Advancing Safe Medication Practices

Development of a Guide to Support the Design of Safe Health Product Labels and Packages

(Health Canada and ISMP Canada)

IMSN - October 10, 2013

1. Overview of Project
2. Incident Review
3. Environmental Scan – Surveys of End Users and Industry
4. Guide Content and Draft Topics
5. Resources and Information Reviewed
6. Literature Review Process
7. Activities to Date

Next Steps

1. Overview of Project

Purpose:

- To develop a good practices guide that outlines principles of design for safe and clear labelling* and packaging of health products for human use.

Scope:

- To be inclusive of all health products for human use: prescription and non-prescription pharmaceuticals, biologics, and natural health products.

* In this context, label refers to the actual label on or affixed to an immediate container or outside of a package. Product monographs and any other package inclusions are not included in the scope of this project.

1. Overview of Project

The draft guide will:

- Identify information to assist manufacturers in the design of labels and packages that are clear, accurate and understandable.
- Draw from regulatory and patient safety content, experience and developments in Canada and other jurisdictions.
- In addition to providing general principles for safe labels and packages, it will consider recommendations for different health product formats.

1. Overview of Project

- Core Working Group: ISMP Canada with Health Canada
- Expert Panel
  - National and international
  - Contribute ideas, provide input and to review and provide feedback to documents

1. Overview of Project

- Expert Panel = consumers, healthcare practitioners and associations, and regulatory agencies (alphabetical order):
  - Canadian Anesthesiologists' Society
  - Canadian Association of Naturopathic Doctors
  - Canadian Nurses Association
  - Canadian Pharmacists Association
  - Canadian Society of Hospital Pharmacists
  - European Medicines Agency
  - Graphic Designer, academic
  - Health Canada
  - Human Factors Engineer
  - ISMP (United States)
  - ISMP Canada
  - Medicines and Healthcare Products Regulatory Agency, UK
  - Medicines Evaluation Board, The Netherlands
  - Patients for Patient Safety Canada
  - Therapeutic Goods Administration, Australia
  - U.S. Food and Drug Administration

2. Incident Review

Aggregate Analysis

- To gain a deeper and overall understanding of medication incidents reported involving labelling and packaging and potential systems based contributing factors

Limitations

- Voluntary reporting
  - True incident rate cannot be established
  - Not comprehensive
- Follow-up not possible in most cases

2. Incident Review

7 Themes

- Drug Selection Confusion
- Nonprescription Product Confusion
- Strength or Dose Confusion
- Route Confusion
- Formulation Confusion
- Solution Confusion
- Other Sources of Confusion

3. Surveys

- Surveys were conducted with end-users: consumers and healthcare professionals (2 questions) and with manufacturers and industry associations (3 questions)
  - through direct contact with individuals
  - through associations

3. Survey – End Users
Top Concerns

- Label content – key information
- Legibility of information – lack of label space; product or package shape
- Look-alike labels or packages
- Confusion caused by package or drug container – label and package not designed for intended use or user
- Use of colour
- Prominence of branding
- Outer label/package issues

3. Survey – End Users
Components of Good Label/Package

- Label includes key information
- Standardized label information and layout
- Legibility of information – uncrowded; large enough to accommodate all components; flat surface for easy reading
- Use of colour
- Label and package designed for intended user

3. Environmental Scan – Industry Challenges

- Packages and labels – dimensional and space constraints; environmental considerations; pharmacy and retailer; technology con
- Smaller containers and product packages – mandatory text; maintaining adequate readability
- Quantity of text and information – limited space; warnings; bilingual labelling; bar coding
- Differentiation versus standardization – similarity of labels or packages; colour; expressions of strength
- Regulatory process – globally; nationally; changes in regulations and guidances
- Changes to labels and packages – time, cost, and complexities; legacy products

3. Environmental Scan – Industry Constraints

- Packages and labels – dimensional and space; technology
- Smaller containers – mandatory text; technology
- Quantity of text and information – limited space; bilingual; bar coding
- Differentiation and standardization – colours; printing and material limitations
- Regulatory process
- Changes to labels and packages – time and cost complexities to introduce into supply chain; equipment

4. Guide Content and Draft Topics
Guiding Principles

- The purpose of the product label and package:
  - to communicate accurate and current information about the product so that it can be used safely and appropriately to minimize the risk of harm
  - to clearly communicate accurate and current information for intended and safe use to the end users (consumers or healthcare practitioners)
- To avoid preventable adverse drug events (i.e., incidents), as identified through historical reporting

4. Guide Content and Draft Topics

What information needs to be most prominent?

- Drug name, concentration, dose, route, etc.
- Consideration of different formats and dosage forms, e.g., injectables, orals, topicals

AND

- Are there ways that the presentation of this information can be enhanced, considering the end user and the environment of use?

4. Guide Content and Draft Topics

- **Human factors principles**
  - importance of end users and their environment
  - user testing and other considerations
- **Label design and layout**
  - placement of information
  - standardization versus differentiation
  - look-alike labelling and packaging
  - proximity and compatibility
  - expression of expiry date, considerations related to lot number

4. Guide Content and Draft Topics

- **Label design and layout** (cont'd)
  - white space
  - text: font, size, upper or lower case, colour, contrast
  - TALLman lettering, reverse highlighting, boldface considerations
  - warning statements
  - bar coding
- **Package design for safe and intended use**
  - e.g., neuromuscular blocking agents – previously agreed upon labelling and packaging for Canada

5. Resources and Information Reviewed

- Health Canada regulations and guidances
- International regulations and guidances
- Canadian association standards (CSA, CSHP)
- International labelling guides (NPSA)
- Canadian incident reviews (ISMP Canada bulletins)
- US incident reviews (ISMP Safety Alert!)
- Literature on medication labelling and packaging, perception, legibility, comprehension, etc.

6. Literature Review Process

Template Is Used in Review Process for Guide Topics

Guide Topic		
Country, Jurisdiction	**References**	**Statements – Summary –**
Canada	**Legislation/Regulations:** *Food and Drugs Act and Regulations, Natural Health Product Regulations* **Guidelines:** Health Canada NHP Labelling Guideline; Draft Guidance Document for Consultation: Labelling of Pharmaceutical Drugs for Human Use; Health Canada GMP Guidelines; CSHP Drug Packaging and Labelling: Guidelines for Manufacturers **Standards:** CSA Labelling of Drug Ampoules, Vials, and Prefilled Syringes **Literature:** Safety, Human Factors Engineering, Psychology, Professional	
Country …	**Regulations** – **Guidelines –** **Standards** – **Literature** –	
Background **Recommendations** • • **References**		

7. Activities to Date

- Expert Advisory Panel formed; 3 meetings
- Aggregate analysis of labelling and packaging incidents reported to ISMP Canada; report and safety bulletin published
- Surveys of EAP members and end users and of manufacturers and industry organizations
- Identification of possible guide topics
- Identification of the critical information on the main panel of a label
- Web presentation to industry stakeholders on September 19, 2013
- Engagement of a human factors expert – usability testing
- Draft outlines for select topics

Next Steps

- **Preparing/Finalizing Guide content –** Fall 2013 / Winter 2014
- **Industry Webcast –** Winter 2014
- **Draft Good Practices Guide –** Winter 2014
- **Consultation –** Spring/Summer 2014