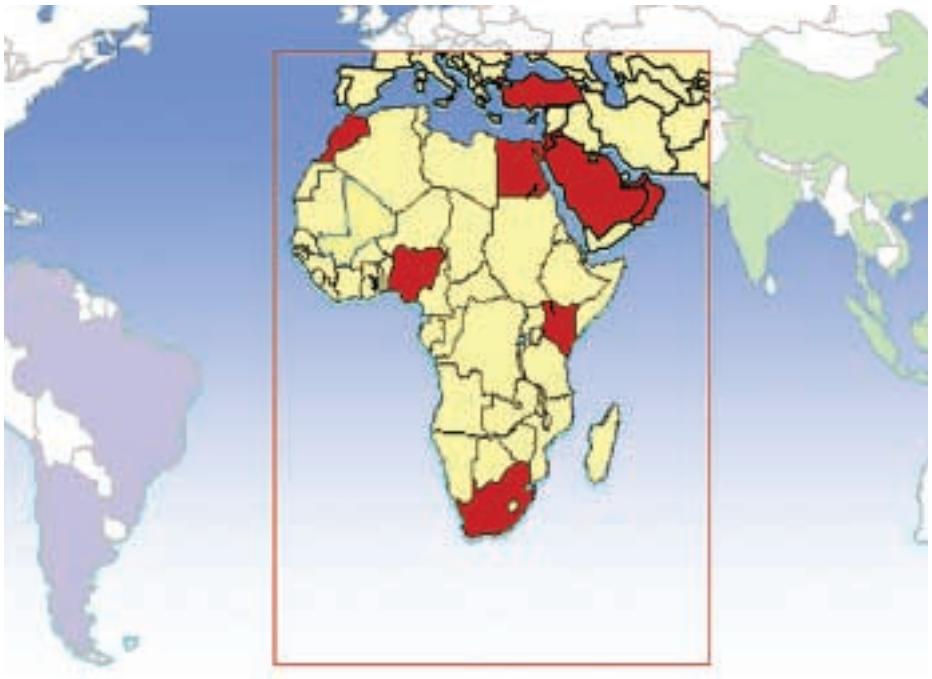
R&D Briefing

Assessing the regulatory environment and its impact on patients' access to new medicines



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Middle East and Africa

CMR International

Institute for Regulatory Science

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Middle East and Africa: Assessing the regulatory environment and its impact on patients' access to new medicines

Highlights from a study among the regulatory agencies in the key emerging markets in the Middle East and Africa and among the companies that operate in those countries.

Key points

The Regulatory Agencies in the Middle East and African region that were included in this study share a common goal with the research-based pharmaceutical companies that they regulate. This is to ensure that new medicines become available to patients in a timely and efficient manner, with appropriate safeguards for the public health. The CMR International Institute study aimed to identify the factors that promote best practices among regulatory agencies and to identify barriers to the timely authorisation of safe and effective new medicines, in the region.

Priorities: Many of the authorities in the study felt that they are hampered by lack of internal resources with the focus primarily on poor IT infrastructure. Some of the smaller countries in the region are also concerned about the lack of experienced reviewers. External factors, relating to the industry, that were perceived as constraints to efficient registration of products were lack of understanding of local issues and poor communication between local affiliates and company headquarters. A top priority for industry is for improved communications and collaboration between companies and agencies with a view to establishing a more effective and transparent regulatory environment.

Approval times: A primary issue for companies in their global strategy for introducing new medicines is the time taken for the regulatory review and approval in the different countries. There is a wide variation in the time taken to review medicines within and between the countries of the Middle East and those of Africa. Although the median approval time for all countries in the study is well below one year, company data indicate that median approval times in South Africa and Turkey are nearer to two years.

Timing of the CPP: A major factor in estimating the time taken to make new medicines available is the requirement for submission of the Certificate of a Pharmaceutical Product (CPP) verifying the authorisation of the product by another recognised authority. In South Africa the CPP is not a prerequisite for applications but in the other countries in the study except Bahrain, a certificate must be obtained before the review commences. This can delay the start of the regulatory process by up to two years, while registration is obtained elsewhere.

Pricing: In most countries of the region the scientific assessment of the safety, quality and efficacy of products and price negotiations are not separated with the result that a final decision on the authorisation of a product depends on agreeing an appropriate price. The exceptions are Kenya, Nigeria and South Africa where scientific and pricing decisions are kept separate. Whilst industry recognises that prices need to be negotiated in individual countries they believe that scientific decisions on the safety, efficacy and quality of medicines should be independent of such discussions.

Transparency is high on the list of important factors that engender confidence and help to create a favourable regulatory environment for making new medicines available. The authorities of the region are varied in their attitude to openness, transparency and a willingness to communicate during the review process.

