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An Overview of the Allopathic Drug Registration Process and Requirements in Ghana

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Abstract

Ghana is one of the most developed countries in the West African region, second only to Ivory Coast. The Food and Drug Authority (FDA) of Ghana regulates the quality, safety, and efficacy of medicinal products. Recently, the government has increased its focus on the healthcare sector, allocating a free zone to promote in-house manufacturing of pharmaceutical products. Drug product registration in Ghana is less complex compared to other developing African countries. Recently, Ghana's National Regulatory Authority (NRA) achieved maturity level 3 according to the WHO GBT scheme. The FDA accepts dossiers in the Common Technical Document (CTD) format as per the ICH guidelines (M4). Additionally, there are special provisions to fast-track the registration process. However, the FDA is still behind in terms of dossier submission via eCTD software, and there is no way to track applications after submission; applicants must visit physically to check the status. Nevertheless, Ghana is continuously improving its processes with the help of the WHO to streamline the registration process. This paper summarizes the process and requirements for the registration of allopathic drugs in Ghana.

Keywords: *Regulatory Affairs, Emerging markets, FDA Ghana, Allopathic Drug, ICH, CTD, WHO GBT, NMRA*

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1. Introduction

Ghana, an English-speaking country officially known as the "Republic of Ghana," is located in the West African region. It shares borders with Côte d'Ivoire (Ivory Coast), Togo, and Burkina Faso, with a population of 34,427,414 in 2024. Demographically, more than half of the population (58.6%) lives in urban areas. (1)

It is a lower-middle-income country with a GDP per capita of US$ 2,260.3 in 2023. (2)

The country faces a high burden of deaths from non-communicable diseases (46.8%) and communicable diseases (43.2%) as of 2021. The leading causes of death are stroke, tuberculosis, and lower respiratory infections. According to WHO data, the top causes of death in Ghana are shown in figure (1). (3)

A major contributing factor to these deaths is the shortage of medicines (drugs), their high prices (which many individuals cannot afford), and concerns about the quality of the medicines. The pharmaceutical sector in Ghana is growing rapidly and is the largest in the West African region. In 2021, the value of the pharmaceutical market was around US$ 443 million, which is relatively small on a global scale. Prescription medicines dominate the market, accounting for 74% of the market share, compared to over-the-counter (OTC) medicines, which make up 26%.

One of the major reasons for this growth is the government's commitment to improving the healthcare system and expanding access to essential medicines at affordable prices. The government of Ghana has implemented the National Health Insurance Scheme (NHIS), which aims to provide affordable healthcare to all citizens of the country. Additionally, the government is making efforts to increase local pharmaceutical manufacturing capability, which will positively impact the pharmaceutical market index. (4)

The Ghanaian pharmaceutical market depends heavily on foreign inputs and pharmaceutical products. Around 70% of medicines are imported from outside the country, while 30% are manufactured locally. India and China are key players in exporting medicines to Ghana. (5,6)

By 2026, healthcare expenditure in Ghana is anticipated to grow at a compound annual growth rate (CAGR) of 7.3% in local currency (8.3% in US dollars) to GHS 24.5 billion (US$ 3.7 billion). Private spending accounts for 55% of the market but is projected to grow at a faster rate than government spending (13.7% vs. 7.4% in local currency).

While total health expenditure is expected to almost double in the long term, annual per capita spending will post a much lower growth rate, increasing from US$ 77.0 in 2021 to US$ 104.4 by 2026. The government provides support for healthcare by regional standards, but most of the support relies on external assistance from international organizations. For example, the United States Agency for International Development (USAID) recently completed a 5-year project with the Ghanaian government and other partners to improve fundamental aspects of the health system. China has provided specialist surgeons to enhance capabilities in Ghana and has trained Ghanaian doctors in China. (4)

According to Pharmexcil data from 2020, the majority of medicine sales in the country are from generic medicines (60%) and patented medicines (9%) as shown in figure (2). Patented or branded drugs are more popular, despite their higher cost, due to their effectiveness and reliability. However, the prices of some branded generic drugs in Ghana are higher than their equivalents in high-income countries. Domestic producers in Ghana mainly manufacture generic drugs. While multinational drug makers operate in Ghana, the market is increasingly shifting in favor of generic medicines, which benefits domestic production. Foreign generic drug manufacturers from India and China have a growing influence. Over the long term, as the domestic industry grows, it is expected that generic drug makers will increase production to meet rising demand and cost-containment measures encouraged by the Ghanaian government. (7)

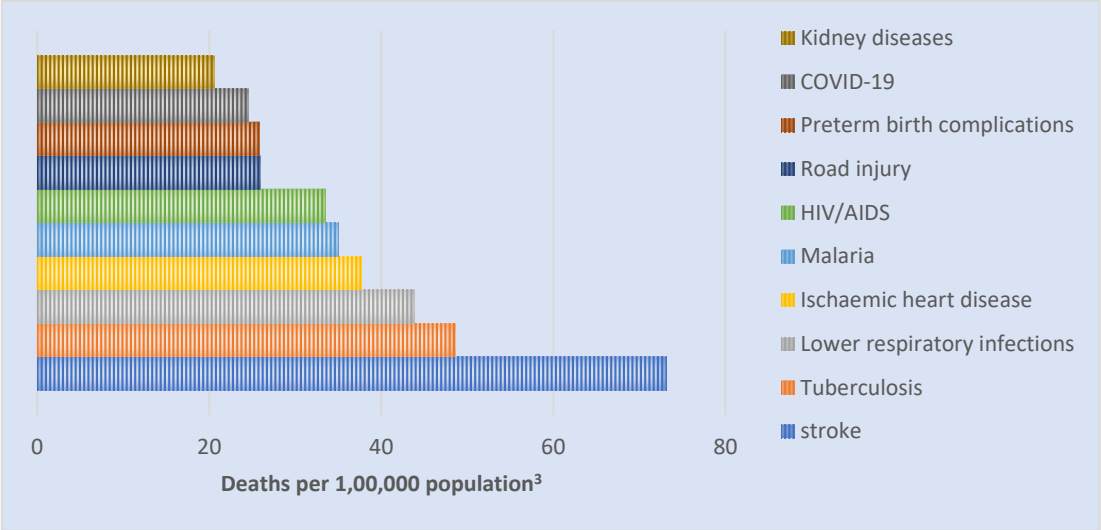

Figure 1. Causes of death in Ghana

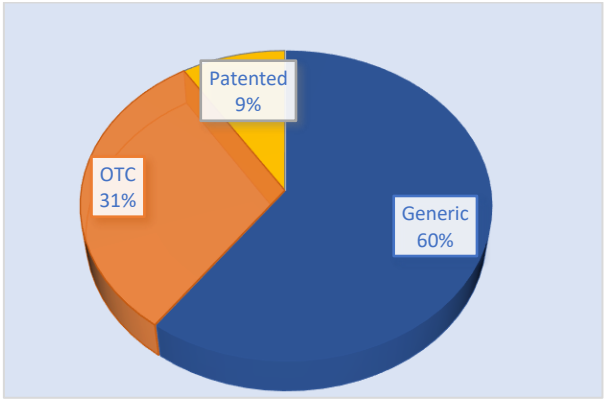

Figure 2. Pharmaceutical market of Ghana

2. Drug Regulation in Ghana

The National Medicines Regulatory Agencies (NMRAs) is responsible for medicines, medical devices, vaccine, and blood product to assure supply of efficacious, good quality and affordable medical product to promote public healthcare and patient care in the country. (8)

In Ghana, "Food and Drug Authority" (FDA, Ghana) is the official NMRA who regulate the quality, safety & efficacy of the medicines and related its products. As per Public Health Act 2012 (Act 851) parts 6, 7 and 8 of the legally mandates the FDA, Ghana. (9,10)

Medical products are highly regulated due to the critical role they play in society and the complexities, and sometimes controversies, associated with assessing their safety, quality, efficacy and effectiveness. (10)

