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Aider les Canadiens et les Canadiennes à maintenir et à améliorer leur état de santé

Natural Health Products Directorate Update

Adam Gibson, Acting Director General
November 2013
• For more than a year, Health Canada has been consulting on and implementing a new approach to natural health products (NHPs).

• Focus has been on streamlining product review and licensing.

• Now there is a predictable, stable regulatory environment to ensure continued efficient licensing.

• In July 2013, the review of non-prescription drugs and disinfectants was transferred to the Natural Health Products Directorate (NHPD) to facilitate alignment in approach to consumer health products.

• Operational alignment for NHPs, non-prescription drugs and disinfectants continues, leveraging best practices developed for NHPs over the past 2 years.
• The operational transition of non-prescription drugs to NHPD does **not** change the standards, processes, and policies applied to NHPs.

• The existing *Natural Health Products Regulations* continue to apply.

• The current requirements for product & site licences continue to apply.

• NHP applications continue to be reviewed at no cost to companies.

• Health Canada will continue to implement the *New Approach to Natural Health Products*, announced in June 2012, focusing on the 10-day review standard for class I products, while continuing to make further progress in other areas.
Policy and Guidance

• New Approach to NHPs – published June 2012
• Pathway for Licensing NHPs guidance documents – published December 2012
• Quality of Natural Health Products Guide – published June 2013

Efficiencies

• Ongoing implementation of a three-class system of product review
• Over 40 monographs, representing hundreds of ingredients published
• Internal tools to increase consistency of reviews and decrease review time

Planning, Reporting & Consultations

• Cross-country stakeholder consultations on the new approach – November 2012
• NHPD Quarterly Snapshot – Q2 snapshot recently released (October 17, 2013)
• NHPD six-month calendar of activities published (for July to December 2013)
• Public consultation on all guidance documents and monographs
Three-Class Review System

Class I

- Applies to applications referencing pre-cleared information (PCI)
- Short term: implementation using attestation
- Long term: electronic “self-serve” web application
- Closer look at the Natural Health Products Regulations
- Post-licensing auditing activity

Class II and III

- Further clarification on policies and additional guidance
- New approach to PCI development
- General health claims
- Additional processing efficiencies
• Streamlined review of some applications based on high level of certainty versus low level of certainty:
  • A streamlined 10-day licensing approach for class I products
  • Aiming to publish guidance for industry on attestation in fall 2013

• Expanding what is considered to be PCI to minimize review time and increase consistency:
  • Combinations of PCI (some exceptions) require more efficient review based on high certainty

• Alignment of level of certainty (i.e. class) with review performance targets.
• While the current process will continue to be an option, NHPD is developing an approach to allow companies to support their site licence with a 3rd party onsite audit.
  • Includes an option for companies that wish to be audited to the drug GMP standard to facilitate export

• An audit may be recommended if critical quality issues are noted. Examples:
  • No quality assurance person
  • Contracting out regulated activities to an unlicensed site
  • Falsified records
  • Product contamination or adulteration

• Revised approach for site licensing to be released for consultation in late fall 2013, pilot to follow.
• Continue to implement the new approach to NHPs

• Further progress on the alignment of consumer health products

• Plain language labelling initiative – next steps

• New patient safety legislation