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Review Article **Open Access**

Navigating Regulatory Diversity: A Comparative Study of Drug Product Registration Frameworks in Malaysia, Ghana, Kuwait and India

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Abstract

Pharmaceutical products have to follow a set of rules that will eventually prove their quality, effectiveness, and safety before they can be sold in the market. However, it is important to note that the process and requirements, such as what is needed from the manufacturer, differ from one country to another. This is a problem for companies that want to register their products in several countries. The aim of this research project is to compare and highlight the regulation of drug product registration in Malaysia, Ghana, and India, as well as the role of the regulatory authorities in these countries and the steps that will be undertaken by companies in order for their products to gain marketing authorisation. There are four major areas that we are going to discuss in detail: what documents are required to be submitted to each country, how each country will evaluate the documents that are submitted to them for approval, the timeframe to get approval from each country, and what document are required to be prepared to get approval. The regulatory process in Malaysia follows the ASEAN common technical dossier (ACTD), whereas in Ghana and India, it follows a different system. In addition to that, some of the similarities and dissimilarities that exist in the regulatory process of both countries will also be addressed in this research. Moreover, it will also highlight how these dissimilarities will create a problem in the expedited approval of product registration services to firms. Finally, it will highlight some of the challenges that pharmaceutical firms are likely to face in a different regulatory environment. The results of the research would be beneficial for the international drug regulatory professionals. It would be beneficial for the researchers of international drug registration. In the end, the significance of the comprehension of the diversity of regulations would be highlighted.

Conclusion: The review also explains a brief about different regulatory requirement for Registration of drug product in Malaysia, Ghana, India and Kuwait. And also, comparative data for registration of dossier application in Malaysia, Ghana, India and Kuwait.

Keywords: Drug Registration Requirements; ACTD; CTD; eCTD; Regulatory Diversity; QUEST 3+; AMRH; WAHO; CDSCO;NPRA

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1. Introduction

Controlling the drug products has become a major component of the contemporary healthcare systems. Each nation has a mechanism of determining, licensing and overseeing medicines prior to their arrival to the patients. These regulation measures ensure that the medicines that the people consume are safe, effective and prepared under controlled circumstances. But despite the similarity in the objective, there is a wide disparity in the way the nations establish and implement their regulatory demands. Such difference results in varying approval procedures and paperwork requirements as well as a schedule. The systems should be understood individually and in the context of others. However, over the last two decades, most nations have enhanced their drug regulatory systems as a result of increasing demands in the general health status, quality requirements, and international consistency. Other organizations such as WHO, ICH, and regional groups such as ASEAN have encouraged nations to use standardized procedures. Nevertheless, this is not entirely consistent, particularly in the new markets where the frameworks of administration, legal frameworks, and technology levels vary greatly. Malaysia, Ghana, Kuwait and India represent four different regions that have varied regulatory environment which is informed by healthcare demands, economic potential and national policies. NPRA has established institutionalized assessment channels and an online submission program in Malaysia known as QUEST 3+. (1)

This facilitates transparent and foreseeable registration. With FDA Ghana, Ghana is still continuing to improve its capacity with WHO-listed authority status and local-

oriented guidelines. (2) Kuwait has a centralized system, whose requirements are influenced by the Gulf health standards and are administered by its Drug Regulatory Authority. India, which is under the supervision of CDSCO, is governed by an extensive system of legislation and performs its processes in accordance with the needs to enhance efficiency and stay in line with international standards. Although all of these countries possess their advantages, there are often complications in situations when an applicant has to work with several regulatory frameworks simultaneously. (3)

These variations may have an effect on the speed of registration of a product, the quantity of paperwork required, and the overall price and effort. These regulatory differences should be known in order to plan good product registration strategies. Even a simple comparison between Malaysia, Ghana, Kuwait, and India can be used to identify similar regulatory factors, some of the country-specific needs, some aspects where processes are more complicated, and opportunities to enhance uniformity or efficiency. The knowledge will help in enhanced regulatory preparedness, minimize submission errors and facilitate a less arduous approval procedure. This paper will attempt to summarize in a concise comparison all the details about these four regulatory systems. The study gives a literary summary by examining their registration requirement, evaluation processes, schedule and post-marketing requirements, which help highlight the significance of regulatory heterogeneity and the necessity to comprehend how different nations address drug products approvals. (1-3)

2. Introduction of Selected Countries:

2.1 Malaysia

Malaysia is also one of the most civilized and structured pharmaceutical regulatory systems in the ASEAN region. Under the Ministry of Health (MOH) is the National Pharmaceutical Regulatory Agency (NPRA) which monitors quality, safety and efficacies of the pharmaceuticals sold in the nation. Drug registration in Malaysia is based on ASEAN Common Technical dossier (ACTD) and ASEAN Common Technical requirements (ACTR). This is indicative of the great interest that the country has in collaborating with the regional partners. As a part of the NPRA, an online submission system named Quest3+ has been established enabling applicants to place, monitor and handle applications electronically. The regulatory system also categorizes the products as new drugs, generics and biologics with specific data submission requirements. Pre-marketing assessments include quality checks, clinical and non-clinical as well as Good Manufacturing Practice (GMP) checks. Malaysia is also involved in international programs, such as PIC/S (Pharmaceutical Inspection Co-operation Scheme), the WHO prequalification programs indicating that it is in line with international standards. Malaysia is the ideal example of regulatory maturity that other member states in the ASEAN could follow since the regulatory processes and guidelines are simple, and the country follows the ACTD format. (1)