The way forward: The study indicated that the way forward for the region is through developing further a constructive dialogue between agencies and pharmaceutical companies on reducing the regulatory impediments to making new medicines available.

Background

The emerging markets, especially those in the newly industrialising countries, are becoming increasingly important to pharmaceutical companies in their global marketing strategies. Traditionally, the focus has been on drug development, regulation and sales in the three major markets of the EU, USA and Japan and many studies have been carried out on these regions. In 2004, however, CMR International initiated a major study that looked beyond these three regions and examined, in particular, the regulatory environment for making new medicines available in the major markets in the 'rest of the world'.

The countries included in this survey (Box 1) all have national procedures for the regulation of medicines. These are at different stages of development but they share a common goal with the longer-established agencies and with the pharmaceutical companies that they regulate. This is to ensure that new medicines become available to patients in a timely and efficient manner, with appropriate safeguards for the public health.

With this goal in mind, the CMR International study set out to identify the factors that promote best practices among regulatory agencies and to identify barriers to the timely authorisation of safe and effective new medicines.

Survey of the Middle East and Africa

The countries in the survey included five of the Gulf States: Bahrain, Kuwait, Oman, Saudi Arabia and The United Arab Emirates (UAE). Five countries from Africa were selected from the northern, southern, eastern and western regions, respectively: Morocco and Egypt, South Africa, Kenya and Nigeria. The two other countries included in the study were Jordan and Turkey.

These represent a diverse group of countries with different medical practices and cultures as well as widespread use of traditional medicines. The pharmaceutical markets in the region, also supports a full range of modern allopathic medicines and their generic equivalents. This study, however, focused on the regulatory procedures for authorising innovative new medicines and making them available to patients.

Data were collected from nine multinational pharmaceutical companies that are actively involved in registering new medicines in the region and enhancing currently marketed medicines through major line extensions (use of the product in new indications, patient populations or disease states). Information was also collected through a survey and from face-to-face interviews with the regulatory authorities in the countries in the study, with the exception of Morocco, Nigeria and Turkey.

The topics covered in the survey are shown in Box 2. Both companies and agencies were asked to provide specific data, where relevant, but they were also given the opportunity to record their perceptions and views on the current regulatory environment.

The three regions in the study

South East Asia and Western Pacific

China
Hong Kong
India
Indonesia
Malaysia
Philippines
Singapore
South Korea
Taiwan
Thailand
Vietnam

Middle East and Africa

Bahrain
Egypt
Jordan
Kenya
Kuwait
Morocco
Nigeria
Oman
Saudi Arabia
South Africa
Turkey
United Arab Emirates

Latin America

Argentina
Brazil
Chile
Colombia
Costa Rica
Mexico
Venezuela

Box 1

Box 2

Topics covered in the CMR International Study: Regulatory Authority and Company questionnaires

Authority overview and performance
Type of agency, its current and future 'mission' and objectives, data on review timelines;

Relevance of regulatory status in other countries
Recognition of the regulatory status in other countries and use of the WHO model Certificate of a Pharmaceutical Product (CPP);

Transparency of the process
Willingness of agencies to provide advice and information on review procedures, including consultation on guidelines;

Application Procedures and Data Requirements
Type of procedures, use of expert committees and outside experts, acceptance of internationally harmonised guidelines for format and content of applications;

Clinical Trials
Regulatory requirements for local clinical trials and companies' experience of official procedures for conducting trials in the country;

Policy and Perceptions
Official policies and the industry perception of policies relating to the grounds for granting and refusing authorisations, the influence of price on decisions and the extent to which intellectual property protection is implemented.

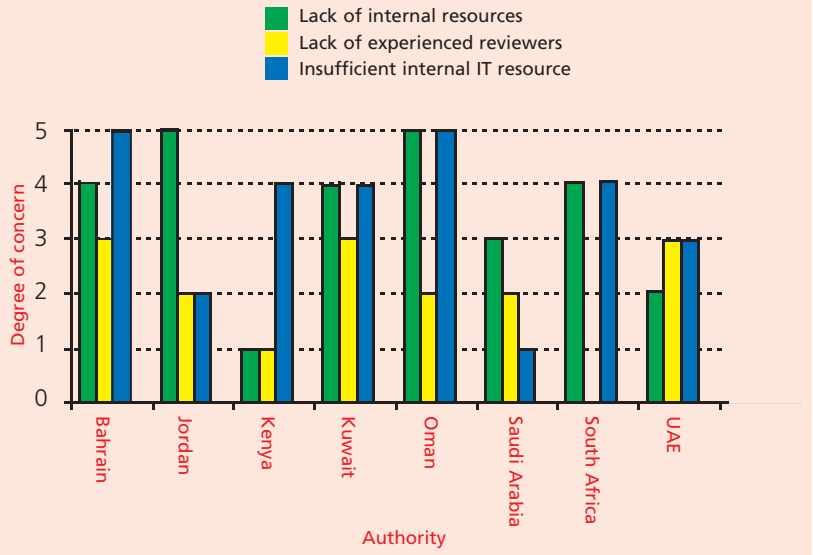
The final section of the questionnaire also asked both companies and regulatory authorities for their views on major hurdles and key success factors for making new medicines available to patients, with a minimum of delay.

