

REPORT

SCOPING OF THE HERBAL INDUSTRY

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1. LIST OF ABBREVIATIONS

Name	Abbreviations
Good Manufacturing Practices	GMP
The Centre for Plant Medicine Research	CPMR
The Ghana Medical & Dental Council	GMDC
Food & Drugs Authority	FDA
Traditional & Alternative Medicine Directorate	TAMD
Ghana Export Promotion Authority	GEPA
Ghana Statistical Services	GSS
Ghana Investment promotion Centre	GIPC
Traditional Medicine Practice Council	TMPC
Ghana Association Medical Herbalists	GAMH
Ghana Federation of Traditional Medicine Practitioners Associations	GHAFTRAM

2. EXECUTIVE SUMMARY

Background

The potential of the herbal medicine sector to contribute to Ghana's economic growth cannot be overstated, as the global market value of herbal medicines is projected to reach US\$ 5 trillion in 2050. In Ghana, an estimated 951 tons of crude herbal medicine were sold in 2010, with a total value of around US\$ 7.8 million. The herbal industry sector contributes indirectly to economic growth by promoting general wellbeing, resulting in a healthy population for wealth creation in addition to reducing the amount of foreign exchange used for the importation of medicines. Directly, the exportation of the herbal medicines can generate significant foreign exchange and create a good number of employment opportunities. However, for this potential to be fully harnessed, the sector must be well structured. Additionally, any challenges that are likely to hinder the growth of the sector must be identified and properly resolved. This report is a result of a consultancy assignment, which was aimed to provide a scoping account of the herbal industry to better understand the challenges of the sector for target interventions to attract potential investors and create employment. The project was funded by the UK Foreign, Commonwealth & Development Office (FCDO) under the JET-Palladium Programme.

Methodology

Qualitative research approaches were adopted due to the short duration of the assignment. Relevant stakeholders, including institutions involved in regulation and governance of the sector, private manufacturers, and advocacy groups, were interviewed. Desk reviews were also carried out to access and analyze secondary data. The study covered four broad areas: regulatory environment, governance, economics, investment, and trade.

Key Findings

- i. In Ghana, herbal medicines are currently classified into two main groups (herbal medicines and herbal supplements), which is consistent with WHO's classification. The products are also classified by the FDA based on the origin (Foreign and Local).
- ii. Although the regulation of the sector (registration and issuance of market authorization) started with the inception of the Food and Drugs Board in 1997, the initial regulatory requirements were relaxed and are gradually being tightened, leading to frequent changes with the overall goal of supporting the herbal medicine manufacturers to attain international standards.
- iii. There is a low level of formal education among the practitioners, resulting in their inability to understand and appreciate the regulatory requirements.
- iv. Compared to the foreign manufacturers and foreign herbal products, the local herbal medicine manufacturers are not able to meet regulatory requirements such as Good Manufacturing Practices, data on clinical or efficacy studies, standardization, and stability testing.

- v. None of the local herbal medicine manufacturing facilities are licensed by the FDA because they do not meet GMP standards.
- vi. The absence of stability data has led to the FDA approving a shelf-life of only one year for the liquid herbal medicines and two years for capsules, tablets, and powders. This therefore limits the volume or quantity of products that can be produced and stocked.
- vii. The lack of clinical or efficacy studies data has resulted in the local herbal medicines not being approved for certain disease conditions.
- viii. On WHO's call to all member states to establish separate guidelines for conducting clinical trials on herbal medicines from orthodox medicines, the Ministry of Health has developed guidelines titled "*Basic Procedures for Assessing Efficacy and Safety of Herbal Medicine Products*". The successful implementation of this guideline will result in the local herbal medicines registered for disease conditions that they are not currently registered for. The manufacturers were, however, not aware of this new guideline for efficacy testing of herbal medicines.
- ix. The branding and packaging of most of the local herbal medicines are not comparable to foreign herbal medicines.
- x. There is a lack of or inadequate local expertise regarding technical support for GMP, production, and packaging.
- xi. Cultivation of medicinal plants is almost non-existent, and plant raw materials are largely obtained from the wild.
- xii. Nineteen (19) herbal manufacturing companies have been identified to have some GMP systems in place and could be supported to attain GMP status.
- xiii. The governance structure of Ghana's herbal sector is not clear. It is made up of four (4) agencies and two (2) private associations, with each of the four agencies reporting directly to the Minister for Health. The Traditional and Alternative Medicine Directorate of the Ministry of Health acts as a coordinating unit. That is, unlike other similar sectors that are overseen by commissions (Forestry Commission, Minerals Commission, Petroleum Commission, etc.), authorities (National Petroleum Authority, Ghana Export Promotion Authority, etc) or councils (Council for Scientific and Industrial Research), the herbal medicine sector is overseen by a small directorate (TAMD).
- xiv. Although opportunities exist in the current governance structure for collaboration among the agencies, there is a low level of collaboration, resulting in slow or lack of implementation of important policies.
- xv. There is an absence of holistic policy, framework, or an Act of parliament that seeks to bring together the various stakeholders in the sector to promote growth and development.
- xvi. Data on Ghana's herbal medicine sector in terms of potential for growth, contribution to economic growth, and opportunity to create jobs is lacking since the herbal sector is lumped with the pharmaceutical sector by most of the relevant institutions. Data from Ghana Statistical Services showed that the total contribution of the pharmaceutical sector to GDP was just 0.60% in 2023.

- xvii. Ghana's herbal sector has a huge potential to contribute significantly to GDP, but its current value is estimated to be only US\$ 0.04 billion, which is about just 0.002% of the value of the global herbal market, which is estimated to be US\$200 billion in 2023, growing at a rate between 15 – 25% and projected to be worth US\$5 trillion by the year 2050.
- xviii. The main economic challenge faced by the herbal medicine manufacturers is a lack of financial resources, which is compounded by high interest rates.
- xix. Lack of policy on restriction of importation of foreign herbal products is adversely affected by affecting the growth of the local industry.
- xx. The local herbal medicines face stiff competition from both orthodox medicines and foreign herbal medicines.
- xxi. The popular herbal products in Ghana's herbal industry are of foreign origin, some of which are prescribed by medical practitioners.
- xxii. Although there are several thousand local herbal medicines crowding a small local market, none is competing on the international market.
- xxiii. The level of investment in the sector is low. However, a few areas have emerged from the study for potential investment. They are; Research and Development (R&D), GMP production facilities including stability testing facilities, Standardization and clinical studies laboratories, Commercial Cultivation and exportation of medicinal plants, and Extraction and Sale of Active Pharmaceutical Ingredients from medicinal plants.
- xxiv. The level of international trade in herbal medicines is low, and a large proportion of Ghana's herbal medicine is sold on the international market as raw medicinal plant materials.
- xxv. To position the Ghanaian herbal medicine for the international market, the quality (GMP, standardization, efficacy, and packaging) must be improved.

