Evolving the Regulatory Review Process

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

WORKSHOP SYNOPSIS
6-7 December 2011
Kuala Lumpur, Malaysia

CIRS Centre for Innovation in Regulatory Science

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The following is a high-level summary of key points from a Workshop conducted by the Centre for Innovation in Regulatory Science (CIRS) on 6-7 December, in Kuala Lumpur, Malaysia. A complete Workshop Report including full presentation summaries and syndicate recommendations will be forthcoming.

BACKGROUND TO THE WORKSHOP

The functions and activities that comprise regulatory review have been found to be similar across agencies in terms of the procedures and necessary steps to assess a medicine for safety, quality and efficacy. Indeed, the requirements of a competent regulatory system have been defined as: scientific soundness legal and scientific consistency, procedural predictability and ability to adhere to time targets.

Regulatory agencies need clear and precisely defined processes, consistent application of those processes and well-trained personnel to conduct quality reviews. The presence of these attributes as well as the quality, efficiency, clarity, transparency and consistency that are the fundamental values of good review management practice (GRMP) all ensure an agency's ability to conduct a good-quality review. To maintain this ability, 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 countries with developing pharmaceutical markets evolve their processes, examples of good practice can be identified from agencies with more experience and the principles of GRMP which underpin a quality review in the established agencies can be adopted.

However, of all the process and practices that are in place, there are specific aspects that agencies and companies believe either enable or hinder regulatory review. Accordingly, in preparation for this Workshop, CIRS surveyed both of these stakeholders in 2011 to identify the critical factors that can facilitate or impede regulatory assessment. For agencies that are evolving rapidly but that may also have resource restriction, the survey sought to identify those key review processes and procedures that could be considered critical enablers of review.

This Workshop was held to bring together agencies and companies to identify and discuss the features of an evolving, globally consistent review process that enable the transparent, timely, predictable and good-quality evaluation of new medicine.

Workshop Objectives

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

KEY POINTS FROM PRESENTATIONS

SESSION: WHAT ARE THE PROCESSES AND PRACTICES THAT CAN ENABLE OR HINDER THE REVIEW?

CIRS Executive Director, **Lawrence Liberti** welcomed participants to the sixth annual 2011 Emerging Markets Workshop, including international representatives from 14 regulatory agencies and sixteen pharmaceutical companies for presentations and discussions of the evolving practice of regulatory review, particularly as it applies to countries with developing pharmaceutical markets.

The healthcare industry has become a powerful engine of economic growth in Malaysia and will play an important role in the country's plans to become a fully developed economy by 2020. **Dato' Eisah A. Rahman,** *Senior Director of Pharmaceutical Services, Ministry of Health, Malaysia,* Malaysia outlined current and future initiatives for the country's government and economic transformation such as the institution of regulatory fast track and best practices programmes and the reorganisation, capacity building and infrastructure development of the regulatory review system.

Although the practice of clinical pharmacology continues to progress, its primary role in the development of medicines remains the same: to ensure that every patient receives the appropriate therapeutic dose **(Figure 1)**. **Day 1 Chairman, Professor Sir Alasdair Breckenridge,** *Chairman, MHRA, UK* discussed advances in pharmacologic precision, enabled by drug-drug interaction and special population studies, predicting that enhancements in pharmacokinetic and pharmacodynamic modelling may result in fewer, more targeted clinical trials in the future.

