ANALYSIS OF DOMESTIC PHARMACEUTICAL SUPPLY CHAINS IN GHANA

Table of Content

Contents

ANAI	YSIS	OF DOMESTIC PHARMACEUTICAL SUPPLY CHAINS IN GHANA	1
Table	of Co	ontent	2
List c	f Abb	reviations	2
SECT	ION 1	: INTRODUCTION	θ
Со	ntext	and background	ε
Ob	jectiv	ves of the assignment	ε
Ар	proad	ch to assignment and analytical framework	7
Sc	оре о	f the report	8
Lir	nitati	ons	8
SECT	ION 2	: TRENDS IN THE PHARMACEUTICAL MARKET	10
Ov	ervie	w of the sector	10
Ind	dustry	r Trade Trends	11
SECT	ION 3	: LEGAL, REGULATORY, AND INSTITUTIONAL FRAMEWORK	13
a)	Leg	gal and policy framework	13
b)	Ins	titutional framework –regulatory, industry associations etc	14
a)	Ke	y stakeholders within the industry	15
SECT	ION 4	: SUPPLY SIDE ANALYSIS	17
Ind	dustry	structure	17
Th	e pha	rmaceutical supply chain: actors, products and issues	17
	(i).	Research and Development	18
	(i).	Sourcing of products/ raw materials	20
	(ii).	Manufacturing	21
	(iii).	Distribution	24
	(iv).	Retail/Dispensing	24
a.	Pul	blic Sector Pharmaceutical Supply Chain and Procurement	26
b.	Pro	oduct analysis, production capacity and inputs	29
c.	Pri	cing in Ghana's Pharmaceutical Industry	30
d.	Ind	lustry Incentives	32
e.	Su	oply Chain Risk analysis in the Pharmaceutical Industry in Ghana	33
SECT	ION 4	: NHIS AND THE PHARMACEUTICAL INDUSTRY	34

The	e NHIS	34
lm	pact of the NHIS on the Pharmaceutical supply Chain	35
	NHIS reimbursable pharmaceutical products march against products by local Manufacturers one.	
	ION 5: CONCLUSION AND RECOMMENDATIONS FOR DESIGN STRATEGY	
a.	Conclusion	40
b.	Recommendations	42
c.	Opportunities	47
Appe	endix	48

List of Abbreviations

APIs Active Pharmaceutical Ingredients

ARVs Antiretroviral medicines

CHAG Christian Health Association of Ghana

CMS Central Medical Stores
CSO Civil Society Organisation
DP Development Partners

ECOWAS Economic Community of West African States

EML Essential Medicines List FDA Food and Drugs Authority

FPP Finished Pharmaceutical Product

FFS fee-for-service

GGRG Ghana Diagnostic Related Grouping

GHS Ghana Health Service

Global Fund Global Fund to Fight AIDS, Tuberculosis and Malaria

GMA Ghana Medical Association
GMP Good Manufacturing Practices
GNDP Ghana National Drugs Programme

GRA Ghana Revenue Authority

INN International Non-proprietary Name
ISO International Standards Organisation

M&E Monitoring and Evaluation

MIS Management Information Systems

MOH Ministry of Health

NCDs Non-Communicable Diseases

NCPv National Centre for Pharmacovigilance

NHI National Health Insurance

NHIA National Health Insurance Authority
NHIF National Health Insurance Fund
NHIL National Health Insurance Levy

NHIML National Health Insurance Medicines List

NHIS National Health Insurance Scheme
NMPC National Medicine Price Committee
NQCL National Quality Control Laboratory

OOP Out-of Pocket

OPD Outpatient Department

OTC Over the Counter

POM Prescription only Medicines
PSGH Pharmaceutical Society of Ghana

RMS Regional Medical Stores

SSA Sub-Saharan Africa

SSNIT Social Security and National Insurance Trust

STG Standard Treatment Guidelines

TB Tuberculosis

UNDP United Nations Development Programme

UNIDO United Nations Industrial Development Organization USAID United States Agency for International Development

VAT value-added tax

WAHO West African Health Organisation

WHO World Health Organisation

SECTION 1: INTRODUCTION

This study was commissioned as part of the Foreign, Commonwealth & Development Office's (FCD0) Ghana Jobs and Economic Transformation (JET) progamme. The JET progamme seeks to help drive economic transformation in Ghana by supporting government to attract increased private investment and create high quality jobs in key industrial sectors. The progamme expects to spawn at least 15,000 quality jobs and stimulate over £50 million in private investment into in anchor industrial sectors of the country. Adopting an industrialization driven approach within key priority sectors (Pharmaceuticals, Automobiles and Textiles & Garments), the JET progamme will realize these results by (a) accelerating anchor investment into priority sectors to drive industrial scaling; (b) building capability of domestic firms and increasing local content and suppliers in facilitated investments; (c) supporting industrial policy development in priority sectors; and (d) building a more enabling environment for stakeholder coordination. The scope of the assignment is limited to controlled medicines.

Context and background

The pharmaceutical sector plays a critical role in the delivery of universal health care in Ghana and the West African sub-region. Increased local production of pharmaceutical products does not only provide jobs but ensures a sustainable supply of essential medicines, particularly when global supply chains are disrupted. Recognizing the massive untapped potential of the pharmaceutical industry, in 2017 the Government of Ghana launched the 10-Point Industrial Transformation Agenda, to expand the manufacturing sector, reduce unemployment and accelerate socioeconomic development. The progamme seeks to drive investment in strategic industries such as the pharmaceuticals industry. The pharmaceutical industry remains a key priority sector under this agenda as well as the government's recently initiated COVID-19 recovery strategy, the Ghana Covid-19 Alleviation and Revitalization of Enterprises Support (CARES) progamme. Like the Ghanaian government, the JET progamme is committed to supporting Ghana to become a manufacturing hub for pharmaceutical products and active pharmaceutical ingredients for the West African and regional Markets. To achieve this, one of the strategies of the progamme is to help guide and implement design of interventions to improve the competitiveness and efficiency of the pharmaceutical supply chains.

Objectives of the assignment

To guide the design of interventions to improve the competitiveness of local companies and explore aspects of pharmaceutical supply chains which require direct investments for the greatest impact to create direct and indirect jobs, the Ghana JET progamme commissioned this study. The main objective of the assignment is to: (a) Identify and map out all the actors of the pharmaceutical supply chain at all levels including their relations, their product portfolios, and margins and (b) Establish in value terms how the NHIS reimbursements and delays impact the pharmaceutical supply chain. Specifically, the study will address the following research questions:

- (a) What is the structure of the pharmaceutical supply chain in Ghana?
- (b) Who are the major players in the supply chain, and what are the functions of the players/actors in the supply chain structure?
- (c) Does the existing local pharmaceutical player's output meet the top 20 NHIS reimbursable products
- (d) What is the gap between local output and the top 20 NHIS reimbursable products?
- (e) How does the local pharmaceutical product out-turn meet the demand of the top 10 OPD prevalent diseases?

(f) What is the economic impact of the NHIS performance on the pharmaceutical supply chain?

Approach to assignment and analytical framework

This study relied on a mixed approach to validate outcomes by factoring in desk-based research, fieldwork, and a multi-stakeholder validation workshop to validate its findings. The objectives and scope of reference for this study were provided by Palladium while ACET defined the analytical framework and executed the assignment. First, the team embarked on a comprehensive desk review of documents on the pharmaceutical industry in Ghana. The secondary data were drawn from sources such as Food and Drugs Authority, Ministry of Health, World Health Organization, the Pharmaceutical Society of Ghana (PSGH), Fitch Solutions, academic articles, newspaper reports, business articles, reports of industry associations, government reports, publications from think-tanks and academic institutions available on the internet, United Nations agency websites such as the World Health Organization and United Nations Development Progamme, as well as the Organization for Economic Cooperation and Development etc. The desk review explored the pharmaceutical industry landscape as well as emerging supply side issues in the industry over the past decade.

Secondly, information gleaned from the secondary data was complemented by primary data collected through key informant interviews or focus group discussions with different stakeholder groups —policy makers and regulators, pharmaceutical companies (both local and foreign), industry associations and development partners. While the timing of the project did not allow the team to meet enough stakeholders, the interviews with a few pharmaceutical firms allowed the team to understand the supply chain of the sector, drivers and challenges of the industry, and opportunities for intervention for the JET progamme. The data collected was analyzed and triangulated to map out factors critical to the competitiveness and job creation potential of the pharmaceutical market/supply chain in Ghana. The purpose of the triangulation was to identify the consistency of major themes or factors that are important to delivering a competitive pharmaceutical sector from the perspective of key stakeholders. A simple interview guide and a data collection template was developed to enable the team to extract the needed information to fill in the gaps in existing literature explored during the desk review stage.

The third and final stage was the closing phase. After the analysis and drafting of the report, the team submitted three drafts of the report to the JET Ghana team for their inputs. After incorporating the feedback from the JET team, the preliminary findings of the study will be presented and validated at a stakeholder workshop leading to the development of the final report. The study process is depicted below in figure 1

Figure 1: A overview of the methodology adopted for the study.

DESIGN	EXECUTION		CLOSE
Desk review documents Identify and map out key stakeholders and the value chains Match opportunities and constraints to development of supply chains. Finalize approach and develop data collection Instruments	Design a sampling strategy and select economic areas (companies) for data collection Interview key informants and identify constraints and opportunities for local content in supply chains Identify key imports and options for local pharmaceutical supply chains	Develop recommendations for the design a strategy for improving supply and value chains Develop case studies and justifications for 20 NHIS reimbursable lists and OPDs to be matched by products of local manufacturers Assess economic impact of NHIS on local supply chains Finalize red draft report.	Stakeholder validation of study findings Finalize and submit final report incorporating feedback from validation workshop

To address the objectives of the assignment, this report will follow the analytical framework below, in order to provide a holistic analysis of the pharmaceutical sector in Ghana. The study will touch on three main blocs of the sectors: (a) the policy and regulatory landscape of the sector; (b) the demand side issues and (c) the supply side issues. The study provides a snapshot of the first two blocs and deep dives into the supply side issues in order to adequately respond to the demands of the study.

Fig. 2: Analytical Framework for the study.



Source: Author's Construct

Scope of the report

The remainder of the paper is structured in the following fashion. Section 2 provides a snapshot of the trends in the pharmaceutical sub-sector in Ghana. In section 3, we explore the legal, and policy framework of the industry and provides a snapshot of the institutional framework for both the regulatory and operations of the sector. In section 4 we explore the supply chain of the sector in detail. In section 5, we highlight the complex relationship between the National Health Insurance Scheme and the pharmaceutical sector. We explore the following questions (a) Does the existing local pharmaceutical player's output meet the top 20 NHIS reimbursable products? (b) What is the gap between local output and the top 20 NHIS reimbursable products; (c) How does the local pharmaceutical product out-turn meet the demand of the top 10 OPD prevalent diseases? and (d) What is the economic impact of the NHIS performance on the pharmaceutical supply chain? Section 5 concludes with the summary, recommendation for future engagement of the JET programme in the industry.

Limitations

In undertaking this quick review of the supply chain of the pharmaceutical sector, the team faced a number of limitations.

- A major limitation was access to data from both the regulatory institutions and the pharmaceutical companies. FDA acknowledged that its data was scattered so was unable to readily provide the data at the required time.
- Averse attitude to data sharing also affected pharmaceutical companies —they were not too transparent with sharing their firm data. ACET had to rely on other sources of data.

While the urgency attached to the assignment required that the ACET team put this together in the shortest possible time, the findings are useful enough to guide the direction of the pharmaceutical portfolio of the JET programme.

SECTION 2: TRENDS IN THE PHARMACEUTICAL MARKET

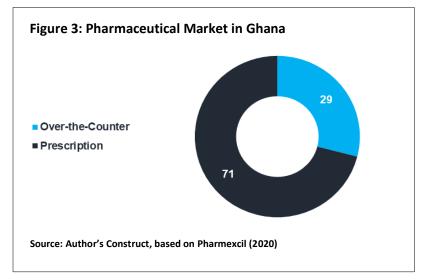
This section of the report briefly discusses trends in the pharmaceutical market in Ghana. It provides an overview of the sector, trends in trade in pharmaceutical products and a general outlook of the industry.

Overview of the sector

The pharmaceutical industry in Ghana has been in existence for well over six decades with one of the largest manufacturers, DAS, tracing its routes to the late 1960s. Despite being quiescent for well over three decades, in recent years the pharmaceutical sub-sector is fast becoming a critical sector of the economy receiving a lot of attention from successive governments.

The demand for quality healthcare continues to rise in Ghana with increasing affluence and rising consumer awareness. Currently, about 2.5% of the country's GDP is expected to be spent on healthcare. ¹This is expected to increase with the growing population and a longer life expectancy, as well as the Government's increasing expenditures on provision of better healthcare facilities and services. Healthcare remains a priority of the Ghanaian Government.

The pharmaceutical industry is one of the key Strategic Anchor Industries under the Ministry of Trade and Industry's 10 Point Agenda for Industrial Transformation to expand the manufacturing sector, reduce unemployment and accelerate socio-economic development. The industry's activities have a strong and positive influence on the Ghanaian economy through the attraction of investments into the sector, contributing to Ghana's export basket and creating jobs.



Ghana's pharmaceutical industry is largely import driven with a relatively small manufacturing Prescription drugs sector. constituted about 71 percent of the total market and 29 percent were over-the-counter drugs² (see figure 3 below). That notwithstanding, there is a large appetite for OTC's. The pharmaceutical market is characterized by high demand for relatively cheaper drugs which can be attributed to the low incomes of the majority of the population and out-of-pocket the increased

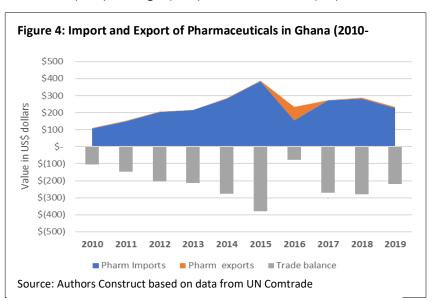
spending on drugs. It is also partly due to the relatively high levels of self-medication in areas where health facilities are inaccessible or among low-income families, leading to increased number of visits in chemical sellers/pharmacies. Majority of local producers therefore serve the OTC segment of the market with the larger segment dominated by foreign firms. Only few local pharmaceutical firms produce. specialized medicines. In 2020, the FDA reported that there are about 126 foreign manufacturing companies with licenses. With respect to prescription drugs, generic drugs constitute 54 percent of the pharmaceutical market while 46 percent being patented drugs. Multinational companies enjoy a monopoly for patented drugs, but these companies also are fast making inroads into the higher end of the market for generic products and continue to charge high prices for their products. Most of the patented drugs were imported

from multinational companies from European countries, mainly Belgium, Switzerland, the United Kingdom and Germany.³ The large MNCs such as Pfizer, Schering Plough, Novartis, Astra Zeneca are mainly licensed importers. Their products, which are mostly branded drugs, are distributed by locally incorporated companies. Indian companies are gradually dominating the space. Due to economies of scale, through lower-priced generic brands and massive brand promotions, Indian companies like Cipla, Ranbaxy, Sun Pharmaceuticals, Cadila and Glenmark currently dominate the generics market.⁴ These Indian companies have established network of local importers and distributors who facilitate their entry and growth into the Ghanaian Market. While the larger more reputed Indian companies compete with multinational pharmaceutical companies and generic companies from other countries, a 2016 study notes that the smaller Indian companies actively participate in the over-the counter and simple formulations segments of the market thus, competing mainly with local manufacturers.⁵ The size of generic drugs continues to grow strongly over the past decade with a market value of US\$376million. With increased health insurance coverage and cost-containment measure of the Government of Ghana, generic prescriptions are more likely to dominate the healthcare system.