Suggested interventions and/or strategies are recommended

To address some of the key challenges, support the sector to grow, and harness its full potential by increasing Ghana's share of the global market share of the herbal industry, which is projected to reach US\$ 5 trillion in 2050, the following interventions and/or strategies are recommended:

Short-term

1. JET should provide additional financial support to the consultants to carry out in depth analysis of the nineteen (19) companies identified to be the big players in the industry. This is critical for target interventions that will be required to develop these companies to become big players in the international herbal medicine industry.
2. Ghana should take advantage of the global demand for raw medicinal plant materials and be a major exporter of these materials. This initiative should be led by GEPA.
3. The FDA should hold dissemination workshops on "*Basic Procedures for Assessing Efficacy and Safety of Herbal Medicine Products*" for all stakeholders. The FDA should

also publish the guidelines on their website. The FDA should speed up the implementation of the guideline.

Medium-term

1. The FDA should strengthen the regulatory regime within the next five (5) years. The herbal medicine manufacturers should be categorized and those that are close to achieving international standards be supported technically by FDA to attain the required standards.
2. The FDA should support eighteen (18) companies and the CPMR to attain GMP status within the next five years.
3. The government of Ghana through its development partners must support the sector by giving the herbal medicine manufacturing companies loans at relatively low-interest rates. A special fund could be created at the Ministry of Finance for it. The nineteen (19) companies that have been identified in the study to have some GMP structures in place can be targeted and the process must be made easy and transparent. This process should be led by the MoTI.
4. Commercial cultivation of essential medicinal plants should be promoted. The FDA should lead this policy change and ensure strict compliance.
5. The Forestry Commission and the Ministry of Food and Agriculture should incorporate the cultivation of medicinal plants in their agriculture and afforestation strategies.
6. The commercial cultivation of any medicinal plant must be matched with scaling up of the production of the product for which the plant is used. This is to avoid what happened in the past, where individuals were encouraged to cultivate the medicinal plant used to produce the herbal medicine used for the management of prostate enlargement without the corresponding investment in scaling up of the production facility resulting in the supply of the plant material exceeding demand leading to most of the farmers losing their investment.

Long-term

1. International investors could invest in establishing of GMP-compliant production facilities across the region to offer contract production services to the herbal medicine manufacturers. This must be led by the Ghana Investment Promotion Centre in collaboration with the FDA.
2. The government of Ghana through its development partners support the analyses and testing laboratories, which are mainly located in the Universities across the country with research grants to be able to acquire the required equipment to support the industry. This should be led by the Ministry of Health in collaboration with the Ministry of Education.

3. International investors could invest in the establishment of ISO certified testing and analyses laboratories to support the industry. This should be led by the GIPC in collaboration with the FDA.
4. The herbal sector should be reorganized under one agency (an Authority and a Commission). The government of Ghana should solicit financial support from development partners to achieve this.

3. INTRODUCTION

According to the WHO, traditional medicine (TM) is the sum of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health and the prevention, diagnosis, improvement, or treatment of physical and mental illness (WHO, 2019). Herbal medicine constitutes a significant aspect of traditional medicine, and about 80% of the global population is said to patronize herbal medicines (WHO, 2019). The WHO classifies herbal medicines to include herbs, herbal materials, herbal preparations, and finished herbal products that contain, as active ingredients, parts of plants, other plant materials, or combinations thereof. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g., animal and mineral materials) (WHO, 2019).

The history of herbal medicine is as ancient as the history of mankind, and herbs have been important sources of pharmaceuticals throughout history (De Pasquale, 1984). The herbal medicine sector, which is an ancient medical system that has provided the world's population with safe, effective, and affordable medicines for many years, has evolved over time. Globally, the herbal industry forms a very important segment of the pharmaceutical industry. The global medicine market value was estimated to be US\$60 billion in 2000 (Handa et al., 2006), US\$200 billion in 2023 (<https://www.futuremarketinsights.com/reports/herbal-medicinal-products-market>) and projected to reach US\$5 trillion by 2050 (Hishe et al., 2016), driven by increasing demand for natural health solutions. some of (Sharma et al., 2021).

Africa has a unique diversity of geographic and climatic factors, and an exceptionally rich, varied flora, with an estimated 68,000 plant species, of which about 35,000 are known to be endemic (Dzoyem et al., 2013). This great biodiversity and climate variation, as well as rainfall and soils, are suitable environments for indigenous medicinal plant growth; as a result, there is an immense diversity and variation of the vegetation in the whole continent (Dzoyem et al., 2013). Tropical and subtropical Africa are endowed with approximately 45,000 species of plants with potential for development, of which 5000 species are used medicinally, constituting nearly 25% of the world trade in biodiversity (Dzoyem et al., 2013). Prior to the introduction of cosmopolitan medicine, traditional medicine, including herbal medicine, used to be the dominant medical system available to millions of people in both rural and urban communities in Africa (Abdullahi, 2011). Indeed, it was the only source of medical care for a greater proportion of the population. However, the arrival of the Europeans marked a significant turning point in the history of this age-long tradition and culture. Thus, centuries of colonialism, have held back the development of African traditional health care in general and herbal medicines in particular. Although significant efforts are being made in many African countries to develop the herbal medicine sector, Africa still lags in terms of the share of the global herbal medicine market.

In Ghana, prior to 1961, the herbal medicine industry was very informal and made of individual traditionalists/spiritualists. Efforts to promote and commercialize traditional medicine practice started in 1961 with the following historical milestones: The creation of the Ghana Psychic and Traditional Healers Association (1961), Establishment of the Centre for Scientific Research into Plant Medicine (CSRPM) now Centre for Research into Plant Medicine (CPMR) (1975), Establishment of the Traditional and Alternative Medicine Directorate at the Ministry of Health (TAMD) (1991), Promulgation of Food and Drugs Laws (PNDCL 305B) (1992), and Traditional Medicine Act (2000), which supported the establishment of the Traditional Medicine Practice Council (TMPC), The preparation of the first Herbal Pharmacopoeia by the Technology Transfer Centre of the Centre for Scientific and Industrial Research (CSIR) (1992), and The introduction of a Bachelor of Science degree in Herbal Medicine in Kwame Nkrumah University of Science and Technology (KNUST) (2001). The Traditional and Alternative Medicine Directorate was expanded in 2003, introducing a code of ethics and standard of practice. The Ghana National Drug Policy, which aims at promoting research, development, and rational use of herbal medicines, was revised in 2004, and Traditional medicine practice Act, Act 575, came into being in the year 2000 but became operational when the Traditional Medicine Practice Council (TMPC) was set up in 2010. This was followed by the release of the 2nd edition of the Ghana Herbal Pharmacopoeia (GHP) in 2007. In 2012, Ghana's Ministry of Health integrated clinical herbal medicine practice into its main healthcare system, following the piloting of herbal clinics in selected government hospitals. The pilot operation as of 2012 covers about 18 government health facilities nationwide.

