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An Evaluation of the Efficiency of the Gulf Cooperation Council's Centralized Procedure by the Gulf Regulatory Authorities and Pharmaceutical Companies: Recommendations for an Improved Model

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Abstract

The aim of this study was to examine the views and experiences of the Gulf Cooperation Council (GCC) states and pharmaceutical companies to identify the strengths and weaknesses of the GCC centralized registration procedure (GCC-CP). Results of a questionnaire designed for the study and completed by GCC regulatory authorities and pharmaceutical companies who registered products through the GCC-CP showed that it is an effective system. However, it demonstrated that there is room for improvement. For example, provision of clear guidelines, transparency of procedures, effective interactions between authorities and companies, an increase in the number of committee meetings, and the use of electronic online submissions would shorten approval times and enhance the quality of review practice as well as encourage pharmaceutical companies to use the GCC-CP system. This research enabled the development of an improved model of the GCC-CP to be proposed to the GCC Health Authorities, which could expedite patients' access to medicines in the region.

Keywords

GCC Central Drug Registration (GCC DR), Gulf Assessment of Centralized Procedure (GACP), Companies' Assessment of Centralized Procedure (CACP), centralized procedure (CP), regulatory authorities' views, pharmaceutical companies' views

Introduction

Harmonization involves the formation of effective networks between regulatory authorities (nationally, regionally and internationally) to facilitate the sharing of best practices, making appropriate use of scarce resources and eliminating duplication of effort.[1] Such networks are an important element in building regulatory capacity and trust between different regulatory systems. The harmonization of regulatory processes in the Gulf Cooperation Council (GCC) states was initiated following the consent of the GCC Health Ministers' Council Decree No. 8 in 1976 regarding the formation of a study group to report on how a centralized registration system should be established to monitor medicines as well as to provide common guidelines for participating authorities (Hashan, unpublished doctoral thesis, 2005). In 1997, the State of Bahrain submitted a proposal for the formation of a Central Committee of Gulf States to register pharmaceutical companies and their products to ensure basic standards for the manufacture of good quality medicines and

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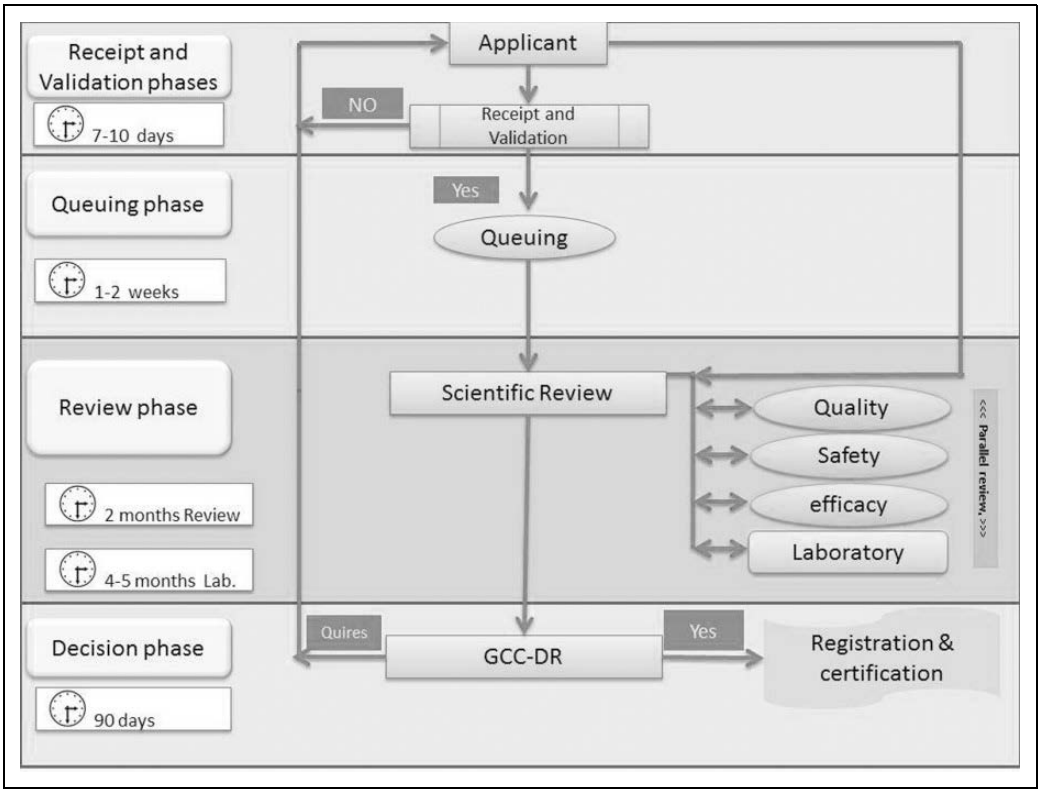

