

Pharmacovigilance and Medication Error Reporting Systems:

Overview of FDA's Pharmacovigilance and Medication Error Reporting Systems

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Medication Errors are a Global Public Health Burden



EMA to Review Methotrexate Overdose and Dosing Errors



ISMP Canada Safety Bulletin
Psychiatric patient given wrong medication due to misspelling
Inspection of Owencurra centre in Cork, found a 'serious medication error'

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

Preventing Medication Errors: A \$21 Billion Opportunity



Spanish medicines regulator, AEMPS, the

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

Dutch hospitals pay out millions

son to medication error

Safe Medication Practices

ch™ (Quarter 3 2017)

medications using the Ellipta device, and loperamide abuse

ed in the Dutch Jour

cost of damage cla

News > Health

SAFETY briefs

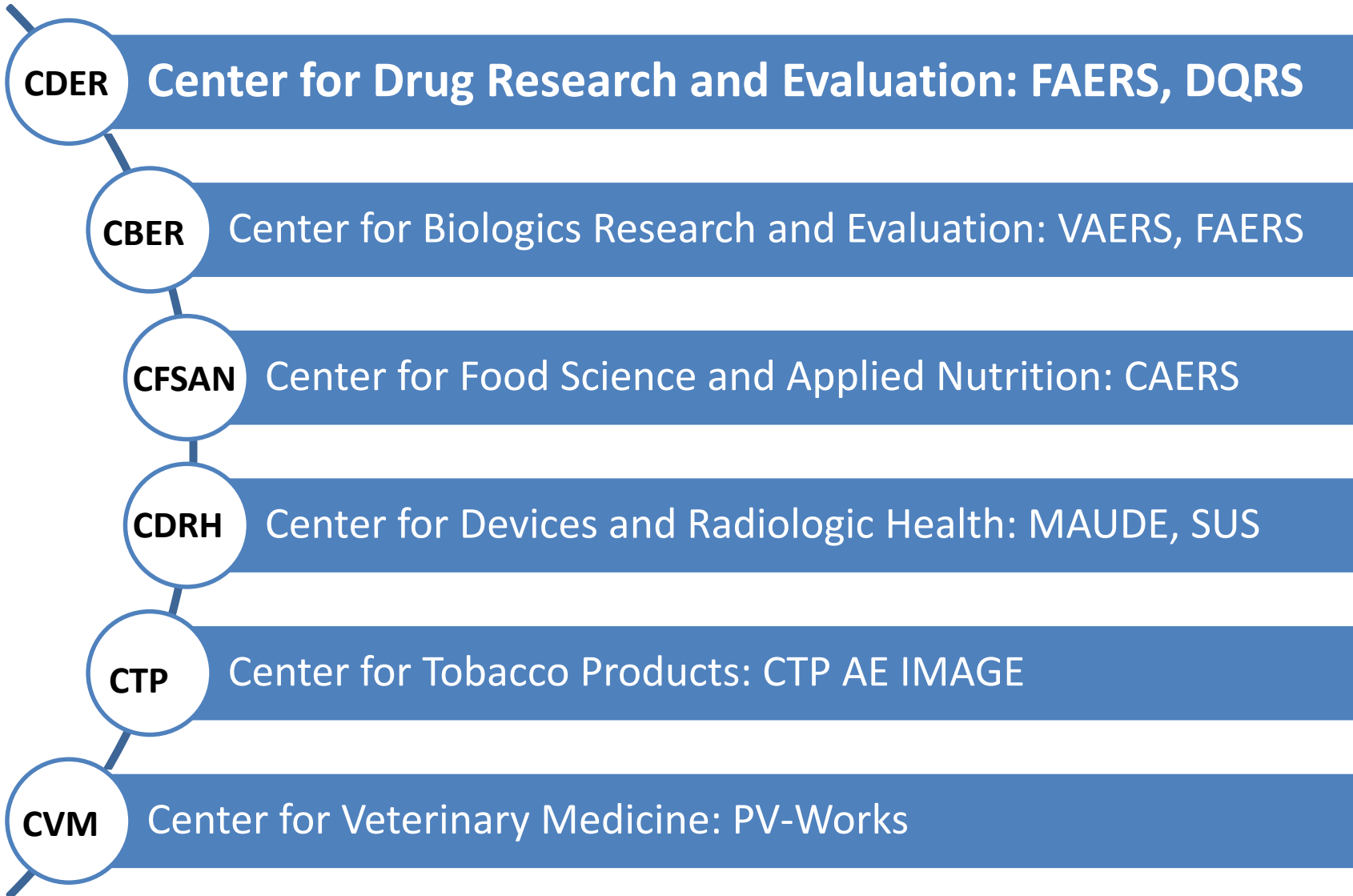
Multivitamin injection label error. The vial label on the single dose INFUVITE Adult multiple vitamins injection, manufactured