Priorities for the Region's Authorities

The Authorities were asked to identify and prioritise the key difficulties that they face, which can cause delays to the timely authorisation of new medicines and their access to patients. Clearly, many agencies feel that they are unable to fulfil their obligations to the public because of limitations and resource constraints that need to be addressed at a higher administrative or political level. Whilst these internal factors are not within the scope of industry to remedy, there were also external factors where changes in company practices could lead to improvements.

Figure 1

Authorities' perception of the internal factors that cause delay to the timely access of patients to new medicines



Rank of importance: 5 = causes a delay/a key concern; 1 = not causing a delay

Internal factors

Figure 1 presents the internal factors that the authorities surveyed cite as reasons that can cause delay to the regulatory process. Insufficient IT resources is seen by several authorities to be as big an issue as a lack of internal resources.

The relatively small population size of Kuwait, Bahrain and UAE may account for concerns about lack of experienced reviewers which is not regarded as an issue in South Africa and Kenya.

Without adequate funding authorities cannot establish an efficient infra-structure, with appropriate IT facilities and it is difficult to attract and retain well qualified, experienced staff. These are seen as the main contributing factors to delays in the regulatory process which, in turn, impede the timely access for patients to new medicines.

External factors

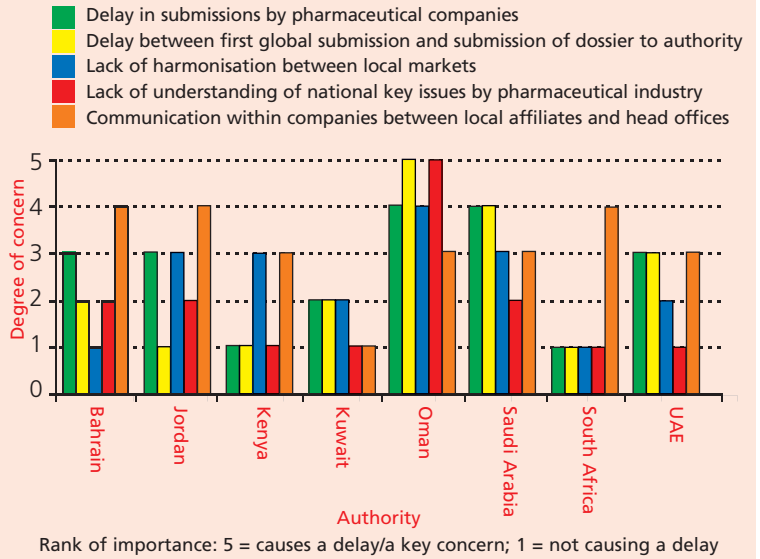
The analysis in Figure 2 presents the authorities' perception of the external factors that have a negative impact on the efficiency of their operations.

Communication within companies between local affiliates and head offices was ranked as a cause of concern by the authorities in Bahrain, Jordan and South Africa. It is believed that this may reflect instances where there has been a misinterpretation of information by the local organisation when reporting back to the company headquarters regarding questions on submissions.

Oman and Saudi Arabia and, to a lesser extent, the other Gulf States indicated concerns about the lag time before applications for new medicines are made in their countries, and the resulting delay between global and local availability. Oman also identified a lack of understanding of local issues, by companies as a factor causing delay.

Figure 2

Authorities' perception of the external factors that cause delay to the timely access of patients to new medicines



Rank of importance: 5 = causes a delay/a key concern; 1 = not causing a delay

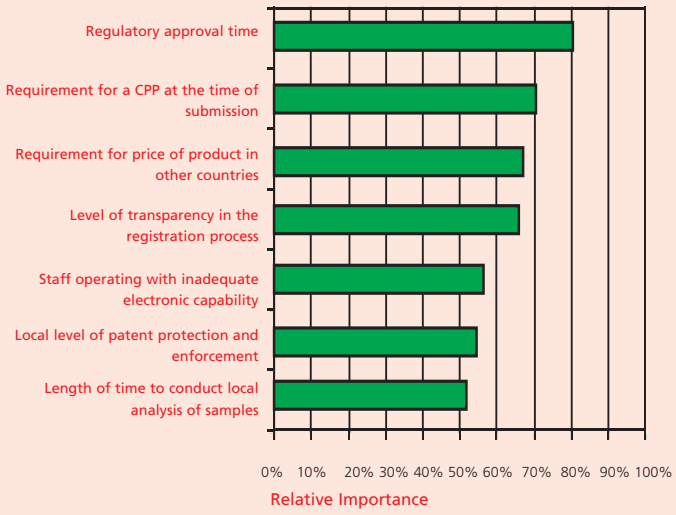
Companies' perspective

Patients' access to new therapies may be delayed if companies are discouraged from doing business in the region by the perception that there are regulatory hurdles that make product authorisation slow or unduly burdensome. Companies were therefore asked to identify their major causes of concern when applying to register medicines in the region.

Figure 3 summarises the company response highlighting the items of greatest concern.

Figure 3

Major causes of concern that may prevent or delay patient access to new medicines: Company data



■ **Transparency in the Review Process:** Experience from the ICH regions has shown the value and benefits of an open and transparent relationship between companies and regulatory authorities.

■ **Inadequate electronic facilities:** The ability to submit data and communicate electronically is becoming increasingly important in improving the speed and efficiency of interaction between authorities and companies. This is particularly important in relation to tracking the progress of applications and obtaining responses to questions.

The Issues

■ **Regulatory Approval times:** The time taken for the authorities in the importing country to review and determine an application is important to companies in planning a launch strategy for a new medicine.

■ **Timing of the CPP:** By definition, a CPP (see below) can only be issued after a new product has been authorised in another country. The need to obtain a CPP before filing an application in the importing country builds an automatic delay into the registration process.

■ **Pricing:** The industry position is that regulatory authorities should assess dossiers on the basis of the scientific data alone, using safety, quality and efficacy as criteria. Whilst recognising that prices need to be negotiated primarily for public sector funding and reimbursement, companies believe that price discussions should not impede the regulatory process or be a criterion for determining an application.

■ **Intellectual Property and Data Protection:** Adequate and enforceable protection of IP rights is regarded as a cornerstone for current and future investment in new medicines. Deficiencies in such protection that could lead to the availability of pirated products and the disclosure of confidential data are major disincentives to the registration of new products.

■ **Analysis of samples:** The main issues for companies arise when authorities demand unrealistic quantities of valuable drug substances or products for testing purposes and when analytical work is carried out sequentially, and not in parallel with the assessment, thus delaying the issue of the authorisation.

Glossary Notes

Certificate of a Pharmaceutical Product (CPP)

Under the WHO Certification Scheme for the Quality of Products moving in International Commerce a regulatory authority that has authorised a medicinal product may be asked to issue a CPP to the authority in an importing country, verifying the regulatory status and confirming that the product complies with standards for Good Manufacturing Practice (GMP).

International Conference on Harmonisation (ICH)

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

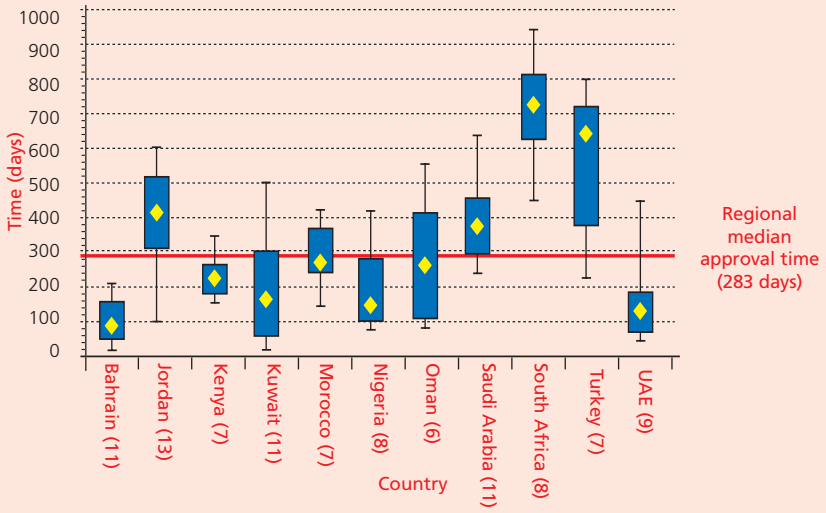
This is a three-region (EU, USA and Japan) six-party (Regulatory Authorities and industry associations) initiative that has agreed over 50 regulatory guidelines for developing new medicinal products ('ICH guidelines').

Regulatory approval times

A knowledge of median approval times and potential variability is important to companies in planning a launch strategy for new medicines in the different countries in the region.

Figure 4

Regulatory approval times for NASs submitted and approved between 2001 and 2003 (calculated from company data)



Data are shown for NAS that were submitted and approved between 01/01/2001 and 31/12/2003. (n) = number of NASs. Box: 25th and 75th percentiles. Whiskers 5th and 95th percentiles. Diamond = median. The regional median indicated by a red line (283 days) is the median approval time for NASs submitted to any country in the region.

The analysis in Figure 4 presents the median approval times (date of submission to date of marketing approval) for new active substances submitted and approved between 2001 and 2003. On the basis of these data, the regional median is 283 days but regulatory approval times vary quite considerably between countries and, in some cases, within countries.

The longest median time was recorded for South Africa (729 days) and the shortest for Bahrain (87). In these particular cases, the differences can probably be explained by contrasting review practices. South Africa carries out a full assessment, independent from reviews carried out in other countries whilst Bahrain uses the CPP and approval in reference countries as the cornerstone of its review.

When looking at the overall time for product approval, account also needs to be taken of CPP requirements. In almost all Middle East countries a CPP is required at the time of application which can delay the submission of the dossier by up to 2 years (see page 6).

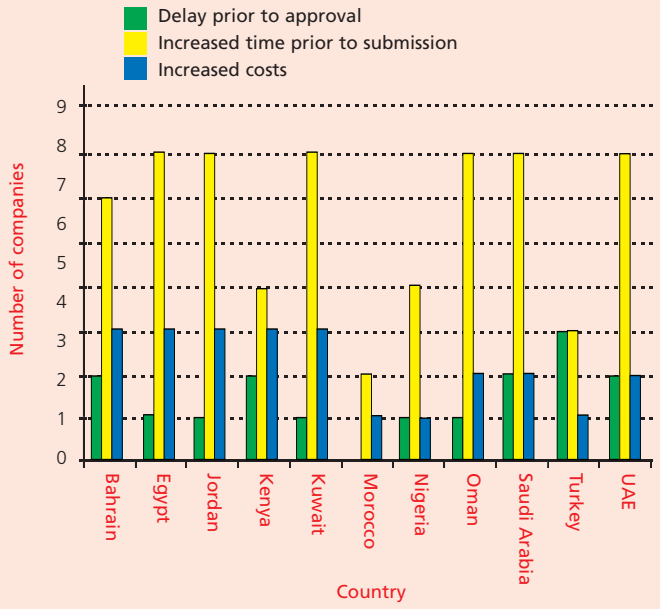
Certificate of a Pharmaceutical Product (CPP)

Certification that a product has been duly registered by an authority that is regarded as a 'reference' agency should be of great advantage when applying for a marketing authorisation in another country.

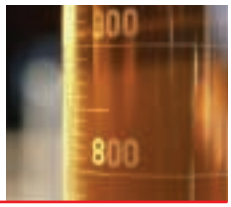
However when companies were asked whether the CPP was an issue in the region, the majority believed it was a cause for concern in all the countries with the exception of South Africa and Morocco. Figure 5 gives the results of a further question asking for views on the ways in which the certification scheme was impeding, rather than expediting, the authorisation of new medicines. The predominant concern in the Gulf States, Jordan and Egypt is the delay before an application can be submitted. This is due to the need to obtain a CPP in advance of submission.

Figure 5

Companies' perception of CPP requirements as an issue



Certificate of a Pharmaceutical Product



The issues from a company perspective

■ Timing of the CPP: Whether the Certificate must be made available:

> At the time of making an application in the importing country while authorisation is obtained elsewhere*; or
> After the application is filed but before authorisation, in which case applications can be filed in the emerging markets within the same time-frame for registration in the ICH regions.

■ Authentication of the CPP: Some agencies in importing countries require certificates to be authenticated by their embassy or consulate in the country where the certificate is issued. Companies consider that authentication by the regulatory agency issuing the certificate (as recommended in WHO Guidelines for the Certification Scheme) should suffice.

■ Source of the Certificate: A strict requirement that the certificate must be issued by the regulatory authority in the country from which the product is actually exported can create problems when manufacture is outsourced to a country where the product may not be registered for marketing.

Companies believe that a CPP from a reference list of regulatory authorities should suffice along with confirmation that the product is manufactured under GMP conditions.

*CMR International data indicates that the median time for obtaining an authorisation through, for example FDA or EMEA is 400-500 days. Requiring a CPP before accepting an application can, therefore, delay the start of the review process by some two years.

Authorities requirements for CPPs

The analysis in Figure 6 shows the authorities' position on the stage at which they require a CPP to be submitted. At the time of the survey, all the regulatory agencies indicated that they required the CPP at the time of making the application although South Africa reported separately that previous registration by another authority is not a prerequisite for authorisation, since the agency carries out a full, independent assessment.

With the exception of South Africa, legalisation through a national Embassy is required by all authorities.

Figure 6

	Bahrain	Egypt	Jordan	Kenya	Kuwait	Oman	Saudi Arabia	South Africa	UAE
CPP to be submitted:									
At the time of application	■	■	■	■	■	■	■	■	■
After application but prior to approval									
Other timing allowed				■					
Authentication of CPP:									
Legalisation by national Embassy required	■	■	■	■	■	■	■		■
No legalisation required								■	

*Since the above results were collected, requirements in Bahrain have changed and the CPP can now be submitted after application but prior to approval.

The issues from an Authority perspective

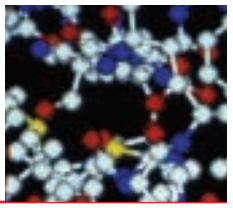
■ Timing of the CPP: The Authority may not wish to commit resources to the processing of an application before it is certain that the product has met the requirements of a major regulatory authority in another country*.

* In practice, this need not be a major concern. CMR International data indicates that over 90% of NMEs that reach the regulatory submission stage will obtain an authorisation from a major regulatory authority (e.g., FDA, EMEA, PMDA).

■ Source of the CPP: Historically, there are political concerns about the export of unauthorised products to developing countries and the regulations do not necessarily take account of current, legitimate sourcing practices among multinational companies.

■ Authentication of the CPP: A differential system would be hard to administer, thus measures that are put in place to guard against forged certificates from unscrupulous traders have to be applied equally to reputable companies.

Pricing



Pricing of products is a sensitive and political issue that raises issues of the affordability of new medicines and healthcare budgets. The regulatory issue is whether the scientific decisions on the safety, efficacy and quality of a medicines should be independent of discussions on price. The study looked at whether negotiations on pricing were carried out as part of the regulatory process or was separated from the regulatory authorities scientific assessment and decision to authorise a product.

- In Kenya, Nigeria and South Africa, price decisions are not part of the regulatory approval process.
- In all other countries in the study price negotiations are integrated into regulatory procedures.

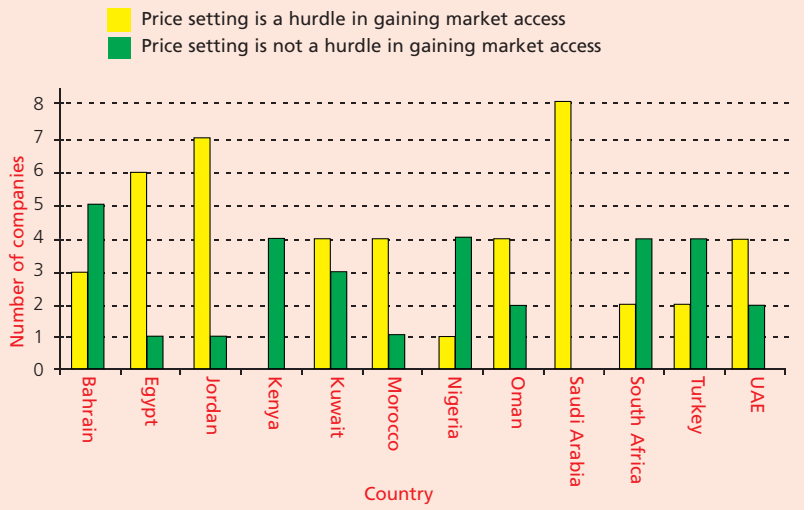
As shown in Figure 7, the interlinking of pricing decisions and the regulatory review process has been highlighted by companies as a major concern, that may act as a deterrent when planning to market medicines in the region.

Holding up registration until prices are negotiated by governments, for the public sector, means that marketing the products in the private sector is also delayed.

In the Middle East countries, the data required to support an application includes information on the price of the product in other markets, usually the country of export but also specific reference countries. The information may be required at a late stage in the regulatory process and can delay the issue of the final authorisation.