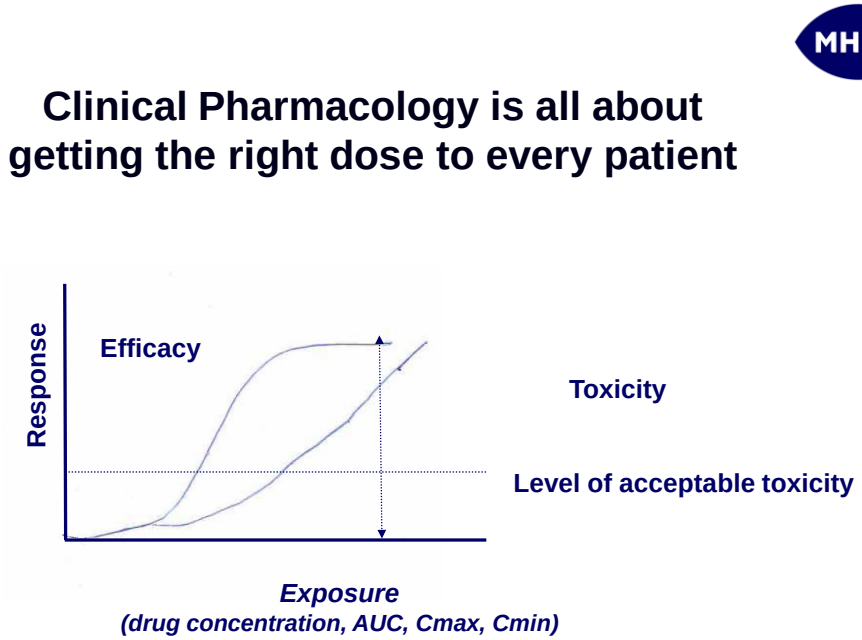


Figure 1. Clinical pharmacology seeks to define the correct dose for diverse patient populations.

The analysis of **Dr Yi Feng**, *Assistant Center Director and Director of the Office of Drug Review Management of the State Food and Drug Administration (SFDA)/Center for Drug Evaluation (CDE), China,* which was presented by **Dr Zili Li,** *Executive Director and Head of Emerging Market Regulatory Strategy, Merck & Co, Inc,* described several ongoing and planned initiatives that have been designed to optimise the capacity and capability of the Chinese regulatory review system. In 2011 the CDE was reorganised to change from a therapeutic-aligned to a

discipline-aligned review structure and three important documents were issued on the topics of guiding principles and procedures, and review and decision-making pathways. Additional issues of focus for the agency include enhancement of timeliness of activities, improving communication with stakeholders and transparency of decision-making, building a risk-based review and decision-making model and applying good review practices (GRevP). Finally, future plans include capacity building through staff education and more extensive interactions with established agencies.

As countries with emerging pharmaceutical markets become important partners in global drug discovery and development. Improvements in the predictability, transparency, timeliness and quality of the review process are needed. Providing examples of recent enhancements of regulatory review practices in emerging markets, **Dr Paul Huckle,** *Chief Regulatory Officer and Senior Vice President, Global Regulatory Affairs, GlaxoSmithKline, USA* explained that optimal global drug development can be fostered through the alignment of regulatory requirements and enhanced collaboration and effective resource utilisation among regulators through joint reviews, the exchange of scientific assessment reports, joint good manufacturing process inspection and clinical trial data recognition.

Prisha Patel, *Portfolio Manager, CIRS, UK* presented the results of the 2011 CIRS Emerging Markets Focus Study. Twelve companies provided responses and scored the attributes that enabled or impeded a transparent, procedurally predictable, timely and good-quality review; in addition, the respondents were asked to rate the performance characteristics of individual agencies relative to those attributes **(Figure 2)**. Among the elements rated as extremely valuable enablers for good review practice by all respondents were the ability to negotiate the timing of dossier submissions, the availability of transparent processes and decision making, robust information management systems, and good opportunities to engage in dialogue/interaction with the agency. Responses to the survey were in the process of being collected from regulatory agencies a complete report will be prepared based on the industry and agency responses.

