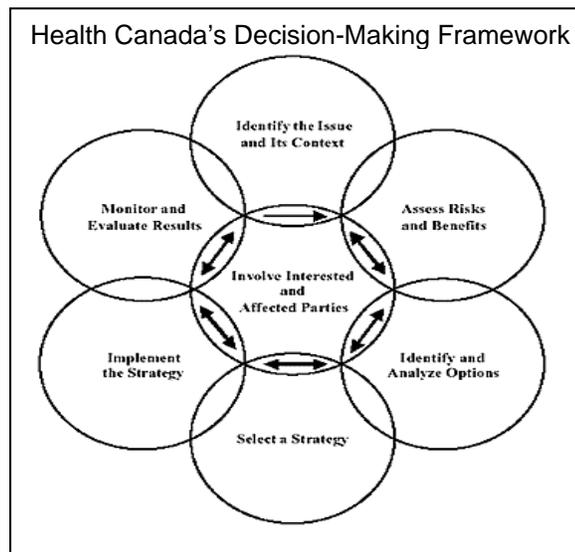
**Part 6 of the *NHPR*** provides amendments, transitional provisions and the coming into force of the regulations.

## **Part 5 – Approach to the Review**

## 5.1 Applying Health Canada's Decision Making Framework for Health Risks

NHPD will be employing the process identified in the *Health Canada Decision-Making Framework (DMF) for Identifying, Assessing and Managing Health Risks* to guide the Review.

The DMF is a quality assurance tool that standardizes decision making with identifiable, traceable steps. It is also meant to standardize the decision making process for health risks throughout Health Canada. It can be considered as occurring in seven overlapping stages: (i) issue identification, (ii) risk/ benefit assessment, (iii) option development (iv) strategy development (v) implementation (vi) monitoring and stakeholder involvement.



The *NHPR* were developed and implemented using the approach outlined in the DMF. With this in mind, the Review is occurring as the next step at the end of a larger DMF process in response to the **monitoring and evaluation** of the results of the implementation of the regulations and regulatory framework. A full copy of the DMF can be viewed at: [http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/risk-risques\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/risk-risques_tc-tm_e.html).

## 5.2 Issues Identified to Date for the Review

As already noted, as part of Health Canada's (HC) ongoing efforts to consult with Canadians on proposed revisions to regulatory frameworks, the Natural Health Products Directorate (NHPD) meets regularly with key stakeholder groups and its advisory committees (Expert Advisory Committee and Management Advisory Committee). During these meetings, the NHPD has gathered input regarding specific regulatory policy issues which have arisen during the initial three years of implementation of the *NHPR*.

In addition, preliminary discussions within the context of the Review took place, via meetings, from July to December 2006, between the NHPD, departmental and federal government stakeholders. These included:

- HC, Health Products and Food Branch Inspectorate, Therapeutics Products Directorate, Food Directorate, Office of Nutrition Policy, Biologics and Genetic Therapies Directorate, Marketed Health Products Directorate and Veterinary Drugs Directorate;
- HC, Healthy Environments and Consumer Safety Branch
- Canadian Food Inspection Agency

The purpose of these discussions was to develop the approach to the Review and formulate the listing of regulatory issues that would be presented to Canadian stakeholders for feedback (see Phase 1 Consultation Section 6.1).

From these discussions NHPD has identified a series of regulatory policy issues needing refinement. Each of these issues is listed below. Those items which Health Canada is moving forward in the short term are identified in Chapter 4. Those issues which are going to require further analysis and will form the topics of the Review can be found, listed by section of the regulations, in Appendices A-D.

### **Part 1 – Product Licences**

1. Compounding of Natural Health Products (NHPs).  
(See Chapter 4 & Appendix A)
2. Definition of Homeopathic Medicines.  
(See Chapter 4 & Appendix A)
3. Food/Natural Health Product (NHP) Interface  
(See Chapter 4)
4. Inadvertent inclusion of biologic products within the scope of the *Natural Health Products Regulations* (NHPR).  
(See Chapter 4 & Appendix A)
5. Regulation of Lowest Risk Products.  
(See Appendix A)
6. Regulatory Framework for Natural Health Products for Use in Animals.  
– Please note: The scope of this issue means that it will likely influence other/all Parts of the regulations  
(See Chapter 4)
7. Regulation of Natural Health Products (NHPs) Derived from Fish.  
(See Appendix A)
8. Regulation of Personal Care Products (PCPs).  
(See Chapter 4 & Appendix A)
9. Use of Human Tissue in NHPs.  
(See Appendix A)