The core function of FDA, Ghana include; marketing authorization (MA); licensing of manufacturing establishments; imports and export control; inspection of manufacturing premises and distribution channels; market surveillance (products quality monitoring, pharmacovigilance, control of drug promotion and advertising); quality control; and oversight of clinical trials on drugs. (8,9)

Earlier Food and Drugs Authority was established as the food and drugs board (FDB) in 1997, following the enactment of the food and drug law (PNDCL 305B) in 1992. The FDB operated as an authority of the Ministry of Health in Ghana to regulate medicinal products for human and veterinary use, medical devices and diagnostics aswell as food. Following the establishment of the FDB, the authority was transformed into the food and drugs authority (FDA) upon the enactment of the Public Health Act 2012 (Act 851). (11)

In West Africa, the FDA Ghana is respected by other NMRAs, because of its regulatory standing in the region. As per WHO data, there are total 54 countries in the African region and out of which 15 comes under the West Africa region[8]. The Ghana FDA is the first country in West Africa to get the World Health Organization Global Benchmarking Tool (WHO GBT) recognition. (12,13)

Currently, total eight countries have achieved the WHO GBT maturity level 3 on a scale of 4. (14)

The WHO GBT maturity level measures how stable, well-functioning and integrated a country's regulatory systems performs. The common regulatory functions of an NMRA are registration and marketing authorization, regulatory inspection, licensing of manufacturing and storage facilities, post-market surveillance, vigilance, quality control and clinical trials oversight. It is the case in most countries that medical products are first registered before they can be made available to patients. (13)

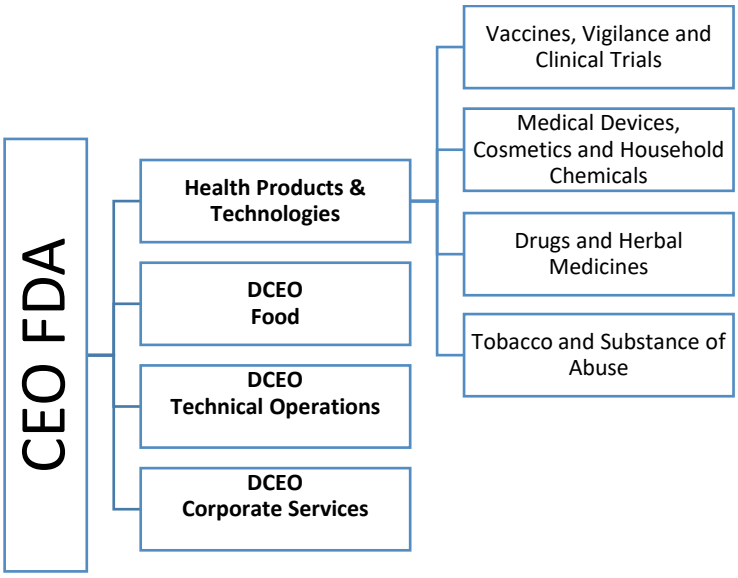

Figure 3. Organogram of FDA, Ghana

3. Food and Drug Authority, Ghana

3.1 Inspectorate Activities

The FDA is committed to safeguarding the safety of our food and the efficacy of medical products. Inspections play a vital role in this oversight, involving meticulous on-site evaluations to ensure compliance with federal regulations. However, inspections are one part of our multifaceted approach to ensuring the ongoing safety and quality of FDA-regulated items. The FDA inspects the manufacturing and storage facilities to ensure that manufacturing activities comply with the requirements of the current codes of Good Manufacturing Practices (cGMP) and storage and distribution conform to the requirements of Good Storage and Distribution Practices (GSDP) Initially an application (documents as per table-1) submitted in the FDA by the local agent. The local agent should be incorporated in a company (must be registered in Ghana) & authorized by the Ghana FDA to import medicine & must hold a wholesale distribution license. After acceptance of application, they will request for the additional documents or give the acceptance for site audit. The FDA informed to the applicant/local gent via mail regarding the site inspection before one month.

