Activity Outline
FDA Drug Topics: FDA's Postmarketing Drug Safety Surveillance System
April 21, 2020
FDA

Activity Coordinator:
Lesley Navin (Lesley.Navin@fda.hhs.gov), Kimberly DeFronzo (Kimberly.Defronzo@fda.hhs.gov), Kara Burke (Kara.Burke@fda.hhs.gov),

Series Description

This series of educational webinars is designed to aid physicians, physician assistants, nurses, pharmacists, pharmacy technicians, certified public health professionals, other health care professionals, and students, to provide better patient care by knowing how to find relevant FDA regulatory information that will improve drug safety.

Lecture Description
This webinar will discuss the FDA's postmarketing drug safety surveillance activities, how adverse event reports are collected and analyzed by FDA and how safety findings are communicated to the public.

References

- World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of medicinal products. (2002). Available at: http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf?ua=1. Accessed January 17, 2020
- Strom BL, Kimmel SE, Hennessy S. Pharmacoepidemiology 5th edition (2012). Hoboken, NJ: Wiley-Blackwell.
- U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) Public Dashboard. Available at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm
- U.S. Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at: https://www.fda.gov/Safety/MedWatch/default.htm
- U.S. Food and Drug Administration. MedWatch Consumer Voluntary Reporting (FORM FDA 3500B). Available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf

Series Objectives

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

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

- Describe FDA's postmarketing drug safety surveillance system
- Identify the components of postmarketing reporting and signal detection
- Summarize how adverse event reports are collected and analyzed by FDA
- Describe how safety findings are communicated to the public

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, physician assistants, and cph - certified public health.

Agenda

Lecture 1 April 21, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	FDA's Postmarketing Drug Safety Surveillance System	Kim Swank, PharmD

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-20-006-L04-P, and ACPE Universal Activity Number JA0002895-0000-20-006-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Swank, Kim, PharmD, pharmacist, FDA - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Kapoor, Rama, MD, Medical Officer, FDA - nothing to disclose
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.