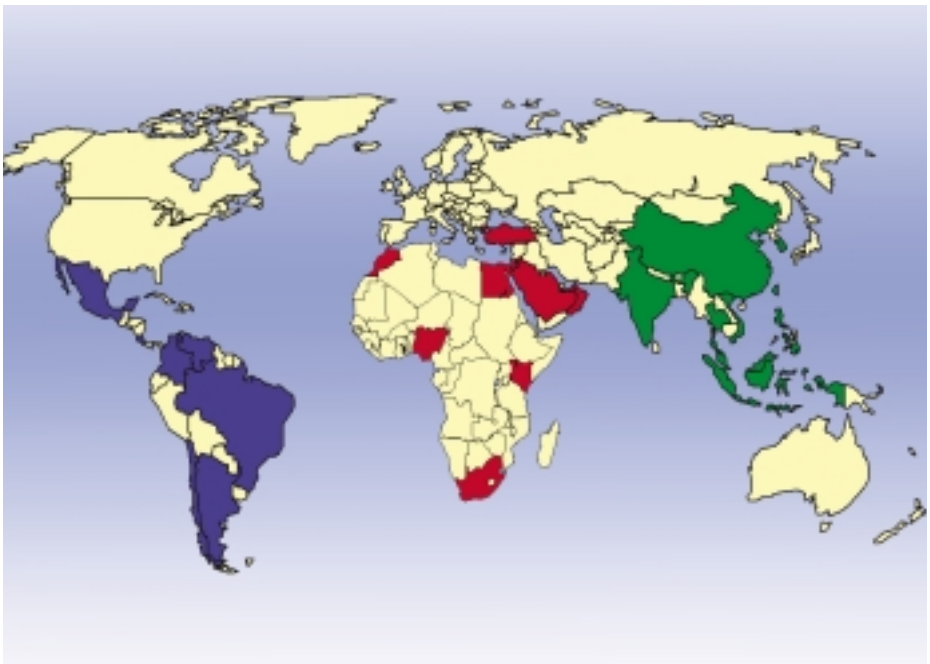
R&D Briefing

A cross-regional comparison of the regulatory environment in emerging markets



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A discussion of the regulatory issues in the emerging markets and the impact on patients' access to new medicines, with reference to a three-region study carried out by CMR International

CMR International

Institute for Regulatory Science

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Institute for Regulatory Science

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A cross-regional comparison of the regulatory environment in emerging markets

A discussion of the regulatory issues in the emerging markets and the impact on patients' access to new medicines, with reference to a three-region study carried out by CMR International.

Key points

The emerging markets of Asia-Pacific, the Middle East, Africa and Latin America are becoming increasingly important to pharmaceutical companies in their global strategies for the registration of new medicines and making them available to patients worldwide.

A major study has been carried out by CMR International that looked at regulatory practices and procedures in these emerging markets from both an agency and industry viewpoint. For the purpose of the study, the countries were divided into three regions:

- South East Asia and the Western Pacific
- The Middle East and Africa
- Latin America

The main objective was to identify factors that facilitate or impede the efficient registration of new medicines and their timely access to patients.

At a regional level, this study revealed many interesting similarities and differences between neighbouring countries and these have been reported separately[1]. When the three regions are compared and a cross-regional view is taken, however, one conclusion becomes evident:

Notwithstanding the apparent differences and diversity between the regions, the regulatory aspirations, barriers, problems and priorities, related to the review and availability of new medicines, are essentially similar.

This Briefing is intended as a background document to encourage discussion of the key issues among and between regulatory agencies and companies. These include:

- Ways to improve the efficiency and timeliness of the regulatory review process for new medicines;
- Best practices for integrating product certification (the CPP) into the approval process;
- The mutual benefits of good communications and transparency in regulatory processes.

[1]*References*

Assessing the regulatory environment and its impact on patients' access to new medicines
R&D Briefing 47: South East Asia and the Western Pacific
R&D Briefing 48: The Middle East and Africa
R&D Briefing 49: Latin America

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Introduction

Emerging Markets

All the major markets for new medicines have been through an 'emerging market' stage and their regulatory agencies have had to learn new skills and adopt new procedures in order to keep abreast of technological advances.

The USA and Western Europe were the emerging markets for introduction of synthetic molecules as 'new drugs' in the pharmacological revolution of the 1950s and 1960s. The fast-growing research-based pharmaceutical companies of the day had their headquarters in the US and Europe but were soon joined by major Japanese enterprises as the market in Japan expanded to meet patients' demand for access to new medicines.

