GHANA
PHARMA MARKET
&
REGULATORY REPORT

Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Government of India)

CONTENTS

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Western Africa
2	Country	Republic of Ghana
3	Capital	Accra
4	Population	29,340,248 (July 2020 est.)
5	Population growth rate (%)	2.15%(July 2018 est)
6	GDP (purchasing power parity)	177.4 $ Billion(2017 est)
7	GDP - real growth rate (%)	1.4%(2017 est)
8	GDP - per capita (PPP)USD	4,300 $(2017 est)
9	Exchange rates	
10	Population below poverty line	46.5%(2017 est)
11	Age structure (%)	0-14 Years-37.44%
		15-24 years 18.64%
		25-54years and over: 5.21%
		55-64 years 4.44%
		65 & above 2.98%

Source: CIA World Fact Book updated to On 4Th June 2020

MARKET REPORT

INTRODUCTION

The progress of the rollout of universal healthcare in Ghana will be the main driving force behind pharmaceutical and healthcare spending in the country. It's important to note, however, that cost-containment policies will remain prominent and limit opportunities for multinational drugmakers in the country. There is a potential downside risk for a prolonged disruption to global pharmaceutical supply chains by Covid-19 which could lead to drug shortages in the country. Scarcity of medicines has the potential to inflate the already high prices of medicines in Ghana.

Ghana Pharma market is the size of $ 586mn in 2019 and is slated to move to $616 in 2020 with a forecasted growth of 5.3%.(Forecasts may not be realized due to its government's main source of income from Petroleum has taken a major hit).

Latest Updates

- In March 2020, Ghana's parliament passed the 'Narcotics Control Commission Bill, 2019', to treat drug dependence as a public health issue rather than focusing on law enforcement, incarceration, punishment and repression.
- In March 2020, Ghana's Government introduced a dedicated section of the Health Service website to help inform the public, journalists and healthcare professionals about any Covid-19 developments.
- In February 2020, Ghana's Ministry of Health introduced an electronic supply chain management system (the Ghana Integrated Logistics Management Information System or GhILMIS), to improve healthcare delivery through a better coordinated demand and supply chain.
- In February 2020, the Ghana Medical Association appealed to doctors trained for Ebola to be ready to handle Covid-19) cases.
- In January 2020, Ghana's President presented 307 new ambulances to the National Ambulance Service, fulfilling a 2016 campaign pledge.

Strengths

- One of the most attractive pharmaceutical markets in West Africa.
- A local manufacturing sector that benefits from government support.
- The National Health Insurance Scheme, which provides basic care to the majority of the population.

Weaknesses

- Low incomes and limited out-of-pocket spending power.
- Pharmaceutical market that is dominated by branded Generics (INN has low profile)
- Highly dependent on pharmaceutical imports.

Opportunities

- Domestic drug makers are moving towards achieving WHO qualification and GMP certification, supported by the government's policies.
- Ghana's evolving demographic and epidemiological profile will provide increased revenue earning opportunities for pharmaceutical companies, particularly those producing non-communicable disease treatments.
- Local drug makers are in a favorable position for entering joint ventures with foreign pharmaceutical firms, particularly as regional exports are becoming more important.
- Partnerships between foreign multinationals and the local government, which aim to upgrade existing infrastructure.

Market Overview

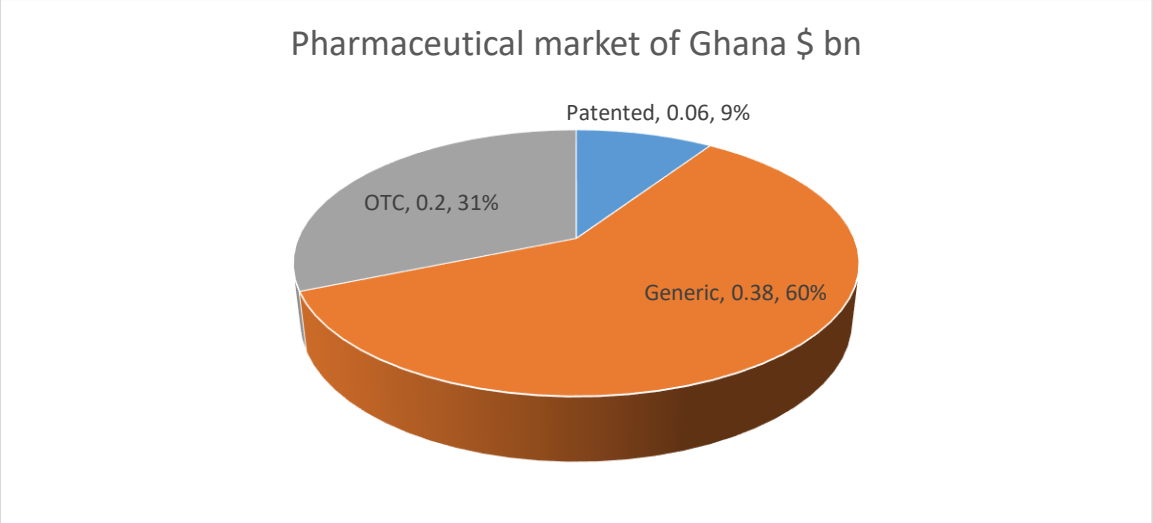
Ghana's pharmaceutical market will continue to grow in the coming years, supported by government plans for the roll out of universal healthcare. However, cost-containment measures will likely mean a slower pace of growth in the sector; although domestic generic drug makers are likely to see increased opportunities in the long-term as effort to boost the sector materialize. Should Covid-19 cause a prolonged disruption, then there is a notable risk it could impact negatively impact medicine availability and affordability in Ghana.

Pharmaceutical sales in Ghana reached USD589mn in 2019, and forecasted figures show rise to USD620mn in 2020. Looking further forward, by 2024 it is expected sales to achieve a compound annual growth rate (CAGR) of 9.8% to SD941mn. This almost double-digit growth rate is characteristic of many pharmaceutical markets in Sub-Saharan Africa, where robust growth in medicine sales will be driven mainly by increased volume consumption within the generic medicines sub-sector. Across the region, generic drug makers will increase production to meet the rising demand and will be further helped by cost-containment measures encouraged by governments. Per capita spending on medicines will increase from USD20 in 2019 to USD41 by 2029, remaining low by global standards.