Industry Trade Trends

Pharmaceutical trade in Ghana largely reflects the trend in Sub-Saharan Africa, where medicine needs are import driven. In Ghana, nearly 70% of pharmaceutical demand is met by imports, mostly from India and China while local companies meet the needs of the remaining 30%. Figure 3 presents the total imports and exports for all pharmaceutical products traded between Ghana and the world from 2010 to 2019 from the UM Comtrade. In terms of trade, according to the United Nations COMTRADE, total trade for pharmaceutical was \$234.89 million in 2019. Exports of pharmaceutical products amounted to \$8.32 million in 2019, an increase of 128%. Ghana's pharmaceutical export destinations have mostly been neighboring West African countries. In 2019 the top 5 destination of Ghana's pharmaceutical export were: Côte d'Ivoire (24%), Liberia (24%), Burkina Faso (23%), Senegal (12%), and The Gambia (5%).

2019 Ghana imported pharmaceutical products worth US\$226.57 million from countries. The top 10 countries accounted for 91% of total imports. India remains the largest source, with a share of 36%, followed by Netherlands (22%), Belgium (8%), United Kingdom (5%), France (5%), Switzerland (4%), China (3%), Germany (3%), Slovenia (2%) and Italy (2%). As already indicated above, imported medicines (both patented and generics) account for the largest part of the pharmaceutical



market. Most imports of originator pharmaceutical products are from the developed markets of the Netherlands, Belgium, United Kingdom, France and Switzerland while imports of generic medicines are largely from India and China. Several large pharmaceutical multinational corporations (MNCs) have set up companies in Ghana operating mainly as importers of their own products. In July 2017, the Food and Drugs Authority (FDA) published a list of registered companies that were importers of finished pharmaceutical products, biological products, herbal products, food supplements and pharmaceutical raw

materials. The list of these companies has been presented in Appendix 1. With the decline in production of APIs from India, leading to India importing about 85 percent of its APIs from China, the pharmaceutical manufacturing companies globally source their active pharmaceutical ingredients (APIs) and excipients from China.

Industry Outlook

Over the last decade, the industry has demonstrated strong growth potential with increased pharmaceutical sales from about US\$300million in 2012 to US\$589million in 2019⁶. The market is expected to grow at a compound annual growth rate (CAGR) of 9.8 percent by 2024 with a gross pharmaceutical sale of about US\$620million. Fitch Solutions (2021) estimates that sales will reach GHS6.55bn (USD896mn) by 2030, corresponding to a local currency CAGR of 9.3% (6.8% in US dollar terms).⁷

The changing trends of Ghana's epidemiology towards increased non-communicable diseases and the tendency of frequent occurrence of communicable disease, suggest that the growth potential of the industry remains positive. The current consumption and supply dynamics suggests that the pharmaceutical industry will be driven largely by imports. This is because despite the increased number of domestic manufacturers venturing into generics, it appears they are unable to meet the domestic demand, leading to dependence on imports. But this also suggests that increased local production will help decrease the pharmaceutical trade deficit in the long-term. Additionally, the market for patented drugs is driven by multinational corporations. These indicate significant market opportunities for not just multinationals that import, but those that establish manufacturing plants in Ghana. The suspension of the 50% benchmark price may incentivize domestic production; however, capacity constraints may only result in increase in prices without increasing capacity to meet domestic demand. Increased localized production will help decrease the pharmaceutical trade deficit in the long-term

With the kick-off of the African Free Trade Continental Area it is expected that Ghanaian pharmaceutical exports to grow rapidly to neighboring countries such as Cote d'Ivoire, Liberia, Burkina Faso. Indeed West Africa presents a massive untapped market for Ghanaian local pharmaceutical manufacturers. Making inroads into the market of other West African countries provides market access to some 365 million people within the region.

Given the low manufacturing base within the region, the Ghanaian pharmaceutical industry has enormous potential and opportunities for the production and supply of essential medicines within the region. West African countries are plagued with similar diseases and issues affecting the manufacturing and delivering of medicines in the region and are therefore highly dependent on imported medicines and other health-related products. With the exception of Nigeria which has about 120 pharmaceutical manufacturers of various sizes (but capacity utilization is about 40%), quite a number of West African countries have less than 2 local pharmaceutical manufacturing firms in operation. Additionally, there is so far no company manufacturing APIs within the region. ⁸

According to Ekeigwe (2019), a myriad of issues across various countries compounds the pharmaceutical supply chain challenges in the region. These include: the lack of good Infrastructure; dearth of pharmaceutical manufacturing companies with WHO (World Health Organization) pre-qualification; inadequate skilled technical personnel in drug development and manufacturing; small profit margins and high cost of business in the pharmaceutical industry in many countries; and generally, government apathy.

SECTION 3: LEGAL, REGULATORY, AND INSTITUTIONAL FRAMEWORK

This section highlights the main characteristics of the pharmaceutical sector and the policy framework in Ghana. It briefly explores the legal and policy framework of the industry and provides a snapshot of the institutional framework for both the regulatory and operations of the sector. Specifically, we seek to explore the following: What are the legal and regulatory frameworks guiding the industry? Who are the major players in the players in the industry, and what are their roles? How do the players interact with one another?

a) Legal and policy framework

There are several legal instruments and policies that guide the operations of the pharmaceutical industry. The major ones include Food and Drugs Act, Public Health Act, 2012 Act 851, Pharmacy Act, 1994 Act 489, Ghana Health Service and Teaching Hospitals Act, 1996 Act 525, National Health Insurance Act, 2012 Act 852, Public Procurement Act, 2003 Act 663.

The Food and Drugs Act, 1992 P.N.D.C.L. 305B which was amended in 1996 prescribes the guidelines to control the manufacturing, importation, registration, licensing, and quality assurance of drugs, herbal medicinal products, cosmetic, medical devices, or household chemical substances. It also gives the legal mandate to the Food and Drugs Authority the National Regulatory Authority mandated to regulate food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco, and tobacco products. It is worth mentioning that, generally, Ghana has relatively well-functioning regulatory systems compared with other countries within the sub-region. However, the Food and Drugs Authority (GFDA) lack the capacity to effectively control the supply of poor-quality medicines and is often under-resourced. ⁹

The Public Health Act, 2012 Act 851 revises and consolidates laws relating to public health to prevent disease, promote, safeguard, maintain and protect the health of humans and animals and to provide for related matters. The Act provides the legal backing for the transitioning of the Food and Drugs Board to the Food and Drugs Authority in 2012.

Public procurement of pharmaceutical goods is governed by the Public Procurement Act, 2003 (Act 663) as amended by the Public Procurement (Amendment) Act 2016 (Act 914). This Act regulates the procurement of goods, works and services financed, in whole or in part, from public funds and the disposal of government stores. All government agencies, institutions, and establishments including the Ghana Health Service and the National Health Insurance Authority —the largest procurer of pharmaceutical goods. Pharmaceutical companies must strictly comply with the Act to satisfy requirements of tender and contract award procedures of the Ministry of Health

The National Health Policy, 2020, Ghana National Drugs Programme; Standard Treatment Guidelines, Essential Medicines List National Medicines Policy, 2017, the Ministry of Trade and Industry's 10 Point Agenda for Industrial Transformation are some of the headline policies guiding the activities and direction of the sector. The recently revised National Health Policy (2020) addresses key health determinants and builds resilience for public health emergencies, while the National Medicines policy proffers policy interventions to further improve efficiency in the pharmaceutical sector including public procurement, the Food and Drugs Authority (FDA), active monitoring and correction of prescribing behavior in line with Standard Treatment Guidelines (STG), as well as support to the local pharmaceutical industry in line with public health goals. The Standard Treatment Guidelines (STG) is a guidance document for the use of drugs by healthcare professional by the Ghana National Drugs Program (GNDP) under the Ministry of Health.

Out of the STG, the Essential Medicines List (EML), the basis on which public procurement of drugs is done. The EML also defines the National Health Insurance Authority (NHIA) -a list of drugs with their corresponding prices reimbursable under the NHIS. The EML and STGs were updated in 2004, 2010 and 2016. 10

In 2021, the government and the Ghana Pharmacy Council launched a policy program that seeks to establish an e-commerce pharmaceutical system to increase citizen's access to quality pharmaceutical and medical services. The reduction in brick and motor sales occasioned by the covid-19 pandemic has made it necessary for local pharmaceutical companies to explore alternatives to increasing reach and market size. Additionally, the e-pharmacy policy seeks to address the surge of counterfeit drugs by middlemen and independent drug suppliers in the pharmaceutical supply chain. Through the e-pharmacy, clients have access to counselling about drug products and their potential effects, licensed pharmaceutical and chemical sellers, and overall protection of client's rights to quality medicines and responsible service delivery. The e-pharmacy policy when fully implement will contribute to increasing domestic pharmaceutical sales in Ghana. Additionally, it will strengthen market competition between retailers which can potentially lead to a reduction in the market price of high demand medicines. Furthermore, the policy can also strengthen primary healthcare in Ghana because the pharmacies are the first point of seeking healthcare. Despite the prospects of the policy, little benefits can be gained if stronger and credible distribution and delivery systems are not implemented. Additionally, the policy may inadvertently exclude citizens in areas where internet penetration is low, and mobile network systems are weak.

b) Institutional framework –regulatory, industry associations etc.

The main institutions within the pharmaceutical industry include the following: the Ministry of Health, the Food and Drugs Authority (FDA), Ghana Standards Authority (GSA), the Ministry of Trade and Industry (MoTI) etc. Table 4 below summarizes the role of all key stakeholders within the pharmaceutical industry.

The Ministry of Health works with the Food and Drugs Authority (FDA) on policy formulation within the sector. The Ghana National Drugs Program (GNDP) which operates under the MOH defines the medicines policy and coordinates policy implementations within the pharmaceutical sector both public and private institutions.

The Food and Drugs Authority (FDA) and the Ghana Standards Authority are the two state regulatory authorities responsible for ensuring compliance with the requirements of relevant laws regarding production processes as well as the quality of the pharmaceutical products. The Food and Drugs Authority (FDA) formerly the Food and Drugs Board (FDB) is the National Regulatory Authority mandated by the public Health Act, 2012 (Act 851) to regulate food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco, and tobacco products. The Act cautions that labeling, packaging and advertisements should not be misleading to consumers with respect to its value or merits and that promotional materials and advertisements must be pre-approved by the FDA. The authority delivers on its mandate through the following 5 specialized divisions: Food Division, Drug Registration and Inspectorate Division, Safety Monitoring and Clinical Trials Division, Cosmetics, Medical Devices and Household Chemicals Division, and Monitoring and Evaluation Division. The authority also runs the official Drug Quality Control Laboratory (DQCL) which oversees testing quality samples obtained from manufacturers, importers, distributors, or other sources. Although represented in all the initial 10 regions, their laboratories are only sited at their headquarters/head offices. Recently the Authority established a Herbal Medicine department to evaluate herbal medicine and food supplement registration applications leading to the registration of herbal medicines.

Until recently, the duplication of roles between GSA and FDA within the pharmaceutical sector led to delays in acquiring regulatory and certifications for products and an increased regulatory cost in the industry. Per the mandates, the Ghana Standards Authority (GSA) is responsible for the maintenance of acceptable standards for product and services and sound management practices in industries and public institutions in Ghana while the FDA ensures that locally manufactured food products meet the standards set by the Ghana Standards Authority (GSA). In essence, the GSA is supposed to define the essential requirements to which food and drugs certifications must conform. This required going through different certifications from both FDA and GSA for product registration and certification. In 2020, the FDA and GSA agreed to harmonize their activities and eliminate existing overlaps by sharing data and harmonizing regulatory and certification processes, as well as inspection procedures to improve ease of doing business in the sector. ¹¹

Besides the regulatory institutions under the government, other pharmaceutical bodies like the Pharmacy Council, the Pharmaceutical Manufacturers Association of Ghana (PMAG), the Pharmaceutical Society of Ghana and the Chamber of Pharmacy Ghana (COPG) play critical roles with the industry. The Pharmacy Act, 1994 (Act 489) mandates the Council to regulate the certification of pharmacists, distribution of pharmacies in Ghana and uphold the professional standards through the disciplinary powers conferred on it. The Council is responsible for licensing anybody that carries out the business of mixing, compounding, preparing, or supplying restricted drugs by retail. The table below provides an overview of the roles of key actors operating in the pharmaceutical industry in Ghana. Until the formation of the Chamber of Pharmacy Ghana (COPG), the pharmaceutical industry was saddled with many splinter groupings, each pursuing its own narrow agenda without the requisite harmonization of ideas to serve the good of the industry as a whole. The other splinter groups under the ambit of the COPG: Pharmaceutical Importers and Wholesalers Association, Community Practice Pharmacists Association (CPPA), Over the Counter Chemical Sellers Association of Ghana (OTCMSA), Association of Ethical and Pharmaceutical Industries (AREPI), Pharmacy Owners Association of Ghana.

a) Key stakeholders within the industry

The industry value chain has many stakeholders playing different roles. Some are domiciled in one node some have relevance across various nodes of the industry. The main stakeholders and their roles shown in table 4.