Despite the efforts and milestones, Africa in general and Ghana in particular have still not fully realized the potential of the herbal medicine industry as one of the fastest growing industries in the world due primarily to limited resources. Currently, the key players in the global herbal medicine industry are Traditional Chinese Medicine (TCM) companies, Ayurvedic medicine companies (India), European herbal medicine companies (e.g., Germany, UK), dietary supplement manufacturers (e.g., US, China) and some pharmaceutical companies with herbal divisions (e.g., Bayer, GlaxoSmithKline).

In Ghana, CPMR has over 37 products in various dosage forms on the market. Apart from that, it has farms for herbal raw material production and under resourced laboratories for quality control checks. There are over 40,000 herbal practitioners distributed in all corners of the country, including remote communities (verbal communication from GHAFTRAM). The practitioners are a very useful group for transformation of the sector to create jobs and attract investments due to the number of people parading as practitioners in every community. However, all these players are faced with numerous challenges that are hampering the growth of the sector.

4. OBJECTIVES

The main objective of this assignment was to provide a scoping account of the herbal industry to better understand the challenges of the sector for target interventions to attract potential investors and create employments

4.1 SPECIFIC OBJECTIVES

The specific objectives of this study were derived from the terms of reference (TOR) as follows:

- Provide detailed analysis to the selected research questions
- Develop key stakeholder analysis and mapping
- Provide recommendations on potential intervention to increase growth and investment, as well as forecast potential impact in jobs and investment.

5. METHODOLOGY

5.1 STUDY DESIGN

A qualitative study design was used for primary data collection. Secondary data were obtained mainly by desk reviews as well as from relevant institutions. The desk reviews involved review of relevant laws, policies and published literature. The qualitative data collection largely involved in-depth interviews with relevant stakeholders. However, some stakeholders opted to response to the questions on the interview guide at their convenience.

5.2 STUDY PARTICIPANTS

The target participants were selected based on the research questions in the terms of reference (TOR). They included both public and private entities involved in promotion, regulation and governance of the herbal industry. Private manufacturers were identified through GHAFTRAM and by interaction with key informants such as the Centre for Plant Medicine Research (CPMR), Ghana Association Medical Herbalists (GAMH) and Food and Drugs Authority (FDA). The participants were sent letters seeking their consent to participate. This was followed by telephone calls in some instances and follow-up visits.

Overall, twenty-two (22) participants were targeted (Table 1) consisting of nine (9) public institutions (#1-9), two (2) private associations (#10-11) and eleven (11) manufacturers (#12-22). Out of the 22 target participants, 15 took part in the study (Table 2) giving an overall response rate of 68%, which is significant and acceptable for a qualitative study of this nature (Morgan, 2017). Furthermore, all the nine (9) public institutions and the two (2) private associations participated giving 100% respondent rate for these groups and five (5) of the manufacturers participated (Table 2) giving 45% for this group.

Table 1: Target Population

#	Name
1	The Centre for Plant Medicine Research (CPMR)
2	The Ghana Medical & Dental Council (GMDC)
3	Food & Drugs Authority (FDA)
4	Traditional & Alternative Medicine Directorate (TAMD)
5	Ministry of Trade and Industry (MoTI)
6	Ghana Export Promotion Authority (GEPA)
7	Ghana Statistical Services (GSS)
8	Ghana Investment promotion Centre (GIPC)
9	Traditional Medicine Practice Council (TMPC)
10	Ghana Association Medical Herbalists (GAMH)
11	Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM)
12	COA Research and Manufacturing Limited Company (COA-RMLC)
13	Amen Scientific Herbal Hospital
14	Executive Prostate Center
15	Medi-Moses Clinic and Herbal Center
16	Capital O2 Herbal Company
17	Kantanka Herbal Pharmaceutical
18	Taabea Herbal
19	KENOCH HG Herbal
20	Agbeve Herbal
21	Tinatett Herbal
22	SIDIBE Herbal Centre

Table 2: Study Participants

#	Name
1	Ghana Association Medical Herbalists (GAMH)
2	The Centre for Plant Medicine Research (CPMR)
3	The Ghana Medical & Dental Council (GMDC)
4	Food & Drugs Authority (FDA)
5	Traditional & Alternative Medicine Directorate (TAMD)
7	Ghana Export Promotion Authority (GEPA)
8	Ghana Statistical Services (GSS)
9	Ghana Investment promotion Centre (GIPC)
10	Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM)
11	Kantanka Herbal Pharmaceutical
12	Taabea Herbal
13	KENOCH HG Herbal
14	Agbeve Herbal
15	Tinatett Herbal

6. CHALLENGES

The main challenge encountered was that some of the manufacturers did not respond to the request to participate in the study.

7. STAKEHOLDER ANALYSIS

Table 3 shows the list of stakeholders in the herbal industry. The table also indicates whether they are private or public, the role they play in the industry and their influence on the sector. The information on the influence of the stakeholders on the sector was collated during the validation workshop held on October 1, 2024. Out of about twenty-five (25) stakeholders, twenty-one (21) have been identified to have a high influence on the sector.

Table 3: List of stakeholders

Stakeholder	Sector	Role/Function	Influence (High/Low)
Food & Drugs Authority (FDA)	Public	Registration and Market Authorization	High
Centre for Plant Medicine Research (CPMR)	Public	Research and Development Herbal Medicine	High
Traditional & Alternative Medicine Directorate (TAMD)/Ministry of Health	Public	Policy	High
Ministry of Trade	Public	Policy	Low
Ghana Export Promotion Authority (GEPA)	Public	Promotion of Export	Low
Ghana Health Services	Public/Private	Provision of clinical services	High
Ghana Pharmacy council	Public	Regulation of Pharmacists	High
Ghana Medical & Dental Council (GMDC)	Public	Regulation of Medical and Dental Professionals	High
Traditional Medicine Practice Council (TMPC)	Public	Regulation of herbal practitioners	High
National Health Insurance Authority	Public	Provision of insurance for medical services	High
Private Medical Insurance Companies	Private	Provision of insurance for medical services	Low
World Health Organization (WHO)	Public/International	Policy	High
Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM)	Private	Mouthpiece of traditional herbalists	High
Association of Ghana Industries (AGI)	Private	Mouthpiece for industries	Low
Ghana Association Medical Herbalists (GAMH)	Private	Mouthpiece of professional medical herbalists	High
Private Herbal Medicine Manufacturers	Private	Manufacturing and Sales of herbal medicines	High
Packaging material manufacturers	Private	Provide Packaging Services	High
Production Equipment Manufacturers	Private	Provision of Manufacturing Equipment	High
Medicinal Plants collectors/cultivators	Private	Provision of Plant Raw Materials	High
Environmental Protection Agency	Public	Provision of environmental safety certification	High
Council for Scientific Industrial Research	Public	Research and Analyses	High
Ghana Standards Authority	Public	Calibration of Equipment	High
National Fire Service	Public	Provision of fire safety certificate	High
Metropolitan, Municipal and District Authorities	Public	Provision of factory permit	High
The Universities	Public/Private	Research and Analyses	High

8. FINDINGS

8.1 THE LEADING COMPANIES AND INFLUENTIAL INDIVIDUALS IN THIS SECTOR, AND THE ROLES THEY PLAY

To obtain information about the leading companies and influential individuals in the sector, key informants such as the Centre for Plant Medicine Research (CPMR), Ghana Association of Medical Herbalists (GAMH) and Food and Drugs Authority (FDA) were asked to indicate the big companies in the industry. In all, a total of eighteen (18) companies were mentioned as the big players in the industry. FDA mentioned eight (8) companies, CPMR mentioned nine (9) and GAMH identified seven (7). This excludes the CPMR, an agency under the MoH, which has also been mentioned as a big player in the industry.