Figure 7

Companies' perception of whether the process of price setting is a major hurdle in gaining market access

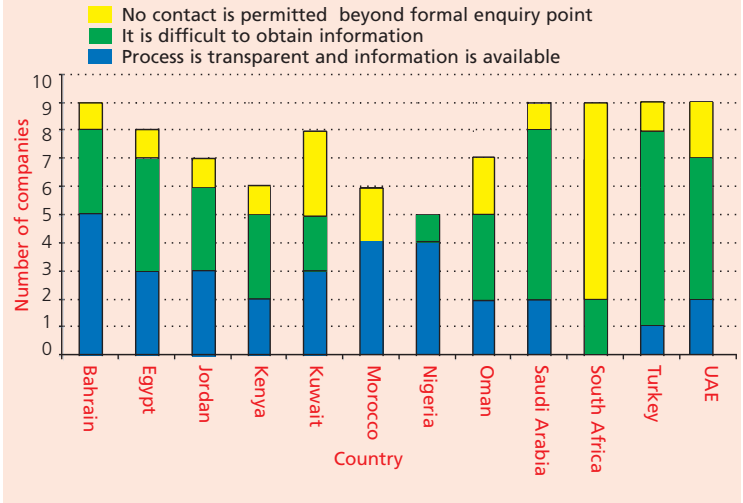


Transparency

Experience from the ICH regions has shown the value and benefits of an open and transparent relationship between companies and regulatory authorities.

Figure 8

Companies' experience of feedback from, and contact with, the regulatory authority following submission



The benefits of transparency in the regulatory environment that encourage companies to register new medicines are:

- A 'level playing field' where the rules are clear and the players are treated even-handedly;
- The ability to seek and obtain information and advice before and during the review process;
- Confidence that industry will be consulted and able to comment on proposals for new laws and guidelines.

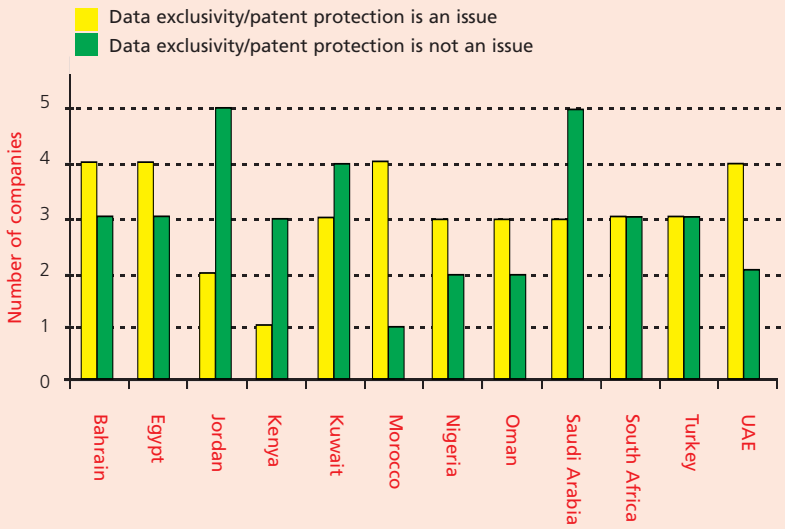
Companies' experience of the transparency and openness of regulatory procedures in the countries of the region are shown in Figure 8. The results are varied but the overall picture suggests that many companies have encountered a lack of willingness to communicate during the review process. The problem appears most marked in South Africa, Saudi Arabia, Turkey and UAE.

Intellectual Property

Adequate and enforceable protection of intellectual property rights is regarded as a cornerstone for current and future investment in new medicines. Deficiencies in such protection that could lead to the availability of pirated products and the disclosure of confidential data are major disincentives, for companies, to the registration of new products.

Figure 9

Companies' perception of whether data exclusivity or patent protection is an issue of concern



- All the regulatory agencies surveyed reported that data and patent protection, had been implemented, either through international treaties or to meet local requirements.

- Companies were asked for their perception of whether protection of intellectual property was an issue of concern in the region. The results shown in Figure 9 indicate that half the companies or more believe that data exclusivity or patent protection remains a problem in the region. The exceptions were Jordan, Kenya, Kuwait and Saudi Arabia where there was majority view that IP protection is not an issue.

Demography of the Region

A snapshot of the diverse characteristics of the countries of the Middle East and Africa that were included in this survey is given in Figure 10 (http://www.cia.gov/cia/publications/factbook)

Figure 10

	Bahrain	Egypt	Jordan	Kenya	Kuwait	Morocco	Nigeria	Oman	Saudi Arabia	South Africa	Turkey	UAE
Geography												
Total area (sq. km)	665	1,001,450	92,300	582,650	17,820	446,550	923,768	212,460	1,960,582	1,219,912	780,580	82,880
Land boundaries (km)	0	2665	1635	3477	462	2018	4047	1374	4431	4862	2648	867
Coastline (km)	161	2450	26	536	499	1835	853	2092	2640	2798	7200	1318
Population												
Est. total (millions)	0.683	77.505	5.760	33.830	2.336	32.726	128.772	3.002	26.418	44.344	69.661	2.563
Median age	29.19	23.68	22.62	18.19	25.86	23.61	18.63	19.13	21.28	23.98	27.7	27.9
Life expectancy at birth	74.23	71	78.24	47.99	77.03	70.66	46.74	73.13	75.46	43.27	72.36	75.24
Economy												
GDP US $ billion	13.01	316.3	25.5	34.68	48	134.6	125.7	38.09	310.2	491.4	508.7	63.67
GDP per capita US$	19200	4200	4500	1100	21300	4200	1000	13100	12000	11100	7400	25200

Future Focus

Specific regulatory hurdles at national level can influence corporate decisions on when – and in some cases whether – to introduce new medicines into new markets, especially where market size is limited.

