Natural Health Products Regulation

Natural and Non-prescription Health Products Directorate

Canadian Health Food Association East Regulatory Forum
September 15, 2016
Today’s Presentation

• Attestation and Audit Results

• Site Licensing Guidance Documents

• Natural and Non-prescription Health Products Directorate (NNHPD) 2015-2016 Statistics

• NHP Submission – Things to Note

• Consultation on the Regulation of Self-Care Products
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 August 25, 2016, the NNHPD has audited over 6,500 submissions.

• The audit failure rate in the random stream was between 30-40% each quarter from the inception to September 2015, with the last three quarters having shown a further upward trend in errors (50-60%).

• 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 which could include changes to the attestational/class approach and/or steps taken when a product fails an audit.
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 SL 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)
NNHPD 2015 Product Statistics

Natural Health Products – Product Licence Applications

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
% Decisions Issued Within the Service Standard

Class I 10 business days 93%
Class II 30 calendar days 85%
Class III 180 calendar days 1 97%

1 After Screening Completed

<table>
<thead>
<tr>
<th>Product</th>
<th>Completed</th>
<th>Completed Total</th>
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<tr>
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<td>Licensed</td>
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<td>Class I</td>
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<tr>
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Monographs

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

Source: Natural Health Products Ingredients Database
As of: February 22, 2016
NNHPD 2016 Product Statistics

Natural Health Products – Product Licence Applications

Total Applications Received (8,613)

- Class I: 3,097
- Class II: 2,013
- Class III: 1,861
- Notifications: 1,642

Total Applications Completed (9,663)

- Class I: 3,218
- Class II: 1,849
- Class III: 2,362

Service Standard

<table>
<thead>
<tr>
<th>Class</th>
<th>Service Standard</th>
<th>% Decisions Issued Within the Service Standard</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>10 business days</td>
<td>99%</td>
</tr>
<tr>
<td>Class II</td>
<td>30 calendar days</td>
<td>93%</td>
</tr>
<tr>
<td>Class III</td>
<td>180 calendar days ¹</td>
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¹ After Screening Completed

Completed

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<tr>
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<tr>
<td>Notifications</td>
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Notifications 2,234

Monographs

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<tr>
<th>Product</th>
<th>Single Ingredient Monographs</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>247</td>
<td>38</td>
<td>13</td>
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Source: Natural Health Products Ingredients Database

As of: August 31, 2016
NNHPD – 2015 and 2016 Site Licensing Statistics

Site Licence Applications 2015 & 2016

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<tr>
<th>Submissions Received</th>
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<td>Notifications</td>
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<td>20</td>
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<table>
<thead>
<tr>
<th>Submissions Completed</th>
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<th>2016¹</th>
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<tr>
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<td></td>
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<tr>
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<td>Withdrawn</td>
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<td>50</td>
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¹ January, 2016 to August 31, 2016

Site Licence Applications since Service Standard implemented in April 2016

Applications received since Service Standard in April 1, 2016 to August 31, 2016

<table>
<thead>
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<tbody>
<tr>
<td>% Decisions Issued Within the Service Standard</td>
</tr>
<tr>
<td>Stream 1</td>
</tr>
<tr>
<td>Stream 2</td>
</tr>
<tr>
<td>Stream 3</td>
</tr>
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</table>
NHP Submissions – Things to Note

epost Connect
• epost is now the primary method of electronic communication for all applicants for submission-related correspondence.

eSubmission Builder (eSB)
• The use of the eSB to submit new NHP applications is encouraged, supporting less manual inputting and fast and consistent processing by the NNHPD to ensure adherence to performance targets.

USB Keys
• As per new Government of Canada IT Security Measures, the NNHPD will no longer be accepting submission packages in USB memory stick format.

New NNHPD Office Location
• A reminder that the NNHPD moved office locations in May 2016. 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.
Consumer Health Products Framework

• In November 2014, Health Canada consulted on a Framework for consumer health products, which set out proposals to modernize the oversight of health products intended for consumer use while continuing to ensure Canadians have access to safe and effective products.
  – To provide Canadians with information that will help them to identify what products are regulated by Health Canada and enable them to make informed choices about products and their use

• Consultation results posted on Health Canada’s website on April 1, 2016. Generally, results indicated:
  – strong support to establish appropriate regulatory oversight, while maintaining primary focus on protection of health and safety
  – the need for flexibility to address the range of risk profiles of health products

• Of the 31 respondents to the consultation, most were from industry; very little feedback from consumers (only 3 self-identified respondents)
What We Heard from Public Opinion Research

• In April 2016, Health Canada conducted public opinion research to learn more about how consumers perceive and use self-care products, via an online survey involving 2,502 Canadians. Key findings included:

  – Canadians have low perceived knowledge of the safety and effectiveness of these products and they generally feel uninformed about them when making a purchase
  – Canadians believe non-prescription drugs are safe, but are less confident in the safety of cosmetics and NHPs
  – Canadians do not categorize self-care products in the same way as Health Canada, tending to categorize products based on use rather than ingredients
  – Canadians have a general understanding of Health Canada’s responsibilities related to product safety, but believe incorrectly that the Department is responsible for specific tasks such as reviewing and approving all labels, and/or testing all self-care products in laboratories
  – Canadians are generally skeptical of claims made on labels, yet also believe these claims have scientific support and are based on proof from manufacturers
What are we proposing?

• Health Canada is examining potential new approaches to the regulation of self-care products. The purpose of the current consultation is to gather feedback on three main proposals:

  1) **Risk-based approach to self-care products**
     • Products of similar risk profiles would be treated in a similar manner

  2) **Health Canada approval of health claims only**
     • The Department would review health claims based on a new definition
     • Companies would require scientific proof to support these health claims

  3) **Compliance monitoring and addressing inconsistencies in post-market powers**
     • A risk-based approach to compliance and safety monitoring would continue

Health Canada's goal is a consistent approach to self-care products, to ensure consumers are protected while still providing access to a wide range of products, and to provide consumers with adequate information so that they can make informed choices about self-care products.
We want to hear from you. Share your views!

- A consultation on the regulation of self-care products was launched on September 7, 2016.

- The consultation will remain open until **October 24, 2016**.

- A report on what we heard will be published online following the consultation.