The development of a strategic plan for strengthening drug regulation in the Gulf region

With the co-operation of drug regulators from the seven Arab Gulf countries, ***Reem Al-Essa***, ***Sam Salek*** and ***Stuart Walker*** have developed a harmonised strategic model for improving medicines regulation in the region.

The time has come for the drug authorities of the seven Arab countries that make up the Gulf Cooperation Council to implement a new harmonised strategic plan to strengthen the regulatory environment for medicines in the Gulf Region.

The GCC countries – Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE and Yemen – have over the past few years established their individual regulatory systems for medicines. They have also made some effort to harmonise their individual regulatory procedures for medicines by developing a set of guidelines and policies. Furthermore, since 1999, GCC drug authorities have had in place a non-mandatory centralised GCC-drug registration (GCC-DR) system to control the access of medicines in the region.

The pharmaceutical market opportunity in the Gulf region is significant; it is estimated to grow at a CAGR of 7%, with pharmaceutical sales doubling to $10.8 billion in 2020 from $5.6 billion in 2010[1]. A new strategic direction would further improve the drug regulatory systems of each GCC country and unify them so as to boost patient access to high quality medicines throughout the region.

In this article, we describe an original piece of research that, with input from all seven GCC drug authorities, has enabled us to identify the key components of a strategic model for harmonising and strengthening drug regulation in the Gulf region. The centralised procedure in the GCC region is critical to the registration of new medicines and we believe that the strategic direction outlined in this paper will make a major contribution to the regulatory environment in the region.

Methods

We sent all seven authorities a questionnaire designed to help us identify common elements in their existing vision and mission statements, values, major goals and objectives, general driving forces and short- and long-term plans.

Before we sent out the questionnaire, we approached each authority with a data provision request and contacted them to identify the most appropriate person to receive the questionnaire and to facilitate the self-completion process. We piloted the questionnaire with Kuwait and UAE to ensure its practicality and appropriateness; we then distributed it to the remaining five states for completion.

We followed up with the authorities to ensure timely completion of the questionnaires. A confidential procedure was used with information coded on receipt to conceal the identity of the individual GCC authority, although all the authorities subsequently agreed to be identified in the final report. The participants submitted their completed questionnaires electronically, which improved the quality of data processing. In addition to the responses from the authorities, we also obtained data from a literature review to provide further clarification about the concept of strategy formulation.

> The fact that the Gulf states already have well-established regulatory authorities has to be taken into account

To establish a clear model for a harmonised strategic plan for the GCC regulatory authorities, it was necessary to define the sequence of activities to be followed. In general, an organisation first needs to know exactly where it stands. It must then determine its destination and how to get there. Since the seven Gulf states have well-established regulatory authorities with long historical backgrounds, it was hard to imagine a future independent of the past. Therefore, it was more appropriate to carry out a situational analysis before deciding on a realistic approach for the strategic direction and future harmonised regulatory plans for the authorities.

Results

The findings of our research will be presented in three parts: stating the current position (organisational values, strengths and weaknesses); setting the strategic direction (goals, objectives and driving forces); and strategy development (short- and long-term parameters).

Organisational values

Organisational values are defined as the collective principles and ideals that guide the thoughts and actions of individuals within an organisation. Our study examined the ideas, beliefs and attitudes of individuals from the seven authorities, enabling us to collectively define the existing state of the art within each authority.

The seven states expressed 28 collective values that guide their actions for better regulatory services. Of these values, seven were most prevalent, namely: efficacy, competency, honesty, integrity, professionalism, confidentiality and transparency. A value audit enabled us to assess existing strategic planning parameters and determine congruence in the behaviour and practices in each organisation.

Strengths and weaknesses

We then performed a SWOT analysis of each authority's internal and external regulatory environment to help us match the authority's resources and capabilities to the challenging arena in which it operates. Internal environmental factors were classified as strengths and weaknesses, while external factors were classified as opportunities and threats.

Regarding strengths, we found that the GCC region has experienced technical staff, well established authorities and appropriate legislations and guidelines. There is also active cooperation between the authorities. For weaknesses, we found that there are not enough experts in Gulf states to advance regulatory systems through appropriate training and continuing educational programmes.