Table 4: Key Stakeholders in the Pharmaceutical Landscape

	Institution	Role
nt	Ministry of Health /Ghana National Drugs Programme (GNDP)	Define drug policy and coordinate implementation of the policies and programs of the pharmaceutical sector; monitor certain performance parameters such as prices, rational use; issue Standard Treatment Guidelines and Essential Medicines List.
men	MOH Procurement Department	Procures drugs for the public sector supply system (CMS) including some (but not all) donor funded drugs.
ern	Food and Drugs Authority	Regulates pharmaceutical market, manufacturing, import, export, advertising, clinical trials
Gove	National Health insurance Authority	Largest payer for drugs in public and private sector; influences prices through regulation (maximum reimbursement) and prescription practices through claims management
	Standards Authority	Responsible for the maintenance of acceptable standards for product and services and sound management practices in industries and public institutions in Ghana

	Ministry of Trade and Industry	The MoTI formulates industrial policies and programs which directly impact the pharmaceutical firms.
	Health Facilities and Regulatory Agency (HeFRA)	Provides license and monitors facilities for the provision of public and private health care services in line with the Health Institutions and Facilities Act, 2011 (Act 829).
	Central Medical Stores and Regional Medical Stores	Supply drugs to public and NGO facilities; RMS can organize their own procurements
	Pharmacy Council	Regulatory body that licenses retail pharmacies and chemical sellers; governed by a board on which the Pharmaceutical Society of Ghana has three seats out of nine. Ensures competency of pharmaceutical care providers and inspects pharmacies and other establishments for drug dispensing
	Pharmaceutical Society of Ghana	Professional society with mandatory membership for all Ghanaian pharmacists; its role is to ensure adherence to professional standards and ethics.
Suc	Pharmaceutical Manufacturers Association of Ghana (PMAG)	Main local pharmaceutical manufacturers association. Interest is to improve business perspectives of local manufacturers
Associatio	Pharmacists and Chemical Sellers	1600 licensed pharmacies, >80% concentrated in Greater Accra and Ashanti region; community-practice pharmacists have their own association. Over 10000 licensed chemical sellers all over Ghana
Industry Associations	Ghana National Chamber of Pharmacy(GNCoP)	The umbrella body for five pharmaceutical industry groupings and the Pharmaceutical Manufacturers Association of Ghana (PMAG). With membership that spans local manufacturers to importers, wholesalers, distributors, retailers, practitioners/consultants, and academia, they seek to protect and pursue the collective needs and interests of its members, while aspiring to be a research hub and advocate on all national issues that are likely to affect the pharmaceutical industry. issues
ers	Universities	Support policy makers through research, for example studying drug prices, quality and usage; pharmaceutical experts participate in commissions supporting GNDP in updating drug lists, treatment guidelines etc.
Other stakeholde	WHO	Country Advisor (National Pharmaceutical Officer) provides technical assistance and advice for policy makers at the MOH and Agencies in coordination with experts from WHO Regional Office and Headquarters an advocacy voice that seeks to speak authoritatively and act proactively on all national issues that are likely to affect the pharmaceutical industry.
Other	Teaching hospitals, GHS providers, CHAG providers	Some health facilities organize their own procurement and define formularies and policies that may deviate from the GNDP endorsed policies
	Catholic Drug Service	Limited pooled procurement of drugs for CHAG facilities (2000) "Policy Note: The Pharmacoutical Sector in Ghana"

Adapted from Seiter and Gyansa-Lutterodt (2009), "Policy Note: The Pharmaceutical Sector in Ghana"

SECTION 4: SUPPLY SIDE ANALYSIS

This section deep dives into the supply side issues of the pharmaceutical sector in Ghana. Specifically, we seek to explore the following: How is the supply chain structure? Who are the major players within each segment of the market, and what are their products? How do the players interact with one another? What is the product range of the local manufacturers? How do controlled medicines flow from the point of manufacture or import down to the ultimate users or patients?

Increased promotion and implementation of universal healthcare policies will increase the pharmaceutical needs of the country. Ghana's pharmaceutical sales is expected to grow by about 9.8 percent compound annual growth rate between 2020 and 2024. ¹² This implies a growth in demand for APIs and excipients, particularly for OTCs and some branded drugs. Additionally, governments ban on imports of certain drugs, removal of benchmark price reduction policy, and VAT exemptions could potentially reduce the cost of producing APIs locally while creating increased domestic demand for locally manufactured drugs. Also, the pandemic and its attendant supply chain disruptions have encouraged local approaches to addressing the supply setbacks through domestic production of core APIs. Furthermore, the increasing number of foreign manufacturing firms would also contribute to increasing the demand for APIs in the pharmaceutical industry in Ghana. These factors are playing a big role in stimulating the supply side of the pharmaceutical supply chain.

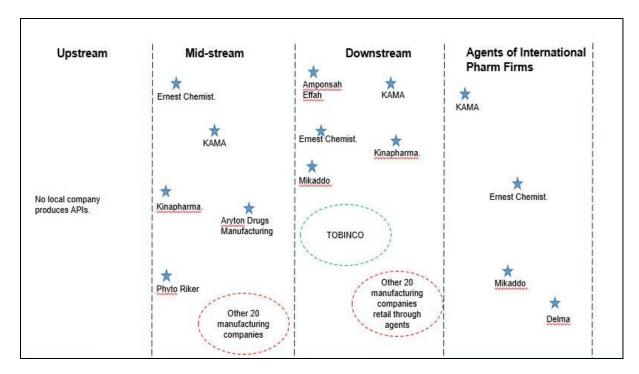
Industry structure

Generally, Ghana's pharmaceutical industry is comprised of many small and medium-sized enterprises (SMEs) engaged in the production and importation of generic and branded drugs. Many of these actors operate at different levels of the industry as distributors, wholesalers, retailers, sales reps, and many others — with significant vertical consolidation (as the same company manufactures, wholesales and retails, for example) and horizontal transfer. To this end, the market structure of Ghana's pharmaceutical industry has the following segments: Sourcing of products/raw materials, Research and Development, Manufacturing, distribution, and retail. Figure 5 below gives a simplified overview of the market structure of the pharmaceutical sector in Ghana.

The pharmaceutical supply chain: actors, products and issues

In view of the above, the supply chain structure of the Ghanaian pharmaceutical sector will be analyzed across the segments of the market. The analysis discusses the supply chain from the upstream activities (Sourcing, Research and Development), mid-stream (manufacturing and distribution) through to the downstream segment of the market (retail). It also discusses how the various segments interact within the supply chain.

Figure 5: TOP PLAYERS AND THEIR ROLES IN THE PHARMACEUTICAL SUPPLY CHAIN



Source: Author's Construct

(i). Research and Development

A critical segment of the pharmaceutical market is the Research and Development (R&D) since it drives innovation and the introduction and approval of new drugs. This segment of the market covers a variety of activities, including the following: (a) invention, or research and discovery of new drugs; (b) development, or clinical testing, preparation and submission of applications approvals, and design of production processes for new drugs; (c) incremental innovation which includes the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications (evergreening); (d) product differentiation, or the clinical testing; and (e) clinical trials for safety-monitoring or marketing purposes. ¹³

There are little to no R&D capabilities in the industry, where they exist in pharmaceutical companies, they are often limited to formulating the processes of manufacturing generic medicines and not developing original medicines. The outcome of engagements with some local manufacturing companies ¹⁴ follows the existing narrative of limited research and capacity development in the pharmaceutical sector. Virtually all the manufacturing companies interviewed did not have an internal research and development unit involved in drug and medical research to address existing domestic capacity gaps, however, the minimal research activities by the local manufacturing firms focus on improving the existing products produced by the firm. Essentially, there is no drug discovery instead what most pharmaceutical manufacturing firms drug development do is. For instance, DAS Pharmaceuticals have internal research purposely to develop alternative ways of improving the generic drugs produced by the firm. The low research investment by the local manufacturing companies can be attributed to the focus on production of generics. The limited and lack of interest in R&D is partly due to weak intellectual property rights, regulatory and financial barriers to commercialization, and a lack of basic infrastructure. ¹⁵

On the government side, health research and development has been weak and characterized by uncoordinated institutional framework and policy interventions. The FDA and the GSA have labs for product testing and certification. Beyond that, there are a number of Research Institutions scattered across the county with a mandate to facilitate health research, but generally undertake health research to support policy in the space. They relate to the pharmaceutical sector through their support for clinical safety for drug and vaccine trials. Only one of the research centers undertakes research into medicine, produces medicines and runs an out-patient clinic, but this is only limited to herbal medicine. In 2015, a study by the UKAid which analyzed the proposals received by the Research Development Division focused on health system research (41%), operations research (21%), and microbiology laboratory test (10%)¹⁶. The study found that only 13 percent of the proposal submitted focused on clinical trials. The top five research areas were malaria, HIV/AIDS, Maternal and Child Health, Tuberculosis, and worm infestation. Also, only 11percent of the proposals received were used for drug products, while 84percent were used for scientific publication, advocacy, and policy change. Clearly, pharmaceutical research, innovation and development has not been prioritized in health research policy of the country. The long term effect is the ad-hoc implementation of programmes or donor-interventions which result in minimal impact on development of a competitive pharmaceutical industry in Ghana.

Table 1: List of Health Research Institutions and Category

Actors	Institutions
Ghana Health	Navrongo Health Research Centre
Service/Ministry of Health	Dodowa Health Research Centre
	Kintampo Health Research Centre
	Centre for Scientific Research into Plant Medicine
	Centre for Scientific & Industrial Research
Academic Universities &	Noguchi Memorial Institute for Medical Research
Affiliates	Kumasi Centre for Collaborative Research in Tropical Medicine
	University of Ghana School of Public Health
Non-Public Sector Health	Centre for Health and Social Services
Research Centers	Centre for Development of People
	Alliance for Reproductive Health
Donor-sponsored	Ghana-Dutch Research Collaboration
Initiatives	

Source: Author's construct (will be further updated)

Aside from the lack of coordinated program to support pharmaceutical research, the pharmaceutical industry appears to be opaque with regards to publication of timely information. Nonetheless, an analysis of registered allopathic drugs in the last ten years reveals a four-fold increase from 486 in 2010¹⁷ to about 1,857 in 2020¹⁸. While the FDA does not report investment in research and development of the manufacturers of drugs locally, the increased number of registrations suggest considerable level of research into new products to address health needs of the country. Additionally, the trend of large imports resonates with the relatively high registration of imported drugs with the FDA. For example, in 2010 out of the 486 products approved by the FDA, 402 were imported. To boost investor confidence in the industry, it is imperative for pharmaceutical manufacturing companies to provide consistent report on average drug spending, research and development investment, and new drugs approved over a period by the manufacturers.

A major challenge to boosting or kickstarting the R&D capacity of the local pharmaceutical industry is the lack of information on research activities by the local manufacturing companies and the near absence of broad industry and multi-stakeholder collaboration on research and development. Also, many of these pharmaceutical manufacturing companies are outsourcing research and innovation activities to existing institutions such as the CSIR or the Noguchi Memorial Institute for Medical Research, whose role are primarily likely to be quality assurance or conducting high level test beyond the manufacturer's capacity. This is mostly driven by the high cost of setting up ultra-modern laboratories and building the requisite human capacity to conduct research. Also, the increased importation of certain OTCs currently produced by PMAG is likely to minimize the incentive to establish research and innovation by the local manufacturers.

Despite these challenges, the GMP baseline studies conducted by the FDA and UNIDO indicates that the pharmaceutical industry has acceptable levels of human resources with adequate level of training ¹⁹. This suggest that with the right institutional and multi-stakeholder synergies formed and adequate support (legal framework, financial, and logistics) provided, the industry has the right human resource to enhance research and development in the pharmaceutical industry. Moreover, the supply chain shocks caused by the Covid-19 pandemic has incentivized some local manufacturing companies to extensively explore opportunities to domestically produce critical inputs. This has the potential to drive increased investment in research by local manufacturers and encourage partnership with research institutions in the academic and non-academic areas. As Ghana continue to improve and extend coverage of internet connectivity, local pharmaceuticals are more likely to adopt artificial intelligence, digital biomarkers, and remote monitoring systems which have the potential to reduce cost of research and incentivize crossindustry collaborations²⁰.

(i). Sourcing of products/ raw materials

There used to be one small-scale manufacturer of active pharmaceutical ingredients located in Ghana but this company (LaGray Chemical Company) is currently defunct. There is very little capacity for the production of any of the critical raw materials needed by the pharmaceutical sector in Ghana and the subregion. Development of pharmaceutical formulation occurs in two main processes; the conversion of raw materials into active pharmaceutical ingredients (APIs) —which in itself is a raw material and the combination of APIs with excipients to formulate the final end-product.

Local production of pharmaceutical products relies heavily on imported active ingredients, despite Ghana's raw material wealth. All Ghanaian pharmaceutical firms globally source their active pharmaceutical ingredients. This includes raw materials, intermediates, active pharmaceutical ingredients (APIs) and other material components for clinical supplies and commercial manufacturing. Equipment needed for the production of medicines in Ghana are also mostly imported. The list of APIs essential for the production of the top NHIS 20 medicines include the following: (a) Paracetamol (b) Artemether (c) Iron (d) Diclofenac (e) Amoxicillin (f) Cefuroxime (g) Metformin (h) Glibenclamide (i) Lisinopril (j) Bendrofluxide (k) Ciprofloxacin I) Gentamicin. About 40-50percent of the cost of drugs is accounted for by the cost of API, making APIs a core determinant of the prices of goods. ²¹ Currently, locally sourced raw materials constitute about 10% of the total raw materials used for production. Packaging items are sourced locally, however, significant quality concerns remain.

Over the years developing countries such as Ghana have faced several challenges in manufacturing critical APIs for producing essential drugs. Key drivers of API production in the world market is the size of market as well as cost of manufacturing the API. However, Ghana's pharmaceutical market is

characterized by high demand for relatively cheaper drugs which can be attributed to the low incomes of the majority of the population and the increased out-of-pocket spending on drugs. As a result, drug producers are more likely to purchase cheaper APIs from the world market. For instance, high quality APIs are more likely to be sold at a premium of between 20-100%, and several consumers in developing markets are less likely to buy drugs at a premium²². Secondly, the capacity of the manufacturing company to remain in business is a key driver of producing APIs. Where demand for a particular drug decline, it becomes less incentive for the API producer to remain in businesses. In addition to these are the energy prices, regulatory fees and taxes, cost of capital for investment to meet GMP standards, and access to the technical and human resource capacity to produce the required APIs. While there are limited evidence on the case of LaGray Pharmaceuticals, anecdotal information suggest that lack of sustained financing resulted in their exit from the API manufacturing in Ghana. Thus, APIs used by local manufacturing companies are imported. The challenge is the import data by the Ghana Shippers Authority and the UNCOMTRADE does not disaggregate the data into APIs and other pharmaceutical products. However, data from the Ghana Shippers Authority shows that pharmaceutical products coming through the Tema Port are largely imported from the Far East, where China and India are the major pharmaceutical producers.

