Activity Outline
FDA Drug Topics: How FDA and ISMP Utilize Medication Error Reports to Improve Drug Safety
October 19, 2021
FDA

Activity Coordinator:
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Description
This webinar will describe the role of the FDA Division of Medication Error Prevention and Analysis (DMEPA) in preventing and addressing medication errors through pre-market and post-market activities. DMEPA collaborates with the nonprofit Institute for Safe Medication Practices (ISMP), to share information from the ISMP National Medication Errors Reporting Program in a way that benefits overall drug safety. Actions taken to address recent medication error reports will be explored, and the role of health care practitioners in identifying, preventing, and mitigating medication errors will be discussed.

References

- Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-drugs.
- Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors.
- Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-product-design-minimize-medication-errors-guidance-industry.
- Guidance for Industry: Applying Human Factors and Usability Engineering to Medical Devices: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices.
- A Lot Happens When You Report a Hazard or Error to ISMP – There's No "Black Hole" Here! https://www.ismp.org/acute-care/medication-safety-alert-november-7-2019.
- Pump Up the Volume: Tips for Increasing Error Reporting and Decreasing Patient Harm https://www.ismp.org/resources/pump-volume-tips-increasing-error-reporting-and-decreasing-patient-harm.

Learning Objectives

- Explain FDA's role in pre-marketing and post-marketing activities to prevent and address medication errors.
- Summarize how HCPs can help identify, prevent, and mitigate medication errors through adverse event reporting.
- Describe how FDA, ISMP utilize medication error reports to address reported safety issues.
- Outline strategies aimed to increase the safe use of drug products by minimizing user error related to the design, naming, labeling, and/or packaging of drug products.
- Review examples of actions taken to address recently reported medication error reports.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health Professionals (CPH), and physician assistants.

Agenda
Day 1 October 19, 2021

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Drug Topics: How FDA and ISMP utilize medication error reports to improve drug safety	Valerie Vaughan Michael Cohen, R. Ph

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 JA0002895-0000-21-074-L05-P, and ACPE Universal Activity Number JA0002895-0000-21-074-L05-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.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

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 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Cohen, Michael, R. Ph, President, ISMP *nothing to disclose*
- Vaughan, Valerie, 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*
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP *nothing to disclose*
- Rama, Kapoor, MD, Medical Officer, FDA *nothing to disclose*

CE Consultation and Accreditation Team

- Catherine Harrison, 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.

Requirements for Certificate of Completion (Non CE)
Must attend 100% of the activity.