According to the FDA, the companies they have identified as big players are the ones that have established some processes towards the attainment of Good Manufacturing Practices (GMP) status.

Table 4: List of big companies in Ghana's herbal industry

#	Name of Company	Recommended by
1.	Centre for Plant Medicine Research	CPMR/GAMH
2.	COA Research and Manufacturing Company Limited	FDA/CPMR
3.	Chocho Industries	GAMH
4.	Amen Scientific Herbal Hospital	GAMH
5.	Executive Prostate Center	GAMH
6.	Ebenage Herbal Company	CPMR
7.	Medi-Moses Clinic and Herbal Center	GAMH
8.	Capital O2 Herbal Company	FDA
9.	Agbeve Herbal	CPMR
10.	Kantanka Herbal Pharmaceutical and Research Centre	FDA/CPMR
11.	Taabea Herbal	CPMR
12.	Angel Herbal	CPMR
13.	Divine Hope Herbal	CPMR
14.	Power Specialist Herbal	CPMR
15.	Tinatett Herbal	FDA
16.	Milyash Herbs Ltd.	FDA
17.	Phytotec Ltd.	FDA
18.	Ganaherb Therapeutics	FDA
19.	Solak Biochemist	FDA

The respondents from FDA said, *“These are the companies that have some processes in place and are earmarked to be giving the needed technical support to achieve Good Manufacturing Practice (GMP) status. And we have sent a proposal to WHO for financial assistance so that we can provide the needed support to these companies so that they can become GMP compliant.”*

8.2 THE REGULATORY ENVIRONMENT IN GHANA

8.2.1 The current classifications for herbal medicine in Ghana

Globally, herbal medicines are classified into two broad categories: medicinal products and non-medicinal products. Herbal products are classified as medicinal products if they claim therapeutic or prophylactic indication and are not considered medicinal products when they do not make these claims. Products not classified as medicinal in most cases belong to the food or cosmetic areas, although they sometimes contain plants that have pharmacological properties.

In Ghana, regarding regulation, there are three components of the herbal medicine industry often referred to as the 3Ps: the products, the practice, and the practitioner, according to the Director in charge of TAMd.

The products, which include all herbal based products that have been prepared by going through a certain production process and exclude medicinal plant materials that are sold in their raw form, are regulated by the Food and Drug Authority (FDA). The practice involved clinical services that use herbal products either in processed or raw form, and the practitioner refers to anyone involved in the practice (consultation and treatment) of herbal medicine. The location of the practice covers all facilities that are used for the practice of traditional medicine or retail of herbal products. Practice, Practitioner, and Location are regulated by the Traditional Medicine Practice Council (TMPC). For this scoping assignment, the focus is on the products.

According to the FDA, the herbal products in Ghana are classified based on two main criteria, which are (1) the type of product and (2) the origin of the product (manufacturer). Regarding the types of products, herbal products are classified as herbal medicines or herbal supplements. The definition of herbal medicines and herbal supplements according to the FDA is consistent with the global definition as stated above. For the origin, the products are classified as local or foreign.

8.2.2 The regulatory bodies that oversee herbal products

The main regulatory body that oversees herbal products in Ghana is the Food and Drugs Authority (FDA), which was established by an Act of Parliament (Public Health Act 851 of 2012). Specifically, Part Seven, Section 80 of Act 851 establishes the FDA. Section 81 spells out the objectives of the Authority, which are to **provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, and medical devices**. Sections 82(a) and (e) are

the functions that directly relate to the regulation of herbal medicine products, devices, and household chemical substances.

82 (a) ensure adequate and effective standards for food, drugs, cosmetics, household chemicals and medical devices.

82 (e) approve the initiation and conduct of clinical trials in the Country.

8.2.3 How Food and Drugs Authority (FDA) of Ghana regulates the herbal medicine sector, and the specific requirements for product registration

A review of the information on the FDA website shows that the organization has the **Health Products and Technologies Division (HPTD)**, which is made up of the following Directorates (<https://fdaghana.gov.gh/health-products.php>):

- Vaccines, Vigilance and Clinical Trials
- Medical Devices, Cosmetics and Household Chemicals
- Drugs and Herbal Medicines
- Tobacco and Substance of Abuse Clinical Trial Department

Therefore, the regulation of herbal medicine products is carried out by the Drug and Herbal Medicines Directorate. The registration of herbal medicines is governed by a guideline which can be downloaded from the FDA website (<https://fdaghana.gov.gh/application-form.php>).

The specific requirements for product registration are as follows:

- The presentation of the product shall not have any resemblance in spelling and pronunciation of name, or packaging to another product, that has been previously registered by the Authority.
- All samples submitted should conform to existing labelling regulations as specified in the Authority's guidelines for product labelling.
- Scientific and/or botanical names of the plants used, as well as the parts of plants used and the quantity of active ingredients used in the preparation, shall be submitted.
- The list of all excipients used and their quantities per dosage units used in the preparation shall be submitted.
- The indications for which the herbal medicinal product is being presented for registration shall be unambiguously stated.
- All documentation submitted shall be in English and must be legibly printed and not handwritten.
- Four (4) copies of the labels and leaflet inserts, conforming to existing labelling regulations in Ghana shall be included in the documentation

- If the product is produced on contract manufacture, evidence of the contract agreement shall be produced in the documentation submitted

The registration process for a new herbal product is as presented in the flow chart (Figure 2). Depending on the type of product, the laboratory analyses prior to submission of the product to the FDA can take two (2) months for products that require only acute toxicity to six (6) months for products that require chronic toxicity studies. According to the FDA, the registration process after submission of the products to the FDA can take up to three months, giving a total of about five (5) to nine (9) months to complete the registration of a new product.