## **Part 2 – Site Licences**

1. Proposed Dual Licensing Regulatory Amendment..  
(See Chapter 4)

## **Part 3 – Good Manufacturing Practices**

1. Inspections for GMPs.  
(See Appendix B)

## **Part 4 – Clinical Trials Involving Human Subjects**

1. Harmonizing NHP Clinical Trial Requirements with the changes to the *Food and Drug Act*.  
(See Appendix C)

## **Part 5 – General**

1. Lack of Advertising Regulatory Provisions in the *Natural Health Products Regulations (NHPR)*.  
(See Appendix D)
2. Clarification of the Extent of the Application of the NHPR for Types of NHPs Intended for ‘Self-Care’ or “Practitioner/Intermediary Intervention”.  
(See Appendix D)
3. Regulation of Personal Care Products (PCPs).  
(See Chapter 4 and Appendix D)
4. Sampling of Natural Health Products (NHPs) to Health  
(See Appendix D)

### ***5.3 Choosing the Best Tool to Produce Effectual Change***

As noted previously in section 4.2 of Chapter 1, to address issues that have arisen in the course of implementing a regulatory framework there are several levels at which refinements can be made: (1) the Act under which the legislation is created can be changed (the *Food and Drug Act*), (2) regulations can be amended, (3) policy and interpretation issues can be modified; or (4) operational practices can be adjusted.

In considering these various options, solutions must be crafted carefully to produce appropriate and real solutions. The tool that is used to refine a framework will depend upon the actual source of difficulties. Changes must be proportional to the challenges faced and targeted in such a way as to not have unintended consequences. Moving too

quickly to make regulatory changes to address issues that may be largely operational may have unforeseen and unwanted long-term consequences.

#### ***5.4 Timelines for Policy and Regulatory Amendments***

There is no uniform timeline which can be applied to addressing all refinements. Health and safety considerations mean that some issues need to be acted on as soon as possible. Other issues will require adequate time and wider input to fully develop the best possible solution.

The identified challenges include policy, operational and regulatory refinements. (See Chapter 2 for continued efforts to improve performance under the Business Improvement Initiative). The regulatory amendments will proceed in no less than three stages:

- (a) In the short term, working from stakeholder input that we have received over the past few years and from internal consultations with other government agencies, a list of issues has been generated.
- (b) Medium Term Actions – Working from those issues which have already been identified and from initial feedback from this consultation NHPD will be proceeding with amendments to the *NHPR*. These amendments would be to address pressing health and safety and regulatory issues that have emerged over the past few years.
- (c) Longer Term Action – A medium and long-term series of actions, including amendments, will be undertaken following the Phase II consultation process outlined in section 6.1. These amendments will seek to develop solutions to many of the more complex issues that face NHP regulation that are fully identified following the consultations. This will be developed through an iterative method of successive regulatory developments. These successive regulatory amendments will be completed in stages, as is practicable, and will be refined with the assistance of the NHPD Management Advisory Committee.

### **Part 6 - What we are Asking from Stakeholders**

#### ***6.1 The Consultation: Phase I (Issue Identification)***

The purpose of the consultation is to obtain broad-based input on the draft Issues List (see **Part 5.2, pages 22-23**) identified to date. The goal is to ensure comprehensiveness and to ascertain stakeholder position respecting priorities and the rationales for these proposed priorities. Developing proposals for issue resolution will rest with the NHPD and be the subject of later stages of consultation. Proposed solutions will be based on identified level of health risk, the need for unified solutions to regulatory issues, and the complexity of the issue(s).

Phase I is designed to provide stakeholders with an opportunity to review and comment on identified issues and priority rank them for issue resolution. To achieve this goal, while ensuring that stakeholders have a clear understanding of the scope of the review,

Health Canada has developed an on-line (web-based) questionnaire through which stakeholders can:

- review a proposed list of issues and provide comment on its comprehensiveness,
- identify top 5 priorities regarding issue resolution along with a rationale for the ranking,
- include comments related to the level of complexity which may influence timelines,
- add issues which are not included in the draft list, and
- link their comments to relevant section(s) of the regulations .

Stakeholder notification of the consultation includes communiqués via the NHPD e-bulletin as well as emailed notification to identified stakeholders. Given the broad scope and cross-sectoral nature of some issues, stakeholders have been identified in cooperation with Branch Directorates to ensure comprehensiveness.

### ***6.2 What are we Doing with Stakeholder Input: Working towards Solutions: Phase II (Options Development)***

Input received during the Phase I of the Consultation will be used to develop preliminary options and a draft medium to long-term action plan for issue resolution. A report on the consultation will be posted on the Health Canada Web site.

HPFB intends to proceed with policy and regulatory amendments through an iterative process. Phase II will seek input from identified targeted stakeholders on an ongoing basis in developing the preliminary options and moving forward the medium to long-term action plan. Phase II of consultation will include the NHPD Expert Advisory Committee, Management Advisory Committee and other stakeholders as appropriate. Specific input will be sought from these stakeholders on options for further action, which can include program/operational, regulatory amendment and policy. Broader consultations on specific issues will occur as required.

