Activity Outline
FDA Drug Topics: Labeling Made Simple: The How, What, and Where of Drug Interactions in Prescribing Information
October 27, 2020
FDA

Activity Coordinator:
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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 presentation will provide an overview of the evolution of prescribing information (PI) format and content, key regulations impacting drug interaction (DI) content in the PI, and the regulatory science behind including essential DI information in the PI. In addition, alternative display methods to enhance readability and utility as well as unique DI related content (e.g., in vitro information, modeling and simulation, and complex DI scenarios) will also be discussed.

References

- Grillo, J. & Tran, M. Translation of drug interaction knowledge to actionable labeling. Clin. Pharmacol. Ther. 105, 1292– 1295 (2019).
- Leape, L.L. et al. Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA 274, 35– 43 (1995).
- Raschetti, R. et al. Suspected adverse drug events requiring emergency department visits or hospital admissions. Eur. J. Clin. Pharmacol. 54, 959– 963 (1999).
- McDonnell, P.J., Jacobs, M.R., Monsanto, H.A. & Kaiser, J.M. Hospital admissions resulting from preventable adverse drug reactions. Ann. Pharmacother. 36, 1331– 1336 (2002).
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products — Content and Format: Guidance for Industry. December 2016. (2016). Accessed August 20, 2020.
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements: Guidance for Industry. February 2013. . (2013). Accessed August 20, 2020.

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:

- Identify key regulations that impact drug interaction content in prescribing information (PI)
- Locate drug interaction content in the PI
- Discuss the content structure of the DRUG INTERACTIONS section in PI
- Identify alternative methods of communicating complex drug interaction content

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

Agenda

Lecture 1 October 27, 2020

Time	Topic	Speaker
1:00 - 2:00 PM	Labeling Made Simple: The How, What, and Where of Drug Interactions in Prescribing Information	Joseph Grillo

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.

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

Disclosure

Faculty

- Grillo, Joseph, Associate Director for Labeling and Health Communication, FDA/CDER/OTS/OCP *My spouse received Salary from Winchester Medical Center for a role as Employee*.

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
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/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.