Review Article

Regulatory Requirements for Generic Drug Approval Process in Gulf Cooperation Council Countries

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ABSTRACT

The study aimed to explore the generic drug regulations in the Gulf Cooperation Council (GCC) countries. The regulatory authorities must guarantee they can access safe and effective drugs; nevertheless, their strategies and practices exhibit substantial variation. The findings are concerned with the different roles of regulatory bodies in GCC countries, which include Bahrain (BH), Kuwait (KW), Oman (OM), Qatar (QA), Saudi Arabia (SA), and the United Arab Emirates (UAE); they consist of the procedure for approving generic drugs, the documents that are necessary for the registration process, review time, fee details and the significant distinctions that exist across these countries. The study describes their regulatory pathways for the generic drug approval process in their GCC countries. Still, the GCC member states' target approval times and order of some activities varied because some processes are parallel. The regulatory frameworks simplify and streamline registration while meeting strict regulatory standards. A comparison of GCC countries' approval procedures and registration requirements has been conducted to ascertain the distinctions between the regulatory authorities.

Keywords: Gulf Cooperation Council, Generic drugs and Regulatory approval process.

1. INTRODUCTION

A regulatory authority is a government agency that safeguards public health and safety. To ensure that it fulfills its mandate, a regulatory agency employs mechanisms like information and decision-making transparency, procedures for consultation and participation, the requirement that administrators justify their actions, and the requirement that administrators adhere to guidelines that support responsive and non-arbitrary decision-making [1]. The GCC activities are planned, coordinated, and reported by the GCC Secretariat, which was established in 1981. Every GCC authority similarly assesses drugs' efficacy, safety, and quality [2].

Most of the drugs on this List are off-patent and available as generics, often cheaper than the brand-name product, saving patients and the healthcare system money. Generic drugs comprise over half of all pharmaceuticals worldwide but only 18% of the pharmaceutical industry's value. A generic medication is any pharmaceutical product that is bioequivalent to the reference product and has the same active ingredient content, both qualitatively and quantitatively, and in the same pharmaceutical form[3].

2. AIM AND OBJECTIVES

The present study compares the regulatory aspects of generic drug approval and the necessary documents for submission in GCC countries. The objectives of the study include understanding the regulatory requirements for approval of generic drugs in GCC countries and conducting a contrast study of the regulatory requirements of the GCC to reduce their disparities and emphasize their similarities.

3. METHODOLOGY

The study uses an extensive review of regulations and registration of generic drugs in the GCC. The methodology involved a literature search using databases such as official government sites, such as International Conference on Harmonization (ICH), Good Manufacturing Practices (GMP) and World Health Organization (WHO) guidelines, regulatory agencies and journals related to generic drugs were used as sources of information. The study involved comparing the registration procedure for generic medications, functions of regulatory bodies, documents required for submission and the period for approval of generic medicines. The specific methods and guidelines followed may vary slightly across GCC countries.

4. DISCUSSION

The generic drugs study in GCC countries comprehensively evaluates generic drugs' quality, safety, and efficacy.
Here's an overview of the process involved:

4.1. Saudi Food and Drug Authority (SFDA)

The SFDA is the regulatory body that ensures food and drug safety. It regulates drug products in Saudi Arabia and enforces drug requirements. The SFDA is responsible for overseeing pharmaceutical products in Saudi Arabia. Its functions include licensing, registration, quality control, inspections, compliance, safety monitoring, labeling, pricing, and packaging[4].

4.1.1. Steps involved in the approval process

Submission of application

The manufacturer submits an application to the SFDA for approval of the generic drug. The manufacturer or their authorized representative applies for marketing authorization of the generic drug to the SFDA through the online portal. The process is represented in Fig. 1.

The process of submitting an MAA consists of two steps:

i. Online submission: Applicants must complete and pay the costs via the Saudi Drug Registration (SDR). They must then upload the product file; its components must meet SFDA website standards.

ii. Validation: The product application will be technically and commercially evaluated to verify that the applicant meets the requirements. The process requires two stages.

a. Technical validation: After the firm submits the file to the SDR site, the system validates it automatically. The applicant will get the validation result via the SDR email.

b. Commercial validation: If any information is missing or wrong, the SDR system will send the applicant an electronic inquiry. The applicant may finish the file within 30 working days. After completion, the file will be assessed.

