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A RETROSPECTIVE APPROACH ON COMPILATION OF DOSSIERFOR OMAN AS PER GCC REGULATION

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ABSTRACT

A Retrospective approach on compilation of dossier for Oman as per GCC is a stringent regulatory procedure meets the ICH standards. The Objective of the review is current trend and regulatory updates in GCC to get the Marketing authorization. The GCC is comprising of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and UAE with two different categorizations of Centralized and De-centralized procedure as per country specific. The current review on dossier compilation of Pharmaceutical product towards GCC market comprising of administrative data, Quality, Quality overall summary, clinical and non-clinical information. In Pharmaceutical registration the dossier meets the CTD and e-CTD standards and structuredto meet the regulatory requirements for a successful marketing authorization as per GCC. The current review clearly states the trends in GCC approval, procedures, Types of review, Organization structure of GCC and Drug registration procedures. Further the review clearly explains registration requirements, review process, assessments as per GCC. Additionally, a defined Oman registration procedure is highlighted as an example.

KEYWORDS: GCC, CTD, eCTD, dossier registration, drug product, approval procedures.

I. INTRODUCTION

The Gulf Cooperation Council (GCC) is a political and economic union involving six Arab states in the Gulf with shared economic and social objectives which was created on May 25, 1981.

1. Statistics of GCC[1]

Table 1: Drug regulating authorities of GCC states.

Sr.No	Country	Flag	Regulatory Authority
1.	Kingdom ofBahrain		National Health Regulatory Authority(NHRA)
2.	State of Kuwait		Kuwait Food and Drug Authority(KuFDA)
3.	State of Oman		Directorate General of PharmaceuticalAffairs and Drug Control
4.	State of Qatar		Pharmacy and Drug Controldepartment

5.	United ArabEmirates		Ministry of Health and Prevention
6.	Kingdom of Saudi Arabia		Saudi Food and Drug Authority(SFDA)

The GCC has already approved Yemen's accession to some areas such as the GCC Council ofHealth Ministers and the GCC Council of Labor and Social Affairs Ministers. However, due to the dramatic differences in socioeconomic status between Yemen and the other six Gulf states, a comparative assessment, which aims at identifying the similarities and differences between the countries, will not be of value for Yemen.

The GCC's primary role is to formulate standardized regulations in various fields such as economics, finance, trade, customs, tourism, health, legislation, and administration, establish scientific research centers, encourage cooperation with the private sector and strengthen ties between their people. Yemen has joined the GCC only in the healthcare and sports initiatives in 2004.[2]

The growth is increasingly moving beyond the use of CRO's and marketing of well- established products to include early-stage research and technology aimed at specific medical needs of patients in these regions. One way to launch new drugs in a timely manner in emerging markets is to include majority of patients from relevant countries in clinical development programs. This practice is routine for most pharmaceutical companies. These development programs attributed to longer life expectancy and lifestyle changes that are possible through rapid economic growth.

Emerging markets are important and expanding globally and has raised the demand for general and lifesaving medicines. Regional cooperation is required to ensure that the scientific capacity is developed. Legislative and political factors are the most critical one, countries need to have support to develop effective national legislation, as well as cooperating regionally which helps to access to essential medicines.[3]

Pharmaceutical Companies and regulatory agencies are collaborating for improving drug development process and approval ex: ICH guidelines for eCTD submission and QbD which contribute to better first-time product quality shortening the review time required by regulatory agency and these guidelines are well accepted by regulated markets and some countries of Emerging market like India and China uses the CTD format.

International conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has brought regulatory authorities and pharmaceutical industries of US, Japan, and Europe together for various aspects of drug registration but there is no such harmonized guideline for emerging market except Association of Southeast Asian Nations (ASEAN) and Gulf Co-operation Council (GCC) where harmonization exist inclusters with their mutual concern.

Ministry of Health of GCC states (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and UAE) are regulatory authorities for the regional pharma sector. They also regulate prices of pharmaceutical products and bring about harmonization of varying prices and the regulatory process, the GCC implemented a centralized system, Gulf Central Committee for Drug Registration (GCC-DR) in May 1999, which currently runsparallel to the regulatory regimes in the region.

Fast-Track Registration and Reliance pathway: In July 2020, GHC published a circular indicating that a reliance model can be applied for products approved in at least 2 GCC countries. In this case, GHC centrally approves the product within 60 calendar days from submitting the scientific reports issued by the GCC countries.[4,5]

2. Trends in GCC

Table 2: Trends of the year.

Sr.No	Year	Trends
1.	2008	The approval time for all approved products in the GCC states during this period varied from about 609 days in Saudi Arabia
2.	2008 to 2010	The study data showed a downward trend in the median approval time for most of the GCC states
3.	2009 and 2010	The approval time for all approved products in the GCC states during this period varied from about 60 days in Qatar andOman

There are many factors which can affect and explain the differences in approval time in the GCC states.[6] The main factor is the difference in the positions of milestones within the approval process, for example.

Table 3: Differences in approval time process.

Parallel Procedure with scientific assessment	Sequential Procedure with analytical step
Where an applicant applies for registration in one GCC country, and the other member states review and approve the application based on the assessment report issued by the Reference Member States. This process helps to streamline the registration process and ensureconsistent standards across all member states.	Where an applicant submits separate applications for registration in each memberstate. In this process each member state independently reviews the application and issues its own marketing authorization based on its own evaluation of the application. It can be more time consuming and costly compared to the Parallel procedure, where the same application can be used for all member states.
Oman, Saudi Arabia, and Qatar	Kuwait and Bahrain

The study identified the negative influence of the sequential procedure on the product approval times.

- The speed and uniformity of the sample analysis can be achieved by fixing a timelimit
- Improve the handling of the analytical procedure along with the required quality control tests to meet the target time.
- Carrying out the quality control analysis in parallel with, rather than after, the scientific assessment would be a rational decision to avoid any impediment to patients' access to medicines.

Regulatory approval times have also been influenced by the type of assessment carried out by different authorities.[7,8]

Table 4: Types of review obtained by GCC country for approval of products.

Verification review	Full review	Abridged review
For all types of products		
Bahrain	Saudi Arabia	Kuwait, Oman, and Qatar

It must be noted that all the GCC regulatory authorities require the submission of the Certificate of Pharmaceutical Product at one point during the registration process as this is the most important requirement for successful completion of the approval process in the five member states.

GCC states could take the Singapore system as an example to reduce the overall approval time by conducting verification review for all types of medicines which are previouslyauthorized by at least two reference authorities, except for biological and biotechnology products.

The GCC states should seek to increase the level of funding to bring about the required expertise and resources to conduct a more extensive review of important medicines, including biological and biotechnology products.[9,10]

3. Hierarchy[11]

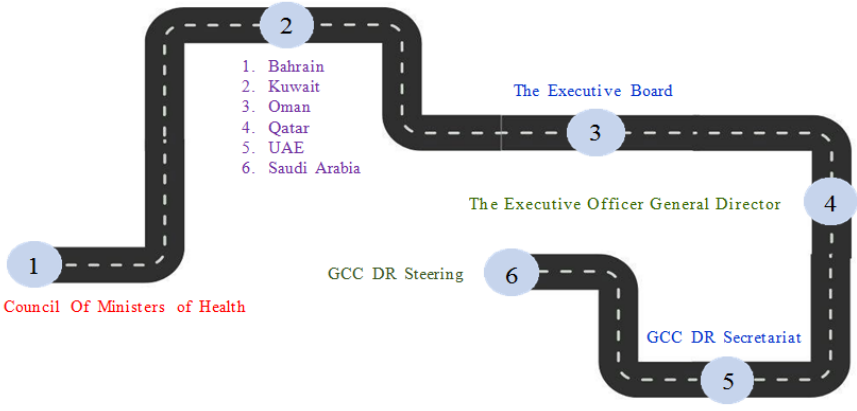


Fig. 1: Flow diagram indicating the organization structure of GCC

II. OBJECTIVES OF GCC

1. To attain designation, assimilation, and interrelationship between member county in all expanses to attain harmony between them
2. To elaborate and exaggerate rationality, network, and range of designation between their society in various expanse
3. To develop conscientious governance in discrete expanse including the following: commercial and fiscal matter, trade, characteristics, and transmission, civilization and elegance, communal and robustness matters, intelligence and touristry.

III. Drug Registration[12,13]

1. In GCC, there are two processes of drug registration are followed namely,

- Decentralized registration procedure
- Centralized registration procedure

Mostly decentralized procedures are followed for various products for GCC member states due to less cost of registration fees in the GCC member states.

1.1. Decentralized Procedure

The registration process for medicinal products involves multiple regulatory agencies in different GCC member states. The DCP allows the applicant to submit a single application to a reference member state and identical applications to the concerned member states. The reference member state takes the lead in the evaluation of the application, with the concerned member states providing input and conducting their own assessments. The DCP allows for the simultaneous evaluation and approval of medicinal products in multiple member states and can be a more efficient and cost-effective alternative to submitting separate applications in each member state.

The degree of decision-making power at the lower echelons in the organization i.e., Decentralized. An organization has a greater degree of decentralization, if the number of decisions made and functions affected at the lower level are higher.

1.2. Centralized Procedure

The registration process for medicinal products allows the applicant to obtain a single marketing authorization that is valid across all GCC member states. Under the centralized procedure, the GCC is responsible for the evaluation of the medicinal product, with input from a committee of experts from the member states.

The place of the decision-making authority in the hierarchy of the management i.e., Centralized. All the important rights and powers are in the hands of the top-level management.

1.2.1.The executive office of GCC-DR assumes the receipt of registration files after ensuring the fulfillment of registration requirements and upon duly filling the following forms:

a. The drug companies' registration form.

b. A pharmaceutical chemical entity/ preparation registration form.

1.2.2.Eight complete files for each chemical entity and 17 samples must be submitted to the executive office and two samples shall be dispatched to each country along with the registration file.

1.2.3.Every country shall study the registration files forwarded to it and then return those files with its recommendation to the committee.

1.2.4.The company needs to provide the laboratory for the analysis of standard materials, methods etc.

1.2.5.The executive office dispatches the samples of chemical entity to reference-accredited laboratory for the analysis

1.2.6.After approving the registration of the company and our chemical entity centrally, the remaining authentication and documentation, fees are finalized on a country basis, as per their prescribed and established policies.

1.2.7.The executive office issues the registration certificate.

1.2.8.The companies reserve their right to lodge their grievances to the executive office within a period of two months effective from the date of notification about the registration by GCC-DR.

2. Registration requirements for GCC

Table 5: Requirements for registration of pharmaceutical products.

Sr. No	Registration Requirements	Specification	Centralized procedure	Decentralized procedure
1.	**Site registration**	Yes	R	R
2.	**Plant GMP approval**	Audit by GCC member countries of FP site	R	R
3.	**Stability Zone**	Zone IV a	R	R
4.	**Stability Requirements**	30 ± 20C, 65% ± 5% RH	R	R
5.	**No. of submission batches**	3 pilot scale	R	R
6.	**Stability Data**	12 months	R	R
7.	**Stability Guideline Reference**	GCC	R	R
8.	**BE study forGenerics**	Against US / EU /Australia reference drugin any country	R	R
9.	**Major Holdup**	Delay in registrations,administrative issues with local regulatory and country laws	R	R
10.	**Dossier Format***	CTD	R	R
11.	**Registration time**	24-36 months	R	R

R- required documents as per country specifications whether it is centralized or decentralized procedure respectively.

Note: *Dossier format have been revised in Oman and has been addressed as "Application for registration of Health Products". Then the Dossier should be submitted as per the regulationsrespectively.*

3. Regulatory review process[14]

3.1. Most of the pharmaceutical products are following the types of review process in the member states. There are three types of review process namely submission phase, evaluation phase, authorization phase.

Table 6: Submission phase.

Review phases	Key milestone	Suggested definition
	Receipt stage	The authority may request a pre-submission document for the application to be accepted, for example, notification to submit from the sponsor.
Submissionphase	Queuing forreview	The received applications are pending for action tobegin. May require checks on completeness of the dossier
	Validation stage	to include all the documents required, checks on legal requirements, status of the company, local agent, manufacturer, etc.

Table 7: Evaluation phase.

Evaluation phase		The assigned member of the scientific committee or a pharmacist from the department carries out the scientific assessment and generates a report.
	Scientific assessment	Sometimes the pharmacist's report will make the final registration decision. In some systems the clock stops when questions are asked and sponsor time can be measured and deducted from the authority review time.
	Questions to sponsor	May be batched and sent at one time or asked Throughout the review process, in which casethe sponsor time is not easily measured.
	Quality control analysis	The national quality control laboratory analyses the Pharmaceutical product as a requirement forregistration and generates a report.

Table 8: Authorization phase.

Authorization phase	Pricing process	All GCC authorities carry out the pricing of products before they are allowed to enter the local market, but they differ in their pricing procedure and the final price approval.
	Authorization process	This is the process after the scientific review whilst the formal authorization is issued. It may be extended by pricing negotiations and finalization of analytical and/or GMP checks.
	Approval time	Time interval from the submission stage to the final issue of the registration certificate.

3.2. Milestone

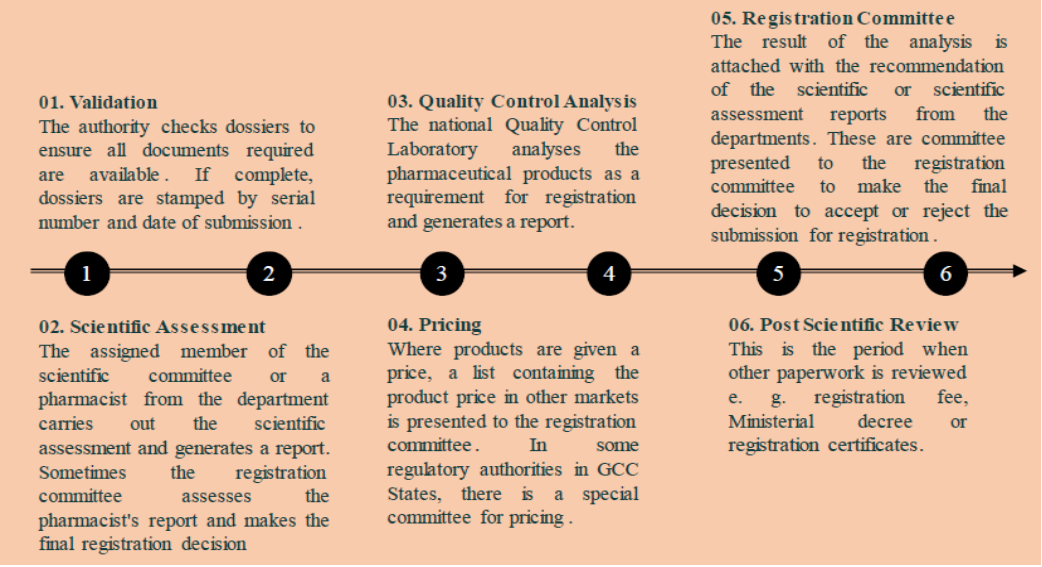


Fig. 2: Flow diagram represent the milestones of review process in GCC.

3.3. Assessment and scientific review

There are three types of review model in the GCC region, consisting of verification review, abridged review, full review, it is common for all the GCC member states.

Table 9: Verification review.

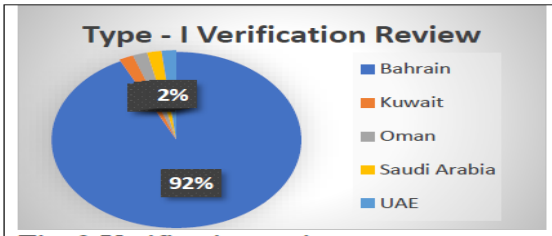
 **Fig. 3:Verification review**	➢ To ensure the accuracy and completeness of the data and information presented in the pharmaceutical dossier submitted by the applicant for product registration. ➢ To verify the data and information are reliable, consistent, and supported by appropriate evidence.

Table 10: Abridged review.

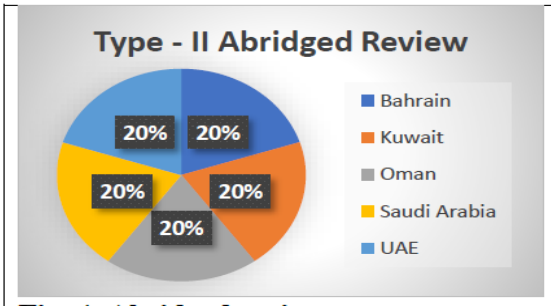
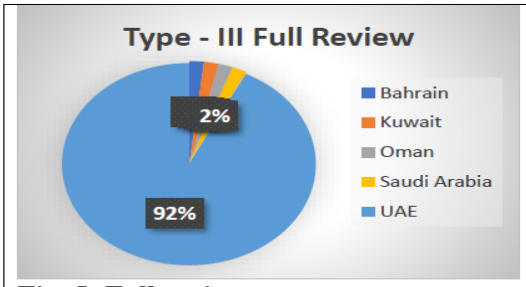
 **Fig. 4: Abridged review**	➢ It is faster and less rigorous than the full review process ➢ This review process allows for a simplified dossier to be submitted by the applicant and requires less clinical trial data than the full review process. ➢ It is available for selected generics products and is subjected to specific eligibility criteria.

Table 11: Full review.

 **Fig. 5: Full review**	➢ It is more extensive and rigorous than the abridged review process ➢ It requires the submission of comprehensive data and information on the quality, safety, and efficacy of pharmaceutical products. ➢ This process is typically required for new chemical entities, innovative products, and products with complex formulations.

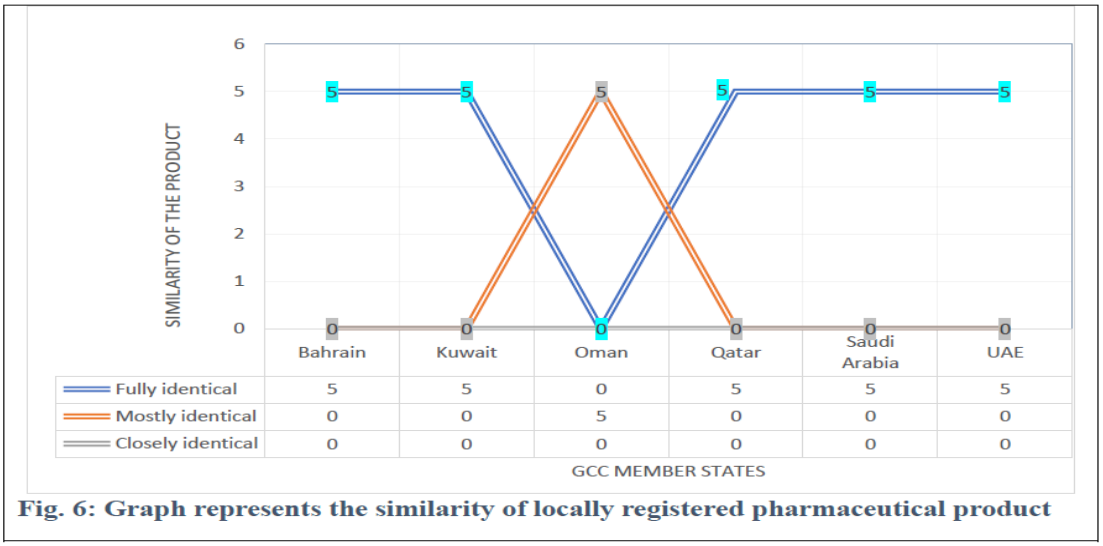


Fig. 6: Graph represents the similarity of locally registered pharmaceutical product

Table 12: Assessment obtained by each GCC member states.

Extent of scientific review	Bahrain	Kuwait	Oman	Qatar	Saudi Arabia	UAE
1. CMC data						
Detailed review	✓	✓	✓	✓	✓	✓
Review when necessary	×	×	✓	×	×	×
2. Nonclinical data						
Detailed	×	×	×	×	✓	✓
Review when necessary	✓	✓	✓	✓	×	✓
3. Clinical data						
Detailed	×	×	×	×	✓	✓
Reviewed when necessary	✓	✓	✓	✓	×	✓
Additional information obtained from						
Other agencies internal review reports	✓	×	×	✓	×	×
Reports available on the internet	✓	✓	✓	✓	×	✓
General internet search	✓	✓	✓	✓	×	✓

3.4. Registration of pharmaceutical product in OMAN[15]

3.4.1.Location

The sultanate of Oman is in the southeastern corner of Arabian Peninsula. The sultanate of Oman borders Saudi Arabia and United Arab Emirates in the west, the Republic of Yemen in the south, Arabian Sea in the East.

3.4.2.Regulations & Registration of pharmaceuticals

The laws of import, distribution, and sale of drugs in the Sultanate of Oman were first enacted in 1973 by Royal Decree No. 10 which was subsequently revised by another Royal Decree No. 41/96 issued on 08-06-1996. The Technical Committee for Registration, an internal committee of the DGPA&DC, authorizes registration of a product based on information prepared by DDC and CLDA staff and after payment of 75 R.O. for each dosage form and strength. The manufacturer of the drug product also must have been registered inthe sultanate of Oman for the sale of product. The registration fee for registration of manufacturer is currently 100 R.O. Criteria for the registration of drugs will be updated to ensure that drugs will only be registered if they meet recognized health needs, have proven effectiveness and safety profiles, meets quality standards and are being used in the country of origin. The cost of the drug will also be considered with the aim of limiting the unnecessary proliferation of different brands of the same drug. The revenue from registration fees will be collected and retained by the MOH to enable the DDC to employ enough staff to function more efficiently.

3.4.3. Registration of Medicines/Drug product

Authorized Local Agents of pharmaceutical companies, and local pharmaceutical factories in the Sultanate of the Oman must register the pharmaceutical product for marketing product.

3.4.4. Steps to follow to request the service

1. Local Agent must submit a request for appointment for the submission of all files.
2. Documents are reviewed. If all documents are correct, a fee of 75 Omani Rials (RO 75) is paid immediately. If not, documents are returned. Special conditions (if any applicable).
3. Manufacturers of pharmaceutical Products must be registered with the Ministry of Health,Oman.
4. All required certificates are authenticated by health authorities in the country of origin and attended by Oman Embassy.
5. Applications are processed within 4 months of the date of receiving the files.

3.4.5.Submission requirements[16]

Table 13: Data requirements in Oman country.

Sr. No	Requirement	Data Submission
1.	Format	CTD framework eCTD suggested.
		Module 1: territorial prerequisite: • Cover letter • Table of contents • Application form • Product information: Summary of product characteristics(SmPC), product information leaflet (PIL) and labelling all in WHO template format. • Knowledge of professional involved in clinical,nonclinical studies. • Environment risk assessment. • Pharmacovigilance • Certificate of pharmaceutical product (COPP)
		Module 2 to 5: according to ICH CTD format
2.	Certificates	Authenticated by the Ministry of Health of the country of originand additionally by Saudi Arabian embassy. Following Certificates required: • COPP/free sale certificate. • CoA • Pork-free declaration • Price list

3.4.6. Validation period

Table 14: Standard estimation.

Sr. No	Type of review model	Oman
1.	Verification review	•
2.	Abridged review	•
3.	Full review	•
4	Number of reviewers	22 days
5.	Validation time	1 day
6.	Queuing time	14-56 days
7.	Scientific assessment	90 days
8.	Positive scientific opinion to final approval	30 days
9.	Overall approval time	120 days

3.4.7. Mapping review

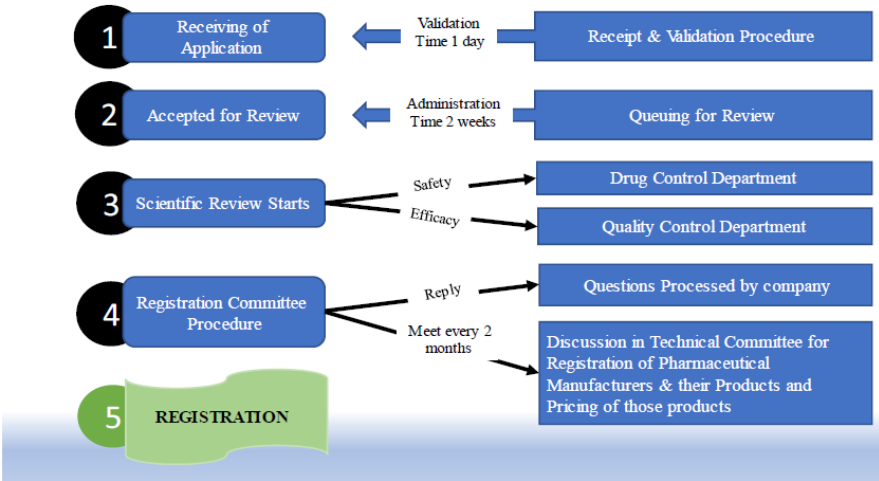


Fig. 7: Process map for the stages of pharmaceutical product

3.4.8. Regulatory review process in Oman[17]

A thorough evaluation of the regulatory process in Oman was undertaken and the milestones identified. The regulatory review process in Oman comprises ten stages

which are considered critical and have an impact on the approval time of medicines.

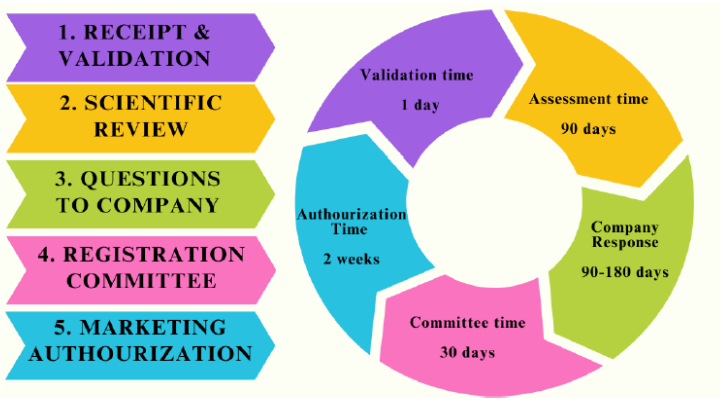


Fig. 8: Process cycle represents the review stages and interval period

a) The Submission Phase

As a common practice, the sponsor submits the product registration file to the authority. All documents must be completed for official acceptance. The following items are checked at the validation stage,

1. Legal status of the applicant/local agent
2. GMP status of the manufacturer
3. Organization of the registration dossier
4. Certificate of a Pharmaceutical Product (CPP) authenticated by the respective embassy or consulate general.

If the application is incomplete, the dossier is rejected and a new application must be made after providing the missing data. After receiving the product dossier, the company must pay the registration fees within one week. Once the validation stage is successfully completed, applications join the queue and must wait for two weeks before being allocated for review. There is no official priority review procedure for fast-track medicines but lifesaving products are unofficially prioritized.

b) The Evaluation Stage

The product enters the scientific review stage, and data on quality, safety and efficacy are assessed in parallel. The safety and efficacy parts are reviewed in the drug control department and the quality part by the quality control laboratory department. There is a formal record for the starting time of the scientific assessment. In the primary scientific assessment procedure, an internal reviewer in the drug control department completes a scientific product report, detailing the trade, generic names, indication and country of origin. Then, the product assessment report is sent to the scientific committee for evaluation. This committee assesses the product report and generates questions, queries, and concerns relevant to the product's quality, safety, and efficacy. The committee also examines any queries that are raised during the assessment process. These questions are returned to the reviewer to be collected in one batch for the sponsor after the scientific committee has given its advice. After sending the questions and queries to the sponsor, there is a time limit of 90 to 180 days given to sponsors to reply to the questions which are entirely dependent on the type of queries addressed, whether they are related to major or minor issues. The sponsor can meet with internal staff to discuss questions and queries that arise during the assessment but they are only permitted to meet the directors and/or section heads. The drug control department refers the marketing authorization application assessment report and their recommendation to the registration committee within 90 days of its receipt and the registration committee decides within 30 days from the date of receipt. The registration committee consists of members from two directorates in the Ministry of Health 1) six members from the Directorate General of Pharmaceutical Affairs and Drug Control and 2) two members from the Directorate General of Medical Supply and all members are pharmacists. Meanwhile, the laboratory sample analysis is carried out in parallel with the scientific review but the analytical step can be waived if the product is registered in Saudi Arabia, UAE, and/or Kuwait, or if it is registered in the GCC Central Drug Registration (GCC-DR) or in a recognized regulatory agency.

c) The Authorization Phase

Finally, the registration committee is responsible for granting the marketing authorization and pricing of the product after completion of the review process. A product registration certificate is issued within two weeks after the committee has provided a positive decision about the product registration which is signed by the chairperson of the registration committee. If the registration committee rejects the application, the sponsor can appeal within 60 days from the date of receiving the committee's decision; otherwise, a whole new submission is required after a 60-day period.

3.4.9.Justification for the selection of drug[18,19]

For example, Allergic rhinitis is a diagnosis associated with a group of symptoms affecting the nose. These

symptoms occur when you breathe in something you are allergic to, such as dust, animal danger, or pollen. Symptoms can also occur when you eat food that you are allergic to.

Allergic rhinitis (AR) is a global health problem and its impact on health-related quality oflife for patients is substantial, and the economic impact is often underestimated. The prevalence of allergic rhinitis in Oman is unknown.

The World Health Organization (WHO) estimates that 300 million people suffer from asthma worldwide; it is the most common chronic illness among children, and one of the most frequent in adults.

In the Phase III International Study of Asthma and Allergies in Children (ISAAC), 13.8% of school children aged 13–14 years worldwide reported that they had had asthma at some time in their lives, although with large regional variability.

Table 15: Medical expenditure for asthma treatment.

	USA	**EUROPE**
Annual direct medical expenditure for asthmatreatment	In 2007	
	32.2 million USD	7.9 billion Euros

In 2009, census data from the Omani Ministry of Economy. Drug usage and costs were provided by the Ministry of Health (MOH).

Typical treatment profiles, including emergency visits, outpatient visits, inpatient stays, and pharmacological treatment use were obtained from the Asthma Insights and Reality for the Gulf and Near East (**r**) study.

In Oman, costs are reported in Omani riyals (OMR) and USD, using the 2010 exchange rate of
1 OMR = 2.60010 USD

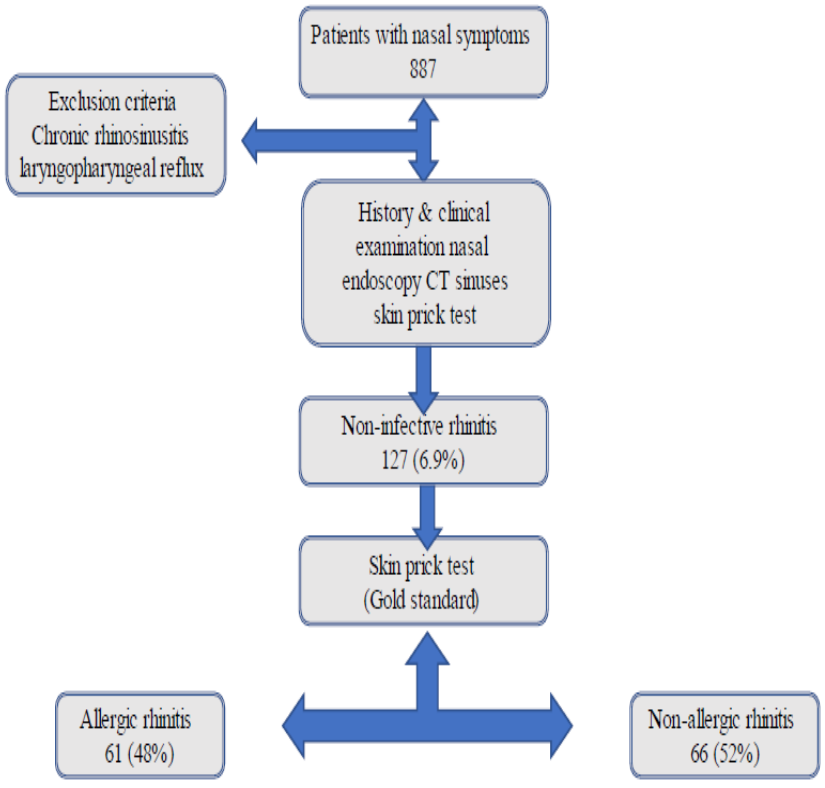


Fig. 9: Example of drug selection, Cross-sectional study to estimate the prevalence of allergic rhinitis and associated co-morbidities among adults in Oman.