2.2 Ghana

Ghana is one of Sub-Saharan Africa's regulatory success stories. The Ministry of Health has a Food and Drugs Authority (FDA Ghana) that regulates pharmaceuticals, medical devices, cosmetics, and food products. The regulatory system of the country is at Maturity Level 3 of WHO Global Benchmarking Tool (GBT), which implies that it has a strong and operational authority that regulates the safety and efficacy of products. It is grounded in the Public Health Act, 2012 (Act 851), according to which FDA has the mandate to enforce regulations, conduct GMP inspections, as well as oversee product safety once they are in the market. Ghana is also an active participant in the African Medicines Regulatory Harmonization (AMRH) program, which aims to harmonize the regulatory practices of the members of the African Union (AU). In Ghana, the dossier is based on the Common Technical Document (CTD) and the registration process entails submission of dossier, however it is not completely in line with the ICH CTD format. Evaluations consist of administrative, quality, non-clinical and clinical data. Also, there are locally required laboratory tests and GMP verification which precedes obtaining approval. Due to its open regulatory operations and progressive developments, the FDA of Ghana has emerged as a role model in the Economic Community of West African States (ECOWAS), and that is of interest in terms of capacity and harmonization development throughout the African continent. (2)

2.3 Kuwait

The pharmaceutical regulation system in Kuwait is under the ministry of health (MOH), which is primarily the Drug and Food Control Administration (DFCA), commonly referred to as the Kuwait Drug and Food Control Administration (KDFCA). Kuwait, being a member of the Gulf Cooperation Council (GCC) is a participant in the GCC-DR (Drug Registration) system. It is a local procedure whereby member states are able to evaluate pharmaceutical products with each other. Nevertheless, Kuwait has its national registration policies even with GCC involvement. This implies that once a product has been approved by GCC, it must still submit one more to the MOH of Kuwait to be approved to market the product in the country. The guidelines of the country are mostly based on GCC Common Technical Requirements (GCC-CTR), which is similar in structure to the ICH CTD. Quality, safety, effectiveness and bio equivalence data are evaluated. Certificates and import licenses are necessary and a foreign applicant has to have a local agent or distributor. The relationship between the regional cooperation and national independence in the regulatory affairs is demonstrated by Kuwait depending on GCC assessment but retaining national powers. The presence of Kuwait in the current study provides a good insight on the Middle Eastern regulatory environment particularly the harmonization of the region (GCC) and local variations in the application.

2.4 India

The pharmaceutical regulatory system in India is very complex and large. Approving, controlling and monitoring drugs and clinical trials are the mandate of the Central Drugs Standard Control Organization (CDSCO) under the

ministry of health and family welfare. These acts form a strong basis of marketing pharmaceuticals, biologics and imported drugs. The format of new drug applications in the country is based on Common Technical Document (CTD) or eCTD, which is very similar to the international standards. The CDSCO has Zonal and Sub-zonal offices, Central Drugs Laboratories and State Drug Control Authorities that gives both centralized permission and decentralized enforcement. The regulatory environment in India has rapidly developed to enhance transparency, the use of online application systems, including SUGAM portal, and to simplify the process of reviewing generics and new drugs. Some reliance pathways have also been embraced by the country. These involve the admission of foreign clinical trial information under specific circumstances and expedited approval of drugs that are already approved by the reference authorities such as the US FDA or EMA. (3)

3. Malaysia Regulatory Landscape

The National Pharmaceutical Regulatory Agency (NPRA), which operates under the Ministry of Health (MOH), is in charge of Malaysia's drug product registration system. The system guarantees that all pharmaceuticals sold in Malaysia adhere to strict safety, efficacy, and quality criteria. The Sale of Drugs Act of 1952 and the Control of Drugs and Cosmetics Regulations (CDCR) of 1984 govern how NPRA operates. and supporting technical guidelines that outline the requirements for submission, evaluation, approval, and post-marketing monitoring. The registration framework follows a structured and transparent sequence of administrative and scientific activities, beginning from the preparation of documentation and submission through the QUEST 3+ online platform and ending with post-approval responsibilities. The main source of information for applicants is the Drug Registration Guidance Document (DRGD) and provides detailed instructions on dossier format, evaluation routes, timelines, and regulatory expectations.

