Workshop

Utilisation of a Common Benefit-Risk Framework: Can it facilitate decision-making and improve communication within and across agencies?

2 - 3 FEBRUARY 2015

FINAL PROGRAMME

Venue: The Westin Hotel, Taipei, Taiwan

CENTRE FOR INNOVATION IN REGULATORY SCIENCE
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Centre for Innovation in Regulatory Science Workshop

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Background

The Benefit Risk decision is the corner stone of regulatory decision-making and indeed this applies irrespective if you are the first agency to review a medicine or one that relies on the approval of a reference agency as it is critical that agencies evaluate the information on new medicines in relation to the local population.

Over the last five years work has been conducted by agencies, companies and CIRS in the construction of a benefit risk framework for use in the approval of medicines. These methodologies all map to an overarching framework called UMBRA (Universal Methodology for Benefit Risk Assessment) (1). The UMBRA approach has 8 key steps which can be used by agencies and companies to structure their benefit risk in a systematic way which enables both the logic and documentation of what was considered and the evidence included in the decision. This systematic, structured approach to assessment of Benefits and Risks is becoming one of the key review tools and an essential component of good review practices.

EU, USA, Heath Canada, TGA , Switzerland and Singapore have good experience in assessing the use of a framework but this has not been widely used outside of these countries. In 2013 and 2014 CIRS has organised some pilot studies in Asia to evaluate the UMBRA framework across countries with different regulatory models and assessed its these agencies in terms of the advantages, challenges and opportunities that agencies perceive in using the UMBRA framework.

The aim of this workshop is to discuss agencies experience and utility of having a systematic structured approach to benefit risk assessment and how this will aid a better understanding both within and across regulatory agencies as well as in communication with companies and other stakeholders

Workshop Objectives

- Identify the process, procedures and considerations that agencies undertake to make benefit risk decision for their jurisdiction and how this process is documented.
- Discuss how a structured systematic utilisation of a Benefit Risk Framework and its documentation within Asian regulatory agencies can aid both the process and communication within and across agencies.
- Make recommendations as to how a benefit risk framework can be best used to optimise internal decision making and external communication of the decision

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting participation is by invitation to maintain a size that encourages a neutral environment that promotes productive dialogue and networking. We aim to advance the debate and discussion around the subject of the Workshop and to produce constructive recommendations based on the Workshop activities.

A Universal Framework for the Benefit-Risk Assessment of Medicines: Is This the Way Forward? Stuart Walker, Neil McAuslane, Lawrence Liberti, James Leong and Sam Salek. Therapeutic Innovation & Regulatory Science published online 1 September 2014

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Day 1: 2 February 2015

08:30 Registration

SESSION 1: UTILISATION OF A BENEFIT-RISK FRAMEWORK - AN ESSENTIAL COMPONENT OF GOOD REVIEW PRACTICES AND OF REGULATORY DECISION MAKING	
09:00	**Chair's welcome and introduction** **Barbara Sabourin**, Director General, Therapeutic Products Directorate, Health Canada
09:05	**Country welcome and introduction by TFDA** **Dr Yu-Mei Chiang,** Acting Director General, TFDA
	Development of frameworks for benefit-risk assessment: What is their role and why is it important for agencies, companies, healthcare providers and patients?
09:15	**EMA Perspective** **Dr Tomas Salmonson,** Chair, CHMP, European Medicines Agency
09:35	**TGA Perspective** **Prof John Skerritt**, National Manager, Therapeutic Good Administration, Australia
09:55	**Industry Perspective** **Prof Thomas Kuhler,** Senior Director, Novo Nordisk A/S, Denmark
10:15	**Discussion**
10:30	**Break**
11:00	**Development of UMBRA and its utilisation as an overarching template for a systematic structured approach to benefit-risk assessment of medicines** **Dr Neil McAuslane**, Scientific Director, CIRS, UK
11:20	**Discussion**
	Assessment of benefits and risks in agencies across Asia: Current process, procedures and considerations for decision making
11:25	**Chinese Taipei - Director Li-Ling Liu,** Director, Division of Medicinal Products, TFDA, Ministry of Health and Welfare
	Assessment of benefits and risks in agencies across Asia: Utilization of a framework approach – challenges, opportunities and future perspectives
11:40	**Philippines** **Pia Angelique Priagola**, Food-Drug Regulation Officer III, Food and Drug Administration, Philippines
11:55	**Malaysia** **Ms Azura Abdullah**, Head of Unit/Section for New Drug Products, Centre for Product Registration, National Pharmaceutical Control Bureau
12:10	**Discussion**
12:30	**Lunch**

Day 1 cont: 2 February 2015

SESSION 2: PRACTICAL APPLICATIONS AND UTILISATION OF A STRUCTURED APPROACH TO BENEFIT-RISK ASSESSMENT	
13:30	**Chair's Introduction** **Barbara Sabourin**, Director General, Therapeutic Products, Directorate, Health Canada
	How the framework can be used: Potential and Practical applications
13:35	**Singapore experience from the assessment of abridged applications** **Dr Yee Hoo Looi**, Regulatory Consultant, Therapeutic Products Branch, Health Products Regulation Group, Health Sciences Authority, Singapore
13:50	**Use of the framework to communicate and facilitate discussion by the committee** **Dra Nurma Hidayati,** Director of Drug and Biological Products Evaluation, National Agency of Drug and Food Control (NADFC), Indonesia
14:05	**Use of the framework to facilitate internal decision making** **Dr I-Chun Lai**, Team Leader/Medical Reviewer, Division of New Drugs, Center for Drug Evaluation, Taipei
14:20	**Discussion**
14:30	**A company assessment of local benefit and risks prior to submission** **Dr Susan Forda,** Vice President, Global Regulatory Affairs International, Eli Lilly and Company, UK
14:50	**Discussion**
14:55	**Introduction to Roundtable Discussions**
15:00	**Break**

