

Workshop 26 – 27 January 2011, Tokyo

CMR INTERNATIONAL INSTITUTE FOR REGULATORY SCIENCE

**REGIONAL ALIGNMENT IN ASIA PACIFIC:
WHAT NEEDS TO BE IN THE REGULATORY
SCIENCE 'TOOLKIT' TO ENABLE GOOD
REGULATORY DECISION MAKING?**

WORKSHOP

**Tokyo Hilton Hotel
Tokyo, Japan
26 – 27 January 2011**

PROGRAMME

Background

Regional Alignment in Asia Pacific: What needs to be in the regulatory science “toolkit” to enable good regulatory decision making

Regulatory agencies are rising to the challenge and the reality of a globalised world in which companies are undertaking not only global clinical trials but are also looking to market their products globally in a timely fashion. In the developing countries this has put pressure on the evolution of regulatory policy, infrastructure and resources. In the developed countries the resource implications along with the duplicative nature of some of the work has been identified and there is now an increasing emphasis on collaboration, sharing of resources where possible and investigating the possibilities of such activities in the future.

The knowledge that all agencies in general follow the same mission of ensuring that patients have access to safe, effective and quality new medicines in a timely manner and that the technical requirements for the development of a new medicines are harmonised in the ICH countries with the adoption or adaptation occurring in the non ICH countries. In addition to the efforts to harmonise the technical guidelines for the development of new medicines, developing countries are proactively looking to align their activities regionally with overarching groups such ICH GCG, LSIF and APEC or ASEAN in Asia, in Latin America, PAHO, PANDRH, and in Africa, SADC.

Initiatives are also being seen amongst individual regulators either with regard to setting up mutual agreements to share resources. In Asia, China, South Korea and Japan have set up a programme to look at very specific topic in terms of ethnic difference in data generated in the three countries, and in the Middle East the setup of the GCC in Saudi Arabia to undertake a centralised review for new medicines.

As more agencies look to take a science based approach to regulation and risk based decision making, a common understanding, and regulatory language is being developed as well as clarity around the resource required to approve and monitor new medicine. This has lead to agencies to start discussing and work out how to co-operate in order to share information and activities, such as safety data and inspections, as well as exchange of staff. In addition some agencies are looking in the future to the exchange of review reports. The challenges for the agencies are around different skill sets and process between agencies. The key question is what are the underpinning components of good regulatory decision making and what are the regulatory science tools that can be used to ensure a timely, high quality, predictable and transparent process whilst ensuring an effective and efficient use of resources.

It is the intent of this Workshop to discuss three key areas that can help underpin good regulatory decisions, performance measurement, quality and a risk based approach to decision making. drug development and review but also improve patient access to medicines.

Workshop Objectives

- **Discuss good-risk based regulatory decision making** and what the components are that need to be built into the review process
- **Identify current initiatives/approaches and** understand how these are enabling the decision making process from companies and agencies perspective.
- **Recommend what should be in the regulatory science ‘toolkit’** and how best this can be used as part of the regional alignment initiatives.

Venue

The Workshop will take place at the Hilton Tokyo, 6-2 Nishi-Shinjuku 6-chome, Shinjuku-ku, Tokyo, 160-0023, Japan and will commence at 08:30 on Wednesday 26th January and finish at 15:00 on Thursday 27th January 2011

Style and Participation

Day one of this meeting will be open to all companies. On day two the syndicate sessions will be open to member companies and regulatory agencies and will follow the agreed practices for Institute Workshops, the size will be limited to allow productive networking and discussions.