As for opportunities, we found that the Gulf authorities have been able to improve their regulatory practices through active collaboration with regional and international regulatory agencies. They have also employed emerging technologies to improve their drug approval processes such as the electronic common technical document (e-CTD). For threats, however, high staff turnover and an increasing number of substandard and counterfeit drugs have limited the capabilities of the authorities.

Setting the strategic direction

The next step in our strategic planning process involved analysing each authority's vision and mission statements.

The vision statement is a concise declaration of what the organisation wants to be at the end of a planning cycle. In the context of the GCC regulatory authorities, the planning cycle was five years, based on their existing resources and capabilities. The mission statement describes the approach the organisation will take to achieve its vision and addresses the organisation's purpose for existing.

Our analysis of the seven vision statements showed that the authorities shared two common aspects:

- to protect public health; and
- to become the leading regulatory authority in the region.

Our mission statement analysis revealed two common purposes for the existence of the authorities:

- to ensure the quality, safety and efficacy of locally marketed medicines; and
- to develop strong regulatory systems.

Goals, objectives and driving forces

In order to collectively steer an organisation in an appropriate direction, its employees must understand the destination to which their organisation is heading and this can be achieved by setting the organisation's goals and objectives in conjunction with its mission.

Of the various visionary goals stated by the GCC authorities, two were most common:

- to provide the ultimate consumer health protection; and
- to master competency and efficiency in the regulatory practices of the region.

These two goals coincide with the common aspects of the GCC vision statements, meaning that they would be achievable if the authorities had the capabilities and the resources discussed in the SWOT analysis of their current individual regulatory environments.

The authorities also provided a set of objectives, of which three were found to be most common in the region:

- to improve the regulatory review process for medicines;
- to develop an efficient post-marketing surveillance system; and
- to improve the legislative procedures in order to implement pre- and post-marketing assessments in the most efficient and competent manner.

The authorities are currently initiating actions to establish post-marketing activities in the region by requesting that companies submit as part of the safety data in the registration dossier for the GCC-DR approval any post-marketing surveillance reports they might have obtained for the drug in markets outside the region.

The respondents collectively stated a number of driving forces for improvement that are likely to have a significant impact on the regulatory authorities in the future. Although no one driving force was shared by all the states, demand for change was found in five areas, as shown in the following five-force model:

1. Demands for regulatory advancement. This is considered the centre of the GCC authorities' focus, which is to expand and improve their regulatory services to cope with the speed of the regulatory advancement.
2. Industry demands. The Gulf authorities are faced with an increasing number of pharmaceutical companies demanding more efficient, effective and transparent regulatory services.
3. Public health demands. There is a need for the GCC authorities to become sufficiently capable of combatting substandard and counterfeit medicines and to effectively monitor the post-marketing surveillance of pharmaceutical products available in the local market. Furthermore, the authorities have the responsibility to provide local patients with innovative and high-quality medicines to treat life threatening diseases or chronic illnesses and to prioritise the assessment of medically urgent medicines.
4. Technological demands. To cope with the latest technological developments in the regulatory field, the GCC authorities need to acquire the appropriate skill sets and expertise as well as the technological resources and facilities to improve their regulatory performance.
5. Market demands. The constant growth of the Gulf pharmaceutical market has resulted in a strong demand for new medicines in the region. Therefore, the Gulf states have become ambitious in attracting more international pharmaceutical and biotechnological companies into the region. The GCC-DR system and the Gulf customs union policies are examples of efforts made by the seven states to expand their pharmaceutical market.

> Developing standard GCC guidelines and SOPs will ultimately ensure the approval of quality, safe and effective medicines

Having explored the common five demand areas for regulatory improvement, we realised it was crucial to identify the most prevalent driving forces for improvement in the Gulf region, namely:

- the rising number of substandard and counterfeit drugs;
- increased patient demand for access to safe and effective medicines; and
- increasing population and growing public awareness of safety of medicines.

It is obvious that the above three driving forces are related to the public health demands, which coincides with the common aspects of the GCC vision statements described earlier.

