Pharmacovigilance and Medication Error Reporting Systems:

Overview of FDA’s Pharmacovigilance and Medication Error Reporting Systems

FDA/IMSN Summit
June 20, 2018

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Medication Errors are a Global Public Health Burden

EMA to Review Methotrexate Overdose and Dosing Errors

Psychiatric patient given wrong medication due to misspelling

Death Associated with an IV Compounding of Care in a Naturopathic Centre

Preventing Medication Errors: A $21 Billion Opportunity

WHO launches global effort to halve medication-related errors in 5 years

Dutch hospitals pay out millions

NHS medication errors contribute to as many as 22,000 deaths a year, major report shows

Medical errors under the spotlight at key forum in Riyadh
FDA Centers and Reporting Systems

CDER  Center for Drug Research and Evaluation: FAERS, DQRS

CBER  Center for Biologics Research and Evaluation: VAERS, FAERS

CFSAN  Center for Food Science and Applied Nutrition: CAERS

CDRH  Center for Devices and Radiologic Health: MAUDE, SUS

CTP  Center for Tobacco Products: CTP AE IMAGE

CVM  Center for Veterinary Medicine: PV-Works
Division of Medication Error Prevention and Analysis (DMEPA)

- Located within CDER (Center for Drug Research and Evaluation)
- Dedicated solely to medication error prevention and analysis for drug products
- Perform premarket reviews and postmarket pharmacovigilance for assigned drug products
- Use FAERS (FDA Adverse Event Reporting System) as primary source for postmarket monitoring of medication errors
Medication Error Reports in FAERS*

*Based on the MedDRA SMQ *Medication errors (narrow)*, V21
Medication Error Signal Detection and Analysis

• Focus on US FAERS reports (non-US products may have different labeling, practice settings, etc.)
• Form partnerships with patient safety organizations, USP, and other drug safety stakeholders
• Host teleconferences and collaborate with other regulatory agencies and FDA Centers
• Review periodic safety reports submitted by industry
• Evaluate and implement tools to use machine learning technology, predictive analytics, and other data sources
Challenges With Medication Error Pharmacovigilance

- Different medication error terminology, reporting requirements, labeling and product design, clinical practices
- Incomplete reports/lack of reporting forms tailored to capture medication error information
- Accurate product identification
  - Nomenclature (e.g., acetaminophen vs paracetamol, biosimilar suffixes)
  - Products with the same proprietary name but different ingredients
- Inconsistent and ambiguous coding of medication errors
- Identifying and reviewing labeling from other countries
- Timely sharing of information
Conclusion

• Medication errors are a global public health burden

• There is a need for harmonization, especially in the areas of:
  – Reporting (to capture relevant information)
  – Product identification
  – Medication error terminology and coding

• The timely sharing of information is imperative for medication error prevention and analysis