Figure 1. The current GCC-CP registration system.

also to unify the regulations relating to the export of medicines from the Gulf States. The Gulf Central Committee for Drug Registration (GCC-DR) was formed in May 1999 and includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates (UAE), and Yemen.

The implementation of the GCC centralized procedure (CP) was subject to criticisms, with challenges both from the pharmaceutical industry who were apprehensive about whether the GCC-DR would be an obstacle to the timely approval of medicines in the region as well as from government officials who were concerned about losing sovereignty to the CP.[2]

In reality, the CP is meant to underline the importance of the key role that national authorities play in the regulation of the use of medicinal products in their respective countries. However, national drug regulatory authorities need to be better equipped to register medicines in a cost effective and timely manner. Increased efficiencies across GCC countries and capacity building would enhance the quality of the registration decisions, while streamlined processes and improved information management will lead to effective medicines control. As a result drug regulatory authorities may enjoy substantial savings and enhanced patient access to innovative medicines. In addition, governments could enjoy further savings through pooled procurement, which is only possible when the same medicine is registered across all participating countries.

As it is now 15 years since the centralized drug registration procedure was established in the Gulf Region, it is timely to conduct an assessment of the CP through studies involving the major stakeholders in the registration process.[3] The 7 regulatory authorities in the Gulf Region have had long experience in collaborating to centrally register pharmaceutical products, despite initial apprehension about the possibility of changing their individual procedures and practices. It is now crucial for the GCC states to identify the most important driving forces to improve the CP so as to make the system more attractive to pharmaceutical companies. It is also important to evaluate the pharmaceutical industry's views about the advantages and disadvantages of the CP and how this has impacted the speed of marketing authorization for their products in each of the Gulf States.

The current process map for the CP (Figure 1) indicates the main steps in the review and approval process and identifies the key milestones for monitoring timelines. There are basically 5 steps for the regulatory authority in the Gulf Centralized Registration Procedure, and some of these steps are critical and constitute a substantial part of the review process. Receipt and validation include the administrative registration, compliance with legal requirements, the status of the company and manufacturer as well as a ''checklist'' validation of the application content.

In the current process, 2 members from each of the 7 GCC countries represent the GCC-DR Committee and 2 member countries are chosen to review the registration dossier. The unbiased alphabetical order selection of these countries ensures that all the GCC countries are equally responsible for evaluating the quality, safety, and efficacy of medicines. Thus, all 7 GCC countries are provided with copies of the product registration dossier for their individual assessments. The GCC-DR meets 4 to 5 times a year to discuss the product review reports issued by the reviewers from each country and an approval decision is made by common agreement. From 1999 to 2010, the GCC-DR received 1,824 medicinal product applications, of which 1,165 (64%) were approved.[3]

The aim of this study was to identify the similarities and differences between the experiences of regulatory authorities and pharmaceutical companies with the CP and to develop an improved model for the GCC-DR based on the outcome of the study participants' evaluation of the CP.