Strategy development

Strategy development is where the various findings from the external and internal analysis are placed in a context with the mission and goals of the GCC authorities in order to determine the best course of action for success. The seven authorities have their own strategies, which were identified in this study. Each strategy shapes the authority's own identity. Therefore, to achieve a harmonised strategy, it was crucial to pinpoint the common strategic parameters from each of their short-term (one to two years) and long-term (three to five years) plans.

These common parameters can be contrasted with the outcomes of the situational analysis and the strategic direction designed to create a harmonised action plan for the region. Information provided from the five-force analysis is key to understanding the authorities' efforts to determine what needs to be done differently to achieve the desired vision.

Short- and long-term parameters

We evaluated eight strategic parameters through the assessment of the short- and long-term strategic plans of six of the GCC regulatory authorities (Qatar did not provide any data with respect to its regulatory short- and long-term strategies). These parameters were guidelines, standard operating procedures, changing requirements, quality assurance, post-marketing surveillance, review process, resources and budgeting.

We found that the short-term strategic parameters coincided with the authorities' missions and objectives. This means that the short-term strategic parameters should enable each authority to carry out its mission efficiently and achieve its objectives in a timely manner. The three most common strategic parameters identified in the short-term strategic plans were: guidelines, SOPs and improving the regulatory review process (see Figure 1). These parameters coincide with the common elements that structured the mission statements of the Gulf authorities.

Developing standard GCC guidelines and SOPs are important for building quality into the regulatory review process and will ultimately ensure the approval of quality, safe and effective medicines. Standard GCC guidelines and SOPs are also essential in creating the fundamental basis for a strong GCC regulatory system.

The three strategic parameters also correspond to the objectives of the GCC

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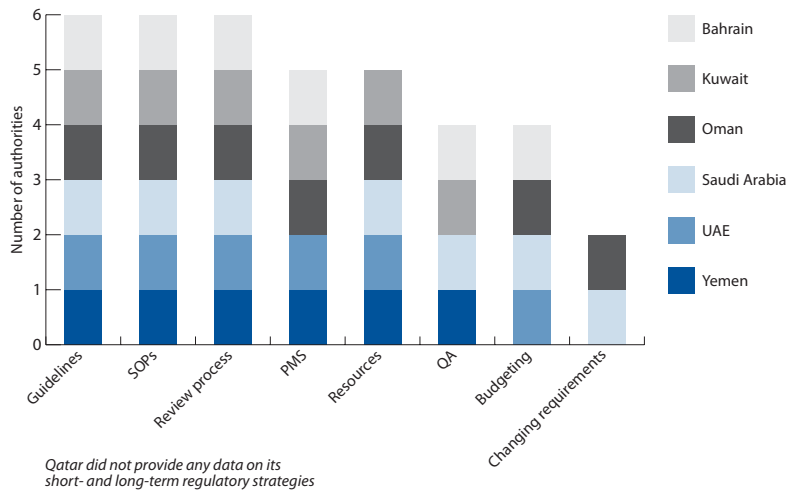
US 510(k) scheme is on a one-way journey

The US Food and Drug Administration's January 2011 action plan set the boat afloat. The Institute of Medicine's (IOM) views fixed the rudder. And then the *NEJM* article got the oars moving in the choppy US device regulatory waters. The US medical device 510(k) approval right now is travelling fast downstream, and its destination looks to be the head of the falls. Will it be seen again? It seems unlikely, reports ?qfjcw Wcm, principal analyst for Informa Business Information, the publisher of *Scrip Regulatory Affairs*.