Ghana has growing influence in the Economic Communities of West African States (ECOWAS). Ghana is attempting to fulfill its ambition of being the ECOWAS' hub for pharmaceutical investment. During the 83rd annual general meeting of the Pharmaceutical Society of Ghana in August 2018, Bawumia disclosed several interventions by the government to support domestic drug makers, some of which are already underway, including:

- Exempting select imported pharmaceutical products from VAT
- Expanding of the list of raw materials exempt from VAT to accommodate inputs to support the local pharmaceutical manufacturing industry
- Providing additional funding to some local pharmaceutical companies to build new production plants and raise their standard of production towards international quality standards. The provisions will be made by Exim Bank Ghana.

In addition to these measures, Ghana's Ministry of Foreign Affairs and the Ministry of Trade and Industry are attempting to remove trade barriers and promote Ghanaian pharmaceutical products within the ECOWAS region. Moreover, a framework is currently being designed that ensures Ghana's Ministry of Health procures more locally manufactured medicines, the government is looking to allocate a designated pharmaceutical manufacturing zone, as well as reforming the national health insurance scheme.



Epidemiology

Ghana's epidemiological profile is currently split relatively evenly between non-communicable and communicable diseases, with the latter creating a moderately higher burden - the most prevalent of which is HIV/AIDS, malaria and tuberculosis.

Over the long term, non-communicable diseases - such as cancer, cardiovascular diseases and neurological disorders - will remain dominant. Communicable diseases such as Malaria, HIV/AIDS and tuberculosis will become less of a burden. However, their frequency will remain high compared to global levels.

Generic Market

Generic drugs will continue to comprise the majority of pharmaceutical sales in Ghana, although their share of the overall market will decrease slightly. Branded drugs remain popular as they are the trusted option when compared with unbranded generics, which are seen as less effective and sometimes unsafe, despite being more affordable. However, the prices of some branded generic drugs in Ghana are higher than equivalents in high income countries.

In 2019, Ghana's generic drugs market was of the size USD376mn, and represented 63.8% of the total market value and 86.6% of the prescription drug market. By 2020, the generic drug market is expected to touch USD395mn. Generic drug sales will grow at a CAGR of 9.6%, to reach a value of USD595mn) by 2024, making up a 63.2% share of the pharmaceutical market in Ghana by this time.

Actual volumes may rise even more dynamically as generic drug makers increase production to meet rising demand and austerity measures encouraged by the Ghanaian government. Generic prescribing will be promoted as health insurance coverage increases and there are further cost-containment measures enacted by the government, encouraging generic substitution. The United Nations Industrial Development Organization has created projects to fund the domestic production of essential generic drugs in both Ghana and Kenya, which should help to boost domestic generic drug manufacturing capabilities. Unbranded generics account for approximately 5% of the generic drug market, but this share will gradually increase over the forecast period.

Pharma Trade

As with most emerging African countries, Ghana has a negative trade balance. According to the Ghanaian health service, only 30% of the national requirements of pharmaceutical products are produced in Ghana, while the remaining 70% are imported. However, the Ghanaian government has emphasized the need to manufacture more locally produced medicines over the next decade, an ambition it shares with many African governments.

Ghana's pharmaceutical trade performance is relatively erratic. Although it's few key local drug makers are known to produce essential medicines for local demand and exports.

Pharmaceutical imports were estimated USD263mn in 2019. This might reach USD312mn by 2024, posting a CAGR of 3.5%. The majority of pharmaceutical imports, predominantly low-value generic drugs, come from India and the EU.

New hospitals are scheduled to be built in Ghana. Increasing access to medicines will raise demand for drugs and therefore imported products, while local manufacturing also expands thanks to European funding and domestic political support. The government is apparently striving to achieve this through national health coverage and may be able to afford a higher import bill for pharmaceuticals when it sees returns on its oil sector.

Exports are forecast to increase from USD3.8mn in 2019 to USD5.8mn by 2024, at a CAGR of 8.8%. This increase is faster than that of imports over the same period, which is set to develop at a considerable pace, albeit from a much lower base.

Local Industry

The competitive environment in Ghana's pharmaceutical market will continue to be dominated by local firms and Indian companies. As of March 2019, drug makers from developed states will slowly increase their presence. According to Ghana's Food and Drug Administration, there were 126 foreign pharmaceutical manufacturing facilities with valid licenses. Of this total, the majority were in India (62), followed by Bangladesh (three), France (two), Germany (two), Nigeria (two), the US (two), Egypt (one), Belgium (one), Sweden (one), Thailand (one) and China (one)

The Pharmaceutical Manufacturers Association of Ghana had 30 registered members, as of 2019. Most of the major local pharmaceutical companies also export their products to other countries in West Africa. Domestic drug makers predominantly produce generic malarial, antiretroviral and OTC medicines such as analgesics. The main domestic players are Danadams, M&G Pharmaceuticals, Ayrton Drug Manufacturing, LaGray Chemical Company, Tobinco Pharmaceutical, Natural Scientific Pharmaceuticals, Aidcom, AlhajiYakubu Herbal Company, CimaPharmaceutical, Goldleaf Pharmacare, Health Concept Pharmaceutical and King David Pharmaceuticals.

Generic Industry

Domestic producers in Ghana chiefly manufacture generic drugs. Although multinational drug makers operate in Ghana, the market is increasingly shifting in favor of generic medicines, thus favoring domestic production. Foreign generic drug makers in 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.

