

The 5th IFPMA Asian Regulatory Conference 2008 – Part II

Asia's role in global drug development, self-regulation by industry and pharmacovigilance were among the many topics discussed at the IFPMA's conference on regulatory affairs in Asia. *Alan Chalmers* reports.

This is *RAJ Pharma's* second report on the 5th IFPMA Asian Regulatory Conference, held this year in Kuala Lumpur, Malaysia. The first report, which was published in the June issue of the journal, examined Asia's place in global harmonisation efforts, good regulatory practices and how to assure quality. This month we look at another set of highly topical issues that were discussed at the conference, which took place on 11-13 March: Asia's role in global drug development, pharmaceutical industry self-regulation and business ethics, pharmacovigilance and the maintenance of product information, and future regulatory challenges.

Asia's increasing role in global drug development was a major topic at the conference

Global drug development: Asian role and responsibility

This session was chaired by Thomas Lönngren, executive director of the European Medicines Agency, and Amar Kureishi of Bayer Asia, Singapore. The panel discussion was based on the two breakout sessions and comprised Yuppadee Javroongrit of the Thai Food and Drug Administration; Murray Lumpkin of the US Food and Drug Administration; S Edmund Tsuei of Roche Australia; Heng-Der Chern of Taiwan's Center for Drug Evaluation; Kazuhiko Mori of the Japanese Pharmaceutical and Medical Devices Agency; and Romi Singh of Amgen, US.

In Asia, much progress has been made regarding the approval of clinical trials, the session found. In South Korea, the regulatory authority, the KFDA, has taken significant steps in the area of clinical trial applications by separating the investigational new drug and new drug application processes. Its Chinese counterpart, the SFDA, has implemented process changes, and there are now unique submission routes for different kinds of products as well as for clinical trials. Changes are also planned in Thailand with respect to clinical trial application processes and requirements. Some unique elements have been identified, such as the South Korean online system for status tracking and a special procedure in China has prioritised the handling of selected clinical trials. Time frames still require improvement in some countries, including China.

Considerable progress has been made in the area of clinical trial approvals...

Asia is now very much a part of global drug development, with a harmonised approach increasingly being seen. A recent development is the inclusion in trials of a mixture of Chinese, Japanese and South Korean patients. Singapore has developed a special focus on early Phase I studies, while Taiwan has set up a neutral government sponsored research centre.

In the ensuing open discussions, Yves Juillet of the French industry association Leem (Les Entreprises du Médicament) and chair of the IFPMA regulatory policy and technical standards committee, asked what the next steps would be. The panel responses again referred to collaboration among China, Japan and South Korea. Dr Mori mentioned that one in four new clinical studies in Taiwan would consider incorporating Japanese data. Dr Yuppadee said that being part of global development would necessitate good checks on dosage regimens, a lot of preparatory work and thus a need to prioritise. Many severe illnesses still lack adequate treatments and co-operation, rather than competition, would be the best way forward. Harmonising the technical guidelines and then looking at increasing capacity in terms of regulatory authority personnel should be the next steps.

The World Health Organization agreed with the view from Thailand that there is also much to do in terms of ensuring good quality of existing products as well as new therapies for existing diseases such as malaria. There is also a need to increase pharmacovigilance in the region. Electronic databases, including those for clinical trials, could be beneficial.

...although there is still much to do to ensure that existing products are of good quality

Other questions dealt with active pharmaceutical ingredients, with reference to current problems regarding the quality of heparin from some sources in Asia. This episode may prove a turning point, as Asia starts to have a bigger share of the global voice on API quality.

The panel was invited to give brief key summary messages. Dr Yuppadee said the aim of global drug development should ultimately be to find cures for chronic diseases; the onus was on the industry to lead this initiative through global clinical development and work towards preventing adverse drug reactions. Dr Lumpkin said that Asia as a region of innovation has a

great deal of potential in terms of new drug development and may significantly contribute to development of treatments for malaria, cancers and HIV. For Dr Tsuei, the industry needs to break down the barriers between regions that prevent better, clinically differentiated medicines reaching patients faster, and to make more use of regional talent in drug discovery.