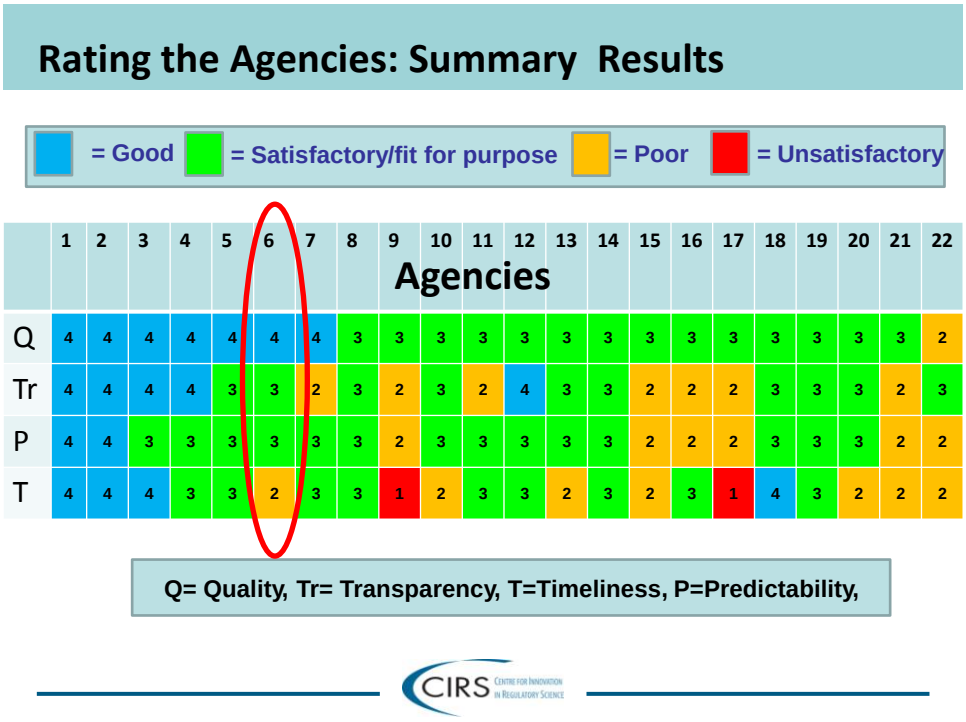
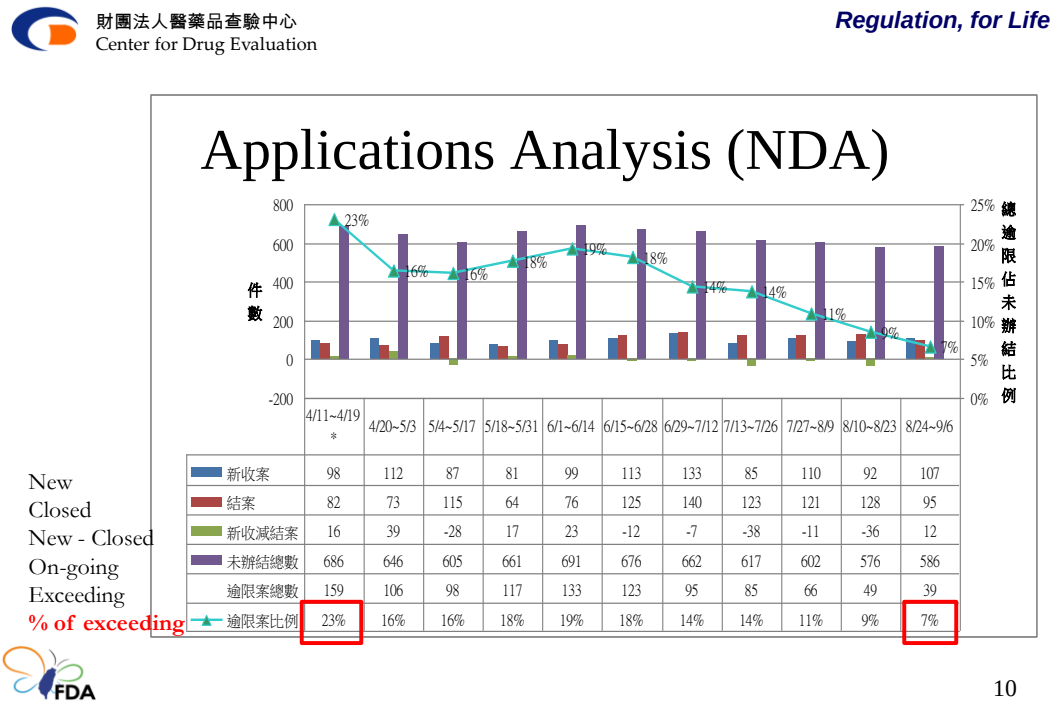


Figure 2. CIRS Emerging Markets Focus Study: A summary of the average ratings of the quality, transparency, timeliness and predictability of regulatory agencies by nine companies.