Statistics

India's Exports

India Pharma exports to GHANA by Category $ Million					
Category	2015-16	2016-17	2017-18	2018-19	Change%
Bulk Drugs & Drug Intermediates	13.33	14.15	17.09	18.57	8.68
Drug Formulations & Biologicals	104.72	121.38	92.27	86.28	-6.49
Ayush	3.52	2.64	2.37	2.14	-9.38
Herbal Products	0.00	0.01	0.04	0.06	66.83
Surgicals	1.13	1.15	1.26	1.17	-7.28
Vaccines	15.03	8.21	4.73	7.44	57.22
Total	137.73	147.55	117.75	115.67	-1.77
Source: DGCIS					

India's Exports of Pharmaceuticals to Ghana During April-March $ Million			
Category	Fy-19	Fy-20	Change%
Bulk Drugs & Drug Intermediates	18.57	13.65	-26.51
Drug formulations & Biologicals	85.26	77.18	-9.48
Ayush	2.14	2.08	-3.17
Herbal Products	0.06	0.01	-82.57
Surgicals	1.99	2.94	48.09
Vaccines	7.64	5.37	-29.67
Total	115.67	101.23	-12.49
Source: DGCIS			

Ghana's Imports

Top Ten Importing Partners of Ghana $ Million						
Rank	**Country**	**2016**	**2017**	**2018**	**Gr%**	**Share%**
1	India	136.37	195.84	87.79	-55.17	32.09
2	France, Monaco	9.96	18.15	70.98	290.97	25.95
3	Belgium	16.23	26.49	24.19	-8.66	8.84
4	Switzerland, Liechtenstein	13.53	24.20	17.90	-26.04	6.54
5	United Kingdom	9.52	18.09	12.31	-31.91	4.50
6	Germany	6.88	12.69	10.05	-20.79	3.67
7	Denmark	23.59	28.86	6.65	-76.95	2.43
8	Italy	0.89	1.30	6.42	393.78	2.35
9	China	7.59	12.59	5.82	-53.80	2.13
10	Slovenia	7.81	12.79	5.67	-55.71	2.07
	World	274.853259	432.830796	273.57	-36.80	100.00

Source: UN comtrade

REGULATORY AND REGISTRATION REQUIREMENTS

➢	Regulatory Authority	:	Food and Drugs Authority, FDA Ghana
➢	Website of regulatory Authority	:	https://fdaghana.gov.gh/
➢	Fees for Drug Registration	:	240 - 360 USD per Annum
➢	Normal time taken for registration	:	06 - 18 Months
➢	Registration Requirement [Dossier Format]	:	CTD
➢	Whether plant inspection is mandatory	:	Yes
➢	Validity of Registration	:	05 yrs

Regulatory

The pharmaceutical market in Ghana boasts certain advantages over its neighboring counterparts, including an open economic policy and comparatively well-established drug regulatory body - the Ghanaian Food and Drugs Authority (FDA). A positive sign for foreign drug makers is that Ghana has established a more rigorous regulatory environment in the form of its own drug-testing facilities as part of its post-marketing surveillance strategy. While this will bode well for investor sentiment and comes across favorably compared to surrounding medicine markets, the drug regulatory environment in Ghana remains in need of supply chain tightening and better policy enforcement.

The registration and inspectorate division is responsible for the evaluation of medicine registration applications leading to the registration of medical products. The safety monitoring and clinical trials division ensures the safety of regulated products from the Public Health Act. In recent years, as Ghana has established a more rigorous regulatory environment, this has enabled the government to support local drug makers as well as limited foreign direct investment (FDI).

The drug registration process in Ghana takes between six and 18 month, which is relatively short compared with other countries in Africa. Due to low purchasing power & high costs of borrowing severely limits returns and limits FDI. Local drug makers have also begun upgrading facilities to meet with international Good Manufacturing Practice standards.

The Pharmaceutical Manufacturers Association of Ghana (PMAG) has proposed that a regional pharmaceutical regulatory body within the Economic Community of West African States (ECOWAS) would increase access to medicines and allow pharmaceutical firms to grow. However, poor border controls and weak drug regulations in other ECOWAS states mean regional harmonization remains a long way off. Complying with Trade Related Aspects of Intellectual Property Rights (TRIPS) will invite multinational drug makers looking for

joint ventures or license agreements in Ghana. In the long run, this would allow medicine manufacturers to export higher volumes of pharmaceuticals within and beyond West Africa.

Ghana FDA:

Drug Evaluation and Registration Department

The Drug Evaluation and Registration Department is responsible for the evaluation of medicine registration applications leading to the registration of medical products. Some of the achievements of the department are detailed below.

- A system of registration of medicinal products has been established over the past 16 years and is well controlled to ensure consistency of activities and regulatory decisions on all medicine registration applications.
- The department has competent dossier evaluation committee that reviews all parts of dossiers submitted for registration. Two of the assessors are currently members of the WHO Prequalification Assessment Team. The department is currently contributing to the WAHO harmonization process.
- The department has a detailed guideline to control the names of products, information on product characteristics and patient information leaflet. This is strictly controlled to ensure that information on product to health professionals and patients are not deceptive. Product brand names and colour schemes are also controlled to avoid prescription errors.
- The department has a system to ensure the monitoring of applications after registrations. Including tracking of variations to registration applications.

Herbal Medicine Department

The Herbal Medicine department is responsible for the evaluation of herbal medicine and food supplement registration applications leading to the registration of herbal medicines in Ghana. Some of the achievements of the department are detailed below:

- Improvement in packaging of herbal medicinal products sold in medicine sales outlets.
- Enforcement of manufacture of herbal medicinal products from designated facilities with basic GMP for herbal medicine facilities.
- Trained over 300 herbal medicine manufacturers and traditional medicine practitioners engaged in extemporaneous preparations in GMP and registration requirements.
- Trained officers of National Drug Regulatory Authorities from some African countries on establishing a regulatory framework for Herbal medicine regulation.

https://fdaghana.gov.gh/index.php/safety-monitoring-department/

Safety Monitoring Department

Mandate

The Safety Monitoring Department derived the mandate to ensure the safety of regulated products from the Public Health Act, 2012, Act 851, Part 7, Section 125. The Department shall continually monitor the safety of the products regulated under the Public Health Act 851 by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary.