Day 1: Wednesday 26th January 2011

08:30 Registration

SESSION 1: EVOLUTION OF GOOD REGULATORY SCIENCE AND PRACTICE – IS THIS THE KEY TO SUCCESSFUL REGIONAL ALIGNMENT AND EFFECTIVE USE OF REGULATORY RESOURCE?		
09:00	Chairman's welcome and Introductory comments	Dr Thomas Lönngren, <i>Former Executive Director, EMA</i>
09:20	<p>Good Regulatory Decision Making: What are the key components that build predictability into the process?</p> <p><i>What are the fundamental components, (timeliness, target times, quality, risk based approach, transparency, training, scientific consultation during development)? What are agencies doing to continually improve decision making? What is the role of regulatory science?</i></p> <p>PMDA</p>	Dr Satoshi Toyoshima, <i>Senior Advisor, Pharmaceuticals and Medical Devices Agency, Japan</i>
09:40	US FDA Viewpoint	Dr Christopher Hickey, <i>Director, China Office, U.S. Food and Drug Administration, China</i>
10:00	Industry Viewpoint	Dr Zili Li, <i>Emerging Markets Regulatory Strategy and Policy Lead, Merck & Co Inc, USA</i>
10:20	Discussion	
10:30	Break	
11:00	<p>Regional Harmonisation Initiatives: Is there a need to have a good regulatory science platform on which to build trust and partnership across agencies and if so how can this be achieved?</p> <p><i>Regional harmonisation is not only about harmonisation of technical guidelines but also about the approaches that will underpin good quality risk based regulatory decision making. The question is how and what needs to be in place to enable this to occur to ensure success?</i></p> <p>View of the Regional Harmonisation Steering Committee-</p>	Mike Ward, <i>Manager International Programs Division, Health Canada</i>
11:20	Agency Viewpoint	Dr Won Shin, <i>Division Director, Korea Food and Drug Administration</i>
11:40	Break	

	Measuring Performance Across Regulatory Agencies: What can and should be measured?	
	<i>Why should regulatory agencies measure performance?, Can such measurement improve performance?, What measures can be used to measure across agencies and are there standardised systematic tools which can enable these measurement for the regulatory review process?</i>	
11:50	What measures can be used across agencies?	Dr Neil McAuslane, <i>Director, Institute for Regulatory Science</i>
12:15	Improving Agency Performance – What needs to be measured?	Dr Petra Dörr, <i>Head of Management Services and Networking, Swissmedic</i>
12:35	Why should regulatory agencies measure performance?	Dr David Jefferys, <i>Senior Vice President, Global Regulatory and Healthcare Policy, Eisai Europe Ltd, UK</i>
12.55	Discussion	
13.00	Lunch	

SESSION 2: RISK BASED DECISION MAKING		
14:00	Chairman's welcome and introduction	Professor Sir Alasdair Breckenridge <i>Chairman, MHRA, UK</i>
14:05	Scientific advice/consultation during development – A critical component in the regulators armament to improve the regulatory outcome and decision making process?	Professor Bruno Flamion, <i>Chairman, Belgian Committee for Reimbursement of Medicines (CTG/CRM), Belgium</i>
14:30	Good Regulatory Review Practice – What are the guiding principles and is this a critical success factor for across agency co-operation?	Dr Supriya Sharma, <i>Director General, Therapeutic Products Directorate, Health Canada</i>
14:50	Discussion	
	Sharing assessment of regulatory approval or assessment reports - could this be an effective way for agencies in Asia Pacific to use regulatory resources?	
	<i>It has been suggested that sharing of pharmaceutical evaluation reports can improve use of regulatory resource and enhance partnership within and across regions. What are the challenges that need to be overcome? And how will this improve global development and patient access to medicines?</i>	
14:55	Agency Viewpoint	Dr Meir-Chyun Tzou, <i>Director, Division of Drugs and New Biotechnology Products, Food and Drug Administration, Taiwan, R.O.C</i>
15:15	Industry Viewpoint	Joseph Scheeren, <i>SVP, Head of Global Regulatory Affairs. Bayer Healthcare, Pharmaceuticals Inc, USA</i>
15:35	Discussion	
15:45	Break	