Regional Harmonisation Initiatives

The **ASEAN** Pharmaceutical - Product Working Group (P-PWG) is developing harmonised guidelines for the regulation of pharmaceuticals, including the **ASEAN CTD**.

APEC, (Asia-Pacific Economic Cooperation) has set up harmonisation initiatives through the APEC Network of Pharmaceutical Science

The **Gulf Cooperation Council** (GCC) has established a centralised procedure for the registration of NASs in the Arab States of the Gulf.

PANDRA, the Pan-American Network for Drug Regulatory Harmonization has been established by the Pan-American Health Organization/WHO Regional Office for the Americas (PAHO/AMRO).

SADC: The Southern African Development Community's Pharmaceutical Programme has regulatory harmonisation within its mandate.

Table 1

By the 1990s the development and regulation of new active substances (NASs) was dominated by the USA, EU and Japan, which have become known as the three 'ICH regions' as a result of a major international initiative, the International Conference on Harmonisation[1] In the late 1990s, however, and increasingly in the first years of this century attention has turned to the emerging pharmaceutical markets in other regions of the world.

The global industry

Pharmaceutical companies are now focusing on 'global drug development' and looking at the rapidly expanding markets in the Asia-Pacific, Latin American, African and the Middle East regions. Companies are not only seeking to make their products available to patients in these 'emerging markets' but also to incorporate, into their worldwide clinical development strategies, those newly industrialising countries that have a sufficiently advanced clinical infrastructure.

A new regulatory environment

Meanwhile, the regulatory agencies in the emerging markets have been changing and evolving. Some have developed in partnership with, and following good practice guidelines established by, the agencies in the US, EU and Japan as well as Canada, Australia and Switzerland. The World Health Organization has also been active, since the early 1970s, in providing guidance and assistance to regulatory agencies in all the so-called 'developing countries'.

Regional harmonisation initiatives (Table 1) and increasing awareness of the role of ICH through membership of the Global Cooperation Group (GCG)[1] have also played a part in encouraging the development of regulatory agencies by improving communications and fostering a better knowledge and mutual understanding.

Patient access to medicines

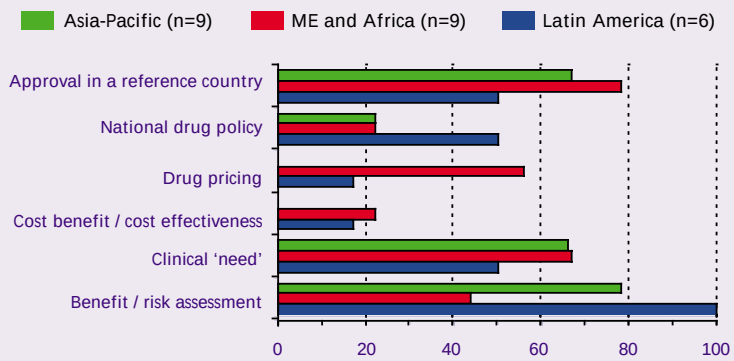
Patients in all regions of the world are becoming increasingly aware of medical innovations and expect timely access to new medicines.

There are, however, many factors that can have an impact on such access. One is the 'lag' time, which may be two or more years, between products being approved in the ICH regions and submitted for registration in the emerging markets. Another is the companies' perception of the local regulatory environment when prioritising their regulatory strategy.

Once applications are made, the decision on whether the new product should be approved and made available in the country may not be made on a scientific evaluation of safety, quality and efficacy alone. Figure 1, indicates some other factors that can influence regulatory outcomes.

Figure 1

Factors other than safety, quality and efficacy that can influence decisions to approve a marketing application



[1] See Glossary, page 9

Different regions but similar issues

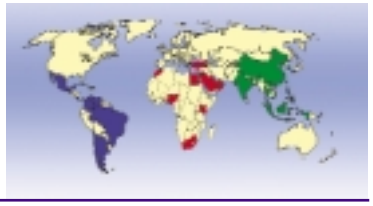
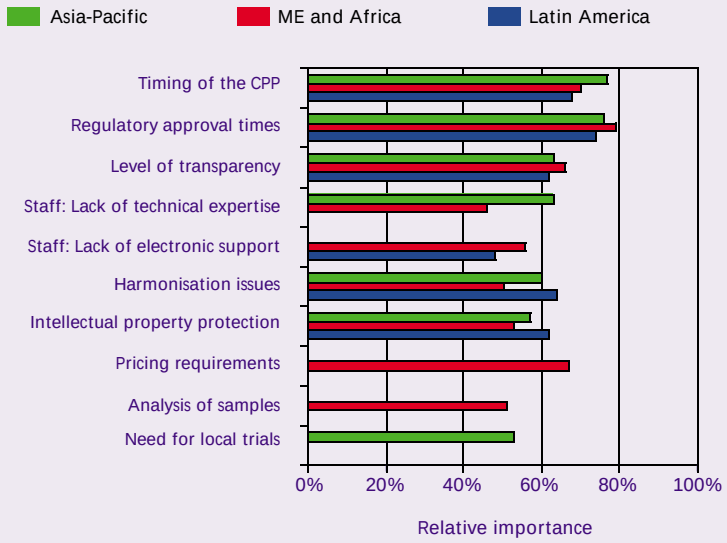