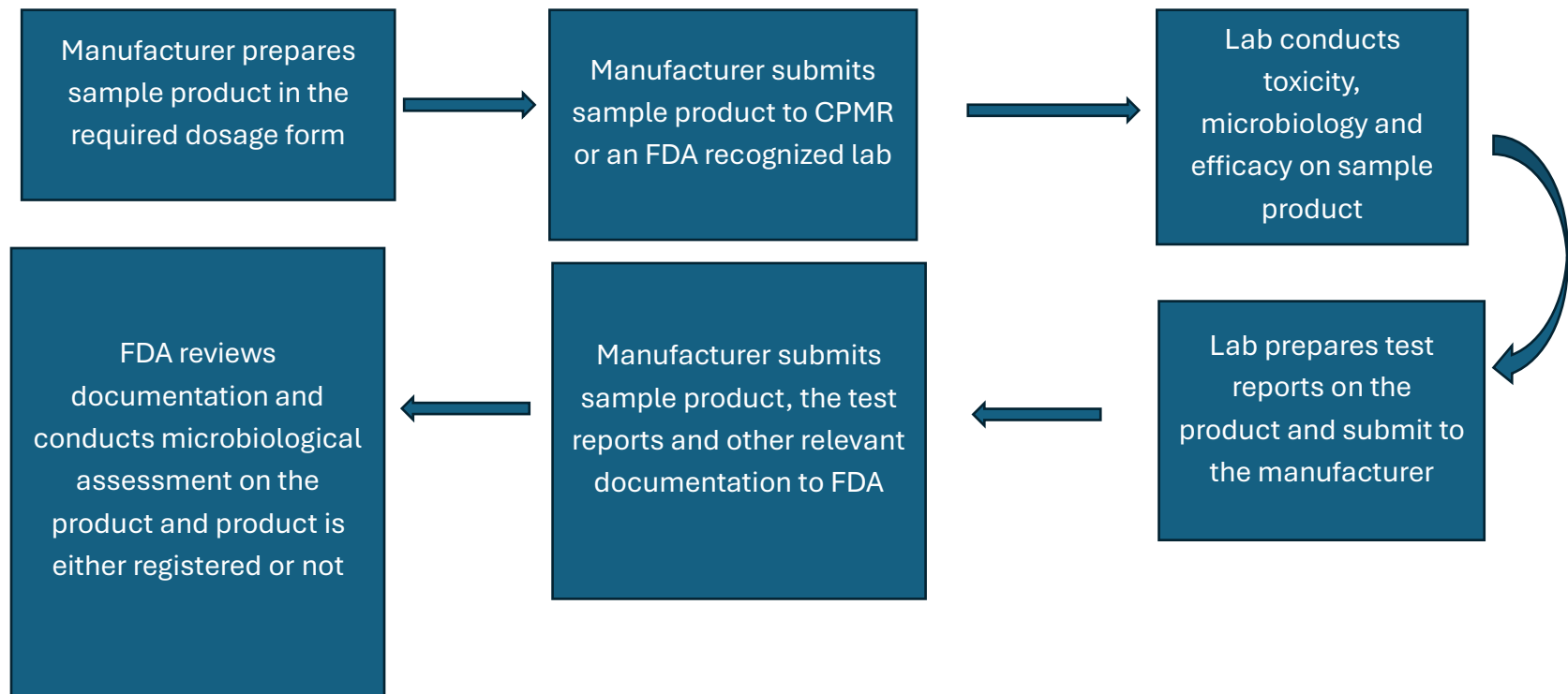


Figure 1: Registration process flow chart for a new herbal product

8.2.4 The main challenges faced by herbal medicine producers in complying with regulatory standards in Ghana

Globally, the broad challenges faced by the herbal industry that hinder its growth include: lack of standardization, regulatory ambiguity, licensing and registration, labeling and advertising restrictions, import/export regulations, patent and intellectual property protection, limited access to funding, stigma and skepticism, Lack of research and development, fragmented industry, conflicting laws and regulations, limited availability of herbal medicine education and training, High costs of compliance and limited access to healthcare systems (Kala et al., 2006).

In Ghana, Asase in 2023 enumerated the following as the main challenges facing the herbal industry (Asase, 2023):

- **Registration of herbal medicines:** The majority of the manufacturers are unable to meet the requirement for pharmacological data (efficacy), toxicity data (safety), and clinical data. Another challenge regarding the registration of herbal medicines is the lack of data on the shelf life of herbal products. Since almost all herbal medicines for FDA registration do not have data on stability studies, the current practice is to license liquid formulations for only 1 year. However, this interim measure is a huge burden to both the regulator and manufacturers because of the annual renewal of registration of products. Registration of herbal medicine products is also hampered by unclear guidelines regarding nomenclature of products, resulting in herbal products with strange names. E.g., Tinatett before, before capsule now Tinatett 230.
- **Certification of herbal medicine practitioners:** Certification of traditional medicine practitioners (including herbalists) and their premises in Ghana is done by the Traditional Medicine Practice Council (TMPC). The Traditional Medicine Practice Act 575 (2000) provides for the certification of practitioners. Nevertheless, the certification process is currently fraught with challenges such as inadequate staff, cumbersome procedures, high fees, and a lack of adequate education.
- **Standardization and quality control:** Standardization and quality control are a challenge in the herbal medicine industry, not limited to Ghana, but criticized as a major weakness of herbal medicine worldwide. As such, there is usually batch-to-batch variation in the same product. This means patients might not have the same benefits from the use of the same product. Quality control also concerns the harvesting and processing of raw plant materials, detecting possible misidentification of species and adulteration through either substitution of different plant materials or plant parts. Species adulteration in the raw herbal trade market can be as high as 80% in some African countries, due to a lack of proper identification methods.
- **Lack of clinical trials to confirm safety and efficacy:** The safety and efficacy represent a major challenge facing the herbal medicine industry in Ghana. Clinical trials are required

for large-scale endorsement and the safe marketing of herbal medicines at international markets. Besides, bioactivity, pharmacodynamics, and toxicity results from *in vitro* bioassay and *in vivo* animal studies might be different from efficacy and toxicity in humans owing to physiologic and metabolic differences between human beings and other animals. To conduct clinical trials on herbal medicines, herbal products must be prepared according to Good Manufacturing Practices (GMP) with appropriate standardization and identification of markers to ensure that the batches of the product being evaluated are always the same. Challenges such as inability to meet regulatory requirements, resource constraints, social acceptance, medicine supply, lack of trained staff, and logistical issues have affected the number of clinical trials conducted on herbal medicines in Ghana.

- **Scientific research and development:** Scientific research on health claims by traditional practitioners is very important to rationalize the use of herbal medicines. There is, however, insufficient investment in scientific research and clinical trials in Ghana.
- **Shortages of raw plant materials:** Shortages of raw plant materials for production threaten Ghana's herbal medicinal industry. Most of the commonly used medicinal plants are harvested from the wild.
- **Biopiracy:** Although Ghana has guidelines for the Intellectual Property Rights Protection Framework for Indigenous Knowledge Related to Health and Medicinal Plant Resources (2008), there is a lack of awareness among practitioners. Most herbal practitioners are not aware of the benefits to be derived from patenting traditional knowledge products and services in Ghana.

