

## Natural and Non-Prescription Health Products Directorate (NNHPD)

### Update: Performance standards for NHP applications

### Stakeholder Meeting Summary

October 28, 2021

#### **Purpose and Agenda:**

- Purpose:
  - To provide an update on the NHP application workload, including an update on COVID-19 site licence transition and to provide a systems update, including an update on trends in product licence applications.
- Agenda:
  - NHP workload update: Product and Site licence applications
  - COVID Site Licence transition update
  - Systems update
  - Informatics, analytics and product trends

#### **Documents shared by Health Canada or stakeholders:**

- Agenda
- Presentation

#### **Summary**

See attached presentation for the update provided by the Natural and Non-prescription Health Products Directorate (NNHPD) on the NHP application workload and systems.

See Annex 2 for tips / reminders for both product and site licence applications.

#### **Action items from the meeting**

1. NNHPD was asked to provide the number of overdue Class III submissions that have not received an information request notice (IRN). **Response:** There are less than 200 overdue Class III submissions that have yet to be picked up by an assessment officer for review. The aim is to have them done in the next few months. As a reminder, not all submissions will necessitate an IRN.

2. NNHPD was asked to provide the current focus of review for site licence renewals.

**Response:** NNHPD is focusing review efforts on renewals received up until March 31, 2021. The aim is to complete them by the end of December 2021.

3. NNHPD was asked about providing overlap between the product licence application (PLA) web form 3.0 and the upcoming 4.0 release. **Response:** NNHPD intends to provide a short transition period between the launch of the updated PLA web form (4.0) and decommissioning version 3.0 of the form. Applicants are encouraged to use web form 4.0 now, as it provides benefits to both the applicant and NNHPD. The use of version 4.0 results in fewer information request notices (IRNs) and an overall reduced refusal rate.

## **Annex 1- Attendees:**

### **Industry Association Participants**

- **Cosmetics Alliance of Canada (CAC):** Richard Parcels
- **Canadian Health Food Association (CHFA):** Krista Jajko, Jasmine Lee, Kira Tryon
- **Canadian Homeopathic Pharmaceutical Association (CHPA):** David Skinner, Joanne DuPuis Ebadi
- **Canadian Herb Specialty Agriculture and Natural Health Products Coalition (CHSNC):** Connie Kehler
- **Canadian Natural Products Association (CNPA):** David Pelletier, Danielle Morissette, Serge Brunet, Isabelle Boucher, Monika Haefele
- **Direct Sellers Association (DSA):** Peter Maddox
- **Food, Health, and Consumer Products Canada:** Teresa Mastrodicasa
- **Groupe provincial de l'industrie du médicament (GPIM) :** Stéphane Lévesque
- **Bath & Body Works, Inc.:** Megan Harriman

### **Health Canada – Natural and Non-Prescription Health Products Directorate Participants**

- Stephanie Reid, Director, NNHPD-BLSS
- Alysyn Smith, Director, NNHPD-BBM
- Lisa Lange, Director, NNHPD-BPRA
- Karen French, Advisor, NNHPD-BLSS
- Heather Gilmer, Manager, NNHPD-BLSS
- Beatrice Lee, Manager, NNHPD-BLSS
- Shawn Lawless, Manager, NNHPD-BLSS
- San Nguyen, Manager, NNHPD-BLSS
- Christine Monteiro, Subject Matter Expert, NNHPD-BLSS
- Dinah Bowden, Regulatory Affairs Manager, NNHPD-BLSS
- Duarte Rodrigues, Regulatory Affairs Manager, NNHPD-BLSS
- Nana Bafi-Yebo, Manager, NNHPD-BPRA
- Virginie Treyvaud-Amiguet, Manager, NNHPD-BPRA
- Anne Deslauriers, Manager, NNHPD-BPRMSE
- Claire DePaul, Policy Analyst, NNHPD-BPRMSE

## Annex 2 – Application Tips and Reminders

To further support our objective of receiving higher quality submissions, the following **NEW** tips and reminders have been developed for NHP product and site licence applications.

### Product licence applications:

1. For Class III applications, the cover letter needs to include the reason why you have deemed the submission to be a Class III (e.g., the element(s) not covered by one or more monographs). As a reminder, evidence must be provided to support the non-monographed element(s) (e.g., ingredient, claim).

### Site licence applications:

1. As a reminder, per section 4.1 of the Guidance Document on How to Interact with the NNHPD Electronically, the designated party authorization (DPA) form is needed in order to process new applications.
  - If a new application is submitted by epost Connect™ from a Delegated User, the Delegated User must have a [Designated Party Authorization \(DPA\) form](#) from the product licence holder and site licence holder. This is because Canada Post's epost Connect™ account acts as the electronic signature for the ePLA and site licence application form (WebSLA), as verified through the Trading Partner enrolment.
2. Complete applications must be submitted using the most recent web-based [Harmonized Site Licence and Foreign Site Reference Number application](#) form (webSLA). As a reminder, PDF versions of the form are no longer accepted and will be subject to refusal.
3. All aspects of the Information Request Notification (IRN) must be addressed to avoid delays in reviewing your application and / or your application's refusal. When responding to an IRN, it is recommended that you reference the relevant IRN question number and letter (e.g., 1a – Response Text), as this will facilitate the review of the IRN response.
4. When non-critical GMP observations (e.g., risk 2 or 3 observations) remain outstanding as part of a site licence application, these may be identified within the site licence issuance letter. For all GMP observations, site licence holders are expected to take corrective and preventative actions (CAPAs) to address them within a reasonable amount of time. At a minimum, the implementation of CAPAs will be monitored at the next site licence renewal. As such, site licence holders should proactively provide an

update on the CAPAs and their implementation as part of their application to renew their site licence, in order to facilitate the review.

5. As a reminder, the following guidance documents are in place to assist you in putting together your site licence application: [Site Licensing Guidance Document](#); [Guidance Document on How to Interact with the Natural and Non-Prescription Health Products Directorate Electronically](#); [Good Manufacturing Practices Guidance Document](#); [Quality of Natural Health Products Guide](#).
  - Other relevant guidance documents can be found in the following link, [Guidance Documents – Legislation and guidelines – Natural health products - Canada.ca](#)
6. Appropriate submission document identification and structure can help avoid delays in processing an application. For example:
  - All electronic documents should be provided as separate files (i.e., not all included as a single large pdf document).
  - The document file name should be limited to 15 characters and abbreviated to relate to the site and record in question. It is suggested to use the following naming convention: Domestic or Foreign site, site number, document type and record number (as applicable) (e.g., DS1\_SNC; DS2\_DEL; FS1\_CoC; FS2\_SOP recall; FS3\_CoA1)
  - Site licence applications are first screened for completeness to ensure that the application is meeting administrative requirements. Those that meet the administrative requirements will receive an Application Acknowledgement Letter confirming receipt of the application. The NNHPD targets to issue acknowledgment letters within 10 days of receiving the site licence application. If an initial acknowledgement letter has not been received within 30 days of submitting the application, you may contact us at [hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca).