Regulatory Review – How do agencies ensure the quality of the decision?

The role of decision frameworks in the review of new medicines: What are the challenges and solutions that can facilitate agencies to make quality decisions?

24 - 25 January 2013

PROGRAMME

Intercontinental Financial Street, Beijing, P.R. China

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

Background

Regulatory Review: The role of decision frameworks in the review of new medicines: What are the challenges and solutions that can facilitate agencies to make quality decisions?

It is well established that the elements of a good quality review are, clarity, transparency, predictability and timeliness and that it is important that the process that an agency undertakes whether to review a new medicine or in its daily activities is both efficient and effective. This has been imbedded in most agencies with the adoption of Good Review and Good Review Management Practices. Although the processes that agencies have set up to enable them to ensure that a science-driven review is undertaken can be identified, these processes need to be built around good decision frameworks, which are less well articulated for regulatory agencies but are equally important as agencies evolve to ensure good quality decision making.

Decision making processes within agencies are guided by the legislative or regulatory frameworks which define the decision making powers that are in place within different jurisdictions. Indeed it has been suggested that the quality of the review and quality of decision making, although the former should facilitate the latter, are two distinct aspects and one of the questions being asked by agencies is how to ensure that they are not only undertaking a good quality review process but that they are also making a good quality regulatory decision.

One way is of course to plot the outcome and consequences of the decision made, which may be different depending on if you are a patient, a company or indeed the health care provider. However this is not often practical, is extremely difficult to measure and indeed a good decision may have poor consequences and a bad decision may end up with good outcomes. Therefore, there is a need to ensure that the decision frameworks within an agency are structured so as to enable consistency around good quality decisions.

The science of decision making is well established and a number of common features have been identified that characterise good quality decisions; A good decision framework; having creative doable options; having meaningful, reliable information; identifying clear values and tradeoffs; using logically correct reasoning; and making a commitment to action. However, the question remains how are these being built into the regulatory decision process?

Work is being undertaken internationally to ensure that there is an acceptable and established framework for the benefit-risk decision component of decision processes, but what are the challenges within agencies to ensuring that quality decisions are being made throughout a regulatory agency across all aspects of the dossier review. It is important that the decision processes within an agency are well understood and characterised, from the processes used by the individual reviewer through to the final decision maker.

Workshop Objectives

The objectives of this workshop are to:

- **Identify the different decision** making frameworks used by agencies
- **Understand the challenges** for regulatory agencies in making quality decisions
- **Discuss and make recommendations** of activities and processes that agency can consider to enable quality decision making

Venue

The Workshop will take place at the Intercontinental Hotel in Beijing, commence at 09:00 on Thursday 24th January and finishing at 17:00 on Friday 25th January 2013.

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting attendance will be by invitation and the number of participants will be limited to allow productive networking and discussions.

PLEASE NOTE: THIS WORKSHOP WILL BE HELD IN ENGLISH ONLY AND TRANSLATION WILL NOT BE PROVIDED

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Day 1: Thursday 24 January 2013

08:30: Registration

SESSION 1: GOOD REVIEW PRACTICES: PROCESSES WHICH UNDERPIN GOOD DECISION MAKING	
09.00	**Chairman's welcome and introduction** **Professor Robert Peterson,** Executive Director, Drug Safety and Effectiveness Network, Canadian Institutes of Heath Research
09.05	**Opening Remarks** **Commissioner YIN Li,** State Food and Drug Administration, P.R. China
09.15	**Framing the workshop: CIRS Introduction** **Lawrence Liberti,** Executive Director, Centre for Innovation in Regulatory Science
09:20	**Keynote: The Center for Drug Evaluation and the role of Good Review Practice in underpinning a quality review process within CDE** **FENG Yi,** Associate Center Director, Center for Drug Evaluation, SFDA, P.R. China
09:50	**How does Good Review Practice become embedded within an agency's philosophy and culture and what are the advantages both internally and externally?** **Barbara Sabourin,** Director General, Therapeutic Products Directorate, Health Canada, Canada
10.10	**Good Review Practices: What does this mean to companies, how important is it and what assurances does it give about the decision making?** **Dr Joseph Scheeren,** Head of Global Regulatory Affairs, Head of Global Development Asia, Bayer Healthcare Pharmaceuticals, China
10.30	**Discussion**
10.35	**Break**
11.05	**APEC Best Practice Project: What are the ambitions of this project and how will this increase the competency for Good Review Practices across APEC?** **Dr Churn-Shiouh Gau,** Executive Director, Center for Drug Evaluation, Chinese Taipei
11.25	**Discussion**
11.30	**Good Decision Making Practice: What role do frameworks have in ensuring a good decision and what aspects need to be considered?** *How do the establishment of frameworks enable a structured and systematic decision making approach which can help provide Logical soundness, a Coherent approach, Consistency and Transparency to both the review and decision making process.* **Prof Stuart Walker,** Founder, Centre for Innovation in Regulatory Science, UK
11.55 *12.15*	**Benefit Risk Decision Making: An example of how the use of a decision framework can improve regulatory decision making** **Regulatory Viewpoint** **James Leong,** Senior Regulatory Specialist, Health Sciences Authority Singapore **Industry Viewpoint** **Dr Mark Goldberger,** Divisional Vice President, Regulatory Policy and Intelligence, AbbVie, USA
12.35	**Discussion**
12.45	**Lunch**

Day 1: Thursday 24 January 2013

SESSION 2: REGULATORY REVIEW: WHAT ARE THE KEY ACTIVITIES THAT CAN INFLUENCE DECISIONS AND WHAT FRAMEWORKS ARE BEING USED TO ENSURE GOOD QUALITY DECISIONS ARE MADE?	
13.45	**Chairman's introduction** **Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency
13.50	**Decision-making within Agencies - What are the key frame works and process?** *Agencies have different legislative and regulatory frameworks, different structures from review disciplines making up a team to single reviewers. What are the decision pathways between the reviewer and the final decision maker, what decision frameworks are available within agencies and how are agencies ensuring the quality of the decision currently?* **Panel – each agency to provide 10 minutes on their internal approach** **Agency 1 – Dr Won Shin**, Division Director**,** Division of Gastroenterology and Metabolism Products, Department of Drug Evaluation, Korea Food and Drug Administration **Agency 2 – Dra Lucky Slamet,** Head, National Agency of Drug and Food Control, Indonesia **Agency 3 – Prof Tomas Salmonson,** Chair, CHMP, Medical Products Agency, Sweden
14:50	**How are the Decision Made to Submit a New Medicine within Companies - What are the key frame works and decision-making processes?** *As companies internally make the decision to submit a dossier to a regulatory agency for a new medicine, what are the internal decision pathways, do they have decision frameworks in place and if so what ?, does it differ/dependant on Jurisdiction and how are they ensuring the quality of the decision making currently?* **Company viewpoint** **Dr Paul Huckle,** Chief Regulatory Officer, GlaxoSmithKline, USA
15.10	**Dispute resolution – How are differences in opinion regarding data interpretation dealt within agencies and within companies?** *What are the challenges and how are internal differences resolved?* **An Agency Approach** **Dr Murray Lumpkin,** Commissioner's Senior Advisor and Representative for Global Issues, Food and Drug Administration, USA
15.30	**Discussion**
15.40	**Break**
16.10 *16.30*	**Use of Advisory committee and External Experts** *External experts and Patients either adhoc or as part of the process are used in a number of ways by agencies, as advisory committees, to provide advice to companies, the review team or act as actual reviewers - How can these be used effectively to enhance internal decision making and what frameworks are required in the use of external advice and how is conflict of interest managed?* **Improving regulatory decision-making: What role do Scientific Advisory Committees play?** **Prof Bruno Flamion,** Past Chair, EMA Scientific Advisory Committee, Belgium **Use of external experts as part of the review** **Noorizam Ibrahim,** Deputy Director, National Pharmaceutical Control Bureau, Malaysia
16.50	**Discussion**

