

PRESS RELEASE

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IMSN and FDA Hold Global Summit on Drug Packaging and Labeling

Bethesda, Md—The International Medication Safety Network (IMSN) and the US Food and Drug Administration (FDA) held a summit for regulators on drug container labeling and packaging safety on June 19 and 20, 2018, to advance global harmonization of standards and reduce overall harm associated with medication errors. One of the goals of the meeting was to create a minimum set of best practices for labeling and packaging aimed at reducing medication errors. Another goal was to promote the use of technologies to reduce medication errors, which led to discussions regarding the need for an international barcode standard.

The summit was held at the FDA White Oak (Silver Spring) campus in MD, and brought together regulators, FDA staff, IMSN members, and invited speakers. The meeting was co-chaired by FDA's Lubna Merchant, Deputy Director of the Office of Medication Error Prevention and Risk Management and Acting Director of the Division of Medication Error Prevention and Analysis, and Michael Cohen, chair of IMSN and president of the Institute for Safe Medication Practices (ISMP).

Summit participants included the Brazilian Health Regulatory Agency (ANVISA), Mexico Federal Commission for the Protection against Sanitary Risks (COFEPRIS), European Medicines Agency (EMA – European Union), Health Canada Portugal National Authority of Medicines and Health Products (INFARMED), Netherlands Medicines Evaluation Board (MEB), United Kingdom Medicines & Healthcare products Regulatory Agency (MHRA), Saudi Food and Drug Authority (SFDA), ISMP, FDA, and the World Health Organization (WHO).

The major issue addressed at the summit was the fact that many product containers in various countries exhibit labeling and packaging issues that contribute to errors. Also, in many countries domestic drug manufacturing does not exist, so drugs are commonly imported, often with features that can result in safety issues. Some international regulators have undertaken successful packaging and labeling changes that have reduced the risk of errors; the June meeting provided an opportunity to share these experiences.

Participants agreed that guidelines are needed regarding the presentation of critical label information to deal with look-alike labels, noting that logos and highly stylized graphics detract from readability of the label. They also suggested review of existing guidelines and consideration of the following best practices related to drug labeling and packaging:

- Include both the per mL and the per container quantity, not the per mL quantity alone, when presenting the concentration for injectables
- Use metric units for products, and eliminate ratio expressions
- Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, or trailing zeros (e.g., 1.0) to express strength

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- Prominently display cautionary statements on carton and immediate container labels of neuromuscular blockers, potassium chloride concentrate injection, methotrexate, and other selected error-prone medications
- Use contrasting label backgrounds for the printing on glass ampules, and recommend font size and label orientation, to improve readability
- Physically link or integrate diluents with drugs that are powders
- Increase the adoption of ready-to-use/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation
- Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdoses
- Include barcodes on packages so they can be scanned at the bedside or other locations where medications are dispensed or administered by healthcare providers

Summit participants also discussed processing and sharing of medication error information by global pharmacovigilance (PV) centers. A recommendation was made for the PV centers to seek input from healthcare practitioners and medication/patient safety organizations such as those already established in many of the IMSN member countries.

Finally, participants agreed to create a white paper to promulgate these best practices. Further meetings and discussions are planned, including a follow-up meeting in Cascais, Portugal, during which industry participation will be sought.

About IMSN: The International Medication Safety Network (IMSN) is an international network of safe medication practice centers established with the aim of improving patient safety. This is achieved by operating medication error reporting programs and producing guidance to minimize preventable harm from medicine use in practice. IMSN promotes safer medication practices to improve patient safety internationally. For more information, visit: www.intmedsafe.net/about/

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