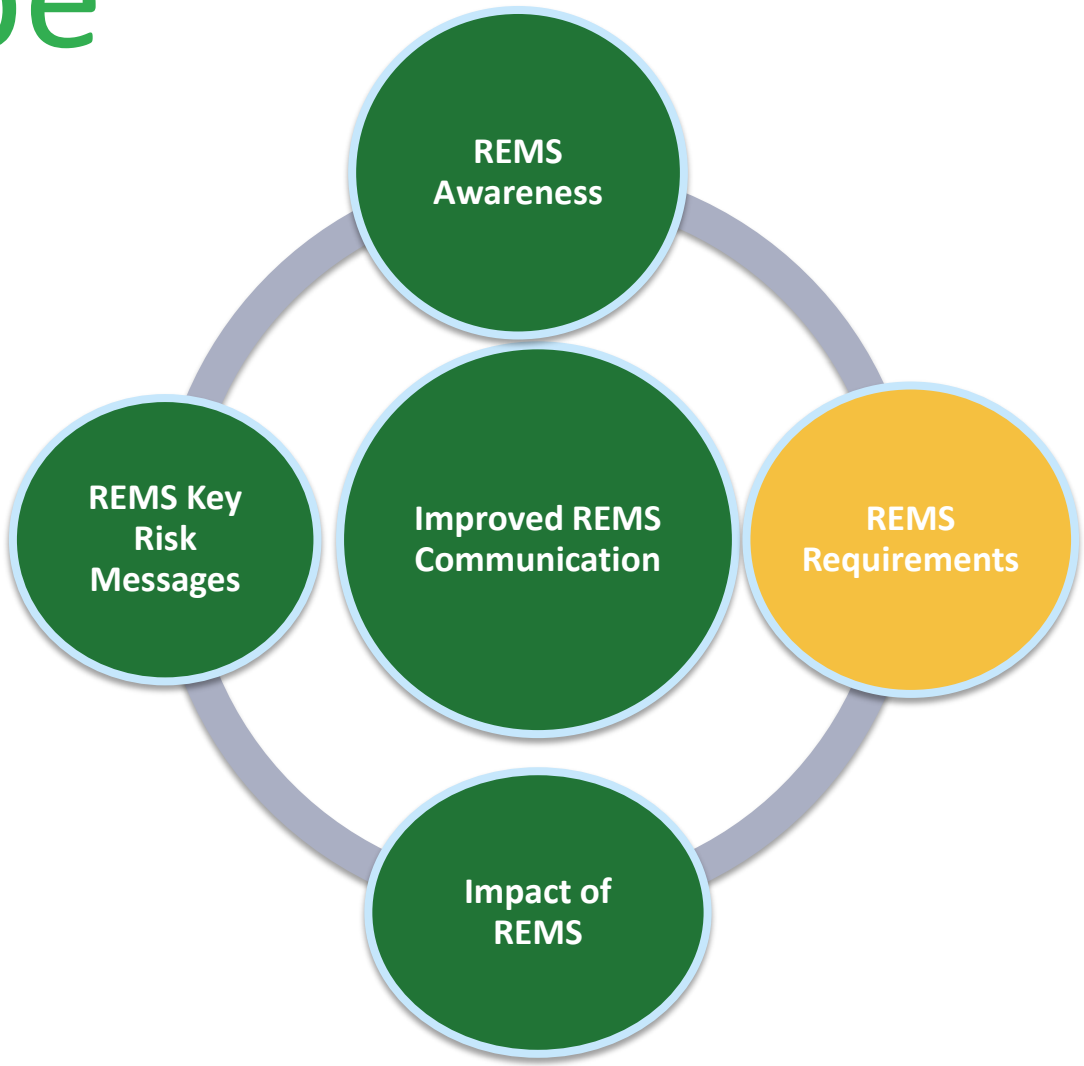
REMS Summary

A new approach to communicating REMS requirements

Gita A. Toyserkani, Pharm.D., MBA
Regulatory Health Policy Analyst
Office of Medication Error Prevention and Risk Management
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Scope


REMS Awareness
REMS Key Risk Messages
Improved REMS Communication
REMS Requirements
Impact of REMS

Purpose

- Develop a method to share clear and consistent information about the REMS requirements --> facilitates integrating REMS into the healthcare system
- Establish best practices and allow for continuous quality improvement

Content

1. **Background**
2. Stakeholder feedback
3. REMS Summary
4. Conclusion and next steps

All REMS come to FDA as a "REMS Document" with "Appended Materials"

REMS Document

Initial REMS Approval: 05/2013
Most Recent Modification: 10/2015

NDA 12345 WELIPAX (Weliparamax)

Access Analogue
FarmaFa Inc.
10901 Public Avenue
Burden, AC 21301
Phone: (800) -555-7777

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

The goals of the Welipax REMS is to mitigate the risk of hepatotoxicity associated with Welipax by:

- Informing patients about the risk listed above associated with the use of Welipax.
- Informing healthcare providers about the risk listed above associated with Welipax.
- Monitoring LFTs prior to receiving each Welipax prescription.