One of the main challenges local manufacturers face in procuring raw materials for production is the lack of domestic industrial capacity to produce pharmaceutical raw materials. For example, most of the starch producing companies produce food starch and less of pharmaceutical starch. The local manufacturers resort to the international market to source API and excipients. The import time lag for imported items to arrive in Ghana affects consistency of production. Also, the size of Ghana's pharmaceutical market does not generate the required economies of scale to incentivize API manufacturers locally. Moreover, producing premium APIs are relatively expensive and requires compliance with numerous international benchmarks which can result in high prices of drugs. With low incomes and social inequalities, people are less likely to buy expensive drugs. Other challenges include difficulties in monitoring international material prices handling price and supply negotiations obtaining documentary assurance of quality. ²³

(ii). Manufacturing

Ghana has a relatively small pharmaceutical manufacturing sector, comprised of mainly small and medium-sized enterprises (SMEs) engaged in the production of generic drugs, traditional medicines, and herbal supplements. Local manufacturing of pharmaceutical industry has been private sector led since the 1960's with companies such as Ayrton Drug Manufacturing Company being the oldest²⁴. Currently, most of the leading players also act as representatives for foreign multinational corporations. The industry is currently scattered across the country but prominent in two main regions: Greater Accra and Ashanti. Currently, according to FDA, there are 38 pharmaceutical manufacturing units in Ghana, of which about 20 are actively involved in manufacturing formulations. the Pharmaceutical Manufacturers Association of Ghana reports about 30 active members in 2019. According to the FDA, only 6 of these manufacturers lead the pack while several smaller ones only serve the OTC market.

No
No
Yes
Yes
,

No locally manufactured pharmaceutical product is prequalified by WHO, only two local manufacturers are certified to ISO 9001. As of 2021, there were thirty (30) registered local manufacturing companies. The FDA reports that none of the 30 pharmaceutical manufacturing facilities under the 2020 Ghana GMP roadmap achieved Grade 'A'. The 30 active manufacturing companies supply 30 percent of the market needs. Virtually all manufacturing companies also import their drugs. The FDA estimates that five pharmaceutical manufacturing companies: Ernest Chemist, Letap Pharmaceuticals, Amponsah Effah Pharmaceuticals, Eskay Therapeutics and Pharmanova Limited are currently constructing new manufacturing facilities as part of the FDA-UNIDO sponsored GMP Compliance Road Map Project

Majority of the domestic producers are involved in the production of generics and OTCs. In 2020, the number of active local pharmaceutical manufacturers were 30 with 12 involved in active production. These indicate capacity surplus as more of the local manufacturers are less active in production and suggests significant number of manufacturers involved in imports. The major local players that have submitted their Corrective and Preventive Actions (CAPA) reports to the FDA as at 2020 are indicated in table 3 below²⁵. The recent report by UNIDO & FDA on the Ghana GMP Roadmap indicate that majority of the manufacturers used for the assessment were high risk manufacturers, indicating non-compliance with the WHO GMP standard. In 2020, the FDA reported that none of the 30 companies have achieved grade 'A' status under the GMP roadmap. By the end of 2021, five companies were expected to achieve grade 'A' and three achieving grade 'B'²⁶ but FDA is yet to confirm this. Moreover, manufacturing companies such as Kinapharma have wholesale and retail outlets in Nigeria, Sierra Leone, and Liberia. Kinapharma also sells throughout the ECOWAS region through the ECOWAS Trade Liberalization Scheme²⁷.

Table 3: Pharmaceutical Manufacturing Facilities that have submitted CAPA Reports

Kinapharma Company Limited	2. Letap Pharmaceuticals	3. GR Pharma
4. Geo-Medicore	5. M & G Pharmaceuticals	6. Ernest Chemist
7. Pharmanova	8. New Global Pharma	9. Trade Wings
10. Eskay Therapeutics	11. Dannex	12. Amponsah Efah
		Pharmaceuticals
13. Kama/Aspen Industries	14. Unichem Industries	15. Poku Pharma
16. Pam Pharmaceuticals	17. Danadams	18. Intravenous Infusion
19. Delma	20. Phyto Riker	21. Entrance Pharmaceuticals
Pharmaceuticals		
22. Sanbao	23. Perfect Pharmaceuticals	24. Starwins Products
25. Lagray Chemicals		

Source: FDA 2021

Manufacturers of pharmaceuticals in Ghana are mostly locally owned and all produce only generic medicines and mainly for the domestic market —but in recent times a few larger companies are increasingly turning to exports. They play in a limited role in the value chain of the pharmaceutical landscape since they are mostly drug-product manufacturers i.e. purchase active pharmaceutical

ingredients (APIs) from other manufacturers and formulate them into finished pills, syrups, creams, capsules, and other finished drugs. Some are even limited to packaging which includes purchasing pills and other finished drugs in bulk from external markets and repackaging them into final products for the consumer. Currently, there are no manufacturing companies in Ghana producing raw materials such as APIs and excipients to support domestic production. Most of the excipients and APIs are imported from the Far East, particularly China.

Despite the focus on OTCs for many of these local manufacturers, companies such as DANADAMS have the capacity to produce specialized products such ARVs and other antimalarial drugs. In 2009, a World Bank report found that none of the domestic manufacturing companies produced TB drugs, NTD drugs and cardiovascular medicines. This indicate both a local capacity gap and a market opportunity for local production as well as imports. While the production of specialized products remains challenging the manufacturing of OTCs remains very competitive in Ghana with a manufacturing margin. To reduce the overall price of medicine and incentivize domestic production, government continues to provide exemption for local manufacturers. In 2009, 66 of 200 basic materials for production were exempted from 12.5percent VAT and 2.5percent NHIS levy²⁸. The approval of the 2021 Budget Statement and Economic Policy by parliament will remove the 50 percent reduction of the benchmark value of some selected imported pharmaceutical products. These are expected to encourage domestic manufacturing of drugs to support the healthcare needs of the country. The domestic production has the potential to reduce the overall price of drugs and ensure competitiveness of local manufacturers.

Like any other manufacturer in the Ghana, pharmaceutical manufacturers high cost of energy and depreciation remains a major threat to the import dependent industry. Ghana has a relatively high average end-user tariff of US\$0.15/kwh compared to US\$0.09/kwh and US\$0.10/kwh of Nigeria and Ivory Coast respectively. In the case of special load consumers, who are likely to be manufacturers they pay an average of US\$0.15/kwh and US\$0.21/kwh for low voltage consumers and pay an additional service charge average of US\$9.27 for low voltage consumers and US\$12.98 for high voltage consumers. High end-user tariff makes local production expensive and unprofitable since they compete with relatively cheap imports in the market. Also, currency depreciation remains one of the major challenges domestic manufacturers face. Almost all the raw materials for production are sourced outside the country, and depreciation of the local currency against major trading currency like the US dollar, increases the cost of manufacturing. Due to sensitivity of the market to price, full pass through of cost to consumers becomes difficult for the local manufacturers.

Another challenge manufacturer's face is the high cost of APIs, especially high-quality APIs. During the pandemic, restrictions on movement of certain goods led to increased prices of APIs, leading to reduced production locally. With a significant share of pharmaceutical purchases done by hospitals who are mostly on the NHIS, the very competitively priced NHIS medicines list, most manufacturers are likely to buy cheaper APIs whose quality may not be guaranteed in order to remain competitive. Moreover, poor investment in research and development continue to affect the ability of local manufacturers to produce high value drugs. Non-compliance with the GMP standards continue to exclude local manufacturers from participating in international bidding and compromises on the quality of drugs produced locally. Other challenges within this segment of the market include higher interest charges and difficulties in accessing business loans, higher costs of imported machinery, lack of technically qualified people, Insufficient capacity within the companies and the dearth of market information on the domestic and regional market makes it difficult to assess to make the financial case to investors. ²⁹

Despite these setbacks of the industry, government policies such as the prioritization of local manufacturers in government procurement, VAT exemption on some raw materials, and list of

restricted products from imports continue to increase the prospects of the local pharmaceutical manufacturing value chain. Additionally, efforts of various donors have set the tone for the development of some selected pharmaceutical manufacturing firms. These include the recently completed UNIDO and FDA project on the Ghana Good Manufacturing Practices (GMP) standards roadmap, and the USP through the PQM program funded by USAID in 2020 30

(iii). Distribution

The supply and distribution network of the pharmaceutical industry is quite complex because most of the actors tend to play different roles along the value chain. Many private sector businesses in the industry begin as retail outlets and grow throughout the value chain. This is a high level of vertical integration of the pharmaceutical industry where one firm participates at all levels of the value chain. Most of the major local manufacturers operate an extensive and networked distribution system as well as agencies to help penetrate the highly competitive pharmaceutical market. They play the role as manufacturers/wholesalers and participate in the value chain as importers/wholesalers. Multinational players in the industry in most cases tend to use agents to distribute their products. These agents are also found to participate in the manufacturing and wholesale value chain. A good number of MNC's also maintain strong marketing teams focused on demand creation, marketing directly to all providers (doctors, private hospitals, pharmacies, and public hospitals).

At the distribution end of the supply chain, many importers/wholesalers or manufacturing/wholesalers tend to have integrated distribution businesses in the chain. The distribution chain begins with a one-stop-shop wholesalers who buys from an importer/wholesaler or manufacturer/wholesaler. Large distribution companies tend to have distribution vans that supply the products to one-stop-shop wholesalers and other small-scale wholesalers in the chain. In rural areas, distribution is completed through teams or agents of the distribution companies who pay commission or salary to persons who distribute in hard-to-reach areas. It must be noted that customers can also buy directly from the wholesale shops without going to the retail outlets.

The multiplicity of distribution companies with small market share and the participation of unlicensed individual distributors makes it difficult to ensure product quality as several suppliers or wholesalers are collecting products from myriad of importers or suppliers. As a result, integrity of all products cannot be guaranteed. Moreover, the individual supplier channels have been abused and used for trafficking counterfeit drugs over the years. Additionally, they are unable to practice good drug handling and may overlook critical factors such as expiry dates. Nonetheless, increase in the number of manufacturing firms requires improved number of distributors to ensure that consumers receive the products timely. Thus, the distribution chain of the industry is more likely to grow in the years ahead using the estimated growth in pharmaceutical sales by a compound annual growth rate of 9.8 percent.

(iv). Retail/Dispensing

At this end of the market, there are many more players who hold FDA wholesale license to distribute controlled medicines. As a result, Ghana has a diverse 'private-sector outlets', operating with varying degrees of regulation, legality and formality.³¹ They include large, up-market, licensed pharmacies in urban centers, to smaller over the counter (OTC) medicine stores (commonly known as 'drug stores' or

'chemical shops'), to grocery stores selling basic medicines and roaming peddlers. A survey in 2007 estimated that there were 700 licensed pharmacies and 11,159 chemical sellers in the retail value chain. Looking at the growth projection, it is expected that the current numbers have more than doubled. The study also found about 328 wholesalers also had retail license. Chemical sellers appear to be very common in the peri-urban and rural areas where there are few outlets involved in medicine supply. They receive stock either through distribution teams or purchase directly from wholesalers.

There are several small-scale retail outlets in the value chain with smaller market share. This tends to affect transparency and reliability of products at the various retail outlets. In addition to the above, there are public hospitals, general practitioners' and specialists' clinic, and private hospitals. These include the 1,625 government hospitals, 928 private hospitals and 220 health facilities from the Christian Health Association of Ghana (CHAG).

Due to the high industry integration, at the retail end of the value chain, pharmacies and chemical sellers actively play key roles in providing medicines for consumers. There manufacturers/wholesalers and importers/wholesalers who also have retail outlets especially in the urban centers. The red-dotted arrows in the figure below refer to individual drug suppliers who do not own retail shops as either chemical sellers or pharmacies. They contact their customers directly and source their supplies from wholesalers. Over the years, this channel has been abused by illicit drug users, counterfeit drugs suppliers, and a source of supply for person's involved in drug abuse. This channel is unregulated and as such it is difficult to monitor or identify the authenticity of the drugs supplied in this channel. In 2019, 12 tonnes of counterfeit drugs were intercepted by government from individual drug suppliers³² from Ivory Coast. In 2009, the FDA estimates indicated counterfeit drugs constituted about 10-20% of the market. This number is more likely to be high due to absence of data on unregistered drugs and unlicensed outlets³³. Sadly, the current systems, mechanisms, and inspection resources are not enough to ensure that inferior medicines and medical devices and supplies do not enter the market or the public sector supply chain system.³⁴ Despite private sector solutions like the one being offered by the Ghanaian tech firm, mPedigree, (a mobile verification service that enables consumers to text a product code on a purchased drug that is then checked against the registry of authentic medicines, instantly verifying that the medicine they have acquired is legitimate and safe), the problem still persists.

Balancing the sale to public institutions vs others: The case of some local pharmaceutical firms.

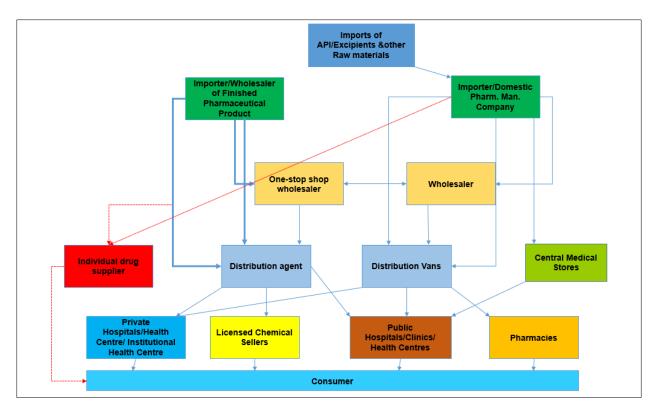
Almost of all the firms indicated that the open market is the main destination of the total production. For instance, DAS sells about 75% in the open market and reserve about 2% to institutions. However, institutions with relatively weak wholesale, distribution, and retail channels rely on institutional sales. For example, Delma relies greatly on institutional sale constituting about 75% of their total sale. Furthermore, private sector institutional sales appear to be lucrative for manufacturers and wholesalers due to timely servicing of invoice. Delays in reimbursement by public institutions delays in servicing of invoice. For example, the average waiting time for public institutions to service invoice from the interviews was 6months to 2years.

Source: ACET, fieldwork (2021)

Increased development of peri-urbans will result in the duplication of pharmacy retail centers across the country. In the rural areas, chemical sellers remain essential to the provision of essential medicines to the people. However, price setting at this level of the value chain can be arbitrary, resulting in high prices of the product. The World Bank

estimates that the price margin at the retail end of the value chain can grow as 200 percent. This leads to increased prices of drugs especially in the rural areas where majority of the people are low-income earners.

Figure 6: General Supply and Distribution Chain of Pharmaceutical products in Ghana



Source: Adapted from the World Bank, (2009)

a. Public Sector Pharmaceutical Supply Chain and Procurement

The government through the Ministry of Health and Ghana Health Service procures medicines for the state-owned health facilities. The Ministry of Health Procurement Department, working with the Public Procurement Authority Act 663 (as amended with Act 914, 2016) undertakes procurement of drugs for the public sector. The procured medicines are allocated by the Ghana Health Service which is responsible for liaising with the private sector suppliers. Health facilities are categorized under the following groups; (a) teaching hospitals (b) regional hospitals; (c) district hospitals; and (d) sub-district hospitals (health centers and CHPS – Community-based Health Planning & Services -Compounds)

Figure 7: Public Pharmaceutical Procurement Structure

International Competitive Bidding

- World Health Organization prequalification and FDA registration is required.
- Drug needs assessment must be completed by respective institutions such as UNAIDS, MoH, WHO for specific drugs.

