Health Canada Santé Canada

Canada

2014 – 2015 Annual Report
and
NNHPD Reconsideration Process
Food and Drugs Act Liaison Office (FDALO)

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Presentation Highlights

- Role of the Food and Drugs Act Liaison Office (FDALO)

- Summary of FDALO's annual report for 2014-2015
  - Stakeholders Noted Improvements in the Regulatory System
  - Stakeholders Requested Improvements in the Regulatory System

- Proposed changes to reconsiderations of negative decisions by the Natural and Non-prescription Health Products Directorate (NNHPD)

- Next steps on the NNHPD Reconsideration Process

Role of the Food and Drugs Act Liaison Office (FDALO)

- Launched in 2008, the Food and Drugs Act Liaison Office (FDALO) offers neutral and impartial dispute resolution services to help address stakeholders' complaints, concerns or enquiries about Health Canada's administration of the Food and Drugs Act.
- The Office is located in the Communications and Public Affairs Branch of Health Canada, to keep it a arms length from Health Products and Food Branch's regulatory activities.
- The Office works to build better stakeholder relations and foster trust and credibility for Health Canada's regulatory role through the enhancement of openness and transparency of decision-making.
- FDALO's role has now been expanded so that it will manage all reconsideration processes for pre-market license submissions.

Summary of 2014-2015 Annual Report

Cases managed:

- 100 cases received; mainly from businesses.
- 64 issues management and 36 information seeking cases.
- Number of cases and ratio of issues management to information seeking cases consistent with previous year.
- Delivered 3 training sessions to staff on effectively managing difficult communications with stakeholders. Trained over 655 employees over 5 years.

New Role:

- Redesigned reconsideration process for prescription drug submissions.
- FDALO now manages the administration of prescription drug reconsideration requests received after April 1, 2015.

Stakeholders Noted Improvements in the Regulatory System

- Combining the regulation of over-the-counter (OTC) drugs and natural health products (NHPs) in NNHPD allows for more consistent application of regulations, policies and procedures for products with similar risk profiles.
- NNHPD's active efforts to align regulations/treatment of similar risk products.
- The Therapeutic Product Directorate's (TPD) elimination of the backlog in generic drug reviews.

Stakeholders Requested Improvements in the Regulatory System

- Review and further streamline regulation of cosmetic-like drugs:
  - Increase administrative coordination between NNHPD and the Healthy Environments and Consumer Safety Branch (HECSB) on regulation of personal care products, specifically regulation of sunscreens.
  - Make GMP requirements for cosmetic-like drug APIs risk-based.
- Service standards for the approval of foreign-sites on an Establishment License should be reduced below 250 days.
- NHP Licensing – explore solutions that would facilitate export of products approved through monograph attestation.
- Defer publication of DINs from time of approval to time of market launch for non-patented DIN products.

Background: Work to Improve Existing Reconsideration Processes

- Phase I - April 2015 - FDALO assumed the management of the prescription drug reconsideration process.
  - FDALO worked with Therapeutic Product Directorate and Biologics and Genetic Therapies Directorate staff to redesign the Human Drug Reconsideration process.
  - Following consultations with stakeholders, the new process was launched in April 2015.

- Phase II - May 2015 - Working Group established to develop proposal for NNHPD Reconsideration Process
  - Intent is to increase impartiality, openness and transparency for stakeholders.

Reconsideration Definition

- Reconsideration is a dispute resolution process designed to ensure that disputes about a specific “natural health” or “OTC or disinfectant” submission are resolved impartially and fairly, in keeping with existing scientific and regulatory standards.

- The reconsideration process applies only to pre-market licensing decisions that have received a Notice of Refusal. These include the following:

NHP’s	OTC’s
• Notice of Refusal to issue a Product Licence; and • Notice of Refusal to amend a Product Licence.	• Screening Rejection Letter (RL); • New Drug Letter; • Notice of Deficiency - Withdrawal Letter (NOD/W); • Notice of Non-compliance - Withdrawal Letter (NON/W); and • Not Satisfactory Notice (NSN).

Proposal

- FDALO assumes the responsibility for managing and communicating with NNHPD staff and the stakeholder during the reconsideration process for both OTC/Disinfectants and NHP reconsiderations.

- OTC or Disinfectant reconsiderations use the Therapeutic Product Directorate process and staff; Office of Science assumes the role of 3rd party neutral reviewer.

- NHP reconsiderations will use a process which makes use of Product Assessment Division (PAD) reviewers not involved in the original review; other PAD staff assumes the role of 3rd party neutral reviewer.

- Applicants/sponsors will be given an opportunity to be heard or a decision based on written submissions.

- All reconsideration decisions signed by DG-NNHPD or Director of Bureau of Product Review and Assessment.

Overview of Reconsideration Process

Steps for NHP & OTC Processes
Filing of Intent to Request Reconsideration by Applicant/Sponsor
Eligibility Assessment of Intent
Receipt of Reconsideration Request Package
Assess Reconsideration Request Package
Convene and Conduct Process
Analysis and Recommendation
Final Decision Issuance
Follow-up Action

Next Steps in NNHPD Reconsideration Process

- From February to May 2016, FDALO and NNHPD will pilot the proposed processes for a select number of cases.
- FDALO will monitor issues to suggest process improvements in the revised guidance document.
- The Working Group will update NNHPD Senior Management in June 2016 with recommendations for moving forward based on the pilot.
- NNHPD & FDALO will consult with NNHPD stakeholders to solicit feedback before the new process is implemented.

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