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 (GCC) 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 5.1 billion dollars in 2010, and predicted sales will reach 10.8 billion dollars by 2020.
- The Gulf Cooperation Council for Drug Registration (GCC-DR) includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates and Yemen.
- The responsibilities of GCC-DR include:
  - 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 staff central registration system for all major applications is an abridged assessment.

Aims and Objectives
- Examine the views and experiences of the Gulf Cooperation Council states and pharmaceutical companies with respect to the staff 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 staff central registration procedure.
- Identify the barriers to implementation of the staff central registration procedure and to recommend measures for improvement.

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 & 2B), with each part calculated into a number of sections.
- The survey questionnaires were then compiled by 15 companies that have registered their products through the centralised registration procedure and national registration systems and 5 regulatory authorities within the GCC region.

Results
- The disadvantage included a lengthy waiting period, concern over possible rejection of applications, lack of coordination in distributing files to the reference countries, and the limited number of meetings with the GCC-DR, delay in the feedback on files submitted, lack of clear guidelines and insufficient number of the GCC-DR personnel.
- Pharmaceuticals companies are divided and the quality of review is improved; in addition, the centralised procedures encourage transparency, realistic decisions and efficient processes.
- The disadvantages included the delay and inflexibility of the procedure and lack of personal relationships with commercial entities that may have a direct or indirect interest.
- The challenge of the existing system for registration is the waiting period for companies and the limited number of meetings with the GCC-DR, delay in the feedback on files submitted, lack of clear guidelines and insufficient number of the GCC-DR personnel.

Discussion
- It is recommended that there is an urgent need for:
  - Development 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 compressed registration process which is rooted in transparency of procedure, fair pricing policies and unbiased scientific opinions.

Conclusions
- It is recommended that there is an urgent need for:
  - Development 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 compressed registration process which is rooted in transparency of procedure, fair pricing policies and unbiased scientific opinions.

Sources

Disclosure
- Authors of this presentation have the following to disclose concerning possible financial or personal associations with commercial entities that may have a direct or indirect interest in the subject matter of the presentation:
  - Mohammed Al-Rubaie: Nothing to disclose
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Figure 1. Process map for GCC central registration

Figure 2A. Questionnaire review pharmacetical companies’ experiences

Figure 2B. Questionnaire review GCC States experiences

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

Figure 4. Pharmaceutical company preference for drug registration

Figure 5. Preference for pricing policy adoption

Figure 2C. Process map for GCC central registration

Figure 3A. Questionnaire review pharmacetical companies’ experiences

Figure 4A. Questionnaire review GCC States experiences

Figure 5A. Preference for pricing policy adoption