3.1 Application Methods:

a) Product Registration Application

- The applicant for product registration, referred to as the Product Registration Holder (PRH), must be a corporate or legal entity that is locally incorporated, have a permanent address, and be registered with the Companies Commission of Malaysia (SSM) (with business scope related to health/pharmaceutical product).

b) The following cannot be reflected in the PRH's name, including the product manufacturer:

- Government agency name
- Higher education/research institute name
- Any name that conveys the caliber of pharmaceuticals, such as <Amalan Perkilangan Baik (APB)=, Good Manufacturing Practice (GMP)
- The name of a disease;
- The name of an organ, such as the kidney, brain, or heart.

c) If the product owner is not the applicant, the product owner must give written consent to the PRH to hold the product registration and be in charge of any issues relating to the product's efficacy, safety, and quality. (1)

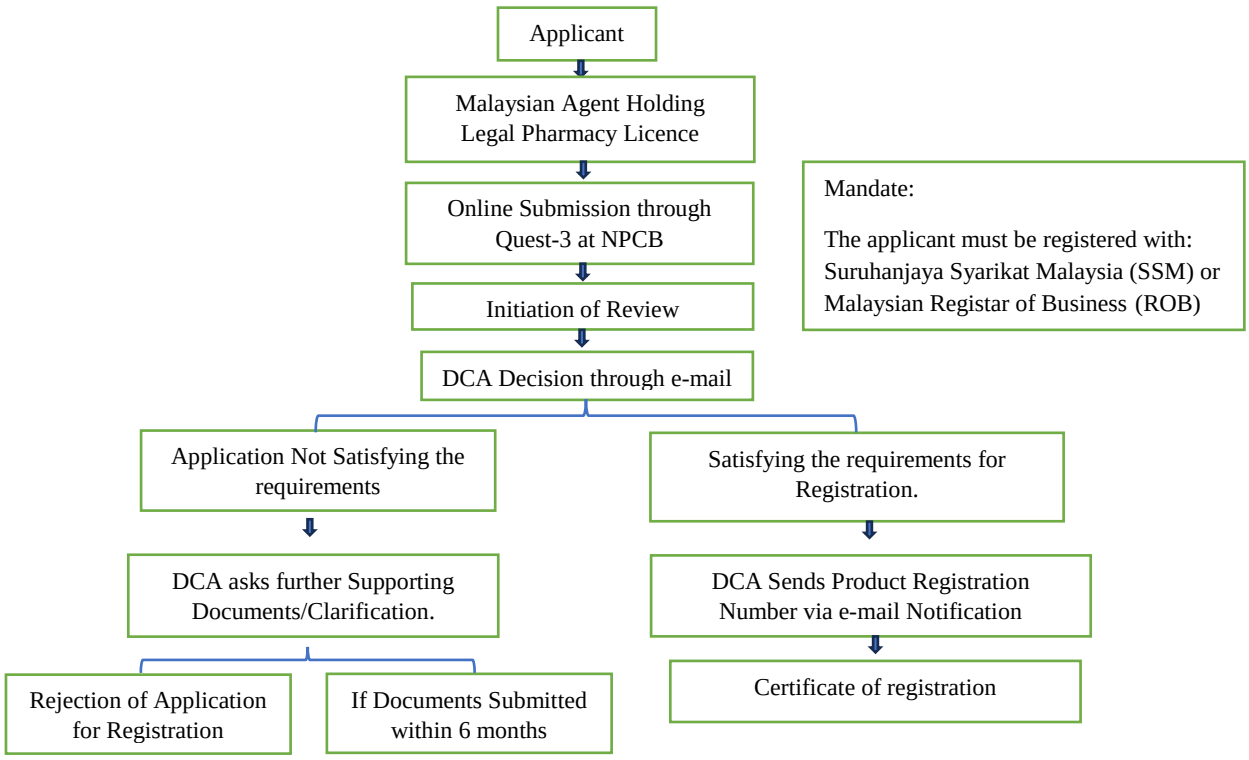


Figure 1. Drug Registration & Approval Process

3.2 Evaluation Process

Table 1. Evaluation Timeline for Approval (1)

No.	Product Category	Evaluation Timeline
(A)	**Full Evaluation**	
	Generic (Schedule Poison)	210 Working days
	Generic (Non-Schedule Poison)	210 Working days
(B)	**Abridged Evaluation**	
	Generic (Non-Schedule Poison)	
	i.) Single Active Ingredient	116 Working days
	ii.) Two or more active Ingredients	136 Working days

4. Ghana Regulatory Landscape

The national regulatory agency in charge of guaranteeing the efficacy, safety, and quality of all pharmaceuticals, medical equipment, cosmetics, home chemicals, and processed foods in Ghana is the Food and Drugs Authority (FDA). The FDA was founded under the Public Health Act, Act 851 (2012), and operates as a separate regulatory body within the Ministry of Health. Its purpose encompasses the entire pharmaceutical product lifecycle, from pre-marketing evaluation to post-market surveillance, guaranteeing that only goods that satisfy accepted scientific and regulatory requirements are made accessible to Ghanaians. The regulatory system of the FDA is structured around internationally recognized principles and aligns with global standards, including WHO, ICH, and regional harmonization projects under the African Medicines Regulatory Harmonization (AMRH) program and the West African Health Organization (WAHO). This convergence has enhanced the powers of the authority in making sure that there is effective control of the imported and locally produced products. Another advantage is that FDA is a WHO-listed authority (WLA), which is an indication that the organization is moving in the right direction to become one of more developed systems of regulation in Africa.

