



# Designing Health Product Labels and Packages for Safety

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# Human Factors and Health Product Labelling and Packaging

- The label and package are the first points of interaction between a health product and a potential user.
- Labels and packages should be designed with consideration to the user's needs and the environment of use
- It's not about asking people to read labels more carefully.
- It's about designing labels that enable users to find the information they need to use the product safely.



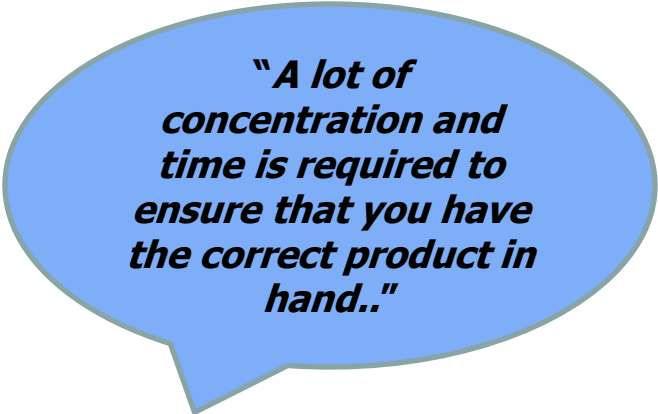
# Labelling and Packaging – An Aggregate Analysis of Reported Incidents

- Review of medication incidents voluntarily reported to ISMP Canada from January 1, 2001, to May 15, 2012
- Over 2000 reports identified labelling, packaging or naming as a contributing factor or concern
- 474 reports specifically identified manufacturer labelling or packaging as a contributing factor



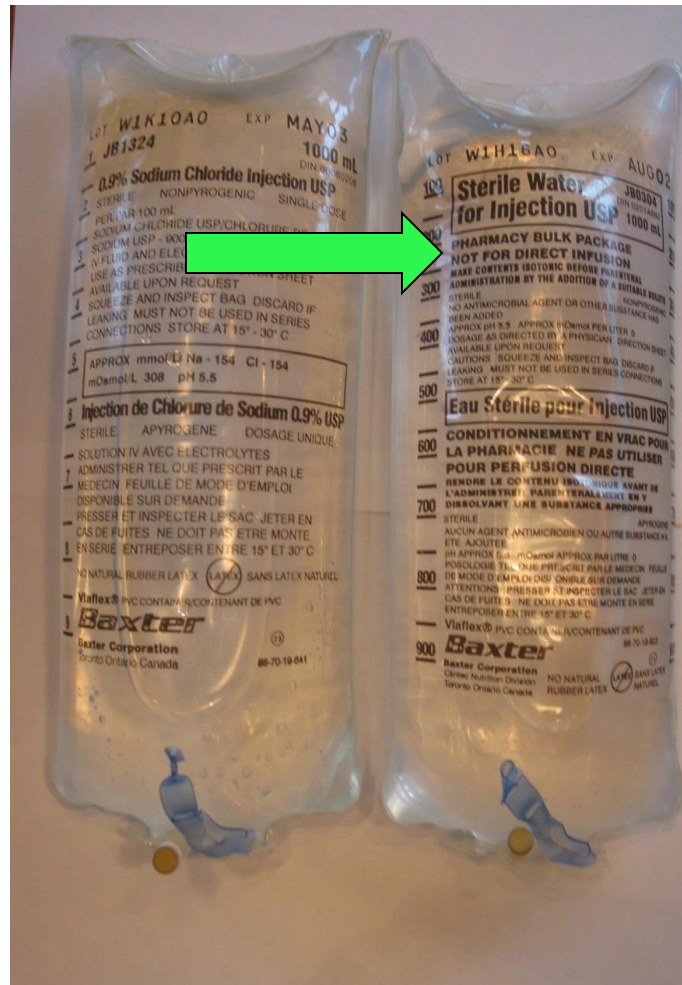
# Common Contributing Factors

- Look-alike labelling and packaging
- Crowding of information on labels
- Confusing layout of information
- Lack of prominence of key information  
e.g., generic name, dose information
- Use of colour
- Readability  
e.g., type size, background (clear), colour contrast between background & text
- Lack of cues for differences  
e.g., concentration or strength
- Similar containers or dosage forms for different routes of administration  
e.g., topical liquid provided in a vial
- Use of abbreviations



***"A lot of concentration and time is required to ensure that you have the correct product in hand.."***

# Solution Confusion



# Changes to Product Label





# Non-prescription Product Confusion



Graphic: ISMP Canada [SafeMedicationUse.ca](http://SafeMedicationUse.ca)  
Alert Vol.13, Issue 2; March 27, 2013



# Changes to Product Label



# Strength or Dose Confusion



# Changes to product label



# **Selected Recommendations for Safe Labelling and Packaging**

# The Proximity/Compatibility Principle

- All information relevant to a common task or mental operation should be displayed close together

Rothrock L, Barron K, Simpson TW, et al. Applying the proximity compatibility and the control-display compatibility principles to engineering design interfaces. Hum Factors Ergonomics Manuf. 2006;16(1):61-81.





