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
Changes to Product Label

The product label of CLEAR CARE® has been updated to include the following changes:

1. The product label now includes a warning about the potential for eye irritation and contact lens dormancy.
2. The label provides instructions for proper care and handling of contact lenses, including the use of the provided lens case and the importance of rinsing the lens with fresh solution.
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5. The product label now includes a warning about the potential for eye irritation and contact lens dormancy.
6. The label provides instructions for proper care and handling of contact lenses, including the use of the provided lens case and the importance of rinsing the lens with fresh solution.

These changes are intended to ensure the safety and effectiveness of the product and to prevent potential complications associated with improper use.
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

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
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

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...
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
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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