Spotlight on medication safety: Designing safe packaging and labeling

Global Patient Safety Considerations for Pharmaceutical Product Labeling
International Medication Safety Network
www.intmedsafe.net

International Medication Safety Network
- Australia
- Brazil
- Canada
- Denmark
- France
- Hong Kong
- Iran
- Ireland
- Israel
- Mexico
- Morocco
- Netherlands
- New Zealand
- Saudi Arabia
- Singapore
- Spain
- Suriname
- Sweden
- United States
- United Kingdom

Some important labeling and packaging problems
- Look-alike labeling
- Inconsistent and unclear expression of strength
- Cluttered labeling
- Highly stylized label graphics
- Overemphasis on company name and logos
- Inadequate prominence of reminders and warnings
- Unsafe application of color coding
- Packaging that fails to take human factors into account
Spotlight on medication safety: Designing safe packaging and labeling

Read labels carefully - 3 times!

- When obtaining package
- When using package
- When discarding package or returning to storage

Confirmation bias

Accept information that agrees with our hypothesis; reject information that does not

Look alike labeling
Spotlight on medication safety: Designing safe packaging and labeling

Canada
Former packaging Herceptin and Rituxan

Canada
Newer packaging Herceptin Rituxan

The new Roche Family Design
Spotlight on medication safety:
Designing safe packaging and labeling

United States
Topical and Internal Liquids in look-alike containers.

Latin America - Colombia

Spain
Spotlight on medication safety: Designing safe packaging and labeling

Australia

New Zealand

New Zealand
Spotlight on medication safety: Designing safe packaging and labeling

Denmark

Confusion between drug product and lab reagent

Name, logo, and "corporate dress"
Spotlight on medication safety: Designing safe packaging and labeling
Spotlight on medication safety: Designing safe packaging and labeling

Readability of the label in use and ambiguous labeling

United States

United Kingdom
Spotlight on medication safety:
Designing safe packaging and labeling

Spain
Note lack of label background – no contrast upon dark background

United States
Color blocks view of drug name

Expression of concentration and strength
Spotlight on medication safety:
Designing safe packaging and labeling

- United Kingdom
- France and French speaking African country
- Greece
- Spain
- United States
- France label above

NITROGLYCERIN
400 mcg/mL

250 mL

United States
Spotlight on medication safety: Designing safe packaging and labeling

Australia

Before and after – both are same strength

United States

2 tablets = 400 mg or 2 x 400 mg tablets?
Spotlight on medication safety: Designing safe packaging and labeling

Multiple Languages

Europe
Spotlight on medication safety: Designing safe packaging and labeling

Location of concentration/strength

Hong Kong

United States
Spotlight on medication safety:
Designing safe packaging and labeling

Communication
(readability of the label - Size of label, clutter, obstructions, etc.)
Spotlight on medication safety: Designing safe packaging and labeling
Spotlight on medication safety:
Designing safe packaging and labeling
Spotlight on medication safety:
Designing safe packaging and labeling

Use of color coding
Spotlight on medication safety: 
*Designing safe packaging and labeling*

**Australia**

Label reminders and warnings; communication of important information
Spotlight on medication safety: Designing safe packaging and labeling

Sweden

United States (before)  
Canadian version similar
Spotlight on medication safety:
Designing safe packaging and labeling

United States (after)

Typography
Spotlight on medication safety:
Designing safe packaging and labeling

- Dobutamine 400 mg
- Dopamine 500 mg
- Chlorpropamide 100 mg
- Chlorpromazine 100 mg
- Hydralazine 50 mg
- Hydroxyzine 50 mg
Spotlight on medication safety: Designing safe packaging and labeling

Dangerous abbreviations and dose designations

United Kingdom

Exelon®
Nortriptyline Hydrochloride
Capsules

Indicated for:
3.0 mg
300 Exelon®

Copyright © 2007 Exelion Pharmaceuticals, Inc. All rights reserved.
Spotlight on medication safety:
Designing safe packaging and labeling
Spotlight on medication safety:
Designing safe packaging and labeling

Lack of response by manufacturer when error is reported

“This report has been brought to the attention of the appropriate Labeling/Regulatory personnel, and we have entered it into the [Company] Product Complaint System for monitoring purposes.”

Questions on labeling, Packaging??