Later, inspection finding report will be provided, applicant has to comply the CAPA within the timelines with the FDA. Soon after the acceptance of CAPA, Ghana GMP will issue to the manufacturer/applicant. This certificate is valid for five years from the date of issue. Now, the manufacturer is eligible to file dossier in the FDA. *As per the author experience, dossier can be submitted along with the GMP application to reduce the approval time.*

There is second option, where manufacturer can by-pass plant GMP inspection. If the manufacturing site is approved and having valid site GMP from any one or more stringent country NRA listed in table-1, can wave the site inspection. The requirement for Product registration in FDA Ghana is shown in table-2.

Table 1. Requirement of Plant GMP audit (15-19)

Title	Remarks	Requirements
Facility GMP	Yes, on-site verification audit by the FDA, Ghana required	The minimum documents will be required 1. Application letter 2. Application form 3. Proof of Business name registered 4. Credentials of pharmacist 5. Site mater file 6. Location plan 7. Proof of payment. The minimum documents ready at the site during the visit 1. Pharmaceutical Quality System 2. Good Manufacturing Practices (GMP) for Pharmaceutical Products 3. Sanitation And Hygiene 4. Qualification and Validation 5. Complaints 6. Product Recall 7. Contract Production, Analysis and Other Activities 8. Self-Inspection, Quality Audits and Suppliers' Audits and Approval 9. Personnel 10. Training 11. Personal Hygiene 12. Premises 13. Equipment 14. Materials 15. Documentation 16. Good Practices in Production 17. Good Practices in Quality Control
Wavier for facility GMP	Yes, on-site verification may not be required	Wavier is applicable if facility is approved by stringent authority like 1. United States Food and Drug Administration (USFDA) 2. Pharmaceuticals and Medical Devices Agency (PMDA) 3. European Medicines Agency (EMA) 4. Therapeutic Goods Authority (TGA) 5. World Health Organization (WHO PQ)
Timelines		Approx. three months for 1st time and two months for renewal
Fees		10,500 USD

Table 2. Product registration requirements (19-35)

Titel	Remarks
Dossier type	CTD Module-1 Module-2 Module-3 Module-4 Module-5
Dossier Language	English
Mode of submission	Physically Complete dossier in PDF format AND QOS, SmPC, PIL in word file in a CD-ROM (2 CD-ROM required)
DMF requirement	A complete DMF is required If CMC restricted part, Letter of Access required
Stability zone	Zone IV b
No. of submission Batches	3 primary batches
Stability data required at the time of submission	Real time 12 month
BE requirement	Yes, Against US /EU/Australia reference drug in any Country
Qualified Person for Pharmacovigilance (QPPV)	QPPV is required & he should be resident in Ghana
Artwork	Dual language English & French
Product data base	http://196.61.32.245:55/publicsearch
FDA Public Assessment Reports (FAPAR)	https://fdaghana.gov.gh/fda-public-assessment-reports/
Fee	
New application	1200 USD
Fast track application	1200 USD
Reliance applications	1200 USD
Renewal application	1200 USD
Timeline	
New application	Within six months (If no query raised by the FDA)

Fast track application	180 Days
Reliance applications	90 days
Renewal application	90 days
Variation application	· Notifications (Do and Tell) · Immediate notification: one month · Annual notification: twelve months · Minor Variations (Do, Tell, and Wait): 3 months. · Major Variations (Requires formal approval): six months Fresh Applications
Query submission	First query: within twelve months Second query: within six months Third query: within three months

4. Product Registration Process

The Regional Center of Regulatory Excellence (RCORE) for Medicine Evaluation Registration in Africa FDA Ghana was designated by the New Partnership for African Development (NEPAD) and the African Regulatory Harmonization (AMRH) as a Regional Centre of Regulatory Excellence (RCORE) in Drug Registration in May 2014.