## CHAPTER 4 – Short Term Action Plan

As noted earlier, the NHPD has developed an action plan that describes how we are going to deal with policy and regulatory initiatives which HPFB is undertaking in the short term. The list of initiatives is comprised of proposed regulatory and policy solutions to address some of the issues/challenges identified by internal and external stakeholders since the implementation of the *NHPR* as well as items that HC had committed to address prior to undertaking the review of the *NHPR*. Some initiatives are well underway and ready to move forward with the proposed regulatory and policy solutions. As part of the iterative process being used in the Review, HPFB intends to proceed with concurrent policy and regulatory amendment on those items that can be undertaken in the short term as they are identified.

The 6 short term activities identified are:

1. **Compounding of Natural Health Products** - To clarify by policy the intent of the *NHPR* to exclude the practice of compounding.
2. **Definition of Homeopathic Medicine** - To address through guidance documents stakeholder concerns with the currently applied definition of homeopathic medicine by expanding the scope to include products commonly used in Canada that are currently excluded.
3. **Dual Licensing Amendment** - To amend the *NHPR*, the *Food and Drug Regulations (FDR)* and the *Establishment Licensing Fees Regulations* to allow Natural Health Product companies to hold an establishment licence (EL), in addition to the required site licence (SL), to alleviate the impediments to export of NHPs which the *NHPR* inadvertently caused.
4. **NHP/Drug/Cosmetic Interface** - To develop short term solutions for the regulation of Personal Care Products.
5. **NHP/Food Interface** - To develop short term solutions for the regulation of products falling within the *NHP/Food* interface.
6. **Schedule 2 Amendments** - To remove products previously regulated under the *FDR* that have been inadvertently captured under the scope of the *NHPR* by proceeding with appropriate regulatory amendments.
7. **Veterinary Natural Health Products** – To include vNHPs into the *NHPR* with appropriate regulatory amendments.

# Natural Health Product Regulatory Review – Short-Term (0 – 9 months) Key Activities and Timeframes

Regulatory Review Initiatives	Short-Term Regulatory Review Key Activities and Timeframes
<p><b>1) Compounding of Natural Health Products</b></p> <p>The practice of compounding is excluded from the scope of the <i>Natural Health Products Regulations (NHPR)</i> through the manufacturer definition: "Manufacturer means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. It was never the intent of the NHPR to regulate the practice of complementary and alternative or traditional medicine.</p> <p>The NHP Compounding Policy was developed to clarify the distinction between the manufacturing and compounding of NHPs.</p>	<p><b>Winter 2007</b></p> <ul style="list-style-type: none"> <li>• Compounding/raw material internal information session on the Compounding/raw materials policy for other government colleagues.</li> </ul>
<p><b>2) Definition of homeopathic medicine</b></p> <p>Certain stakeholders have expressed concern with the current definition of homeopathic medicines (in our various guidance documents) used by the Natural Health Products Directorate (NHPD). These stakeholders argue that the current definition excludes many products commonly used in Canada. NHPD made a commitment to review the definition as part of the regulatory review.</p>	<p><b>Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Key stakeholder e-consultation on proposed homeopathic definition changes for guidance document.</li> </ul>

Regulatory Review Initiatives	Short-Term Regulatory Review Key Activities and Timeframes
<p><b>3) Dual Licensing Amendment</b></p> <p>The purpose of the proposed dual licensing regulatory amendment is to alleviate the exporting challenges arising from the coming into force of the <i>NHPR</i>. It will allow, on a voluntary basis, natural health product (NHP) companies to hold an establishment licence (EL) pursuant to the <i>Food and Drug Regulations (FDR)</i>, in addition to the required site licence under the <i>NHPR</i>. It is necessary for certain NHP companies to hold an EL, the licence issued for pharmaceutical drugs, and obtain the accompanying export certificates in order to export their NHPs to countries that classify the NHPs in question as drugs.</p> <p>The proposed amendment consists of a two part regulatory package intended to come into force at the same time: 1) amendments to the <i>NHPR/FDR</i>, authorized under section 30 of the <i>Food and Drugs Act</i>; and 2) amendments to the <i>Establishment Licensing Fees Regulations</i> authorized under section 19.1(a) of the <i>Financial Administration Act</i>.</p>	<p><b>Winter/Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Preparation and finalization of documents.</li> <li>• Publication in Canada Gazette I.</li> </ul>
<p><b>4) NHP/Drug/Cosmetic Interface</b></p> <p>Depending on their ingredients, intended purpose, and claims, personal care products may fall under three different regulatory frameworks (<i>Natural Health Products Regulations, Food and Drug Regulations</i> and <i>Cosmetic Regulations</i>).</p> <p>Each regime applies varied level of oversight, especially with respect to: labelling requirements, packaging requirements, and premarket review.</p> <p>There is a need to clarify the regulatory requirements for these products. Health Canada is undertaking a principled assessment of regulatory and policy processes to ensure that products are regulated appropriately while respecting the health protection objectives in the <i>Food and Drugs Act</i> and <i>Regulations</i></p>	<p><b>Winter/Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Developing short-term policy solutions for the regulation of products at the NHP/drug/cosmetic interface.</li> </ul>