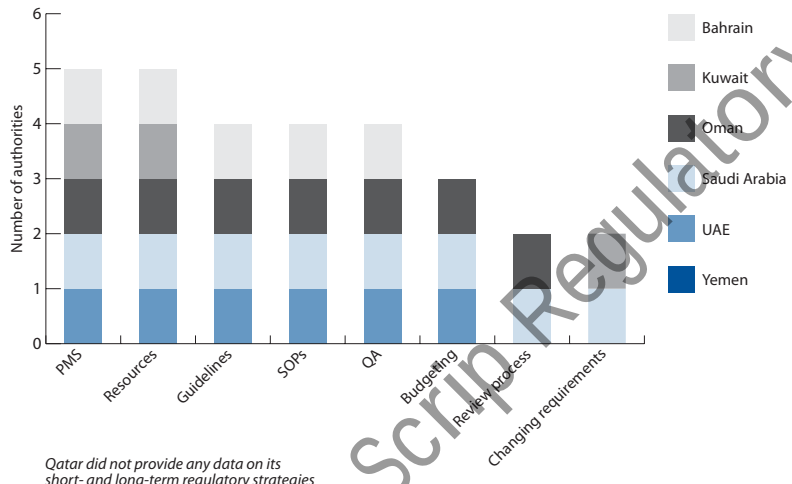
www.scripregulatoryaffairs.com

Figure 1. The GCC short-term regulatory strategic parameters



Qatar did not provide any data on its short- and long-term regulatory strategies

Figure 2. The GCC long-term regulatory strategic parameters



Qatar did not provide any data on its short- and long-term regulatory strategies

authorities, namely, to develop a post-marketing surveillance system, to improve the legislative procedures and to improve the review process. Developing standard guidelines and SOPs for the region are essential for developing the basic foundation for a post-marketing surveillance system and for improving the regulatory review process and the legislative procedures. Therefore, the mission statements, the objectives and the short-term strategic parameters are correlated, which suggests the possibility for the successful development and implementation of the short-term strategic plans.

The two most commonly identified long-term strategic parameters were post-marketing surveillance and resources (see Figure 2). These parameters correspond to the shared aspects of the seven vision statements as well as the two common goals of the GCC authorities. The provision of sufficient resources requires: the availability of qualified and trained experts; advanced drug approval technologies; and sufficient funding and work facilities to improve the performance of the seven authorities.

Our study revealed four common parameters in both the short-term and long-term strategic plans (see Figure 3). These parameters were guidelines, SOPs, post-market surveillance and resources. This means that to develop a successful harmonised regulatory strategic plan for the region, the authorities should develop standard guidelines and SOPs. They should provide sufficient resources to support efficient and effective regulatory services such as qualified and trained experts and technological facilities that improve the quality of the Gulf regulatory performance. The authorities also recognise the importance of setting up guidelines and SOPs and providing sufficient resources to support the development and implementation of an efficient post-marketing surveillance system for the region.

Discussion

Harmonisation of strategic plans is critical for the future of the GCC regulatory authorities and has been of interest to senior managers in the region since the centralised procedure for evaluating medicines was established in the EU.

The first positive finding in our study to support developing a harmonised GCC strategic plan was the active co-operation between authorities, which was stated by Bahrain, Kuwait, Oman and Saudi Arabia as a strength. This co-operation is also evident in the joint reviews performed by the seven authorities for the GCC-DR system.

The second positive finding was the opportunity to work in collaboration with regional and international agencies. This was a view shared by Bahrain, Kuwait, Oman, Saudi Arabia and UAE and these collaborative efforts are essential to building the assessors' knowledge and skills in the area of dossier review. However, training should be formalised and emphasised to achieve the desired outcomes in terms of quality. The downside of not enforcing training programmes was perceived as a weakness by the Gulf states because it is a critical element to achieving good quality in regulatory practices.

The third positive factor, shared by Bahrain, Kuwait, Saudi Arabia and UAE, was the opportunity for advancement through the use of new technologies for the drug approval process such as the eCTD, which has been introduced by the Saudi Food and Drug Authority, for example. All the positive findings are considered critical to overcome the threats that concern the authorities such as high staff turnover and the growing flood of counterfeit and substandard medicines into the market.

The strategic direction part of our study showed that the four components of the GCC strategic planning processes (vision statements, mission statements, goals and objectives) were closely linked to each other and, therefore, they can be achieved with success. Furthermore, we learnt that the most prevalent forces driving the authorities to improve their practices revolve around public health demand and better regulatory services in the region.