Vision

The vision of the Safety Monitoring Department is to improve nationwide patient safety and well being by reducing the risk of medicines used by patients and the general public.

Mission

To ensure the patients and the general public obtain the best outcome from their medical intervention or treatment. This is achieved by;

- Creating awareness and educating health professionals and the general public on the need to monitor and report adverse events to medicines and other products regulated by the Food and Drugs Authority.
- Ensuring that Marketing Authorization Holders continually monitor their products on the Ghanaian market

Functions

The Safety Monitoring Department has two Units, the Risk Management and Vigilance Unit. The Broad objectives of the Department are monitoring of product safety, creation of awareness amongst the general public and healthcare professionals about the need to report adverse events.

- **Risk Management Unit**

The Unit is responsible for ensuring compliance by industry of the requirements in the Public Health Act, 851. This is done through activities including conduct of Pharmacovigilance Inspections and review of safety information submitted e.g. Risk Management Plans for new products. The Unit is also responsible for ensuring incorporation of pharmacovigilance into Public Health Programmes (PHPs) and ensuring the successful implementation of safety monitoring activities undertaken in collaboration with the PHPs.

- **Vigilance Unit**

The Unit is responsible for the management and maintenance of the database of safety information (Adverse Events, ADR, AEFI). This includes ensuring availability and accessibility of reporting forms (Adverse Drug Reaction (ADR) and Adverse Events Following Immunization (AEFI)) Pharmacovigilance promotion activities in healthcare facilities and to the general public is undertaken by the unit. This is done through sensitization activities organized for these stakeholders and the generation of Information Education and Communication (IEC) materials for them.

Goals and Strategies

- Medicines and Healthcare Regulatory Agency (MHRA):- technical assistance regarding adverse drug reaction reporting by consumers and development of local E2B compliance database
- US Food and Drugs Administration (FDA):- technical assistance in the form of training for members of staff through the annual international forum for drug regulators.
- World Health Organization /Uppsala Monitoring Centre:- Technical Assistance in the form of training and provision of online databases (i.e. *VigiFlow* and *CemFlow*) for the transmission of medicine safety information.
- Other Agencies:-the Department also collaborates with other agencies like USAID [United States Agency for International Development through the SHOPS (Strengthening Health Outcomes through the Private Sector) Programme], WAHO (West African Health Organization), WHO-CC (WHO-Collaborating Centre for Advocacy and Training in Pharmacovigilance) and other International Regulatory Agencies.

Public Health Programmes

- Expanded Programme on Immunization (EPI):-coordinates AEFI monitoring during vaccination campaigns and process adverse event following immunization (AEFI) reports during routine immunization programmes. The Department ensures that the reports are evaluated by the Technical Advisory Committee for Safety and feedback provided to the EPI and other stakeholders.
- National Malaria Control Programme (NMCP):- Cohort Event Monitoring of artemisinin-based combination therapies (ACTs) and other anti malarials
- National Tuberculosis Control Programme (NTBCP):-Assist the National TB programme to implement Pharmacovigilance as a component of the management of TB patients
- GHS:-Working with the GHS to adopt a tool for the assessment of Pharmacovigilance as part of the performance review of the facilities.

Conferences/Training programs

- Annual Pharmacovigilance Training Course organized by the WHO Collaborating Centre for International Drug Monitoring Training programme to update participants on issues related to pharmacovigilance
- International Society of Pharmacovigilance (ISoP)
- Annual Meeting for National Centres Participating in the WHO Programme for International Drugs Monitoring.

Awareness Creation and Sensitization Activities for Healthcare Professionals

As part of achieving its strategy of increasing Pharmacovigilance awareness and reporting of drug-related problems among healthcare professionals through sensitization lectures, the

National Pharmacovigilance centers have sensitized 629 healthcare professionals in 23 healthcare facilities in the first half of 2013.

PHARMACOVIGILANCE SYSTEM IN GHANA click to view

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/SafetyMonitoring/Pharmacovigilance%20System%20in%20Ghana.pdf

https://fdaghana.gov.gh/index.php/monitoring-2/

MONITORING AND EVALUATION DIVISION

Overview of the Monitoring and Evaluation Division

The Monitoring and Evaluation Division ensures the development of comprehensive operational policies, sustainable strategic plans, systems, programmes and budgets to cover all activities of the Food and Drugs Authority.

It is mandated to track the implementation and outputs systematically and measure the effectiveness of projects and programmes of the Organization and helps determine exactly when a project or programme is on track and when changes may be needed.

It caters for the design and application of monitoring and evaluation systems and tools for the purposes of assessing the operational effectiveness of projects and programmes of the FDA.

It is responsible for the overall monitoring and evaluation of the performance of the Food and Drugs Authority.

Objective

The main objective of the Monitoring and Evaluation Division is to help improve performance and achieve results. Its goal is to improve current and future management of outputs, outcomes and impact.
https://fdaghana.gov.gh/index.php/management-structure/

FDA MANAGEMENT STRUCTURE

The Chief Executive takes executive responsibility for operational management, service delivery and strategic issues of the FDA Ghana.

The office of the Chief Executive consists of the Internal Audit Unit, Human Resource Unit, Public Education and Communications Unit, Project, Research and Management Information System Department, Finance Department, Administration Department, Import and Export control Department, Laboratory Service Department and Regional Offices.

Under the Chief Executive are five Specialised Divisions, namely; Food Safety Division, Food Inspectorate Division, Cosmetics, Medical Devices and Household Chemicals Division, Drug Registration and Inspectorate Division and Safety Monitoring and Clinical Trials Division.