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

PAMELA COWAN, REGINA LEADER-POST Upd

Medical errors under the spotlight at key forum in Riyadh

FDA Centers and Reporting Systems



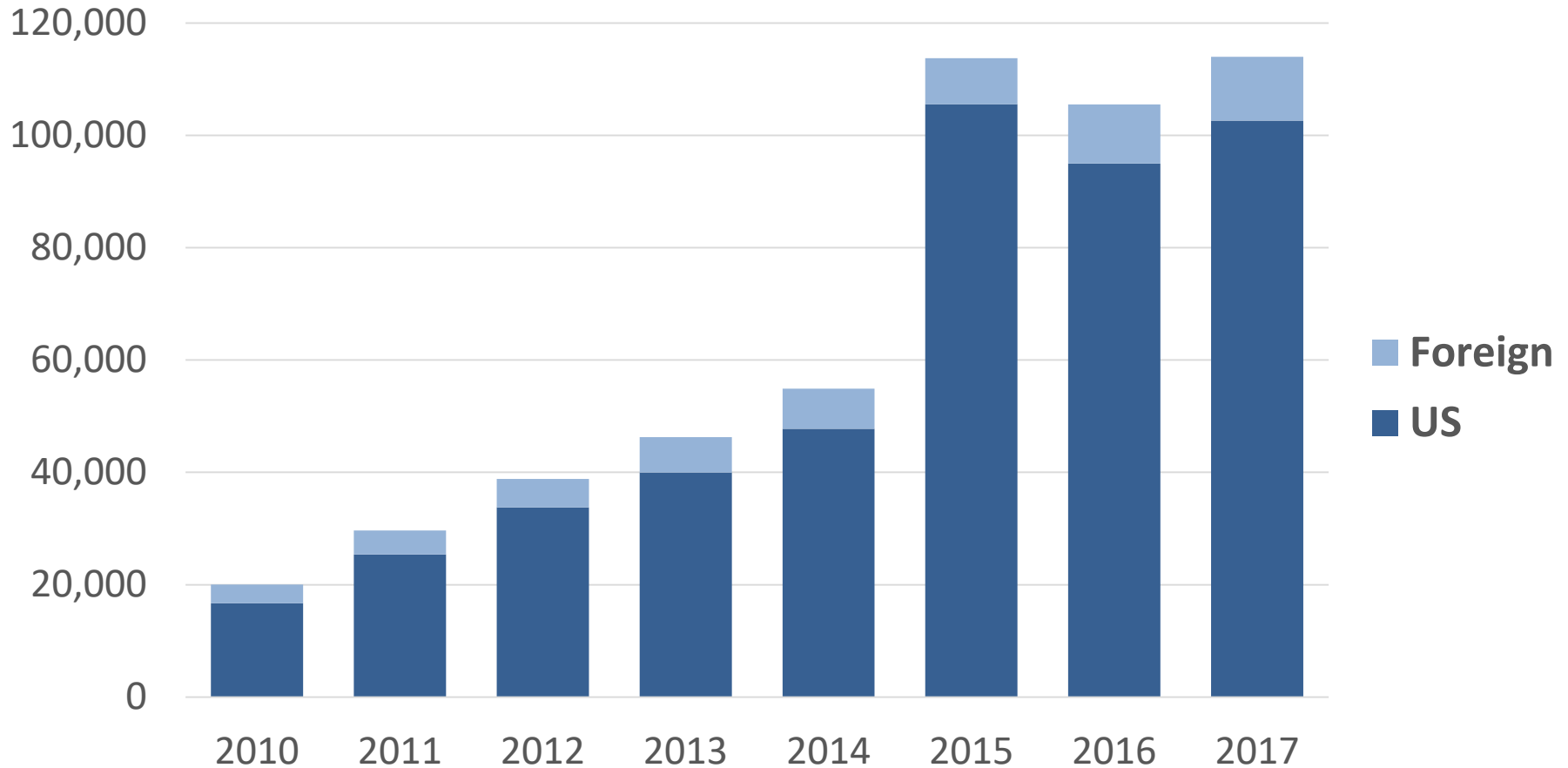


Division of Medication Error Prevention and Analysis (DMEPA)

- 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