Regulatory Review Initiatives	Short-Term Regulatory Review Key Activities and Timeframes
<p><b>5) NHP/Food Interface</b></p> <p>The Health Products and Food Branch (HPFB) has initiated a review of food-like NHPs with a view to determining how best to regulate these particular products in a way that reduces risk and reflects the manner in which they are used. Food-like NHPs could fall under two regulatory frameworks (<i>Natural Health Products Regulations</i> and <i>Food and Drug Regulations</i>). Given that food-like NHPs are presented in a noticeable food format (e.g., drinks, juices, cakes, bars, gums, etc.) Canadians may have a tendency to consume these products freely without taking into consideration the recommended conditions of use and the fact that they contain medicinal ingredients which, if over-consumed, increase the risk of potential adverse effects.</p> <p>NHPD’s proposal is to amend the <i>Natural Health Products Regulations</i> to exclude food-like NHPs from the purview of the NHPR. This regulatory amendment would make it clear that these products are not regulated as NHPs.</p> <hr/> <p>The Food Directorate (FD) is currently developing a framework for managing health claims. It is not anticipated that consultations on this health claim framework will completely resolve the food/NHP interface. It is the intention of the FD &amp; NHPD to hold targeted consultations to resolve any outstanding issues not addressed by their exclusion from the <i>NHPR</i> or their inclusion under the food framework.</p>	<p><b>Winter/Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Discussion with departmental and federal government stakeholder to develop an approach for reviewing this issue.</li> </ul>

Regulatory Review Initiatives	Short-Term Regulatory Review Key Activities and Timeframes
<p><b>6) Schedule 2 Amendments</b></p> <p>To remove products previously regulated under the <i>Food and Drug Regulations</i> (i.e. oral vaccines, insulin, medical gases) that have been inadvertently captured under the scope of the <i>Natural Health Products Regulations</i> by proceeding with appropriate regulatory amendments.</p>	<p><b>Winter/Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Internal discussions and policy work.</li> </ul>
<p><b>7) Veterinary Natural Health Products</b></p> <p>The <i>Natural Health Products Regulations (NHPR)</i>, which came into force on January 1, 2004, exclude natural health products for use in animals (vNHPs) . Most vNHPs are currently regulated as New Drugs under Division 8 of the <i>Food and Drug Regulations (FDR)</i>. As is the case for human NHPs, this regulatory framework is not appropriate for this relatively low risk category of products, as many aspects of the <i>FDR</i> pose challenges for vNHPs.</p> <p>The Veterinary Drugs Directorate (VDD) has determined that the most appropriate regulatory framework for vNHPs would be the NHPR. This is also in line with the Government of Canada’s Smart Regulations initiative. VDD intends to develop these proposed amendments in collaboration with NHPD, since many vNHPs are similar to NHPs used in humans.</p> <p>The <i>Organic Products Regulations (OPR)</i>, published on December 21, 2006, require, in their accompanying Standard, that any therapeutic product used in food-producing animals organic farming be authorized by VDD. These Regulations have a 2-year transition period. Most products used in organic farming are vNHPs.</p>	<p><b>Spring 2007</b></p> <ul style="list-style-type: none"> <li>• Stakeholder consultation on the Issue Identification and vNHP definition</li> <li>• Call for nominations for the vNHP Advisory Committee</li> </ul> <p>For updates on developments in on vNHP Issues, please refer to the Web site: <a href="http://www.hc-sc.gc.ca/dhp-mps/vet/index_e.html">http://www.hc-sc.gc.ca/dhp-mps/vet/index_e.html</a></p>

# Appendix A

## NHPR Part 1 – Definitions and Product Licences

**1.1. SHORT TITLE:** Compounding of Natural Health Products (NHPs)

**1.2. SHORT TITLE:** Definition of Homeopathic Medicines

**1.3. SHORT TITLE:** Inadvertent inclusion of biologic products within the scope of the *Natural Health Products Regulations* (NHPR).