Figure 2

Major areas of concern as seen by industry: Factors relating to Authorities' procedures that delay applications and approvals of NASs



CMR International Study

The data used to illustrate the points made in this briefing were collected in a major study carried out by the CMR International Institute for Regulatory Science in 2004. The study covered thirty countries in three geographical regions (see Table 2) and involved ten pharmaceutical companies that were actively marketing new medicines in one or more of the three regions.

One of the major 'messages' to emerge from this study was that, notwithstanding the diversity of the different regions that were studied, the priority issues for improving the registration process for new medicines were essentially similar

Both companies and agencies were asked similar questions about the hurdles in the way of efficient registration of new medicines and timely access of new medicines to patients.

The similarities were more pronounced in the responses from companies (Figure 2) than among the regulatory agencies (Figure 3).

Not unexpectedly, both companies and authorities identified the lack of resources available to the government agencies as an important impediment to the registration of new medicines (although the authorities in Latin America were less concerned about his aspect).

Ways to ensure that valuable but limited resources are used to best advantage are among the items discussed further in this briefing.

Figure 3

Major areas of concern as seen by agencies: Internal and external factors that delay reviews and patient access to NASs

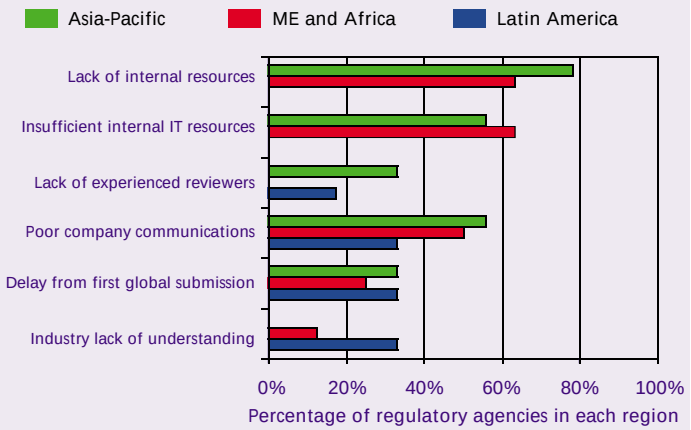


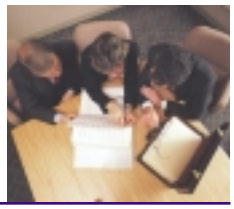
Table 2

Countries included in the CMR International Institute Study

South East Asia and West Pacific		Middle East and Africa		Latin America	
China* (9)	**Singapore** (9)	**Bahrain** (9)	**Nigeria*** (6)	**Argentina** (7)	**Costa Rica** (7)
Hong Kong (9)	**South Korea** (9)	**Egypt** (9)	**Oman** (8)	**Brazil** (7)	**Mexico** (7)
India (8)	**Taiwan** (8)	**Jordan** (9)	**Saudi Arabia** (9)	**Chile** (7)	**Venezuela** (7)
Indonesia (9)	**Thailand** (9)	**Kenya** (7)	**South Africa** (8)	**Colombia*** (7)	
Malaysia (8)	**Vietnam*** (8)	**Kuwait** (9)	**Turkey*** (7)		
Philippines (9)		**Morocco*** (6)	**UAE** (9)		

(n)= Number of participating companies in the country
* Data obtained only from companies operating in the country and not from the local agency

Regulatory agencies: Cross-regional perspectives



The regulatory agencies that participated in the CMR International Study provide a wide spectrum of regulatory philosophies and review practices.

■ **Full reviews:** Some agencies, e.g., Brazil, Singapore, South Korea, South Africa and Taiwan are establishing the internal resources and expertise to carry out full reviews of NAS application data.

■ **CPP:** The Certificate of a Pharmaceutical Product is essential for the registration of products in the large majority of countries with many requiring this to be available before an application is made.

■ **Pricing:** The price of new products must be negotiated as part of the approval process in many of the Middle East countries.

■ **Future objectives:** Several authorities, including Argentina, Brazil, Chile, Egypt, India, Malaysia, Singapore, South Korea, Taiwan and Thailand listed encouraging local clinical development among the future goals for the country

Table 3 provides an extract of the responses from the authorities to questions on key aspects of their procedures.

Table 3

Authority data from the CMR International Study	Asia-Pacific								Middle East and Africa									Latin America					
	Hong Kong	India	Indonesia	Malaysia	Philippines	Singapore	South Korea	Taiwan	Thailand	Bahrain	Egypt	Jordan	Kenya	Kuwait	Oman	Saudi Arabia	South Africa	UAE	Argentina	Brazil	Chile	Costa Rica	Mexico	Venezuela
Review process and data requirements																								
Previous registration is essential for authorisation	■	■		■	■			■	■	■	■	■	■	■	■	■		■		■		*		■
Previous registration is not always a pre-requisite			■			■	■										■		■		■	*	■	
ICH CTD format is not accepted (a)									■		■		■		■	■		■		■	■		■	*
All ICH guidelines are accepted	■					■																		
Selected ICH guidelines only are accepted		■	■	■	■		■	■	■	■	b	■	■	■	■	■	■	■	■	■	■	■	■	■
Certificate of a Pharmaceutical Product (CPP)																								
CPP is required with application	■		■		■				■		■	■	■	■	■	■	c	■	■		■	■	■	
CPP accepted later but prior to approval		■		■		■	■	■		■										■				■
Legalisation of CPP required by Embassy		■						■		■		■	■	■	■	■		■		■	■	*		■
Other policy and procedural issues																								
IP protection laws implemented (d)	■	e	■	■	■	■	■	■	■	■	e	■	■	■		e	■	■	■	■	■	e	■	■
Pricing is part of approval										■	■	■			■	■	■	■		■				
Local clinical trials required for registration		■	f		f					■													f	

**= No response*
a: The ASEAN CTD may replace the ICH CTD in ASEAN countries
b: ICH is not implemented in Egypt
c: CPP not essential in South Africa but, if available, must be submitted with the application
d: Intellectual property protection to meet TRIPs requirements (see page 9)
e: IP protection implemented after the survey
f: Requirement for CTs may depend on the type or regulatory status of product

Extracts from authority mission statements

Singapore

"… contribute to the development of the biomedical sciences by administering a robust, scientific and responsive regulatory framework …"

Costa Rica

"…by using Governance, with full involvement of social stakeholders to contribute to maintaining and improving quality of life among the population…"

India

"…to provide an enabling environment for introduction of new medicinal products of proven safety and efficacy…"

South Africa

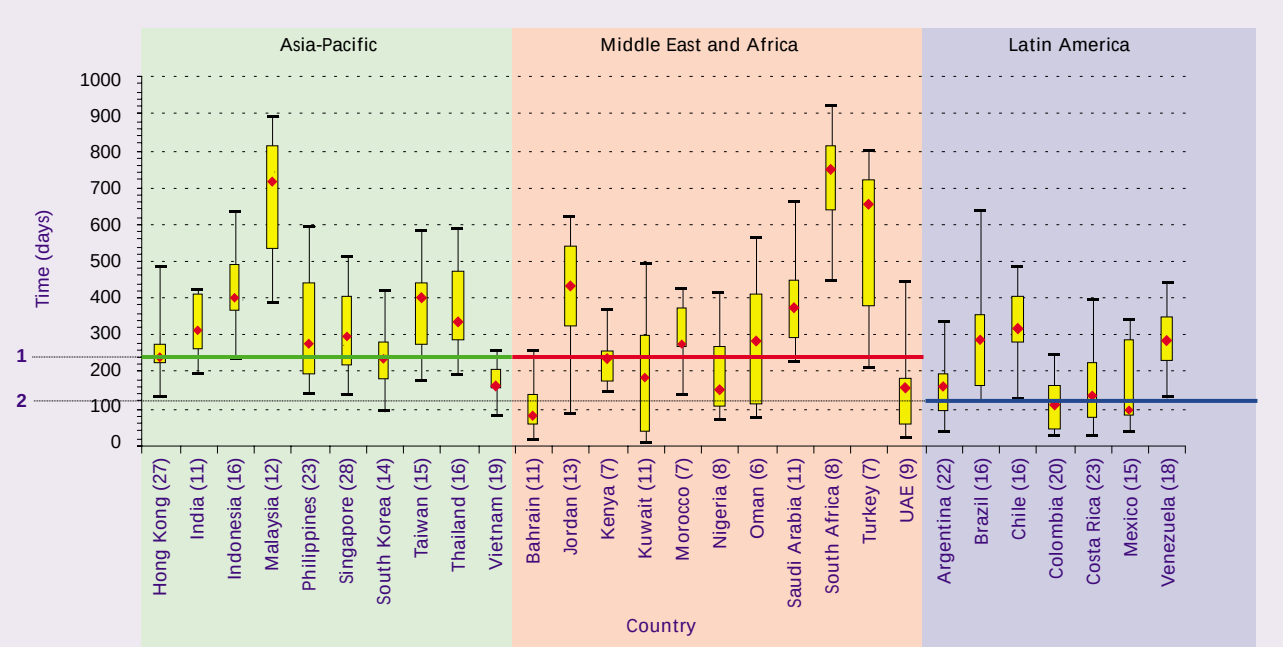
"…To safeguard public health through timely access to quality medicines. … To have a transparent and accountable regulatory authority. …"

The Issues: Review processes and timelines

A major factor in the timely access of new medicines to patients is the time taken by national regulatory authorities for the review and approval of applications. This is, of course, also a major preoccupation for pharmaceutical companies when planning their global registration strategies for innovative new medicines. *Figure 4* gives the range of regulatory approval times in different countries, based on data provided for the NAS applications included in the CMR International study.

Figure 4

Regulatory approval times (from date of submission to date of marketing approval) for NASs submitted and approved between 2001 and 2003



1 Regional median approval times for Asia-Pacific: 282 days, and ME-Africa: 283 days
2 Regional median approval times for Latin America: 175 days

Data are shown for NASs that were submitted and approved between 1 January 2001 and 31 December 2003. (n)= number of NAS. Box: 25th and 75th percentiles. Whiskers 5th and 95th percentiles. Diamond = median

Practices that can impact on review times

Factors that speed

- Setting target times and deadlines for different stages of the review e.g.
  - Validation
  - Scientific Review
  - Company responses to questions
- Implementing management systems for monitoring timelines and work flow
- Establishing service level agreements with outside assessors to ensure that deadlines are respected
- Providing facilities for companies to discuss submissions before and during the review process
- Seeking opportunities to provide training programmes and incentives for agency staff

Factors that impede

- Reviewing different sections of the application (quality, safety, efficacy data) in sequence rather than in parallel
- Sending major questions to companies ad hoc throughout the assessment of the application and asking for extra data late in the review process
- Allowing analytical work on samples to become a time-limiting step in the authorisation process
- Including price negotiations as part of the regulatory review process rather than assessing applications on safety, quality and efficacy alone
- Expecting staff to work efficiently with inadequate resources and IT facilities

The Issues: Both sides of the fence

THE CERTIFICATION SCHEME AND CERTIFICATE OF A PHARMACEUTICAL PRODUCT (CPP)

Company perspective

Timing of the CPP: If authorities insist on receiving the CPP at the time that an application for a new medicine is made, the company cannot start the application process until an authorisation has been granted elsewhere. Since registration in the first market (e.g., EU or USA) can take up to 18 months, registration in the new market will be significantly delayed.

Source of the CPP: Some agencies require the CPP to be issued by the authority in the 'country of origin' (manufacture). In today's environment, however the manufacturing site(s) for a NAS may not be in a country where the authority carried out the primary review. Companies feel that a single CPP from a major reference agency such as FDA, EMEA, PMDA should suffice, provided that GMP certification for the actual manufacturing site is included.

Legalisation: Some agencies (see *Table 3*) still require legalisation of the CPP by the local Embassy or Consulate rather than authentication by the regulatory agency issuing the certificate. This builds additional delays into the submission process.

The Certification Scheme

The WHO *Certification Scheme on the Quality of Products moving in International Commerce* was originally set up primarily to help regulatory authorities obtain information on the GMP status of imported products. In 1988 the Scheme was extended to include product information and the regulatory status.

The **Certificate of a Pharmaceutical Product** (CPP) is issued by a regulatory authority that has authorised the product for national sale or for export to the authority in the importing country. The CPP certifies that the product is manufactured under GMP conditions and gives information on the terms of the marketing authorisation.

Authority perspective

Timing of the CPP: Receipt of the CPP with the application ensures that the product has been reviewed and approved by a recognised regulatory agency. In the absence of this assurance, time and effort could be spent on processing an application for a product that ultimately fails to gain approval in its primary market.

Smaller agencies often rely on the CPP rather than carrying out their own full scientific review of NASs. It can therefore seem illogical to argue that the CPP need not be included at the time of making the application.

A number of agencies are, however, prepared to be flexible and will accept applications and start the review process before the formal CPP documentation is available.

Legalisation: The need for an Embassy or Consulate to authenticate the CPP is often a statutory requirement outside the remit of the agency.

TRANSPARENCY OF THE REVIEW PROCESS AND COMMUNICATION WITH REGULATORY AGENCIES

Company perspective

Experience has shown the value and benefits of an open and transparent relationship between companies and regulatory authorities. A good regulatory environment is an important factor in encouraging early registration of new medicines.

Consultation before implementing new regulations or guidelines is also an important part of the 'partnership' with industry that provides valuable benefits and an additional resource for the authorities.

Elements of Transparency

- Published information on the review process and company access to advice from authorities before submitting an application
- Secure company access to the status of applications once submitted
- The ability to meet agency staff to discuss technical and procedural issues when problems arise
- Agency accountability for the speed and quality of reviews
- Clear communication throughout the review process

Authority perspective

Providing facilities for communication and interaction with companies and access to secure electronic application tracking systems may be difficult to justify when resources are limited.

When agencies do establish 'open door' policies they expect companies to respect the privilege and ensure that staff and experts will not be subjected to excessive demands on their time.

The Issues: Both sides of the fence

HARMONISATION OF TECHNICAL REQUIREMENTS FOR NASs

Company perspective

History has shown that a lack of harmonisation can lead to unnecessary duplication of effort. Unless there is a sound scientific justification and rationale, the need to carry out additional or alternative testing to meet local guidelines is regarded as a waste of valuable resources.

Such requirements may act as a deterrent to the early registration of valuable new medicines, in the emerging markets.

The Issues

The large majority of NASs are currently developed in the three ICH regions and tested according to ICH guidelines[1]. Similarly, the supporting data for these applications will have been assembled in the ICH CTD format.

Many regional harmonisation initiatives (*Table 1*, page 2) are primarily concerned with the registration of generic products although the GCC initiative and the development of an ASEAN CTD have implications for NAS applications.

Authority perspective

ICH guidelines were not developed with the local conditions of the emerging markets in mind. An example is the climatic conditions covered in the Stability Guidelines.

Many authorities are, however, prepared to be flexible in accepting data and information on NASs that has been generated according to ICH norms.

MULTIPLE INSPECTIONS OF MANUFACTURING SITES

Company perspective

Multinational companies often source products from several different manufacturing sites.
The companies themselves carry out inspections and audits to confirm that all sites meet GMP standards and validate products from different sites to ensure they are interchangeable.

Whilst expecting to be inspected by the authority through which the product is first registered (normally FDA, EMEA or PMDA) they believe that GMP certification from a major authority should subsequently be recognised and accepted by other agencies.

The Issues

There are concerns about the resource implications for both agencies and companies when multiple inspections are carried out by different authorities.

Authority perspective

Few of the authorities in the emerging markets have mutual recognition agreements (MRAs) with other countries for the inspection of pharmaceutical manufacturers.

Although concerns about poor quality and substandard products do not relate primarily to NASs from multinational companies, the requirement for GMP inspections for imported products is often a legal requirement or a question of government policy.

INTELLECTUAL PROPERTY PROTECTION

Company perspective

Companies need to be confident that technical data submitted to regulatory agencies will remain confidential and that IP legislation will protect patent violations and the marketing of pirated products.

Deficiencies in IP protection are major disincentives to companies planning the registration of products in new markets.

The Issues

Adequate and enforceable protection of IP rights is regarded as a cornerstone for current and future investment in new medicines.

This was recognised in the adoption of the TRIPS agreement[1] to which the large majority of emerging market countries are signatories

Authority perspective

Regulatory agencies accept their responsibilities for safeguarding the confidentiality of the data in submissions.

The enforcement of patent and other IP legislation, however, is often outside the remit of the regulatory agencies.

[1] See Glossary, page 9

The Industry: Cross-regional perspective

Length of time companies have been operating in the three Regions

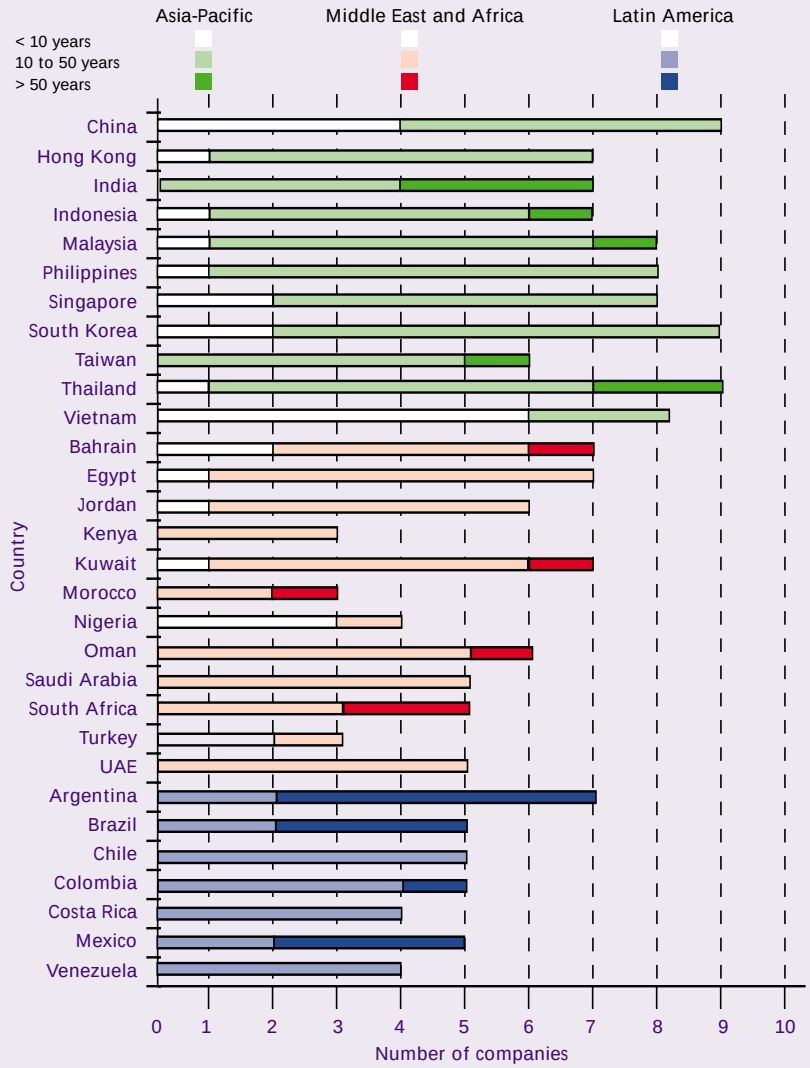


Figure 5

Multinational companies

The participating companies in the CMR International Study are research-based firms involved in worldwide R&D and marketing of innovative new medicines.

There is a range of experience among these companies, when looking at the time they have been operating in the different countries (Figure 5). Companies have been established longest, many over 50 years, in the Latin American countries, India, Taiwan and South Africa. Companies have least experience in Vietnam, China, Nigeria and Turkey.

There are marked regional differences in the way in which the companies are represented at country level. In Asia-Pacific and Latin America, the majority have established local subsidiaries whilst in the Gulf States and Jordan, it is much more common for companies to act through a local agent, although this is not the case in Egypt and the countries studied in Africa.

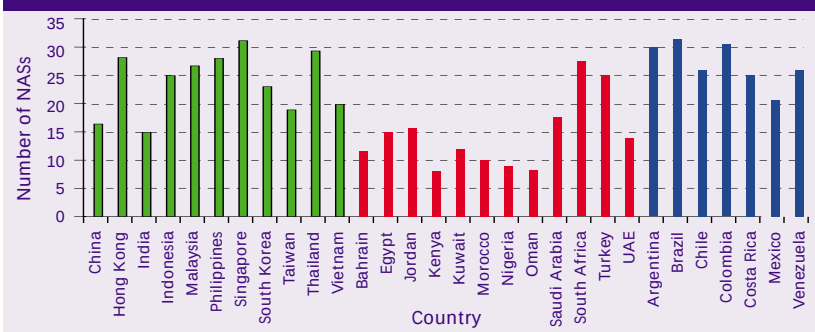
An area of concern identified by the regulators (*Figure 3*, page 3) was poor communications within companies (i.e. between local level and headquarters). Interestingly this is perceived as a greater problem in Asia-Pacific, where subsidiaries are the norm, than in the Middle East-African region where much of the communications is via agents.

Figure 6

New Active Substances

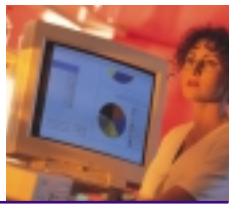
The CMR International Study, as noted, focused on the submission and registration of new active substances[1] and collected data on submissions made between January 2001 and December 2003. *Figure 6* gives a comparison of the number of NAS applications made in the different countries.