Methods

Due to the limited information and a lack of data regarding the CP, there was a need to develop suitable measurement tools to obtain the relevant information required for this study. Two questionnaires were designed to assess the CP with the 2 groups of stakeholders in the GCC. The first questionnaire, Gulf Assessment of Centralized Procedure (GACP) evaluated the experience and opinions of all 7 Gulf regulatory authorities with the GCC Centralized Registration. The second questionnaire, Companies' Assessment of Central Procedure (CACP) evaluated the experiences and views of pharmaceutical companies with respect to the CP. The GACP questionnaire consisted of 5 sections: (1) value of CP, (2) utilization of resources, (3) regulatory expertise, (4) importance of GCC-DR, and (5) general observations. The CACP questionnaire also consisted of 5 sections: (1) general introduction, (2) centralized registration procedure, (3) interaction with GCC-DR, (4) scientific opinion, and (5) general observations.

All authorities who are responsible for the regulation of pharmaceutical products in the 7 Gulf States participated in the survey (100%); however, the evaluation of the 100 pharmaceutical companies recruited to report of their experiences with the CP was limited by the response rate of 30%. This was despite an extensive follow-up of the companies who did not respond or who had limited experience with the CP. The 30 responses were from 17 international, 7 GCC, 3 non-GCC Arab, and 3 Asian companies.

Results

This was the first time that the similarities and differences between the experiences of the Gulf States regulatory authorities and the pharmaceutical companies with respect to the Centralized registration system had been evaluated since its establishment in 1999. During that time there had been significant criticisms for some aspects and approval for others of the CP from both the member states and the pharmaceutical companies.

It is of interest that the study reported here revealed that both companies and regulatory authorities were generally satisfied with the CP. They also agreed that the procedure is an effective system for authorizing the marketing of medicinal products in all the GCC States in 1 process and is the way forward, but that there is room for improvement both in the procedure and its follow-up. A common single registration for medicinal products results in cost savings and an efficient follow-up opportunity in all the 7 Gulf States. A well-coordinated, reliable centralized regulatory framework effectively reduces the administrative burden and duplication of scientific evaluations by participating member states. The companies believed that if this procedure was faster, streamlined and transparent, then it could be the system of choice.

At the beginning of 2014, the GCC-DR initiated use of the NeeS (non-eCTD electronic submissions) format, which is currently implemented by internationally recognized agencies and within the next two years (2015-2016), will be the only eCTD format that will be accepted. This approach is useful in that it assists pharmaceutical companies in understanding the rules of the submission process and thus helps both the industry and the authority to make better decisions.

In general, analysis of the results showed very little difference between the companies in their responses. However, the majority (17 out of 30) of the pharmaceutical companies that took part in this study preferred reviews to take place at a national level and this included 11 international, 3 GCC, 2 non-GCC Arab, and 1 Asian company. This was mainly due to their experience with the national regulatory authorities, which makes it easier to gain market authorization. The long duration of the CP review and fear of ultimate rejection by the centralized authority also contributes to the preference for national submissions. This tendency of the pharmaceutical companies to apply to national authorities was confirmed by the survey responses of the individual regulatory authorities, who indicated that the number of national applications is greater than those submitted to the centralized authority. This adds to the workload of the national regulatory authorities in addition to their CP share of the review.

Despite the preference of the pharmaceutical companies for national submissions, they indicated that registration through the CP is better and more efficient. Ease of communication was reported for both national procedures and the GCC-DR, although pharmaceutical companies have no direct access to the GCC-DR authorities.

Most of the national regulatory authorities of the member states concurred that shortening the duration of the process to

obtain market authorization through the CP would make it more appealing to applicants. Both companies and authorities recognized that this could be achieved by increasing the number of GCC-DR committee meetings per year. Despite effective collaboration and sharing of information between the Gulf States, the lack of regulatory authority resources and expertise also contributes to the delays. Recruiting external experts would aid the authorities, but there is a fear that this will impact the quality of the review. The demand for additional requirements by individual Gulf States also adds to the delay and length of the process. Ultimately, the most effective way to optimize the process of evaluation would be to develop a more appropriate model for the CP.

According to the regulatory authorities' views, standardization of the system would also be a means to improve and facilitate the regional registration process and maintain the supply of safe and effective medicines within a reasonable time frame. The Gulf States have found that the shared experience, ideas and knowledge at the centralized meetings has enriched their own experience, which has reflected in their performance at the national level. Collaboration and joint effort among the 7 Gulf States has produced an improved scientific opinion and a higher quality of decision making. The pharmaceutical companies also indicated their agreement with this opinion, finding that consistent evaluation of submissions and a better scientific opinion was received from the GCC-DR than from the national authorities, leading to a more efficient system.