Dr Chern suggested more partnership and more pressure to link up ASEAN and East Asia, with the Global Cooperation Group of the International Conference on Harmonisation and the WHO taking the lead. Dr Mori called for harmonisation of regulations and procedures, sound competition with openness and new opportunities in biotechnology.

Ms Singh noted that development plans for Asia are an integral part of global development plans, and that there is a need to break down barriers and challenge bureaucratic regulations. Mr Kureishi wanted a greater degree of collaboration in drug development: new drug development should not be left to industry alone, and more sharing of efforts is required between industry and regulators. Mr Lönngrén suggested continuing to follow up discussions from this Asian Regulatory Conference and returning to measure progress at a future one. Good manufacturing practice for active pharmaceutical ingredients and good clinical practice would be good areas for Asia to focus on in this period.

There were calls for more industry/government co-operation in the field of new drug development...

Clinical trial application processes and requirements

This session was chaired by Dr Lumpkin and Dr Tsuei. Participants said that in order to facilitate global development, the process of harmonisation with respect to IND and CTA requirements needed to continue. This objective was pursued by discussing the various technical requirements, timelines and medical practices, which constitute a major challenge to global study planning.

"The EU Clinical Trials Directive: The EMEA Roadmap to 2010" was presented by Mr Lönngrén. He noted that clinical trial approvals in the European Union are still the responsibility of the national authorities, not the EMEA. The EU Clinical Trials Directive (2001/20/EC), however, has harmonised the requirements, backed by the Good Clinical Practice Directive (2005/28/EC), which defines GCP standards, and the technical requirements relating to the investigational medicinal product. The EudraCT system is a register of all clinical trials (including those in connection with a paediatric investigation plan, or PIP). Within the EMEA's Committee for Medicinal Products for Human Use (CHMP), there is a clinical trial facilitation group.

...and for the process of harmonisation with respect to IND and CTA requirements to continue

In-Sook Park of the KFDA presented "IND Processes and Global Clinical Trials in Korea". International harmonisation efforts have greatly influenced the pharmaceutical regulations in South Korea. The enforcement of Korean GCP, the adoption of the bridging study concept and the separation of INDs and NDAs have been the most significant moves affecting the environment for clinical trials. The new IND regulations since 2002 have resulted in a significant increase in the number of international clinical studies conducted in South Korea, from 17 in 2002 to 147 in 2007. The institutional review board review process can now be conducted in parallel to the clinical trial application to the KFDA. The KFDA has also reinforced its GCP inspection systems. Further international harmonisation is planned¹.

"Requirements for Clinical Trial Applications in the PR China" was presented by Ding Jianhua, director of the Chinese SFDA. Clinical trial approvals are required for domestic new drugs, domestic generics, imported drugs, multicentre international studies and investigational products. These are reviewed and approved by the Center for Drug Evaluation and the SFDA. Four thousand clinical trials are processed each year, 80% of which are for generic products. Since 1 October 2007, new procedures have been introduced for clinical trial approvals including acceptance of the Common Technical Document format, test programmes for INDs, a more open and transparent process and the strengthening of Chinese GCP.

"Clinical Trial Application Process in Thailand" was presented by Dr Yuppadee, who is also co-chair of the ASEAN Consultative Committee for Standards and Quality Pharmaceuticals Product Working Group (ACCSQ/P-PWG), and ASEAN observer to the ICH GCG. She said Thai GCP had been successively introduced since 1997, and that the Thai FDA had actively supported the necessary regulations in harmony with ASEAN and international ICH requirements. The International Clinical Research Collaboration Centre now handles about 291 trials annually. Further changes are planned to enable Thailand to be involved in more early IND clinical trials, more IRBs and independent ethics committees and more global international studies while encouraging regional harmonisation to meet international standards. Amended regulations are expected for the review process, GCP inspections, the monitoring of serious adverse drug reactions, and parallel submissions of CTAs with IRB approvals.

ASEAN has already adopted many ICH safety and efficacy guidelines...

