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Phase I Action Plan: Natural Health Products Regulatory Review

Natural Health Products Directorate
Health Products and Food Branch

February 2010



Canada 

“Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our vision is to play a vital role in protecting and promoting the health and safety of all Canadians by excelling as a trusted scientific and regulatory authority for health products and food in Canada and internationally.”

Health Products and Food Branch

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

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This document describes the four themes of the framework and also provides an outline of the first phase (Fall 2009 – Fall 2010) of the Action Plan. The NHPD will report on issues considered under the scope of this Action Plan in multiple phases determined by priority. If not in Phase I, the NHPD hopes to explore each policy issue compiled in later phases of this Action Plan.

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The Framework

In November 2008, the *Final Report on the Regulatory Review Consultation* was posted on the Health Canada Web site at http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/nhpr-rba_erpsn-final-eng.php. The report provided a summary of the results of the Natural Health Product Regulatory Review e-consultation which took place from March 2007 to May 2007. Further to that report, a commitment was made to continue to analyse comments received during the consultation and to consider the input in the development of an action plan for issue resolution.

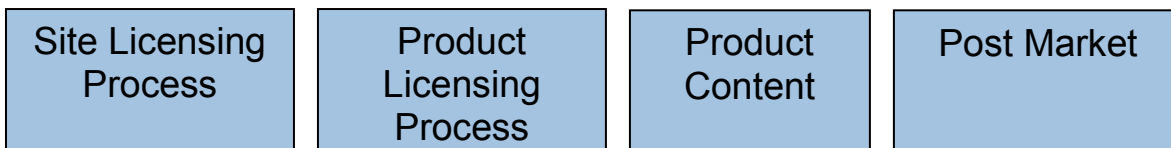
During the consultation, the most prevalent comment raised by all stakeholder groups was the need to regulate natural health products (NHPs) proportional to their level of risk. In response, Health Canada's Natural Health Products Directorate (NHPD) has developed a new Risk-Based Approach to the regulation of NHPs. The Fact Sheet on this approach can be found at http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/nhpr-rba_erpsn-gbr-eng.php.

Also stemming from the Regulatory Review, internal discussions, and other stakeholder comments, the NHPD has compiled a list of roughly 50 policy issues to be addressed or explored. These issues have been organized in a framework of four themes that will help the NHPD systematically explore the issues.

The four themes of the Framework of policy issues are briefly described below.

Under the newly developed Action Plan, the NHPD will continue to address issues in a systematic manner to facilitate consumer access to NHPs that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.

NHPD Regulatory Review Action Plan – The Framework



1. Site Licensing Process

As noted above, the NHPD began developing a new Risk-Based Approach to the regulation of NHPs as a result of the Regulatory Review, and in support of the comments received from stakeholders during the online consultation.

As a part of the development of the new Risk-Based Approach, the NHPD is working on the development of a strengthened site licensing system that would include, but not be limited to, modified GMP requirements for site licensing and renewal purposes, and on-site assessments of GMP compliance. The NHPD will be reporting on these issues under the scope of the new Risk-Based Approach to Site Licensing for NHPs.

2. Product Licensing Process

Recently, the NHPD has made significant strides in improving its product licensing process. Many initiatives, not captured under the scope of this framework, have facilitated a more efficient approach to licensing. Initiatives under the scope of this framework aim to add those process improvements. Among the issues to be explored under this theme of the framework are issues such as product licence amendments and notifications, multi-ingredient product applications, and consideration for market notification prior to sale as a part of the licensing process.

3. Product Content

There are many initiatives currently underway at the NHPD dealing with the question, "What is an NHP?"

Several issues have been grouped under this theme to clarify the scope of the NHP definition under the *Natural Health Products Regulations* (NHPR). For example, the Food/NHP interface, the Cosmetic-Drug interface, and Schedule 2 additions are being considered under this theme.

The Schedule F initiative which is looking at potential modifications to naturally-occurring medicinal ingredients of Schedule F of the *Food and Drug Regulations* (FDR) is also included under the scope of this theme.