One major aspect of the CP approval, which was reported as efficient and effective by both companies and member states, was the centralized pharmacovigilance procedures and reporting systems. In addition, the member states found the GCC guidelines to be sufficient and appropriate for their intended purpose. On the other hand, pharmaceutical companies, submitting to the centralized authority, claimed that they found difficulty due to the absence of appropriate guidelines, leading to inconsistency. In addition, the companies indicated that there were differences with regard to market access at a national level owing to issues such as re-requesting documents already submitted for the CP or not approving the product for distribution after attaining GCC-DR registration.

Certain aspects of the registration procedure could be modified to move forward and improve the quality of the experience. Both the national regulatory authorities of the member states and the pharmaceutical companies agreed that the use of electronic on-line submissions to the centralized authority, as well as electronic communication between the member states, is one way to expedite the process. This is the current method implemented in the recognized established authorities worldwide such as EMA and US FDA. Recognition of the assessment by established mature regulatory authorities through implementation of the verification or abridged procedure is another means of improving the process and easing the burden of the high workload on the national regulatory authorities and for the pharmaceutical companies as well.[4]

The Gulf States identified the need for training, seminars and workshops to improve the experience of their expert staff. Pharmaceutical companies made the same suggestion, also stating that additional interactions between companies and the national regulatory authorities would improve the authorities' overall knowledge and take advantage of companies' worldwide experience. In addition, this would result in further enhancement of relationships and communication between companies and authorities. The companies stated that they were willing to help draft, improve, and refine guidelines, including those of the Good Manufacturing Processes (GMP).

One of the key concerns, highlighted by the companies, was the limited number of GCC-DR committee meetings per year. The quarterly meetings to validate the pharmaceutical products are clearly insufficient to meet the increasing demands for product registration and approval. The companies recommended that the frequency of these meetings needs to be at least 8 per year or every 45 days. In addition, subcommittees should be formed with more frequent meetings to handle specialized matters such the registration of life-saving products.

The companies also recommended that the comments and opinions of the countries where the products have been registered nationally should be considered when those products are being evaluated by the GCC-DR. In this way, the approval process would be expedited, facilitating faster approvals at a national level after the products have been approved by the GCC-DR.

Over half of the companies supported the CP, while 17 out of 30 companies preferred the national registration system. The main reason for this move toward local registration is the delay and queuing for the CP. Nevertheless, the companies agreed that if the CP improves, it will increase acceptability of the marketing authorizations issued centrally in other markets.

The only way to improve support for registration through the CP is to provide some advantages over the national registration for companies who choose this route. It is important to note that most companies are seeking the establishment a single registration system, either national or centralized for their products, as dealing with 2 registration systems in the same region is considered impractical. For these reasons, companies usually adopt the most economically viable registration system that meets their corporate objectives. The key issues to be considered in any new proposed GCC model are displayed in Figure 2.

Discussion

The results of this study clearly indicate that for the pharmaceutical companies to fully embrace the Gulf Centralized Registration System, certain improvements are required. Therefore, it was considered prudent to benefit from the past

