AGENDA PAPER 2.1

Benefit-Risk Framework for the Assessment of Medicines:

Maximising the value of PBRERs: Company approaches to post-approval benefit-risk assessment

Technical Workshop

Draft Programme

12 December 2013

Sofitel Hotel

Philadelphia USA

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

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Centre for Innovation in Regulatory Science Workshop

Background

Any benefit-risk framework should be flexible so as to incorporate evolving scenarios, particularly as knowledge increases about a new medicine. This has led agencies and companies to focus on the importance of the post-approval period in providing a better understanding both of the benefits and harms of medicines. This has been reflected in the recent ICH E2 guideline which now requires companies to provide continually updated information on the benefit-risk balance. This process should also include a structured benefit-risk evaluation, not just when new information becomes available, but also when medicines are being periodically re-evaluated.

This guideline, although articulating the need for a structured benefit- risk evaluation does not specify detailed agency requirements. As a result, companies have designed formats which they believe will satisfy requirements. As a structured benefit-risk evaluation is now mandatory in the post-approval setting, this has been a major focus for companies over the past year.

CIRS has established a programme to examine benefit-risk in the post-approval stage. The annual workshop in 2014 will focus specifically on this topic, and will address current challenges and future expectations. However, to inform this workshop, CIRS have agreed to hold a technical forum to discuss and examine the challenges and experiences of companies as they comply with the requirements of the PBRER. This meeting will also provide a forum for discussing, from the company , the anticipated future requirements, as well as the development of appropriate methodologies for providing evidence of benefits and risks in the post-approval stage.

Workshop Objectives

- **Discuss structured approaches** to evaluating the evidence in balancing benefit-risk in the post-approval period:, the challenges, the hopes, and expectations
- **Discuss company experience** in implementing PBRERS and how agencies have responded to their submissions
- **Develop proposals** for applying a benefit-risk framework in the post- approval setting and how this can help drive the evidence generation, the presentation of the evidence and the appropriate methodologies for providing post- approval benefit- risk evaluations.

Venue

The Workshop will take place at the Sofitel Hotel, Philadelphia, Pennsylvania, USA, commencing at 8.30 AM and finishing at 17.00 PM on Thursday, 12 December 2013.

Thursday 12th December 2013

SESSION 1: DOCUMENTING BENEFIT-RISK ASSESSMENTS IN THE POST-APPROVAL SETTING: WHAT ARE COMPANIES DOING AND ARE THESE APPROACHES FIT-FOR-PURPOSE?	
08:30	**Chairman's Introduction** Professor Stuart Walker, Founder, CIRS
08:40	**Moving from a risk-based post-approval approach to a new Benefit- Risk landscape - what are the driving forces and the challenges?** Prof Sir Alasdair Breckenridge*
09:20	**Discussion**
	Focus on PBRERs - How have companies prepared for the introduction of PBRERS? What have been the experiences and challenges? Case Studies
09:30	**Company Experience 1 – Eisai** Dr David Jefferys, Senior Vice President, Eisai Europe, UK*
09:50	**Company Experience - 2 - Bayer** Dr Jutta Pospíšil, Head TA Primary Care, Global Pharmacovigilance, Bayer HealthCare Pharmaceuticals, Germany*
10:10	**Company Experience - 3 Roche** Dr Daiva Masanauskaite, group Medical Director, F.Hoffmann-La Roche, Switzerland*
10:30	**Company Experience – 4 – Amgen** Andre Daniels, Executive Medical Director PVS Standards, Amgen, USA*
10:50	**Discussion**
11.00	**Break**
11.30	**Roundtable Discussion and feedback**
13.00	**Chairman's Summary**
13.15	**Lunch**

SESSION 2: POST-APPROVAL – MEASURING BENEFIT-RISK: WHAT ARE THE CHALLENGES?	
14.15	**What are the current issues in measuring Benefit-Risk in the post-approval period?** Dr Bennett Levitan, Director, Quantitative Safety Research, Janssen Research Foundation, USA*
14.45	**Discussion**
14.55	**The traditional methodology of Observational Studies – What are the challenges for regulatory agency acceptance?** Dr Carmen Bozic, Senior Vice President, Global Head Safety and Benefit-Risk Management, Biogen Idec, USA*
15.20	**New approaches/technologies to capture Benefits and Risks in the post-approval Phase – What are the practical and regulatory challenges?** Dr Marilyn Metcalf, Senior Director, Benefit Risk Evaluation, GlaxoSmithKine, USA*
15.45	**Break**
16.00	**Roundtable Discussion and Feedback: Methodologies for measuring post-approval benefit-risk - what needs to be considered?**
17.30	**Chairman's Summary**
18.00	**Close of meeting**