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Original Article

GENERIC DRUG REGISTRATION AND COUNTRY-SPECIFIC REQUIREMENTS IN SAUDI ARABIA, QATAR, BAHRAIN, AND OMAN

GUNASEELAN J.[1], ASHA SPANDANA K. M.[2*]

[1]Pharmaceutical Regulatory Affairs Group, Department of Pharmaceutics, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Sri Shivarathreeshwara Nagar, Mysuru-570015, Karnataka, India. [2]Department of Pharmaceutics, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Sri Shivarathreeshwara Nagar, Mysuru-570015, Karnataka, India

[*]Corresponding author: Asha Spandana K. M.; [*]Email: asha@jssuni.edu.in

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ABSTRACT

Objective: This research aims to examine the regulatory framework and prerequisites for generic drug registration in the Middle East and North Africa (MENA) region, with a specific focus on the countries that make up the Gulf Cooperation Council (GCC). This will enable a deeper understanding of the procedures, records, schedules, and discrepancies related to registration.

Methods: The study makes use of an extensive examination of the rules, regulations, and practices about the registration of generic drugs in the MENA. Official government sites, regulatory agencies, and respectable trade journals for the pharmaceutical sector were used as sources of information. The main procedures for registering generic drugs were explained and inspected, encompassing the submission of documents, dossier preparation, bioavailability/bioequivalence tests, and application filing.

Results: There are substantial growth prospects for generics. Research highlights the sequential registration process for generic drugs, submitting documents electronically using the Common Technical Document (eCTD) method. For registration to be successful, specific records and data such as bioavailability/bioequivalence research data must be provided.

Conclusion: The effective registration of generic medications in the MENA region, especially in the GCC nations, depends on understanding and abiding by nation-specific regulatory standards. The research offers a tactical guide that outlines the essential procedures, paperwork needs, and regional variances in the generic medicine registration process. The goal is to offer affordable healthcare solutions by navigating the regulatory landscape meticulously and streamlining the approval and market entry process for generic pharmaceuticals in the MENA region.

Keywords: Generic drug, Registration, Country-specific, Middle east, Variation

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INTRODUCTION

Generic drugs make contemporary drugs more widely available and reasonably priced; they are vital to the treatment of medical conditions in all countries' healthcare systems. For these advantages to remain throughout the future and for crucial medications to continue being made affordable to as many individuals as feasible without regard to price, the generic drug industry must remain sustainable. Both now and in the future, there is no denying the advantages of a robust and vibrant generic drug market [1].

Based on geographical area, the market for generic products is divided into five areas such as North America, Europe, Asia-Pacific, latin America, and the Middle East and Africa. According to research, the pharmaceutical market in the Middle East and North Africa (MENA) has surpassed $25 billion in value, exhibiting an increasing trend. The region known as the Middle East is a geographic and historic area that includes sections of southern Europe and northern Africa alongside western Asia. The Mediterranean Sea delineates the western boundary of the Middle East [2, 3].

For generics, the MENA area offers significant development potential as well as certain difficulties. This is brought about by the population's constant growth, rising governmental expenditures in the healthcare field, stable price conditions, the developing health insurance market, and affordable manufacturing and production processes [4]. Over the projected period, the generic medication industry is expected to grow at a steady rate, mostly due to changes in consumer behavior. A growing number of people choose generic medications each year due to long-term medication use for conditions including cancer, diabetes, cardiovascular reasons, central nervous system disorders, and others whose incidence is rising. Middle Eastern nations include Morocco, Algeria, Tunisia, libya, Egypt, Israel, lebanon, Syria, Jordan, Saudi Arabia, Kuwait, Bahrain, Qatar, United Arab Emirates, Oman, Yemen, Iraq, Turkey, and Iran. Marketing Authorization (MA) and the procedure for obtaining a license for the sale of drugs are different for each country [5].

Gulf Corporation Council (GCC)

On May 25th, 1981, the Cooperation Council for the Arab States of the Gulf-abbreviated as GCC for Gulf Cooperation Council was established. The United Arab Emirates, the Kingdom of Saudi Arabia, the Sultanate of Oman, the States of Qatar, Bahrain, and Kuwait are the initial Member States (MS). Its goal is to make partner collaboration easier in the areas of global trade, instruction, shipping, and tourism. Some countries follow GCC procedures. Countries that come under the GCC are Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates [6].