4. Post Market

A few issues related to the post-marketing of NHPs are being explored. First and foremost, the NHPD and the Health Products and Food Branch Inspectorate (HPFBI) are exploring options for an updated risk-based approach for compliance and enforcement to be phased in beginning in the winter of 2010 with an initial focus on education and outreach. Workshops with stakeholders were held in November 2009 during the Natural Health Products Program Workshop Series.

Other issues are also being considered under the scope of this theme, including a review of the current practice related to international trade certificates for NHPs.

Also, the NHPD will also be exploring the idea of sampling and advertising of NHPs as was discussed in the Regulatory Review Consultation Report.

Regulatory Review Action Plan – Phase I

As was mentioned above, a commitment was made at the time of the posting of the Regulatory Review Consultation Report to continue to analyse comments received during the consultation and to consider the input in the development of an action plan for issue resolution.

The most prevalent comments raised by stakeholders are being addressed through the new Risk-Based Approach to the regulation of NHPs. However, the NHPD has considered all comments in the development of this action plan for addressing the remaining policy issues.

In addition to organizing issues into a framework, the NHPD is, as was mentioned, adopting a phased approach to implementation of the activities captured in the four themes. Below is an outline of Phase I of the Action Plan. This table consists of the key activities which have already taken place, or will be taking place in Phase I under the scope of the Action Plan.

The NHPD will report on future initiatives under the scope of this plan during the next phases. Also, the NHPD will, as necessary, provide updates to the Phase I action plan as new information becomes available.

Regulatory Review Action Plan – Phase I		
Theme	Initiatives	Short-Term Activities and Timeframes (Phase I: Fall 2009 – Fall 2010)
Product Content	<p>1) Food/NHP Interface</p> <p>Health Canada has received over 1300 Product Licence Applications for products in food format which have characteristics of both NHPs and foods. There have been regulatory challenges in classifying these products since they could fall under the NHPR and/or Parts A, B and D of the <i>Food and Drug Regulations</i>.</p> <p>In March 2009, Health Canada posted the Guidance on the Classification of Products at the</p>	<p>Ongoing:</p> <ul style="list-style-type: none"> - Product licence applications for products at the Food/NHP Interface are being assessed by NHPD. Licences will be issued where requirements of the NHPR are met. <p>Fall/Winter 2009/2010:</p> <ul style="list-style-type: none"> - Communicate the policy direction/intent with regards to the management of products at the Food/NHP Interface.

