Natural and Non-Prescription Health Products Directorate (NNHPD)
Update: Performance standards for NHP applications
Stakeholder Meeting Summary
September 23rd, 2020

Purpose and Agenda:

- Purpose:
  - To provide an update on NHP performance standards, including site licences, product licenses and client services, as well as on application forms.

- Agenda:
  - Site Licences
  - Product Licences (Class I & II)
  - Product Licences (Class III)
  - Client Services
  - Application Forms

Documents shared by Health Canada:

- Agenda

Summary:

Status update on performance standards for NHP applications:

- NNHPD's top priority is to protect the health and safety of Canadians by continuing to contribute to the Government of Canada's coordinated response to the COVID-19 pandemic.
- As of September 18th, **4,033** new alcohol-based hand sanitizers have been licensed and **2,045** interim COVID site licences have been issued by NNHPD. Though the volume of COVID-19 related applications has declined, NNHPD still needs to maintain dedicated resources to review covid related applications (for both product and site).
- NNHPD acknowledges the delays in issuing regulatory decisions and is making progress to regain its performance standards.
- Recap of the June plan for regaining 90% performance against service standards:
  - Class I: eliminate the backlog by the end of September 2020;
  - Class II: eliminate the backlog by the end of December 2020;
  - Class III: eliminate the backlog by the end of March 2021;
  - New and amendments: eliminate the backlog by the end of July 2020;
  - Renewals: the period of validity for site licences set to expire between March 10 and November 30, 2020 was extended until December 1, 2020

- NNHPD does not anticipate that a second wave of the Covid-19 pandemic would impact its business; NNHPD is prepared to continue operating in a remote setting for the foreseeable future.

Site Licence applications:

- New and Amendments: progress has been delayed based on original target; 80% completed to date; approx. 5% refusal rate (excludes Covid related applications received post July 13, which have a 68% refusal rate to date)
    - **Post meeting note**: Top deficiencies relate to having no GMP evidence and incomplete IRN response. Top IRN reasons include: GMP evidence not acceptable, finished product testing or stability testing not provided, observations found in the records provided (such as missing testing, methods, specifications, or out of specifications tests results)
- Since July, the incoming volume of new site licence applications has been significantly higher than usual. In addition, more than 60% of applications require at least one IRN and a significant number have not been able to respond to the IRN on time. We are exploring options regarding IRN extensions going forward.
    - **Post meeting note:** If applicants are not able to respond to the IRN in a timely manner, they will be encouraged to withdraw their application.
- As a reminder, if the information requested in the IRN is not provided – and no rationale provided, the application will be refused. Furthermore, if an application is received without any GMP evidence at all, it will be refused.
- Renewals**:** A total of 339 domestic site licences are set to expire December 1, 2020, with 64% of expected renewals having been received to date. As the focus to date has been on new and amendment site applications, 10% of the renewals have been completed to date; these renewals were prioritized based on risk.
- As a reminder, an application to renew a site licence should only contain active sites, as this will help focus the review. In addition, an application to renew cannot contain new sites, as those must be filed as an amendment. Any new sites will not be considered as part of the renewal. If an application to renew a site licence (for licences expiring December 1st) is not received before December 1st, the site licence will not be renewed.
    - **Post meeting note**: Site licences that are set to expire post December 1st should continue to renew as usual, meaning that an application to renew must be received no later than 30 days before the licence expires.

- NNHPD is considering options to manage the remaining site licence renewals, including foreign sites. Though NNHPD extended the period of validity for domestic sites, a similar measure was not taken for foreign sites. NNHPD is considering whether such a measure would be supported based on risk considerations.

Product licence applications:

Class I: On track to meet, 98% completed; 21% refusal rate (excluding hand sanitizers)

- NNHPD will meet the target of eliminating the backlog by the end of September, with some exceptions; meaning some Class I applications may remain in backlog for reasons such as they are linked to a risk issue.
- The 21% refusal rate represents a 7% increase in the refusal rate compared to last year. The top deficiencies relate to risk information, errors with medicinal ingredients, dosing information, claims and brand names.
- The target was met, in part, because the incoming volume did not exceed the forecast. Receiving a higher volume of Class I, submissions will impact our ability to both maintain our performance for Class I submissions and our ability to eliminate the backlog for Class II and III submissions.
- As such, applicants are asked to limit the volume of Class I submissions to critical submissions at this time and withdraw those that are hypothetical.

Class II: still working towards the end of December; 30% completed to date (**Post-meeting note**: now 43%, with 50% of the remaining backlog almost complete); 42% refusal rate

- The top refusal reasons relate to claims, dosing information (quantity), and risk statements not consisted with or supported by a monograph.
- Applicants are asked to limit the filing of Class II submissions to critical submissions.
- The vast majority of review time is dedicated to incomplete or non-compliant applications. NNHPD is considering stopping the review when a significant deficiency is identified and issuing a refusal notice. This would significantly cut down on the review time. The applicant would be responsible for ensuring a fully compliant application should they decide to resubmit. Almost half the resubmissions received to date are from only three companies.
    - **Post meeting note**: As of October 1st, NNHPD will stop its review when a significant deficiency is identified.