Among the tasks of the FDA is the registration of its products, the licensing of manufactures and importers, the inspection of production facilities, laboratory testing, pharmacovigilance, and the protection of the health of people. The product registration mechanism makes sure that the pharmaceutical commodities presented to the marketing authorization have specific quality, safety, and therapeutic effectiveness standards. The authority must receive dossiers in formats like, the CTD (Common Technical Document) Evaluation involves an extensive scientific examination, the GMO verification, an evaluation of the stability data, clinical or bioequivalence evidence and the risk-benefit examination. The FDA has a transparent evaluation process that is facilitated by advisory committees, which give expert advice to the final decisions.

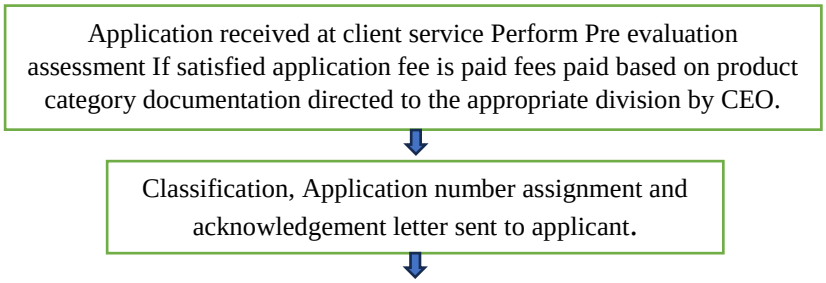
4.1 Drug product Registration Procedure

Registration starts with pre-submission stage where the applicants can seek prior advice of the FDA on dossier requirements, regulatory routes and local demands. The foreign manufacturers are required to have a local authoritative representative who will handle communication and regulatory requirements in Ghana. This stage allows applicants to clarify technical requirements, reduce submission errors, and ensure that all needed documents align with FDA standards.

Following pre-submission, the applicant proceeds to the submission stage, where a complete dossier is submitted in CTD format, along with application forms, samples, proof of payment, and all required certificates. FDA Ghana accepts electronic submissions to increase efficiency and reduce administrative burden. Once submitted, the dossier undergoes a validation (screening) phase. In this phase, the FDA verifies the completeness of the dossier, ensuring that all CTD modules and required administrative documents are present. Failure to meet completeness criteria results in the application being returned for correction before formal evaluation begins.

- ❖ CTD Modules
- ❖ Quality Information Summary (QIS)
- ❖ Quality Overall Summary (QOS)
- ❖ Samples requirement. (2)