**1.4. SHORT TITLE:** Regulation of Lowest Risk Products

**1.5. SHORT TITLE:** Regulation of Natural Health Products (NHPs) Derived from Fish

**1.6. SHORT TITLE:** Regulation of Personal Care Products (PCPs)

**1.7. SHORT TITLE:** Use of Human Tissue in NHPs

## **1.1. SHORT TITLE:** Compounding of Natural Health Products (NHPs)

**(See Chapter 4 for actions being undertaken in the short term relating to compounding of Natural Health Products (NHPs)).**

### **DESCRIPTION OF ISSUE:**

Compounding is an activity performed by a health care practitioner in the context of a practitioner-patient relationship. Compounding is generally understood as a process whereby a health care practitioner mixes, or prepares health products (natural, medicinal, etc.) to an exact specification tailored to a patient's needs, and in a vehicle desired (cream, lotion, gel, drops, capsules, pellets, etc.). Compounding is generally used to:

1. Provide products unavailable or not readily available in the specifications needed by a practitioner (e.g., strength) to address the specific health concerns, symptoms and needs of a particular patient, and/or to meet the specific requirements of a particular health care practice;
2. Provide products free of preservatives, dyes and chemical allergens; and
3. Prepare palatable flavoured dosage forms.

The practice of compounding is excluded from the scope of the *Natural Health Products Regulations (NHPR)* through the manufacturer definition: "Manufacturer means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient." It was never the intent of the *NHPR* to regulate the practice of complementary and alternative or traditional medicine. The Regulatory Impact Analysis Statement (RIAS) published with the *NHPR* in the *Canada Gazette*, Part II, contains a statement that clarifies this policy intent. It indicates that the NHPD intends to adopt a guidance document regarding the distinction between manufacture and sale of NHPs and compounding and distribution of compounded products by complementary and alternative health care practitioners and Aboriginal healers.

The NHP Compounding Policy was developed to clarify the distinction between the manufacturing and compounding of NHPs, including whether or not a site licence is required for a particular activity. It can be found at [http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/legislation/pol/policy\\_compound-politique\\_compose\\_e.html](http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/legislation/pol/policy_compound-politique_compose_e.html).

Compounding is an activity that generally falls under provincial or territorial jurisdiction. A site licence is therefore not required to compound, and the compounded product does not require a product licence to be sold. Responsibility for the safety, efficacy and quality of the compounded product is assumed by the health care practitioner.

The NHPD has received input from the Aboriginal community that an express exemption in law is required with respect to Traditional Aboriginal Medicines.

## 1.2. SHORT TITLE: Definition of Homeopathic Medicines

(See Chapter 4 for actions being undertaken in the short term relating to the definition of homeopathic medicines).

### DESCRIPTION OF ISSUE:

The definition of Homeopathic Medicine does not appear within the text of the *Natural Health Products Regulations (NHPR)*. NHPD has defined a homeopathic through guidance documents, for more information see the Evidence for Homeopathic Medicines Guidance Document at: [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh\\_e.html#about](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html#about).

Certain stakeholders have expressed concern with the current definition of homeopathic medicines used by the Natural Health Products Directorate (NHPD). To be considered a homeopathic medicine, a product must meet two criteria. It must be:

1. Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:
  - *Homeopathic Pharmacopeia of the United States* (HPUS)
  - *Homöopathisches ArzneiBuch* (HAB) or *German Homeopathic Pharmacopoeia* (GHP)
  - *Pharmacopée française* or *French Pharmacopoeia* (PhF)
  - *European Pharmacopoeia* (Ph.Eur.)
  - *Encyclopedia of Homeopathic Pharmacopoeia* (EHP)
2. Prepared in accordance with the methods outlined in one of the homeopathic pharmacopoeias listed above, as they are amended from time to time.

These stakeholders argue that the current definition excludes many products commonly used in Canada. NHPD made a public commitment in May 2006 to review the definition as part of the regulatory review.

After the NHPR came into force on January 1, 2004, the Health Products and Food Branch Inspectorate began taking enforcement measures against products which did not meet the NHP definition. As a result, many practitioners claimed they found it more difficult to import products. They began a letter-writing campaign to the Minister of Health and NHPD in autumn 2005 to protest the loss of access. In response, NHPD organized two well-attended meetings with practitioner associations, held in April 2006 in Vancouver and Ottawa. One key issue identified at both meetings was the limitations of the existing definition of homeopathic medicines (HM).

Most other jurisdictions do not restrict HM ingredients to those found in a pharmacopoeia, as long as the method of preparation is in accordance with a recognized homeopathic pharmacopoeia. Many commonly used homeopathic ingredients are missing from the pharmacopoeias, as well as less well known and newly proven remedies.

**1.3. SHORT TITLE:** Inadvertent inclusion of biologic products within the scope of the *Natural Health Products Regulations (NHPR)*.

