Development of Shared System REMS

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Shared System REMS

- Include more than one sponsor
- May include multiple NDAs and their ANDAs
- Generally have a single REMS document, REMS materials (except MGs), and supporting document applicable to all drugs
- Share ETASU elements, database, infrastructure

Shared System REMS

- Single, shared system REMS are generally required under the statute for ANDAs and the reference listed drug (RLD).
- To reduce the burden to the healthcare system of having multiple REMS for multiple products in the same class, FDA has also encouraged shared system REMS that involve multiple innovators.

Benefits of a shared system

- Reduces burden for different stakeholders
  - single portal to access materials and other documentation and information about the program
  - prescribers, pharmacies, and healthcare settings complete certification and other administrative requirements once rather than for each individual drug
- Potential for cost sharing among all sponsors

Existing Shared System REMS*

	Name of Shared System REMS	Initial Approval Date	Current Sponsor & Application Info
1	Isotretinoin REMS	10/22/2010	6 Sponsors 8 Applications (7 ANDAs)
2	Transmucosal Immediate-Release Fentanyl (TIRF) Products REMS	12/28/2011	8 Sponsors 9 Applications (3 ANDAs)
3	Extended Release & Long-Acting Opioid Analgesics (ER/LA) REMS	7/9/2012	34 Sponsors 65 Applications (46 ANDAs)
4	Mycophenolate REMS	9/25/2012	13 Sponsors 30 Applications (25 ANDAs)
5	Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) REMS	2/22/2013	12 Sponsors 16 Applications (14 ANDAs)
6	Clozapine REMS	9/15/2015	10 Sponsors 14 Applications (11 ANDAs)

* Based on information posted on REMS@FDA website

Shared System REMS Development Process

- Companies usually form an “industry working group” (IWG) to develop a proposal for the shared REMS
  - FDA instructs the IWG sponsors to identify a single point of contact to represent the IWG, and emphasizes the importance of first working out the cost and governance structures
  - IWG provides bi-weekly updates to the Agency
- The Agency forms a REMS review team including staff from a number of Offices within the Center
  - FDA communicates expected timeframes for milestones
  - FDA schedules periodic teleconferences with the IWG

Shared System REMS Development Process

- When a company indicates to the Agency that another company (brand or generic) in the IWG is not receptive or responsive to efforts to develop a shared REMS, the Agency may serve as facilitator to aid in reaching resolution.
- Once developed, the shared REMS proposal is submitted by the companies to the Agency for review.
  - FDA instructs the IWG how to submit the REMS proposal.

Issues to be Addressed in Negotiations

- Confidentiality
- Voting structure
- Cost-sharing
- Product liability concerns
- Anti-trust concerns
- Experience/trust gap(s)

Expectations for Expanded Opioid REMS

- Expand current REMS requirements to include IR Sponsors and products, utilizing existing infrastructure of the ER/LA RPC
- Incorporate other modifications to the REMS if/when appropriate (e.g., expand blueprint to include pain management)

Expectations for IR Sponsors

- Work with current ER/LA Sponsors to join the RPC
- Recommend focusing initially on threshold issues such as cost sharing, necessary agreements
- Provide monthly updates to FDA on progress

Expectations for RPC

- Facilitate entry of IR Sponsors into existing RPC organization
- Provide monthly updates to FDA on progress

Citation and Helpful Links

- FDA REMS Website: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
- FDA Webinar: REMS Basics: http://www.fda.gov/aboutfda/transparency/basics/ucm325201.htm

Thank you