16:15	<p>Enabling the acceptability of other agency reviews - What are the critical success factors?</p> <p><i>A number of agencies use or are considering routes of assessment which enable them to use verification or abridged routes based on a trusted third party (agency) approval. For this to be considered what needs to be in place and what data needs to be evaluated?.</i></p>	<p>Dr Christina Lim, <i>Deputy Group Director, Health Products Regulation Group, Health Sciences Authority, Singapore</i></p>
16:35	<p>Discussion</p>	
16:40	<p>Making the Benefit Risk decisions: Is there a role/need for a standardised structured systematic benefit risk framework to enabling risk based decisions making?</p> <p><i>Many agencies do not undertake a full review but they are still charged with protection of patients and understanding the benefit risk of a new medicine for the local population. How can this be best achieved and what role would a benefit risk framework have?</i></p> <p>Who Viewpoint</p>	<p>Dr Lembit Rågo. <i>Coordinator, Quality Assurance and Safety: Medicines (QSM), World Health Organization</i></p>
17:00	<p>Institute for Regulatory Science Viewpoint</p>	<p>Prof Stuart Walker, <i>Founder CMR International</i></p>
17:20	<p>Discussion</p>	
17:30	<p>What needs to be in the regulatory science 'toolkit' to enable good regulatory decision making? Summary of Key Points</p>	<p>Professor Robert Peterson, <i>Executive Director, Drug Safety and Effectiveness Network. Canadian Institute of Health, Canada</i></p>
17:50	<p>Chairman Summary</p>	
18.00	<p>Close of meeting</p>	

DAY 2: Thursday 27th January 2011 - Closed Meeting for invited participants

SESSION 3: CLOSED MEETING		
08.30	Chairman Introduction	Professor Robert Peterson
08.35	Introduction to the Syndicate Sessions	
08.40	<p>Syndicate session discussions on</p> <p>A regulatory science tool kit: What should be in it to ensure that alignment initiatives encourage science based regulatory decision making?</p> <p>Syndicate A: Benefit Risk balance</p> <p><i>Discussion on Benefit Risk evaluation and what the development of a Standardised Structured Proforma for different types of regulatory review (Verification, Abridged, Full) in the emerging markets encompass.</i></p> <p>Syndicate B: Scorecard on the review and dossier submitted</p> <p><i>To review the Scorecard developed for ICH countries and to discuss how this could be used to aid emerging market countries and what parameters need to be included/excluded to ensure value to the agencies and companies.</i></p> <p>Syndicate C: Sharing Assessment Reports for the review of new medicines</p> <p><i>Assessment reports provide key insights into the rationale for the approvals of a new medicine. Sharing Assessment Reports among agencies may in theory assist in the review process, thereby streamline time to final decision. The use of a standardised report template could be key to meeting reviewers' expectations and contributing to a consistent and high quality review. As agencies move to share assessment reports what needs to be place for this to occur and what would such a document look like?</i></p>	<p><i>Chair: Dr Lucky Slamet, Deputy for Therapeutic Products, Narcotics, Psychotropic and Addictive Substance Control, National Agency of Drug and Food Control, Indonesia</i></p> <p><i>Rapporteur: Jerry Stewart, Regulatory Policy Head Emerging Markets, Pfizer Inc, USA</i></p> <p><i>Facilitator Prof Stuart Walker, CMR International</i></p> <p><i>Chair: Mike Ward, Manager International Programs Division, Health Canada</i></p> <p><i>Rapporteur: Carolyn Maranca, VP, Global Regulatory Affairs – Asia Pacific and Latin America, Johnson & Johnson PRD, USA</i></p> <p><i>Facilitator Neil McAuslane, CMR International</i></p> <p><i>Chair: Dr Heng-Der Chern, Executive Director Center for Drug Evaluation, Taiwan, R.O.C</i></p> <p><i>Rapporteur: Patrick O'Malley, Senior Director, International Regulatory Affairs, Eli Lilly & Co, USA</i></p> <p><i>Facilitator: Larry Liberti, CMR International</i></p>
10.30	Break	
11:00	Syndicate discussion restart	
12.30	Lunch	
13.30	Syndicate feedback	
14.30	Discussion	
14.55	Chairman Summary/CMR Next Steps	
15.00	Close of meeting	