Administrative review

The SFDA reviews the application to guarantee assessment eligibility. It includes inspection for correctness & completeness, verifying the manufacturer's license & GMP certification.

Technical review

The technical examination ensures that generic medicine meets Saudi Arabian marketing authorization criteria. The SFDA technically reviews the dossier to assess the generic drug's quality and non-clinical and clinical features.

Bioequivalence study evaluation

These studies are essential for assuring that the generic medicine is as effective and safe as the reference product. The SFDA checks the bioequivalence study report for compliance.

Quality control tests

When a generic medicine fails SFDA requirements, the agency will ask the manufacturer for further information. To prevent evaluation delays, the maker must react to requests within the required period, which must be maintained to avoid delays in evaluation. Quality control tests are necessary for the quality, safety, and effectiveness of generic medicines[5].

GMP Inspection: The SFDA inspects the production plant for GMP compliance.

Price Approval: It evaluates the proposed price of the generic drug & approves or negotiates it.

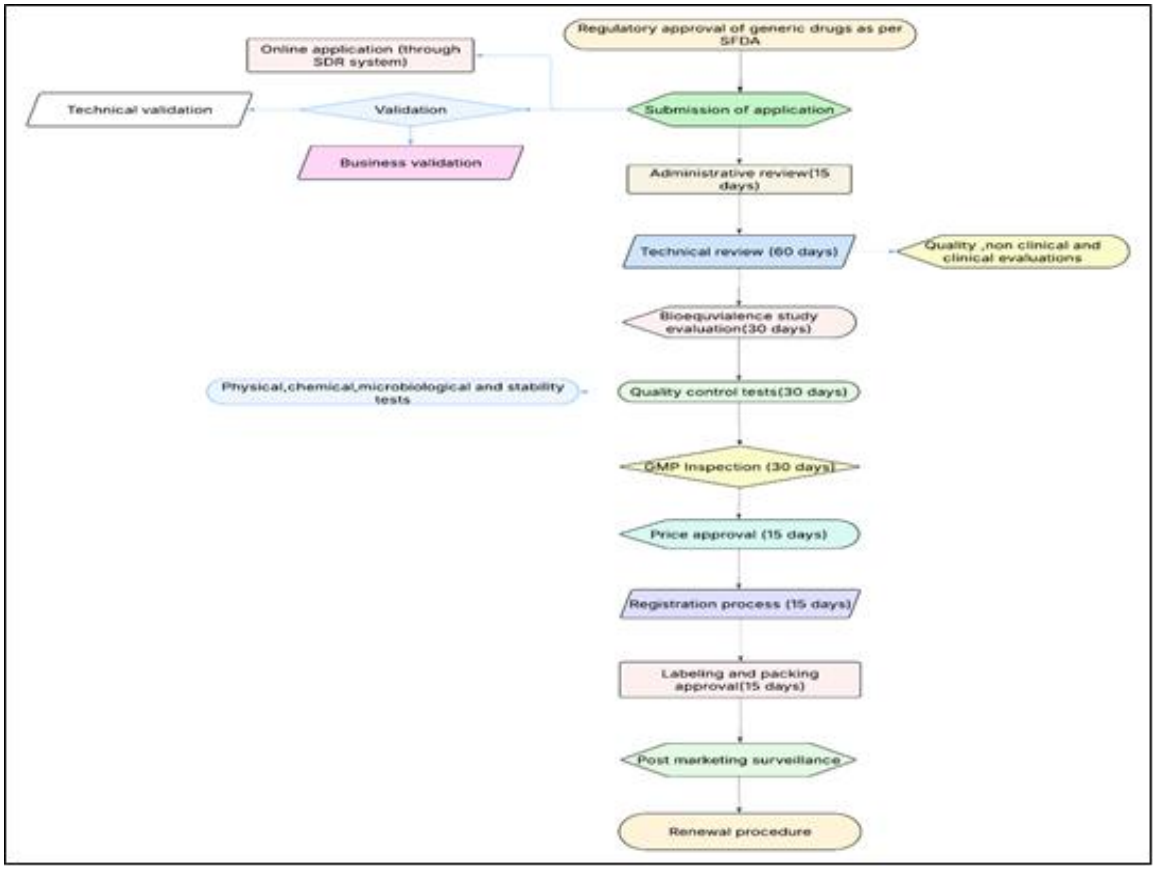

Figure 1: Generic drugs approval pathway as per SFDA

Figure 2: Generic drugs approval pathway as per NHRA

Registration

It is the final step in the approval process for generic drugs. The SFDA completes the registration process for the generic drug. It includes the issuance of a registration certificate and the assignment of a license number.

