Assessment and Reporting of Adverse Drug Reactions
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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