**(See Chapter 4 for actions being undertaken in the short term relating to Schedule 2 amendments).**

**DESCRIPTION OF ISSUE:**

Some health products historically considered, and therefore regulated as biologics, have been inadvertently included in the natural health product (NHP) regulatory framework. The use of the inclusion and/or exclusion criteria as part of the NHP definition and the lack of an updated definition of a biologic in the *Food and Drug Regulations (FDR)* have contributed to this issue. The result is that certain biologic products, considered high risk products, now fall within the definition of an NHP. Given that the NHPR were intended to regulate low risk products suitable for over-the-counter (OTC) use (i.e. products that do not require a prescription), the biologics in question are better regulated under the *FDR*.

Amending the *NHPR* so that existing and/or new biologics and related products that were inadvertently included in the NHPR may be regulated as biologics would ensure that the quality, safety, and efficacy of these health products are subject to the *FDR*. Further, the Biologics and Genetic Therapies Directorate (BGTD), as the regulator of biologics, possesses the infrastructure (e.g., lot release program, laboratories, on-site evaluation process, standard operating procedures for comprehensive safety and quality reviews, extensive scientific capacity, expertise, and experience) necessary to regulate high risk biologics. As such, BGTD is in the best position to manage any existing or emerging risks associated with biologics.

#### **1.4. SHORT TITLE:**Lowest Risk Products

##### **DESCRIPTION OF ISSUE:**

The Natural Health Products (NHPs) definition encompasses a broad spectrum of products such as homeopathics, traditional medicines with varying levels of risk. Some products have a higher risk profile depending on their ingredients and claims, while others could be considered relatively low risk based on a number of factors, including historical use, marketing experience, clinical research, safety and efficacy of the product.

The Natural Health Products Directorate (NHPD) has developed and implemented measures to facilitate the issuance of product licences in recognition of the fact that different levels of evidence are required, depending on the risk profile of the product in question. One such measure is the development of NHPD's Compendium of Monographs which allows NHPD to fast track the review of lowest risk products through the compendial stream. Applicants citing a published monograph are eligible for the 60-day disposition provision as prescribed under section 6 of the *Natural Health Products Regulations*, meaning that their product licence applications will be reviewed within that time frame.

The NHPD recognizes that certain lowest risk products may not need the level of scrutiny that is currently being applied. The NHPD is reviewing other models within the Department for the evaluation of lowest risk products in order to put forward an appropriate model for NHPs. Such a model may entail lowest risk products not requiring pre-market assessment. The NHPD will, however, continue to ensure that the level of scrutiny/oversight of all products is proportional to the risks they pose to the health and safety of Canadians.

## **1.5 SHORT TITLE:** Regulation of Natural Health Products (NHPs) Derived from Fish

### **DESCRIPTION OF ISSUE:**

Health Canada (HC) and the Canadian Food Inspection Agency (CFIA), working together, have identified certain issues relating to the regulatory regimes governing fish and NHPs under the *Fish Inspection Act (FIA) & Regulations (FIR)* and the *Natural Health Products Regulations (NHPR)* respectively. These issues have resulted in licensing and related export certification challenges for stakeholders.

The definition of “fish” in the FIA does not distinguish between food and drugs, and thereby includes NHPs derived from fish by-products. Establishments that process fish by-products for human consumption as food under the authority of the FIR must register with CFIA and operate with a Quality Management Program (QMP) Plan. Establishments licensed by the Natural Health Products Directorate (NHPD) that process fish by-products as NHPs for human consumption are exempt (via policy) from the requirement to be registered with CFIA since they hold a valid site licence from NHPD and operate in accordance with the good manufacturing practices (GMPs) outlined in Part 3 of the *NHPR*. For most stakeholders, this is not a problem: they either register with CFIA if they produce a food product, or obtain a site licence from NHPD if they produce an NHP. However, some stakeholders have a product line for NHPs and another line for fish by-products that would be considered as food, food ingredients or raw materials shipped to other establishments which may or may not use those raw materials to manufacture NHPs. This results in both CFIA and NHPD becoming involved in the regulation of the stakeholder.

Furthermore, there are challenges for some exporters because certain importing countries do not recognize NHPs as a distinct category of product and classify them as food, drugs or even technical products. This means that the export certificates currently issued by NHPD (international trade certificates) are often challenged by importing countries. In contrast, the *FIR* provides CFIA with the authority to certify fish as safe for human consumption. Fish by-product establishments that require access to export certificates pursuant to the *FIR* must be registered with CFIA to obtain such certificates. As a result, companies exporting fish-based NHPs are seeking registration with CFIA to access the necessary export certificates. This results in stakeholders being subject to duplicate, and sometimes, conflicting and different regulatory requirements.

Finally, certain importing countries require animal health attestations to import animal materials. Given the lack of inspection component in the *NHPR*, the NHPD’s export certificates are often not acceptable to these countries (e.g., exporting NHPs containing bovine gelatine either to the US or to the EU would require certification by a CFIA veterinarian).