<p><u>Food-NHP interface: Products in Food-Formats</u> and is currently reviewing the classification of products at the food-NHP interface with the intent of transitioning most of these products to the food regulatory framework over a period of time.</p> <p>2) Cosmetic/Drug (NHP) Interface</p> <p>Depending on their ingredients and claims, personal care products may fall under one of three different regulatory frameworks (NHPR, FDR and <i>Cosmetic Regulations</i>).</p> <p>In fall 2008, Health Canada posted its <u>Guidance on the classification of Products at the Cosmetic-Drug Interface</u> to clarify the manner in which these products are classified. Health Canada is currently implementing the guide.</p> <p>Also, three Product Assessment Against Criteria documents for <u>Antiperspirants</u>, <u>Diaper Rash Products</u>, and <u>Medicated Skin Care Products</u> were posted in the summer of 2009.</p> <p>3) Schedule F Initiative</p> <p>NHPD has completed science assessments on 11 naturally-occurring medicinal ingredients currently listed in Schedule F of the <i>Food and Drug Regulations</i>.</p> <p>The purpose of this initiative is to determine which substances should remain unchanged, be modified, or be removed entirely from the Schedule.</p>	<p>Spring/Summer 2010:</p> <ul style="list-style-type: none"> - Development of a Guidance Document on Labelling of NHPs in Food-Formats. <p>Ongoing:</p> <ul style="list-style-type: none"> - Classification of product categories at the Cosmetic/Drug (NHP) interface using the principles outlined in the <u>Guidance on the Classification of Products at the Cosmetic-Drug Interface</u>. <p>Spring/Summer 2010:</p> <ul style="list-style-type: none"> - Completion of Product Assessments Against Criteria for next group of product categories at the Cosmetic/Drug (NHP) interface: acne therapy, antidandruff products, antiseptic skin cleansers. <p>Fall 2009:</p> <ul style="list-style-type: none"> - Issuance of the second <u>Notice to Stakeholders</u> to provide an update. <p>Winter 2009/2010:</p> <ul style="list-style-type: none"> - Three <u>Notices of Intent</u> regarding the proposed amendments were published in the <i>Canada Gazette</i>, Part I (Notice 1 – pg. 3843; Notice 2 – pg. 3847; Notice 3 – pg. 3851). There is a 75-day consultation period for the Notices of Intent.
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	<p>Health Canada's Drug Status Scheduling Committee subsequently provided recommendations on these 11 naturally-occurring medicinal ingredients.</p> <p>These proposed amendments may result in substances that were previously only available in Canada as prescription drugs being available as over-the-counter NHPs and drugs.</p> <p>Stakeholders had previously been informed of the ongoing assessments through publication of a Notice to Stakeholders on March 2, 2009.</p> <p>4) Security Packaging</p> <p>Since the NHPR came into force on January 1, 2004, concern has been raised by the personal care product industry regarding the application of section 95 (security packaging) of the NHPR. Specifically, it has been suggested that the requirements to place tamper-evident security packaging on all NHPs places unnecessary financial burden on industry for products that are generally low-risk in nature.</p>	<p>Fall 2009:</p> <ul style="list-style-type: none"> - Reviewing the issue of Security Packaging requirements for NHPs. <p>Winter 2009/2010:</p> <ul style="list-style-type: none"> - The NHPD provided a targeted group of stakeholder a 30-day period to comment on an Issue Analysis Summary prepared by the NHPD. - NHPD to present issue to the NHP Program Advisory Committee for feedback. <p>Summer 2010:</p> <ul style="list-style-type: none"> - Communication of approach to stakeholders.
<p>Post-Market</p>	<p>1) Compliance Plan</p> <p>The Compliance Policy for NHPs was developed to provide a reasonable transition period to allow distributors of NHPs to apply for</p>	<p>Fall/Winter 2009/2010:</p> <ul style="list-style-type: none"> - Fact sheet distributed to stakeholders outlining common questions and answers regarding compliance in 2010.

	<p>product licences while bringing their products into compliance with the requirements of the NHPR.</p> <p>Discussions have begun to identify the appropriate approach to compliance and enforcement for 2010 and beyond as the NHP program moves into a sustainable workload environment.</p> <p>The NHPD is working collaboratively with the HPFBI in the development of an updated risk-based approach for compliance and enforcement.</p> <p>2) International Trade Certificates</p> <p>Companies exporting NHPs from Canada are often asked by foreign customers or foreign governments to supply certification relating to products subject to the NHPR. The NHPD issues export certificates for industry (exporters) in order to facilitate export and customs processes for NHPs.</p> <p>The NHPD, in the summer of 2009, reviewed the current approach in order to identify areas that may require update to appropriately reflect the current situation related to the Canadian NHP market.</p>	<ul style="list-style-type: none"> - Cross-country workshop sessions with stakeholders to discuss options regarding the compliance plan going forward. - Establish a NHP Program Advisory Committee Working Group for Compliance and Enforcement to assist in the development of a risk-based compliance and enforcement approach. <p>Spring/Summer 2010:</p> <ul style="list-style-type: none"> - Development of a revised risk-based compliance and enforcement approach. <p>Winter 2010:</p> <ul style="list-style-type: none"> - Commence stakeholder education and outreach. - Commence adoption of revised compliance approach. <p>Winter 2009/2010:</p> <ul style="list-style-type: none"> - Communication of the NHPD's new approach with regards to International Trade Certificates for NHPs. - Revision of the current policy on International Trade Certificates to reflect new approach to issuance of international trade certificates for NHPs. <p>Spring 2010:</p> <ul style="list-style-type: none"> - Implementation of new approach.
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