Companies were asked to identify the areas that each of the authorities might focus on when making changes for the future. The following refers to priorities that were selected by at least 70% of responding countries.

Figure 11

	Bahrain	Egypt	Jordan	Kenya	Kuwait	Nigeria	Oman	Saudi Arabia	South Africa	Turkey	UAE
Greater collaboration between the authority and industry	■	■	■	■	■	■	■		■	■	■
Greater flexibility with respect to manufacturing sourcing	■				■		■	■			■
International harmonisation of regulatory requirements			■						■	■	
Intellectual property protection		■							■		

Other priorities also identified for South Africa were performance/process improvement and greater collaboration/cooperation with other regulatory authorities

The Regulatory Authorities were also asked to look towards the future and identify overall goals in terms of encouraging more local research and clinical development and forging closer links with the pharmaceutical industry. The responses are summarised below.

Authority	Future Priorities
Bahrain	Educational courses for authority employees, is a priority including technical training, administrative courses and special laboratory courses. Staff members are trying to work more closely with industry.
Egypt	The government is trying to encourage local research and develop an infrastructure that would allow local clinical development. Closer links with industry, and increased transparency, including a tracking system, are also goals.
Jordan	With the drug directorate becoming part of the autonomous Jordanian FDA, and the introduction of user fees, the IT infrastructure will be upgraded with electronic archiving and acceptance of some data electronically.
Kenya	Whilst local research and clinical development is not a priority, the agency gives high priority to finding training opportunities for staff – especially pharmacists – through pharmaceutical companies and independent organisations.
Kuwait	Continuing medical education for the agency personnel is a priority and they hope to be working more closely with industry.
Oman	Educational priorities are for training in Good Manufacturing Practice (GMP) and post marketing surveillance (PMS).
Saudi Arabia	The government is trying to encourage local research and develop a more transparent relationship with companies. Staff are sent overseas to study regulatory affairs and to visit other agencies for short training courses.
South Africa	The agency believes that it already has a good relationship with the industry but is keen to find continuing opportunities for training employees and workshops between industry and the authority.

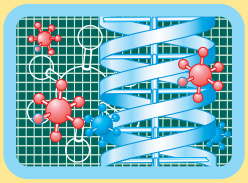
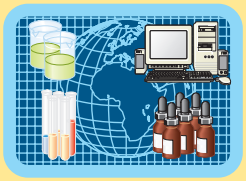
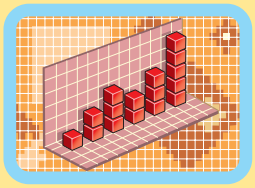
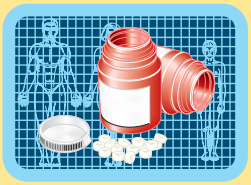
Key Questions for the future

What steps can be taken at country and regional level to engage both regulators and industry in meaningful discussions on medium- to long-term improvements in regulatory procedures?

- Are regulatory authorities sufficiently aware of the importance of setting, and adhering to, reasonable targets for completing the regulatory review process? Are there similar targets and commitments for company response times when questions are raised by agencies?
- How can industry and regulatory agencies move forward to identify 'best practice' for harmonised implementation of the WHO Certification Scheme, in order to streamline and expedite procedures for making new medicines available?
- Is there scope for industry to discuss with authorities the perceived benefits of separating the scientific procedures from price negotiations in order to increase the efficiency of the authorisation of new medicines?
- Are there lessons about the benefits of openness and transparency that can be learned from the more communicative authorities in order to influence those that place less emphasis on good communications?

CMR International Institute for Regulatory Science

Assessing Regulatory Policy and Performance

Regulatory science	Global drug development	Regulatory processes	Patient Access to Medicines
			

2005 Agenda

A New Model for Benefit Risk Assessment	A New Paradigm for Clinical Research	Post-Approval Commitments and Conditional Authorisations	Impact of Regulation on Access in Emerging Markets

Past and future topics

Pharmacogenetics and pharmacogenomics Risk management and benefit-risk assessment Biomarkers and surrogate end-points	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 Good regulatory practices Critical success factors in regulatory performance	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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