Health Canada Santé Canada

Canada

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 was gap 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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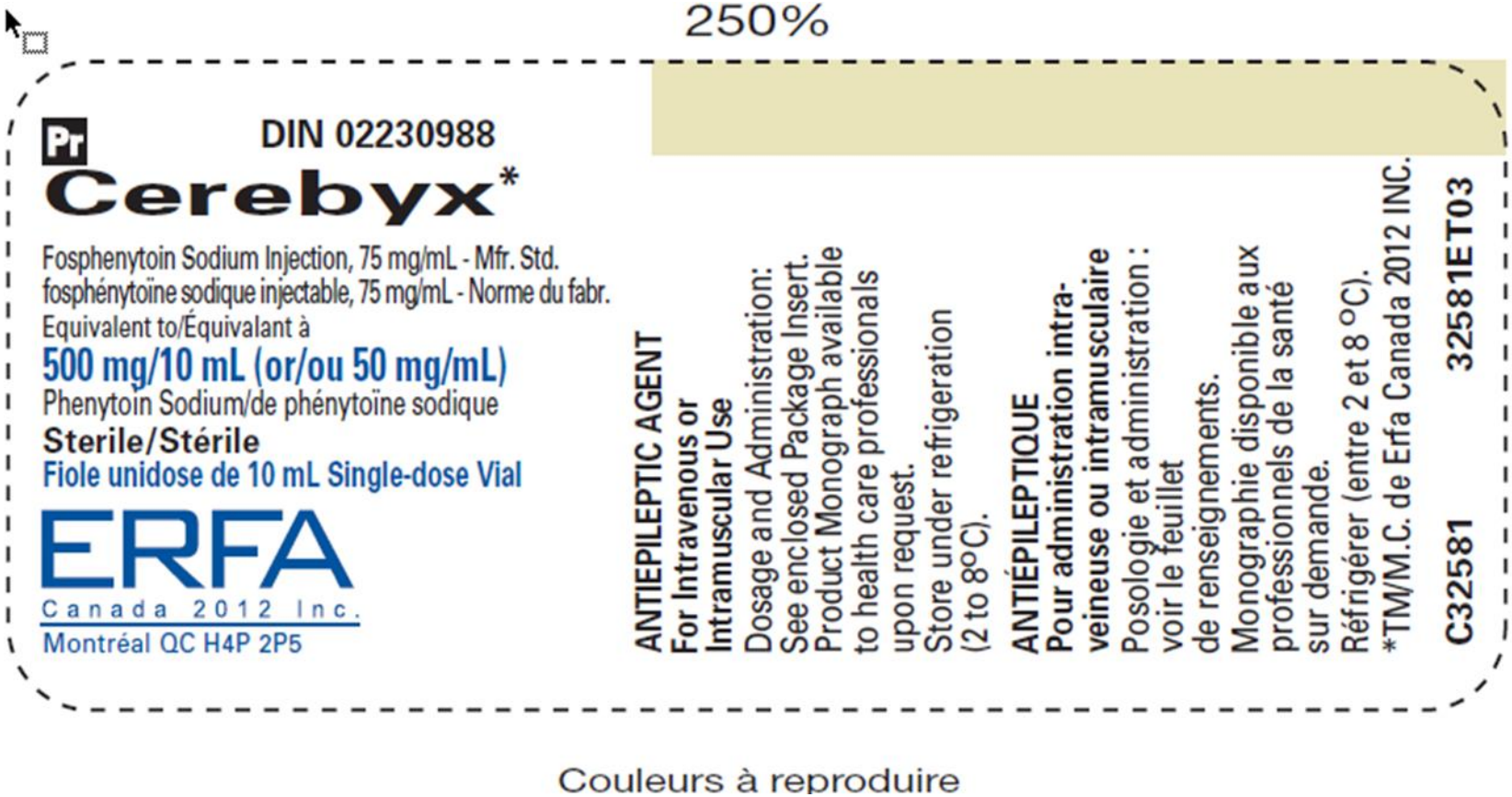
