REMS – Risk Evaluation and Mitigation Strategy

The Role of a Pharmacy Technician with REMS drugs

DATE: NOVEMBER 4TH, 2023 PRESENTED BY: ALLISON MISHKIN, CPhT

DISCLOSURE STATEMENT

There are NO relevant financial relationships:

Allison Mishkin, CPhT for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.

LEARNING OBJECTIVES

At the conclusion of these slides, participants will be able to:

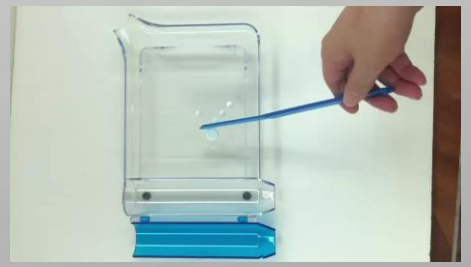
- Define the FDA REMS Program and understand various components of a REMS drug
- Be able to recognize some drugs with a REMS program
- Know the role(s) a CPhT has in a Pharmacy that dispenses REMS drugs

PRE-TEST QUESTIONS

- Why did the FDA create the REMS program?
  a) The program prevents medications from going generic too soon
  b) It is used to deter patients from using certain medications
  c) To ensure certain medications with safety risks can to come to market
  d) The FDA wanted to allow manufacturers to charge more money for costly drugs

PRE-TEST QUESTIONS

- What would make you think you are filling a REMS drug prescription?
  a) The Pharmacist must log in to a website and obtain an authorization to dispense
  b) The patient has to verify a pregnancy test has been completed
  c) The medication must be sent to a provider's office and the patient cannot pick up
  d) All of the above



PRE-TEST QUESTIONS

- How can a Pharmacy Technician help in ensuring Pharmacies stay compliant?
  a) The CPhT can counsel patients for REMS drugs only; using a medication guide
  b) Making sure all REMS drugs are double counted before returning the stock bottle to the shelf
  c) Retrospectively audit patient charts to ensure required elements are documented

"Trust yourself. Create the kind of self that you will be happy to live with all your life. Make the most of yourself by fanning the tiny, inner sparks of possibility into flames of achievement."

—Golda Meir

WHAT IS THE FDA REMS PROGRAM

- Created by the FDA which allows certain medications with safety risks to come to market, but require additional action to reduce the frequency and/or severity of adverse events
- The mitigation strategies used are unique to each drug
- Without a REMS, these medications would not be available to the patients who need it

RISKS TO MITIGATE

Examples of risk	Examples of action required
Liver damage	Patient must get a liver test before and during treatment
Severe birth defects	Patient must have a negative pregnancy test at all times
Anaphylaxis	Administered in a healthcare setting
Neutropenia	Get an Absolute Neutrophil Count

THE COMPONENTS OF A REMS DRUG

- A combination of required communication and/ or activities

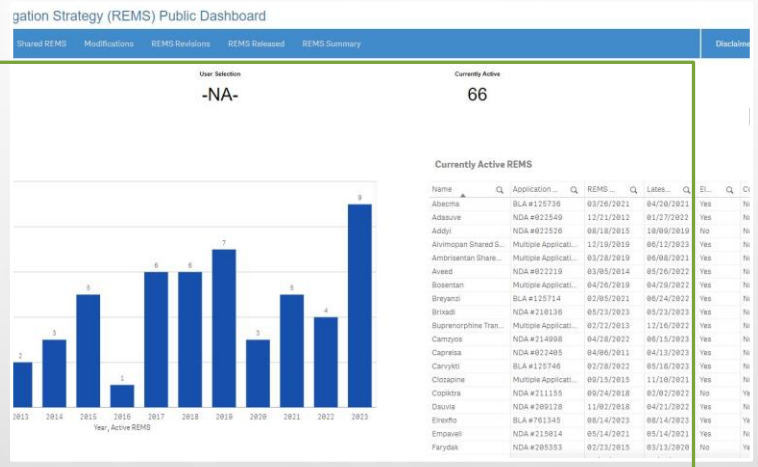
Printing a med guide or a patient package insert