Results of a recent study of the quality of dossier submissions for new and generic drug applications in Indonesia revealed that supportive data in these applications were not always adequate, particularly for active

pharmaceutical ingredients and product development. To reach the common goal shared by industry and regulators for consistently high-quality products that will exert a positive effect on public health, **Lucky Slamet,** *Deputy, Therapeutic Products, Narcotics, Psychotropic & Addictive Substance Control, National Agency of Drug & Food Control, Indonesia*, suggested that the developers of new medicine should understand and strive to comply with guidelines and requirements such as those for good laboratory, manufacturing and clinical practices. In addition, sponsors must provide data as required by specific regulations or guidances and respond to agency questions in a timely manner, thereby building effective communication with regulators based on mutual trust.

Dr Chih-Liu Lin, *Deputy Executive Director, Center for Drug Evaluation (CDE), Taiwan* reported that the percentage of new drug application regulatory reviews that exceeded timing targets was reduced from 23% to 7% within 6 months of the introduction of the Integrated Medicinal Products Review Office (iMPRO) in Taiwan in 2011 **(Figure 3)**. Formerly, the administration and final resolution of each application was handled by the Taiwan Food and Drug Administration (TFDA) and the technical review and recommendations performed by the CDE, each with the oversight of separate project management teams. iMPRO combines the resource capacity of the two divisions, with unified standard operating procedures and flow control.



	4/11~4/19 *	4/20~5/3	5/4~5/17	5/18~5/31	6/1~6/14	6/15~6/28	6/29~7/12	7/13~7/26	7/27~8/9	8/10~8/23	8/24~9/6
新收案	98	112	87	81	99	113	133	85	110	92	107
結案	82	73	115	64	76	125	140	123	121	128	95
新收減結案	16	39	-28	17	23	-12	-7	-38	-11	-36	12
未辦結總數	686	646	605	661	691	676	662	617	602	576	586
逾限案總數	159	106	98	117	133	123	95	85	66	49	39
逾限案比例	23%	16%	16%	18%	19%	18%	14%	14%	11%	9%	7%

Figure 3. Regulatory reviews exceeding time targets were reduced from 23% to 7% with the implementation of a single project management system in Taiwan.

As the former *Executive Director of the European Medicines Agency* and the current *Director, Pharma Executive Consulting*, **Dr Thomas Lönngren** discussed methods to ensure consistency in regulatory practice from the perspective of an established agency, including developing and adhering to practical review procedures, implementing a quality assessment system, developing a competent staff and striving for transparency in process and results. In addition, the predictability and auditability of regulatory decisions will be enhanced if the methodology used for the benefit-risk assessment of medicines becomes more systematic and consistent, using well-defined and well-valued parameters and encompasses the use of qualitative and quantitative methodologies.

Patrick O'Malley, *Senior Director, Global Regulatory Affairs – International, Eli Lilly and Company, USA* cited three aspects of regulatory review that enable the assessment of medicines: first, consultation and access, that is, the opportunity to discuss trial design, the positions of other regulators, the submission package and other key issues; second, process consistency and predictability, in which the review process, including associated steps

and timelines, is well defined and consistently managed across different regulatory groups and agencies; and third, the degree of clarity and level of situational specificity of regulatory requirements. Mr O'Malley provided agency-specific examples of regulatory successes enabled by these characteristics as well as examples of challenges created by their absence.

Dialogue or communication between regulatory agencies and pharmaceutical companies should be a bilaterally positive experience that can educate, clarify or inform. However, as **Dr Murray Lumpkin,** *Commissioner's Senior Advisor and Representative for Global Issues, US Food and Drug Administration,* pointed out, dialogue is also extremely resource intensive for both parties, and like other aspects of product development, it is a process that must be well managed to be successful. Sponsors must optimise opportunities for communication by carefully considering the purpose of the interaction and reviewing, documenting and following up the results, while agencies must be accessible and engaged while maintaining objectivity.