ASEAN has adopted many ICH safety and efficacy guidelines, with 26 guidelines now in place. Correct implementation of these is a critical factor. There are now 16 members of the

Consortium of Thai Medical Schools linking up key research centres. The Thai Pharmaceutical Research and Manufacturers Association is also very active in supporting these improvements and has always been supportive of training in GCP and other areas.

“An Industry Perspective and Experiences of CTA Process, Timelines across the Asia region” was the final presentation before the Q&A session, and was delivered by Dr Tsuei. The ten years since the introduction of ICH GCP requirements have seen a dramatic increase in clinical studies in the Asia region, and as a result CTA processes have been rationalised. The majority of studies are conducted in Australia, Taiwan, Japan, South Korea and China, but also in other countries throughout the region. With the exception of China (where IND approval can take a year), all countries can approve a CTA within four months. In many countries the deterrent factor to commencing a clinical trial is no longer regulatory approval of the CTA but rather ethics committee approval and logistical matters.

While it had been mentioned by Dr Tsuei that Australia (and also Thailand) had no formal approval process for the CTA, Australia’s Therapeutic Goods Administration’s Clinical Trial Notification Scheme still requires certain undertakings and signatures.

Question and answers

A number of questions were raised in the Q&A session. Is Asian data accepted in the EU? It depends, as always, on the quality of the data, age, gender, trial design, concomitant medications and medical practice. Does China still need a Certificate of Pharmaceutical Product? Yes, but not for international multicentre clinical trials. What is the situation in Hong Kong, and can China use data from Hong Kong? There are three SFDA-approved sites in Hong Kong, which can be used for China as long as Chinese SFDA requirements are met. And can multinational/multicentre clinical studies be used to get a bridging data or bridging study waiver in South Korea? Yes, but there is no specific guideline on number of patients necessary, so companies are recommended to discuss this with the KFDA beforehand.

Asia’s involvement in global clinical trials

The harmonisation of interests and needs in respect to study outline and clinical practice as well as regulatory requirements were key topics for this breakout session, as the execution of global studies is a challenge for both authorities and companies. The session was chaired by Dr Chern of the CDE in Taiwan and Stephen Wise, director of the Lilly-National University of Singapore Centre for Clinical Pharmacology.

“The Challenge and Future Direction for Asia Drug Development” was the introductory presentation by Dr Mori, who highlighted the diversity within the region and the need for further harmonisation efforts.

Dr Chern gave a presentation on “Clinical Trials in Taiwan from 1994 to 2007 and beyond – A Perspective of Regulatory Environment and Strategy”. Local registration of clinical trials was introduced in Taiwan in 1993, and was replaced by the bridging study evaluation in 2000. GCP has been in place since 1996 and the CDE was set up in 1998. A streamlined IND assessment was introduced in February 2007. As a result of all these measures, Taiwan is now one of the preferred sites in Asia, especially for multinational clinical trials, which constituted 75% of the 167 INDs in 2007. As of 31 January 2008, there were 573 clinical studies ongoing, which compares well with the 665 in Australia. ICH E5 guidelines (on ethnic factors in the acceptability of foreign clinical data) are utilised and, within the Asia Pacific Economic Cooperation network, foreign non-Chinese data are accepted. The introduction of more formalised data-sharing on agency assessment reports (similar to the previous Pharmaceutical Evaluation Report scheme) was advocated.

A presentation on “Global Clinical Development in India” expanded the conference’s geographic coverage westward. Dr Singh indicated that many multinational healthcare companies have been considering India as a new opportunity to access talent and patient populations on a cost-effective basis. While being a preferred R&D location, India still presents challenges and differences in the conduct of clinical research. This is evolving and India will be a key country for the execution of global clinical studies in future.

Combining his expertise as principal investigator at the Lilly NUS Centre for Clinical Pharmacology and associate professor of the National University of Singapore, co-chair Dr Wise demonstrated the considerable advances there had been in, and the opportunities there were for, conducting clinical studies in Asia. An “Update on Clinical Trials in Asia and Action Plan with Authority in Japan”, the final presentation in the session, was given by Tetsuto Nagata, associate director of Pfizer Japan and chair of the clinical evaluation committee of the Japan Pharmaceutical Manufacturers Association. Early introduction of GCP in Japan, he said, had resulted in high-quality studies but very extensive and expensive resources were necessary.