4.2 Evaluation Process (4)



Application Acceptance Phase

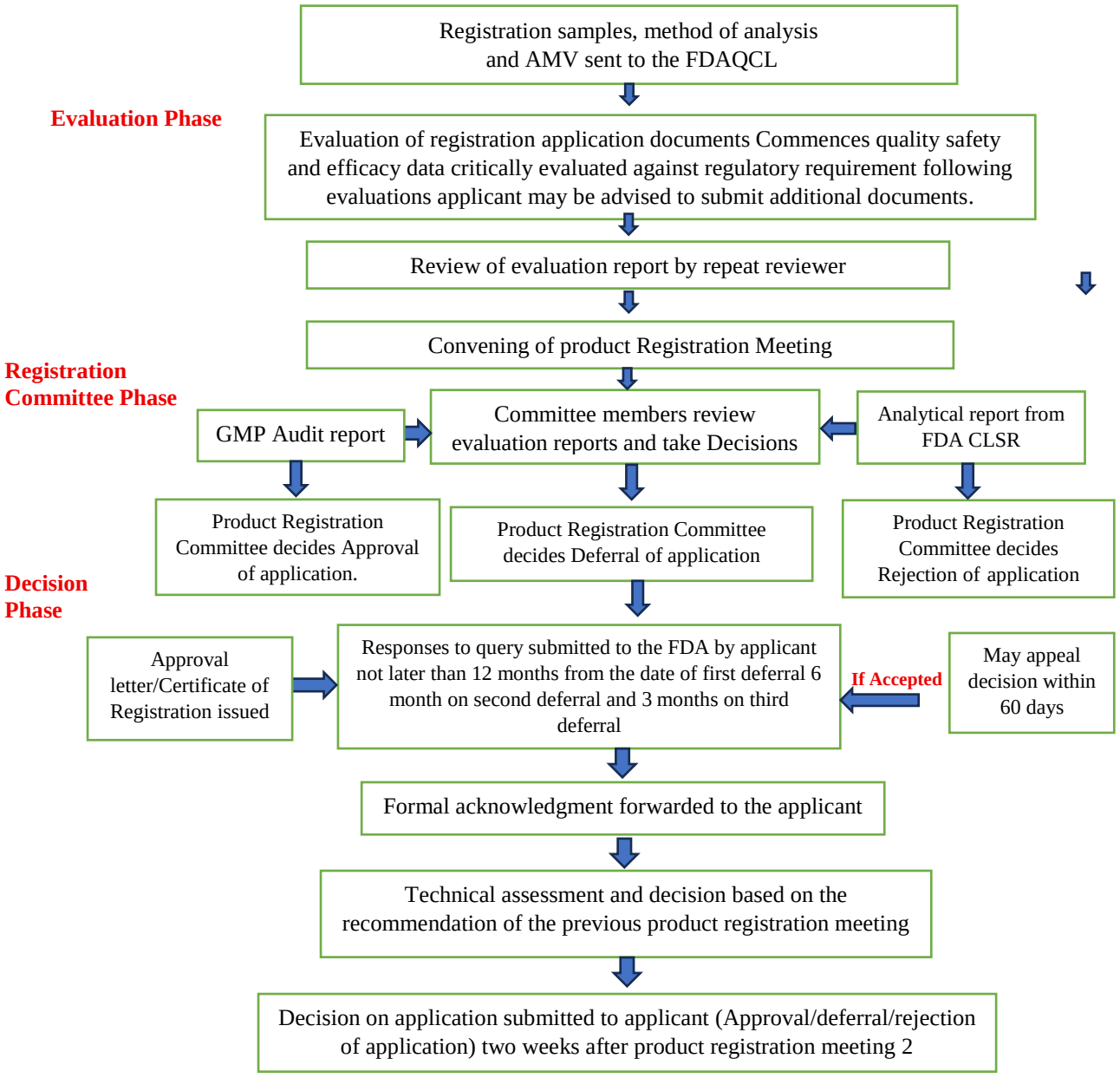
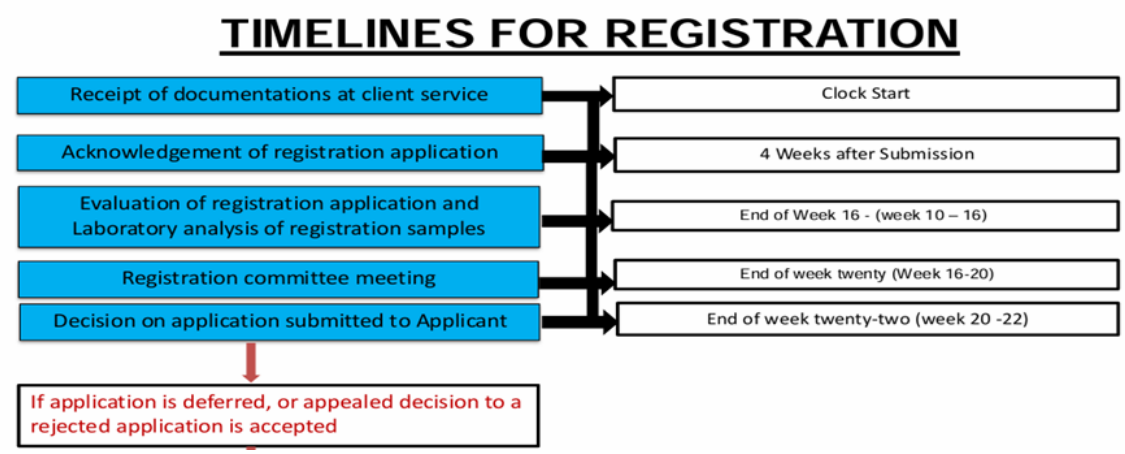


Figure 2. Evaluation Process for Ghana

4.3 Timeline for Registration (5)



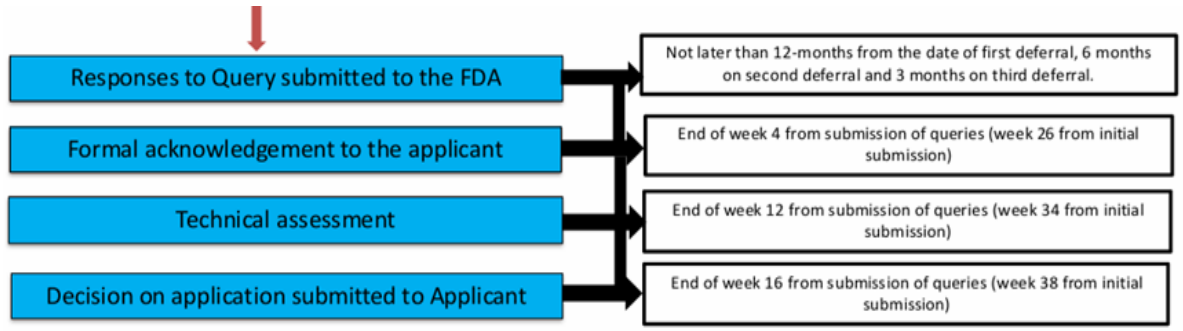


Figure 3. Timeline for Approval in Ghana

5. India Regulatory Landscape

India's national regulatory body, the Central Drugs Standard Control Organization (CDSCO), is in charge of guaranteeing the effectiveness, safety, and quality of medications, medical equipment, vaccines, blood products, and cosmetics that are sold there.

