Activity Outline
FDA Drug Topics: An update to the FDA Adverse Event Reporting System (FAERS) Public Dashboard
October 9, 2018
FDA

Activity Coordinator
Lesley Navin
Lesley.Navin@fda.hhs.gov

Series Description

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

Lecture Description
This webinar will provide an updated overview of the changes in the FAERS Public Dashboard, a highly interactive web-based tool that allows for the querying of FAERS data in a user-friendly fashion. These changes includes displaying report counts by quarter and month, search by reactions and data export. The intention of this tool is to expand access to the FAERS data to the general public to search for information related to human adverse events reported to the FDA by the pharmaceutical industry, healthcare providers and consumers. FDA anticipates that this increased transparency will help to spur the submission of more detailed and complete reports from consumers, health care providers and other members of the public.

References

- FDA Adverse Event Reporting System (FAERS) Public Dashboard at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm
- Questions and Answers on FDA's Adverse Event Reporting System (FAERS) at: https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm2007060.htm

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances 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 the FAERS public database and summarize the recent updates.
- Demonstrate how to use the FAERS public dashboard to view information on adverse event reporting metrics.
- Illustrate use of FAERS public dashboard to view adverse event information on a specific product.

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

Agenda

Lecture 1 October 9, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	An update to the FDA Adverse Event Reporting System (FAERS) Public Dashboard	Suranjan De

Continuing Education Accreditation

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

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.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 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 JA0002895-0000-18-027-L04-P, and ACPE Universal Activity Number JA0002895-0000-18-027-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).

Requirements for Receiving CE Credit

Physicians, 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 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

- De, Suranjan, SUPERVISORY HEALTH SCIENCE, FDA - nothing to disclose

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI - nothing to disclose
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Navin, Lesley, RN, MSN, CSO, FDA/CDER/DDI - nothing to disclose
- Weinstein, Edward, M.D., Ph.D., Medical Officer, CDER FDA *My spouse received Salary from EndoCentre of Baltimore for a role as Employee.*

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, 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.