FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
October 14, 2015: 9:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Purpose

To continue discussion of FDA and Industry post-market proposals.

Participants

FDA		Industry	
Bob Ball	CDER	Beatrice Biebuyck	BIO (Alexion)
Aloka Chakravarty	CDER	Jeffrey Francer	PhRMA
Mwango Kashoki	CDER	Kay Holcombe	BIO
Melissa Robb	CDER	Rob Metcalf	PhRMA (Eli Lilly)
Aaron Sherman	CDER		
Terry Toigo	CDER		
Craig Zinderman	CBER		

Industry Real World Evidence Proposal:

Industry discussed a literature compendium completed to document published articles that describe uses of real world evidence (RWE), specifically in supporting benefit-risk assessment for medical products. They also mentioned specific examples (case studies) of the use of RWE in benefit/risk assessment, and planned to present more details at a future meeting. Industry reiterated their view that, given significant advances in data analysis and available data, RWE likely has a role to play in augmenting or possibly replacing traditional data sources for benefit-risk decision making in the post-market setting. Industry expressed its desire for FDA to initiate a public stakeholder process to explore how RWE may be used in this area. Industry and FDA agreed that, due to the fast-moving nature of scientific exploration in this area, any deliverables should account for the relevant evolution of scientific principles in this area. Industry and FDA agreed to continue discussions about what might be achievable with regards to RWE use to support efficacy over the course of PDUFA VI.

FDA Real World Evidence Proposal:

FDA provided industry with information on funding sources for Sentinel over the course of PDUFA V. Industry noted the importance of, and expressed its support for continued development of Sentinel, and asked about the balance of user fees and appropriations in the current funding of Sentinel. FDA noted the importance of a lifecycle approach to pharmaceutical products, and the value of PDUFA funding to demonstrate commitment from the user-fee program to support post-market activities related to drug safety. Discussion continued over the appropriate way to secure the long-term financial stability of the Sentinel Initiative. Industry inquired, and FDA agreed to provide information on how FDA's proposal would adjust the nature of Sentinel resource bases, if at all.

When discussing FDA's plan to explore new sources of RWE for safety, Industry agreed with the need to better understand possible new uses of RWE for safety. FDA and industry voiced concern about the implications for using certain data sources such as social media for drug-safety reporting purposes. Discussion then continued on the interrelatedness of the two aspects of FDA's proposal. FDA and Industry agreed that Sentinel expansion and new sources of RWE for safety could be complementary.

Industry requested additional information regarding the separate resource needs of each aspect of FDA's proposal.

Agenda for Next Meeting:

This meeting was concluded by discussing the agenda for the following week, and identifying new information needed to inform ongoing discussion. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.