

The 5th IFPMA Asian Regulatory Conference 2008

Held in Kuala Lumpur, Malaysia, the IFPMA's latest conference on regulatory affairs in Asia looked at the region's place in global harmonisation efforts, good regulatory practices, and how to assure quality. *Alan Chalmers* reports.

The 5th IFPMA Asian Regulatory Conference, held this year in Malaysia, was organised by the International Federation of Pharmaceutical Manufacturers Associations in co-operation with the Ministry of Health of Malaysia, in collaboration with the World Health Organization and with support from the Pharmaceutical Association of Malaysia (PhAMA). It was attended by over 300 delegates from regulatory authorities, international organisations and pharmaceutical companies. Speakers, discussants and participants had been invited from the health ministries and regulatory authorities of all Asian countries, as had expert representatives from all the International Conference on Harmonisation regions, international organisations and the pharmaceutical industry. The Organising Committee chaired by Alistair Davidson collaborated closely with Odette Morin, director of regulatory and scientific affairs at the IFPMA, and her team.

The welcome address was given by Harvey Bale, director general of the IFPMA. On behalf of PhAMA president Ewe Kheng Huat and the WHO, delegates were welcomed to Malaysia. The keynote address and official opening were made by Y Bhg Tan Sri Datuk Dr Hj Ismail Merican, Malaysian director general of health, on behalf of the Minister of Health of Malaysia. Malaysia aspires to be a fully developed nation in the global arena by putting in place the necessary international standards and practices. In the healthcare sector, it has introduced measures and mechanisms to ensure that clinical trials and research projects, as well as the development of medicinal products, comply with accepted global standards.

This 5th conference, which took place on 11-13 March, was the latest in the series of IFPMA Asian Regulatory Conferences held in Hong Kong SAR (1997), Singapore (1999), Bangkok (2001) and Beijing (2004); the proceedings of the 4th conference have also been published in this journal¹. The 5th conference programme covered the following topics:

- ICH and its Global Cooperation Group (GCG): how Asia fits into the global picture;
- good regulatory practices: are agencies ready?
- quality: how to ensure quality of products;
- Association of South East Asian Nations harmonisation: current status and future perspectives;
- global drug development: Asian role and contribution;
- pharmaceutical industry self-regulation and business ethics: global and regional challenges;
- pharmacovigilance and maintenance of product information: how agencies and industry work together to protect patients; and
- future regulatory challenges: is Asia ready?

The first four topics are reviewed in this article; the second part of the proceedings to be published in July's *RAJ Pharma* will review the remaining four.

ICH and GCG: how Asia fits into the global picture

This session reviewed the interaction with stakeholders outside the three ICH regions seeking partnership in the harmonisation challenges facing the ICH. It was chaired by Toshiyoshi Tominaga of the Japanese Ministry of Health, Labour and Welfare, who represents the MHLW on the GCG, as well as Yves Juillet of French industry association Les Entreprises du Médicament (LEEM) and chair of the IFPMA Regulatory Policy and Technical Standards Committee.

Overview of ICH activities, with focus on new ones

Justina Molzon of the US Food and Drug Administration and also a GCG member for the FDA outlined the ICH steering committee functions and the sub-committees, including the GCG and CTD [Common Technical Document] Implementation Working Group. Among a number of current "hot topics", she covered:

Delegates included regulators, international organisations and pharmaceutical companies

The conference covered topics such as harmonisation and good regulatory practices

The first session reviewed interactions with stakeholders outside the ICH regions

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- the Pharmacogenomics Expert Working Group, which had reached Step 4 in the ICH meeting held in Yokohama, Japan;
- E14 clinical evaluation of QT/QTc interval prolongation and anti-arrhythmic drugs with a meeting scheduled in June 2008;
- the Quality Informal Working Group focusing on ICH guidelines Q8 (pharmaceutical development), Q9 (quality risk management) and Q10 (quality systems); and
- E7 studies in support of special populations – geriatrics.