II. REMS ELEMENTS:

A. Medication Guide or PPI

A Medication Guide will be dispensed with each Welipax prescription in accordance with 21 CFR 208.24.

B. Elements To Assure Safe Use

A. Healthcare providers who prescribe Welipax are specially certified.

a. To become specially certified to prescribe Welipax in the Welipax REMS Program, healthcare providers must:

i. Review the Prescribing Information for Welipax.

ii. Complete the Welipax training and successfully complete the knowledge assessment.

iii. Enroll in the Welipax REMS Program by completing and submitting the Prescriber Enrollment form.

1. As a condition of certification, prescribers must:

i. Enroll each patient in the Welipax REMS Program by the following:

1) Counsel the patient about the risk of severe hepatic injury associated with

+

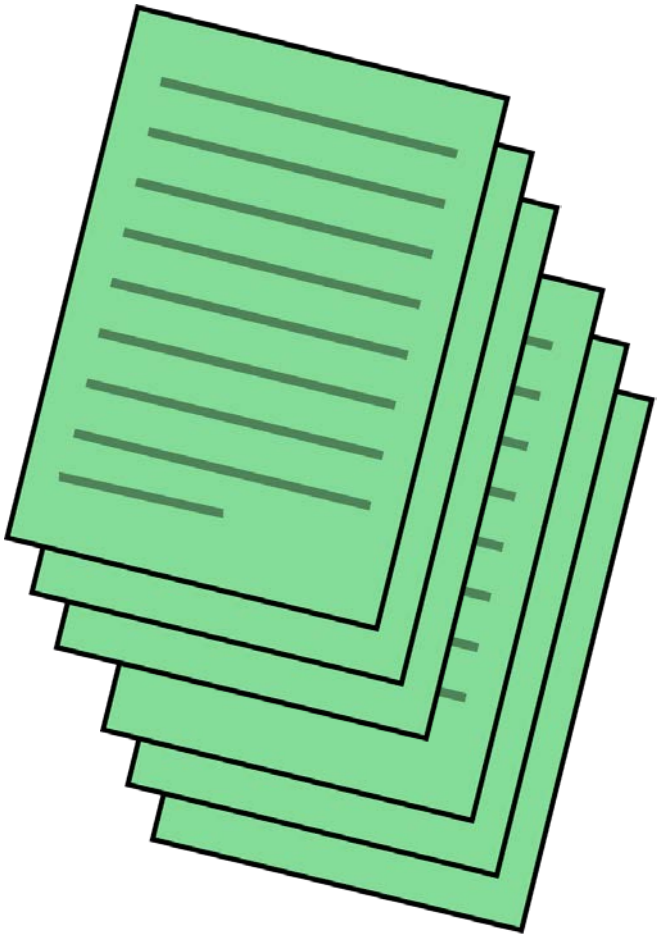
Appended Materials

REMS Document

- The 'face' of the REMS
- Serves several purposes:
  - Designed for regulatory purposes and uses regulatory terms
  - Communicate the REMS requirements for sponsors
  - Communicate the REMS requirements for stakeholders (e.g., prescribers, pharmacists, healthcare administrators, distributors, patients)
- The only document that captures the requirements for all applicable stakeholders
- Organized by "elements" (e.g., Medication Guide, communication plan, Elements to Assure Safe Use (ETASU))

REMS Appended Materials

- Medication Guide
- REMS program communications
- REMS Print Materials
- REMS training materials
- Enrollment forms to support certification
- Patient-Prescriber Agreement Form (PPAF)
- Additional REMS materials
- REMS-dedicated Website