The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, together provide the legal foundation for the production, importation, distribution, and regulation of pharmaceuticals in India.

As the top regulatory agency, CDSCO is essential to preserving public health and guaranteeing the availability of pharmaceuticals that have undergone quality assurance and scientific evaluation throughout India's extensive and varied healthcare system.

CDSCO is headed by the Drugs Controller General of India (DCGI), who serves as the principal regulatory authority for new drug approvals, clinical trial oversight, import licensing, and the overall coordination of regulatory functions across the country. CDSCO operates through a network of zonal, sub-zonal, port, and central laboratories, allowing it to maintain regulatory oversight over both domestically manufactured and imported products. Its collaboration with State Licensing Authorities (SLAs) forms a dual regulatory system—while CDSCO oversees new drugs, large-scale approvals, and imports, the SLAs manage manufacturing site licenses and distribution at the state level. (3)

5.1 Drug Product Registration Procedure

a) Registration Certificate Application (Form 40)

- Using Form 40, the manufacturer or authorized agent requests the Registration Certificate.
- The application must contain comprehensive details regarding the pharmaceutical items to be registered for import into India, the manufacturer, and the manufacturing facilities.
- Declarations and undertakings pertaining to production procedures, labeling, packaging, quality standards, and adherence to the Drugs and Cosmetics Act are necessary.

b) Supporting Documents

- A power of attorney that gives the Indian agent permission.
- Form 8: Request for authorization to import medications other than those listed in Schedule X.
- Form 9: Notarized undertaking accompanying the import license application.
- Covering letter specifying the intent and a list of documents submitted.
- Fees as prescribed under the Drugs and Cosmetics act.
- Good Manufacturing Practice (GMP) certificate or Certificate of Pharmaceutical Product (CPP) of the foreign manufacturer.
- Registration Certificate in Form 41 issued by CDSCO for the proposed drug.
- Wholesale license or manufacturing license for sale or distribution issued by the State Licensing Authority.
- Market authorization.

c) CTD Modules

5.2 Evaluation Process

- Filling out Form 40 with supporting documentation, such as a Power of Attorney, a GMP certificate, a Free Sale Certificate, product details, and more.
- A thorough examination of drug product registration data (Schedule DII) and manufacturing site registration (Schedule DI).
- Manufacturing facilities may be inspected or audited.
- Samples of drugs Approved laboratories may evaluate drug product samples.
- Evaluation of adherence to the Drugs and Cosmetics Act and Regulations.
- It is necessary to offer and verify compliance commitments pertaining to production modifications, adverse reactions, labeling, packaging, and other areas.

5.3 Timeline for Approval

- Within nine months of receiving the application, the licensing authority will issue the Registration

Certificate if the application is complete and the information in Schedules DI and DII is correct.

- This time frame may be extended by up to three months in extraordinary circumstances, with written justification.

6. Kuwait Regulatory Landscape

The pharmaceutical regulatory mechanism in Kuwait is designed to facilitate stringent control of human drug products in order to safeguard the health of the people. This majorly occurs via the Pharmaceuticals and Herbal Medicines Registration and Control Administration (KDRA) in the Ministry of Health (MOH). The foreign manufacturers will be required to work through a licensed local agent and present complex electronic Common Technical Document (eCTD) dossiers. This has been ensured since September 2025 under Administrative Decision No. 82/2025 and this is after the harmonization process of the Gulf Health Council (GHC). It aids in a market penetration process and gives priority to those products that have been cleared by the world regulatory authorities such as the FDA or EMA.

KDRA, which is a branch of MOH has the sole mandate to certify, assess and supervise all human pharmaceuticals in Kuwait. Foreign firms are not allowed to apply directly, they should choose an exclusive agent in Kuwaiti local, this may be a pharmacy or trading company. Such an agent is required to possess legitimate MOH import and distribution licenses, registration with the Ministry of Commerce and Industry, and adherence to the Civil ID regulations. The KDRA collaborates with GCC Drug Technical Committee in an attempt to develop standardized standards. They also provide fast-tracked reviews, which last approximately30 days, to pre-approved products in EMA, FDA or Health Canada, provided they contain Certificates of Pharmaceutical Product (CPP) and Free Sale Certificates. Decisions can be appealed to the MOH Undersecretary and the process is transparent through the use of a public e-Portal. (6)

6.1 Drug Product Registration Procedure (6)

This is done in sequential phases, taking 120-240 days for normal cases, though this is less for FDA/EMA approved products. Each phase has its requirements, responsible entities, deliverables, and deadlines, as well as potential pitfalls, based on Ministerial Decree No. 361/2019, Decree No. 16/2021, and e-CTD guidelines.