Labeling and packaging

To guarantee regulatory compliance, the SFDA reviews generic medicine labelling and packaging. It must be accurate and compliant for patient safety and informed decision-making.

Post-marketing surveillance

The generic medication maker must monitor its safety and effectiveness after commercialization. The manufacturer must promptly and accurately report adverse occurrences. It covers significant and non-serious adverse outcomes, including hospitalizations and fatalities.

Renewal: The company must apply to renew the generic drug's SFDA registration every 5 years[6].

4.1.2. List of documents required for registration:

- Application form for generic drug registration
- Certificate of registration from the manufacturer's
- Free sale certificate from the manufacturer's
- GMP certificate

Table 1: Review stages and period as per SFDA

S. No	Review of stages	Period (Days)
1	Submission of application	30
2	Administrative review	15
3	Technical review	60
4	Bioequivalence study evaluation	30
5	Quality control tests	30
6	GMP Inspection	30
7	Price Approval	15
8	Registration time	15
9	Labelling and packaging approval	15
	Overall approval time	240 days

4.2. BAHRAIN

Bahrain's Law No. 38 of 2009 created the independent National Health Regulatory Authority (NHRA) in 2010. The NHRA's website states it aims to regulate healthcare in Bahrain and assure appropriateness, continuity, efficiency, and safety in government and commercial sector health services[7].

4.2.1. Steps involved in the approval process

Submission of application

The maker of generic drugs applies to the NHRA of Bahrain. Obtaining clearance to promote and sell their generic medication in Bahrain starts with this stage. The process was displayed in Fig. 2.

Administrative review

The NHRA conducts an administrative evaluation to guarantee application accuracy. Before proceeding, every document and information must be in order.

Technical evaluation

The evaluation of generic medicines quality, safety, and effectiveness. The assessment procedure relies on this step.

Bioequivalence study

The studies are crucial to generic medicine approval. The generic drug's pharmacokinetic and pharmacodynamic features are compared to the reference product.

GMP Inspection

Verifying that the manufacturing facility meets GMP standards is vital to approval.

Approval committee review

The review includes medical, pharmaceutical, and regulatory experts. They thoroughly analyze the application, considering administrative, technical, bioequivalence, and GMP inspection results.

Registration

The generic medicine registration certificate meets quality, safety, and effectiveness criteria and verifies that the maker followed international requirements.

Post-marketing surveillance

The manufacturers must provide post-marketing monitoring and periodic safety update reports (PSURs). The manufacturer must submit PSURs to the NHRA every 6-12 months to prove safety and effectiveness[8].

Table 2: Review stages and period as per NHRA

S. No	Review of stages	Period (Weeks)
1	Administrative review	1-2
2	Technical review	4-6
3	Bioequivalence study review	4-6
4	GMP inspection	2-4
5	Approval committee review	2-4
6	Registration	2-4
	Overall duration time	20-40 weeks (5-10 months)

4.2.2. Required documents

- Obtain a WHO-authorized COPP for drugs from any GCC mission.
- All safety data, including test procedures and validating statements, were stored in a separate document for the testing lab.
- A manufacturing process.
- Contact information for participating contract research organisations (CROs)[9].

4.3. KUWAIT

The Ministry of Health (MOH) oversees public health in Kuwait and creates a health policy plan. Ahmad Abdulwahab Al-Awadhi leads the 1936-founded organization. Kuwait regulates medicines in terms of quality, safety, effectiveness, pricing, and patent protection[10].

4.3.2. Steps involved in the approval process

The regulatory route is divided into many stages that ensure the quality of pharmaceutical goods to support consistent growth and development. These stages are shown in Fig. 3.

Submission phase

The local agent sends the registration dossier and covering letter to the Kuwait Drug and Food Control Manager (KDFC) to request pharmaceutical material registration. A generic medicine formulator must know the regulatory requirements of each nation where the medication will be submitted.