Drug registration procedures

Drugs in GCC countries can be registered by two procedures.

1. Centralised Procedure

The Centralized Procedure in the GCC region delineates the opportunities for registering pharmaceutical products throughout the area.

2. Decentralised Procedure

The DCP can be applied to acquire an MA in numerous MS if the company has not yet obtained marketing authorization in any country.

What is MA?

An MA is a procedure used to examine and evaluate the documentation supporting a drug that has been given the go-ahead

by a nation's regulatory body. The product's MA, granted by the relevant regulating body, gives its owner the right to put it on the open market. "MA" is required for medications that satisfy the safety, efficacy, and quality requirements before they may be marketed or prescribed. This permission encompasses all major operations related to the sale of pharmaceuticals. Next, the medication that receives an MA is referred to as "licensed" "approved" or "registered" [7].

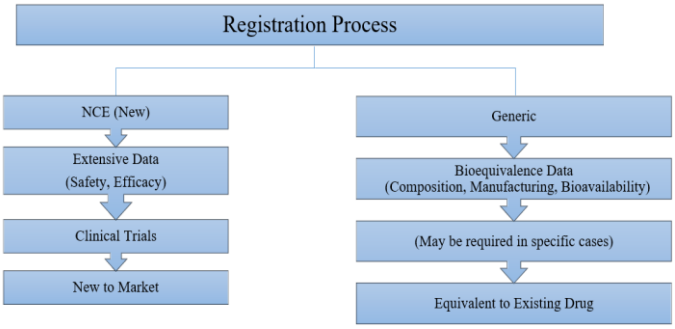


Fig. 1: Registration process [8]

Research methodology

Four factors were chosen for the study's purpose to better understand and research the rules and regulations since generic medicine registration in Middle Eastern nations is a sequential procedure.

Step 1: Prerequisite for application

The generic medication application should contain all the data required by the specific country.

Step 2: The necessary documentation and study data for submission

One of the most crucial components of any type of regulatory filing is gathering information regarding the volume of data and information.

- Legal documents: to be signed are the GMP-Good Manufacturing Practices certificate, the lOA-Letter of Authorization, the COPP-Certificate of Pharmaceutical Product, and the FSC-Free Sale Certificate
- Pharmaceutical information: The Middle East nation's dossier comprises primarily pharmacological information, which is contained in normative documents
- Specific Requirements: Declarations for the content of alcohol, Pork-free preparations, CEP-Certificate of suitability for TSE/BSE, usage of coloring and dilution agents in the drugs' formulation

Step 3: Dossier compilation and submission

The dossier's creation must adhere to specific guidelines and specifications, such as the Common Technical Document (CTD) structure, which includes modules for different types of information, like administrative, quality, non-clinical, and clinical information records about a medicinal product's quality, safety, and effectiveness. A legislative body will receive the document for assessment, and if the application is approved, commercial permission for the product will be given [9].

Step 4: Bioavailability and bioequivalence study information

Bioavailability refers to the amount and rate of absorption of the drug, while bioequivalence is the comparative assessment of the bioavailability of different formulations or drug products [10]. Important information related to Comparative bioavailability studies, Bioequivalence study design, Sample size, statistical methods, and *in vivo* and *in vitro* studies should be included [11].

CTD and eCTD

A globally recognized format known as the CTD is used to prepare marketing authorizations (MAs), which are subsequently submitted to regulatory bodies in the USA, EU, Japan, and three additional ICH areas as well as in some other nations and regions.

A uniform framework for creating an organized dossier is provided by the CTD. It makes use of the modular structure that ICH Topic M4 outlines. Consult the most current version of the ICH CTD guiding materials in conjunction with this one [12].

There are five modules in the CTD. Module 1 is unique to a certain region. It is intended for modules 2, 3, 4, and 5 to be universal throughout all areas. Below fig. 2 examines the module's outline fig. 2.

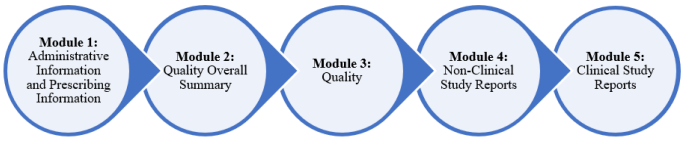


Fig. 2: Common technical document modules [13]

An electronic version of the CTD is called the eCTD. The folders, files, and structure names match those found in the CTD. However, it has extra technological components like a submission format that allows management of the product's lifespan as well as the lifecycle of individual files inside the program.