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/GL%20FOR%20PHARM%20FACILITY%20INSPECTION.pdf

GUIDELINES FOR cGMP INSPECTION OF PHARMACEUTICAL MANUFACTURING FACILITIES

LIST OF GMP GUIDELINES, THEIR TITLES OF PUBLICATION AND WEB ADDRESSES

1. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

2. WHO good manufacturing practices for active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2. http://www.who.int/medicines/publications/44threport/en/

3. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2 http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

4. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirtyninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

5. WHO guidelines on good manufacturing practices for heating, ventilation and airconditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5 http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

6. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4 http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

7. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1 http://www.who.int/medicines/publications/44threport/en/

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10.WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11.Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12.General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13.WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

14.WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

15.WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

16.WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

17.WHO Guidelines on good manufacturing practices: validation, Appendix 7: nonsterile process validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

18. WHO General guidance on hold-time studies WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

19.WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

20.WHO Recommendations for quality requirements when plant – derived artemisin is used as a starting material in the prosecution of antimalarial active pharmaceutical ingredients. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 6
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

21.WHO good manufacturing practices for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

22.Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

23.WHO general guidance on variations to multisource pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 10
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex10.pdf

24.WHO good manufacturing practices for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

Application form for Registration of an Allopathic Drugs

(to be submitted as two electronic copy (Modules 3-5 in pdf on a CD-Rom) including Modules 1 and 2 in MS-Word)

For FDA use only			
Application Number			
Date of submission of the dossier			
Name of the 1st Evaluator		Signature	
Name of the 2nd Evaluator		Signature	
Date of 1st evaluation			
Date of 2nd Evaluation			
Number of files and CD(s) received			
CONCLUSION OF THE ASSESSMENT **RECOMMENDED** *(no outstanding issues)* **QUERY RAISED** *(Indicate the sections where query is raised)* **REJECTED** *(indicate the module(s) that led to the rejection)* ***(Please delete which does not apply)***			
TYPE OF APPLICATION – HUMAN, BIOLOGICAL OR VETERINARY PRODUCT *(Please delete / change which does not apply)*			
MODULE 1: ADMINISTRATIVE INFORMATION			
SECTION 1: PARTICULARS OF THE PRODUCT			
1.0 Attach a cover letter			
1.1 Table of content of the application (MODULE 1-5)			
1.2 Application Information			
For FDA use only			
1.2.1	**Trade Name/Proprietary of the product**		
For FDA use only			
1.2.2	**Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical Ingredient (API)**		
For FDA use only			
1.2.3	**Dosage form and route of administration of the product:**		
For FDA use only			
1.2.4	**Strength of API per unit dosage of the product**		
1.2.4.1	Dosage form of the product:		
1.2.4.2	Route*(s)* of administration		
For FDA use only			
1.2.5	**Commercial presentation of the product:**		
For FDA use only			
1.2.6	**Nature and content of container**		
1.2.7	**Description of the product**	*(Add as many rows as necessary)*	

1.2.8	**Country of Origin**
1.2.9	**Category of distribution**
1.2.9.1	POM (Prescription only medicine) *(Please delete which does not apply)*
1.2.9.2	P (Pharmacist initiated medicine) *(Please delete which does not apply)*
1.2.9.3	OTC (Over-the-counter medicine) *(Please delete which does not apply)*
1.2.9.4	**VETERINARY DRUGS**
1.2.9.4.1	Veterinary Medicines (VM) Prescription
1.2.9.4.2	Veterinary Medicines (General Dealer) – (V.M.G.D)
1.2.10	**Pharmacological classification and indication**
1.2.10.1	Pharmacological classification
1.2.10.2	Indication
For FDA use only	

1.2.11	**Proposed shelf life (in months) and storage conditions:**
1.2.11.1	Proposed shelf life:
1.2.11.2	Proposed shelf life (after reconstitution or dilution):
1.2.11.3	Proposed storage conditions:
1.2.11.4	Proposed storage conditions (after reconstitution or dilution):
For FDA use only	

1.2.12 Name and address of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:
For FDA use only

1.2.13	**Name(s) and complete address (es) of the manufacturer(s)**
1.2.13.1	**Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer.** *(Add as many rows as necessary)*
Name: Company name: Address: Country: Telephone: Telefax: E-Mail: **If the manufacturer is different to 1.1 above, explain the relationship:**	
1.2.13.2	**Name(s) and complete address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API)** *(Add as many rows as necessary)*
	Name: Company name: Address: Country: Telephone: Telefax: **E-Mail:**

1.2.14	**Manufacturing and marketing authorisation(s)/international registration status**
1.2.14.1	Product Marketing Authorisation issued by the national regulatory authority in the country of origin and other countries (If not registered in the country of origin state reasons).

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.2.14.2	Attach a valid certificate of pharmaceutical product from the country of origin.
1.2.14.3	Valid Manufacturing authorisation from the country of origin and Good Manufacturing Practice certificate (GMP).
1.2.14.4	Valid manufacturing contract agreement between the applicant and manufacturer, in addition, for loan license manufacturing a valid manufacturing contract agreement and Supporting documentation from the competent drug regulatory authority for the manufacturing license code should be submitted.
1.2.15	Copy of Certificate of Suitability of the European Pharmacopoeia (CEP) including any annexes. (if applicable)

For FDA use only

1.2.16	**Name and complete address of the Authorised Local Representative of the applicant (local agent)**

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

For FDA use only

1.3	**Prescribing information**
1.3.1	**Product information for health professionals (Products subject to medical prescription)**
1.3.2	**Patient Information leaflet**
1.3.3	**Labelling (Outer and inner labels)**
1.4	**Samples of the product as per FDA sample schedule**

For FDA use only

1.5 Batch number(s) of the FPPs used in *(Add as many rows as necessary)*

Clinical/bioequivalence studies			
Stability studies			
Validation/production scale batches			

Comments [e.g., batch size, explanation of NA (not applicable) answers]

Composition of clinical, primary stability and validation/production FPP batches (kg)

Ingredients	Administration Unit		Bioequivalence <batch number>		Primary stability <batch number>		Production <batch number>	
	Mg	%*	Kg	%*	Kg	%*	kg	%*
Core tablet / capsule contents / injections / suspensions, etc. (*Please delete / change which does not apply*)								
API 1								
API 2								
API 3								
Please add / delete as many rows as necessary								
Excipient 1								
Excipient 2								