National Bidding Process

- •This stream is used to procure drugs through IGF by MoH and GHS.
- •FDA certification and GMP registration required.
- About 1% of ARV and anti-malaria drugs are procured useing this stream.

Donations

 Huge volumes of vaccine are donated by development partners to treat chronic disease such as the Six killer disease, and diseases that affect children.

Central Medical Stores

- Where drugs are in shortage, the CMS keeps a large pool of suppliers.
- The CMS complements national and international procurements.
- Significant number of essential drugs are procured through CMS.

Drugs procured through International Competitive Bidding (ICB) and the National Bidding Process (NBP could be single sourced through restricted tender or open bidding. They are received by the Central Medical Stores (CMS) under the Ministry of Health. The drugs are distributed to the District Medical Stores and allocated to the various health facilities (tertiary, secondary and Primary). The drugs are dispensed to customers by the health facilities pharmacy units. However, in the case antiretroviral drugs and neglected tropical diseases, the distribution can be done by specialized units like the JUST Clinics. The distribution chain is illustrated in the figure below.

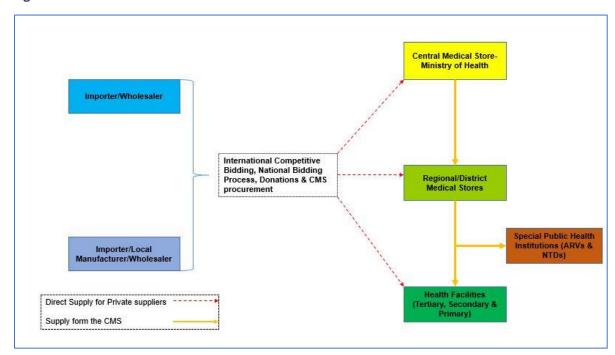


Figure 8: Public Pharmaceutical Distribution Chain

Source: Adapted from: Frost & Sullivan Research Service, Pharmaceutical Industry in Ghana and Nigeria (Mountain View, California, 2011).

The Central Medical Stores (CMS) is the main source drug supply for regional, district, and community hospitals through the regional and district medical stores. Medicines procured and distributed by the Central Medical Stores, fall under two categories: (a) medicines funded by international donors and medicines purchased by the Ghanaian Government from its own resources.

Medicines funded by donors like such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and distributed through the CMS go through a competitive bidding process restricted to manufacturers that have WHO pre-qualification for the relevant pharmaceutical products. In essence, this market is out of reach of all local manufacturers since none is WHO pre-qualified. ³⁵ These drugs are referred to as programme drugs.

For medicines funded by the government of Ghana, public procurement is done centrally, through the Ministry of Health (MoH) and regionally through the Regional Medical Stores and 3 teaching hospitals. First, the regional medical stores make a request to the CMS for some volume of drugs. The CMS will then issue a Certificate of Non-Availability (CAN), indicating to the RMS to buy the outstanding drugs in the market. Based on the CAN, the RMS will float a tender for supplies. Hospitals and other health facilities also makes a requisition for drugs at RMS. The RMS will also issue a CNA to the hospitals to float a tender for supplies of outstanding drugs.

This structure of procurement suggest that pharmaceutical companies can participate in multiple tenders concurrently from the CMS, RMS and at the hospital and health institutional level. The challenge arises where the hospital is a service provider for the NHIS because drugs procured and serviced to NHIS clients can only be reimbursed to the supplier when the NHIS reimburses the hospitals. Additionally, this indicates local manufacturers with stronger wholesale and distribution chain can benefit from the huge

procurement opportunities in the public sector. For example Delma sells almost 75% to institutions. Another risk of this chain is that prices are quoted with little mark-up.

b. Product analysis, production capacity and inputs

To determine the product range of the local manufacturers and the frequency of the annual production each product in a typical year, ACET was supposed to secure this information from the pharmaceutical companies interviewed as part of the fieldwork. Unfortunately, though some committed to sharing this information after the interviews, virtually all the pharmaceutical companies interviewed did not share the information during the follow ups. ACET therefore had to fall on available information from various online sources —which was also scant.

While there are scanty data due to weak market research in the pharmaceutical industry, the most recent market survey by Frost and Sullivan (2011) on Table 1 presents the drugs produced by top five local manufacturers in Ghana. As already established in sub-section (a) domestic manufacturing are largely generics and more concentrated around OTCs. Furthermore, the local production fulfils only 30percent of domestic demand, indicating weak domestic capacity. This also suggest that more than 60 percent of OTCs and generics are imported. Data on the type of drugs supplied by importers are scanty or non-existent due to the multiple channels of imports. Nonetheless, aggregate data on the import of pharmaceutical products suggest that most of the drugs imported into Ghana are sourced from India (36%), Netherlands (22%), Belgium (8%), United Kingdom (5%), France (5%), Switzerland (4%), China (3%), Germany (3%), Slovenia (2%) and Italy (2%).

Table 5: Key Market Players and Drugs Produced

Local Manufacturer	Drugs Produced		
Ernest Chemist	Antibiotics, antimalarials, anthelmintics, antihistamines, analgesics, diuretics, antidiabetics, gastrointestinal medicines, vitamins and supplements, cold and cough preparations		
KinaPharma	Antihypertensives, hypolipidaemic agents, antibiotics, antimalarials, antihistamines, analgesics, vitamins and supplements, cold and flu preparations		
Phyto Riker	Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, psychotherapeutics		
DAS	Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, vitamins and supplements, cold and flu preparations		
Kama	Antibiotics, antimalarials		

Source: Frost & Sullivan Research Service, Pharmaceutical Industry in Ghana and Nigeria (Mountain View, California, 2011).

Data on the product range of importers are not publicly available, but our interviews with various pharmaceutical firms revealed that local manufacturing companies have an average product line of about 10 except DAS that has an aggregate product line of about 80 due to the merger between Dannex, Aryton and Starwins with Dannex as the majority shareholder. Majority of local manufacturing companies produced branded generics. This contributes to the low investment in organizational research and development of new products. The current research units of the firms are focused on alternatives to improving the existing generics produced by the firms.

It appears that multinational companies have monopoly over the patented drugs and certain types of generics where local capacity is limited. As a result, the multinational firms charge higher prices for

patented products and other high-demand products, resulting in relatively high overall price of drugs in the market. With active brand promotion and advertisement, generic manufacturing firms in Ghana, especially Indian firms, continue to charge relatively lower prices, leading to higher competition at the generic and OTC end of the market where local capacity is available. These suggest that while local capacity exist for OTC and generics, the local manufacturers are unable to effectively compete with the multinationals.

c. Pricing in Ghana's Pharmaceutical Industry

The local drug market is divided into the institutional market and retail market. The institutional market relates to the procurement of drugs by Government of Ghana through the Procurement Department of the Ministry of Health and distributed through the Central Medical Stores, Regional Medical Stores as well as the health facilities themselves. A National Medicine Price Committee (NMPC) established by the Minister of Health in line with the National Medicines Policy manages the medicine pricing system in Ghana—at least within the public sector institutions. ³⁶ The NHIS works with the NMPC to set the maximum reimbursement prices for all pharmaceutical reimbursements under the scheme. In this market, the quoted price is the only source of product differentiation because manufacturers or importers (especially, local firms) are unable to compete based on brand. This can also be attributed to the over-concentration of local producers on OTCs and generics. Due to over-reliance on price as the determining factor, generic drugs are more likely to be sourced from India firms because they tend to sell at lower prices. This explains the high imports from India. Branded products tend to be relatively expensive, which act as a disincentive for government to procure more branded products.

Although the Ministry of health through the National Medicine Price Committee (NMPC) and the NHIS has a price control mechanism for public sector engagement with the pharmaceutical supply chain, majority of the prices in the pharmaceutical market are arbitrarily set by manufacturers and importers. The retail market appears to be open based on product promotion and price. More than 60 percent of drugs purchased are through out-of-pocket, and thus product differentiation through price and brand is very high in this market. In most cases, people do not understand the difference between products especially in low-income areas. As a result, they are more likely to be influenced by the price. In the middle- and upper-income group, brand may be a determining factor due to the perceived association between high price, branded goods and quality.

In 2012, a study compared the prices of certain products and prices between the Indian retail market (Ghana's largest import market) and Ghana's retail market. The results –see figure below –show massive disparities of more than 20% for ciprofloxacin, Amlodipine (5mg) Diazepam (5mg), Paracetamol (500mg) and Lisinopril (5mg). The report found that for drugs produced locally, the price difference between the Ghanaian market and Indian market is relatively high for some products while the cost of production are almost the same for both markets. This indicates that when drugs are produced in Ghana, it is more likely to be able to compete with similar products on the Indian market, making it competitive to produce locally instead of importing from India. This is clearly seen in the case of paracetamol, cetirizine and diazepam. The study compared the price differential in Indian retail market and Ghana market for tablets that were not produced in Ghana.

The below also suggests that the price margin for drugs not manufactured in Ghana is very high, particularly for Indian importers. As a result, it is more profitable to import branded products to Ghana for multinational companies and local importers. The high price difference also indicates that while India is benefitting from reduced cost of pharmaceutical production, importing countries receive the drugs at either inflated prices or abnormal prices. Thus, there is a high profitability for firms involved in drugs that

are imported. This also suggest that Ghanaian manufacturing firms must begin to invest in capacity in high earning products of the market in order to effectively compete with multinationals. The data also indicates that it is relatively profitable to import patent and generics to Ghana than producing locally. It must be noted that the data used compared 2011 prices in Ghana to 2013 prices in India. It is possible that these prices have changed, and current market survey is needed to make conclusions on price differentials in the last 10years.

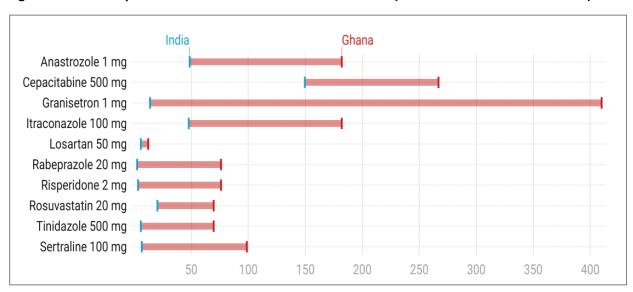


Figure 9: Price Comparison in Retail Markets India and Ghana³⁷ (Tablets Not Produced in Ghana)

Source: UNDP Report³⁸

A study conducted by the World Bank³⁹ indicated that most importers/wholesalers and manufacturers/wholesalers normally provide between 5-10percent discount to attract distributors and other agents. The one-stop shop wholesalers then add a margin of 10-30percent to the final price. The study found that prices at one-stop shop wholesalers were sometimes equal to or higher than the price of importer/wholesaler. The highest margin was found at the retail end of the supply chain where retail margin could range between 30-40 percent for some products and 30-200percent for other products. However, low customer traffic at this end of the chain may compel the pharmacies and chemical sellers to add groceries, household items, and other non-pharmaceutical products to attract customers. It is important to note that the margin may be lower for public sector tender where competition between suppliers is driven by price, thus suppliers are more likely to reduce margins when participating in public tender. A study by the Ministry of Health⁴⁰ revealed that regional medical stores benchmarked their retail prices to the private sector prices at unofficial margin between 30percent to 50percent compared to the official margin of 10-15percent. **Table 3** illustrates the margin in the industry based on a 2009 market survey.

Table 6: Company Margin in the Supply Chain

Manufacturing	10-50%
Wholesaler	10-30%
One-stop Shop	5-10%
Retailer	30-200%

Source: World Bank, 2009

The results of our interviews suggest that for most locally manufactured packaging constitute a significant share of price buildup of their products. The Packaging materials currently being used in Ghana are very similar in shape among the processors and range from plastic containers to glass bottles. While majority of the manufacturers who target the export market depend on imported top range packaging materials for packaging, virtually all the products intended for the local market are packaged in locally produced materials and pricing is the determining factor.

d. Industry Incentives

Despite the above issues in the supply chain of the pharmaceutical sector, government policies such as the prioritization of local manufacturers in government procurement, VAT exemption on some raw materials, and list of banned products continue to increase the prospects of the local pharmaceutical manufacturing value chain. The efforts to achieve the WHO GMP standards through the Food and Drugs Authority, and prospect of improved finances through the EXIM Bank Ghana, continue to create incentives for investors and domestic pharmaceutical actors to thrive. A few of the supply side incentives over the past decade include the following:

- In 2009, 66 of 200 basic materials for production were exempted from 12.5percent VAT and 2.5percent NHIS levy⁴¹. The approval of the 2021 Budget Statement and Economic Policy by parliament will remove the 50 percent reduction of the benchmark value of some selected imported pharmaceutical products. These are expected to encourage domestic manufacturing of drugs to support the healthcare needs of the country.
- In 2016, the government provided US\$27 million to six pharmaceutical companies in the country as part of efforts to boost the local pharmaceutical industry to increase its market share.
- In 2017 the Ministry of Trade and Industry (MoTI) launched the 10-Point Industrial Transformation Agenda, which seeks to expand the manufacturing sector, reduce unemployment and accelerate socioeconomic development in areas like the pharmaceutical industry
- In 2018, the Ministry of Health introduced a five-year strategic plan called known as the Ghana Integrated Logistics Management Information System (GhILMIS) to facilitate the effective management of health commodities. With a significant number of all health centers and "functional" CHPS signed into the system, the GhILMIS is heling address shortage of medical supply due to delayed approval and procurement processes and the lack of adequate data on medical supplies stock and this was quite useful at the height of the covid pandemic in Ghana.
- In 2019 the government inaugurated the Dawa Industrial Zone which forms part of the 8.1m-sq-metre Dawa Industrial Park designed to house industrial and residential developments. Among other things, the zone, which is owned by LMI Holdings seeks to support strategic industries including the pharmaceutical industry. 42
- As part of the government's flagship "One District One Factory" initiative, another industrial transformation agenda, a few pharmaceutical manufacturing companies are receiving government support to build WHO GMP compliant facilities.
- The government seems committed to upgrading existing pharmaceutical companies to Good Manufacturing Practices (GMP) standards and has since commenced works towards establishing the Bioequivalence Centre (at Noguchi) to support the local pharmaceutical manufacturing industry is a priority. The implementation of the national COVID-19 economic recovery program, CARES programme is expected see the upgrade of at least one existing first tier pharmaceutical

- manufacturing company to achieve World Health Organization GMP Standards to enable them enhance export capacity, particularly under AfCFTA.⁴³
- In the 2022 budget, the government expressed its commitment to the establishment of a National Vaccine Institute to coordinate production of vaccines locally. Currently, three local pharmaceutical firms have expressed interest and the government is expected to secure global partnerships to help selected pharmaceutical manufacturing firms to acquire fill-and-finish technology and capacity gaps as well as provide support towards securing licenses. 44 Additionally, the country is currently exploring the feasibility of manufacturing vaccines locally.