Dr Jason Ferla, *Acting Principal Medical Adviser, Therapeutic Goods Administration (TGA), Australia* provided information on Australian Public Assessment Reports (AusPARs). Published by the TGA within one month of product approval or ninety days of product rejection, AusPARs are modelled on the similar *European Public Assessment Report* implemented by the European Medicines Agency, and contain data about the evaluation of a prescription medicine and the considerations that led the TGA to approve or reject an application. In addition to providing product information, the publication of such summary bases of decisions increases the transparency of and confidence in the regulatory process.

Although as **Dr Zili Li**, *Executive Director and Head of Emerging Market Regulatory Strategy, Merck & Co, Inc,* reported, the *summary basis of approval* varies globally in name, format and amount of content, its public disclosure is beneficial to both the pharmaceutical industry and regulatory agencies, particularly in countries with emerging pharmaceutical markets .Dr Li pointed to the summary basis of decision, as published on the Health Canada website as a model of the clear, consistent and comprehensive provision of information regarding regulatory decision making **(Figure 4)**. In countries building experience in the development and regulation of new medicines, this public disclosure can serve both as an aid to company understanding of the rationale for agency decisions and as a driver for enhancement of regulatory agency capabilities.

Figure 4. The summary basis of decision, as published on the Health Canada web site.

SESSION: DRIVE TO ACHIEVE A CONSISTENT REGIONAL UNDERSTANDING - EVOLVING THE REGULATORY PROCESS – WHERE ARE WE HEADING?

Day 2 Chairman, Associate Prof John Lim, *Chief Executive, Health Sciences Authority, Singapore* summarised the presentations and discussion of the first day of the Workshop with the observation that six factors impact regulatory review. capacity, communication, collaboration, systems, stratification of risk and strategic and horizon innovation scanning. Professor Lim posed the question, *Are limitations in regulatory review linked to limitations of regulatory science, agency or industry matters, or political, national or cultural factors?*

Discussing his review of medical regulatory agency websites, **Dr Lembit Rägo,** *Coordinator of Quality and Safety: Medicines, Essential Medicines and Pharmaceutical Policies, World Health Organisation,* said that over the past eight years the number of regulatory agency websites has more than doubled. However, although there has been considerable improvement in the amount and comprehensiveness of the information provided, there is still room for improvement in all topics on these websites, including in key subjects such as information for applicants, regulatory guidance, pharmacovigilance and registries of medicinal products.

The mission of the Gulf Centralized Committee for Drug Registration (GCC-DR) is to provide Gulf States of Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates and Yemen with safe and effective medications at reasonable prices through the pre-marketing evaluation, marketing authorisation, post-marketing review, GMP inspection and the provision of technical guidelines for new medicines. **Mohammed Al- Rubaie,** *Director of Drug Control, Ministry of Health Oman,* explained that the advantages of the GCC-DR include process efficiency, transparency and harmonisation, as well as improvements in capacity, but challenges remain including inadequate staff, differences in local regulatory systems, guidelines implementation and the time-consuming registration processes **(Figure 6).**.