Excipient 3								
Please add / delete as many rows as necessary								
Subtotal 1								
Purified water/other solvent(s)								
Film coat / capsule shell / printing ink (*Please delete / change which does not apply*)								
Proprietary film-coating mixture**								
Please add / delete as many rows as necessary								
Subtotal 2								
Grand total								
Purified water/other solvent(s)								
Equivalence of the composition or justified differences			The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. (*Please delete / change which does not apply*)					
* Each ingredient is expressed as a percentage of the grand total. ** All components (……..) of the proprietary mixture are described in the compendia								
For FDA use only **OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE**								

MODULE 2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES

2.1	**CTD TABLE OF CONTENTS OF MODULES 2, 3, 4, AND 5**
2.2	**INTRODUCTION**
2.3	**QUALITY OVERALL SUMMARY**
For FDA use only	
2.3.S	**OVERVIEW OF ACTIVE PHARMACEUTICAL INGREDIENT(S) [API(S)]**
2.3.S.1	General Information of the API(S)
2.3.S.1.1	Nomenclature
For FDA use only	
2.3.S.1.2	Structure
For FDA use only	
2.3.S.1.3	General Properties of the API(s)
For FDA use only	
2.3.S.2	Manufacture of the API(S)
2.3.S.2.1	Name and address of API(s) Manufacturer
For FDA use only	
2.3.S.2.2	Description of Manufacturing Process and Process Controls
2.3.S.2.3	Control of Materials used in Manufacture of API
2.3.S.2.4	Controls of Critical Steps and Intermediates
2.2.S.2.5	Process Validation and/or Evaluation
For FDA use only	
2.3.S.3	Characterization of the API(S)
2.3.S.4	Control of the API(S))
2.3.S.5	Reference Standards or Materials of the API(S)
2.3.S.6	Container Closure System of the API(S)
2.3.S.7	Stability of the API(S)
For FDA use only	
2.3.P	**OVERVIEW OF FINISHED PHARMACEUTICAL PRODUCT [FPP]**
2.3.P.1	Description and Composition of the FPP
2.3.P.2	Pharmaceutical Development of the FPP
2.3.P.3	Manufacture of the FPP

2.3.P.4	Control of Excipients for the FPP
2.3.P.5	Control of the FPP
2.3.P.6	Reference Standards or Materials of the FPP
2.3.P.7	Container Closure System of the FPP
2.3.P.8	Stability of the FPP
2.3. A	**APPENDICES**
	REGIONAL INFORMATION
For FDA use only **OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE**	
MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION	
3.1	**TABLE OF CONTENTS OF MODULE 3**
3.2	**BODY OF DATA**
3.2.1	**PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)]**
3.2.1.1	General Information of the API(S)
3.2.1.2	Manufacture of the API(S)
3.2.1.4	Control of the API(S))
3.2.1.6	Container Closure System of the API(S)
3.2.1.7	Stability of the API(S)
3.2.2	**PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]**
3.2.2.1	Description and Composition of the FPP(S)
3.2.2.3	Manufacture of the FPP(S)
3.2.2.5	Control of the FPP(S)
3.2.2.7	Container Closure System of the FPP(S)
3.2.2.8	Stability of the FPP(S)
DECLARATION BY AN APPLICANT	
	1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection. 3. The product shall not be imported, distributed for sale or advertised in Ghana until the product has been duly registered by the FDA. 4. I also agree that the applicant will implement a Pharmacovigilance plan for this product in accordance with FDA requirements 5. I also agree that I am obliged to follow the requirements of the FDA Act, which are related to pharmaceutical products. 6. I also consent to the processing of information provided by the FDA. Name: ……..…….. Position in the company:…… Signature: ……..…… Date:…….. Official stamp:……..

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/GUIDELINES%20FOR%20REGISTRATION%20OF%20%20ALLOPATHIC%20DRUGS.pdf

Fee:

https://fdaghana.gov.gh/images/stories/pdfs/FEES%20SCHEDULE/FDA%20Fees%20Schedule.pdf

GUIDELINES FOR REGISTRATION OF ALLOPATHIC DRUGS

TABLE OF CONTENTS

1.2. OBJECTIVE
1.3. SCOPE

2.0. GLOSSARY

3.0 SPECIFIC MODULE REQUIREMENTS

MODULE 1: Administrative Information and Prescribing Information

1.0. Cover letter
1.1 Table of contents of the application including module 1 (module 1-5)
1.2 Application information
1.2.1 Trade/Proprietary name
1.2.2 Approved / INN / generic name
1.2.3 Dosage form of the product
1.2.4 Strength of the product
1.2.5 Commercial presentation
1.2.6. Nature and content of container
1.2.7 Description of the drug
1.2.8 Country of Origin
1.2.9 Category of distribution
1.2.10 Pharmacological classification and indication
1.2.11 Proposed Shelf life of the product
1.2.12 Applicant
1.2.13 Name and complete address(es) of the manufacturer(s) of the FPP
1.2.14. Manufacturing and registration/international registration status
1.2.15 Copy of Certificate (s) of Suitability of the European Pharmacopoeia (CEP) (including any annexes)
1.2.16 Authorised Local Representative (local agent)
1.2.17 Declaration

1.3 Prescribing information
1.3.1 Product information for Health Professionals (For All Products subject to Medical Prescription)
1.3.2 Patient information leaflet
1.3.3. Labeling (outer and inner label)
1.4 Samples

MODULE 2: CTD Summaries- Chemical, Pharmaceutical, Non-Clinical and Clinical Overviews and Summaries

2.1 CTD Table of contents (module 2-5)
2.2 CTD Introduction
2.3 Quality Overall Summary (QOS)
2.3. S Drug Substance (Active Pharmaceutical Ingredient)
2.3. P DRUG PRODUCT
2.3. P.1 Description and Composition of the Drug Product
2.3. P.2 Pharmaceutical Development (name, dosage form)
2.3. P.3 Manufacture
2.3. P.4 Control of Excipients (name, dosage form)

