Activity Outline
DDI Webinar Series: FDA Post-Marketing Drug Safety Surveillance
March 7, 2017 1:00-2:00pm EST
Webinar

Description
This series of educational webinars is designed to aid Pharmacists, Nurses, Physicians, Physician Assistants, students, and other health care professionals in providing better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety. This webinar will provide an overview of pharmacovigilance, which is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems, and will describe FDA's pharmacovigilance activities.

References

- Arthur N et al. The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products. WHO 2002.
- Drug Safety Communications: http://www.fda.gov/Drugs/DrugSafety/ucm199082.htm
- Guidance for Industry- Post-marketing Safety Reporting for Human Drug and Biological Products including Vaccines, March 2001: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074850.htm
- Guidance for Industry- Good Pharmacovigilance Practices and Pharmaco-epidemiologic Assessment, March 2005: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program: http://www.fda.gov/Safety/MedWatch/default.htm
- MedWatch Medical Product Safety Information: http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm
- MedWatch Safety Alerts: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.htm
- MedWatch Safety Alert RSS Feed: http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/MedWatch/rss.xml
- Post-market Drug Safety Information for Patients and Providers (FDAAA 915): http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm
- Post-marketing Drug and Biologic Safety Evaluations: (FDAAA 915): http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm
- Potential Signals of Serious Risks/New Safety Information Identified from AERS (FDAAA 921): http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm#QuarterlyReports

Series Objectives
- Explain how to utilize FDA's drug information, medication safety resources, and regulatory guidance documents, to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling changes which would impact prescribing and medication management to optimize patient care.

Session Learning Objectives
After completion of this activity, the participant will be able to:

- Define pharmacovigilance and adverse drug reactions
- Describe the Division of Pharmacovigilance (DPV)
- Identify the components of post-marketing drug safety surveillance
- Cite regulatory requirements and the role of MedWatch for reporting post-marketing safety information
- Summarize how adverse event reports are collected and analyzed by FDA/CDER/DPV

Target Audience
This activity is intended for physicians, nurses, pharmacists, pharmacy technicians, physician assistants, students, and other healthcare professionals.

Schedule

Time	Title	Lecturer(s)
Time: 1:00 PM to 2:00 PM	DDI Webinar Series: FDA Post-Marketing Drug Safety Surveillance	LT. Ofir Noah Nevo, PharmD, BCPP

Continuing Education
The Food and Drug Administration, Center for Drug Evaluation and Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Food and Drug Administration – Center for Drug Evaluation and Research designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians and Physician Assistants should claim only the credit commensurate with the extent of their participation in the activity.

The FDA-Center for Drug Evaluation and Research is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. (ACPE Universal Activity No. 0601-0000-17-025-L04-P and ACPE Universal Activity No. 0601-0000-17-026-L04-T). This program meets the criteria for 1 contact hour(s) of pharmacy education and pharmacy technician education.

This activity is a knowledge-based activity. These CE activities are primarily constructed to transmit knowledge (i.e., facts). The facts must be based on evidence as accepted in the literature by the health care professions.

FDA, Center for Drug Evaluation and Research is an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
This 1 contact hour Education Activity is provided by FDA, Center for Drug Evaluation and Research. Each nurse should claim only the time that he/she actually spent in the educational activity.

Requirements for receiving CE credit
Physicians, nurses, pharmacists, and pharmacy technicians, and those claiming non-physician CME: attendance is verified by Adobe Connect login or by a sign-in sheet, and completion of the final activity evaluation. Final activity evaluations must be completed within two weeks after the activity.

Pharmacists and Pharmacy Technician participants: partial credit cannot be awarded therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists and Pharmacy Technicians will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Statements of Credit
Physicians and Nurses Statements of Credit for CE will be issued 10 weeks after the last session of this activity. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

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Disclosure
Faculty:
- LT. Ofir Noah Nevo, PharmD, BCPP, Safety Evaluator, FDA/CDER/OSE/OPE/DPV-nothing to disclose.

Planning Committee:
- Kara Burke, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Kimberly DeFronzo, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Virginia Giroux, MSN, ARNP, CE Program Administrator, FDA/CDER/OEP/DLOD-nothing to disclose
- Lesley Navin, RN, MSN, Consumer Safety Officer, FDA/CDER/OCOMM/DDI-nothing to disclose
- Danielle Molnar, PharmD, Consumer Safety Officer, FDA/CDER/OCOMM/DDI – nothing to disclose
- Edward Weinstein, MD, Medical Officer, Office of New Drugs, Division of Anti-Infective Products-nothing to disclose

CE Consultation and Accreditation Team
- Justin Gorinson, CHES, ORISE Fellow, FDA/CDER/OEP/DLOD-nothing to disclose

- Karen Zawalick, CE Consultation and Accreditation Team Leader, FDA/CDER/DLOD-nothing to disclose

Registration Fees and Refunds
Registration is complimentary therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the lectures (verified by a sign-in sheet).

Initial Release Date: March 7, 2017