Introduction to ICH/GCG current activities – training opportunities

This was presented by Kohei Wada, co-chair of the ICH GCG and ICH steering committee member for the Japanese Pharmaceutical Manufacturers Association.

Emerging in response to a growing interest in the ICH and ICH guidelines in countries beyond the ICH regions, the GCG was originally formed to respond to information requests but had evolved in active partnership with regional harmonisation initiatives in many regions globally.

Training was now a key focus. The ICH/Asia Pacific Economic Cooperation Workshop on Q8/Q9/Q10, scheduled for 13-14 September 2008, was one example of fruitful co-operation in the Asia Pacific region, along with APEC workshops on clinical trials assessment in March and August 2008 in Bangkok. The GCG was being expanded to include representatives from individual drug regulatory authorities, reflecting the recognition by the ICH in 2007 that certain changes to GCG principles and procedures were necessary to accommodate recent trends in global drug development.

The GCG is expanding to include representatives from individual regulatory authorities

Partnership with APEC – Life Sciences Innovation Forum

This was outlined by Ding Jianhua of the State Food and Drug Administration, People's Republic of China. Hot harmonisation topics included:

- bridging studies;
- stability in climatic zones of the APEC region;
- clinical trials;
- GMP and GCP implementation;
- Q8/Q9/Q10; and
- clinical data for Korea, Japan and China – collaborative opportunities.

Good regulatory practices: are agencies ready?

Chaired by Young-Ok Kim of the Korea Food and Drug Administration and Ismet Samji of GlaxoSmithKline, this session considered that GRPs needed to be able to adapt to the challenges triggered by new technologies and new scientific outcomes in the rapidly changing global regulatory environment. A main objective was to share the experiences of regulatory authorities that had already established "good review and evaluation practices" and consider where best practices could be used in Asia.

"European Good Regulatory Practices: how to help new countries accede to the EU" was addressed by Thomas Lönngrén, executive director of the European Medicines Agency (EMA). Consistency and quality of assessments could be ensured by adequate benchmarking. The report on benchmarking of European medicines agencies had helped national authorities to compare, learn, find better procedures, be cost effective and efficient and to function well. A combination of self assessment and friendly auditing was utilised for this purpose. ISO 9004:2000 was the rating scale employed.

The EU had increased from 15 to 25 member states, and more recently to 27 with the 2007 accession of Romania and Bulgaria, and while this had been challenging it was helped by such GRP assessments. Active support was being given to Croatia, Macedonia and Turkey. Plans for other potential members included Serbia, Albania, Bosnia Herzegovina, Kosovo and Montenegro in 2009-2013.

"US Good Regulatory Practices" were presented by Dr Molzon. Established in 1995, these GRPs cover the quality, efficiency, clarity, transparency and consistency of review². The FDA also has a manual of policies and procedures ensuring a consistent approach.

"The ASEAN Viewpoint on Good Regulatory Practices" was presented by Maria Lourdes Santiago of the Bureau of Food and Drugs (BFAD) in the Philippines. The ASEAN policy guidelines on standards and conformance formed the main basis for regulation within ASEAN. Regulatory impact assessment was another key tool in achieving GRP. The importance of consultation among regulators of the member countries was emphasised.

Representatives from the EMA and the US FDA discussed GRPs in their regions...

...while a Philippine regulatory official presented ASEAN's view

“Monitoring Regulatory Performance in the Emerging Markets: Models for the Regulatory Review of Medicines and Good Regulatory Review Practice” was the ambitious topic addressed by Stuart Walker, director of the CMR International Institute for Regulatory Science, UK. Results of an international study conducted in 2007 were presented. Factors accelerating review procedures included target deadlines and decision timeframes, use of outside assessors, allowing applicants to have presubmission discussions with regulatory authorities and adequate training of reviewers. Factors impeding rapid reviews included sequential rather than parallel assessments, analytical work on samples of the product and ingredients, pricing discussions and inadequate resources. Professor Walker concluded from the results of the study that there were major differences in the amount of processing involved; regulatory review times did vary considerably across countries but were being reviewed and improvements could be detected; and risk stratification and level of scrutiny varied across reference countries.