Despite these incentives, as already indicated, the pharmaceutical market in Ghana is largely import driven with domestic production meeting just 30 percent of medicine/pharmaceutical needs of the country. In addition to that, significant supply chain constraints remain in the industry and there are major inefficiencies with storage and handling of drugs and relatively high lead time. These have culminated in relatively high prices of drugs compared with international benchmark prices, shortage of some essential drugs, which makes industry less competitive while placing significant strain on the financial sustainability of the National Health Insurance Scheme.

e. Supply Chain Risk analysis in the Pharmaceutical Industry in Ghana

The following are some of the identified supply chain risks in the literature: (a) Relatively high taxes on some manufacturing raw materials. Few manufacturing products have been exempted from VATs. The process for claiming the exemptions is very bureaucratic. (b) High cost of borrowing (c) High end-user electricity tariff for industries.(c) Currency risk given the weak performance of the Cedi against the Dollar (d) weak market research to guide investment planning in the industry; (e) Complex distribution chain systems in Ghana. The current chain is open to abuse by large players in the industry. (f) Limited transport facilities and other human and logistics challenges.

Risk factors	Risk
Political	Weak Governance and Procurement Systems
	Lack of transparency in the Procurement Systems
	Low Patronage by Governments and Donors for locally
	produced medicines
Economic	Inadequate Healthcare budgets
	Dependence on imported brands
Social	Traditional and religious beliefs about disease
	Self-medication and over medications making drugs ineffective
Technological	Technological obsolesce as new technological cycles accelerate
	Patents being stolen
Environmental	Potential impact of drugs manufacture on environment e.g.
	disposal of toxic waste that can bring backlash from
	communities
Legal	Unstable legal and regulatory regime that keeps changing
	Illegal and fake drugs not policed
	Lack of intellectual property enforcement

SECTION 4: NHIS AND THE PHARMACEUTICAL INDUSTRY

This section of the paper explores the potential impact of the National Health Insurance Scheme (NHIS) on the pharmaceutical industry in Ghana. As part of this, the section will analyze how the NHIS reimbursements and delays impact the local pharmaceutical sector. It will also assess how the top 20 NHIS reimbursable pharmaceutical products march against products by local manufacturers to be done and how this can be used to stimulate local sector

The NHIS

After adopting the concept of Universal Health Coverage, in 2004, Ghana became the first sub-Saharan African (SSA) country to introduce a National Health Insurance Scheme (NHIS). Established through the National Health Insurance Act of 2003 (Act 650), the NHIS was underpinned by the principles of equity, equality, risk sharing, cross-subsidization, community ownership, good governance and transparency. The Act also gave mandate to the establishment of the National Health Insurance Authority (NHIA, the managing body of the NHIS), the Council (the governing body or the Board of the Authority), and the National Health Insurance Fund (NHIF). The social health protection component of the program seeks to increase access to healthcare for the population living in extreme poverty and areas where healthcare needs are unmet. Since its establishment, the scheme has grown significantly with enrollment figures rising from 1.3 million members in 2005 to 8.9 million people in 2012. By 2018, the scheme had presence in nearly 163 districts across the country and covered 37 percent of the population -up from 6 percent in 2005. Following the introduction of digital options for membership renewal through mobile money wallets, NHIS membership coverage increased astronomically to 41 percent (12.29 million people) by the end of 2019. That notwithstanding, a high proportion of rural population are yet to enroll as they are unable to afford the NHIS registration fee. ⁴⁵ Poverty-stricken regions like the upper west, upper east and northern areas, have recorded low enrolment in the scheme compared to urban areas. The social protection component of the scheme exempts beneficiaries of the Livelihood Empowerment Against Poverty (LEAP), aged, and other category of applicants from paying the subscription fees. The share of NHIS card holders classified in the exempt category decreased from 68.0 percent in 2018 to 61.0 percent in 2019.46 This used to be about 70% in 2017.47

Over the years, the NHIS has become the main driver of the health sector, leading to increased drug consumption and pharmaceutical sales. The scheme covers about 95 percent of disease conditions including outpatient and inpatient services, oral health and eye care services, maternity care and emergencies. It also covers curative services and curative drugs for outpatient and inpatient care of members of the scheme. Some services and drugs for some chronic and long-term illnesses which are covered by the Ministry of Health are however excluded. HIV/AIDS treatment is also excluded with major development partners already providing support in that area. Additionally, the introduction of the health insurance scheme has made essential medicines affordable to over 40% of the population by greatly reducing individual out-of-pocket expenditures.

Despite the significant boost to the healthcare services since the inception of the NHIS, there has been lasting concerns about the sustainability of the scheme. Experts bemoan that the scheme seems to be too generous in relation to the available funds. While the scheme was designed to rely heavily on the NHIS levy of 2.5 percent, 2.5 percent Social Security Contributions and the premiums of members, direct government support seems to be covering a significant share of the resource envelope of the scheme. The recent introduction of the COVID-19 Health Recovery Levy through an increase in the NHIL is expected to boost the funding to NHIS to meet emergency needs, but revenue generation will still remain a challenge since premiums, taxes, and reinsurance payments for NHIS are not actuarially determined. The

premiums for many informal sector workers on the scheme are low relative to the cost of care and the revenues.⁴⁹ The scheme also has major cost containment issues due to the rapid expansion of enrollments, ineffective referral system and misaligned incentives across insurers and provider types. More expenditure rationalization, cost-inefficiency interventions will be needed to sustain the scheme.

Impact of the NHIS on the Pharmaceutical supply Chain

Due to the dearth of credible and comprehensive quantitative data in the pharmaceutical sector, ACET was not able to robustly assess in value terms the impact of the NHIS on the pharmaceutical supply chain. NHIS was unwilling to share the needed information for this analysis. The findings from our desk research and interviews with various pharmaceutical firms interviewed however helped us draw the following conclusions.

In spite of the high sale of pharmaceuticals through out-of-pocket, the NHIS remains the highest institutional market for local pharmaceutical manufacturers and suppliers. Currently, the scheme covers over 40 percent of the population, indicating that about 30-40% of the population are likely to buy pharmaceutical products through the NHIS. Though in Ghana, most drug purchases are largely financed through out-of-pocket spending which constitute about 64 percent of purchases, 23 percent of this is reimbursed through the NHIS⁵⁰. Thus over 50% of the expenditure of NHIS goes directly into medicines and medical products. ⁵¹ In the rural part of Ghana, the NHIS is the dominant source of access to drugs for insured individuals. These suggest that a growth in the coverage (subscribers and product categories) has the potential of translating to a growth in pharmaceutical sales. Domestic pharmaceutical companies have a greater opportunity to benefit from the growth in the NHIS because the scheme procures largely generic prescription drugs, which are the main production lines of domestic manufacturing companies. The NHIS would continue to create an institutional market for pharmaceutical companies, however domestic producers can only benefit from this market when they improve capacity in the production of the top 20 EML of the NHIS.

Despite the economic benefit of the NHIS to the pharmaceutical sector, the pricing regime of the NHIS is unfavorable to sustain local pharmaceutical manufacturing. The local manufacturing companies are faced with high importation costs of APIs which are vulnerable to foreign exchange risk, high utility tariffs, high import duties and relatively high cost of labor. According to interviewed local pharmaceutical companies, these result in high prices of domestically manufactured drugs. Over the years, the NHIS quotation prices for its products are not cost reflective for domestic producers. This makes it economically unsustainable to supply to the NHIS institutional health facilities, especially those in the rural part of Ghana. In the long run, pharmaceutical importers who are able to source relatively cheaper prescription generics are more likely to benefit from the NHIS systems. For this reason, in one of the major pharmaceutical firms interviewed indicated that they have deliberately reduced their production allocation to the NHIS to as low as 2 percent.

Delays in reimbursement and debt servicing significantly impact the pharmaceutical supply chain. The NHIS has a fee-for-service (FFS) system where accredited providers are reimbursed for services and drugs prescribed to NHIS beneficiaries.

But as indicated above, the reimbursement process seems to be creating challenges as several providers complained that the delay is affecting their performance; they are unable to purchase drugs and other products on a timely basis.⁵² For instance, despite reforms to the NHIL contribution which saw the NHIL

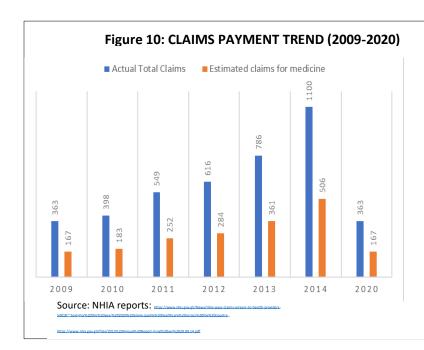
being decoupled from GETFund levy in the VAT buildup of the country, as of December 2019, the NHIS owed eight months of claims to care providers (i.e. May to December 2019). 53 Indeed, some reports from the Ministry of Health suggest that as of 2017, the NHIS had never met the requirement of settling claims within 12 weeks. A 2016 report indicated that there were variations in the speed of processing claims across the country. While hospitals in the southern zone and middle zone had to wait for between 3 to 4 months to be reimbursed, on average those in the northern zone wait for less than 1 month after claims submission. ⁵⁴ Consequently, this has led to the withdrawal of services to NHIS subscribers by providers, unauthorized copayments and denial of service to NHIS subscribers which ultimately dampened confidence in the scheme. In such instances, provider hospitals and health facilities are unable to meet their debt obligations to the suppliers. For instance, in 2020, the Chamber of Pharmacy Ghana (COPG) and the Pharmaceutical Manufacturers Association of Ghana (PMAG) withdrew credit supplies to regional medical stores and the health facilities for failure to pay for pharmaceuticals products supplied to them for more than 12 calendar months. 55 During our interviews, some pharmaceutical firms indicated that reimbursement by the NHIS can stall for about 6months to 2 years. This eventually constrains the ability of these small manufactures to pay for imports or manufactured drugs and in some cases job losses. Some interviewees were quick to add that there were huge disparities in the speed of reimbursements in fairly urbanized centers like the greater Accra region, Ashanti region and the Eastern region and rural areas. Some interviewees also noted that some private hospitals in urban areas are also able to prefinance supplies even before the NHIS reimburses them

The reimbursement challenge is due to two major reasons: the liquidity constraints at the NHIS and the nature and timing of processing. On the former, despite enrollment increasing and health expenditure fast rising with it, revenue generation under the scheme seems to have remained stable over the past few years, causing problems for reimbursing claims under the scheme. As already indicated above, the NHIS is largely funded through tax revenues from the NHIL component of VAT and other import levies. In 2013 for instance, claims cost alone constituted 78.48% (GH¢785.64 million) of the total expenditure the NHIS. Also, the social protection objective of the NHIS means that premium must be lower to cover low-income earners. For example, over 1 million beneficiaries of the Livelihood Empowerment Against Poverty Progamme do not pay premium, and children below 12 years and the aged pay subsidized premiums. Additionally, SSNIT Contributors, SSNIT pensioners, pregnant women and indigents are exempted. As of 2017, almost 65% of net beneficiaries were in the exempt category. 57

These factors coupled with the recent capping of the NHIS revenues by the Ministry of Finance tend to negatively affect the financial capacity of the NHIS to reimburse hospitals and the pharmaceutical companies who supply them drugs within the 90 days window. In addition to the liquidity challenges, other studies suggest that NHIS' claims processing and management systems are not capable of handling current volumes which has increased astronomically in recent times —due to increased enrollment. According to a recent World Bank report, NHIA's system has major challenges reviewing every claim, processing is manual, and the authority lacks common standards for certain crucial coding systems, such as procedures and pharmaceuticals. Generally, the challenge with reimbursements affects the sustainability of domestic pharmaceutical firms who largely sell to public health facilities, especially in the rural areas. Additionally, this development is gradually breeding a network of corruption and insider manipulation between NHIS officials, hospitals, and pharmaceutical actors to accelerate payment processes for politically connected actors. It is also worth noting that on the flipside, the inefficient and

complex pharmaceutical supply chain System, has also led to high cost of medicines on the NHIS medicines list.

The NHIS has become a major instrument for financing health care delivery in Ghana and is undoubtedly the financial mainstay of over 4, 600 credentialed healthcare service providers in the country. The scheme accounts for more than 85% of funds that flow into healthcare facilities to treat NHIS members. ⁵⁸ Given the central role played by the NHIS within the healthcare industry, solving the reimbursement challenge will go a long way to not ensure the stability of the pharmaceutical supply chain. In 2021, the NHIS trained a total of 1,834 providers from eight regions on its recently introduced e-claims and paperless systems. ⁵⁹ It was expected that by December 2021, 60 percent of providers would have submitted electronic claims, and this will hopefully improve claims management and reimbursement processes of the Authority.



Using publicly available data, figure 10 presents the claims payment trend for NHIS from 2009 to 2020. An analysis of 2014 claims expenditures in some regions suggest that on the whole, 46% of claims expenditure went into payment of medicines -38% of which went into outpatient treatments while the remaining was for inpatient treatments. 1 Based on the assumption that claims on medicines constituting 46% of claims expenditure of the NHIS, we conservatively estimate the claims on medicine for NHIS for 2020 to be around GH167 million. This implies for each month of delay in reimbursements of claims, the pharmaceutical industry is deprived of some GH14million in operational capital each month. NB: This is just an estimate based on available data, so exercise caution in drawing conclusions from this data

20 NHIS reimbursable pharmaceutical products march against products by local Manufacturers to be done.

As already indicated above, the NHIS is the biggest indirect institutional purchaser of medicines in Ghana —this is because the NHIS covers about 80 percent of OPD users in the country. This indicates that persons who experience the top 20 OPD cases are more likely to rely on the NHIS for subsidization of overall healthcare cost when they visit health facilities. The NHIS scheme reimburses service providers (clinics, hospitals, contracted private pharmacies) upon completion of claim forms submitted to the NHIS Secretariat. The rules of engagement between the NHIS and service providers are based on the Standard Treatment Guidelines, or the revised Standard Treatment Guidelines developed by the Ministry of Health. The NHIS Medicine List provides the list of drugs that are covered by the scheme and how much of the drug is reimbursed by NHIS. The NHIS Medicines list was last reviewed in consultation with healthcare providers and relevant stakeholders in 2020.