A communication plan for healthcare providers

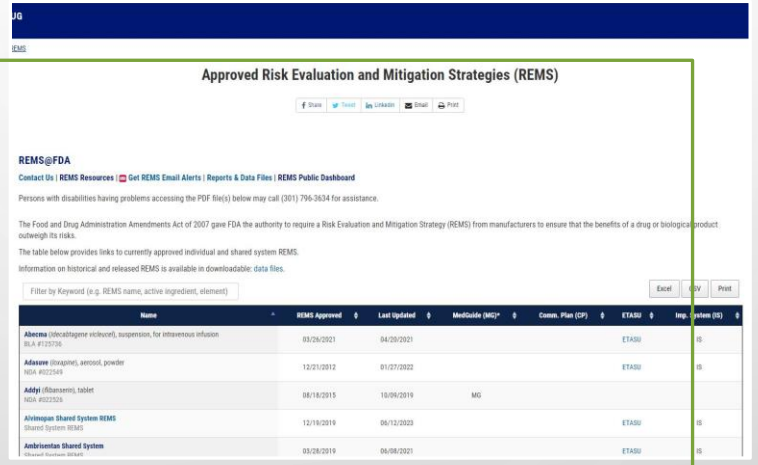
An implementation plan or system

Elements to assure safe use (ETASU)

LEARN HOW TO IDENTIFY A REMS DRUG



FDA REMS Public Dashboard



FDA REMS Main Page

REMS@FDA Updates for August 2023

1. TECVAYLI (teclistamab-cqyv) and TALVEY (talquetamab-tgvs) REMS modified August 9th, to update the REMS name from TECVAYLI REMS to TECVAYLI and TALVEY REMS in the labeling and proposed modifications to the approved TECVAYLI REMS to form a combined REMS with talquetamab.

2. HEPZATO (melphalan) REMS approved August 14th.

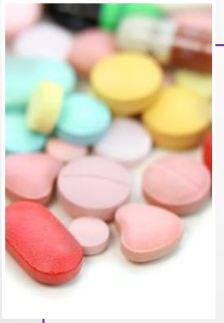
3. ELREXFIO (elranatamab-bcmm) REMS approved August 14th.

4. TYSABRI (natalizumab) REMS modified August 24th to make changes to the following materials:

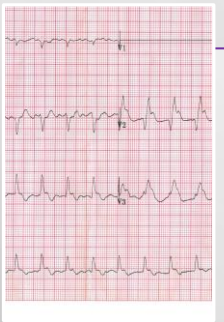
- REMS Document
- Prescriber Enrollment Form
- Patient Enrollment Form – Multiple Sclerosis
- Patient Enrollment Form – Crohn's Disease
- Pharmacy Enrollment Form
- Infusion Site Enrollment Form
- Educational Slide Set
- Overview

FDA Emailed Updates

DIFFERENT TYPES OF DRUGS AND MONITORING



Some drug classes in the REMS program are Opioid Analgesics, the much talked about abortion pill, a few anti-psychotics/anti seizure and some cancer targeting medications



Some programs are in place specific to the sex of the patient, other programs require some monitoring, others simply require a med guide be given to patient

Many require documentation and record keeping

THE ROLE PHARMACY TECHNICIAN

- There are opportunities for Pharmacy Technicians to participate in dispensing REMS drugs to patients

- As the duties of a Pharmacy Technician evolve, so do the opportunities. REMS drugs are highly regulated and require extra attention from Pharmacy staff

- In order to maintain the privilege of dispensing REMS drugs we must adhere to the REMS requirements at every step

CONCLUSION

- In 2008, The FDA created a program that allows medications with risk to come to market for patients who need it
- The REMS programs are unique to each medication
- Pharmacy Technicians can play an important role in ensuring Pharmacies remain compliant

POST-TEST QUESTIONS AND ANSWERS

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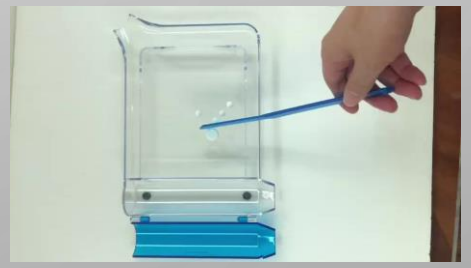

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QUESTIONS AND ANSWERS

REFERENCES

- https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
- https://fis.fda.gov/sense/app/ca606d81-3f9b-4480-9e47-8a8649da6470/sheet/dfa2f0ce-4940-40ff-8d90-d01c19ca9c4d/state/analysis
- https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

THANK YOU