Key measures for GRP include:

- key quality documentation;
- professional development of reviewers;
- quality assessments;
- internal reviews;
- benchmarking and key performance indicators;
- critical improvement activities;
- regular industry consultation; and
- transparency.

In conclusion, quality measurement and a range of quality systems were deemed as important as continuous improvement initiatives; further steps in good regulatory review practices are expected in the next two years.

Quality: how to ensure quality of products

Quality of pharmaceuticals is a major topic not just in Asia but globally. Reflecting this, the conference devoted a plenary session and two parallel break-out sessions to the topic. The plenary session, chaired by Abida Syed M Haq, deputy director of the National Pharmaceutical Control Board (NPCB) of Malaysia, and Malcolm Holmes, quality control director of GSK UK, focused on some key quality areas pertinent to the submission, approval and maintenance of products of appropriate quality and safety on the market, including discussion of measures employed by industry and regulators to assure quality while maximising use of resources. The session on assuring quality reviewed GMP and inspections for both drug products and substances, and appropriate use of resources including mutual recognition agreements.

An “Update on ICH Quality Topics” was presented by Robert Baum of Pfizer USA, ICH quality expert for the US industry body PhRMA. In 2003 a consensus ICH quality vision had been created to develop a harmonised pharmaceutical quality system applicable over the life cycle of a product, emphasising an integrated approach to risk management and science. ICH Q8/Q9/Q10 would contribute to this overall objective. Q9 had reached Step 4 in November 2005 and Q10 was expected to reach Step 4 in June 2008. Q8 had needed to go straight into further development: a revised Q8R had reached Step 2 in November 2007 and is currently in a 12-18 month consultation period. An expert working group was reviewing critical quality attributes and critical process parameters, respectively, to achieve desired product quality. An international working group had been formed in October 2007 to achieve global consistency internationally with Q8/Q9/Q10 and a status assessment was expected in June 2008.

An ICH guideline was being generated on Development and Manufacture of Drug Substances (S2 of CTD) with a concept paper in spring 2008 and a start to drafting a guideline by June.

“GMP and Inspections” were discussed by Malcolm Holmes, who said that quality risk management could facilitate better and more effective decision making in this area. He pointed to a European Federation of Pharmaceutical Industries and Associations survey of 22 companies: it was clear that preparation for inspections could take as much as 80-100 person days, inspection management 17 days and follow-up 20 days. These 22 companies had been inspected 939 times (on 337 of these occasions by “foreign” inspectors). The major inspectors were the US FDA, the EU, Japan, Korea and Taiwan. It was argued that there was considerable scope for a better focus of regulator and industry resources without any adverse effect on patient safety. A move to more risk-based assessment with more local inspections was advocated.

David Cockburn of the EMEA Inspectorate discussed “API/Drug Substance Assurance”. Outlining the EU approach, he stated that the route for active pharmaceutical ingredients would be more risk-based. Emphasis was placed on the responsibility of the marketing authorisation holder

Factors such as pricing discussions and inadequate resources slowed review times

The work of the ICH on a harmonised pharmaceutical quality system is progressing

Quality risk management could facilitate better decision making in GMP and inspections

or applicant in the EU more than that of the actual API manufacturer. A new EU guideline was being prepared as of April.

ISO 9001 certification is considered to be the minimum standard for quality management

“Maintaining Quality in the Supply Chain” was overviewed by Judith Villanueva (Zuellig Pharma) using the example of a regional quality management system for storage and distribution devised and implemented in Asia by Zuellig Pharma. ISO 9001 certification was considered to be the minimum standard with which to comply.

The session then turned its attention to assuring quality in the regulatory submission – the Certificate of Pharmaceutical Product. This also served as an introduction to the following break-out session (see below).

