Workshop on

Evolving the Regulatory Review Process

What are the features which enable a transparent, timely, predictable and good quality review?

6 – 7 December 2011

PROGRAMME

Intercontinental Hotel, Kuala Lumpur, Malaysia

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

Background

Evolving the Regulatory Review Process – What are the features which enable a transparent, timely, predictable and good quality review?

When the review process is assessed across all regulatory agencies the function and activities are very similar in terms of the mission, the procedures and steps required to assess a medicine for safety, quality and efficacy. Indeed what is required of a regulatory system has been defined as one which is scientifically sound; legally and scientifically consistent; procedurally predictable and within time targets. To make good quality decision agencies need good clear and defined process, consistent application and well trained people. If these along with the fundamental values of good review management practice (GRMP) quality, efficiency, clarity, transparency and consistency are imbedded in an agency then one could assume that an agency meets what is required of them in terms of accepted activities.

Regulatory agencies in established markets are continuously evolving their process and practices to ensure that they are using the best tools and techniques. As agencies in newly developing countries evolve their process, examples of good practice can be identified from agencies with more experience. As such agencies are adopting the principles GRMP which underpin a quality review in the established agencies.

However of all the process and practices that are in place, there are specific process and practices that agencies and companies believe either enable or hinder the review. In 2011 CIRS have surveyed both companies and agencies to identify which in their perception are the critical factors that can enable or hinder the process. For agencies that are evolving rapidly but also have resource restriction, the key question is what are the key elements of all the processes and procedures undertaken to review a new medicines which are critical and can be identified as enablers of the review?

This Workshop is being held to bring together, agencies and companies to discuss what are the features of an evolving, globally-consistent review process that enable a transparent, timely, predictable and good quality review.

Objectives

- **Review of the approval process and practices** that can enable as well as hinder the review of new medicines
- **Identify practices and processes** for companies and agencies for new medicines review that underpin a timely, predictable and good quality review
- **Discuss and make recommendations** on what key practices and process should be considered or adopted as enablers for an evolving review process in the 21st Century.

Venue

The Workshop will take place in at the Intercontinental Hotel in Kuala Lumpur, Malaysia commencing at 09:00 on Tuesday, 6 December and finishing at 13:00 on Wednesday, 7 December 2011.

Style and Participation

Following the agreed practices for CIRS Workshops, the meeting will be closed and the size will be limited to allow productive networking and discussions. Please contact Gill Hepton at ghepton@cirsci.org for further information and a registration form.

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DAY 1: TUESDAY 6 DECEMBER 2011

SESSION 1: WHAT ARE THE PROCESSES AND PRACTICES THAT CAN ENABLE OR HINDER THE REVIEW?		
09.00	**Introduction to the Workshop**	**Lawrence Liberti,** Executive Director, CIRS
09.05	**Current and Future Drug Regulation in Malaysia**	**Dr Eisah Rahman,** Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia
09:15	**Chairman's welcome and introduction**	**Professor Sir Alasdair Breckenridge,** Chairman, MHRA, UK
	What are the expectation and requirements of the regulatory review process to deliver the needs today and for the future?	
09:30	***A Perspective from CDE***	**Dr Yi Feng,** Assistant Center Director, SFDA/Center for Drug Evaluation, Director, Office of Drug Review Management, SFDA/CDE, China
09:50	***A Company viewpoint***	**Dr Paul Huckle,** Chief Regulatory Officer & Senior Vice President, Global Regulatory Affairs, GlaxoSmithKline, USA
10:10	**Discussion**	
	What are the key processes and practices that are seen by companies and agencies as enablers and barriers to the review process?: Outcome of a CIRS Survey	
10.15	**CIRS Survey Results**	**Prisha Patel,** Portfolio Manager, CIRS
10:35	**Break**	
	Apart from resources, what are the key processes and procedures that enable a timely and predictable review?	
11:05	**Developing agency 1: The role companies can play (understanding the requirements, full data provision responding to questions in a timely manner)**	**Lucky Slamet,** Deputy, Therapeutic Products, Narcotics, Psychotropic & Addictive Substance Control, National Agency of Drug & Food Control, Indonesia
11:15	**Developing agency 2: The role of project management and target times**	**Dr Chih-Liu Lin,** Deputy Executive Director, Center for Drug Evaluation, Taiwan
11:25	**A Developed agency: How to ensure consistency of practice**	**Dr Thomas Lönngren,** Independent Strategy Advisor, Pharma Executive Consulting,
11:35	**Company viewpoint: Examples of practices that have enabled or hindered the review**	**Patrick O'Malley,** Senior Director, Global Regulatory Affairs – International, Eli Lilly and Company, USA