III. MATERIALS AND METHODS

1. Origin of NDA/ANDA product development process[20]

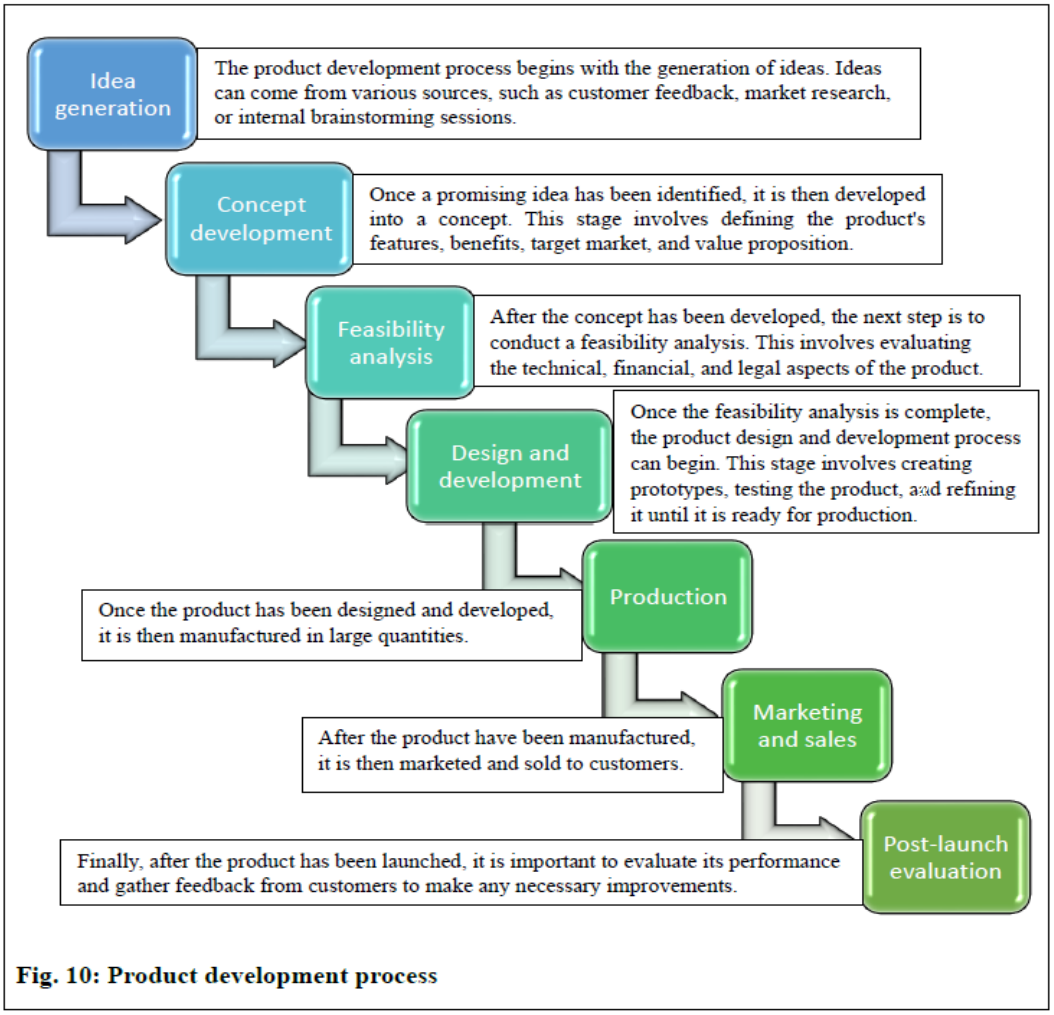


Fig. 10: Product development process

It is worth noting that the product development process may vary depending on the type of product and industry. Additionally, local regulations and cultural factors may also influence the process in Oman.

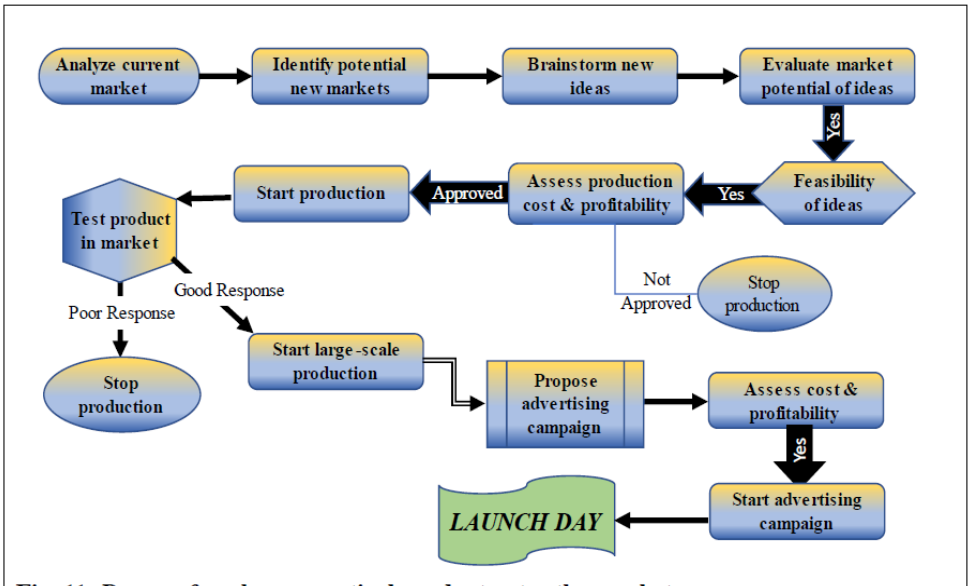


Fig. 11: Process for pharmaceutical product enter the market

2. Preparing & Organizing the CTD[21,22]

In CTD, the display of information should be unambiguous and transparent, to facilitate the review of the basic data and to help a reviewer become quickly oriented to the application contents.

- Text and tables should be prepared using margins that allow the document to be printed on both A4 paper and 8.5 x 11 paper.
- A margin of at least 0.75 inches from the bound edge of the printed page is required to prevent information from being obscured and to place the paper in a binder.
- Narrative text is submitted in Times New Roman 12-point font.
- Generally, font sizes 9 to 10 points are considered acceptable in tables.
- Ten-point fonts are recommended for footnotes. Acronyms and abbreviations should bedefined the first time they are used in each module.

2.1. The CTD is divided into five modules

- Module 1 - Administrative and prescribing information
- Module 2 - Overview and summary of modules 3 to 5
- Module 3 - Quality (Pharmaceutical documentation)
- Module 4 - Nonclinical document safety (toxicology studies)
- Module 5 - Clinical document efficacy (Clinical studies).

2.2. Documents required for product registration include

a) Administrative documents

1. Legalized cGMP certificate of the manufacturer.
2. List of affiliated branches & related manufacturers with address.
3. List of countries in which the company is registered.
4. List of the products manufactured by the Company.
5. If the marketing authorization holder is different from the manufacturer(s),

5.1. Legalized cGMP Certificate of the marketing authorization holder

5.2. A certificate showing the relation between the two companies (marketing authorization holder & manufacturers).

6. Legalized Certificate of Pharmaceutical Product (C.P.P) (WHO Certification Scheme or similar) or Free Sale Certificate.
7. List of countries where the product is registered & marketed supported by photocopies of registration certificates (if available)

2.3. Registration of company

Local agents of pharmaceutical companies and local pharmaceutical factories accredited inthe Sultanate and those companies willing to market medicines produced by these companies in the local market must be registered with Ministry of Health, Sultanate of Oman.

a) Process steps

1. The Local Agent must submit a request for appointment to present the Company's Registration File. In case the file is complete, it will be received, and in case of non- completion the file will be returned to the agent at the same time as file submission.
2. All the documents required for registration of manufacturer must be included in the file to be checked. Documents required for registration will be provided in the Application form.
3. After the payment of the Prescribed Fee of 100 R.O and submission the company's file isevaluated.
4. The file is presented to the technical committee for registration to take the appropriatedecision.
5. Applications are processed within 4 months from the date of receiving the file in case itwas complete from all aspects.

The application for registration of pharmaceutical company to the competent department should be signed by the legal representative of the company or of authorized agent of the foreign company. The application shall be accompanied by documents proving the availability of the required conditions, to be documented and certified by the Embassy of the Sultanate also should be attached to the application.

Table 16: Applications of CTD & ACTD.

ICH CTD	ASEAN CTD	Description	Remarks
Module 1 - Regional and Administrative Information	Part I	• Contains specific documents to eachregion. • This module is not part of CTD. • Basically, consists of administrativedocuments like ✓ Application form ✓ Legal documents (GMP, Licenses etc.) ✓ labeling etc.	G & ND
Module 2 - Overall Summary		• This module summarizes the Module 3, 4, 5. • It includes Quality Overall Summary, Summary of Non-Clinical Overview andClinical Overview. • The summary provides reviewer the abstract of documents provided in the	G & ND For generics summary on Quality part only required.

