



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



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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

gation Strategy (REMS) Public Dashboard

Shared REMS | Modifications | REMS Revisions | REMS Released | REMS Summary | Disclaimers

User Selection: -NA- | Currently Active: 66

Name	Application	REMS	Labels	EL	CI
Abeceira	BLA #125736	03/26/2021	04/20/2021	Yes	No
Adasave	NDA #021549	12/21/2012	01/27/2022	Yes	No
Adly	NDA #022926	08/18/2015	10/09/2019	No	No
Advionon Shared S	Multiple Applicat...	12/19/2019	06/12/2023	Yes	No
Ambrientan Shared S	Multiple Applicat...	03/28/2019	06/08/2021	Yes	No
Aveed	NDA #022219	03/05/2014	05/26/2022	Yes	No
Bosentan	Multiple Applicat...	04/26/2019	04/29/2022	Yes	No
Sneyanci	BLA #125714	02/05/2021	06/24/2022	Yes	No
Sinoxal	NDA #210136	05/23/2023	05/23/2023	Yes	No
Supernorphine Tran	Multiple Applicat...	02/22/2023	12/16/2022	Yes	No
Camryce	NDA #214998	04/28/2022	06/15/2023	Yes	No
Caprisa	NDA #022485	04/06/2011	04/13/2023	Yes	No
Carvykti	BLA #125746	02/28/2022	05/18/2023	Yes	No
Clozapine	Multiple Applicat...	09/15/2015	11/10/2021	Yes	No
Capztra	NDA #211195	09/24/2018	02/02/2022	No	Yes
Clavira	NDA #091720	11/02/2016	04/21/2022	Yes	No
Eleprex	BLA #213143	08/24/2023	08/24/2023	Yes	Yes
Empaveli	NDA #215014	05/14/2021	05/14/2021	Yes	No
Farydak	NDA #208353	02/23/2015	03/13/2020	No	Yes

FDA REMS Public Dashboard

Approved Risk Evaluation and Mitigation Strategies (REMS)

REMS@FDA

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The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

Information on historical and released REMS is available in downloadable data files.

Filter by Keyword (e.g. REMS name, active ingredient, element)

Name	REMS Approved	Last Updated	MedClass (MCC)*	Comm. Plan (CP)	ETASU	Imp. Dates (IS)
Abeceira (lisdexamfetamine dimesylate), suspension, for intravenous infusion BLA #125736	03/26/2021	04/20/2021			ETASU	IS
Adasave (lurasidone), extended-release, powder NDA #022489	12/21/2012	01/27/2022			ETASU	IS
Adly (lurasidone), tablet NDA #022926	08/18/2015	10/09/2019	MG			
Advionon Shared System REMS Shared System 30365	12/19/2019	06/12/2023			ETASU	IS
Ambrientan Shared System Shared System 30365	03/28/2019	06/08/2021			ETASU	IS

FDA REMS Main Page

REMS@FDA Updates for August 2023

- [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.
- [HEPZATO \(melphalan\) REMS](#) approved August 14th.
- [ELREXFIO \(elranatamab-bcmm\) REMS](#) approved August 14th.
- [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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QUESTIONS AND ANSWERS



REFERENCES

- <https://www.accessdata.fda.gov/scripts/cder/remes/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-remes>





THANK YOU