With the aim of improving the speed of clinical trials and using resources more efficiently,

...and there has been a dramatic increase in clinical studies in the region in the ten years since ICH GCP requirements were introduced

Taiwan is now one of the preferred sites in Asia for multinational clinical trials

India is also a preferred R&D location

the government had launched development programmes for clinical trial infrastructure, while the pharmaceutical industry and institutions had collaborated in promoting the efficiency of existing processes. An interesting new development was the increasing interest in, and conducting of, collaborative studies with other Asian countries.

Pharmaceutical industry self regulation and business ethics: global and regional challenges

This session was chaired by Richard Bergström, director of the Swedish industry association LIF and chair of the IFPMA code compliance network, and Wong Kok Seng of Pfizer Malaysia.

The new IFPMA code came into effect on 1 January 2007 and since then the IFPMA has engaged in regional activities to promote the code and facilitate its implementation at the national level. Key elements of the new code are more restrictive provisions on travel, gifts and scientific events, and the establishment of both a code complaints procedure and a code compliance network bringing together code experts from all over the world. This session aimed to address this important aspect, as the promotion of innovative medicines is a key part of the discovery, production and marketing of medicines – an essential element of information to healthcare professionals about new medicines and new uses for existing medicines.

The new IFPMA code is intended to have a global reach

“Global Ethical Promotion Challenges and the IFPMA Code of Pharmaceutical Marketing Practices” was the opening presentation by Mr Bergström. The new IFPMA code is intended to have a global reach, and has an ambitious comprehensive mandate (although it does not cover direct-to-public advertising). Challenges ahead include geographical discrepancies, sector discrepancies such as with generics or domestic products, external parties and providers. The IFPMA code is seen as a joint effort with the World Medical Association; early talks with FIP (Fédération Internationale Pharmaceutique) have been held, liaison with the WHO is maintained and possible future discussion partners could include the OECD and the World Bank.

Frédérique Santerre of the IFPMA explained “Dispute Resolution under the IFPMA Code: Review of the Code Operating Procedure”. The code was updated in 2006 with a preamble, application and rules, and a Q&A section. Full details are on the new website².

“Malaysia Ethical Promotion, Trends and Challenges” was presented by co-chair Dr Wong Kok Seng, who as well as being medical director of Pfizer in Malaysia is a member of the ethics committee of the Pharmaceutical Association of Malaysia (PhAMA). The IFPMA code has been adopted in Malaysia and the companies work closely with the Medicines Advertisements Board of Malaysia. Further information is available on the website³.

“China Ethical Promotion, Trends and Challenges” was addressed by Jeff Schultz, executive director of the R&D-based Pharmaceutical Association in China (RDPAC). One of the RDPAC’s main and very successful activities has been to introduce medical representative certification; training courses are conducted by the association. In 2008, training for a further 10,000 medical representatives is planned in various major cities throughout China including Nanjing, Zhejiang and Guangdong, as well as Beijing and Shanghai as before.

There is also a WHO code available for regulatory authorities. A meeting was held on this in 2007 in Bangkok, Thailand.

Clinical research is currently not part of the code

Clinical research is currently not part of the IFPMA code. In the EU, however, Efpia (the European Federation of Pharmaceutical Industries and Associations) concluded that the code applies also to clinical trials and is in fact to be viewed as applicable comprehensively.

Pharmacovigilance and maintenance of product information: how can agencies and industry work together to protect patients?

The session on pharmacovigilance and maintenance of product information was chaired by Leonie Hunt, director of the drug safety and evaluation branch at Australia’s TGA, and Allen Chu, director of regulatory affairs for Eli Lilly, Australia. The session aimed to discuss global efforts in risk management through the life cycle of a drug; highlight any recent global changes and learning in pharmacovigilance and product information implementation; share recent experiences and developments in pharmacovigilance in Asia; and provide a forum for the industry to share experiences and concerns over current global trends and regulatory requirements.