## **1.6. SHORT TITLE:** Regulation of Personal Care Products (PCPs)

**(See Chapter 4 for actions being undertaken in the short term relating to the Regulation of Personal Care Products).**

### **DESCRIPTION OF ISSUE:**

Personal care products (PCPs) are generally defined by the cosmetic industry as products which are applied to the surface of the body, hair, nails, teeth and muscosa for the purposes of cleansing, moisturizing/lubricating, beautifying and/or perfuming.

Depending on their ingredients, intended purpose, and claims, PCPs can fall under three different regulatory frameworks under the *Food and Drugs Act*: the *Cosmetic Regulations*, the *Food and Drug Regulations*, or the *Natural Health Products Regulations*.

Approximately 85% of PCPs sold in Canada are regulated as cosmetics. The remaining 15% are regulated as drugs, either as nonprescription drugs or as natural health products (NHPs). For example, products containing natural therapeutic ingredients permitted on Schedule 1 of the *Natural Health Products Regulations* (and not excluded by Schedule 2), which make acceptable therapeutic claims, are NHPs, although the product may otherwise resemble a cosmetic.

Industry is requesting that the Department clarify and improve the current legislation affecting these products so that they are regulated in a more timely, less onerous and consistent manner. Health Canada has committed to reviewing the regulation of personal care products.

## **1.7. SHORT TITLE:** Use of Human Tissue in NHPs

### **DESCRIPTION OF ISSUE:**

As written, an NHP that is a homeopathic medicine or a traditional medicine may contain human tissue. All other NHPs may contain “non-human animal material” as specified in item 1 of Schedule 1.

The *Natural Health Products Regulations (NHPR)* includes the following definition of an NHP:

“Natural health product means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

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

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.”

For the purposes of the *NHPR*, a substance or combination of substances or a traditional medicine is not considered to be an NHP if its sale, under the *Food and Drug Regulations*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.

# Appendix B

## Part 3 – Good Manufacturing Practices

### 3.1. SHORT TITLE: Inspections for Good Manufacturing Practices

#### DESCRIPTION OF ISSUE:

GMPs are one of the main prerequisites that must be met before a site licence is issued. When the proposed regulations were published in the *Canada Gazette*, Part I, it was proposed that applicants would be required to submit either a report from a Health Canada inspector or a third party audit report to demonstrate compliance with GMPs. Based on stakeholder concerns regarding costs, and timeframes associated with this process, it was decided that site licence applicants would be required to submit a report by the internal quality assurance (QA) person (as required under the GMP provisions). The report covers all areas of the GMPs and gives sufficient detail for NHPD to assess compliance with the GMPs. This approach allows companies to save time and expense while adjusting to the new requirements of the *Natural Health Products Regulations*, while still ensuring that products are manufactured, packaged and labelled, both domestically and abroad, in accordance with GMPs to ensure safety and quality.

In keeping with the commitment made in the Regulatory Impact Analysis Statement (RIAS) to these regulations, NHPD will re-examine these GMP provisions, with the intent to determine if it is necessary to increase the requirements to the use of third party auditors or Health Canada inspectors.

# Appendix C

## Part 4 – Clinical Trials Involving Human Subjects

**4.1.SHORT TITLE:** Harmonizing NHP Clinical Trial (CT) Requirements with changes to the *Food and Drug Regulations (FDR)*

**DESCRIPTION OF ISSUE:**

There are sections in the *NHP Regulations* that are not consistent with current Division 5 of the *FDR*. This may cause confusion for applicants who are trying to meet standards, through clinical trials, of both regimes.

Division 5 of the *FDR* is currently under regulatory review. Changes to Division 5 of the *FDR* resulting from the regulatory review, once finalized, may need to be applied to Part 4 of the *NHPR*, where appropriate, to ensure consistency is maintained within the Health Products and Food Branch's various regulatory frameworks..

Some of the changes to Division 5 of the *FDR* may be driven by the Progressive Licensing Framework (PLF), (addressing issues related to the clinical testing of products once released to the marketplace). As a result, it may not be appropriate to apply all current Division 5 requirements to Part 4 of the *NHPR* until the two reviews are complete (i.e. the CT and the PLF).