Continued

Day 1: Thursday 24 January 2013 - Continued

16:55	**Utilisation of another agency's information/assessment reports in the decision making process: How can that this be used effectively and what are the challenges? Agency Viewpoint** **Citlali Minerva Paz Nogiuez,** International Analyst, Federal Commission for the Protection from Sanitary Risks, COFEPRIS, Mexico
17.15	**What do companies see as the benefits and the issues for agencies sharing information/work to help inform their own decision making process? Company viewpoint** **Dr Florence Houn,** Vice President Regulatory Policy and Strategy, Celgene, USA
17:35	**Discussion**
18:00	**End Day One**
19.00	**Reception**
19.30	**Workshop Dinner**

DAY 2: Friday 25 January 2013

SESSION 3: HOW SHOULD AGENCIES ENSURE THE QUALITY OF THEIR DECISIONS?	
08.30	**Chairman's introduction** **Prof Sir Alasdair Breckenridge,** Former Chairman, Medicines and Healthcare products Regulatory Agency, UK.
08.35	**Introduction to the Syndicate Session**
08.40	**Syndicate sessions 3 topics to be confirmed** **Syndicate 1 topic: What are the key elements of the review for which decision frameworks are required - both from an agency and company perspective** **Chair: Dr Murray Lumpkin**, Commissioner's Senior Advisor and Representative for Global Issues, Food and Drug Administration, USA **Rapporteur: Chris Walker,** Executive Director, Regulatory Affairs, Amgen, UK **Syndicate 2 topic : Communication between companies and agencies: How can this aid both quality of the submission and quality of the final approval decision?** **Chair: Dr Paul Huckle,** Chief Regulatory Officer, GlaxoSmithKline, USA **Rapporteur: Leyla Lister-Mora,** Head of Emerging and Regional Affiliates, F. Hoffmann-La Roche Ltd, Switzerland **Syndicate 3 topic: What role do external stakeholder input have to enable high quality decision-making?** **Chair: Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency **Rapporteur: Sharon Olmstead,** Global Head, Development and Regulatory Policy, Novartis, USA
12.00	**End of Syndicate Discussions**
12.15	**Lunch**
13.15	**Chairman's Introduction**
13.20	**Feedback of syndicate discussion**
14.00	**Panel viewpoint following syndicate discussion** **Company Representative: Local – Dr Peng Wang,** Chief Scientific Officer, Simcere Pharmaceutical Group, China **Company Representative: MNC – Dr Zili Li,** Executive Director and Head of Emerging Market Regulatory Strategy Merck & Co, USA **Agency 1 - Prof Thomas Salmonson -** Chair, CHMP, Medical Products Agency, Sweden **Agency 2 – Dra Lucky Slamet,** Head, National Agency of Drug and Food Control, Indonesia
14.50	**Sharing of regulatory resources/expertise to improve capacity, reduce timelines and build competency – is this the approach agencies should be taking?** **Dr Petra Dörr,** Head of Management Services and Networking, Swissmedic, Switzerland
15.10	**How the evolution of Regulatory Science supports training, alignment, and regulatory convergence which can underpin GRPs (Quality, Transparency, Clarity, Consistency, Timeliness) and good decision making practices?** **Dr Lembit Rägo,** Coordinator of QSM, World Health Organisation, Switzerland
15.30	**Break**

16.00	**Transparency of decisions a key component of good decision making practices – how good are agencies in communicating their decision to their stakeholders?** **Prof Steffen Thirstrup,** Director of Licensing Division, Danish Health and Medicines Authority
16.20	**The Center for Drug Evaluation – what are the future challenges, opportunities and strategies to evolving the core competency and capacity of the CDE?** **ZHANG Peipei,** Center Director**,** Center for Drug Evaluation, SFDA, P.R. China
16.45	**Discussion**
16.50	**Chairman summary and final words**
17.00	**Close of Workshop**