“Rational Use of the CPP – An Industry View” was given by Fraser Stodart of Pfizer UK and Efpia chair of the CPP Task Force. While he did not doubt the considerable value of the WHO Certification Scheme including CPP in the past, he said its continued appropriate use needed to be seen in the context of relevant agencies’ capabilities. Key to future CPP use was finding the right way for individual agencies to use this tool – in tandem with the other processes, requirements and systems used for regulatory review – so that delays to new product introduction were minimised.

CPPs should not be more than six months old to ensure current validity and ease review

“Rational Use of the CPP – An Authority View” was presented by Leticia Barbara Gutierrez, director of BFAD in the Philippines, who outlined the WHO Certification Scheme in detail. CPPs, she said, should preferably not be more than six months old to ensure current validity and ease review. The standardised format was considered an advantage and was a mechanism for international information exchange. With two very different interpretations of the value of the CPP in the current regulatory environment, the stage was set for an interesting break-out session on the topic of CPPs, with a parallel session also on GMP.

Break-out session 1: GMP quality

Chaired by Karen Maigetter of Roche, this session looked at other ways of maximising inspection resources such as acceptance of a CPP as evidence of GMP standards, the adoption of risk-based approaches and MRAs such as PIC/S (Pharmaceutical Inspection Cooperation Scheme). PIC/S was explained by Abida Syed M Haq of the Malaysian NPCB. Malaysia has been a PIC/S member since 2002, the only other member in the Asian region being Singapore. Thailand has applied for membership and inspections took place in January. Indonesia and the Philippines are considering an application for membership. Experiences in Malaysia had been good as membership offered training opportunities. Local manufacturers had been encouraged to seek new export markets, facilitated also by the higher GMP standards. The PIC/S experience of both Malaysia and Singapore would form the basis of the planned ASEAN mutual recognition agreement on GMP. This would be drafted by February 2009, permitting the successive entry of ASEAN states starting with Malaysia and Singapore as international GMP standards were achieved.

More than 505 drugs listed on the internet are thought to be counterfeit

“Anti-Counterfeiting Initiatives” were presented by Dr Juillet of LEEM and the IFPMA. The regulatory group of the WHO’s International Medicinal Products Anti Counterfeiting Task Force (Impact) was explained. Counterfeiting is an increasing international problem exacerbated by the internet – more than 505 drugs listed on the internet are thought to be counterfeit. Many regulatory authorities have taken action, including the US FDA, as have international organisations including Impact, which was set up in February 2006. Its latest plenary meeting was held in Lisbon on 11-14 December 2007. Five working groups have been set up on issues such as aspects of good distribution practice and good pharmacy practice. The World Health Assembly also discussed counterfeiting in May. Security in distribution channels was a key factor: track-and-trace systems were needed, Efpia’s choice being Data Matrix 2D.

“WHO Prequalification Project: How to Ensure Quality Medicines are Supplied to Countries” was presented by Lembit Rago of the WHO, Coordinator of Quality Assurance and Safety of Medicines. Starting with HIV/AIDS drugs and those for malaria and tuberculosis, the aim was to have a prior selection of products based on adequate quality. Some 184 products have been prequalified, and up to January 2008 over 100 products were in the pipeline for assessment. Essentially the scheme is an action plan for expanding patient access to some essential medicines for specific disease areas³. The scheme was supported by the International Conference of Drug Regulatory Authorities at their meetings in 2002, 2004 and 2006. The 2008 meeting will be in Bern, Switzerland, in September, hosted by Swissmedic. Another source of information is the WHO’s 41st Technical Report issued in 2007 on the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Questions/answers and discussion

One questioner asked why the FDA and the EMEA were going for different anti-counterfeiting systems. Final decisions have not yet been made, said Dr Juillet. Their positions are complementary

but totally aligned, but since there is no one universal solution this reflects that position. Was it the intention of ASEAN to allow GMP for PIC/S:ASEAN members, and would it apply across ASEAN? An MRA would need to be agreed by other ASEAN countries, not just between Malaysia and Singapore, as is currently the case.

Another questioner pointed out that the WHO also plays a key part in EU Article 58 approvals (those dealing with products for public health needs), and asked whether prequalification could be issued at the same time as an Article 58 approval.