2.3. P.5 Control of Drug Product (name, dosage form)
2.3. P.6 Reference Standards or Materials (name, dosage form)
2.3. P.7 Container Closure System (name, dosage form)
2.3. P.8 Stability (name, dosage form)
2.3. A APPENDICES
2.3. A.1 Facilities and Equipment
2.3. A.3 Excipients
2.3. R REGIONAL INFORMATION

2.4 OVERVIEW AND SUMMARY OF NON CLINICAL AND CLINICAL DOCUMENTATION
2.4.1 NEW CHEMICAL ENTITIES ONLY
2.4.1.1 NONCLINICAL OVERVIEW
2.4.1.2 Content and Structural Format

2.5 CLINICAL OVERVIEW
2.6 NONCLINICAL WRITTEN AND TABULATED SUMMARIES
2.7: CLINICAL SUMMARY
2.7.3 Summary of Clinical

MODULE 3: Chemical-Pharmaceutical Documentation

3.1 Table of Contents of Module 3
3.2 Body of Data
3.2.1 Particulars of Active Pharmaceutical Ingredient(S) [API(S)]/ Drug Substance
3.2. S Drug Substance
3.2. S.1 General Information
3.2. S.2 Manufacturer
3.2. S.3 Characterisation
3.2. S.4 Control of Drug Substance
3.2. S.5 Reference Standards or Materials
3.2. S.6 Container Closure System (name, manufacturer)
3.2. S.7 Stability
3.2. P DRUG PRODUCT
3.2. P.1 Description and Composition of the Drug Product (name, dosage form)
3.2. P.2 Pharmaceutical Development
3.2.P.3 Manufacture
3.2.P.4 Control of Excipients .
3.2.P.5 Control of FPP
3.2. P.6 Reference Standards or Materials
3.2.P.7 Container Closure System
3.2.P.8 Stability
3.2. A APPENDICES
3.2. A.1 Facilities and Equipment
3.2. A.2 Adventitious Agents Safety Evaluation
3.2.A.3 Novel Excipients
3.2. R REGIONAL INFORMATION
3.2. R.1 Production documentation
3.3 LITERATURE REFERENCES

MODULE 4: Nonclinical Study Reports For New Chemical Entities Only

4.1 Table of Contents of Module 4
4.2 Study Reports
  4.2.1 Pharmacology
  4.2.2 Pharmacokinetics
  4.2.3 Toxicology
4.3 Literature References

MODULE 5: Clinical Study Reports

5.1 NEW CHEMICAL ENTITIES ONLY
  5.1.1 Table of Contents of Module 5
  5.1.2 Tabular Listing of All Clinical Studies
  5.1.3 Clinical Study Reports
    5.1.3.1 Reports of Biopharmaceutic Studies
    5.1.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports
    5.1.3.1.3 In Vitro – In Vivo Correlation Study Reports
    5.1.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies
    5.1.3.2 Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials
    5.1.3.2.1 Plasma Protein Binding Study Reports
    5.1.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies
    5.1.3.2.3 Reports of Studies Using Other Human Biomaterials
    5.1.3.3 Reports of Human Pharmacokinetic (PK) Studies
    5.1.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports
    5.1.3.3.2 Patient PK and Initial Tolerability Study Reports
    5.1.3.3.3 Intrinsic Factor PK Study Reports
    5.1.3.3.4 Extrinsic Factor PK Study Reports
    5.1.3.3.5 Population PK Study Reports
    5.1.3.4 Reports of Human Pharmacodynamic (PD) Studies
    5.1.3.5 Reports of Efficacy and Safety Studies
    5.1.3.6 Reports of Post-Marketing Experience
    5.1.3.7 Case Report Forms and Individual Patient Listings
  5.1.4 Literature References
5.2 INTERCHANGEABILITY OF GENERIC DRUGS – (GENERIC DRUG APPLICATIONS ONLY
  5.2.1 Reports of Biopharmaceutic Studies
  5.2.1.2 In vitro dissolution tests
5.3 SAFETY AND RESIDUES DOCUMENTATION (FOR VETERINARY PRODUCTS ONLY)
  5.3.1 Requirements for Animal Safety
  5.3.2 Requirements for Human Safety

4. LANGUAGE
5. DATA PRESENTATION

6. OFFICIAL REFERENCES AND TEXTS

7. SUBMISSION OF APPLICATION

  7.1 New applications for registration
  7.2 Applications for Renewal of Registration

7.3 Application for Variation of a registered medicinal product

8. PAYMENT OF FEES

9. AN OUTLINE OF THE EVALUATION PROCESS
9.1 Receiving of new applications
9.2 Evaluation process
9.3 Review of application by Drug Registration Committee

10. APPEAL FOR A REJECTED APPLICATION
10.1 Process for Applying

11. TIMELINES
11.1 Processing of Expedited review applications
11.2 Processing of new applications

SUMMARY OF PRODUCT CHARACTERISTICS:

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/TEMPLATE%20SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS%20(SmPC).pdf

QUALITY INFORMATION SUMMARY (QIS)

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/TEMPLATE%20QUALITY%20INFORMATION%20SUMMARY%20(QIS).pdf

QUALITY OVERALL SUMMARY: PRODUCT DOSSIER (QOS-PD)

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/TEMPLATE%20QUALITY%20OVERALL%20SUMMARY%20PRODUCT%20DOSSIER%20(QOS-PD).pdf

LABELLING

https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/TEMPLATE%20LABELLING.pdf

VARIATION GUIDELINES FOR ALLOPATHIC MEDICINES
https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/FDA%20VARIATION%20GUIDANCE.pdf

https://fdaghana.gov.gh/index.php/operational-guidelines-2/

DRUGS REGISTRATION

- GUIDELINES FOR REGISTRATION OF ALLOPATHIC MEDICINES CONSIDERED FOR SMALL SCALE MANUFACTURE
- TIMELINES FOR MEDICINAL PRODUCT REGISTRATION
- TIMELINES FOR MEDICINAL PRODUCT RE-REGISTRATION
- GUIDELINES FOR REGISTRATION OF UK GENERICS
- GUIDELINES FOR IMPORTATION OF DRUGS