In the table below, we match the top 10 OPD reported cases reported by the Ministry of Health with the top Prescribed drugs in the NHIS Medicine list to ascertain areas where local producers have the capacity. Currently, the top 10 OPD reported cases include are: Malaria, Upper Respiratory Tract Infections, Diarrhoea Diseases, Rheumatism and Other Joint Pains, Anaemia, Hypertension, Acute Urinary Tract Infection, Acute Eye Infection, Diabetes Mellitus, and Vaginal Discharge. For these top OPD cases, we find 27 drugs on the NHIS medicine list that are used to treat these cases. Out of these, only 44% are produced locally. Table 7 below presents the list of STG recommended drugs along with the NHIS medicine list, and medicine produced by local pharmaceutical manufacturing firms in Ghana.

These are some of the drugs produced in Ghana for NCDs: Ciprofloxacin 500 mg Amlodipine 5 mg Metformin 500 mg Paracetamol 500 mg Diclofenac 50 mg Lisinopril 5 mg Atorvastatin 10 mg Cetirizine 10 mg Metronidazole 200 mg. 60

Table 7: List of STG recommended drugs, NHIS medicine list for top OPD cases (2020)

	TOP 11 OPD cases	STG RECOMMENDED DRUGS	NHIS MEDICINE LIST	TOP 20 NHIS LIST	MEDICINE PRODUCED BY LOCAL PHARM MAN. FIRMS
1	MALARIA	Artesunate + Amodiaquine, Artemether + Lumefantrine, Dihydroartemisinin + Piperaquine	Artesunate + Amodiaquine, Artemether + Lumefantrine, Dihydroartemis in + Piperaquine Granular Powder	Artemether + Lumifantrine, Artemether + Amodiaquine Tablets, Artesunate Injection	Artemether + Lumifantrine, Amodiaquine Tablets
2	UPPER RESPIRATORY TRACT INFECTIONS	Paracetamol (oral), Sodium Chloride 0.9% (nasal drops), Xylometazoline (nasal drops), Cetirizine (oral)	Paracetamol Suppository/syrup/tablet, Sodium Chloride Nasal Drops, 0.9%, Cetirizine SyruP/Tablet,	Amoxicillin 250mg & 500mg Capsules, Amoxicillin + Clavulanic Acid 625mg & 1g Tablets, Amoxicillin + Clavulanic Acid Injection	Amoxicillin 250mg & 500mg Capsules
3	DIARRHOEA DISEASES	Ciprofloxacin, oral,Cefuroxime, IV, Cefuroxime, oral,Metronidazole, oral,Tetracycline, oral, Doxycycline, oral,Erythromycin, oral,Zinc supplement, oral,	Ciprofloxacin Tablet,Cefotaxime Injection/Tablet, Metronidazole Injection/suspension/supposi tory/tablet, Tetracycline Capsule, Doxapram Injection/tablet, Erythromycin Tablet/syrup, Zinc Tablet,	Ciprofloxacin Tablets, Infusion & Syrup	Ciprofloxacin 500 mg
4	RHEUMATISM & OTHER JOINT PAINS	Prednisolone, oral, Esomeprazole, oral, Diclofenac, oral/rectal, Celecoxib, oral, Paracetamol, oral, Calcium supplements	Prednisolone tablet/oral solution, Esomeprazole Capsule, Diclofenac Tablet/suppository, Celecoxib Tablet, Paracetamol Suppository/syrup/tablet, Cal cium supplements	Diclofenac 75mg Capsules Diclofenac 75mg Injection	Diclofenac 75 mg
5	ANAEMIA	Ferrous sulphate (dried or anhydrous), oral,Ferrous fumarate, oral, Iron sucrose, IV, Iron dextran, IV, Vitamin B12 (Hydroxocobalamin), IM,Folic Acid, oral,	Ferrous Sulphate (BPC) Syrup/Tablet,Ferrous Fumarate Tablet,Iron Dextran Injection,Folic Acid Tablet,	Iron (III) Polymaltose Complex Capsule, Iron (III) Polymaltose Complex Syrup	Iron (III) Polymaltose Complex Syrup

6	HYPERTENSION	Bendroflumethiazide, oral, Hydrochlorothiazide, oral, Amlodipine, oral, y Nifedipine retard, oral, Lisinopril, oral, Ramipril, oral, Losartan, oral, y Candesartan, oral, y Valsartan, oral, y Atenolol, oral,Bisoprolol, oral,Metoprolol, oral,Carvedilol, oral,Labetalol, oral, Methyldopa, oral,Hydralazine, oral, Prazosin, oral, Spironolactone, oral,	Bendroflumethiazide Tablet,Nifedipine Tablet/capsule, Lisinopril Tablet,Ramipril Tablet,Losartan Tablet,Atenolol Tablet,Bisoprolol Tablet, Metoprolol Tartrate Tablet, Carvedilol Tablet, Labetalol Tablet,Methyldopa Tablet,Hydralazine Tablet,Prazosin Tablet, Spironolactone Tablet	Lisinopril 5, 10 & 20mg Tablets, Bendrofluaxide 5mg Tablets	Lisinopril 5 & 10mg Tablets, Bendrofluaxide 5mg Tablets
7	ACUTE URINARY TRACT INFECTION	Ciprofloxacin, oral/IV,Cefuroxime, oral/IV, Gentamicin, IV,Ceftriaxone, IV,Amoxicillin + Clavulanic Acid, IV,	Ciprofloxacin Tablet,Cefotaxime Injection/Tablet,Gentamicin Injection,Ceftriazone Injection,	Cefuroxime 250 & 500mg Tablets, Cefuroxime Injection, Ceftriaxone 750mg Injection	Cefuroxime 250 & 500mg Tablets
8	ACUTE EYE INFECTION			Ciprofloxacin Eye Drops Gentamycin Injection and Eye Drops	
9	DIABETES MELLITUS	Insulin Premix, SC, Soluble insulin, SC, Insulin NPH, SC, Metformin, oral, Glibenclamide, oral, Gliclazide, oral, Glimepiride, oral, Tolbutamide, oral, Saxagliptin, oral, Sitagliptin, oral, Vildagliptin, oral, Pioglitazone, oral, Insulin NPH, SC,	Insulin premixed , Insulin Soluble HM,Metformin Tablet, Glibenclamide Tablet,Gliclazide Tablet,Glimepiride Tablet,Tolbutamide Tablet, Pioglitazone Tablet,	Insulin 70/30 Injection Hm Insulin Soluble Hm Metformin Tablet Glibenclamide Tablets	Metformin 500 mg Glibenclamide Tablets
1 0	VAGINAL DISCARGE	Metronidazole, oral, Secnidazole, oral, Clindamycin cream, Fluconazole, oral, Clotrimazole, vaginal tablets, Miconazole vaginal tablets, Clotrimazole cream, vaginal, Cefixime, oral, Azithromycin, oral, Ceftriaxone, IM, Doxycycline, oral, Erythromycin, oral,	Metronidazole Injection/suspension/supposi tory/tablet,Secnidazole Tablet,Clindamycin Capsule injection, Fluconazole Capsule/suspension/tablet,Cl otrimazole Cream,Azithromycin Oral Suspension/tablet, Doxycycline Capsule,Erythromycin Syrup/Tablet	Clotrimazole 100 & 500mg Vagina Pesseries Clotrimazole Skin Cream & Vagina Cream	Clotrimazole 100 & 500mg Clotrimazole Skin Cream & Vagina Cream

Source: MOH, NHIS,

SECTION 5: CONCLUSION AND RECOMMENDATIONS FOR DESIGN STRATEGY

a. Conclusion

It is increasingly clear that Ghana's pharmaceutical industry demonstrates significant market opportunities and growth prospects. These market opportunities and growth prospects are further deepened by the increased universal healthcare provision through a growing national health insurance progamme, Ghana's strategic position in the ECOWAS sub-region, Africa Continental Free Trade Area and the stable political environment, which makes Ghana a favorable investment destination. Despite the supply chain fragilities and capacity constraints, the market continues to demonstrate high competition between local and foreign suppliers, which is capable of driving innovation, controlling prices, and improving service delivery to clients. The market competition is further reinforced by increasing public sector procurement of drug needs from local suppliers and the prioritization of domestic manufacturing companies for tax incentives and other stimulus products. In the long term, the full implementation of the electronic pharmacy system will enhance Ghana's potential to leverage digital technologies to increase pharmaceutical sale, enhance clients access to quality health information and curb the menace of counterfeit drugs.

Despite these conceivable opportunities and prospects, development of a resilient pharmaceutical industry requires that a comprehensive national strategy targeted at increasing pharmaceutical research into product development and provision of conducive business incentives for local investors. Additionally, it is imperative to build stronger and stable financial stimulus that accelerate domestic manufacturing firms to secure timely raw materials and broaden local capacities in high yielding aspects of the global pharmaceutical value chain. Ultimately, the success of the pharmaceutical industry also rests on the ability of government to simplify the NHIS reimbursement procedures and strengthen the financial viability of the progamme to timely service debt owned local manufacturers. Therefore, a broad government and private sector collaboration is critical if domestic manufacturers can meet international standards and benefits from the high financial and social rewards of the global pharmaceutical value chain.

High-Level Findings

- With respect to the structure of the pharmaceutical supply chain in Ghana, While Ghana's supply chain comprise (a) upstream activities (Sourcing, Research and Development), (b) midstream (manufacturing and distribution) and (c) downstream segment of the market (retail), there is very limited activities at the upstream segment of the market.
- The major players in the supply chain are 5 local pharmaceutical companies (Ernest Chemist, KinaPharma, Phyto Riker, DAS, Kama) who are actively involved in all the segments of the supply chain and act as representatives for multi-national pharmaceutical companies.
- This is a high level of vertical integration of the pharmaceutical industry where one firm participates at all levels of the value chain.
- The pharmaceutical industry is characterized by weak research and development as well as minimal innovative approaches to develop drugs to address the country's health needs.
- While the NHIS service providers remain a significant institutional market opportunity, their financier's price quotation and reimbursement processes are economically unsustainable for domestic manufacturers.

- In terms of range of products, the existing local pharmaceutical player's output does not meet
 the top 20 NHIS reimbursable products. There are significant challenges with domestic
 manufacturing companies producing all the top 20 EML of the NHIS. Out of the drugs on the
 NHIS medicine list that are used to treat top OPD cases only 44% are produced locally by
 pharmaceutical manufacturers.
- Legal, regulatory and institutional systems have improved over the years, however, they have been less optimal in enhancing the capacity of domestic pharmaceutical industry to meet the WHO GMP standards, address the menace of counterfeit drugs, and ensure stronger regulatory oversight.
- None of the domestic manufacturing companies have achieved full compliance with the WHO GMP standards. It was expected that five companies will graduate to grade 'B' and one company to graduate to grade 'A' by the end of 2021.
- Domestic manufacturing capacity constraints have resulted in high dependence on imports largely from China and India.
- There is currently no domestic capacity to produce Active Pharmaceutical Ingredients (API) and excipients.
- Price margins are relatively higher at the retail end of the supply chain —as much as 200%.

b. Recommendations

Pharmaceutical Value Chain	Identified Problems	Recommendations			
		Short-Term	Medium-Term	Long-Term	
Research and	1. Weak government	1. Government working	1. Cross FCDO and GoG	1. Advocacy campaign	
Development	policy framework to	with the Pharmacy	collaboration to provide	towards encouraging	
	support research in the	Council (PC), Ghana	technical assistance to	government to implement	
	pharmaceutical industry.	Chamber of Pharmacy (GCP), and	existing public and private research institutions to	its commitment to the 2% investment of national	
	2. Weak institutional	Pharmaceutical	explore pharmaceutical	health expenditure into	
	partnerships between	Manufacturers	research targeted at the	health research as	
	pharmaceutical industry	Association of Ghana	NHIS EML to support	indicated in the WHO 58th	
	players.	(PMAG) to establish a	domestic production.	World Health Assembly	
		formal pharmaceutical		Resolution and Decision in	
	3. Low investment in	research foundation. This	2. Direct technical	2005.	
	research and	can be funded through	assistance to selected		
	development by domestic	FCDO support for Ghana	manufacturing companies	The advocacy campaign	
	pharmaceutical	JET Project.	compliant with the WHO	must encourage	
	manufacturing		GMP standard to enhance	government to dedicate a	
	companies.	Exchange programs for	research and	portion of the 2% to	
		researchers to build their	development of new	pharmaceutical industry	
	4. Limited cross	skills	products. This would	research.	
	Government of Ghana		encourage other facilities		
	pharmaceutical research		to accelerate compliance	Have government R&D	
	collaboration with other	Establish Triple Helix	to receive technical and	centres integrated	
	countries and	Innovation platforms to	financial support to new	forward to do	
	development partners.	increase collaboration	product development	manufacturing and thus	
				increasing	
	5. Weak cross academic		Target some institutions	commercialization of R&D	
	institutions and		and fund them well for		
			R&D and let them become		

	pharmaceutical companies collaboration.		centre of excellence in some select area	
Sourcing of Raw Materials	1. Weak local capacity to produce core APIs. 2. Relatively expensive local sourcing of APIs from domestic importers. 3. Inconsistent application of tax exemption policy on pharmaceutical raw materials. The benchmark discount on pharmaceutical raw materials are not consistently applied due to lack of information and poor integration of the policy into the Customs duties framework. Also, The benchmark discount on pharmaceutical raw materials are not consistently applied due to lack of information and poor integration of the policy into the Customs duties framework.	1. Government and FCDO working with GRA to review the implementation constraints of the existing tax exemption regime for local pharmaceutical manufacturers. 2. FCDO can work with the Joint Customs Consultative Committee, PMAG, and the Ghana Chamber of Pharmacy to improve monitoring of enforcement of tax exemption policies for local pharmaceutical manufacturers. 3. FCDO can work with PMAG to establish a temporary portal for local manufacturers to report enforcement of tax exemptions. This would assist the PMAG to demand accountability from government with regards to tax exemptions on APIs.	1. Collaboration between PMAG, FCDO and Association of Ghana Industries to determine the local industrial capacity to develop core APIs. This assessment will be based on the common product lines of PMAG and core APIs required. The assessment will also reveal the existing local industrial capacity constraints to produce APIs. 2. collaboration with in Manufacturing of other inputs such as packaging materials, excipients and engineering expertise required to maintain and service pharmaceutical equipment	1. A cross GoG and FCDO collaboration to provide technical assistance to members of AGI and PMAG with the capacity to produce core APIs. Help make a financial case 2. An advocacy to encourage government to provide tax exemption and business stimulus such as subsidized utility tariffs for domestic industries producing core APIs.