The answer was that the WHO is more directly involved as the gatekeeper in Article 58 applications, which have mainly been used for vaccines. An arrangement with the EMEA is being planned.

The WHO serves as the gatekeeper for applications dealing with products for public health needs

Break-out session 2: CPP

This session was chaired by John Lim, CEO of the Health Sciences Authority, Singapore, and Pfizer's Mr Stodart. The aim was to discuss the value of the CPP in regulatory review and opportunities to use alternative documentation.

Regarding the "WHO model CPP", Dr Rågo outlined the WHO Certification Scheme including the CPP and model batch certificates and model statement of licensing status. Since its conception the CPP has provided a standard information exchange for authorities. It can also oblige certifying authorities to divulge necessary information. The scheme has limitations and relies on the integrity of the parties involved. Requirements vary between countries (eg concerning generics) and counterfeit CPPs have been detected. More transparency is needed, and international exchange training and joint inspection programmes could be beneficial.

Murray Lumpkin, deputy commissioner for international and special programs at the US FDA, presented the "Issuing Agency Perspective". The FDA's Center for Drug Evaluation and Research issued 7,748 CPPs between 1 October 2006 and 31 September 2007, with the Center for Biologics Evaluation and Research issuing 444 CPPs in the same period. The FDA's CPP certification pertains to products labelled and manufactured in the US. The FDA finds this time-consuming and costly and believes resources could be used more cost effectively. Issuing electronic certificates could be an advantage, and may also help prevent counterfeit documentation. A central electronic databank could be worth considering.

Issuing electronic CPPs could save time and prevent counterfeit documentation

The "Industry Perspective" was presented by Michael Gebauer of Bayer-Schering, Singapore. Although the CPP was designed to accelerate and facilitate the regulatory approval process, numerous practical examples showed that in fact the opposite was the case.

The demand for CPPs and multiple CPPs actually hampered the approval and introduction of new products. It was questioned whether it was really necessary to provide a CPP from the country of manufacture. Replacing the CPP with an electronic version was also advocated as a step forward.

Questions/answers and discussion

A representative of Singapore's HSA asked if the US FDA was planning an electronic CPP. The answer was that there were no immediate plans to do so, but this could be considered in the context of the Asian Regulatory Conference. Would an electronic version meet the needs of all authorities? As this is a WHO scheme it was also suggested that the WHO act as the "white knight" in this matter and take the initiative. As a minimum step forward the need for more than one CPP should be addressed. The requirement from many countries for formal legalisation of CPPs was also considered an unnecessary burden and delaying factor. Some companies had been using FDA Authorisation Letters when publicly available; however the comprehensive picture regarding manufacturing sites is normally fully disclosed in the new drug application, so authorisation letters do not tell the full story. Regulators wishing to join the CPP scheme were advised by the WHO to contact the WHO directly.

The US FDA suggested the WHO should take the initiative on developing electronic CPPs

In response to a question from industry about obtaining a CPP from a country other than the manufacturing country, the FDA said it would in such cases not issue a CPP. If the recipient country still insisted on a CPP from the FDA, then the company should discuss it with the agency. Industry representatives raised the fact that where a CPP was issued by the EMEA following a centralised procedure, the EMEA did not like to use the trade name. It was suggested that this could be resolved by the company writing a letter explaining the situation to the recipient country.

In conclusion, Dr Lim said that regulators could be more flexible and he supported the WHO in its role as "white knight". Mr Stodart expressed the frustration experienced by many in the industry at the various challenges thrown up around CPPs, but looked forward to agencies re-approaching this in a fresh way so that CPP use could appropriately match the capabilities of each agency.

ASEAN harmonisation

This session was chaired by Eisah Abdul Rahman, chair of the ASEAN Consultative Committee for Standards and Quality Pharmaceuticals Product Working Group (ACCSQ/P-PWG) and deputy director at the Malaysian Ministry of Health, and Taryn Rogalski-Salter of Novartis USA. Experiences were shared on both the regulatory and industry perspective gained during implementation as well as on the impact of ASEAN harmonisation now and in the future.

The current status of ASEAN harmonisation was presented

"The Origin and Current Status of ASEAN Harmonisation" was presented by Yuppadee Javroongrit, assistant director of the FDA of Thailand, co-chair of ASEAN ACCSQ/P-PWG and ICH GCG Observer for ASEAN. Full ASEAN implementation for new products was expected by 31 December 2008 and for currently registered products by 1 January 2012. This would contribute greatly to the aim of establishing an ASEAN Economic Community by 2015.

Lucky Slamet of the Indonesian National Agency of Drug and Food Control (NA-DFC) reported on "ASEAN Stability Implementation". Since 1995, ASEAN had agreed on stability requirements on a minimum of three batches at real time stored at 30 °C +/- 2° and 75%RH +/- 5% RH (measured at 0, 3, 6, 9, 12, 18 and 24 months) and accelerated conditions of 40 °C +/- 2 °C and 75% RH +/- 5% RH (measured at 0, 3 and 6 months). The situation had most recently been reviewed at the 14th ACCSQ-P-PWG in Laos in February. Implementation was foreseen by 1 January 2009, although many products were not yet ready.

Full implementation of the ASEAN CTD is expected by 2009

Lee Hui-Keng of HSA, Singapore, presented an "Experience of ASEAN Implementation from an Agency Perspective". Singapore accepts both ASEAN CTD (ACTD) and ICH CTD (see Figure 1). Full implementation of the ACTD is expected by 2009. The Implementation Working Group now has industry representatives, which is viewed as an advantage. The APC is the pharmaceutical industry group representing the interests of ASEAN companies, and APRIA, set up in August 2006, is the ASEAN Pharmaceutical Research Industry Association, representing multinational companies through national trade associations. Lessons should be learnt from models in other parts of the world; critical success factors include a strong partnership between regulators and industry and the political will. ASEAN GMP is now equivalent in standard to PIC/S GMP. A limited inspection list is being signed off in 2008.

The other "Agency Perspective" was given by Nguyen Thanh Lam, deputy head of the Drug Administration of Vietnam. This highlighted the differences in experience and capabilities of some of the more recent ASEAN member states and the importance of training for regulatory staff.

"An industry perspective" was presented by Celine Ting, chair of APRIA, Singapore, and managing director of Eisai Singapore. Ms Ting proposed an action plan:

- short term (2008-2009): post final ACTR/ACTD through ASEAN Secretariat website, and set up technical working group and training for regulators and industry;
- mid term (2009-2011): harmonise variation requirements and study existing guidelines and draft common ASEAN guidelines to avoid country-specific requirements; and
- long term (2012-2015): harmonise packaging/labelling, have mutual recognition agreements within ASEAN and recognise future pan-ASEAN product registrations.