4.1 Type of dossier review process

The review of the dossier carried out by three types of robust procedure i.e. Verification, Abridged & Full review. These procedures designed to fasten review procedure without compromising the quality so that patients will access the medicine soon as possible. In each category there is consideration for expedite the additional priority/fast track review application.

a) Verification review

This procedure applied to those products that are already gets the authorization from WHO-PQ. The Ghana FDA will only verify the status of product and ensure that the product for local marketing conforms to the authorized product. The condition is that the product should be identical to the WHO-PQ registered in terms of dosage form, strength, ingredients, indications, dosage, warnings, and precautions. The WHO-PQ letter or certificate of product along with complete CTD dossier needs to submit.

b) Abridged review

This procedure applicable when the product previously registered in stringent regulatory authority, namely United States Food and Drug Administration (USFDA), United Kingdom Medicines and Healthcare products Regulatory Agency (UK MHRA), Health Canada or those reviewed by the European Medicines Agency (EMA) centralized registration procedures. A rapid assessment is carried out to obtain pharmacological, marketing/ commercialization, pharmacovigilance and clinical trials information. This assessment is carried out in relation to the benefit-risk assessment of the product under local conditions. The product should be same with reference to dosage form, strength, ingredients, indications, dosage, warnings, and precautions. A complete CTD dossier is required to submit in FDA.

c) Full review

This procedure is applicable to all other situation. It requires complete assessment of Quality, safety (pre-clinical) and efficacy (clinical) data. Information on prior registration elsewhere may be a prerequisite to final authorization and the dosage form, strength, ingredients, indications, dosage, warnings and precautions must be identical to the authorized product. A completed dossier in the CTD format including data for all modules must be submitted.

4.2 Product registration process flow

Review process of dossier is of mainly three-step process as shown in figure 4 namely pre-evaluation assessment, Evaluation phase & Decision phase.

a) Pre-evaluation assessment phase

After the submission of application along with CTD dossier, a pre-evaluation will start. In this assessment, they will check the completeness of the file. If they satisfied, applicant has to pay the fees after wards gets the acknowledgement letter & application number. This phase will be completed in one month from the date of submission of application.

The process will be assessed on a first-in-first-out basis unless the product did not fall under the expedite/fast-rack review process. If the application is for the HIV/AIDS, malaria, tuberculosis, reproductive health, neglected tropical diseases or an expanded program of immunization, paediatrics, Ministry of Health tender purposes, WHO prequalification collaborative registration process and any other disease or conditions as may be determined by the FDA from time to time will go through the fast-track process.

b) Evaluation phase

The technical team of FDA review quality, safety & clinical documents of the products. There is a separate team for each section for documents review. The FDA technical team review the dossier, sample-testing report & GMP plant audit report. Afterward they compile the entire question/gaps points and send it to Drug Registration Committee for the decision. The question/gaps points point will be sanded to the applicant. The sponsor can hold a meeting with the committee or reviewer to discuss the gaps points that he received.