Day 1 cont: 2 February 2015

SESSION 3: ROUNDTABLE DISCUSSIONS	
15:30	**Roundtable Discussions** *Each roundtable is asked to review, debate and make recommendations for the following:* **Roundtable A: Improving local submissions by the use of a structured benefit risk approach** **Chair: Prof Robert Peterson**, Executive Director, Drug Safety Effectiveness Network. Canadian Institute of Health Research **Rapporteur: Dr Eyal Schwartzberg,** Head of Pharmaceutical Division, Ministry of Health, Israel **Roundtable B: How could a structured decision-making framework assist in enabling patient input into the benefit risk assessment of medicines?** **Chair: Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency **Rapporteur: Dr Michael Rozycki**, Vice President, Regulatory Affairs Asia Pacific, Allergan Inc, Singapore **Roundtable C: Maximizing the value and utility of public summary basis of decision documentation** **Chair: Dr Tomas Salmonson,** Chair, CHMP, European Medicines Agency **Rapporteur: Dr Harindra Abeysinghe** Vice President, Head of Asia Pacific Regulatory Affairs, Johnson & Johnson Pte Ltd, Singapore **Roundtable D: What are the key elements of different review models that can be used for risk based approaches to decision-making?** **Chair: Dr Justina Molzon,** Former Associate Director for International Programs, FDA, USA **Rapporteur: Prof Bruno Flamion,** Professor of Physiology and Pharmacology University of Namur, Belgium **Roundtable E: Monitoring post-authorization benefits and risks: What are the common elements of a realistic approach for a developing economy?** **Chair: Prof Sir Alasdair Breckenridge,** Former Chairman, MHRA, UK **Rapporteur: Assoc Prof Silke Vogel** Associate Professor / Deputy Director, Centre of Regulatory Excellence, Duke-NUS Graduate Medical School, Singapore
17:30	**End of Session**
19:00	**Reception**
19:30	**Dinner**

DAY 2: 3 February 2015

SESSION 3: ROUNDTABLE SESSION CONTINUES	
08:30	**Roundtable discussions resumes**
09:45	**End of roundtable discussions and break**
10:30	**Chairman's Introduction** **Professor John Lim**, Deputy Director of Medical Services, Ministry of Health, Singapore and Executive Director, Centre of Regulatory Excellence, Duke-NUS Graduate Medical School, Singapore
10:40	**Feedback by roundtable rapporteurs and panel reflection** - What are the next steps and opportunities for the utilisation of a systematic structured Benefit Risk framework as standard practice in the review of new medicines? Viewpoints from: **Dr Petra Doerr,** Head of Communication and Networking, Deputy Director, Swissmedic **Luiza Novaes Borges**, Health Surveillance and Regulation Specialist, Brazilian Health Surveillance Agency **Gloria Hung**, Asia Regional Director, Regulatory, Pfizer, Hong Kong **Lawrence Liberti,** Executive Director, Centre for Innovation in Regulatory Science
12:20	**Discussion**
12:30	**Lunch**

DAY 2: 3 February 2015

SESSION 4: BENEFIT-RISK FRAMEWORKS – CRITICAL ELEMENTS TO FACILITATING TRUST AND UNDERSTANDING BETWEEN AGENCIES AND OTHER STAKEHOLDERS	
13:30	**Chairman's Introduction** **Dr David Jefferys,** Senior Vice President, Global Regulatory, Government Relations, Public Affairs and European Product Safety, Eisai Europe Ltd, UK
	The utilisation of a common Benefit Risk Framework across countries – How could this underpin trust and understanding between agencies?
13:35	**A critical component for regions interested in undertaking shared assessments** **Barbara Sabourin**, Director General, Therapeutic Products Directorate, Health Canada
13:55	**Enabling the translation of reference agency decisions to the local jurisdiction for benefit risk assessment** **Dr James Leong,** Head of Education, Centre of Regulatory Excellence, Duke-NUS Graduate Medical School, Singapore
14:15	**A corner stone of good review practice and an enabler of convergence across regional alignment** **Dr Justina Molzon**, Former Associate Director for International Programs, Food and Drug Administration, USA
14:35	**Discussion**
14:40	**Break**
	Building Quality into the Decision-Making process: What role do frameworks have in ensuring a quality of decision and what aspects need to be considered?
15:00	**CIRS Perspective** **Prof Stuart Walker,** Founder
15:20	**Mature Agency Perspective** **Prof Hans-Georg Eichler**, Senior Medical Officer, European Medicines Agency
15:40	**Emerging Markets Agency Perspective** **Dr Joey Gouws**, Registrar of Medicines, Medicines Regulatory Authority, Department of Health,South Africa
16:00	**Company Perspective** **Tracy Baskerville,** Vice President, Regulatory Affairs, Area and Affiliate, AbbVie, USA
16:20	**Discussion**
16:30	**Chairman's summary and close of Workshop**