The elements that make up an eCTD are the files, folder organization, and XML backbone [14].

Country-specific requirements

1. Cover letter

For every submission, the candidate must attach a cover letter.

1. Table of content (TOC)

All of the papers that are part of each Module must be listed in the submission's TOC.

2. Form for Application

The application form needs to be sent with all fields filled out and signed. Application forms will differ for each country.

3. Product Information

It must contain the following information

- Summary of Product Characteristics (SPC): Product name, its strength, pharmaceutical form, posology, administration method, indication, contraindication, etc.
- Labelling: Since the labeling is a component of the product's permission, it needs to be authorized by the relevant authorities.
- Patient Information leaflet (PIL): The leaflet should be provided in both Arabic and English
- Artwork (Mock-ups): it is a flat artwork design in full color.
- Samples: The finished product samples should be submitted to perform testing.

4. Experts Information

Quality, Non-Clinical, and Clinical – This section should contain the Resume of the respected experts

It is important to emphasize that well-prepared expert reports greatly facilitate the task of evaluating the dossier and contribute towards the speedy processing of applications.

5. Assessment of environmental risk

The applicant shall include an evaluation for any potential risks of the product to the environment. This should include risks to the environment arising from the use, storage, and disposal of products and not risks arising from the synthesis or manufacture of products.

6. Pharmacovigilance (PV)

- A PV system is a tool used by a company to carry out its legal obligations for PV. It is intended to track any changes to the risk-benefit ratio of approved pharmaceuticals and ensure their safety.
- Risk Management Plan-It must specify how to further characterize the security characteristic of the relevant medication as well as determine the safety characteristics of the product.

7. Documents and Certificates

Refer to table 1 for the required documents and certificates.

8. Pricing

Drug pricing application and price of the product in other countries.

9. Responses to questions

All the responses related to any queries should be updated in this section [16, 17].

Table 1: Documents and certificates required for drug approval

Certificates required	Documents to be submitted	Timeline	References
Good Manufacturing Practices Certificate	Facility GMP and API GMP should be submitted	1-3 mo approval timeline	Data Requirements for Human Drugs Submission (Content of the Dossier) [15]
CPP or Free-sale	CPP is issued by the exporting country and legalization is granted by the importing country	20 d	
COA for drug substance and drug product	Drug Substance vendor COA and Formulation COA should be submitted	Usually provided by the manufacturer upon completion of production batches	
Excipients COA	COA for all the excipients, both vendor and formulation COA	Provided by excipient suppliers upon request	
Declarations	Declaration should be given that the pharmaceutical product manufactured does not contain Alcohol, Pork, or no ingredients of animal origin.	-	
Content of alcohol, Pork-free CEP for TSE/BSE			
The product formula's diluents and coloring agents	Declaration letter stating the use of diluents and coloring agents in the product	-	
Patent Information	Declaration letter related to the status of the patent	Provided by the patent holder upon request	
LOA or acknowledgement to Drug Master File	Letter from the DMF owner or an authorized agent granting permission to refer to data in the DMF on the applicant's behalf	-	

Discussion of various regulatory requirements

❖ **Saudi Arab. IA: (SFDA) Saudi food drug and authority**

The SFDA was established under the Council of Ministers resolution No. (1) dated 07/01/1424 H, as an independent corporate body that directly reports to The President of the Council of Ministers.

SFDA is primarily responsible for regulating, overseeing, and monitoring food, cosmetics, drugs, and medical devices, as well as establishing mandatory requirements for regulated products. Food, drugs, medical devices, cosmetics, pesticides, and feed are all regulated by SFDA [18].

Drug registration process

Step 1: SDR online application form

Fill out the application form through the SDR system. Verify that there is an account in the Drug Establishments National Registry (DENR) system before accessing the SDR system. For GCC-registered products, provide the GCC certificate number and add a copy of the GCC certificate in the cover letter.

Step 2: File presentation

Upload the complete dossier, such as administrative information, Quality overall summary, Quality, Non-Clinical Study Reports and Clinical Study Reports. The file format should be according to eCTD for human products. If it is an initial submission cover letter should be included.

Step 3: Business `validation

The Regulatory Affairs (RA) team will review the uploaded file and the results will be either.

Accepting the file-if the file is accepted, it will be forwarded to the concerned department by the RA team and the applicant will be notified by email over the SDR system.