Class III: still working towards the end of March 2021; 20% completed to date; 8% refusal rate

- Though the refusal rate is low, NNHPD has provided much flexibility in responding to IRNs. As such, the top refusal reasons to date are related to a failure to respond to an

IRN (and request an extension) and insufficient evidence. NNHPD is considering options regarding IRN extensions going forward.
    - **Post meeting note**: If applicants are not able to respond to the IRN in a timely manner, they will be encouraged to withdraw their application.
- To support progress in achieving the target, NNHPD will be batching submissions for review that have sufficient similarities to garner some economies of scale. This could mean that submissions are pulled for review out of order, but the final regulatory decision will continue to be issued based on the date of receipt.
- Going forward, NNHPD will no longer ask for additional evidence as part of the IRN to address deficiencies with the application as submitted. As a reminder, it is the applicant's responsibility to submit evidence to support the application as presented.
- Applicants are asked to limit the filing of Class III submissions to critical submissions and withdraw submissions that hypothetical or known to be deficient

Client Services:

- NNHPD has received over **25K** inquiries since March and **92%** of them have received a response.
- As previously advised, NNHPD is not responding to requests for a status update unless it is determined that the application was not received or was missed. The Client Services generic account issues an automated response to indicate this fact and it is being updated with the latest performance information.
- During this time, pre-submission meetings are being limited to information that cannot be readily found in public guidance or policy.
- Any company thinking about submitting a larger volume of submissions should contact NNHPD directly to work out a filing plan.

Application Forms:

- This June marked a milestone for the NNHPD with the release of the validated web product license application form. This form enables the validation of class I submissions directly through the web form.
- The majority of submissions (75%) submitted using the new web form are for hand sanitizers. Excluding the hand sanitizer applications, 18% of submissions received since June made use of the web new form.
    - **Post meeting note**: For Class I submissions using the new web form, only 2% resulted in a refusal (compared to the overall 21% refusal rate for all Class Is).
    - If you can use the new web form, do so as it is to everyone's advantage.
- There are currently 162 monographs supported by the form. Additional development is ongoing to support the validation of some larger monographs, including the multivitamin and minerals monograph.
- The next web form release is planned for this fall.

- NNHPD is also working to replace the site licence application forms this fall. The new site form will build on the infrastructure developed for the product web form and allow NNHPD to move away from paper applications.

Next steps:

- The next stakeholder call will be held in December.
- As was done in June, NNHPD will send an update to all current applicants and include the written summary from this call.
- NNHPD will consider the feedback received on the proposed changes to the application review and will communicate any adjustments to its review.
    - **Post meeting note**: Some decisions have been communicated within this summary as via post-meetings notes, while others are still under consideration.
- NNHPD will provide an update specific to amendments.
    - **Post meeting note**: The progress report provided does not account for all amendments. The NNHPD has over 2,000 post-licence changes (majority being notifications) that need to be processed, but has dedicated resources to do so. The NNHPD offers the following tips regarding post-licence changes:
        - The best way to speed along the process is to ensure applicants are submitting complete and valid submission packages, which includes clearly identifying the change. If the change is not identified either by the use of the ANF or a cover letter, it will not be processed.
        - Notifications and amendments should be submitted using the ANF. If submitting the ANF, do not also submit the ePLA form, even though the ANF currently indicates that the ePLA should be submitted in certain instances.
        - Ensure the ANF is finalized and submitted in both xml and pdf versions.
        - Though the ANF permits the submission of both notifications and amendments, only **one** of the two should be submitted at a time, to enable a more efficient process.
        - Ensure a designated party authorization form (or DPA) is provided if the package is submitted by a consultant company or a delegated user.
        - If there is a technical issue with the ANF that does not allow its use, applicants can use the pdf version of the PLA form. NNHPD is actively working on a fix to this issue and expects the fix to be implemented in the coming weeks. Once implemented, NNHPD will expect the ANF to be used for all changes.

Annex 1- Attendees:

Industry Association Participants

- Caroline Piché, Directrice générale, Association pour le Développement et l'Innovation en Chimie au Québec
- Richard Parcels, Assistant Director, Cosmetics Alliance of Canada
- Dan Demers, A/President, Canadian Health Food Association
- Krista Jajko, Director, Regulatory Affairs, Canadian Health Food Association
- Kristin Willemsen, Director, Scientific and Regulatory Affairs, Food, Health and Consumer Products of Canada
- David Pelletier, President, Canadian Natural Products Association
- Peter Maddox, President, Direct Sellers Association
- Connie Kehler, Herb Spice and Speciality Agriculture

Health Canada – Health Products and Food Branch Participants

- Robin Churchill, A/Director General, Natural and Non-Prescription Health Products Directorate (NNHPD)
- Stephanie Reid, Director – NNHPD-Bureau of Licencing Services and Systems (BLSS)
- Natacha Cardinal, Director – NNHPD-Bureau of Strategic Planning and Business Services
- Kevin Bernardo, Director – NNHPD-Bureau of Policy, Risk Management and Stakeholder Engagement (BPRMSE)
- Lisa Lange, Director – NNHPD-Bureau Of Product Review And Assessment (BPRA)
- Alysyn Smith, Director – NNHPD-Bureau of Business Systems Modernization (BBSM), NNHPD
- John Field, Manager – NNHPD-BLSS
- Heather Gilmer, Manager – NNHPD-BLSS
- Nana Bafi-Yeboa, gestionnaire – Manager – NNHPD - BPRA
- Virginie Treyvaud Amiguet, Manager – NNHPD - BPRA
- Parminder Dhami, A/Manager – NNHPD-BPRMSE