Comparisons of the Gulf States' and Pharmaceutical Companies' Perspectives on the Effectiveness of the GCC Centralised Procedure

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Background

- The Gulf Cooperation Council states are similar in language, geography, values, traditions, economic resources, and social and cultural factors (population 62.4 million)
- The pharmaceutical market in these countries reached 5.6 billion dollars in 2010, and predicted sales will reach 10.8 billion dollars by 2020
- The Gulf Central Committee for Drug Registration (GCC-DR) includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates and Yemen
- The responsibilities of GCC-DR include:
  - The centralised procedure for registration of pharmaceuticals (**Figure 1**)
  - Registration of pharmaceutical companies
  - Inspection of pharmaceutical companies for GMP compliance
  - Review of technical and post-marketing surveillance reports
- The company registration must be approved prior to the product registration and the model used by the Gulf central registration system for all major application is an abridged assessment

Methods

- Two different structured questionnaires were developed to study pharmaceutical companies and the 7 Gulf Cooperation Council states
  - A pilot study was carried out to validate the questionnaires with 5 companies and 2 GCC states
- Both questionnaires consist of 5 parts (**Figures 2A/B**), with each part subdivided into a number of sections
- The survey questionnaires were then completed by 15 companies that have registered their products through the centralised registration procedure and national registration systems and 5 regulatory authorities within the Gulf region

Figure 3. Does registering through the centralised system take more time than local registration?

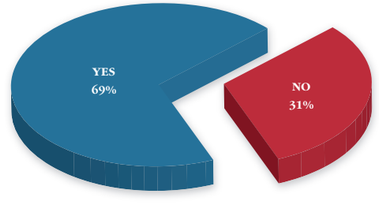


Figure 5. Preference for pricing policy adoption

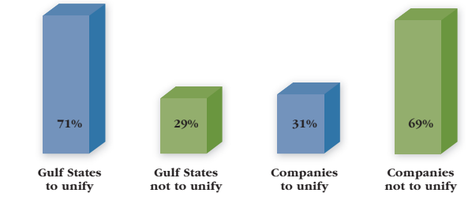


Figure 1. Process map for GCC central registration

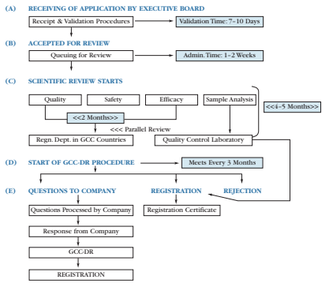


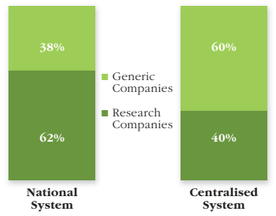
Figure 2A. Questionnaire sections: pharmaceutical companies' experiences

Part I	General
Part II	Centralised registration procedure
Part III	Interaction with GCC-DR
Part IV	Scientific opinion
Part V	General observations

Figure 2B. Questionnaire sections: Gulf States' experiences

Part I	Value of centralised procedure
Part II	Utilisation of resources
Part III	Regulatory expertise
Part IV	Importance of GCC-DR
Part V	General observations

Figure 4. Pharmaceutical company preference for drug registration



Discussion

- The challenge of the existing system for registration is the waiting period for companies after submission of dossiers to the regulatory authority
- These timelines could be shortened by increasing the frequency of meetings, adopting the common technical document format with good IT support and increasing the number of personnel dedicated to the process
- The adoption of one common evaluation template by all member states together with an official clock-stop would improve the company response time

Conclusions

It is recommended that there is an urgent need for:

- Formulation of policies and guidelines that are practical, concise and clear
- A healthy interaction between regulatory agencies and pharmaceutical companies at an early planning stage
- A competent registration process which is rooted in transparency of procedure, fair pricing policies and unbiased scientific opinions

Aims and Objectives

- Examine the views and experiences of the Gulf Cooperation Council states and pharmaceutical companies, with respect to the Gulf central registration procedure
- Compare the views and experiences of the regulatory agencies with that of the pharmaceutical companies
- Identify the barriers to implementation of the Gulf central registration procedure and to recommend measures for improvement

Results

Pharmaceutical Companies

- The common issues raised by the companies that delay the registration process were the limited number of meetings with the GCC-DR, delay in the feedback on files submitted, lack of coordination in distributing files to the reference countries and the request for additional information
- Major advantages of the centralised procedure included transparency, realistic decisions and efficient processes
- The disadvantages included a lengthy waiting period, concern over possible rejection by GCC-DR, which would affect national registration, poor communication, lack of clarity in guidelines and insufficient number of the GCC-DR personnel
- Most companies reported that registration through the centralised system took longer than through the national procedure (**Figure 3**) and results showed that research-based companies preferred national registration (**Figure 4**)
- Recommendations made by the companies to improve the system were to increase the frequency of meetings and to improve communication and review times

Results

Gulf States

- The Gulf States rated their decision-making as "good" and believed that if the companies conformed to the guidelines, the outcomes would be improved, and specified that the Gulf central agency needed more experts and personnel dedicated to the centralised procedure
- They also supported the continuity of national registrations in parallel to the centralised procedure and a standard pricing policy within the GCC region
- The advantages of the centralised procedure were that the burden and workload is divided and the quality of review is improved; in addition, the centralised procedures also provide the possibility of sharing previous track records and a review of pharmacovigilance and bioequivalence data by several internal and external experts
- The disadvantages included the delay and inflexibility of the procedure and lack of direct communication with the applicant to clarify issues
- Pricing policy: Gulf States reported preferences to unify their pricing policies, while companies reported the opposite (**Figure 5**)

Sources

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Disclosure

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