The session on global risk management was presented by Kaori Nomura, chief of the Safety Information Division of the PMDA in Japan and a rapporteur for the Ministry of Health, Labour and Welfare on ICH guideline E2B(R3) on clinical safety data management. Dr Nomura emphasised the need for a global risk management plan, with vigilance activities throughout the life cycle of the product. Reference was made to the IFPMA brochure on pharmacovigilance and to a report from a UK Medicines and Healthcare products Regulatory Agency symposium in 2006 on

The need for a global risk management plan was highlighted

drug safety and public health. It was suggested that early consultation with regulators concerning pharmacovigilance would be helpful to global developments.

Leonie Hunt presented "Recent Trends in Pharmacovigilance in Australia – Pharmacovigilance and Impact on Product Information". The Australian pharmacovigilance system emphasises the whole product life cycle, including postmarket monitoring. Key features include a high proportion of voluntary reports and contributions to international data collection. Recent initiatives include a web-based electronic reporting form, a dedicated public consumer reporting line and risk management plans to cover the life cycle management of approved products.

Challenges include the mainly spontaneous reporting, data mining potentials and pitfalls and pharmacoepidemiology.

Product information in Australia, mainly for consumers, reflects the pharmacovigilance experience. There is a need to adapt the communication methods for product information, with clear messages being essential. Further information is available on two websites⁴.

The perspective of the host nation was given by Tan Lie Sie of Malaysia's National Pharmaceutical Control Bureau in a presentation entitled "Evaluation of Safety Reports in Asia: Regulators' Perspective and Awareness".

Ms Tan said the system in Malaysia has proved very useful since it was introduced in the 1990s. There has been a major shift in emphasis towards reducing reliance on reference countries, with increased awareness of local ADR reporting. Malaysia has an online reporting system that is widely used by hospital pharmacists in particular. Periodic safety update reports are needed for new chemical entities.

In 2007, 3,068 reports were made to the Malaysian Adverse Drug Reaction Committee (MADRAC). At regular meetings of MADRAC, actions are discussed and, if necessary, the Drug Control Authority takes steps to implement policy. As in the whole ASEAN region, consumer reporting is still not very well established.

In terms of ASEAN harmonisation, there is already a memorandum of understanding between Malaysia and Singapore as well as between Singapore and Australia. There is also a pharmacovigilance discussion group involving Australia, New Zealand and Singapore.

Currently the Malaysian ADR database is not accessible to the public but there is increasing pressure for more transparency, driven by the wide range of information available via the internet. The greater emphasis on patient safety necessitates a bigger pool of trained pharmacovigilance regulatory staff, and improved collaboration with the industry would be welcomed.

"The Industry Perspective on How to Communicate Globally on Safety Issues including Safety Impact on Product Information" was presented by Martin Huber of the Schering-Plough Research Institute in the US. The primary concept in moving towards a risk management plan is to proactively identify potential safety issues (risk identification or signal detection). For pharmaceutical products, the product labelling/product information is the primary tool for risk communication. Having a core data sheet is a common global communication approach by the industry. This helps to develop a global position on safety issues, ensures that physicians on a global basis have access to the relevant safety information and also provides guidance on risk mitigation as appropriate. Precautions should alert physicians to exercise special care in particular situations and warnings should help physicians avoid the occurrence of serious adverse reactions.

Conclusion: there needs to be urgent consideration of new tools and processes so that the emergence of safety signals and new labelling can be turned quickly and effectively into meaningful communication to, and understanding by, healthcare professionals and patients.

Malaysia is making efforts to rely less on reference countries in the field of pharmacovigilance

New tools are needed in all markets to enhance communication on safety issues

Future regulatory challenges: is Asia ready?

The final session, on future regulatory challenges, was chaired by Eisah Abdul Rahman, chair of the ASEAN ACCSQ/P-PWG and deputy director of pharmaceutical services at the Malaysian Ministry of Health, and Mark Paxton, associate vice president, international regulatory affairs, of PhRMA in the US. The session aimed to explore some of the newer developments and concepts in Asia as well as to seek recommendations for obtaining flexibility, adopting existing best practices and creating plans for future regulatory excellence in the region.