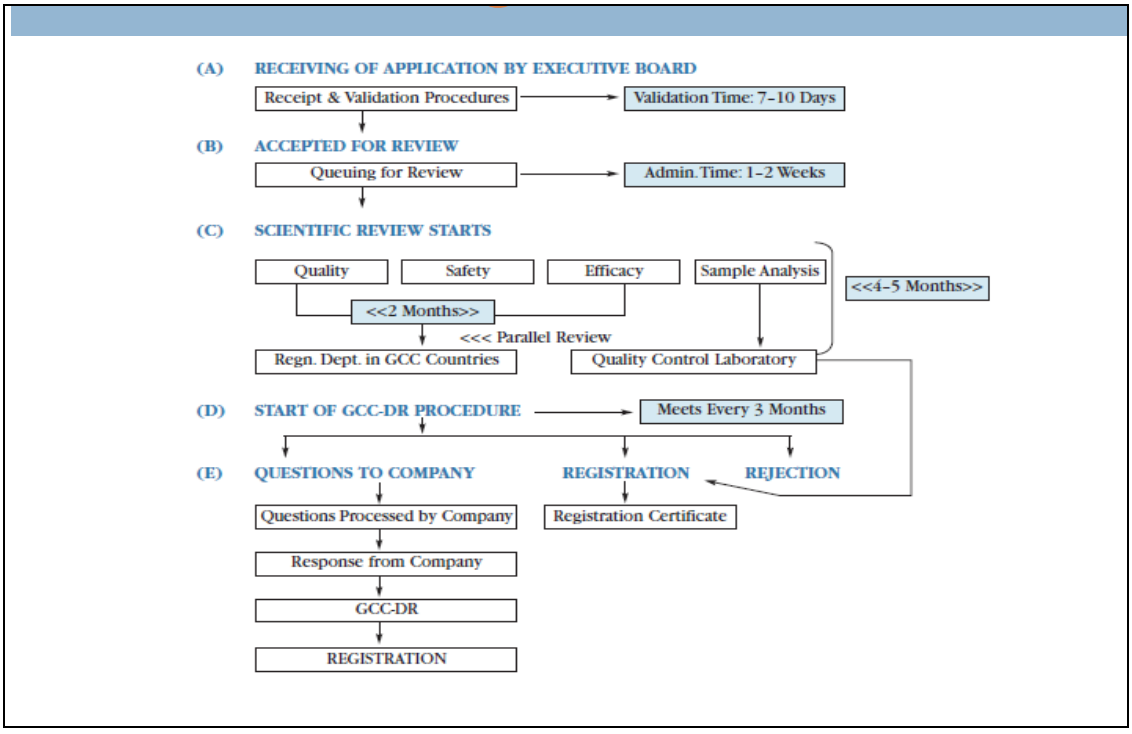


Figure 6. The process map for GCC registration.

Resource constraints in Africa result in a general lack of availability of affordable medicines The African Medicines Regulatory Harmonization (AMRH) initiative seeks to improve public health by increasing access to quality, safe and efficacious medicines for the treatment of priority diseases, through harmonising the requirements and standards and strengthening and building the capacity of local and regional regulatory systems. **Margareth Ndomondo-Sigonda**, *Pharmaceutical Coordinator, African Union – New Partnership for Africa's Development (NEPAD) Agency, South Africa* called for interested partners to join forces and support these efforts at the AMRH launch on 29 March 2012 in Arusha-Tanzania.

Chao-Yi (Joyce) Wang, *Senior Specialist, Food and Drug Administration, Taiwan,* explained that the Asia-Pacific Economic Cooperation (APEC) Best Regulatory Practice Project was developed to facilitate the adoption of good regulatory practice (GRevP) among regulatory authorities and stakeholders within APEC; reduce regulatory burden; provide patients with timely access to medicines and to provide a platform for regulatory dialogue and experience sharing. Components of the project include a survey to examine the disparities of GRevP and approaches to scientific assessments among APEC economies, a pilot study on the use of available regulatory review reports from other participating agencies, and a series of GRevP training workshops covering both pharmaceuticals and medical devices, the most recent of which was successfully held in October 2011 in Taipei City, Taiwan.

The four-agency consortium comprising Swissmedic, the Health Sciences Authority of Singapore, the Therapeutic Goods Administration of Australia and Health Canada was initiated in 2007 on the basis of a network of bilateral agreements. **Cordula Landgraf**, *Head of Networking, Swissmedic,* said that the consortium has progressed from information sharing on safety, policy, guidelines and clinical trials to labour sharing in Working Groups for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and in completed pilots and planned projects for parallel scientific review. In addition, an electronic template for the qualitative benefit-risk assessment of medicines was developed by the consortium in cooperation with CIRS and is currently being tested by the four agencies.

