Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #8 Summary

December 2, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting is to review and clarify Industry and FDA questions on REMS assessments and pregnancy safety proposals.

PARTICIPANTS

FDA		**Industry**	
Bob Ball	CDER	Robert Kowalski	PhRMA (Novartis)
Jason Bunting	CDER	Ann Kurowski	BIO (Alkermes)
Nancy Derr*	CDER	Camelia Thompson	BIO
Mary Ross Southworth	CDER	Lucy Vereshchagina	PhRMA
Terry Toigo	CDER		
Craig Zinderman	CBER		

*Note taker

DISCUSSION SUMMARY

The meeting began with updates on minor record-keeping issues.

The first topic of discussion was REMS assessments. FDA had responded to several Industry questions related to speeding up the process for assessing REMS reports. Industry discussed some of the feedback it had received from its members including possible opportunities for streamlining the REMS assessment process and clarification around processes for REMS elimination.

The Subgroup explored possible options for increasing the efficiency of the review process, including adjusting the time interval for REMS assessments. FDA agreed to take a number of questions on timing and process back to its REMS experts.

The second half of the day's discussion focused on FDA's proposal on Sentinel and pregnancy safety. Relevant issues raised during the discussion included Industry's interest in the need to assess when pregnancy registries are producing useful data and when other methodologies might work better at assessing pregnancy health outcomes. FDA emphasized that the key focus of its pregnancy safety effort is to develop an evidence-based framework for determining necessity and type of pregnancy PMRs, including pregnancy registries.

FDA has proposed several Sentinel demonstration projects related to this effort and agreed that it would provide more details in its proposal for the next meeting, including a breakdown and explanation of the needed resources.

Discussion moved briefly to the use of Sentinel analytics and health outcomes of interest (HOI). The full FDA HOI proposal cannot be supported by Industry at this time. However, Industry asked if one pregnancy HOI validation could be done in conjunction with FDA's pregnancy safety proposal. FDA agreed to consider this and will work an example of an HOI into the details of one of the demonstration projects for the next meeting. Industry agreed to consult with its analytics experts and ask them to provide an example of how analytics (e.g., IPCW) could be used in the pregnancy safety project.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.