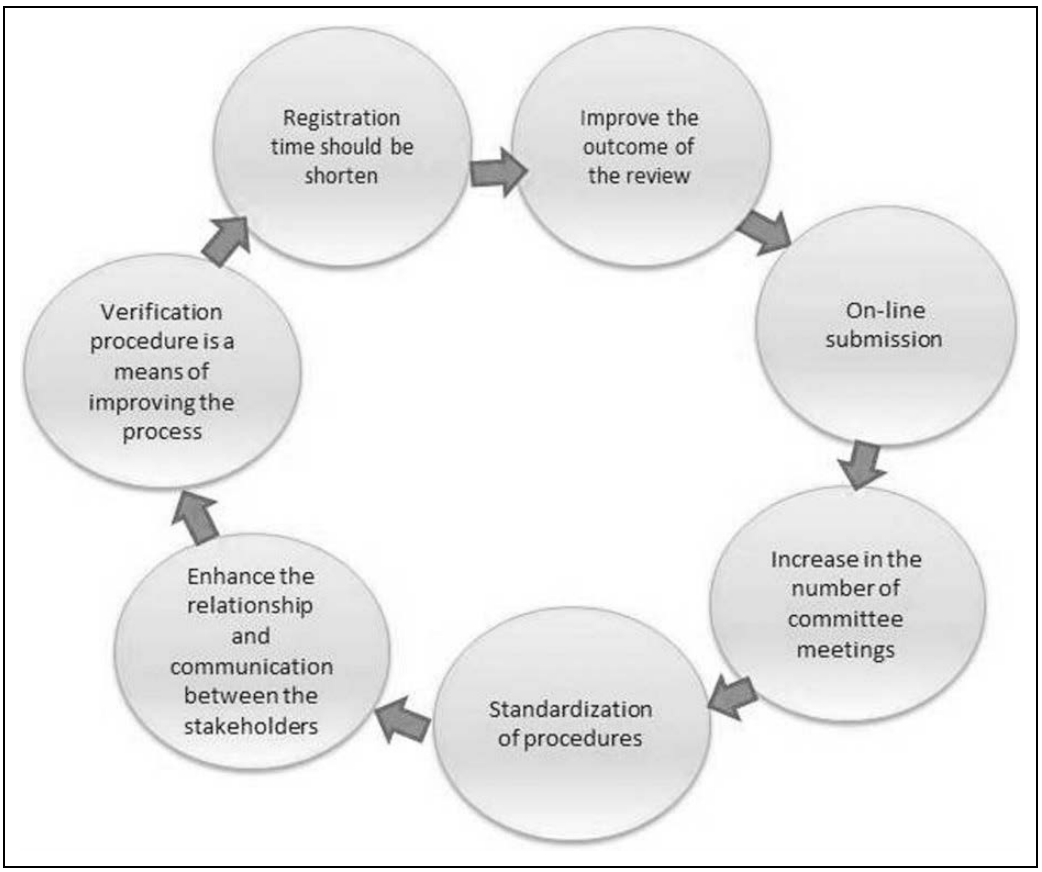

Figure 2. Key issues to be considered in the new proposed GCC model.

experiences of other centralized systems elsewhere such as EMA and US FDA. Consequently, the EMA audit of the centralized and decentralized drug registration procedures, published in October 2000,[5] was reviewed for this purpose. This audit, referred to as ''The Evaluation of Community Producers for the Authorisation of Medicinal Products,'' was based on interviews with and/or questionnaire responses from trade associations, national drug registration authorities, professional and patient associations, national ministries with interests in drug approvals and pharmaceutical companies. The survey examined many aspects of both the centralized and mutual recognition procedures in Europe. The auditors did not limit their research to EMA activities, but also investigated member states' responses to EMA decisions. This survey, which examined the level of satisfaction with the CP found that of the 30 companies that had obtained marketing authorizations by this route, 88% were satisfied with the system and 3% very satisfied.

An analysis and understanding of the views of both the Gulf States regulatory authorities and pharmaceutical companies regarding the CP has underpinned a proposal for an improved model. Although the time taken to register a pharmaceutical product differs from country to country and from product to product, it is still possible to complete the review process within a reasonable time frame if the data are available and adequate. Furthermore, many countries have legislated maximum times allowed for the review of a dossier. For example, the target time-frame for completing the review process in the EU centralized system is 210 days, although the clock is stopped if it is necessary to ask the applicant for clarification or further supporting data.[6] This compares with the median of 304 days taken by the US FDA.[7]

In their efforts to successfully operate the centralized system during the last 15 years, the GCC health authorities have encountered several challenges and the need for regulatory reforms to improve their individual systems and to unify their procedures to expedite improved patients' access to high-quality medicines throughout the region. Initially, the GCC-DR were challenged to convince companies to consider submitting their dossiers via this procedure. However, pharmaceutical companies, whose goals include completing the registration requirements and gaining access to the national GCC markets in the shortest possible time, still have mixed feelings about whether they can gain faster marketing authorization through the national regulatory systems or the CP.

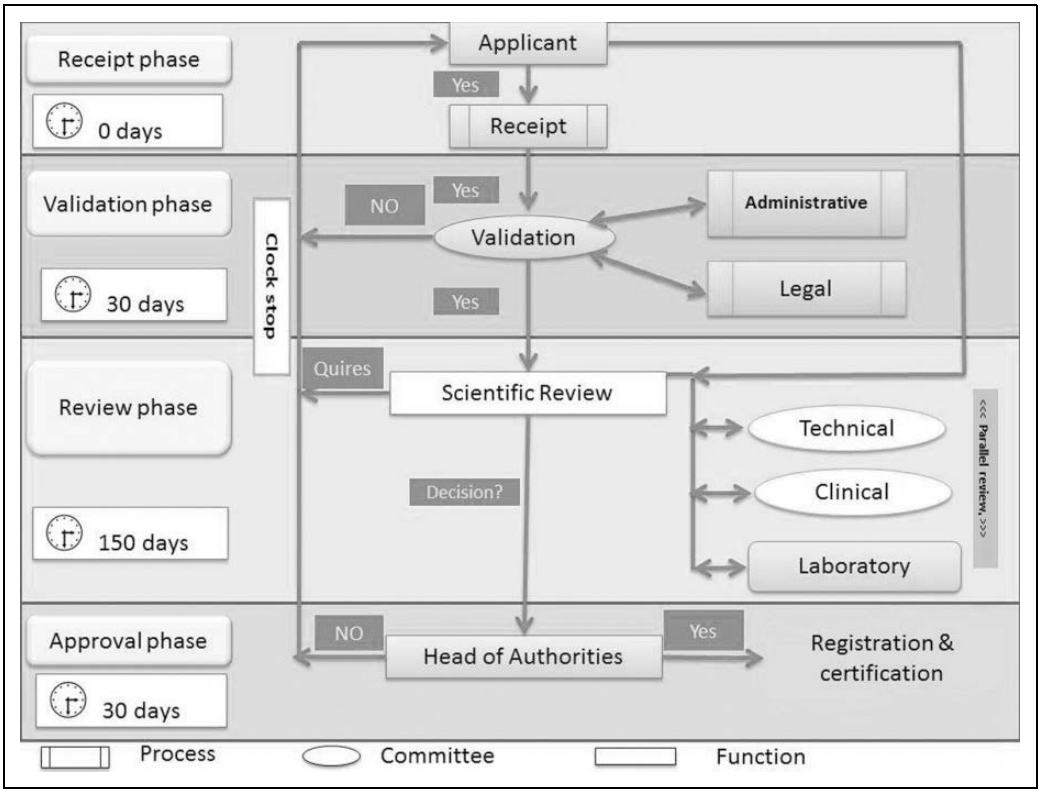

Figure 3. The proposed model for the GCC-CP.

It is crucial for the GCC states to identify the most prevalent driving forces for improving the CP and to attract the pharmaceutical companies to use this system. As a result of this study an improved model is proposed based on the current CP (Figure 3). The model's main features are as follows:

- Maintenance of the main structure of the CP
- Amendment of the time-consuming sections of the current CP
- Involvement of all member states in the review process with conclusions reached in a timely manner
- Implementation of an electronic system of review which in turn would enable an increased frequency of meetings by allowing the possible remote participation of all member states
- Adoption of electronic communication with applicants regarding application deficiencies
- Initiation of an automated review process with clock-stop timing.

This model is based on the current GCC review process. It maintains the main features of the approval process, namely receipt and validation, management of the overall dossier review cycle, registration approval by heads of authorities and upholding the independence and sovereignty of member states.

