

Health Canada Guidances on Designing Labels & Packages for Safety

FDA/IMSN International Regulators Summit
June 20, 2018



YOUR HEALTH AND SAFETY... OUR PRIORITY.

Real World Safety

- Medication incidents due to naming, packaging & labelling lead to adverse patient outcomes
- A safety gap was identified between the regulatory review of health product safety and the real world perspective of safe health product use
- In practice settings, naming, packaging and labelling influence the safe use of health products.

Plain Language Labelling Initiative

- A key focus for Health Canada is improving the safe use of drugs by making drug names, labels and packages easier to read and understand
- The Plain Language Labelling (PLL) Initiative is a multi-phased project to:
 - Reduce preventable medication incidents
 - Improve safe and effective use of drugs
 - Support Canadians in making informed choices about drugs

Plain Language Labelling (cont'd)

- The Plain Language Labelling regulations came into force for prescription products and those administered or obtained through a health professional on June 13, 2015.
- For non-prescription pharmaceutical drugs on June 13, 2017.
 - Does not apply to submissions already in queue on that date
 - Full compliance at retail level by June 30, 2021
- For natural health products, regulations to be drafted by 2019
 - Full compliance at retail level estimated 2024

Plain Language Labelling (cont'd)

- Regulations introduce the following requirements for human drugs (Rx, non-Rx and biologics):
 - **Plain Language:** clear, understandable labels; format or presentation of labels must not impede user comprehension; consideration to be given to certain elements, such as clear writing, colour contrast, font size and layout of text.
 - **Submission of Mock-ups of Labels and Packages:** displaying an accurate representation of what will be available on the market after the product is approved.
 - **Look-alike Sound-alike (LASA) Name Assessment:** evidence that drug names will not be confused with other authorized products
 - **Drug Facts Table:** to present key information in a standard format for non-prescription drugs.
 - **Contact information:** contact information on label to report problems.

Health Canada's Guidance Documents

Under PLL, Health Canada has developed and amended guidance documents for industry:

- Guidance Document Questions and Answers: Plain Language Labelling Regulations
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs and Contact Lens Disinfectants
- Guidance Document for Industry: Review of Drug Brand Names
- **Good Label and Package Practices Guide (GLPPG) for Prescription Drugs**
- **GLPPG for Non-prescription Drugs and Natural Health Products**
- Guidance Document: Drug Facts Table for Non-prescription Drugs
- Guidance Document: Electronic Canadian Drug Facts Table Technical Standards

Good Label and Package Practices Guides

- Objective to provide direction to sponsors in designing safe and clear labels & packages
- Collaboration between Health Canada and ISMP Canada
- Significant volume of evidence reviewed:
 - Canadian and international regulations, standards, policies and guidelines
 - Health Canada risk communications
 - Published reports of safety incidents
 - Analysis of error reports submitted to ISMP Canada
 - Human factors principles
 - Patient Safety Agency publications
- International, multidisciplinary expert advisory panel
 - Health professional associations
 - International regulators
 - ISMP US
 - Patient advocacy group
- Consultants in human factors and medication safety

Good Label and Package Practices Guides*

Label and package factors contributing to errors:

- Crowding of information on labels
- Readability (font size and type, colour contrast)
- Expression of strength
- Warnings unclear or absent
- Trade dress and brand name/corporate logo
- Lack of prominence of non-proprietary name or ingredients
- Look-alike labelling and packaging (high-alert medications)
- Similar containers for formulations intended for different routes of administration

*<https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs.html>

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Good Label and Package Practices Guides

- Design and layout
 - Type style & size
 - White space
 - Colour & contrast
 - Abbreviations, symbols & dose designations
 - Bilingual labelling
 - Trade dress
- Label information
 - Key elements on principal display panel
 - Expression of strength
 - Warnings
 - Automated identification
- Packaging
 - Small containers and small-volume
 - Blister
 - Pediatrics
 - Transdermal patches
- Drug Facts table (non-prescription drugs)
- Human factors principles and assessment methods

Label – Regulatory Requirements

250%

Pr **DIN 02230988**

Cerebyx*

Fosphenytoin Sodium Injection, 75 mg/mL - Mfr. Std.
fosphénytoïne sodique injectable, 75 mg/mL - Norme du fabr.
Equivalent to/Équivalent à
500 mg/10 mL (or/ou 50 mg/mL)
Phenytoin Sodium/de phénytoïne sodique
Sterile/Stérile
Fliale unidose de 10 mL Single-dose Vial

ERFA
Canada 2012 Inc.
Montréal QC H4P 2P5

ANTIÉPILEPTIC AGENT
For Intravenous or Intramuscular Use
Dosage and Administration:
See enclosed Package Insert.
Product Monograph available to health care professionals upon request.
Store under refrigeration (2 to 8°C).

ANTIÉPILEPTIQUE
Pour administration intraveineuse ou intramusculaire
Posologie et administration : voir le feuillet de renseignements.
Monographie disponible aux professionnels de la santé sur demande.
Réfrigérer (entre 2 et 8 °C).
*TM/M.C. de Erfa Canada 2012 INC.

C32581 32581ET03

Couleurs à reproduire

Label – Design for Safety

Pr **DIN 02230988**

Cerebyx *

Fosphenytoin Sodium Injection, - Mfr. Std. ← **C**
 fosphénytoïne sodique injectable, - Norme du fabr.

Equivalent to/ ← **A**
 Équivalent à **500 mg/ 10mL**

of phenytoin sodium / de phenytoïne sodique ← **B**
 (or/ou 50mg/mL)

Sterile/Stérile

ERFA ← **F**
 Canada 2012 Inc.
 Montréal QC H1P 2P5

Fiole de 10mL Single-dose vial ← **E**

AGENT ANTIÉPILEPTIQUE
 Pour administration intraveineuse ou intramusculaire
 Fosphenytoïne sodique 75mg/mL, norme du fab. (750mg de fosphenytoïne sodique par fiole, équivalent à 500mg de phénytoïne sodique après administration)
 Posologie et administration: voir le feuillet de renseignements.
 Monographie de produit disponible aux professionnels de la santé sur demande.
 Réfrigérer (entre 2 et 8°C)

ANTIPILEPTIC AGENT
 For intravenous or intramuscular use
 Fosphenytoin sodium 75mg/mL, Mfr. Std (750 mg of fosphenytoin sodium per vial, equivalent to 500 mg of phenytoin sodium after administration)
 Dosage and administration: see enclosed package insert
 Product monograph available to health care professionals upon request
 Store under refrigeration (2 to 8°C)

* TMMC de ERFA Canada 2012 INC C32581 32581ET04

Next Steps

- Continued phased-in implementation of the Plain Language Labelling initiative for non-prescription products
 - Mock-ups, Drug Facts table, brand name review
- Development and implementation of PLL for natural health products
- Ongoing learning and sharing on practices that support the safe use of health products in Canada

Thank You!