SYNDICATE DISCUSSIONS

Key Points from the Syndicate Discussion 1

Timely and predictable review process: What does this mean? Assuming resources were not an issue, what process and procedures would an ideal agency adopt?

- *Timeliness:* Syndicate members agreed that multiple issues can impinge on a timely regulatory review. Internal factors such as the number and competency of reviewers and regulatory staff have an impact, as can adherence to time targets due to limited case management and project tracking skills. Regulatory agencies may conduct complex, full evaluations or rely on the reviews of reference agencies to expedite certain types of reviews. Finally, the types and clarity of questions raised by agency and the time required by the sponsors to answer those queries have an obvious effect on overall timelines.

- *Predictability*: As with timeliness, the number and competency of regulatory reviewers and regulatory staff, the depth of reviews and the types and clarity of agency questions all exert an influence on process predictability. An understanding by companies of processes and procedures and assessment criteria are absolute requirements for regulatory agency predictability as are the agency's use of a scientifically sound decision-making framework and supportive guidelines. Additionally, agencies must engage in open and timely dialogue with sponsors, ensure consistency between reviewers and submissions and achieve transparency of decision making

- Clear definitions of *timeliness* and *predictability* are required:

    - *Timeliness* should encompass realistic goals that are dependent on medical need and access priority. It must be measured from submission to outcome and divided into different stages, with properly defined milestones and target timelines. Target timelines should be constructed dependent on the type of review (for example, full, abridged or verification) and should additionally incorporate consideration of the amount of required resources, both in manpower and competencies. Response time by companies should be stated.

    - *Predictability* requires that companies understand and comply with dossier requirements and that submissions be of good quality. It also requires agency transparency and the employment of the necessary number of reviewers with appropriate competencies, governance and accountability to patients' needs, and ensuring that reviewers are consistently using proper evaluation criteria. Predictability entails understanding that because it is dependent on individual judgement, some variability in regulatory review is unavoidable, although it can be minimised with the use of standard quality management templates and good review and regulatory practices.

- *A timely and predictable timeline* requires resources in terms of manpower, competency and training, the use of a standard assessment template and training for the template's use. This training must incorporate consideration of the relevance of data to specific markets. Additionally, companies should strive to adhere to scientific advice and provide full and timely responses to agency queries.

Key Points from the Syndicate Discussion 2

Good quality review: What does this mean to companies and agencies and what are the key components?

- *Actively building quality into the review process:* It was the consensus of this Syndicate that the quality of a regulatory review is highly dependent on the quality of the internal regulatory processes such as the supportive standard operating procedures and adherence to good review practices. Staff capacity is

another important factor in review quality and as ideal performance targets should be the goal to be reach, addressing the competence of the staff through training needs to be a continuous process. Programmes for professional development of review staff are an important factor in retaining qualified personnel and all assessors should be formally trained in benefit-risk evaluation. Alignment of review processes should be promoted at the regional level and international collaboration and cross-agency training and the sharing of information (through appropriate legal avenues) and resources must be encouraged.

- *Measuring quality of the review process:* An inbuilt continuous improvement process could be developed through the use of such tools as a "customer" survey of both agencies and companies, the refinement and expanded use of an independent survey such as the CIRS Quality Scorecard programme, the use of internal and external audits, agency-to-agency review or a review of post-approval regulatory events (ie, an analysis of serious unexpected or other adverse events). Quality documentation and the review of procedures and products through the use of assessment templates and key performance indicators should be an integral part of regulatory policies and standard operating procedures. Another option might be the use of an integrated peer review system such as an independent advisory committee. Such ongoing and scheduled reviews could enhance accountability for the regulatory review process.

- *The quality of decision making:* delinking the regulatory review process from the process of making decisions should be explored. Although the quality of decision making is of equal importance to the quality of review process and procedure, methods for enhancing and measuring that quality have yet to be outlined.

Key Points from the Syndicate Discussion 3

Transparency of the review process before, during and post approval: What should be transparent and how should this be measured?