a) Pre-Submission Preparation (MAH & Local Agent; 4-8 Weeks)

- Appoint an exclusive Kuwaiti local agent (pharmacy/trading firm) holding MOH Category A/B import license, Ministry of Commerce registration, and storage approval. MAH provides a legalized Power of Attorney (PoA; e-Apostille/Embassy Attestation), GMP Certificates (site-specific, issued within 3 years), CPP (WHO Format), and Manufacturing Licenses. Prepare a full e-CTD v4.0.1 dossier (Modules 1-5) for Kuwait/GHC, including Zone IVb data (30°C/75% RH, 12+ months), Arabic labels, and a Kuwaiti import license. Validate using free e-CTD tools; agent will register on https://eservices.moh.gov.kw/SPCMS/pharmproduct.aspx.

b) Online Submission (Local Agent; Day 0)

- Log in to KDFC e-Portal, submit application (new registration, variation, or renewal), and upload e-CTD (in e-Portal, <100 MB per leaf, virus scan), and pay fees (KD 100-300 for new drugs). Flag physical sample request if necessary. e-Portal will automatically send an acknowledgment receipt.

c) Administrative Screening (KDRA; 10 Working Days)

- KDRA checks for completeness: agent's credentials, Module 1 docs (PoA, CPP, labels), fee payment, and eCTD compliance. If incomplete, files returned to agent via portal, and no fee is refunded. If administrative gaps exist, queries raised (e.g. Arabic PIL missing). If complete, files proceed to technical evaluation. Metrics: ~90% pass rate after baseline phase.

d) Technical Evaluation (KDRA Experts; 90-150 Working Days)

- Parallel panels for technical evaluation:
- Quality (Module 3): Impurities (ICH Q3), stability, and manufacturing controls.
- Nonclinical (Module 4): PK/tox bridging for generics and biosimilars.
- Clinical (Module 5): Efficacy and safety, RMP, and PSURs.

6.2 Evaluation Process

- Auto-validation (eCTD compliance);
- Admin review;
- Parallel expert panels (quality: impurities/stability; nonclinical: tox/PK; clinical: efficacy/RMP);
- Risk-benefit matrix (GCC DRP score);

Director approval/rejection letter with rationale; pharmacovigilance integration via PSURs.

6.3 Timeline for Approval

Table 2. Approval Timeline for Kuwait

Category	Target Timeline
FDA/EMA Fast-Track	30-90 working days
New Drugs/Generics	120-180 days
Renewals	60 days
Screening	10 days