Rejecting the file–if deficiencies are identified, the file will be rejected and deficiencies will be sent over to the SDR system. The applicant should submit the requested information within the timeframes.

Step 4: Pricing

The Pricing Department will review the product's price according to the "FDA's pricing rules" and the product's price will be forwarded to Registration Committee.

Step 5: Responses to inquiry

General Inquiries: In Module 1, section 1.9, response to questions, include a document that lists the inquiries with the corresponding narrative text response for each question. Each question should be

followed by the name of the section, page number, and a hyperlink where the answer can be found in the concerned module.

Laboratory Inquiries: Once the inquiry is posted, submit the required samples and working standards to the laboratories under 1.3.5 Samples.

Step 6: Registration decision

When the registration process is completed, the applicant shall receive a notification from the eSDR website noting the decision either:

- Accepted
- Rejected

If the application is accepted, submit an electronic request to issue a product certificate by going to the SDR system [19].

Requirements for hardware copy

For the submission of hard copies, please ensure the inclusion of all required documents: a cover letter expressing our intentions clearly, an accurately filled-out application form, samples showcasing our products or services, a CPP or Free-sale certificate to validate compliance and authenticity, an lOA or acknowledgment to DMF to signify adherence to regulatory standards and a comprehensive price list for transparency. Each document plays a crucial role in presenting our candidacy effectively and professionally, and their collective inclusion ensures a thorough and complete submission.

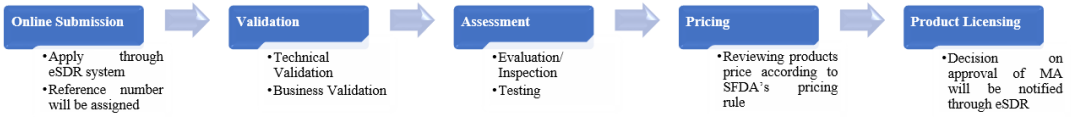


Fig. 3: Drug registration process

Table 2: Drug registration fee

Category	Type	SFDA Fees (SAR)	SFDA eSDR Fee (SAR)
Generic	Registration	40000	8000
	Renewal	10000	1000

Approval timeline

Generic human drug: 165 working days

❖ **QATAR: MORPH**

Department: PDCD-Pharmacy and Drug Control Department

The nation's drug policies are mostly formulated by the Pharmacy and Drug Control Department. It additionally engages in the drafting of legislation and rules regulating the field of pharmacy and establishes guidelines for the importation, distribution, and dispensing of pharmaceuticals. All of these activities positively impact the development of pharmaceutical care [20].

Registration process

- **Application-online filing**

The candidate must complete the relevant application using the PDCD E-system. Following an initial administration investigation regarding the application, a time slot will be set aside for the file's submission. The agent may email the Office of Administration of the Human Medicines licensing division to request a modification in the scheduled time.

- **Acceptance of submission**

The PDCD team will do a preliminary evaluation of the document to verify that all submitting requirements have been met by the PDCD eCTD protocol.

- Application system without deficiency: A tangible receipt notifying the applicant that their application has been approved will be sent at the same time, and the record will be moved straight to the following phase of the procedure.

- Inadequate Application: If any shortcomings are found, the candidate will be reminded of them during that particular session. Please take note that applicants may seek to reschedule an appointment to resubmit their files, provided that the request is made at least one month after an initial session.

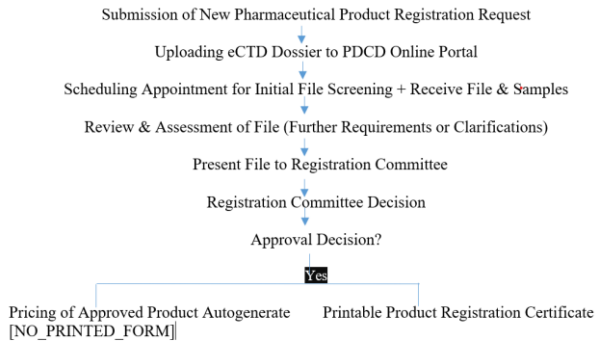
- **Evaluation**

A product's application will be evaluated according to its kind, and if any remarks or problems are found, the applicant will be contacted by email and given four months to respond. The onus is on the applicant to confirm that the remarks have reached the Marketing Authorization Holder (MAH). The application will be deemed denied and the applicant will be notified to pick up the file if the conditions are not met within the allotted four months. If not, the file will automatically advance to the following step.

- **Application acceptance**

The licensing committee will evaluate the file once it has completed the verification and evaluation stages and satisfied all standards set out by the MAH. The committee may bring up specific problems or request further documentation. The committee's decision will be communicated to the applicant. The applicant will have four months (or the equivalent amount of time to complete a study recommended by the committee) to reply to these remarks if the committee requests additional requirements. The application will be immediately deleted and a fresh application must be made if the firm does not answer within this time frame [21].

Process flow [22]



Gulf corporation council-centrally registered product

Products that have already been centrally recognized by GCC may have their new registration applications evaluated more quickly according to the PDCD, which also spares them from a thorough evaluation. Full data requirements, however, have to be filed along with a regular new registration. The product's central GCC registration should be made obvious on the application form, and a

copy of the current GCC registration document together with all of its attachments, should be included in the file. The replica must bear the same stamp as the original from the GCC executive office. In the cover letter, the corporation should state that the research and product information presented are exactly as approved by GCC and should not be altered in any way [23].

Hard copy requirements for module I

- Cover letter –
- It should contain information about the local agent, Company name and address, Trade name, ATC (Anatomical Therapeutic Chemical) Code, Dosage Form and Strength, INN, No. of CDs/DVDs provided. Registration certificate of the drug in the regulated market such as the US, EU, and TGA (Optional)
- It should include at least two GCC country's drug registration certificates of the same drug mandatory
- Application Form – the name of the product, use, unit, shelf life, and other approvals
- Reference standards and samples (along with their certificates of analysis)
- Documents and Certificates

Good Manufacturing Practice Certificate, Certificate of Pharmaceutical Product, Alcohol-free declaration, Pork-free declaration, the diluents and coloring agents in the product formula, Patent Information, letter of access or acknowledgment to DMF

- Certificate for prize [24]
- **Bahrain: Nhra-national Health Regulatory authority**

Department: Pharmaceutical Products Regulation Department (PPR)

A separate supervisory organization founded in 2010 under law No. 38 of 2009 is the National Health Regulatory Authority (NHRA). The goal of the NHRA is to control the delivery of healthcare in Bahrain and assure adequacy reliability, efficiency, and safety in the delivery of medical services for both the public and private sectors. In compliance with global standards, it will be founded on the most accurate scientific data and industry best practices in healthcare. The Kingdom of Bahrain's NHRA is in charge of developing and enforcing health rules in the public and commercial sectors [25].

Drug registration requirements

Before submission

Before submission of the medicine licensing application, below are vital instructions:

- Batch releaser for all formulations must have a valid site license issued by NHRA.
- First-time generic formulation only, Applications must include pertinent documentation from the GCC Patent Office and the Bahrain Patent Office (MOICT).

Data requirement

All necessary information must comply with Gulf Holding Company (GHC)and ICH CTD in eCTD format.

Regarding generic drugs, the GCC BE standard states that the comparative BA/BE research report must be included under module 5. A centre authorised by the GCC or by any of the following regulatory bodies WHO, USFDA, Health Canada, TGA, MHRA, or EMA—should carry out the study. The study center's approval from the relevant authorities is necessary, and the report must be included with the application.

Module 1

Additional data

- New medicine registration checklist.
- MAH's affirmation that the SmPC presented is accurate and comparable to the one that was authorized in the country of origin/MAH country. Any discrepancy must be disclosed by the business.
- Status of global registration (marketed date, authorized, under authorization, and denied).
- Bioequivalence study summary template for generic application by GCC bioequivalence guideline

Analysis in the lab

A license cannot be issued until the product samples have been analyzed for new certification applications. A laboratory analysis dossier with a sample has to be filed at the same time as a new registration request. In case the product fails in lab analysis initially, another request for analysis will be made. If the product fails again in lab analysis it will be rejected after discussion with the licensing committee [NO_PRINTED_FORM].

Documents to be submitted are as follows

Many important papers that are necessary for review should be included in the submission package. First, product samples that are accompanied by the corresponding Certificate of Analysis offer information on the composition and quality of the product. Furthermore, consistency and dependability are guaranteed by reference standards for related chemicals and active components as well as their Certificates of Analysis. The components and their ratios are further explained in a Product Composition Certificate. Important features and specifications are outlined in the detailed product specifications. Material Safety Data Sheets provide important details on possible risks and management. Finally, for thorough inspection and convenience of access, all papers should be supplied in hard copy as well as electronic version, ideally on CD, DVD, or USB. This all-encompassing method of submitting paperwork guarantees accuracy and adherence to legal requirements.

Submission and verification

The candidate must properly file a scheduling request document and send it to the specified email address to submit a fresh medical licensing registration. First-come, first-assigned appointments are made. For any Phase I or Phase II validated appointment request, the applicant should apply with an appointment request form along with a validation certificate. Only appropriate applications will be approved, and NHRA personnel will verify that all needed papers are in the file on the day of the appointment. The same holds for any file that has been verified in Phase I or Phase II. The applicant is responsible for paying the necessary submission costs if their application is approved. The applicant receives a signed copy of the medication licensing checklist, which is then put into the new medicine's file record. NHRA staff will validate the hardcopy documents with the submitted eCTD

Acceptance or approval

The medical licensing committee decides whether to accept or reject a medicine for licensing once the evaluation, laboratory analysis, and price of medication is finished. The applicant cannot pick up the license until the committee has approved it and the necessary costs have been paid. The five-year license is applicable for medicine [26].

Table 3: Registration categories and fees structure

Service categories	Subcategories	Application type	Fees (in BHD)
Medicine and Pharmaceutical Products New Registration	Medicine	Registration	60
		Renewal	20
	Pharmaceutical Product	Registration	40
		Renewal	10

Oman: ministry of health

Department: DGPA and DC-Directorate General of Pharmaceutical Affairs and Drug Control

Whether pharmaceuticals are produced domestically in Oman or imported from outside, the DGPA and DC is the regulatory authority in charge of ensuring that they are effective, safe, and of high quality in the country, and that going to be achieved by implementing pharmacy practice law issued against the Royal Decree No 41/91 and its amendments.

Drug control department

Drug control department: - includes 4 sections (Registration, drug clearance, dangerous drug, and international communication sections). This department is responsible for the registration and pricing of the products, also responsible for giving clearance for imported drugs, issuing licenses for import and dealing with narcotic and psychotropic drugs) as well as post-marketing surveillance (Pharmacovigilance) [27].

Registration process

Schedules for the submission of applications

The candidate should submit a request for a meeting to apply for MOH-DGPA and DC. Products developed or released in batches by enterprises registered with the MOH-DGPA and DC will be scheduled appointments. The day and time of the appointment will be communicated to the applicant. A fresh appointment request must be issued if the applicant fails to show up on the appointed day (no-show). It's vital to remember that appointments are not necessary for variations. If the product was registered in any GCC country, the applicant should attach a copy of a Certificate of Analysis along with the appointment letter. The same should also be enclosed in the dossier.

Applying

The candidate must be available at the allotted hour on the actual day of submitting. Both the CDs or DVDs and the attached dossiers will be checked against a list of all the documentation needed to meet the MOH-DGPAandDC submitting requirements.

Initial phase(I) validation

The authority will scan again the submission to check for viruses. An importation tool will be used for technical verification of the file, and the 32-digit MD5 checksum that is created should match the one that was supplied by the applicant.

Post-I (Validation) phase

After validation is finished, one of the subsequent results occurs:

If the application is valid

The candidate will be given a copy of the application form with the assigned eCTD application number. After that, the documentation is sent for review and appraisal.

If the application is invalid

The application will receive a validation report outlining all the issues along with the documentation and samples back if any mistakes are discovered. The applicant has thirty days from the date of application to correct any inaccuracies. After the mistakes have been fixed, the applicant should get in touch with the MOH-DGPA and DC to schedule a time to submit the dossier again. The application will be sent to the relevant staff member for additional processing and evaluation if the applicant gives the specified information within 30 days. The applicant has the remaining thirty days to fill in the missing information if, after providing the needed information, it is still incomplete. If the drug application is not submitted within 30 days, it will be denied.

Phase II-review

Following the effective finishing of the technological and content confirmations, the dossier of documents will be sent for evaluation. If, during the assessment process, any problems are found, the applicant will get a request asking them to submit the necessary papers within ninety days of the request date. The answer has to have the proper sequence number and be in eCTD format. The following results are contingent on the applicant's response:

The applicant replies in ninety (90) d: documents will be assessed and if the response is unsatisfactory, the requirements will be sent to the applicant and another 90 days will be given.