- *Different levels of transparency:* Certain details of the development and regulation of medicine are not amenable to transparency for business, legal or personal privacy reasons, such as manufacturing specifications and patient–specific data. Furthermore, implementing transparency policies is resource-intensive and could become a barrier to the fulfilment of the primary mission of regulators, that is, the efficient and timely assessment of medicines. Finally, it is not clear that it would be useful or practical for patients to be informed of all aspects of the data in a submission (ie, how would patients interpret all avaiable safety data for each new product?).

- *Summary basis of approval:* It was the opinion of this Syndicate that the publication of the summary basis of approval or decision could be a tool to create transparency and quality, but the target audiences and therefore, the nature of the content for this document should be considered. For example, such documentation may not always serve as a sufficient sole basis for another regulatory agency's approval of the medicine but may, for some low-risk medicines, provide sufficient background to support a decision..

- *What do companies want from agencies:* In order to prepare high-quality applications, pharmaceutical companies need transparent guidelines. After submission, sponsors expect that the agency will follow consistent review criteria guided by consistent internal processes and procedures, supported by communication tools to enhance regulator-sponsor discussions and a tracking system to monitor the progress of review timelines and key steps.

- *What do agencies want from companies:* Agencies would benefit from advance alerting of upcoming applications, to staff appropriately and prepare their internal resources. In addition, post-approval safety data presented in a useful format (ie as a database rather than a static PDF), information regarding off-label use where available and information about critical queries from other agencies that have been resolved can all prove useful and valuable to regulators.

Conclusions

Whilst mindful of the challenges presented by limited resources and divergent priorities in countries with emerging pharmaceutical markets, great progress has been made in the enhancement of the timeliness, predictability, and transparency of regulatory review. However, emerging market countries encounter barriers to this progress that are similar to those experienced in established markets.

Timeliness of the review may be impacted by the quality of the dossier or by the period for sponsor responses to agency queries. Predictability can be subject to the variability of individual judgement or regional differences in the perceived applicability of data. Transparency can be affected by legislated restrictions, concerns for protection of privacy and intellectual property, and the fact that resources that are expended to ensure transparency may be diverted from fulfilling the primary mission of efficient regulatory review.

Enablers of quality that can and should be modelled from regulatory agencies in established markets include the development of and adherence to standard operating procedures, the use of standardised review templates, implementation of processes for continuous improvement and evaluation, and the use of programmes for staff development and training. In addition, emerging market economies should consider the alignment of regional requirements and embarking on programmes of cooperation and work sharing to mitigate the effects of resource restrictions thereby facilitating timely, quality reviews.

Considerable benefit can be realised from these efforts. As remarked by Professor Lim, there is an “ongoing need for commitment, vision and courage on part of agencies and industry to continue this important work,” work that will ultimately expedite patient access to important new medicines.

SPECIAL THANKS TO

The Workshop Chairs

Professor Sir Alasdair Breckenridge, *Chairman, MHRA, UK*

Associate Prof John Lim, *Chief Executive, Health Sciences Authority, Singapore*

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Prisha Patel, *Portfolio Manager, CIRS, UK*

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Dr Chih-Liu Lin, *Deputy Executive Director, Center for Drug Evaluation, Taiwan*

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Patrick O'Malley, *Senior Director, Global Regulatory Affairs – International, Eli Lilly and Company, USA*

Dr Murray Lumpkin, *Commissioner's Senior Advisor and Representative for Global Issues, US Food and Drug Administration*

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Dr Zili Li, *Executive Director and Head of Emerging Market Regulatory Strategy, Merck & Co, Inc*

Dr Lembit Rägo, *Coordinator of QSM, World Health Organisation*

Mohammed Al- Rubaie, *Director of Drug Control, Ministry of Health. Oman*

Margareth Ndomondo-Sigonda, *Pharmaceutical Coordinator, African Union - NEPAD Agency, South Africa*

Chao-Yi (Joyce) Wang, *Senior Specialist, Food and Drug Administration, Taiwan*

Cordula Landgraf, *Head of Networking, Swissmedic*

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