

Natural and Non-prescription Health Products Directorate (NNHPD) Updates

Performance Standards for NHP Applications
October 28, 2021



Outline:

- NHP workload update: Product and Site licence applications
- COVID Site Licence transition update
- Systems update
- Informatics, analytics and product trends

Workload update: Product and Site licence applications

Non-COVID Submissions Summary (April 2021 to September 2021)

Product Licence Submissions:

- Licensed **5,045** NHPs
52% Class I; 15% Class II; 33% Class III
- Refused **1,390** submissions

Site Licence Submissions:

- Licensed or renewed **362** Sites
- Refused **213** submissions

Client Service Inquiries:

- Received **8,887** inquiries
 - 97% of inquiries received a response



Non-COVID Product Licence Applications

- **Class I:** Continuing to meet 90% performance against the 60-day service standard for new applications and amendments.
 - Total Refusal Rate: **14%**
- **Class II:** Continuing to meet 90% performance against the 90-day service standard for new applications and amendments.
 - Total Refusal Rate: **36%**
- **Class III:** 57% performance year-to-date for new applications and amendments against the 210 day service standard.
 - Total Refusal Rate: **19%**
- **Notifications:** Completed 99% of notifications received prior to 2021.
 - 46% of notifications received in 2021 have been completed

Non-COVID Site Licence Applications (As of October 13, 2021)

- **Stream I:** Currently at 54% year to date performance for new applications and amendments.
 - Total Refusal Rate: 31%
- **Stream II:** Currently at 86.6% year to date performance for new applications and amendments.
 - Total Refusal Rate: 36%
- **Renewals:** completed **162** renewals this fiscal year
 - Total Refusal Rate: 35.5%
 - Reminder that the acknowledgment letter includes an extension of the period of validity until a decision is issued on the renewal.
 - NNHPD continues to apply a risk-based approach to renewals, as implemented for the December 1st renewals.



Applicant driven issues impacting licence renewal completions:

- Failure to submit an application to renew the site licence at least 30 days before the licence expiry
- Failure to submit an application to renew the site licence through the correct channel (e.g., applications submitted via old ePost conversations)
- Failure to respond to an information request notice (IRN) on time (e.g., multiple requests for extensions)
- Failure to submit a complete and compliant application to renew the site licence (i.e., GMP deficiencies prevent further assessment)
- Failure to submit **ONLY** an application to renew a site licence (i.e., requests for modification like to add a new foreign site must be submitted as a amendment)

Questions?



Contact us directly at:

hc.nnhpd.consultation-dpsnso.sc@canada.ca

Interim COVID-19 Site Licence - update

COVID-19 SL Transition

Transition requirements:

- Applicants were required to demonstrate compliance with the Good Manufacturing Practices (GMPs) outlined in Part 3 of the NHPR, including testing.
- Clear refusal criteria, with no IRNs issued for incomplete applications.

Transition timeline:

- SL applicants who applied by **September 30, 2021** can continue activities under their interim COVID-19 SL until a licensing decision is issued.

Transition update:

- **174** companies submitted a transition application
- **107** COVID-19 SL holders provided an administratively complete application on time
 - Refusal rate for incomplete applications: 35%
 - Reasons for refusal include: no DPA, no GMP evidence, company code errors, no application form
- Companies who did not apply have been asked to confirm by October 25, 2021 that they have ceased activities

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NHP Systems Updates

Upcoming Releases

- **Web Product License application form v4.3 – Release Winter 2022**
 - Features will include:
 - Ability to validate all monographs
 - Improved support for kit submissions
 - Improved NMI filtering
 - Improved error messages
- **Decommissioning web form 3.0 Winter 2022**
 - Version 3.0 of the web form will no longer be able to finalize
 - Still able to view files and reply to IRNs
- **Electronic site form – Winter 2022**
 - Improvements to assist in the processing and screening stages with more success and a reduction in the need for IRNs
 - Improved in-form validation
 - Introduction of a notification table

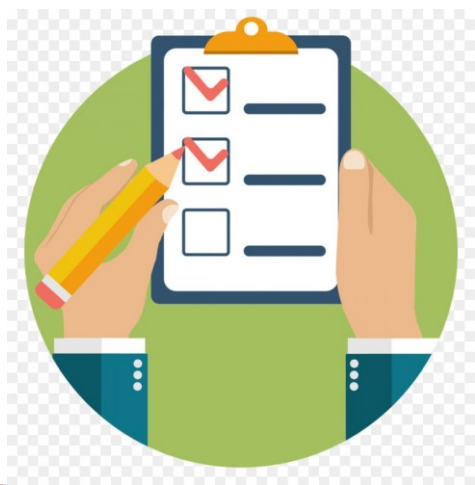


Secure Portal

Stakeholder consultation



- In the coming weeks a questionnaire will be sent out to targeted license holders and Associations
- Seeking feedback on features of existing Health Canada secure portals
 - Requesting feedback on which features would be considered essential
- Clients will be given two weeks to provide a response



Your feedback is important!