Evaluation phase

After entering scientific review, the reviewer will assess chemistry and manufacturing control (CMC) data, concentrating on the following:

- Analyzed total stability for projected consumer shelf life.
- Raw material specifications and analytical processes.
- Detailed material descriptions and analysis methodologies for completed goods.

Authorization phase

After a thorough assessment, the DRRS makes the ultimate approval decision, which the authority's director endorses.

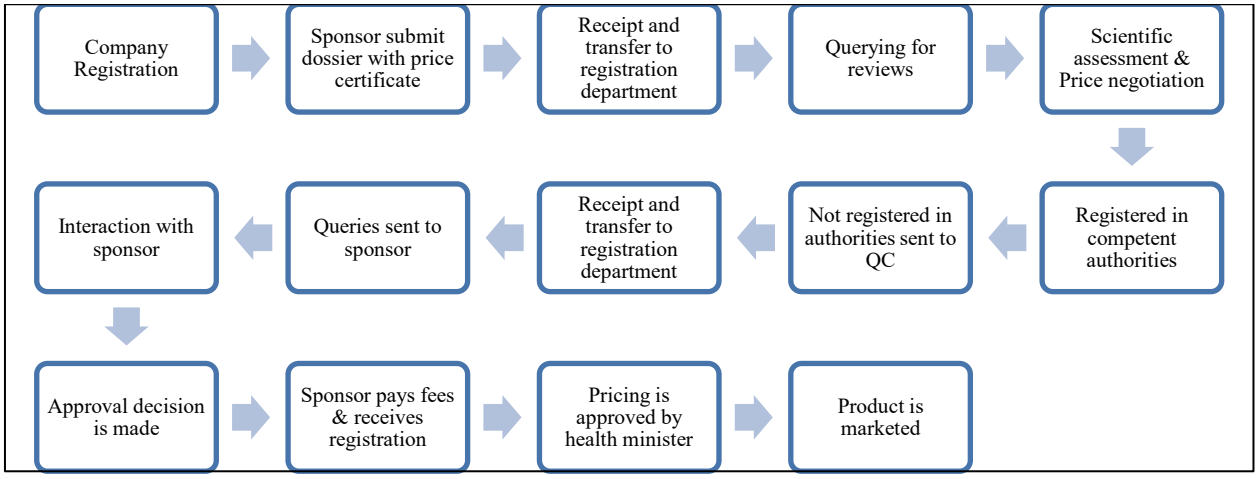

Figure 3: Generic drugs approval pathway

4.3.3. Required documents for submission

- Reference with certificate of analysis
- Patient information leaflet
- Source of supply of API and excipients
- Finished and raw material criteria
- Stability data long-term & accelerated studies
- Bioequivalence study data[10].

4.4. OMAN

Directorate General of Pharmaceutical Affairs and Drug Control (DGPA & DC).Whether pharmaceuticals are produced domestically or imported, the DGPA and DC must ensure they are effective, safe, and high-quality. The DGPADC under the Ministry of Health (MOH) regulates generic pharmaceuticals in Oman[11].

4.4.2. Steps involved in the approval process

The regulatory process in Oman has the following essential phases that affect pharmaceutical approval time.

Submission phase

Sponsors usually submit product registration files to the authorities. Completed documents are required for formal acceptance. During validation, the following factors are checked;

- Legal status of applicant/local agent
- G.M.P. status of the manufacturer
- Registration dossier organization
- Certificate of a pharmaceutical product (CPP) validated by the embassy/consulate general.

Evaluation phase

The product quality, safety, and effectiveness data are reviewed scientifically. Sponsors have 90 to 180 days to respond to inquiries, depending on whether they are about big or small concerns. The drug control department sends the marketing permission application evaluation report and suggestion to the registration committee within 90 days, which determines within 30 days.

Authorization phase

After reviewing the product, the registration authority approves the marketing and price. The authorization committee chair signs a product registration certificate within two weeks following the committee's affirmative decision. If the registration committee rejects the application, the sponsor may appeal within 60 days, or a fresh submission is necessary.

4.4.3. Required documents for registration;

- The manufacturer's legalized cGMP certificate.
- List of Company products.
- Legalized CPP
- Registered and marketed nations list with photocopies of registration documents.
- A document proving the relationship between the firm's[12].

Table 3: Review stages and interval periods per DGPADC

S. No	Review of stages	Period (days)
1	Validation time	1
2	Assessment time	90
3	Company response	90 - 180
4	Committee time	30
5	Authorization time	2
	Overall approval time	120

4.5. United Arab Emirates (UAE)

The UAE is in the Persian Gulf, southeast of the Arabian Peninsula, bordering Saudi Arabia to the south and Oman to the east. The UAE government wants to improve healthcare governance to deliver world-class care. The UAE has the Ministry of Health (MoH), the Health Ministers' Council for the Gulf Cooperation Council, the Health Authority of Abu Dhabi (HAAD), and the Dubai Health Authority[13].

4.5.1. Steps involved in the approval process

Submission of application

The manufacturer applies for generic medicine registration with the UAE regulatory body. Drug registration, often called product licensing or marketing permission, is crucial to drug regulation. Only manufacturing plant inspection and laboratory quality control analysis can ensure product quality and safety[14]. The submission steps are illustrated in Fig 4.

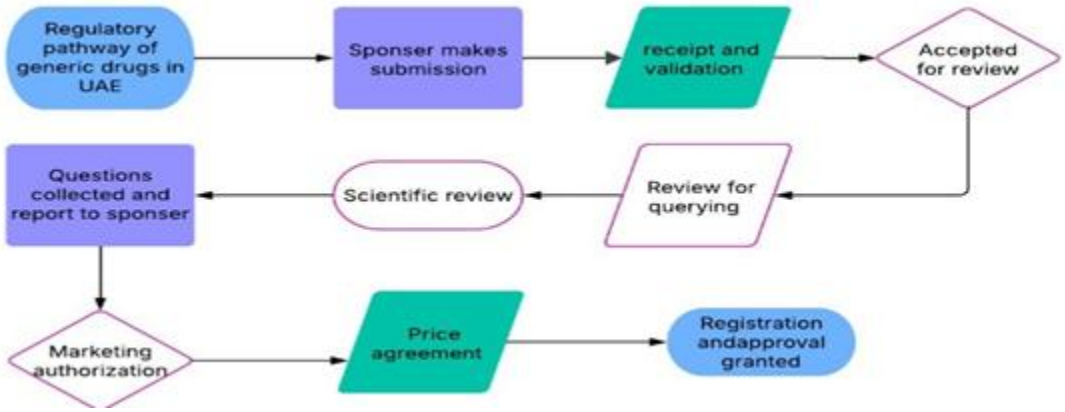

Figure 4: Regulatory pathway for generic drugs

4.5.2. List of documents required

- The product has a legal free sale certificate from the authorities, confirming its registration and marketing under the same name and content.
- An attested analysis certificate from health authorities and the place of origin.
- Identify developed nations where the product is registered

- Pharmaceutical product sterility and pyrogen-free certificate.
- Post-market monitoring and bioavailability studies[14].

4.6. QATAR

Qatar earned USD 227 million in 2010 from its growing pharmaceutical sector. Qatari German Company for Medical Devices (QGMD) and Scientific Medical Applied Research and Development Company (SMARD) are contemporary pharmaceutical industry advancements. The Pharmacy and Drug Control Department decides the national drug policy[15].

4.6.1. Steps involved in the approval process

Application-online filing

The applicant must use the PDCD E-system to complete the application. After the administration reviews the application, a submission time will be scheduled. The agent may email the Human Pharmaceuticals Licensing Division administration for a timing change.

Acceptance of submission

The PDCD team will review the paper to ensure the procedure meets all submission criteria. Non-deficient application system: The applicant will get a physical confirmation confirming their application's approval, and the record will advance to the next step.

Evaluation

The applicant will be informed by email and given four months to respond to any comments or issues once a product's application is considered. The applicant must indicate that the marketing authorization holder received the comments. If the prerequisites are not satisfied within four months, the application will be refused, and the applicant will be told to pick up the file.

Application acceptance

The licensing committee will review the file after verification, assessment, and after the applicant meets the MAH criteria. The applicant will receive the committee's verdict. If the committee requires further information, the applicant has four months to respond[16]. The entire process represented in Fig 5.

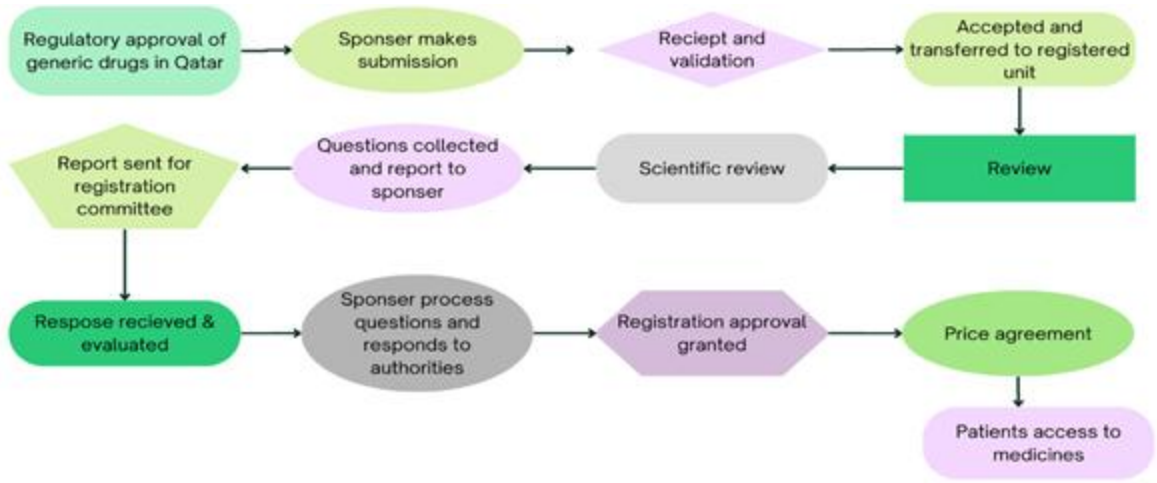

Figure 5: Regulatory pathway for generic drugs

4.6.2. Documents required for submission:

- Completed application form for generic drug registration.
- Product information.
- Manufacturing facility information.
- Bioequivalence study report.

Labelling and packaging materials[17].

Key differences

This research sought to investigate GCC regulatory review procedures for comparison. Identifying the steps similar to GCC review procedures and calculating the best schedule for completing each milestone created a standard base for a uniform review process.

CONCLUSION

In this study, we found that the registration procedure may vary slightly and needs to be consistent so that applicants do not change the format and information is clear and transparent to facilitate review and help reviewers get started. A comparative analysis of the regulatory approval procedures, timelines, fee payment and required documents for submission used by the GCC authorities has been provided in the present study. It was possible to propose the new method because of the similarities and differences in several of the significant milestones and activities carried out in the GCC states. This method has the potential to support the degree of standardization necessary for a robust regulatory body that facilitates an effective drug approval process for the region, which may contribute to other initiatives in other areas.

Table 1: Comparison study of Gulf counties[18, 19 and 20]

Countries group	Saudi Arabia	Qatar	Oman	Bahrain	UAE	Kuwait
Regulatory authority	Saudi Arabia Drug Authority (SFDA)	Ministry of Public Health Organization (MPHA)	Ministry of Health Muscat (MHH)	National Health Regulatory Authority (NHRA)	United Arab Emirates, Ministry of Health & Prevention (UAE-MHP)	Kuwait Food and Drug Authority (KFDA)
Manufacturing license	Required	Required	Required	Required	Required	Required
Registration validity	5years	5years	5years	5years	5years	5years
Registration time	24-36 months	24-36 months	24-36 months	24-36 months	24-36 months	24-36 months
Registration fees #	USD10,666	USD250	USD160	160USD	AED7100	--
Plant inspection fees	80,000 SAR	No fees are required	Yes	RM20,000.00	AED50000	--
Auditing	GCC member countries of the FP site	GCC member Countries of FP site	Oman FDA	GCC member countries of FP site	GCC member countries of FP site	GCC member countries of FP site
No of submission batches	3 pilot scale batches	3 pilot scale batches	3 pilot scale batches	3 pilot scale batches	3 pilot scale batches	3 pilot scale batches
Labelling requirements	Arabic translation artwork & description of a product is required according to stability studies.					
BE studies (Generics)	Gulf Health Council approved or endorsed the study sitebyanyof2competentauthorities, WHO, USFDA, TGA & MHRA.					
Any other requirements	Data requirement for each application will differ depending on the drug submission type. Required data should follow the GHC & ICH CTD in eCTD format. Registration fees apply to country-specific rules and laws.					

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