Activity Outline
FDA Drug Topics: Role of FDA and ISMP in Preventing Medication Errors
June 30, 2020
FDA

Activity Coordinator:
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Description

This webinar will describe the role of the Division of Medication Error Prevention and Analysis (DMEPA) in preventing and addressing medication errors through pre-market and post-market activities. DMEPA also collaborates with external stakeholders, such as the nonprofit Institute for Safe Medication Practices (ISMP), a federally authorized patient safety organization (PSO). The webinar will illustrate how information from the ISMP National Medication Errors Reporting Program is shared with FDA in a way that benefits overall drug safety. Actions taken to address recent medication error reports will be explored, as well as the role of pharmacists in identifying, preventing and mitigating medication errors.

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- Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs: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- Draft Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors: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.
- ISMP. Start the New Year Off Right by Preventing These Top 10 Medication Errors and Hazards. https://www.ismp.org/acute-care/medication-safety-alert-january-16-2020.

Learning Objectives

- Describe FDA's role in pre-marketing and post-marketing activities to prevent and address medication errors.
- Outline strategies aimed to increase the safe use of drug products by minimizing use error that is related to the design, naming, labeling, and/or packaging of drug products.
- Review examples of recent medication error reports.
- Summarize how HCPs can help identify, prevent, and mitigate medication errors.

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

Agenda
Day 1 June 30, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	FDA Drug Topics: Role of FDA and ISMP in Preventing Medication Errors	Mishale Mistry, PharmD 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 JA0002895-0000-20-025-L05-P, and ACPE Universal Activity Number JA0002895-0000-20-025-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.

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

- Cohen, Michael, R. Ph, President, ISMP - nothing to disclose
- Mistry, Mishale, PharmD, Associate Director, 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.

Requirements for Certificate of Completion (Non CE)
Must attend 80% of the activity.