Number of New Active Substances submitted for the first time during 2001-2003



[1] See Glossary, page 9

Performance ratings: An industry view



The CMR International study asked companies for their views and opinions on many of the issues that may have an impact not only on the successful registration of new medicines but also on decisions about priorities for the registration of new medicines in their global regulatory strategy. Whilst it is recognised that opinions may be subjective and influenced by specific events, we nonetheless present the following 'Award' table based on companies' perception of regulatory performance.

Accolade	Country	Score	Accolade	Country	Score
Shortest review times Median review times calculated on NASs submitted 2001-2003	Vietnam	156 days	**Harmonisation** Guidelines harmonised with ICH and/or WHO guidance	Hong Kong	6/9 companies
	Bahrain	87 days		Oman and UAE	7/7 & 6/6 companies
	Mexico	101 days		Argentina	4/7 companies
Pre-submission advice Contact encouraged, good relationships established	Indonesia	7/9 companies	**Lack of local bias** Imported and local products treated equally	Hong Kong	8/8 companies
	Kuwait and UAE	5/8 companies		Kenya	4/5 companies
	Brazil	4/6 companies		Colombia	5/7 companies
Transparency Feedback during review: Process rated as 'transparent'.	Singapore	9/9 companies	**IP and data protection** Not a problem in the country	Singapore	6/8 companies
	Nigeria	4/5 companies		Jordan	5/7 companies
	Argentina	6/7 companies			
Quality of advice Rated as Excellent or Good	India	5/7 companies	**Clinical trials** No barriers to conducting local trials	Malaysia	6/7 companies
	Kuwait and UAE	6/8 companies		Kuwait	5/6 companies
	Argentina	4/6 companies		Chile	5/7 companies

Glossary

New Active Substance (NAS)

For the purpose of the CMR International Survey NASs were defined as a chemical, biological, biotech or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans

TRIPS

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) covers a wide range of IP-related subjects including patents, copyright and trademarks and trade secrets. TRIPS sets minimum standards of intellectual property protection that WTO Members must provide. Members designated as 'developing countries' had until 2000 to implement the agreement and least developed countries had until 2006.
A Fact sheet on TRIPS and pharmaceutical patents is available via the WTO website: http://www.wto.org

ICH: International Conference on the Harmonisation of Technical Requirement for the Registration of Pharmaceutical Products for Human Use.

ICH brings together the regulatory authorities of the EU, Japan and the United States (with observers from Canada, Switzerland and WHO) and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

Common Technical Document (CTD) ICH has established a common format for regulatory submissions setting out the order and structure for reporting the scientific data that supports a marketing application for a NAS.

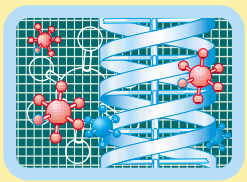
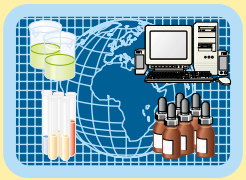
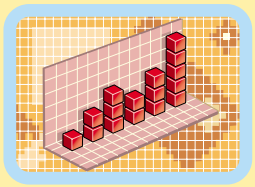
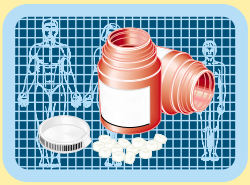
ICH guidelines, agreed through the harmonisation process and implemented by the regulatory bodies, cover the development of NASs and requirements for testing and monitoring their safety, quality and efficacy. Over 50 have been adopted.

Global Cooperation Group (GCG)

This was set up in 1999, as a subcommittee of the ICH Steering Committee. Its purpose is to make information on ICH widely available among agencies and companies worldwide. The regional, organisations involved in regulatory harmonisation outside the ICH regions (see Table 1, page 2) have been invited to designate permanent representatives to the GCG.

CMR International Institute for Regulatory Science

Assessing Regulatory Policy and Performance

Regulatory Science	Global Drug Development	Regulatory Processes	Patient Access to Medicines
			

2006 Agenda

New Technologies and Biomarkers	Asia's Role in Global Drug Development	Quality of Decision-making in Product Development and Review	Impact of Regulation on Access to Medicines in Emerging Markets

Past and future topics

Pharmacogenetics and pharmacogenomics Risk management: regulatory strategies and communication A new model for benefit-risk assesment	Integrated parallel development for the global market Declining submission rates for new medicines Acceptance of foreign data and implementation of the ICH E5 guideline	Performance metrics for regulatory processes Critical success factors in regulatory performance Building quality into regulation Post-approval commitments and conditional authorisations	The changing regulatory environment in the emerging markets Early patient access to medicines of therapeutic significance Initiating clinical trials in non-ICH environments

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