Development of a Guide to Support the Design of Safe Health Product Labels and Packages
(Health Canada and ISMP Canada)

IMSN - October 10, 2013
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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 concerns;
- 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

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<tr>
<th>Guide Topic</th>
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<td><strong>Country, Jurisdiction</strong></td>
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| **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


• Consultation – Spring/Summer 2014