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Informatics, Analytics and Product Trends

Advancements in Informatics and Automation

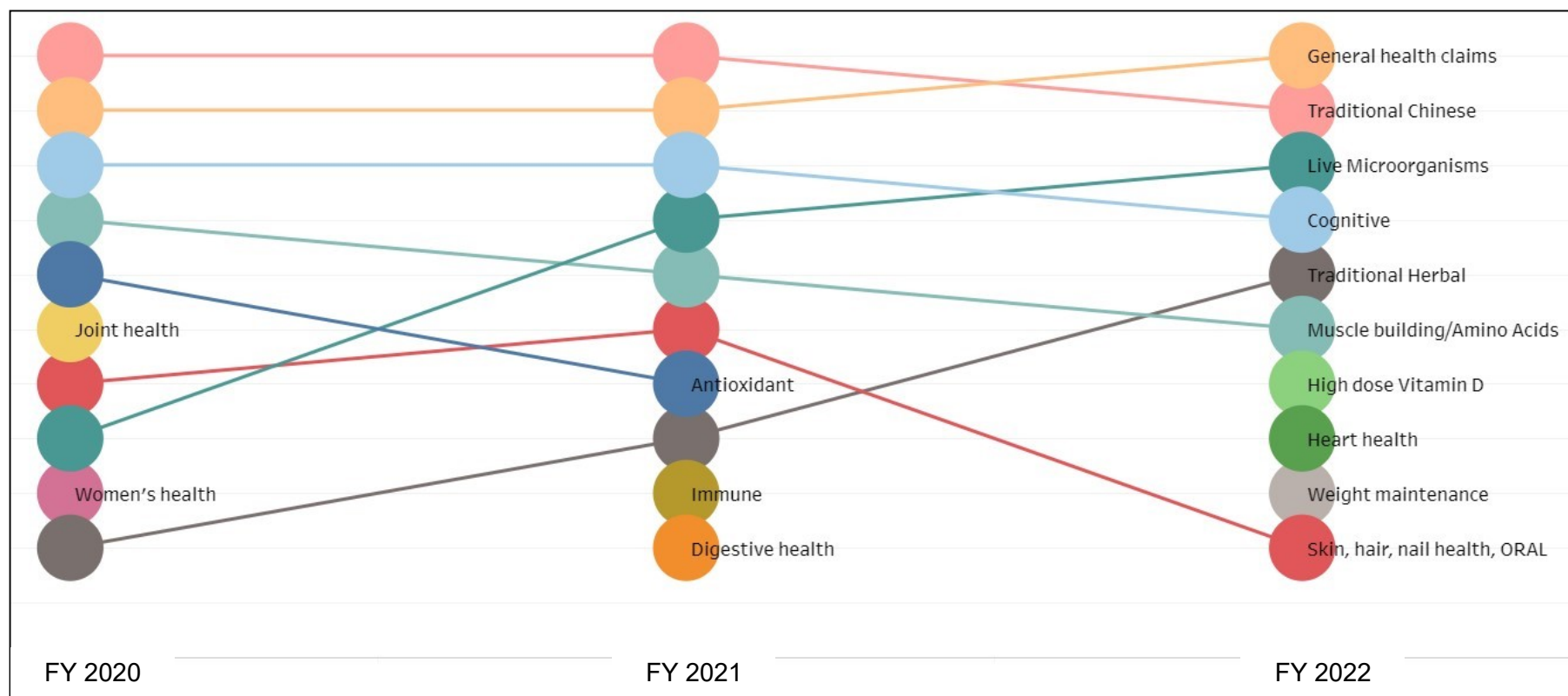
- Improved monitoring and tracking from the moment the file enters ePost until a decision is rendered.
- Having electronic forms and implementing automation allows us to reduce error rates with respect to downloading information from ePost, and allows for increased tracking and monitoring of submissions, resulting in more accurate workload.

Areas of Work

- Development of automated tools
- Enhancement of workload tracking and monitoring
- Identification of trends and forecasting
- Application of advanced analytics for process optimization and efficiencies



Trends of Class 3 Claims (Over the Past 3 Fiscal Years)



Q&A



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