- GUIDELINES FOR REGISTRATION OF ALLOPATHIC DRUGS
- GUIDELINES FOR STABILITY TESTING OF ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PHARMACEUTICAL PRODUCTS
- TEMPLATE QUALITY INFORMATION SUMMARY (QIS)
- TEMPLATE QUALITY OVERALL SUMMARY PRODUCT DOSSIER (QOS-PD)
- TEMPLATE LABELLING
- GUIDELINES FOR REGISTRATION OF ALLOPATHIC DRUGS-QUALITY PART
- TEMPLATE PATIENT INFORMATION LEAFLET
- TEMPLATE SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
- VARIATION GUIDELINES FOR ALLOPATHIC MEDICINES
- GUIDELINES FOR CONDUCTING BIOEQUIVALENCE STUDIES
- GUIDELINES FOR THE REGISTRATION OF MEDICINAL PRODUCTS CLASSIFIED FOR FAST TRACK PROCESSING
- GUIDELINES FOR THE REGISTRATION OF PARALLEL IMPORTED DRUGS OR HERBAL MEDICINAL PRODUCTS
- GUIDELINES FOR REGISTRATION OF VETERINARY NUTRITIONAL/DIETARY SUPPLEMENTS
- GUIDELINES FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS
- GUIDELINE FOR DONATION OF DRUGS
- GUIDELINES FOR LABELLING OF DRUGS
- GUIDELINES FOR THE CANCELLATION/ SUSPENSION OF A REGISTERED DRUG
- GUIDELINES FOR REGISTRATION OF AN ORPHAN DRUG
- PRODUCT LITERATURE STANDARD FOR VETERINARY PRODUCTS

https://fdaghana.gov.gh/index.php/operational-forms-2/

DRUGS DIVISION

- ABRIDGED CTD APPLICATION FORM FOR REGISTRATION OF PHARMACEUTICAL PRODUCT (SMALL SCALE)
- ALLOPATHIC DRUG CTD FORMAT
- APPLICATION FORM FOR RE-REGISTRATION OF ALLOPATHIC DRUG
- APPLICATION FORM FOR ADVERTISEMENT OF DRUGS, COSMETICS, HOUSEHOLD CHEMICALS AND MEDICAL DEVICES
- AUTHORIZED PERSONS IN PHARMA & CHEMICAL INDUSTRY
- COSMETICS
- APPLICATION FORM FOR SAFE DISPOSAL OF DRUGS, COSMETICS, HOUSEHOLD CHEMICALS, MEDICAL DEVICES AND INVESTIGATIONAL PRODUCTS
- FOOD,DIETARY , NUTRITIONAL SUPPLEMENT
- HOUSEHOLD CHEMICAL SUBSTANCE
- REGISTRATION AS AN IMPORTER OF TOBACCO PRODUCT
- REGISTRATION OF TOBACCO PRODUCT
- LABELLING OF PRODUCTS
- LICENSE TO MANUFACTURE DRUGS, COSMETICS, HOUSEHOLD CHEMICAL SUBSTANCES AND MEDICAL DEVICES
- LICENSING OF STORAGE FACILITIES OF IMPORTERS, EXPORTERS, WHOLESALERS AND DISTRIBUTORS OF FINISHED PHARMACEUTICAL

PRODUCTS, BIOLOGICAL PRODUCTS, HERBAL MEDICINES, FOOD SUPPLEMENTS AND PHARMACEUTICAL RAW MATERIALS
- LICENSE AS AN IMPORTER OF COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCES
- APPLICATION FORM FOR LICENSE AS AN IMPORTER OF MEDICAL DEVICES
- APPLICATION FORM FOR THE REGISTRATION OF DIAPERS (BABY & ADULT), SANITARY PADS AND MOP-UP TOWELS
- APPLICATION FORM FOR THE REGISTRATION OF CLASS I MEDICAL DEVICES
- APPLICATION FORM FOR THE REGISTRATION OF CLASSES II–IV MEDICAL DEVICES
- APPLICATION FORM FOR BLOOD FACILITY PRODUCTS LISTING IN GHANA
- APPLICATION TO REGISTER AS AN IMPORTER OF BIOLOGICAL PRODUCTS
- APPLICATION FORM FOR LICENSING BLOOD FACILITIES IN GHANA
- APPLICATION FORM FOR VARIATIONS TO A BIOLOGICAL PRODUCT
- REGISTRATION AS IMPORTER OF FINISHED PHARMACEUTICAL PRODUCTS, BIOLOGICAL PRODUCTS, HERBAL MEDICINES, FOOD SUPPLEMENTS AND PHARMACEUTICAL RAW MATERIALS
- REGISTRATION APPLICATION FORM FOR BIOSIMILAR PRODUCTS
- REGISTRATION APPLICATION FORM FOR VACCINES
- REGISTRATION RENEWAL APPLICATION FORM FOR BIOSIMILAR PRODUCTS
- REGISTRATION APPLICATION FORM FOR BIOLOGICAL PRODUCTS
- REGISTRATION RENEWAL APPLICATION FORM FOR BIOLOGICAL PRODUCTS
- REGISTRATION RENEWAL APPLICATION FORM FOR VACCINES
- RENEWAL OF LICENSE FOR THE MANUFACTURE OF DRUGS, COSMETICS, MEDICAL DEVICES AND HOUSEHOLD CHEMICAL SUBSTANCES
- HERBAL MEDICINAL PRODUCT
- HOMEOPATHIC MEDICINES
- VARIATION
- VETERINARY SUPPLEMENT APPLICATION
- VETERINARY DRUG APPLICATION

****

Details of Indian Embassy abroad: https://www.hciaccra.gov.in/

Details of importing country Embassy in India: https://ghana-mission.co.in/

List of local pharma organization abroad:

Pharmaceuticals society of Ghana	• https://psgh.societymanager.org/ • Off Victory Bible Junction, Spintex Rd, Accra, Ghana, Phone: +233 30 291 0263