The main step to be eliminated relates to the questions raised by member states following the review. Clearly, this step raises the concern as to why member states would raise questions that are not highlighted by the 2 reviewing authorities. This at best produces doubts regarding the review capabilities of certain member states, while at worst raises doubts about the GCC review process in general. On the one hand, each member state must be allowed the possibility to state their views regarding the application, while on the other there is a need to achieve review time efficiency. Below, we summarize the model proposed to realize such a target.

The Proposed Model for the GCC-CP

A. Receipt phase

Receipt of the application is carried out in accordance with the published GCC guidelines for New Active Substances (NASs) and Existing Active Substances (EASs). The applicant should request a submission date for the application, which would be provided by the GCC office. It is important that the applicant provides a statement that the application is being submitted in accordance with relevant GCC guidelines. This statement has a functional effect on the target time, as it is quite frequently observed that applicants submit partially completed dossiers, especially the local industry, making promises to bring missing or complete data at a later date. The applicant

must be held accountable in such cases and this can only be done according to local laws if such documents are provided, otherwise the receiving officer will usually be held responsible. Furthermore, the statement will serve as time zero for the target time. The receipt process should be conducted at the GCC Executive Office and performed by GCC staff. This phase is maintained as the current practice of application receipt at the GCC office.

B. Validation phase

The validation phase, whereby the submission is screened to ensure that the data are complete and of suitable quality for review, may be critical for agencies like Health Canada, US FDA, or EMA, when many dossiers are submitted by the applicant. In this phase of the CP, the submission is checked against the requested formal requirements. This should include the administrative registration reference number and checks on legal requirements, the status of the company and manufacturer, as well as a validation of the application content such as technical sections or Certificate of Pharmaceutical Product status against application checklists.

Further checks on patent compliance are also made at this time and any contractual arrangements such as contract manufacturing or licensing agreements are also validated. The allocated target time for both processes of administrative and legal formalities should be 30 days. The validation processes are carried out at the GCC office. In effect, the validation process should ensure that the submitted application is in compliance with the formal requirements as stated in module 1 of the CTD specifications together with further checks that all the required technical data are provided. This phase is maintained as the current practice of application validation by the GCC office.

C. Review phase

The scientific assessment stage is the major part of the review process and requires considerable evaluation of data relevant to the safety, efficacy, and quality of the pharmaceutical product. Therefore, it is essential to focus attention on providing the appropriate skill sets and the facilities as well as establishing guidelines, standard operation procedures, training and continuing education programs and the electronic handling of the review process to implement the desired good review practices. In the new proposed model, the scientific review should be overhauled to allow all member states to participate in the review process in a 1-step approach. This necessarily means that steps (C), (D) and most of (E) of the current GCC practice would be merged into 1 step in the proposed model. In this phase, 2 committees should be established from all member states. Therefore, each member state is represented in each of the 2 committees to ensure the active participation of all states. The 2 committees should be as follows:

1. **Clinical committee**: this committee should consist of experts from the member states and should be responsible for reviewing the clinical requirements for both NAS and EAS dossiers. In effect, this committee is concerned with safety and efficacy modules 4 and 5 of the approved GCC CTD standard.
2. **Technical committee**: this committee should consist of experts from the member states and should be responsible for reviewing and approving active pharmaceutical ingredients and excipients in the formula as well as the finished product. This committee is very similar to the European Directorate for the Quality of Medicines committee in the EU, in addition to the technical review committee in respective EU member states. This committee would focus on module 3 of the GCC CTD standard.

The clinical and technical committees should cover all aspects with regard to the safety, efficacy, and quality of the product while any legal aspect that may relate to the product would have already been checked during the application validation process. The clinical and technical committees' approach to the product's review compared to the 2-step approach of the current model would lead to considerable time saving and review process efficiency and transparency. Each member state would be able to indicate their approval or concerns during the review process in that particular committee. A letter of deficiency from that committee would be issued to the applicant with a time limit for the applicant to respond.

The committee's meeting time could be organized in a manner to allow for the review of new applications while keeping about 30% of the meeting time for replies to issued letters of deficiencies. The committees should meet at least once a month to keep the process efficient and timely. The allocated target time for both committees concurrently would be 150 days. The tasks performed in the committees would be accomplished primarily by members of staff from health authorities of the member states and not from the GCC office staff.