11:45	**Discussion**	
	Agency to company and company to agency dialogue, presubmission, during approval and post approval – Is this important to an effective and efficient review process but what are the conditions?	
11:55	***An agency perspective***	**Dr Murray Lumpkin,** Commissioner's Senior Advisor and Representative for Global Issues, US Food and Drug Administration
	Availability and publication of the summary basis of approval: What should be included and is publication a sign of a transparent and good quality review?	
12.15	***An agency perspective***	**Dr Jason Ferla,** Acting Principal Medical Adviser, Therapeutic Goods Administration, Australia
12.30	***A company Perspective***	**Dr Zili Li**, Executive Director and Head of Emerging Market Regulatory Strategy, Merck & Co, Inc, Co-chair of FDA Alumni Association International Network
12.45	**Discussion**	
13.00	**Lunch**	
14:00	**Industry Panel Discussion: What are the key factors from an industry perspective that should be considered by the Syndicate Groups?**	
	Timeliness and Predictability:	**Raj Long,** DRA Head AMAC, GEM, LATAM, Novartis Pharma AG, Switzerland
	Good Quality Review:	**Dr Graham Burton,** Senior Vice President, Global Regulatory Affairs, Pharmacovigilance and Corporate QA Compliance, Celgene Corporation, USA
	Transparency:	**Erika Eckel,** Head of Regional Management, Regulatory Affairs, F. Hoffmann-La Roche, Switzerland

SESSION 2: SYNDICATE SESSIONS		
14:30	**Introduction to the Syndicate Sessions**	**CIRS Speaker**
14:45	**Syndicate sessions on: Best practices for 2020 review process** **TOPIC A: Timely and predictable review process: What does this mean and, assuming resources were not an issue, what process and procedures would an ideal agency adopt?** **Chairperson: Lucky Slamet,** Deputy, Therapeutic Products, Narcotics, Psychotropic & Addictive Substance Control, National Agency of Drug & Food Control, Indonesia **Rapporteur**: **Dr Raymond Chua,** Deputy Group Director, Health Products Regulation Group, Health Sciences Authority, Singapore **TOPIC B: Good quality review: What does this mean to companies and agencies and what are the key components?** **Chairperson: Prof Bruno Flamion,** Chair, Belgian Committee for Reimbursement of Medicines, University of Namur, Belgium **Rapporteur**: **Arun Mishra,** Director, Global Regulatory Affairs (Asia-Pacific, Japan and Emerging Markets), GlaxoSmithKline, UK **TOPIC C: Transparency of the review process before, during and post: What should be transparent and how should it be measured?** **Chairperson: Prof Robert Peterson,** Executive Director, Drug Safety and Effective Network, Canadian Institutes of Health Research, Canada **Rapporteur**: **Dorte Strobel,** Senior Regulatory Intelligence Manager, Novo Nordisk A/S, Denmark	
16:30	**Break**	
16:45	**Syndicate resumes**	
18:00	**End of Syndicate Discussion and end of day one**	
19:00	**Reception**	
19:30	**Dinner**	

DAY 2: Wednesday 7 December 2011

SESSION 3: DRIVE TO ACHIEVE A CONSISTENT REGIONAL UNDERSTANDING - EVOLVING THE REGULATORY PROCESS – WHERE ARE WE HEADING?		
08:30	**Chairman's Introduction**	**Associate Prof John Lim,** Chief Executive, Health Sciences Authority, Singapore
08:35	**Feedback of syndicate discussion**	
09:15	**Panel Discussion: Regulators' Reactions to Syndicate Recommendations** **South Korea: Dr In-Sook Park**, Director of Pharmaceutical Standardization Division, Korea Food and Drug Administration **Malaysia: Dr Eisah Rahman**, Senior Director of Pharmaceutical Services, Ministry of Health **Mexico: José Raúl Ramírez Ramírez,** Executive Director of International Operation, COFEPRIS, Mexico **Australia: Dr Jason Ferla,** Acting Principal Medical Adviser, Therapeutic Goods Administration, Australia	
10:00	**Regulatory Authority Websites: What information is publically available and what is the quality of the information?**	**Dr Lembit Rägo,** Coordinator of QSM ,World Health Organisation
10:30	**Break**	
11:00	**Gulf Cooperation Council Drug Registration procedure in the Middle East: What are its strengths and how does it need to evolve?**	**Mohammed Al- Rubaie,** Director of Drug Control, Ministry of Health. Oman
11:25	**Regulatory convergence efforts and evolving an agency towards a more transparent and efficient reviewing process – A view from COFEPRIS?**	**José Raúl Ramírez Ramírez,** Executive Director of International Operation**,** COFEPRIS, Mexico
11:50	**African Medicines Regulatory Harmonisation: What is the status?**	**Margareth Ndomondo-Sigonda** Pharmaceutical Coordinator, African Union - NEPAD Agency, South Africa
12:15	**APEC Best Practice Regulatory Practice Project: An update and future direction?**	**Chao-Yi (Joyce) Wang**, Senior Specialist, Food and Drug Administration, Taiwan,
12:40	**Agency consortium: Evolving a work sharing model that will streamline approval and enable effective resource utilisation**	**Cordula Landgraf**, Head of Networking, Swissmedic
13:00	**Discussion**	
13:15	**Chairman's Summary and Close of Workshop**	