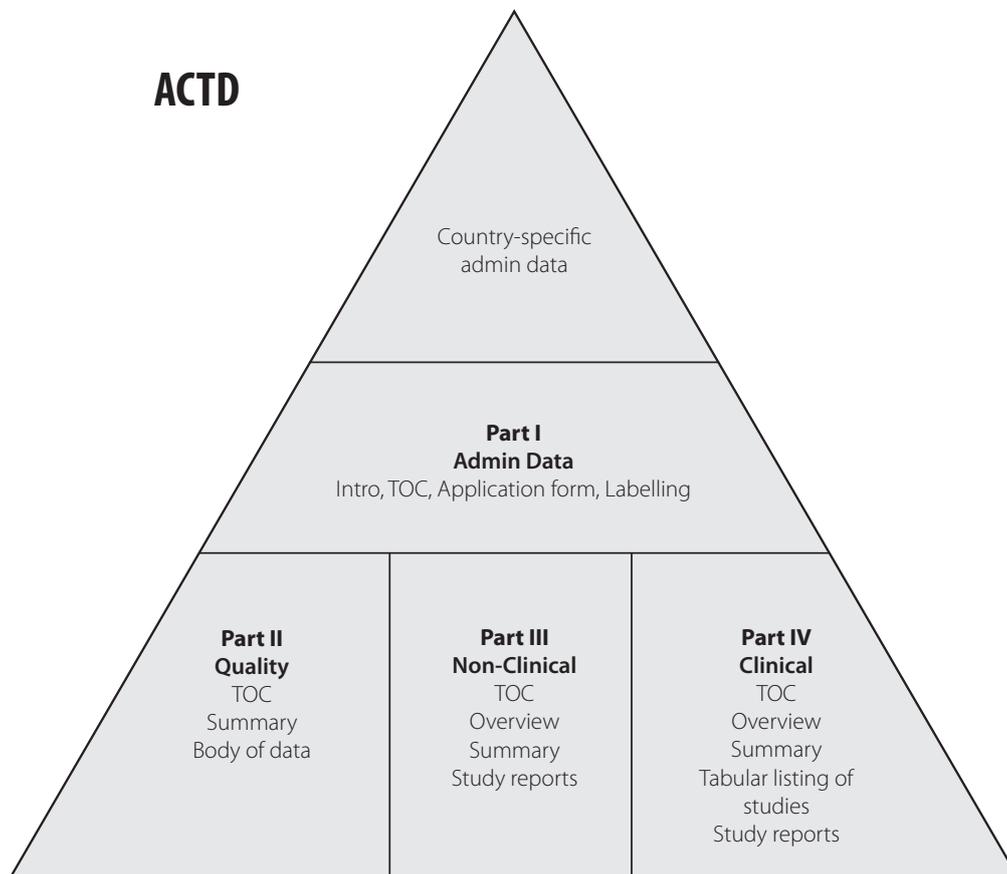
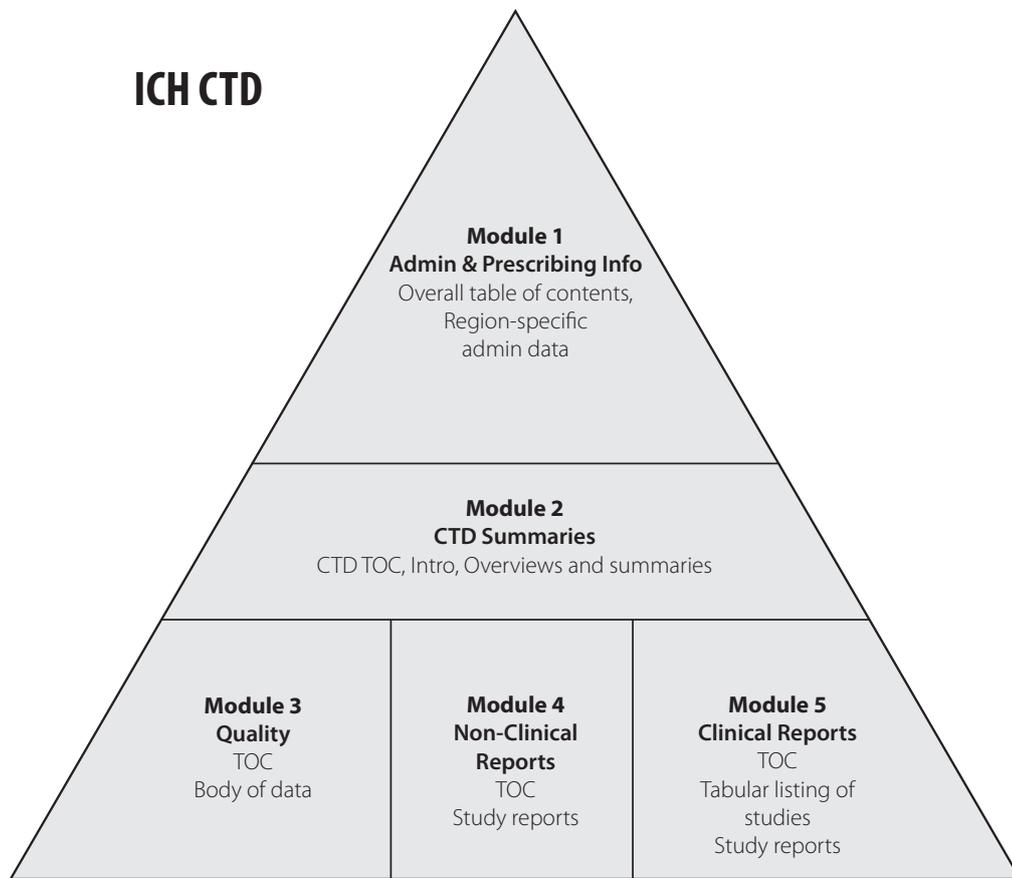
The Pharmaceutical Product Working Group has been instrumental in achieving many of ASEAN's harmonisation objectives