The results of the field study corroborated the global challenges enumerated above and the Ghana-specific challenges highlighted by Asase (2023). Overall, the absence of stability data on local products, regulatory requirements for herbal medicines not harmonized and therefore vary from country to country, unstable or frequently changing regulatory guidelines, absence of clinical trial or efficacy data on local products, inability to meet GMP requirements, low level of formal education among herbal medicine manufacturers or lack of knowledge and understanding of manufacturing regulations by indigenous herbal medicine producers, absence of robust system for identification, characterization and standardization, high cost of research, lack of technical and financial support for efficacy studies, tedious registration processes, delays in registration processes, and lack of local expertise to produce modern production and packaging equipment were some of the challenges identified. In addition, it was observed that compared to foreign herbal products, the quality of the local herbal products is low in terms of branding, packaging, and scientific data.

The low quality of the local herbal products and the inability of the local herbal medicine manufacturers to comply with regulatory requirements were attributed to financial constraints and lack of access to modern equipment and plant raw materials, with the latter said to be due to deforestation and environmental degradation. The lack of technical expertise in

manufacturing, branding, and packaging equipment was also observed to be partly responsible for the low quality of local herbal products.

The frequently changing regulatory environment was attributed to the fact that although the regulation of herbal products started in 1997 with the inception of the Food and Drug Board, the regulation started with a few minimal requirements. The reason was not to push manufacturers and practitioners out of business but rather to support them to gradually attain acceptable standards (GMP). This is because of the history and the informal nature of the industry. The regulatory regime is therefore being strengthened gradually with the aim of raising the standard of the local herbal medicines to an international level.

The lack of efficacy data is said to be the reason local herbal products are not registered for only a few disease conditions using folkloric evidence and not for chronic diseases and bacterial and viral infections. To support the local manufacturers regarding efficacy data and in response to the WHO's call on member states to develop guidelines for conducting clinical trials on herbal medicines separate from guidelines for orthodox medicines (WHO, 2005), the Ministry of Health has developed guidelines titled “*Basic Procedures for Assessing Efficacy and Safety of Herbal Medicine Products*” (a hardcopy of this document was seen during the team's visit to the FDA). However, our interaction with the manufacturers revealed that they are not aware of the guidelines. In addition, the FDA was not certain when the implementation of the guidelines will begin.

The respondent at FDA had this to say: “*The herbal medicine manufacturers are struggling to produce clinical trial reports, so the ministry has developed this guideline for efficacy testing. All the stakeholders are ready, so we will soon ask them to conduct the efficacy testing based on the guidelines so that herbal medicines can be registered for some disease conditions.*”

GMP-compliant is key to improving the quality of the local herbal medicines and crucial not only in getting the needed permit to enter the international market but also in enhancing public confidence in the local herbal medicines. Unfortunately, the study revealed that none of the local herbal medicine-producing facilities is GMP-compliant and therefore is not licensed by the FDA.

Additionally, there is generally a low level of formal education among herbal medicine manufacturers and practitioners, which makes it difficult to implement quality control measures in their facilities.

It was also observed that there is strict regulation of the advertisement of herbal products. The reason was attributed to the kinds of advertisements and claims that manufacturers and practitioners put out in the public domain. Although the manufacturers stressed that it is

significantly affecting the marketing of their products, the FDA insisted that it is to protect public health, which is their main mandate. The position by the FDA was supported by the GAMH, which indicated that there is often advertisement of indigenous practices without due diligence, thus promoting unsubstantiated claims.

8.2.5 Recent changes or proposed amendments in the regulatory framework that could impact on the herbal medicine sector

The study identified three proposed amendments and one recent change to the regulatory framework that could or is impacting the industry. The only recent change that has been mentioned to be impacting the industry is the ban on “*live presenter mention*,” where radio presenters are banned from mentioning herbal products and their mode of action live on air.

One manufacturer mentioned “*ban on live presenter mention of herbal products*.” This, he said, is significantly affecting sales since the herbal medicine industry relies heavily on advertisements.

The following proposed amendments were mentioned:

- **A proposed Traditional and Alternative Medicine Bill.**

According to the Director of TAMd, the bill that established TMPC, which regulates the practice and practitioners, is being reviewed and named the Traditional and Alternative Medicine Bill. This is because the current bill does not cover alternative medicines. Since the TMPC does not directly regulate herbal products, the review of the bill is not expected to have any effect on the regulation of herbal medicine products.

- **Roadmap on GMP**

According to the FDA and the manufacturers, there is a roadmap to upgrade some of the manufacturers to GMP standard.

The respondent at the FDA said: “*The manufacturers have been analyzed and categorized in terms of their readiness to attain the GMP standards. We are looking for support from WHO to start with the ones that have some structures in place.*”

- **Requirement for efficacy data**

As stated in Section 8.2.4, the Ministry of Health has developed guidelines titled “*Basic Procedures for Assessing Efficacy and Safety of Herbal Medicine Products*.” These guidelines were developed in response to WHO’s directive to member countries to establish guidelines for conducting clinical trials or efficacy studies on herbal medicines separate from orthodox medicines.

FDA mentioned the requirement for efficacy data as part of the changes to registration requirements that will soon be rolled out. The implementation of this policy will offer the opportunity for the local herbal medicines to be approved for certain disease conditions that they are not currently registered for.

8.2.6 Opportunities for improving the regulatory environment to support the growth of the herbal medicine industry

Three (3) main opportunities for improving the regulatory environment were identified: industrial support to herbal medicine manufacturers, quality assessment support to the industry from FDA-recognized institutions, and issuance of **free sale certificates** to local manufacturers to aid in the export of the FDA-registered products to foreign countries.

FDA has an Industry Support Unit, which provides support to all industries in Ghana, especially the small and medium enterprises. This offers a good opportunity for assisting the herbal manufacturing companies to be able to comply with regulatory requirements. There are also FDA-recognized laboratories that offer laboratory services to herbal medicine manufacturers. Finally, there is an opportunity to resume the issuance of **Free Sale Certificates** to local manufacturers to aid in the export of the FDA-registered products to foreign countries.

The study also identified other areas that could be improved to support the industry's growth. They include:

- Stabilization of the regulatory environment. The frequent changes in the regulatory regime are creating lots of challenges for the manufacturers and making it difficult for them to plan and comply.
- Digitization of the regulatory processes. This will not only speed up the rate of processing of registration requests but can also be a good source of data on the sector that can be used for policy and planning purposes.
- Training professionals in the herbal industry (Regulators and Practitioners) and increasing funding for regulatory activities.