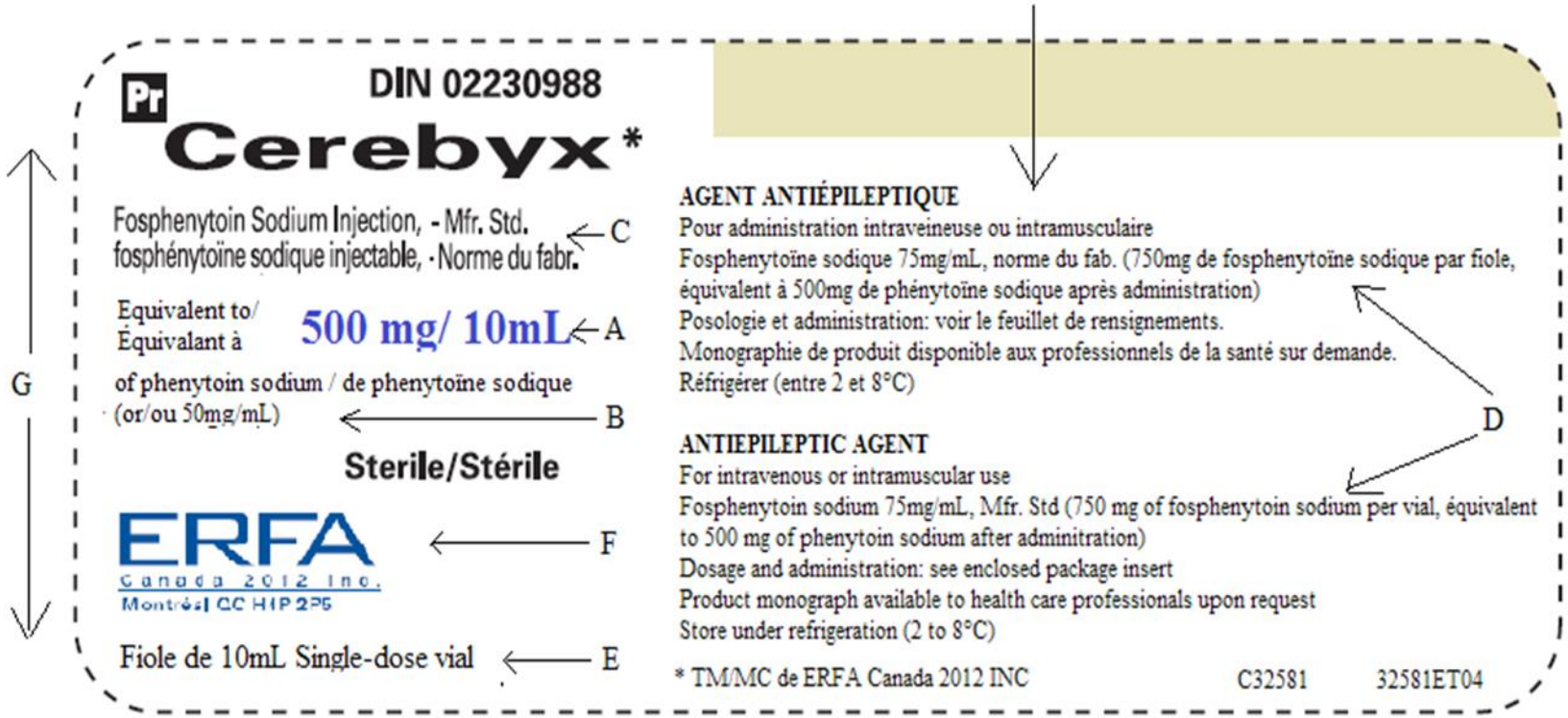
Good Label and Package Practices Guides

- 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



Label – Design for Safety



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!