"The Future of ASEAN Harmonisation – The Next Steps" was presented by Eisah Abdul Rahman of the Ministry of Health, Malaysia. Within APEC and ASEAN there was ever-increasing trade and co-operation. The Pharmaceutical Product Working Group had been instrumental in achieving many of the harmonisation objectives for pharmaceutical requirements within ASEAN. This had been demonstrated at the 14th ACCSQ held in Vientiane, Lao PDR, on 18-22 February. The APEC blueprint envisages a single market and production area fully integrated into the global economy and forming a highly competitive economic region. The way forward includes, for ASEAN: redefining the terms of reference of the IWG; streamlining the structure of the PPWG; collaborating with APC and APRIA; implementing ACTD and technical guidelines; signing sectoral MRAs on GMP inspections; and having an ASEAN regulatory science training accreditation scheme.

There is already an ASEAN Charter in place, signed so far by Brunei Darussalam, Malaysia and Singapore. There is an ASEAN Trade Facilitation Work Project and an ASEAN Trade In Goods Agreement. In future the PPWG will need new terms of reference. Other plans include an ASEAN Pharmaceutical Directorate and Pharmaceutical Committee; future initiatives for integrating the pharmaceutical sector; other sectoral MRAs such as those on bioavailability/bioequivalence studies; and a harmonised placement system for pharmaceutical and medical products in the ASEAN market according to the overall roadmap.

Mr Lönngren commented on the various presentations and on the experiences of the EMEA in its harmonisation efforts. After 40 years this was still a difficult challenge, he said. Key aspects were competence, knowledge, interpretation of the legislation, procedures, guidelines and practical implementation.

Figure 1. ICH Common Technical Document and ASEAN Common Technical Document



Interpretation of bioavailability studies is often a cause of disagreement

Interpretation of bioavailability studies, especially for generics, was still often a cause of disagreement. Probably training was the most important overall; this should include how to interpret the guidelines. Mutual acceptance would be important for the future. Meanwhile, the introduction of a benchmarking system, such as the WHO Model System, would be beneficial. From the EMEA perspective, two other areas to move forward in ASEAN would be GMP for products and APIs, and GCP because of the increasing number of clinical trials in Asia.

Regulators felt training was a regulatory matter, but industry could play a role

Questions/answers and discussion

After these presentations a lively discussion ensued. As to whether industry could help with training, the regulators' view was that this was a regulatory matter but industry associations such as APC or APRIA could play an important role. Training schemes could also involve the ICH GCG, to include Japan and the EU. Industry technical experts could perhaps also help in training. Nominations of appropriate experts could be sent to APRIA for training planned this October in the Philippines.

Would countries other than Singapore accept the ICH CTD? This would be discussed at the ASEAN meeting in August in Brunei Darussalam. Would Singapore still accept ICH CTD after 2009? Yes, it would. And would variations be accepted following the same ACTD or ICH CTD as the initial submission? Yes. Finally, someone asked whether the ICH CTD would be allowed for new chemical entities and biologicals even after 2009. Yes, but this still needed to be reviewed.

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2. US FDA, Good Review Practices, www.fda.gov/cder/other/grp.htm
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