# Appendix D

## Part 5 – General

**5.1. SHORT TITLE:** Lack of Advertising Regulatory Provisions in the *Natural Health Products Regulations* (NHPR)

**5.2. SHORT TITLE:** Natural health products carrying a “for professional use” claim

**5.3. SHORT TITLE:** Clarification of the Extent of the Application of the NHPR for Types of NHPs Intended for “Self-Care”

**5.4. SHORT TITLE:** Sampling of Natural Health Products (NHPs) to Health Professionals

**5.1. SHORT TITLE:** Lack of Advertising Regulatory Provisions in the *Natural Health Products Regulations (NHPR)*

**DESCRIPTION OF ISSUE:**

Advertising of natural health products (NHPs) is subject to the provisions of the *Food and Drugs Act (FDA)*, particularly Section 3(1) and Section 9(1). The *Food and Drug Regulations (FDR)*, contain specific provisions with respect to the advertising of drugs for example, Section C.08.002 of the FDR requires that the terms of market authorization of a drug be established prior to sale or advertising (only products for which the terms of market authorization have been established can be advertised in Canada). Section C.01.044 also contains specific requirements for Schedule F drugs (prescription drugs).

However, the *NHPR* do not include any specific advertising regulatory provisions. *NHPR* address the sale of NHPs. Section 4(1) of the *NHPR* states that sale of NHPs cannot occur until a Product Licence has been issued. This Section does not apply to advertising of NHPs. Note that this could also be applicable to a number of other sections within the *NHPR*. The Health Products Advertising Fact Sheet clarifies that only products authorized for sale by Health Product and Food Branch (HPFB), HC may be advertised (for NHPs a Product Licence is required). However, this is not stated anywhere in the *NHPR*.

## **5.2. SHORT TITLE:** Natural Health Products Carrying a “for Professional use” Claim

### **DESCRIPTION OF ISSUE:**

One of the key principles of the *Natural Health Products Regulations (NHPR)* is to regulate products that are appropriate for self-care when used in accordance with the recommended conditions of use. A related issue that the Natural Health Products Directorate (NHPD) has encountered is the use of “for professional use” claims on NHPs.

The NHPD has adopted, as part of its Compendium of Monographs, all of the Therapeutic Products Directorate (TPD) Labelling Standards and Category IV Monographs for products containing medicinal ingredients that meet the definition of a NHP. This adoption has resulted in the transfer of products which carry a "for professional use" claim from TPD to NHPD. NHPD's product licensing framework allows applicants to reference a NHPD monograph in support of a product's safety and efficacy provided that the product is used under the conditions specified in the monograph.

The majority of products carrying the "for professional use" claim meet the *Labelling Standard: Dental and Oral Care Products for Professional Use*. For example, many are toothpastes with levels of sodium fluoride greater than 0.27 % but less than 2.74 %. The claims made by these products are all acceptable as per the Labelling Standard e.g., "Fluoride gel to aid in the prevention of dental caries." The products also carry the target sub-population for which they are intended and all the risk information required in the Labelling Standard (e.g., "Keep out of reach of children").

NHPD must determine for products carrying the "for professional use" claim what labelling will be required to mitigate the risks associated with these products.

**5.3. SHORT TITLE:** Clarification of the Extent of the Application of the *NHPR* for Types of NHPs Intended for “Self-Care”

**DESCRIPTION OF ISSUE:**

There is a need to clarify of the scope of the regulations for the treatment of NHPs. Potentially there are two types of products which fall under the *NHPR*, (1) those which are completely suitable for self selection and self care, and (2) those which are unsafe for self selection and self care.

A long standing conception of the *NHPR* is that it is primarily to regulate products that are appropriate for “self-care” when used in accordance with the recommended conditions of use. Although this policy intent was captured in the Regulatory Impact Analysis Statement that was published with the *NHPR*, it was not explicitly included in the provisions of the *NHPR*. Therefore, some products that may not be appropriate for "self-care" are being captured by the *NHPR*.

It has been proposed that the *NHPR* be amended to clarify that they only address those NHP products which are suitable for self selection and self-care. This would exclude all NHPs which are unsafe without the interventions of a health care provider or which cannot otherwise be used safely by a consumer.

#### **5.4. SHORT TITLE: Sampling of Natural Health Products (NHPs) to Health Professionals**

##### **DESCRIPTION OF ISSUE:**

Section 14(1) of the *Food and Drugs Act (FDA)* prohibits the distribution of samples. As per Section 14(1) “No person shall distribute or cause to be distributed any drugs as a sample”. However, Section 14(2) of the Act creates an exemption to the prohibition in Section 14(1) which essentially permits sampling to certain health professionals under prescribed conditions. As per Section 14(2) “Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.” These conditions are defined in Section C.01.048 & C.01.049 of the Food and Drug Regulations.

The *NHPR* do not prescribe any conditions for the distribution of NHP samples as permitted under Section 14(2), by way of a specific provision, incorporation by reference of C.01.048 and C.01.049. The current regulatory structure is inconsistent therefore: the Act allows the distribution of samples of prescription drugs and nonprescription drugs to health professionals, but not of samples of NHPs to the same category of people. No similar conditions exist within the *NHPR* and it has been proposed that provisions consistent with the *Food and Drug Regulations* be included in the *NHPR*.