Little standardization on how REMS processes are described

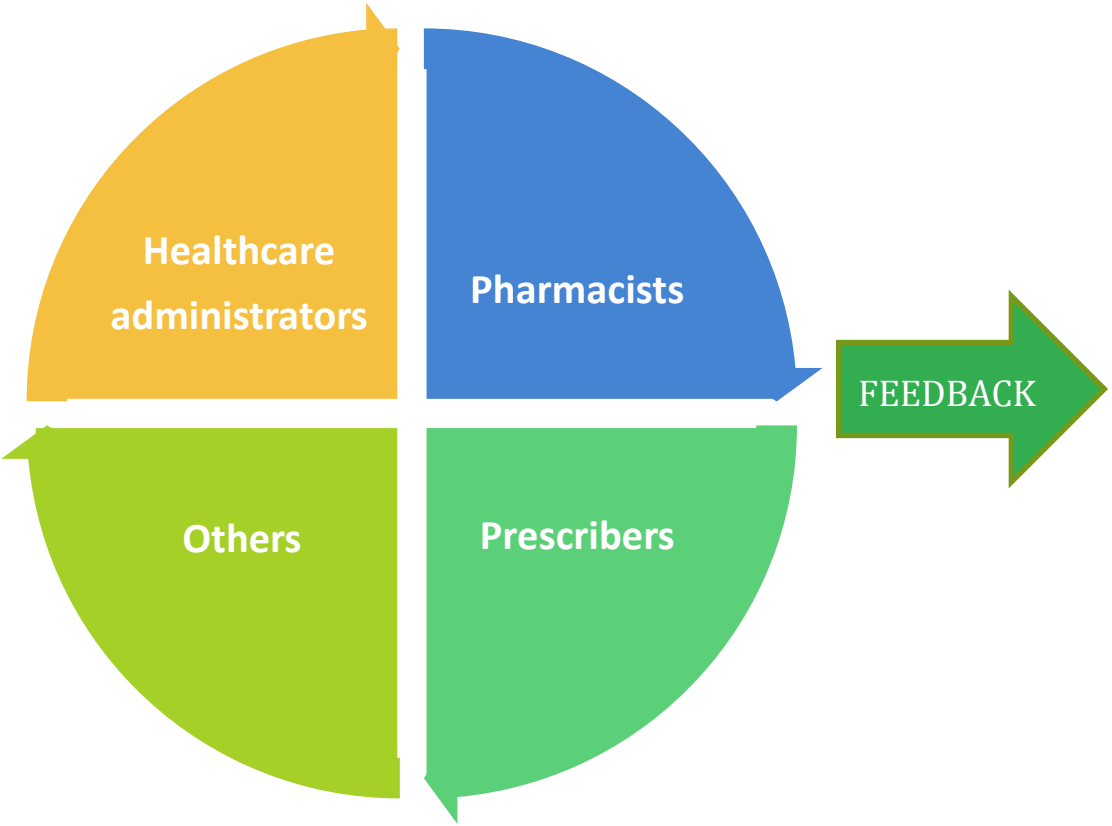
REMS are described in a variety of ways, and REMS requirements are often unclear to stakeholders:

- The format of REMS documents/materials varies
- REMS lack consistent terminology
  - Similar concepts often have different names
  - Different concepts may have the same name
  - REMS are often described using regulatory terms like “ETASU”, “Communication Plan” and “Element A-F”, which do not provide useful information about how REMS programs work.
- It’s not always easy to find information on what is expected of healthcare providers and patients.

Content

1. Background
2. **Stakeholder feedback**
3. REMS Summary
4. Conclusion and next steps

Stakeholder feedback on REMS requirements



- Requirements for a particular REMS are difficult to find
- Requirements are not communicated in a clear and consistent manner
- Unclear who is responsible for implementing each REMS requirement
- Too much time spent trying to understand and comply with REMS

Stakeholder feedback - continued

- First material that stakeholders see should include all of the relevant information about REMS program requirements and logistics
- Difficult to integrate REMS materials and procedures into their existing health information systems and health care delivery processes
- Lack of standardization of REMS poses challenges
  - Variation makes it difficult for stakeholders to adapt to new REMS programs

Content

1. Background
2. Stakeholder feedback
3. **REMS Summary**
4. Conclusion and next steps

Efforts to improve how REMS requirements are captured

To address stakeholder concerns, we have taken the following steps:

1. Characterized existing REMS by creating an inventory of all REMS requirements and various ways they have been communicated across REMS programs
2. Created a new way of communicating REMS requirements called the 'REMS Summary'
   - Standardized how REMS requirements are described and minimized unnecessary variations
   - Made REMS requirements more consistent, predictable and easier to understand

The REMS Summary

- Includes all requirements in a REMS Document that are directed towards stakeholders other than the sponsor
- Provides an overview of what stakeholders who participate in REMS with ETASU (e.g., healthcare providers, patients, distributors) are required to do
- Organized by the care process into "stakeholder-friendly" tables
  - Tables show *who* has to do *what*, and *when*
  - There is a section devoted to the patient and to wholesalers
- Uses standardized language to facilitate consistency across REMS programs

The stakeholder sections capture the "4 W's" of REMS

"W"	Description	Examples
"Who"	The party that must meet the REMS requirement	prescriber, dispenser, health care setting
"When"	A particular "stage" in the treatment process around which REMS activities may occur	certification, prescribing, dispensing, administration
"What"	a clinical or administrative activity that must be performed as part of the REMS	counseling a patient, completing an enrollment form, lab testing
"With What"	Approved REMS material with which the requirement is carried out	enrollment form, medication guide, educational pamphlet

