Health Canada Santé Canada

Helping the people of Canada maintain and improve their health

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

Natural Health Products Directorate's presentation to the Canadian Association of Professionals in Regulatory affairs

CAPRA Education Day 2014

- Year in review- what has been achieved
- Future direction- where the future priorities lie
- Ongoing operational work- supporting the future direction of the Natural Health Products Directorate

Implementation of New Approach for NHPs

- For more than a year, NHPD has been consulting on and implementing a new approach (i.e. 3 class system for product authorization, site authorization, and C/E).

- The focus has been streamlining product review and licensing of NHPs; the result of which is a predictable and sustainable product authorization function.

Operational Alignment of NHPs/Non-Rx Drugs

- In July 2013, the responsibility for review of non-Rx drugs and disinfectants was transferred to the NHPD to facilitate greater alignment of product authorization functions for both NHPs and non-Rx drugs.

- Operational alignment for NHPs and non-Rx drugs continues to be analysed, leveraging the best practices of both functional areas.

Pathways for Licencing

- Guidance documents completed (evidence requirements for class II, III).
- Auditing applications for completeness prior to development of electronic “self-serve” web application tool.
- As of January 2014, accepting class I attestations

Application Management Policy

- Guidance on class review - how to apply, submission process, & associated performance timelines (aligns level of certainty w review) ▪ Includes guidance for industry on attestations. ▪ Posted for consultation in December 2013.

Quality (C&M)

- Guidance developed and implemented (June 2013). ▪ Accepting attestations.

Monographs

- Over 40 monographs, representing hundreds of ingredients published (2013).

- 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 Good Manufacturing Practices (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 published for consultation, with a pilot to follow in the fall of 2014.

Desired Outcomes

1. General alignment between NHPs & non-prescription, distinct from prescription.
2. Stratification of all products based on risk, using a flexible mechanism for assembling products (vs. static classifications).
3. Requirements and authorities to support modern regulatory oversight activities, such as:
   - Acceptance of third party audits of Canadian facilities where appropriate;

- Increasing market-driven compliance through transparency initiatives;
  - Authority to respond appropriately to on-market issues.

Product Type	Legislation		
	FDA	FDR	NHPR
NHPs	✓		✓
Non-prescription drugs	✓	✓	
Disinfectants	✓	✓	

NHPs	Non-prescription	Disinfectants

Product Authorization

- Support Bill C-17, proposed *Protecting Canadians from Unsafe Drugs Act*.
- NHPD re-naming to reflect current responsibilities (Summer of 2014).
- Address product interfaces at the cosmetic/drug interface including identification of products which may not belong (e.g. certain cosmeticlike products).
  - Guidance for cosmetic advertising/labelling.
- Expert advisory committee development (Summer of 2014).

Product Authorization Continued

- Disinfectants -
  - Published 5 new guidance: evidence standards for (i) disinfectant drugs, (ii) hard surface disinfectants, (iii) high level disinfectants, and (iv) contact lenses solutions; as well as an application process guidance .
  - Revision of monographs has begun & ongoing PMRA/FD collaboration.
  - Plain language labelling (PLL) -
- Guidance to outline LASA standards for CHPs, distinct from Rx drugs (MHPD lead), as well as standards for umbrella branding.
- Drugs fact table guidance.
- Switch guidance & PDL governance .

Establishment/Site Authorization

- Implementation of site licence third party inspection pilot and development of guidance (launch pilot in June 2014).

Information for Canadians & Health Care Professionals

- Development of seasonal public communications calendar (e.g. proper use of CHPs during flu season, how to look for product authorization, etc.).
- Promoting awareness of NHP regulation to health professionals.

Compliance and Enforcement

- Contribute to completion of transition period in advance of September 2014.

- Explore mechanisms to recognize leading products at point of sale (e.g. product authorization, site inspection, & positive compliance history).

- NHPD re-naming announcements (external & • Summer 2014 internal).
- External consultations on the re-constitution of expert • Summer 2014 advisory committee.
- CHP Initiative: consultation with stakeholders through • Fall 2014 regularly scheduled bilateral meetings & speaking engagements.
- CHP Framework: potential external consultation on • Fall 2015 regulatory proposal.

Website: www.healthcanada.gc.ca/nhp From this main page you can access most popular sections including What's New, Quarterly Reports, Licensed NHP Database, and Forms and Guidance.

Website: http://www.hc-sc.gc.ca/ dhp-mps/prodpharma/index-eng.php From this page you can access information about non-prescription drug products.