Failure to respond within the timeline: such applications will be forwarded to TCR and P for decision-making.

Phase III (Decision)

Decision on the application will be taken by the Technical Committee of Registration of Pharmaceutical Companies and Products of Human Medicine and Pricing (TCR and P) [28, 29].

Hard copy requirements

Cover letter, Application Form, Samples, CPP or Free sales, Patent Information, lOA or acknowledgment to DMF, Price list**.**

Variations

Variation refers to a change or difference in something, which can be either continuous or discontinuous. In the pharmaceutical context, a variation is a change made to the terms of a marketing authorization that may affect the quality, safety, or efficacy of a medicine.

Types of variations

A. Minor variations

Type IA: “Do and Tell” procedure

Such minor modifications don't need permission before being implemented. Variations of Type IAIN must be provided right away, no later than 14 days after implementation. On the other hand, further type IA variants may be combined into a single variation application, which must be filed to the SFDA by January 31st of every year.

Type IB: “Tell, Wait and Do” procedure

Although they don't need official permission, these small changes must be reported to the relevant authorities by the MAH before implementation. However, before adjusting, the MAH has to wait a little to make sure the application is accepted.

B. Major variations:

Type II: Such notable deviations, which need prior permission before adoption, may have a substantial influence on a pharmaceutical product's quality, safety, or efficacy [30].

CONCLUSION

In conclusion, navigating the generic drug registration landscape in the Middle East demands a nuanced understanding of the region's diverse regulatory frameworks. The generic drug registration process, dissected throughout the article, underscores the critical stages of marketing authorization, dossier compilation, and the pivotal role of bioavailability/bioequivalence studies. The incorporation of essential frameworks like CTD and its electronic counterpart (eCTD) emerges as a key player in ensuring a streamlined and efficient registration process, aligning with stringent regulatory standards. Country-specific nuances in Saudi Arabia, Qatar, Bahrain, and Oman further emphasize the need for tailored strategies. The unique processes, timelines, and fees outlined by regulatory bodies such as SFDA, Ministry of Public Health, National Health Regulatory Authority, and Ministry of Health underscore the importance of a customized approach. As companies navigate the complexities of environmental risk assessments, pharmacovigilance systems, and expert reports, adherence to sequential study parameters becomes paramount. The article serves as a comprehensive guide, providing a roadmap to successfully navigate generic drug registration. By emphasizing the significance of understanding and adhering to country-specific requirements, the article aims to empower pharmaceutical companies in fostering a

sustainable and dynamic generic medicines sector. Ultimately, this knowledge proves instrumental in ensuring continued accessibility to essential medications in the ever-evolving pharmaceutical landscape of the Middle East.

ABBREVIATIONS

ATC-Anatomical Therapeutic Chemical, CEP-Certificate of Suitability, COA – Certificate of Analysis, COPP OR CPP-Certificate of Pharmaceutical Product, CTD-Common Technical Document, DCP-Decentralised Procedure, DENR-Drug Establishments National Registry, DGPA and DC-Directorate General of Pharmaceutical Affairs and Drug Control, DMF-Drug Master File, eCTD-electronic Common Technical Document, FSC-Free Sale Certificate, GCC-Gulf Cooperation Council, GHC-Gulf Holding Company, GMP-Good Manufacturing Practices, ICH – International Council for Harmonization of Technical Requirements of Pharmaceuticals for Human Use, LOA-letter of Authorization, MA-Marketing Authorization, MAH-Marketing Authorization Holder, MENA-Middle East and North Africa, MOPH-Ministry of Public Health, NCE-New Chemical Entities, NHRA-National Health Regulatory Authority, PDCD-Pharmacy and Drug Control Department, PIL-Patient Information leaflet, PPR-Pharmaceutical Products Regulation Department, PV – Pharmacovigilance, SFDA-Saudi Food Drug and Authority, TOC-table of Content

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AUTHORS CONTRIBUTIONS

GJ played a comprehensive role by conceptualizing and designing the study and was involved in literature search, data acquisition and analysis, statistical analysis, manuscript preparation, editing, and review. Supported in study design and was actively involved in content preparation, data synthesis, manuscript preparation, editing, and review of the same. ASKM contributed to manuscript preparation, editing, and review and helped in the study conceptualization and review of the manuscript.

CONFLICTS OF INTERESTS

The authors declare no conflict of interest.

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