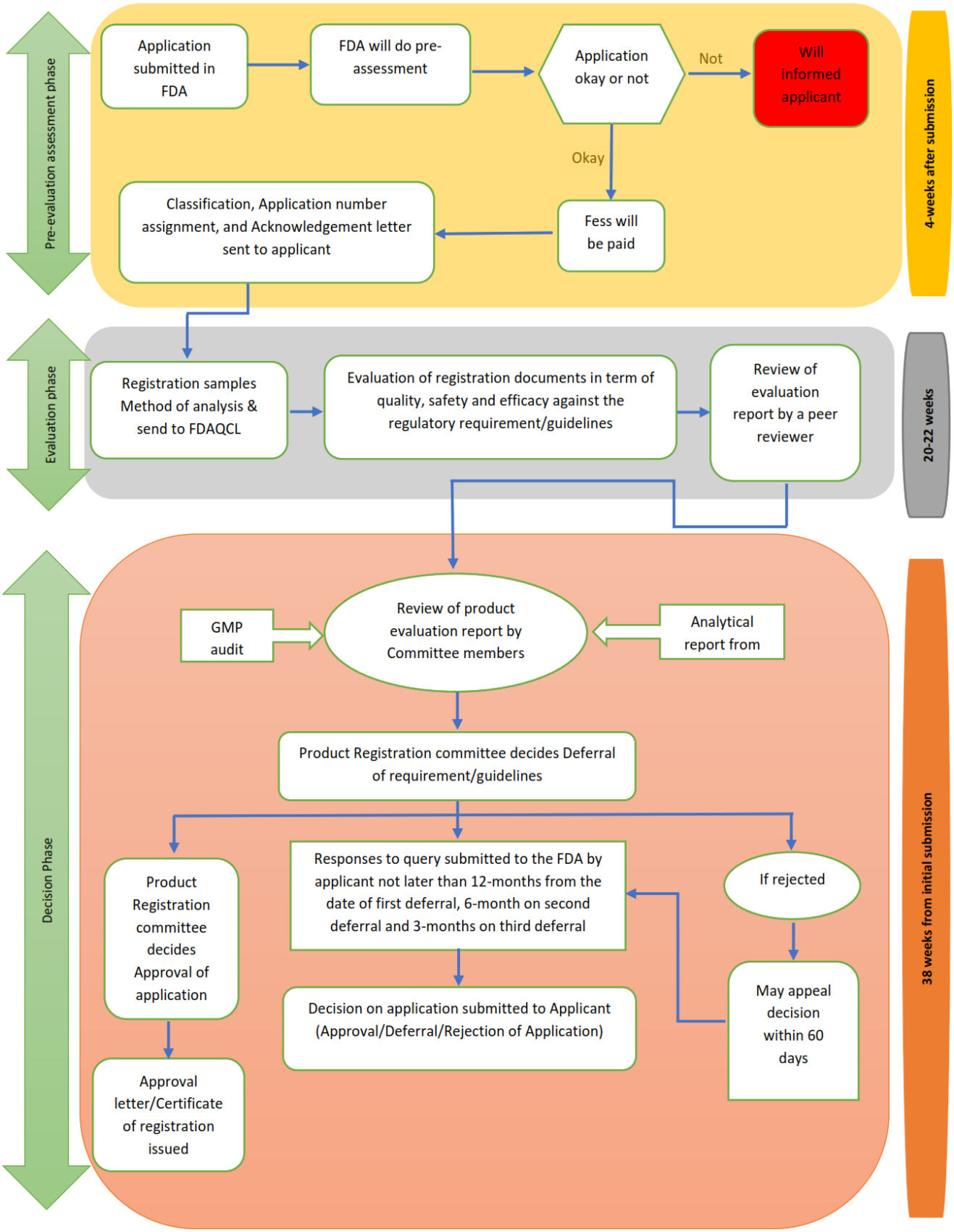

Figure 4. Process flow chart of drug registration process in Ghana FDA (29)

After receiving the deferral letter the timeline to respond the authority will start, for first time sponsor have to reply within twelve months from the date of first deferral, six month on second deferral and three months on third deferral. If the applicant failed to do so, the application will be rejected and he has to start from the initial.

c) Decision Phase

Drug Registration Committee will review all the points that were received from the technical assessment team regarding the dossier, sample analysis & GMP audit report. The final decision will be taken and report will send to the CEO of FDA.

4.3 Renewal of registration

The renewal of product registration applied before three months of the exiting certificate. The process is same as new registration only PSUR has to be submit additionally.

4.4 Variation of registered product

All applications for variation to a registered product shall be made according to requirements stipulated in the FDA Application Guideline for Variation of Registered Medicinal Products. The MAH can file the variation as per the changes falls under the category of annual notification, immediate notification, minor variation, major variation.

5. Conclusion

The product registration in Ghana is flexible as compare of other emerging market countries. The less entry barrier for the market attracts more pharmaceutical companies to enter the market hence creating much competitive market. The plant GMP approval is must prior to filing product dossier. However, MOH can file both plant GMP as well as dossier application simultaneous. Still FDA is not fully adopted the digital work for the all the work related to stakeholder. There is no online way to check the status of application submitted in the FDA, which create the non-transparency in the system. The WHO is continuously boosting the FDA by providing the training and helping them to prepare the guidelines as per the current regulatory demands. Recently, FDA Ghana received the Regulatory Systems Maturity Level 3 by the WHO. This will open new doors for the stakeholders in the vaccine division (fill & finished).

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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