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

The Future of Regulation of Non-prescription and Natural Health Products

Natural Health Products Directorate

Consumer Health Products Canada Fall Conference
September 27, 2013
• For more than a year, Health Canada (HC) has been consulting on and implementing a new approach to 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 to facilitate alignment in approach to consumer health products

• Operational alignment for NHPs and non-prescription drugs and disinfectants continues, leveraging best practices developed for NHPs over the past 2 years
• HC is working to align its approach to consumer health products

• Any potential regulations will be in line with HC’s *Regulatory Roadmap for Health Products and Food*, which outlines a multi-year plan to deliver simpler, more efficient, and more transparent food and health product regulations
  - Specific timing of any potential regulatory amendments will depend on the development of a Consumer Health Product Framework and follow public consultation.

• Operationally, this has begun with the housing of NHP & OTC drug review under one roof

• Current focus is on realizing alignment through policy and operational changes
  - Results from the NHP experience demonstrate that significant change can be realized within existing regulatory frameworks
Canadians
• Harmonized approaches to what appears on product labels
• Access to the products they want and more comprehensive information to support informed product decisions

Health Care System and Industry
• Regulator that is mindful of how industry/market and the practice of medicine is organized.
• Consistency and efficiency in decision making, streamlined and consolidated government interactions.

Health Canada
• Fewer operational interfaces with other program areas and clearer accountabilities
• Harmonized requirements and approaches to product authorizations and labelling
• Consolidated expertise
• Over the past 2 years much progress has been made on getting the oversight for NHPs right and streamlining review and licensing (details in Annex A)

• Many valuable lessons learned about balancing oversight with product certainty

• While OTC performance standards and timelines remain the same, NHPD is exploring the feasibility of applying to OTC review elements of the NHP three-class review system
  ▪ this system focuses on matching review time with level of certainty associated with product

• NHPD is launching a sunscreens monograph pilot to align the assessment of NHP and OTC drug sunscreen products

• Alignment will ensure consistency in the review of:
  ▪ brand names, nano-technology requirements, non-medicinal ingredients, labels, cosmetic claims, animal tissue forms
Next Steps: Implementation of Approach to NHPs

• **Product Licensing**
  - Continued implementation of three-class system for product review
  - Publish guidance in fall 2013 on Class I attestation process (10-day review target)

• **Site Licensing**
  - Publish proposal for consultation and pilot it in fall 2013

• **Compliance and Enforcement**
  - Currently in a compliance transition period for NHPs that provides companies time to adjust business practices and phase-out non-compliant products.
  - Development of new model for compliance and enforcement underway
Product Licensing: Three Class Review System

Class I

• Applies to applications referencing PCI
• Short term: implementation using attestation
• Long term: electronic “self-serve” web application
• Closer look at the *Natural Health Product 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
Applications submitted to Health Canada in support of switching a medicinal ingredient from prescription to non-prescription are referred to as "switch submissions".

NHPD will be involved in all cases where a medicinal ingredient is removed from the PDL.

Drafting a guidance document to outline for sponsors the evidence that can be provided for review by Health Canada to support the safety and efficacy of a medicinal ingredient in a non-prescription product that previously was sold by prescription.

Process outlined in the Question and Answer document posted on the Health Canada website:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_qa_fin_ordeng.php#a3
Scientific Advisory Committee Update

• Reviewing of the Terms of Reference and membership of both the SAC-NPD and NHPD’s existing Natural Health Products Program Advisory Committee (NHP-PAC)

• Goal is to reflect scope and alignment of consumer health products.

• SAC-NPD membership tenures will all end in the fall of 2013 and tenures for the NHP-PAC ended as of July 31, 2013. Given the review, membership renewals will not be pursued at this time.

• Transition steps and the review are first towards aligning how we approach products of similar risk/certainty profiles.
• Objective is to increase quality assurance for products through independent audit of sites by a 3rd party and to facilitate export of NHPs

• While the existing process continues to be an option, companies can choose to submit a 3rd party audit to support their site licence

• Where critical deficiencies are noted in the application of the current process, an audit may be recommended

• NHPD consulted on an early concept during the November 2012 cross-country consultations
• Proposal for consultation and launch of pilot scheduled for fall 2013.

• The NHP site licensing pilot will evaluate whether a voluntary onsite audit approach by a 3rd party is an effective way to provide independent verification of GMP compliance and quality assurance.

• Will be exploring the applicability of the approach to other product lines with similar risk/benefit profiles.
Recently, a regulatory amendment was published that extends the requirements for DEL and GMP compliance to API facilities (new regulations will come into force in November 2013).

Stakeholders have raised concerns about the application of these requirements to all OTC drugs regardless of risk (NHPs are excluded).

Health Canada is working to ensure that the application of these requirements:

- does not create unnecessary administrative burden
- treats consumer health products in a manner consistent with their risk

Please direct any questions to Insp_pol@hc-sc.gc.ca
Annex A: Progress Under the New Approach to NHPs

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 three-class system of product review (see Annex A)
• 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 – new simplified format released July 2013
• NHPD six-month calendar of activities published (for July to December 2013)
• Public consultation on all guidance documents and monographs