Natural Health Products Regulation

Natural and Non-prescription Health Products Directorate

Canadian Health Food Association West Conference
May 12-13, 2016
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Consumer Health Products (CHP) Framework

- In November 2014, Health Canada consulted on a Framework for consumer health products, which proposed to modernize the oversight of health products intended for consumer use. Objectives include:
  - continuing to ensure that Canadians have access to safe and effective products
  - providing more clarity to consumers about the products they use, so that they can make informed choices
  - providing flexible and proportional oversight of these products, based on their risk profiles

- Results of the consultation were posted on Health Canada’s website on April 1, 2016. Generally, results indicate:
  - strong support to establish appropriate regulatory oversight
  - protecting the health and safety of Canadians should be the primary focus
  - the CHP Framework should provide flexibility to address the range of risk profiles of health products
CHP Framework – Consultation

- What we heard about natural health products (NHPs):
  - Concern about NHPs being regulated under the same framework as non-prescription drugs
  - Desire for NHP oversight to continue to reflect lower-risk nature of products
  - Request that any changes to allow sampling of non-prescription drugs be extended to NHPs
  - Appeal to address loopholes (via the CHP Framework) created by the personal importation policy
  - Seeking the creation of a category for professional-use NHPs
  - Desire for more details on whether Health Canada plans to pursue cost recovery for NHPs
CHP Framework – Next Steps

• Of all comments received, only three were from consumers

• CHP Framework is about products for consumers
  – We need to know more about how they perceive and use products

• Public opinion research was conducted in April 2016
  – Additional consumer engagement opportunities to follow

• Briefing the Minister on proposed next steps on the CHP Framework
NNHPD 2015 Statistics

Natural Health Products

Total Applications
Received (13,364)

- Class I: 2,596
- Class II: 3,304
- Class III: 2,450
- Notifications: 5,014

Total Applications
Completed (13,984)

- Class I: 2,775
- Class II: 3,535
- Class III: 2,582
- Notifications: 5,092

Service Standard

<table>
<thead>
<tr>
<th>Class</th>
<th>Service Standard</th>
<th>% Decisions Issued Within the Service Standard</th>
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<tbody>
<tr>
<td>Class I</td>
<td>10 business days</td>
<td>93%</td>
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<tr>
<td>Class II</td>
<td>30 calendar days</td>
<td>85%</td>
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<tr>
<td>Class III</td>
<td>180 calendar days</td>
<td>97% (1) After Screening Completed</td>
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Product Completed

<table>
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<tr>
<th>Product</th>
<th>Completed Total</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>5,092</td>
</tr>
<tr>
<td>Class II</td>
<td>2,582</td>
</tr>
<tr>
<td>Class III</td>
<td>3,535</td>
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<tr>
<td>Total (New)</td>
<td>11,209</td>
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<tr>
<td>Notifications</td>
<td>2,775</td>
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Monographs

<table>
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<tr>
<th>Monograph Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Ingredient Monographs</td>
<td>247</td>
</tr>
<tr>
<td>Product Monographs</td>
<td>38</td>
</tr>
<tr>
<td>Abbreviated Labelling Standards</td>
<td>13</td>
</tr>
</tbody>
</table>

Source: Natural Health Products Ingredients Database
As of: February 22, 2016
Attestations and Audit Results

• As outlined in the Application Management Policy, “NNHPD will conduct random and risk-based post-licensing audits of monograph-based applications, focusing on errors, inconsistencies, and deviations from the monograph(s).”

• A submission fails the audit if any one or more items are not in line with the monograph to which the applicant has attested. This can include:
  – Missing: Risk statements, Directions for Use, Duration of Use, etc.
  – Not Supported by the Monograph: Source; Claim; Dose; Method of Preparation; Sub-population, etc.

• Audits can occur at any time after licensing; however, the NNHPD strives to randomly audit licences typically within a few weeks of licensing

• Applicants are notified of failures identified during the post-licensing audit
Attestations and Audit Results

• As of March 17, 2016, the NNHPD has audited over 5,700 submissions

• The audit failure rate in the random stream has been between 30-40% each quarter since the inception, with the last quarter having shown a further upward trend in errors

• The NNHPD has raised concerns about this failure rate with associations at the last few rounds of bilateral meetings

• The NNHPD continues to analyze the results and is exploring options to address the failure rate
Class II Expansion Pilot - Update

- In 2014, a pilot aimed at expanding the Class II definition was launched
- Approximately 1,000 Class III applications were considered and reviewed during the pilot
- The pilot provided some benefits, including additional monograph developments

However:
- Some significant challenges were identified, such as:
  - volume of applications to be completed within the shorter review timelines
  - limited time available for applicants to provide adequate responses to Information Request Notices

- As a result, the NNHPD is not proceeding with any changes to the current class definitions
Site Licensing Guidance Documents

• The NNHPD consulted on proposed revisions to NHP Site Licensing (SL) guidance in June 2014. This included revisions to:
  – Site Licensing Guidance Document
  – Good Manufacturing Practices (GMP) guidance documents
  – Quality Assurance Report form

• Final documents were posted online on December 1, 2015. Some key revisions included:
  – Introduction of a three-stream process for site licence application review and associated 35, 65, and 95 *business day* service standards for SL application review
  – Introduction of Pre-Cleared GMP evidence types and clarification with respect to use of alternative standards and/or accreditations
  – New instructions on filing a Foreign Site Reference Number application
  – Inclusion of Risk Classification of Natural Health Products GMP Observations guide

• The NNHPD held a Webinar series between January 26 and February 9, 2016 (3 English and 1 French session), to present the changes
Site Licence Application Review Timelines – Summary

Stream 1: All sites must be based on Pre-Cleared GMP evidence

Stream 2: 1 or more sites based on Non Pre-Cleared GMP evidence
(To a maximum of 9 sites/SL submission)

Stream 3: 1 or more sites based on Non-Pre-Cleared GMP evidence
(10 or more sites/SL submission)
Multi Vitamin Monograph – Highlights

• Addition/Revisions to claims, source ingredients, risk information, etc.
  – Maximum dose of selenium (from 400 to 200 mcg)
  – Risk statements for iron and high dose calcium
  – Change to when Folate-containing products must include Vitamin B12

• Comments were received from several stakeholders including the CHFA and member companies. Key points raised included:
  – Flexibility in transition to new monograph
  – Availability of annotated monograph versions
  – Opportunity to comment prior to finalization

• Comments to be addressed/incorporated prior to finalization
NHP Submissions – Tools

epost Connect

• **epost** to become the primary method of electronic communication for all applicants for submission-related correspondence

• Benefits include:
  – Easy to use, **NO FEE** system
  – No paper involved, all documents transmitted are electronic **COLOUR** copies (including the Product Licence)
  – History of application review correspondence is in one location and readily viewed
  – Real time tracking
  – Secure and confidential

eSB

• Use of the **eSubmission Builder (eSB)** to submit new NHP applications = **less manual inputting** = fast and consistent processing by the NNHPD to ensure adherence to performance targets
NNHPD Relocation Information

May 6 - 13, 2016: NNHPD move

- In its efforts to respect service standards during the move, the NNHPD encourages applicants to submit applications via epost Connect.

April 2016: Stakeholders were notified via:

- A notice posted online with the updated addresses, at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/index-eng.php#mov
- An RSS feed on the topic

Note: Please ensure that all submissions and/or enquiries are directed to the appropriate NEW mailing and/or email addresses. (The NNHPD is not responsible for packages sent to its former address.)