8.3 GOVERNANCE OF THE SECTOR

8.3.1 Key Associations and Organizations involved in the governance of Ghana's herbal medicine sector

The governance structure of Ghana's herbal sector is such that there are four (4) agencies (TAMD, CPMR, FDA, and TMPC) under the MoH, each reporting directly to the Minister for Health. In addition to these, two associations of practitioners (GHAFTRAM and GAMH) that play advocacy roles are also involved in the governance of the sector. Specifically:

- The Traditional and Alternate Medicine Directorate (TAMD) is a Directorate established in 1991 by a policy of the Ministry of Health. Its mandate is to formulate policies,

coordinate, and monitor policies in accordance with WHO guidelines for herbal and alternative medicines.

- The Centre for Plant Medicine Research (CPMR), established by an ACT of parliament (ACT 833) with the mandate to research and develop herbal medicine in Ghana.
- The Food and Drugs Authority (FDA), established by an ACT of parliament (ACT 851) to regulate and give market authorization to herbal medicines.
- The Traditional Medicine Practice Council (TMPC), established by an ACT of parliament (ACT 575) to promote, regulate, and control the practice and practitioners of herbal medicine.
- Ghana Federation of Traditional Medicine Practitioners Associations (GHAFTRAM) is an association of local traditional medicine manufacturers and practitioners and acts as their mouthpiece.
- The Ghana Association of Medical Herbalists (GAMH) is a professional body of trained medical herbalists, which also acts as their mouthpiece.

8.3.2 Challenges faced by entities in terms of sector governance and industry collaboration

The governance structure in the herbal sector is not very clearly defined. As indicated in Section 8.3.1., there are multiple agencies involved in the governance of the herbal medicine sector, each reporting directly to the minister. The absence of a well-defined governance structure is said to have resulted in: low level of collaboration among the agencies involved in the governance of the sector; slow pace in implementation of policies; and low budgetary allocation to some of the agencies.

Thus, unlike other sectors that are governed by commissions (Forestry Commission, Minerals Commission, Petroleum Commission, etc.), authorities (National Petroleum Authority, Ghana Export Promotion Authority, etc.), or councils (Council for Scientific and Industrial Research), the herbal medicine sector is overseen by a small directorate (TAMD) in the Ministry of Health. The MoH, unlike other ministries such as the Ministry of Education and the Ministry of Agriculture, which are a bit homogenous, is highly heterogeneous and often overwhelmed by health sector challenges facing the Ghana Health Service and Teaching Hospitals and therefore does not pay much attention to the herbal sector.

According to GMDC, the current structure does not support the development of the industry. The GMDC indicated that although the CPMR ACT empowers the Center to research and develop herbal medicines, it does not cover all the key stakeholders (traditional herbalists and medical professionals). They also mentioned that unlike Ghana, where parallel medical professionals are being trained to practice in the herbal sector, in China, the herbal medicine practice is taken as an area of specialization by trained medical professionals. To them, Ghana's approach does not promote full integration of herbal medicines into the healthcare system. They went further to recommend the establishment of an agency (Authority or Commission) with a full mandate to promote the development of the sector.

The respondents from GMDC remarked as follows:

“To us, the issue is about ownership. Who owns that sector? People just stand up and claim they had a dream, and certain formulations were revealed. So, they prepare concoctions and start marketing and administering them to people without thorough scientific study. We cannot accept that.”

“There should be an agency where anyone with any idea will report to and submit his/her formular for a thorough scientific study up to clinical trials. There must be policies put in place to protect the owners of the traditional knowledge, which will make them willing to submit their formulas for scientific investigations.”

“The herbal sector is a sleeping giant, and the government must play a role in helping realize the full potential of the industry.”

8.3.3 Opportunities for strengthening sector governance through partnerships, policy interventions, or other means

Currently, the only opportunity available for strengthening sector governance is through partnerships. As indicated by CPMR, the Acts that established the various entities involved in the governance of sector have made provisions for a representation of each of the entities on the governing boards of another entity. For instance, GHAFTRAM and the CPMR are represented on the FDA Board. Similarly, the FDA and GHAFTRAM are represented on the CPMR Board. This offers an opportunity for collaboration. However, collaboration among these entities has not been smooth. For instance, since CPMR started commercial production of herbal medicines, its relationship with GHAFTRAM has never been smooth. CPMR has been accused of being a referee and a player and stealing private practitioners' formulas. This calls for the need to decouple the production arm of CPMR from research and development.

The study identified the need for a policy intervention that supports the reorganization of the sector under an agency (an Authority or a Commission). This will harmonize the activities of the entities involved in the governance of sector and promote the growth of the sector. GMDC, for instance, bemoaned the lack of clear policy guidelines for the development of the herbal medicine sector. They highlighted the need for a clear, comprehensive policy for the development of herbal medicine in Ghana, which considers critical issues such as intellectual property, scientific investigation, and clinical practice. They stressed the need to bring all the stakeholders together to develop this policy or framework. They advocated the establishment of a single entity (an Authority or a Commission) to spearhead the development of the herbal sector.

The respondent in TAMD remarked, *“In China, the herbal sector is an independent ministry on its own. Maybe we should go and learn from them.”*

8.3.4 Challenges faced by entities in terms of market dynamics

The main challenges identified in terms of market dynamics are negative images (stigma and skepticism) created about herbal medicines in social media and the low quality of the local herbal medicines compared to the foreign herbal products.

The study also revealed that the local market is overcrowded with numerous but similar herbal products. For instance, each of the manufacturers interviewed mentioned having not less than 10 products. Since there are currently 6,000 practitioners on the GHAFTRAM register, it is estimated that there are at least 60,000 herbal medicines on the market. Most of these medicines are similar in composition and claim to cure the same ailments.

Strict regulation of advertisement and the cost of advertising are also some of the challenges faced by manufacturers. The high cost of advertising is said to be compounded by the proliferation of media houses such that to effectively advertise a product, a manufacturer will have to pay several media houses.

The competition for market share by these several thousand practitioners has also contributed significantly to the slow pace of the implementation of the policy on essential herbal medicines list for the National Health Insurance Scheme. The completion of the essential herbal medicines list would have paved the way for the inclusion of herbal medicines in the list of medicines approved by the NHIS, which would have increased the market share of the manufacturers.

Apart from the CPMR, which indicated they are not able to meet their market demands, all the private manufacturers indicated that they were able to meet their market demand. However, when asked how they arrived at that conclusion, they could not give a convincing explanation. According to them, the fact that they do not run out of stock means they are able to meet market demand. That is, they always have products left in stock. Thus, the response by the manufacturers to the ability to meet market demand is not supported by any scientific data. In effect, the manufacturers do not seem to know the actual market demand for their products.

