Health Canada’s Post-Market Surveillance Program

Update on new and ongoing initiatives

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Updates on current initiatives

- Look-Alike Sound-Alike (LASA)
- Plain Language Labelling (PLL)
- Canada Vigilance Projects

Update on Adverse Reaction Reporting

Looking Forward
Updates on Current Initiatives
Update: Look-Alike Sound-Alike (LASA)

- Feedback gathered via the Spring 2013 consultation on the revised guidance for LASA brand name review identified the desire for a separate guidance covering OTC products.

- In respecting the feedback gathered and Health Canada’s directions for balanced regulation of health products, work will be done to identify an approach that upholds safety standards while at the same time recognising the nature of the products and the marketplace.

- As a next step in the process of developing a name assessment framework for OTC products, more discussion will held on risk mitigation strategies appropriate to the prevention and management of confusion that can result from similar brand names.
Update: Plain Language Labelling

• Proposed amendments pre-published in CG1 in June 2013 with comment period closing in early September 2013.

• The new regulations would introduce for human drugs (non-prescription and prescription drugs and biologics) the following 5 targeted requirements:
  
  – plain language labelling to assess elements such as colour contrast, font size and layout of text
  – contact information to report problems
  – drug facts tables to present key information in a standard format for non-prescription drugs
  – mock-ups of labels and packages for review
  – Look-alike-sound-alike (LASA) evidence that drug names will not be confused with other authorized products

• Stakeholder feedback is currently being complied and analysed.
Update: Canada Vigilance Projects

• Implementation of a pharmacovigilance database to manage both Clinical Trial and Post-Market AR Reports to enhance the overall efficiency of processing and managing adverse reaction reports over the life cycle of a product.

• Implementation of Electronic Reporting of all ARs (domestic and foreign) coded with MedDRA for small, medium & large Industry to account for varying technological capability.

  • Includes data analysis capabilities including a data mining and signal detection tool.
  • Incorporates international standards as recommended by ICH.
  • Brings Health Canada in-line with other Regulators (FDA, EMA, etc.) who have e-Reporting.
Update on Adverse Reaction Reporting
Update: Domestic AR reports (All Products)

Canada Vigilance Database: January 1, 2012-March 31, 2013

- Pharmaceuticals (OTC and Rx) (56.63%)
- Biotechnology Products (38.61%)
- Natural Health Products (1.46%)
- Radiopharmaceuticals (0.68%)
- Blood Products & Biologics (1.45%)
- Cells, Tissues, and Organs (0.12%)
- Vaccines and Diagnostics (1.05%)
Looking Forward
The Marketed Health Products Directorate currently:

- monitors and collects AR and medication incident data;
- reviews and analyses marketed health product safety data;
- conducts risk/benefit assessments of marketed health products;
- communicates product related risks to health care professionals and the public;
- carries out regulatory advertising activities;
- develops policies to effectively regulate marketed health products;
- conducts active surveillance.
Health Product Vigilance

- Key element of the life-cycle approach of health products.
Vigilance Activities

- Vigilance oversight is dynamic/flexible, and is applied on a risk-based approach.
- Highest level of compliance and enforcement and safety surveillance reserved for the most serious risk.
- Increased oversight may also be needed for products with low certainty or low information on risk profile.
- Can we profile our vigilance activities in a better way?

Compliance and Enforcement
Labelling revisions
Risk Communication

Increased Oversight: Targeted monitoring of CV database / Request for additional safety data from Industry

Standard Monitoring:
Enviroscanning (literature, foreign regulatory agencies)
Routine monitoring of Canada Vigilance AR database
Drivers for Change

- Following the Pathway for Licencing, it is time to re-balance the pre and post market oversight of these products.

- The “life cycle” approach to health product regulation needs to be supported by enhanced post-market oversight.

- The need for a proactive and systematic approach to obtaining and evaluating evidence in support of both the benefits and risks of health products.
Safety Surveillance Continuum

Spontaneous

DSEN (database analysis)

Risk Management Plans / PV Plans

Mining of electronic health records

External canvassing

Issue-specific reports

DSEN (study design)

Prescription Event Monitoring

Pharmacoepidemiological studies

Drug utilization studies

Targeted analysis of spontaneous reports

Data mining of spontaneous reports

Periodic reports (PSUR, Annual, DSUR)

Spontaneous AR, AE and Med Incident Reporting

Pre-organized, Continuous

Clinical Trials

Sentinel systems

Patient, product registries

DSEN (Active Surveillance)

Solicited Reporting

Stimulated Reporting

Proactive

Reactive
How Could Post Market Oversight Look?

- Re-balance between active and passive surveillance.
  - Post-market reporting requirements indexed against product risk
  - Targeted surveillance of conditionally licensed products informing product licensing

- A focus on proactive analysis of market data through research to assess trends and a predicative model that can forecast safety signals.
  - May involve partnerships with industry and other stakeholder groups.

- Continuous assessment of feedback received from users of risk management approaches (e.g., Canada Vigilance, risk communications) to assess effectiveness.