	Part II	whole application.	
Module 3 –Quality		• Documents related to Chemistry, Manufacturing and Control of both Drug Substance and Drug Product	G & ND
Module 4 –Safety	Part III	• Non-Clinical Study Reports – Data on pharmacologic, pharmacokinetic, and toxicological evaluation of the pharmaceutical product is provided.	Only for ND
Module 5 –Efficacy	Part IV	Clinical Study Reports – A critical assessment of the clinical data and relatedreports is provided in this module	Not required for generics except BE study

G – generics; ND – new drugs; BE – bioequivalence

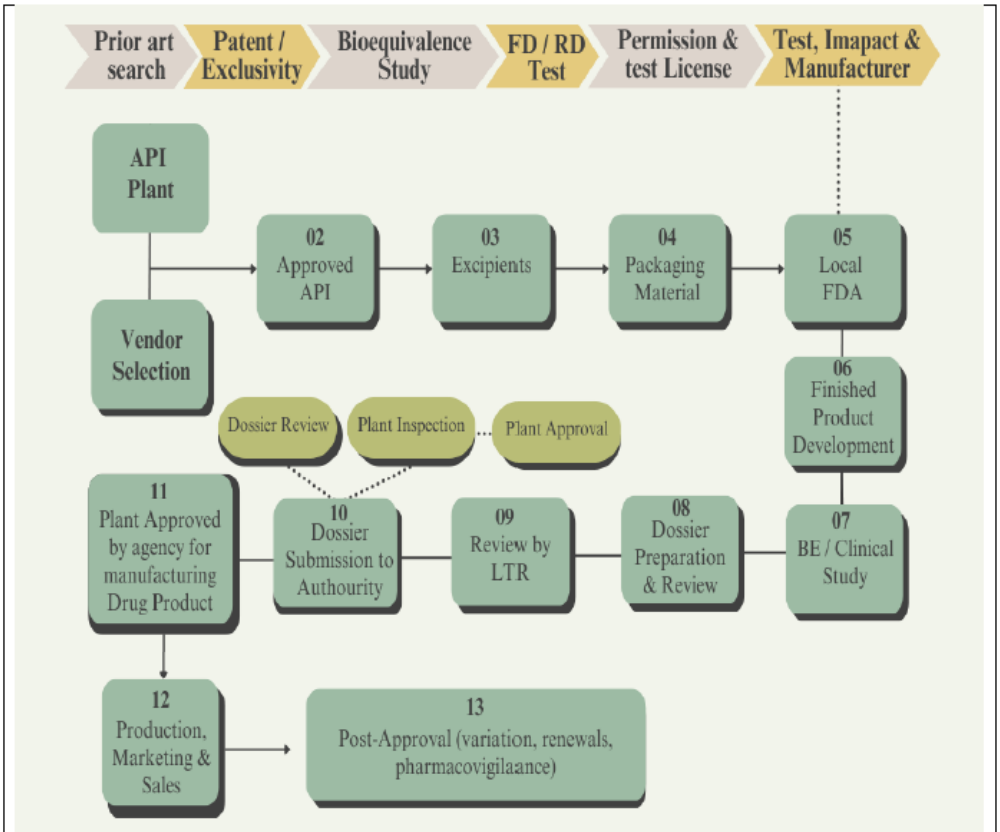


Fig. 12: Dossier application filing in emerging market

IV. RESULTS AND DISCUSSION[23,24,25]

- To develop effective guidelines & PMS system
- To improve legislative procedures
- To improve the regulatory review process
- Maintain stringent SOP's
- To improve the resource

Harmonization of strategic plans is critical for the future of the GCC regulatory authorities. It has been of interest to the GCC regulatory senior managers since the establishment of the European Centralized Procedure. The GCC authorities decided to collaborate in their efforts to face the regulatory challenges together. However, prior to commencing the process of strategic planning, the concept of strategy should be

- Strategy is a plan: it is a direction or a course of action for the future of the GCC regulatory authorities. Strategy is a pattern: it demonstrates consistency in the performance of the GCC regulatory authorities.
- Strategy is a position: it is the place within the environment where the authorities can seek out resources and opportunities from their surroundings
- Strategy is a perspective: it is the fundamental way of performing within the authorities according to their internal capabilities
- Strategy is a ploy: a specific "manoeuvre" intended to overcome any regulatory challenges

After using the five-force model to analyze the competitive capacities of the GCC authorities, it is reasonable to generate a framework for the harmonized GCC strategic plan using the balanced scorecard approach. The balanced scorecard is a performance measurement methodology for organizations to track progress in achieving their strategic goals. For the GCC authorities to implement a successful harmonization strategy, they need to create a balance in their performance between four strategic dimensions.

- Patient dimension: this is a patient-focused organizational performance.
- Resource dimension: this focuses on organizational performance associated with the availability of resources.
- Internal practice dimension: this measures the internal practices and system processes ofefficiency and effectiveness.
- Growth and learning dimension; this measures the progress towards achieving the attraction, development, and retention of staff.

Pharmaceutical-regulated firms are subject to strict regulatory requirements, which must be followed to protect the health needs and well-being of the public. Depending on the need of the country, there may be different regulatory constraints from one to the next in the Gulf co- operation council.

CONCLUSION

The compilation of documents for the dossier preparation of pharmaceuticals in GCC Countries is perfectly updated towards current regulatory needs. The global regulatory environment has changed dramatically over the past several years with a greater emphasis on strategic collaborations, harmonization, and convergence. Regulatory Affairs professionals help the company to avoid problems caused by badly kept records, inappropriate scientific thinking, or poor presentation of data by following country specific regulatory guidelines. The current article provides updated regulatory information of GCC which leads to successfulproduct registration, to have safe and effective drug towards patient population.

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