Activity Outline
FDA Drug Topics: FDA's Web Resources Available to Healthcare Providers Who Prescribe and Dispense Medications with Risk Evaluation and Mitigation Strategies (REMS)
June 26, 2018
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, 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 introduce healthcare professionals to web resources about Risk Evaluation and Mitigation Strategies (REMS), including a REMS resource portal and the REMS@FDA website, and will focus on what type of information is available, where, and how to navigate these resources.

References

- Food and Drug Administration. REMS@FDA website [Internet]. Silver Spring (MD); 15 Jun 2015. Available from: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.
- Food and Drug Administration. REMS resource portal [Internet] Silver Spring (MD); 29 Jan 2018. Available from: https://www.fda.gov/Drugs/DrugSafety/REMS/default.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 web resource that defines a REMS and provides high-level descriptions of the roles of different healthcare providers in a REMS.
- Describe the web resource that provides a current listing of approved REMS and specifies the requirements of healthcare providers for each REMS.
- Locate additional REMS information and educational resources, as well as get answers to frequently asked questions.
- Summarize requirements for health care providers for the most recently approved REMS.
- Recognize how to provide feedback to FDA about these web resources.

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

Agenda

Lecture 1 June 26, 2018

Time	Topic	Speaker
1:00 - 2:00 PM	FDA's Web Resources Available to Healthcare Providers Who Prescribe and Dispense Medications with Risk Evaluation and Mitigation Strategies (REMS)	Amy Ramanadham Gary Slatko

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 1.00 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.

Pharmacy participants: partial credit cannot be awarded, therefore you must attend the entire activity to receive CPE credit. 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

- Ramanadham, Amy, Senior Regulatory Research Officer, U.S. Food and Drug Administration - nothing to disclose
- Slatko, Gary, Associate Director, FDA *My spouse received Salary from Abbvie Pharmaceuticals for a role as Employee.*

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

- 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.