In "Attractiveness of Asia Region for R&D and Business", Mark Paxton set the scene with challenging figures on drug development globally. There is considerable R&D expansion around the globe, including in Asia. Major initiatives include the Critical Path Initiative in the US, the Innovative Medicines Initiative in the EU, and the EU-US Transatlantic Administrative Simplification initiative. In Japan, the MHLW has held a workshop on evaluation of PK/PD data similarities in East Asian populations.

Regional harmonisation initiatives are being followed successfully in ASEAN and APEC countries, including resource sharing, a harmonisation education centre dedicated to regulatory authorities (which will be in Seoul, South Korea) and the Life Science Innovation Forum.

The debate covered how best to promote good regulatory practices...

...and challenging areas such as biosimilars, orphan drugs and counterfeits

Biosimilars was the very topical subject addressed by Jacques Mascaro of Roche, Switzerland. This presentation highlighted the definitions of identical and similar biotechnological products and the differing approaches to the topic in the EU and the US. Reference was also made to the WHO guidelines emanating from discussions in April 2007. Safety is a crucial consideration and this was demonstrated on the basis of several recent product examples. A risk management plan is essential. Key points included the use of the brand name, lack of interchangeability, adequate quality standards, adequate preclinical and clinical testing, appropriate use, labelling, etc.

The issue of orphan drugs was addressed by Lamine Messaoudi of Abbott, US. The definition of an orphan drug differs from one country to the other. In the US, it is for a disease that affects 200,000 people or fewer, while in the EU the figure is fewer than five per 10,000 people, and in Australia there is a limit of 2,000 patients. There is orphan drug legislation in Australia, the EU, Hong Kong, Japan, Singapore, South Korea, Taiwan and the US. Brazil introduced orphan drug prioritisation regulations in April 2007.

In a presentation on "The View of the Ultimate Stakeholders: Doctors and Patients", SP Chan, professor of medicine at the University of Malaysia, stressed the need to make new innovative drugs available with a minimum of delay from regulatory hurdles. These new drugs should be appropriately used and well monitored, and timely and updated product information is essential. There is also still the need to eliminate counterfeit medicinal products.

In "Challenges and Options for Managing an Evolving Environment", Alistair Davidson of GlaxoSmithKline UK appropriately presented the final review and forward view as chair of the IFPMA organising committee. Mr Davidson said the healthcare and regulatory environment was continually evolving as were healthcare performance and patients' expectations. Adaptation and adjustments based on experience were necessary to meet the challenge.

Resources are a key factor, Mr Davidson declared. In the US, the Prescription Drug User Fee Act and the FDA Modernization Act have been instrumental in providing the necessary resources and capacity, while in the EU, new medicines legislation, rolling reviews and an awareness of life cycle management have been pivotal. The EMEA supports innovative drug development, and is active in hot topics such as biosimilars, clinical trials and global developments. Transparency and collaboration are key elements. There is also increased sharing of information between the EU and the US.

Other key players on the global stage include Canada, Australia and Switzerland. They share: adoption of ICH guidelines; independent review; priority reviews; facilitation of R&D; transparency and accountability; rational prescription-to-OTC switches, and many more topics.

A harmonised dossier, format and content have increasingly been the case in the ICH and associated countries since the last Asian Regulatory Conference. The CTD is now widely accepted, with country-specific requirements increasingly being eliminated. This is a good model for Asia.

New tools are also readily available, including priority reviews, orphan drugs, CPP sourcing, managing product safety, building in flexibility and – last but not least – focusing on patient needs. Resources remain a big issue, as does predictability. Sharing resources may be a solution. Certainly involving industry in developments is desirable: agencies and companies together can conduct quality reviews.

In the closing ceremony, Mr Davidson thanked all those involved in the organisation, the speakers and participants and the host country Malaysia. Based on the successful outcome of this fifth conference and the extremely positive feedback from both the regulatory agencies and the industry, whether presenter or participant, it is now simply a question of when the 6th IFPMA Asian Regulatory Conference will take place. Is Asia ready for future regulatory challenges? Or rather, is the rest of the world ready to meet the challenges emerging from Asia?

References

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Remaining big issues include resources and predictability