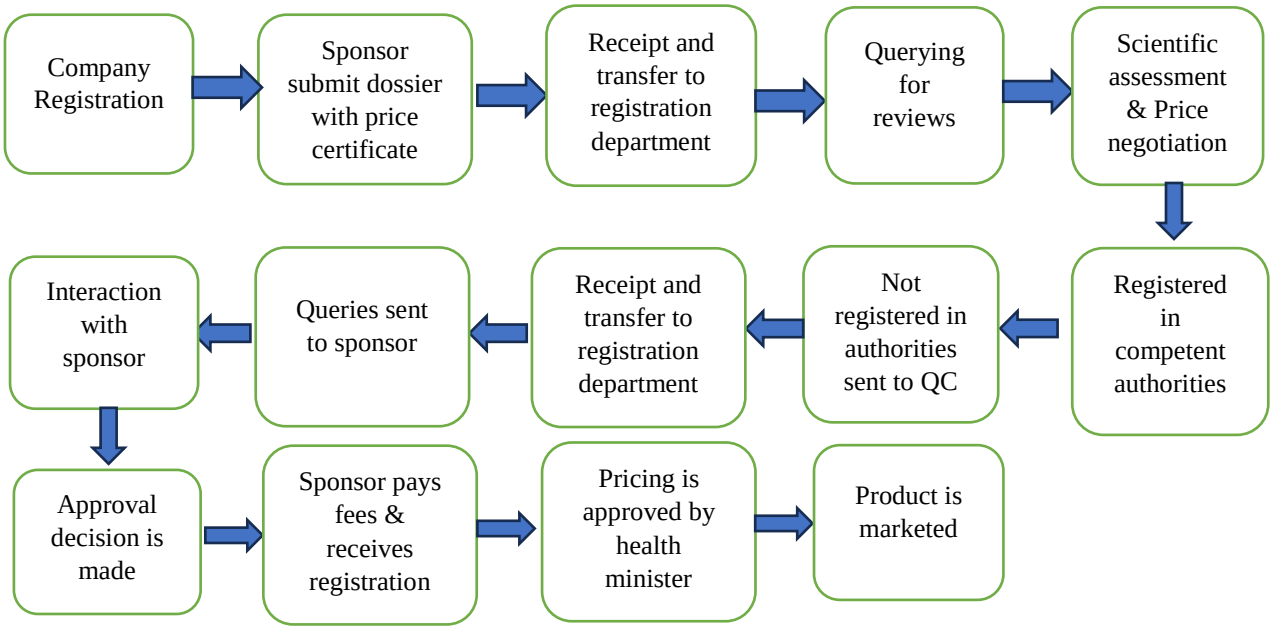


Figure 4. Drug Product Registration for Kuwait

7. Comparison of registration requirements of Malaysia, Ghana, India and Kuwait

Table 3. Comparative Overview for all Countries

Parameter	Malaysia	Ghana	India	Kuwait
Regulatory Authority	National Pharmaceutical Regulatory Agency (NPRA) under the Ministry of Health	Food and Drugs Authority (FDA Ghana) under the Ministry of Health	Central Drugs Standard Control Organization (CDSCO) under MoHFW	Ministry of Health (MOH) & Kuwait Drug Regulatory Authority
Legal Framework	Drug Registration Guidance Documents (DRGD)	Public Health Act, 2012 (Act 851)	Drugs & Cosmetics Act, 1940 and Rules, 1945	Law No. 82/2025 and Ministerial Decision No. 164/2021
Application Format	ACTD (ASEAN Common Technical Dossier)	CTD format (Common Technical Document)	CTD format	eCTD format
Who Can Apply	Local agent registered with NPRA	Local representative or marketing authorization holder	Indian authorized agent or importer	Local authorized representative or agent
Pre-requisites	GMP certificate from authority	Free Sale Certificate, GMP certificate, and CPP	Site and product registration (Form 40), GMP/COPP certificate	GMP certificate, FSC, CPP (Legalized)
Key Documents	Cover letter, ACTD modules, GMP, CPP, product label, stability data	Dossier in CTD format, GMP, COPP, Free Sale Certificate, label samples	CTD Modules, Form 40, Power of Attorney, Manufacturing & Wholesale License	eCTD dossier, GMP, CPP, FSC, labeling, stability data, PoA
Evaluation Process	Administrative screening → Technical evaluation (quality, safety, efficacy) → Committee review → Decision	Dossier screening → Technical review → Expert Committee evaluation → Final approval	Dossier review by CDSCO → Laboratory testing of 3 batches → Site inspection (if required) → Approval	Screening → Review → Committee → Approval
Timeline for Approval	Approx. 210-220 working days (8–9 months)	Approx. 6–9 months for full review; fast-	9 months (extendable to 12 months in special cases)	6-12 months

		track available for priority products		
License Validity	5 years	3 years	5 years	5 years
Renewal Requirement	Submit renewal application 6 months before expiry	Renewal 3 months before expiry	Renewal 9 months before expiry	Submit renewal application 6 months before expiry

Table 4. Comparison of Dossier Format

Module/Part	CTD (Common Technical Document)	ACTD (ASEAN CTD)	eCTD (Electronic CTD)
Overall Structure	5 modules: Regional admin + summaries + quality/nonclinical/clinical	4 parts: Admin/product info + quality/nonclinical/clinical (summaries embedded)	Same 5 modules as CTD, but XML-based with backbone for lifecycle
Module 1/ Part I	Regional Administrative Information	Administrative and Product Information	Regional admin (granular XML folders)
Module 2/ Part II	CTD Summaries (quality, nonclinical, clinical overviews)	Quality (embedded in Part II)	Quality Summaries (XML-indexed)
Module 3/ Part III	Quality/CMC data	Nonclinical Study Reports	Quality (file folders, metadata)
Module 4/ Part IV	Nonclinical Study Reports	clinical Study Reports	Nonclinical Study Reports (XML-linked PDFs)
Module 5	Clinical Study Reports	--	Clinical Study Reports (XML-linked PDFs)

Table 5. Comparison of Documents Requirement

Document	Malaysia	Ghana	India	Kuwait
Application Form	NPRA form with cover letter	FDA application form	Form 40/41 for import	PDCD application dossier
Dossier Format	ACTD modules	CTD format	CTD modules	eCTD format
GMP Certificate	Valid GMP from authority	GMP + Free Sale Certificate	GMP/COPP	GMP from origin authority
Free Sale/CPP	CPP or Free Sale Certificate	CPP, COPP, Free Sale Certificate	COPP	CPP + Free Sale Certificate
Power of Attorney	From manufacturer to local agent	To local representative	To Indian importer/agent	To local sponsor/agent
Product Labels	Draft and final labels	In French and English	Labeling compliance	Arabic/English labels
Manufacturing License	Site licenses	Manufacturer details	Form 20B/21B licenses	Manufacturing authorization

8. Conclusion

The processes for regulations in Malaysia, Ghana, Kuwait, and India vary considerably. Efforts to harmonize and expedite these processes can facilitate the approval and access of essential medicines for patients.

Drug registration in Malaysia, Ghana, Kuwait, and India. There are considerable differences in dossier styles, assessment schedules, and approval mechanisms. These differences impact the swiftness of drug access. Efforts to harmonize and expedite these processes can facilitate the approval and access of essential medicines for patients. Understanding the diversity in drug regulations empowers pharmaceutical professionals to plan smarter strategies for global drug registrations.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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