Stakeholder-friendly REMS Requirements

REMS Document

Initial REMS Approval: 05/2013
Most Recent Modification: 10/2015

NDA 12345 WELIPAX (Weliparamax)
Access Analogue
FarmaFa Inc.
10901 Public Avenue
Burden, AC 21301
Phone: (800) -555-7777

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

The goals of the Welipax REMS is to mitigate the risk of hepatotoxicity associated with Welipax by:

- Informing patients about the risk listed above associated with the use of Welipax.
- Informing healthcare providers about the risk listed above associated with Welipax.
- Monitoring LFTs prior to receiving each Welipax prescription.

II. REMS ELEMENTS:

A. Medication Guide or PPI

A Medication Guide will be dispensed with each Welipax prescription in accordance with 21 CFR 208.24.

B. Elements To Assure Safe Use

A. Healthcare providers who prescribe Welipax are specially certified.

a. To become specially certified to prescribe Welipax in the Welipax REMS Program, healthcare providers must:

i. Review the Prescribing Information for Welipax.

ii. Complete the Welipax training and successfully complete the knowledge assessment.

iii. Enroll in the Welipax REMS Program by completing and submitting the Prescriber Enrollment form.

1. As a condition of certification, prescribers must:

i. Enroll each patient in the Welipax REMS Program by the following:

1) Counsel the patient about the risk of severe hepatic injury associated with

REMS Summary

1. Healthcare Providers who prescribe Welipax

To be able to prescribe	1. Review the drug's prescribing information. 2. Review the Welipax training materials. 3. Complete the Knowledge Assessment Form and submit the successfully completed knowledge assessment to the application holder. 4. Enroll in the REMS by completing and submitting the Prescriber Enrollment Form or using Welipax REMS website
Before the first prescription	5. Counsel the patient using the Medication Guide. 6. Provide the patient with the Patient Enrollment form.

REMS Summary example*

1. Healthcare Providers who prescribe Welipax

To be able to prescribe	1. Review the drug's prescribing information. 2. Review the Welipax training materials. 3. Complete the Knowledge Assessment Form and submit the successfully completed knowledge assessment to the application holder. 4. Enroll in the REMS by completing and submitting the Prescriber Enrollment Form or using Welipax REMS website
Before the first prescription	5. Counsel the patient using the Medication Guide. 6. Provide the patient with the Patient Enrollment form.

* Fictional drug

REMS Summary example

2. Patients who are prescribed [drug/class name]

Before the first prescription	1.	Review the [educational material]. **OR** Review the educational materials for patients, including: [educational materials].
	2.	Complete [Patient Agreement Form] with the prescriber.
	3.	Enroll in the REMS by completing the [Patient Enrollment Form] with the prescriber.
	4.	Get [description of lab test or monitoring].
	5.	Receive counseling from the prescriber on [topic]. **OR** Receive counseling from the prescriber using [REMS material]. **OR** Receive counseling from the prescriber on [topic] using [REMS material].
	6.	Complete [patient questionnaire]
Before each subsequent prescription	7.	Get [description of lab test or monitoring].
	8.	Complete [patient questionnaire]
During treatment	9.	For females who can get pregnant: Use contraception (unless continuously abstinent). **OR** For females who can get pregnant: Use contraception (unless continuously abstinent) as described in [name of contraceptive guidelines].
	10.	Adhere to the safe use conditions described in the [patient educational material].
[At specified interval] during treatment	11.	Get [description of lab test or monitoring].
[At specified interval] after discontinuing	12.	Get [description of lab test or monitoring].
At all times	13.	Inform the prescriber if [conditions under which prescriber should be contacted].

Limitations of the REMS Summary

- Only standardizing the description of the REMS requirements
  - The REMS requirements themselves may vary
- The REMS Summary only addresses the REMS Document
- The REMS Summary is currently an approach that is being implemented in other initiatives (REMS Website, REMS SPL)

Content

1. Background
2. Stakeholder feedback
3. REMS Summary
4. **Conclusion and next steps**

Conclusion

The REMS Summary

- Creates a stakeholder-friendly summary of the REMS program requirements
  - Improves communication to stakeholders
  - Improves operationalizing REMS within the healthcare system
- Is a feature of the FDA REMS Website and is being currently tested on the REMS Website
- Standardizing REMS information for including in SPL
  - Facilitates the coding of REMS SPL data elements

Next Steps

- Receive feedback from stakeholder groups on the REMS Summary
- Improve the REMS Summary by incorporating feedback from the different initiatives (REMS Website, REMS SPL)
- Continued effort to standardize REMS requirements