The five-force model presented a clear view of the factors influencing the decision-making process in the region. Therefore, it was reasonable to generate a framework for a harmonised strategic plan using the balanced scorecard approach. In order for the GCC authorities to implement a successful harmonisation strategy, they need to create a

Figure 3. Shared strategic parameters in the short-term and the long-term GCC plans

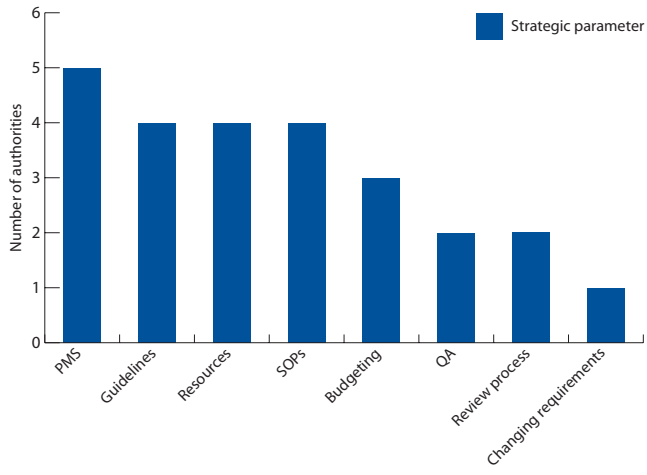
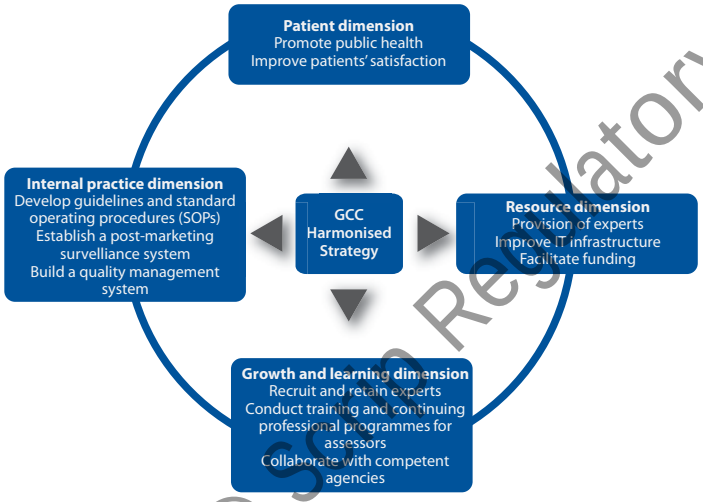


Figure 4. Balanced scorecard framework for the GCC harmonised strategic planning process



balance in their performance between four strategic dimensions (see Figure 4), namely:

- patient dimension: a patient-focused organisational performance;
- resource dimension: focusing on the availability of resources to improve performance;
- internal practice dimension: measuring the efficiency and effectiveness of internal systems; and
- growth and learning dimension: measuring the progress towards attracting and retaining staff.

The idea is to develop two or three measurements for each dimension that can be directly linked to the shared aspects of the GCC strategic vision and goals. The patient dimension is the most critical strategic dimension in this study, as the aim of any regulatory authority is to protect patients from harmful effects of medicines and to make safe and effective medicines available to them in a timely manner.

However, to achieve this, the GCC authorities must ensure the availability of appropriate financial, technological and human resources.

Furthermore, the authorities need to improve their internal practices such as developing guidelines and SOPs, establishing efficient and effective post-marketing surveillance and quality assurance systems.

Finally, the authorities should ensure that their technical staff are updated with the latest developments in the regulatory field. In addition, it is essential to recruit experts, though retaining them can be difficult. Therefore, the authorities must ensure that these experts receive appropriate remunerations, training and professional development to ensure job satisfaction within the region. Also, the Gulf authorities should enhance their presence in the global regulatory arena by collaborating with competent authorities in their attempts to improve the quality of their regulatory practices through knowledge transfer and the sharing of best practices.

Should the GCC authorities decide to instigate the harmonisation initiatives that have emerged from our study, they will need to constantly monitor and revise them to accommodate any change according to the identified priorities. Consolidating redundant systems and eliminating unnecessary processes in each of the authorities is the first step towards a harmonised strategic plan.

The authors would like to thank all the members of the Gulf Cooperation Council (GCC) control drug registration (GCC-DR) committee, namely Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE and Yemen.

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