

Assessment and Reporting of Adverse Drug Reactions

Dr. Christine Chamberlain, PharmD, BCPS, CDE

Resources for Further Reading

Drug labels: DailyMed.nlm.nih.gov and Drugs@FDA:
<https://www.accessdata.fda.gov/scripts/cder/daf/>

MedWatch: <http://www.fda.gov/Safety/MedWatch/>

REMS Basics: <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm>

FDA Postmarket Drug and Biologic Safety Evaluations:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm>

European Medicines Agency (See "Patient Safety" tab): <http://www.ema.europa.eu/ema/>

Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS):
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/UCM082196>

References (in the order cited)

The Importance of Pharmacovigilance, World Health Organization 2002 (Slide 9)

Drug labels: DailyMed.nlm.nih.gov and Drugs@FDA (Slide 22)

Livertox (NLM and NIDDK) and Micromedex (Slide 22)

FDA Safety Alerts at
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/default.htm> (Slide 22)

Naranjo CA. *Clin Pharmacol Ther* 1981;30:239-45 (Slide 28)

Electronic Code of Federal Regulations, <http://www.ecfr.gov/cgi-bin/text-idx?SID=b79d08f290d0fe79d912bd82e97bd16f&node=21:5.0.1.1.4.2.1.11&rgn=div8> (Slide 31)

MedWatch: <http://www.fda.gov/Safety/MedWatch/> (Slide 32)

Guidance for Industry - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, March 2005:
<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071696.pdf> (Slide 34)

Uppsala Monitoring Center, Pharmacovigilance, Signals. <https://www.who-umc.org/research-scientific-development/signal-detection/signal/> (Slide 39)

Note that all websites were accessed on 09-Jan-2018