# Type Style and Size

- Use sans serif, non decorative type styles
- Use the largest point size possible.
- For smaller point sizes, use a background colour that is significantly different from the type colour



# Text Orientation



ISMP Canada Ontario Critical Incident Learning; Issue 7; Feb 2014; Available from [http://ismp-canada.org/download/ocil/ISMPCONCIL2014-7\\_SmartPumpsNeedSmartSystems.pdf](http://ismp-canada.org/download/ocil/ISMPCONCIL2014-7_SmartPumpsNeedSmartSystems.pdf)



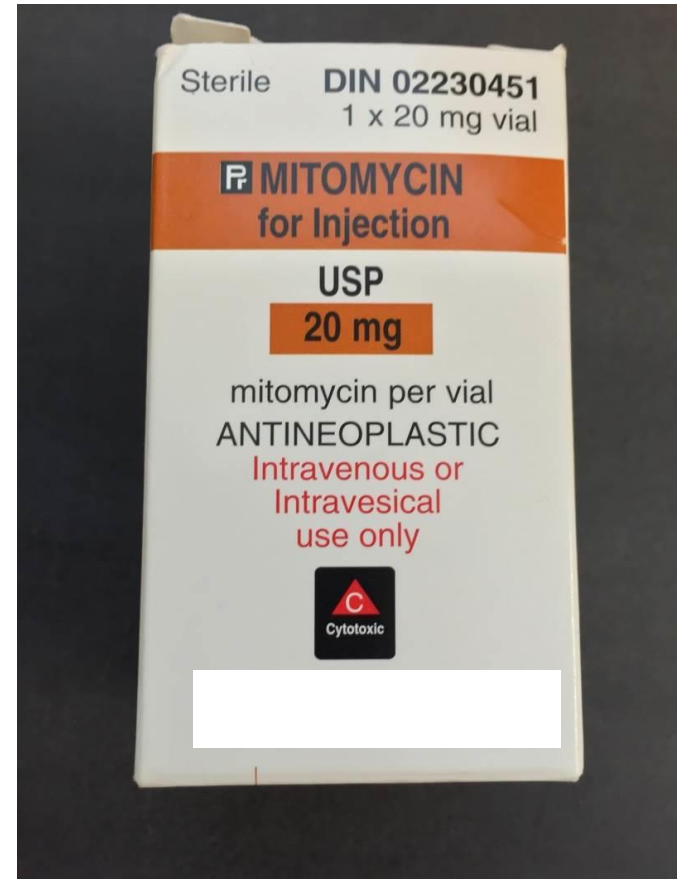
# Colour and Contrast

- Colour can be used to:
  - draw attention to key information e.g. product name, strength, warning statements
  - differentiate one product from another e.g. different strengths of same product
- Good contrast between text & background can enhance legibility of text



# White Space

- Should be used as liberally as possible
- Use to:
  - Frame a grouping of text
  - Separate unrelated information
  - Around headings and key information to emphasize their importance



# General Packaging Considerations



INJECTABLE

TOPICAL

ISMP Can Saf Bull [Internet]; 2009 [cited 2014 Feb 19];9(2):2. Available from: <http://www.ismpcanada.org/download/safetyBulletins/ISMPCSB2009-2-InadvertentInjectionofEpinephrineIntendedforTopicalUse.pdf>

# Packaging of Multi-Part Products



# Blister Packaging

- Provide information on each blister cell
- Avoid placing information across two blister cells
- Perforations should allow for separation of each individual dose from the



50 mg per tablet or  
50 mg per 2 tablets?

# User Testing

- Assesses usability and identifies problems experienced by users
- Provides a realistic view of label and package function in the “real world”
- Should be considered when there is a heightened risk of harm if product is used in error

# The Good Label and Package Practices Guide

- Draft developed collaboratively by Health Canada and ISMP Canada
- Provides direction to industry on the design of safe and clear health product labels and packages.
- External stakeholder consultation completed 2015



## DOCUMENT FOR INDUSTRY

Good Label and Package Practices Guide

DRAFT FOR REVIEW  
CONFIDENTIAL  
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Good Label and Package Practices Guide



# In Conclusion

- The design of health product labels and packages play an important role in facilitating safe product use.
- Labels and packages should provide the user with the information they need to use the product safely.
- Design of health product labels and packages should consider human factors, user needs, and the environments in which the product will be used

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