Laboratory analysis. The required laboratory tests should be performed concurrently with the application review process of both clinical and technical committees. The allocated target time for the laboratory to complete the required tasks would be 120 days, which is well within the 150 days' time allocated for both clinical and technical committees. This should be the default and implies that the work of both clinical and technical committees and the laboratory is harmonized and synchronized to complete the work within the 150-day time limit.

D. Approval phase

Once the 2 committees grant approval for their part as well as the laboratory decision to approve the product, their respective

decisions are transferred to the head of authorities meeting to give the approval to issue the registration certificate. If for any reason the heads of the authorities are concerned regarding any aspect of the application they would issue a letter of concern to the appropriate organization, which might be the GCC management staff, specified committee(s), the laboratory or the applicant. Once the concern is answered, then an instruction to issue the registration certificate is mandated.

The heads of authorities' approval would be required to ensure that the approval process steps and an adequate review are observed and would represent a quality assurance task performance to guarantee good review practices at the GCC office. The allocated target time for this phase should be 90 days and the tasks would be entrusted to the heads of health authorities of the GCC member states. The heads of authorities in this case should be considered as the Approval Council, which should meet every month. The allocated target time for this committee is 90 days, which takes into account the meeting frequency, making sure that once an application passes all formal and substantive requirements, its final approval by the heads of authorities would be compliant with the target time. Once the approval is granted by the Approval Council, then the GCC office should issue the registration certificate for the product under application.

Other Criteria

For the above proposed model to function, the following are required:

1. Clear guidelines for the review process should be developed by the Approval Council. Good review practices should be mandated in such guidelines. The GCC should elect 1 authority to host an Institute for Regulatory Science for all training aspects related to the sciences and skills needed by the GCC and member states staff involved in the review process. It is pertinent that Singapore, South Africa and India are currently establishing Institutes of Regulatory Science to initiate similar objectives.
2. Electronic management (computerization) of the whole review process is required, including an electronic review system that allows committees to hold meetings remotely, utilizing modern computer software and communication tools and devices. Using modern meeting techniques will result in cost savings, process efficiency and significant review time saving. Further electronic process management will enable external experts to participate in meetings of the various committees if required, giving expert support to the work of the GCC reviewing process without the need for travel.

This proposed model eliminates the main timing bottleneck represented by questions to applicants by allowing for a clock-stop approach. The time saving should allow the GCC to commit to 210 calendar days for the review of NASs and ideally fewer days for EASs, but the same mandated maximum. It is imperative that clear guidelines for the clock-stop concept and the use of such a concept be documented and communicated. Adopting the clock stop dictates that the expected response time to questions and date would be indicated to the applicant. Failing to meet the response date by the applicant should allow the GCC to remove the application from the review process after warning, to reduce the review pipeline.

Laboratory analysis should be performed in a manner that eliminates delays in the analysis process and member states' laboratories should declare their readiness to meet the target time. Even though Kuwait, Oman, UAE, and Kingdom of Saudi Arabia Quality Control (QC) laboratories are well equipped to conduct analyses of pharmaceutical products, member states should agree on accreditation criteria for QC laboratories to officially certify that these laboratories are able to meet these accreditation criteria. In addition, each member state with the ability to meet the accreditation criteria should also be able to accommodate a 120-day target time to complete the assigned task. Analysis tasks should be assigned to member state laboratories that declare their ability to meet the target time requirements to assign analysis tasks in a fair manner, allowing all participating laboratories equal opportunity to contribute to the process of product approval in the GCC system. The adoption of such an approach to laboratory analysis in this model should eliminate the long analysis time and undue waiting currently experienced.

Conclusions

This study, which is the first to be carried out, has demonstrated that the CP has contributed to an improved review process both at the GCC-DR and national levels. However, the GCC-DR needs to be revised and developed to become an independent authority for granting marketing authorizations, providing applicants with one license that covers all seven Gulf States. The new model for the CP proposed here should resolve many of the difficulties currently facing the GCC-DR and improve its effectiveness and efficiency.

Declaration of Conflicting Interests

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