Manufacturing	1. High cost of raw	1. Collaboration between	1. Cross GoG, FCDO and	1.	Cross GoG and
	materials.	Ministry of Health, Ghana	PMAG project towards		FCDO
		Health Service, PPA and	identifying feasible		collaboration to
	2. Expensive utility tariffs	the various medical stores	opportunities to reduce		continually review
	, ,	and public health	utility tariffs for PMAG		capacity gaps of
	3. Capacity constraints in	institutions to prioritize	members without		local
	meeting the WHO GMP	domestic manufacturing	government losing		manufacturers
	standards.	companies where capacity	significant revenue.		and provide
		is available during			technical support
	4. Inconsistent	procurement of	2. Collaboration between		on alternative
	enforcement of tax	pharmaceutical products.	Pharmacy Council, PMAG,		approaches to
	exemptions and		FCDO and GoG to provide		meeting the WHO
	prioritization of domestic	2. PMAG working with	technical assistance to		GMP standards.
	suppliers during public	Ministry of Health and	domestic manufacturers	2.	
	procurement.	NHIS to accelerate	towards improvement in		collaborate more
		payment of	facilities to produce		closely with
	5. Limited focus on the	reimbursement to direct	imported NHIS EML		industry in R&D
	production of patented	pharmaceutical retailers	products.		and
	drugs.	accredited with the NHIS.	2 5050		manufacturing.
			3. FCDO working with		Maybe establish
			PMAG to identify the		science and
			capacity constraints and		technology parks devoted to
			opportunities to improve PMAG members		Biomedical
			compliance to the GMP		sciences
			standards. This can be		sciences
			done through provision of		
			grants and other forms of		
			technical assistance to		
			companies who improve		
			capacity from grade C to		
			B.		

Wholesale & Retail	1. Multiplicity of distribution chains leading the proliferation of unlicensed pharmaceutical distributors. 2. Abuse of the supply chain by independent drug suppliers.	1. PMAG working with licensed distributors and licensed independent suppliers to check the influx of unlicensed distributors and retailers. 2. FDA and GHS working with PMAG and Ghana Chamber of Pharmacy to	4. FCDO can provide technical support towards participation in international competitive bidding for companies who progress from grade B to A on the WHO GMP standard. Incentivise Chinese manufacturing APIs to locate to Ghana leveraging AFCFTA. This will bring know how that can spill over 1. FCDO working with FDA to provide technical assistance targeted at product surveillance through digital platforms. This can be done through application of specialized bar code and serial numbers generated by FDA to check product	
	distributors. 2. Abuse of the supply chain by independent	distributors and retailers. 2. FDA and GHS working with PMAG and Ghana Chamber of Pharmacy to	This can be done through application of specialized bar code and serial numbers generated by FDA to check product	
	3. Unregulated pricing across the value chain, particularly the retail section of the market.	develop and communicate regulated prices of products to prevent arbitrary prices charged by retailers. This can be strengthened	originality.	
	4. Weak monitoring and surveillance of the market by regulatory institutions.	through the E-pharmacy project.		

	Consumer campaigns on dangers of fake drugs and how to detect them.	Further consolidation of the sector to create large retailers that have economies of scale and can stimulate manufacturing		
NHIS	Relatively low price quotation of NHIS EML medicines. Delays in payment of reimbursement.	1. PMAG working with GHS, Ministry of Health and NHIA to ensure compliance with the 90-days window stipulated in the contract framework.	1. Provide financial support to local manufacturing companies to explore production of more NHIS EMLs.	Model NHIS along British NHS which also owns hospitals and thus has more resources and can better control costs

c. Opportunities

Following the extensive analysis of the supply chain of the Ghanaian local pharmaceutical manufacturing landscape, the following opportunities emerge.

- There is huge demand for API to be used in the manufacturing of local pharmaceuticals as well as
 for export to other pharmaceutical companies within the sub-region presents a unique
 opportunity for potential investors. AFCFTA and other related policies on trade within the region
 as well as the commitment of WAHO to building such an industry will no doubt facilitate the
 export into neighboring countries.
- 2. There is also an opportunity to invest in other higher value-added products and services crucial to the supply chain and pharmaceutical market in Ghana. These products include innovator drugs, vaccines, biopharmaceuticals, inhalation products drug discovery activities or new chemical entity (NCE) and novel delivery systems. The government has already expressed its commitment in supporting local pharmaceutical companies that are ready to produce vaccines.
- 3. With the focus on getting a critical set of Ghanaian local pharmaceutical manufacturers to be GMP compliant, Ghana's geopolitical advantage within the region presents an opportunity for contract manufacturing. To leverage cheap labor in developing economies while freeing resources to concentrate on time consuming and costly 'gene hunting' methods of R&D for new drug discovery, many major global drug companies are outsourcing their manufacturing operations to other countries. Ghana could capitalize on this development by manufacturing generic and patented products of these companies on contract basis.
- 4. With the high demand for generic drugs, foreign pharmaceutical companies are encouraged to set up facilities in Ghana to manufacture off-patented drugs.
- 5. A lot of opportunities for manufacturing of other inputs such as packaging materials, excipients and engineering expertise required to maintain and service equipment

Appendix

list of registered companies that were importers of finished pharmaceutical products published by the FDA in July 2017

Afrimed Medical Supplies Limited	Ebenezer Chemist Limited	Kofikrom Pharmacy Limited	Population Services International Ghana	Valley view Pharmacy
Alfies Pharmacy	Ernest Chemist Limited	Kojach Limited	Reiss And Co (OH) Limited	Vicbarns Limited
Aniniwah Medical Centre Limited	Eskay Therapeutics Ltd	M & G Pharmaceuticals Ltd	Rik-Dark Company Ltd.	Vicdoris Pharmaceuticals
ANR Pharma Limited	Fiina Pharmacy Limited	Maridav Ghana Limited	Rock Chemist Ltd	Vitatree Ghana Limited
Ansa Pharma Limited	Forever living	Mega Lifesciences Ghana Ltd	Royal Dach Pharmaceuticals	Worldwide Health care
As Allah Dey Company	GB Pharma Limited	MosanFontlife Pharmacy	Sharp Pharmaceuticals	
		Ltd.	Limited	
Asterisk Life Sciences (Gh) Limited	Gokals Laborex	Xen Pharma Centre Ltd	Suntai Enterprise Co. Ltd	
C4C Homeopathic Hospital	Gokals Limited	Northland Industry Group Limited	Senes Pharma Company Limited	
C & J Medicare Hospital	Herbalife Ghana Ltd	OA &J Pharmaceuticals Limited	Shalina Healthcare (GPS) Ltd. (socomex)	
Camden Pharmaceuticals Limited	Hills Pharmacy	Omega Meyer Gh. Limited	Supra Pharma Limited	
Carefx Logistics Ltd.	Imperial Health Sciences	Palb Pharmaceuticals Ltd.	Tobinco Pharmaceuticals Limited	
Cedar Point Chemist Limited	Joehanzy Pharmaceuticals Company Ltd	Pharmatrust Limited	Telad Limited	
Curist Pharma Limited	K.O.D Ghana Company Limited	Phillips Pharmaceuticals (Ghana) Limited	UK Chemicals Co. Ltd	
Dannex Limited	Knad Services Limited	Phinas Pharma Limited	Unichem (Ghana) Limited	
East Cantonments Pharmacy Ltd.	Kobi Memorial Pharmacy Ltd	Pobb's Enterprise/Impact Healthcare	Unichem Industries Limited	

 $^{^1\,}https://mofep.gov.gh/sites/default/files/news/2022-Budget-Statement.pdf$

 $^{^2\} https://adphealth.org/upload/resource/Ghana_Local_Pharma_Production.pdf$

³ https://adphealth.org/upload/resource/Ghana Local Pharma Production.pdf

⁴ https://adphealth.org/upload/resource/Ghana_Local_Pharma_Production.pdf

https://adphealth.org/upload/resource/Ghana Local Pharma Production.pdf *Ghana Pharma Market & Regulatory Report (pharmexcil.com)

https://www.fitchsolutions.com/pharma-healthcare/ghana-continues-work-towards-increasing-local-pharmaceutical-production-21-04-2021

- 8 https://www.unido.org/sites/default/files/2016-01/ECOWAS Regional Pharmaceutical Plan 0.pdf
- 9 https://www.sciencedirect.com/science/article/pii/S0277953619303545#bbib69
- ¹⁰ https://www.moh.gov.gh/wp-content/uploads/2020/07/NMP-book-file-1.pdf
- 11 https://www.graphic.com.gh/news/general-news/gsa-fda-harmonisation-on-october-1.html?fbclid=lwAR0RI-8zc-
- LK3ydDBoXQpzrMi0dWgmzBVIvHXQG4E-F69sFjJWIfn5nZ4Qg
- 12 https://pharmexcil.com/uploads/countryreports/Ghana Market Regulatory report2020.pdf

13

- $\frac{\text{https://www.cbo.gov/publication/57126\#:} \sim : text=The\%20 pharmaceutical\%20 industry\%20 devoted\%20\%2483, safety\%2D monitoring\%20 or \%20 marketing\%20 purposes.}$
- ¹⁴ Sanbao, DAS, Ernest Chemist, Delma and Entrance
- 15 https://gh.bmj.com/content/4/2/e001047
- ¹⁶61251-Ghana_Health_Research_Mapping_FINAL_REPORT.pdf (publishing.service.gov.uk)
- ¹⁷ Executive Summary (fdaghana.gov.gh)
- ¹⁸ 2020 FDA Annual Report final.pdf (fdaghana.gov.gh)
- ¹⁹GHANA GMP ROADMAP (unido.org)
- ²⁰Impact of COVID-19 on Pharmaceuticals Market Size Report, 2020-2027 (fortunebusinessinsights.com)
- ²¹World Bank Document
- ²² World Bank Document
- ²³ http://ghscs.com/wp-content/uploads/2017/12/Boateng-pharma-manufacturing-Ghana.pdf
- ²⁴https://www.bing.com/newtabredir?url=https%3A%2F%2Fwww.adphealth.org%2Fupload%2Fresource%2FGhana Local Pharma Production. pdf
- ²⁵2020 FDA Annual Report final.pdf (fdaghana.gov.gh) . The purpose of the corrective and preventive action (CAPA) IS to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. The outcome and recommendations from these assessments are meant to help these pharmaceutical companies to become World Health Organization (WHO), Good Manufacturing Practices (GMP) compliant. GMP compliance consists of processes, procedures and documentation that ensures manufacturing products, such as pharmaceutical goods, are consistently produced and controlled according to set quality standards.
- ²⁶2020 FDA Annual Report final.pdf (fdaghana.gov.gh)
- ²⁷Kinapharma products sales Wholesale venues | Kinapharma
- ²⁸World Bank Document
- ²⁹ http://ghscs.com/wp-content/uploads/2017/12/Boateng-pharma-manufacturing-Ghana.pdf
- 30 https://www.usp-pqm.org/sites/default/files/pqms/article/pqm-234b-end-of-program-report.pdf
- ³¹ https://www.sciencedirect.com/science/article/pii/S0277953619303545
- ³²Fake drugs: How bad is Africa's counterfeit medicine problem? BBC News
- 33 World Bank Document
- https://www.moh.gov.gh/wp-content/uploads/2020/07/NMP-book-file-1.pdf
- 35 https://adphealth.org/upload/resource/Ghana_Local_Pharma_Production.pdf
- 36 https://www.moh.gov.gh/wp-content/uploads/2020/07/NMP-book-file-1.pdf
- ³⁷https://www.bing.com/newtabredir?url=https%3A%2F%2Fwww.adphealth.org%2Fupload%2Fresource%2FGhana Local Pharma Production. pdf. For Ghanaian prices, we used the Medicines List (February 2011) of the Ghanaian National Health Insurance Scheme. Prices in Ghanaian cedis were converted to Indian rupees using the annual average exchange rates for 2011.
- 38https://www.bing.com/newtabredir?url=https%3A%2F%2Fwww.adphealth.org%2Fupload%2Fresource%2FGhana_Local_Pharma_Production.pdf
- ³⁹ World Bank Document
- ⁴⁰ Ghana: Assessment of Medicines Procurement and Supply Management in the Public Health Sector A Country Report; MOH, GHS, 2007
- ⁴¹World Bank Document
- ⁴² https://www.hciaccra.gov.in/docs/1618554652Market%20Access%20Survey%20on%20Pharmaceduitical%20sector%20in%20Ghana.pdf
- $^{43}\,https://mofep.gov.gh/sites/default/files/news/2022-Budget-Statement.pdf$
- 44 https://mofep.gov.gh/sites/default/files/news/2022-Budget-Statement.pdf
- ⁴⁵ Kusi A, Enemark U, Hansen KS, Asante FA. Refusal to enroll in Ghana's National Health Insurance Scheme: is affordability the problem? Int J Equity Health. 2015;**14**:2. doi: 10.1186/s12939-014-0130-2.
- ⁴⁶ NDPC Annual Progress Report, (2020)
- ⁴⁷ https://www.moh.gov.gh/wp-content/uploads/2018/09/2017-Holistic-Assessment-Report_Final_09.08.2018.pdf
- ⁴⁸ National Health Insurance Authority. (2021). Benefits Package. Accra: NHIS. Retrieved April 6, 2021, from http://www.nhis.gov.gh/benefits.aspx . The scheme excludes the following:
- $^{49}\,https://openknowledge.worldbank.org/bitstream/handle/10986/27658/9781464811173.pdf$
- ⁵⁰Ghana Local Pharma Production.pdf (adphealth.org)
- 51 https://openknowledge.worldbank.org/bitstream/handle/10986/12297/NonAsciiFileName0.pdf?sequence=1&isAllowed=y
- ⁵² https://openknowledge.worldbank.org/bitstream/handle/10986/27658/9781464811173.pdf
- $^{53}\ https://www.jointlearningnetwork.org/news/earmarking-in-ghana-impacts-on-the-financial-sustainability-of-national-health-insurance/sustainability-of-nationability-o$
- $^{54}\,\underline{https://globalization and health.biomedcentral.com/track/pdf/10.1186/s12992-016-0171-y.pdf}$
- 55 https://ghchamberofpharmacy.com/chamber-of-pharmacy-withdraws-credit-supplies-to-regional-medical-stores-others/

 $^{^{56} \}frac{\text{https://www.nhis.gov.gh/files/2013\%20Annual\%20Report-Final\%20ver\%2029.09.14.pdf}}{\text{https://www.moh.gov.gh/wp-content/uploads/2018/09/2017-Holistic-Assessment-Report_Final_09.08.2018.pdf}}$

⁵⁸ https://www.nhis.gov.gh/News/nhia-pays-claims-arrears-to-health-providers-

^{5301#:~:}text=For%20this%20year%202020%20alone,quality%20healthcare%20across%20the%20country.

59 https://mofep.gov.gh/sites/default/files/news/2022-Budget-Statement.pdf

60 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5607056/#CR15