The respondent from GMDC remarked as follows: *“For us, we do not think there should be something like herbal medicine or orthodox medicine. Medicine is medicine. If the herbal medicine went through the rigorous testing and approval, then they should be available in the pharmacies in the various hospitals. So, it will just be a matter of preference. I will be willing to prescribe them.”*

8.4 ECONOMIC GROWTH: OPPORTUNITIES AND CHALLENGES

8.4.1 Contribution of the herbal medicine sector to Ghana’s economic growth

The herbal medicine industry sector contributes directly to the economic growth of Ghana by generating wealth, including foreign exchange, in addition to creating employment opportunities. Indirectly, the herbal industry contributes to the reduction in the amount of foreign exchange spent on the importation of medicines, coupled with the fact that a vibrant herbal medicine industry will

enhance access to affordable medicines, which will ultimately result in a healthier population for increased wealth creation.

Although comprehensive data on Ghana's herbal medicine sector in terms of potential for growth and contribution to economic growth is lacking, Van Andel and colleagues estimated that 951 tons of crude herbal medicine were sold at Ghana's herbal markets in 2010, with a total value of around US\$ 7.8 million (Van Andel et al., 2012).

The GSS did not have separate data on the contribution of herbal medicine to GDP but rather on the pharmaceutical sector in general. Figure 2 depicts the percentage contribution of the manufacturing sector and the pharmaceutical sector to Ghana's GDP from 2011 to 2023. While the whole manufacturing sector contributes on average 12% to GDP, the pharmaceutical sector contributes just about 0.60%. Ghana's GDP in 2023 was US\$76.37 billion (<https://tradingeconomics.com/ghana/gdp>).

Thus, the pharmaceutical sector as a whole, including the herbal medicine industry, contributed just about US\$0.46 billion in 2023, which is far lower than 1% (US\$0.6 billion) of the global market value of herbal medicine (US\$60 billion) in 2000 (Ha da et al., 2006) and less than 0.5% of the estimated value of the global herbal medicine market (US\$200 billion) in 2023 (<https://www.futuremarketinsights.com/reports/herbal-medicinal-products-market>).

Data from GEPA showed that about US\$4 million worth of herbal products (largely raw medicinal plant materials) was exported in 2023. The average estimated annual sales of each of the nineteen (19) big players in the industry are approximately US\$2 million, giving an estimated total annual sale of approximately US\$40 million. This figure is woefully low compared to China's and India's share of the global herbal medicine marketing, which stood at US\$6 billion and US\$1 billion, respectively, in 2008 (Verma & Singh, 2008).

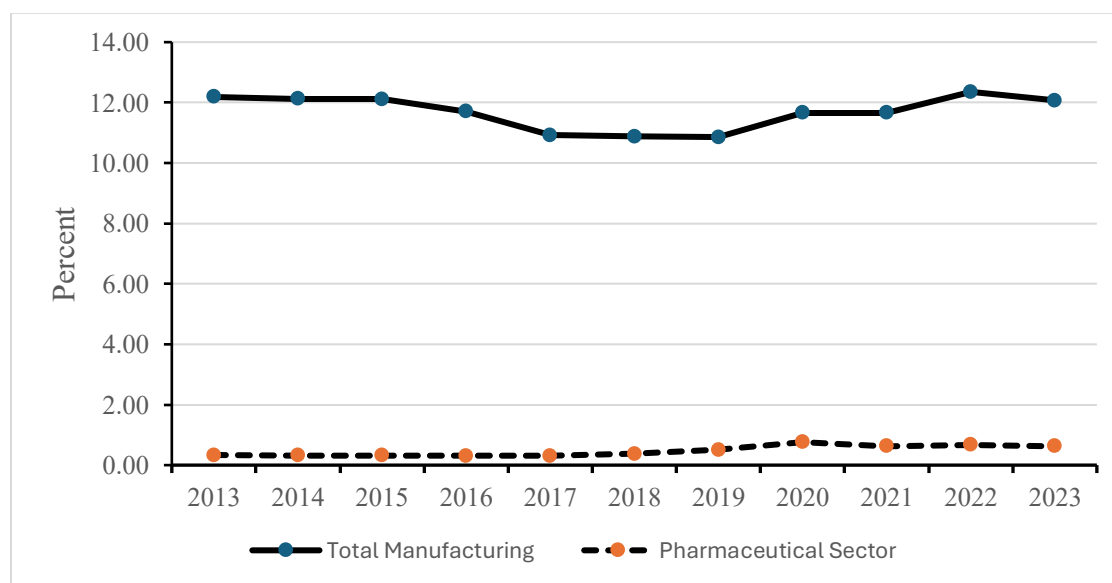


Figure 2: Percentage Contribution to GDP (GSS)

8.4.2 The main economic challenges faced by stakeholders in this sector

The study identified lack of funds as the main economic challenge facing the manufacturers. This was observed to be compounded by high interest rates. The high interest rates, according to the manufacturers, have made it almost impossible to borrow money to invest in their businesses.

High costs of inputs (equipment, consumables, including packaging materials), exacerbated by high inflation and taxes, have also been identified to have worsened the already difficult economic challenges created by a lack of funds. Additionally, a lack of restrictions on the importation of foreign herbal products is said not to be favoring the growth of the local herbal companies.

Finally, the one (1) year shelf life being given to the herbal products creates additional economic challenges in that it does not offer the opportunity of economies-of-scale in the production process since it limits the volume and quantity of products that can be stocked. Furthermore, any time the herbal industry market slows down, manufacturers face the risk of having to recall large quantities of products that will be getting close to their expiry dates.

8.4.3 The potential opportunities for economic growth within the herbal medicine industry

According to the USA International Trade Administration report on Ghana's economy, health and social work was the fourth main sub-sector of the economy that expanded in 2022 year-on-year with an average growth of 9% (<https://www.trade.gov/country-commercial-guides/ghana-market-overview>). The herbal industry constitutes a significant proportion of the health sector.

The GSS did not have data on the contribution of the herbal medicine industry to GDP. However, the herbal medicine industry is one of the fastest growing industries globally. The estimated value of the global herbal medicine industry in 2000 was US\$60 billion and US\$200 billion in 2023, growing at a rate between 15 – 25% and is projected by the WHO to be worth US\$5 trillion by the year 2050 (Ha da et al., 2006). One percent (1%) of the estimated global herbal medicine market share in 2023 is approximately US\$2 billion. As illustrated in **Section 8.4.1**, the value of Ghana's herbal industry is currently far less than 0.5% of the global market value. The information from the GSS valued the whole pharmaceutical sector at just about US\$0.46 billion, and estimated data from the field study valued the herbal sector at about US\$0.04 billion, indicating a huge room for improvement and potential for growth. The WHO rates Ghana's herbal medicine system as one of the most well-established in the sub-region, implying that the country already has some recognized systems in place. For instance, Ghana is the first country in the sub-region to start training medical herbalists, integrating herbal medicine into its primary healthcare system, and regulating herbal medicine products, practices, and practitioners.

To further illustrate the potential of the herbal medicine industry to contribute to wealth creation and economic growth, the potential of Uro500 is illustrated as a case study below:

Uro500 is one of the approximately 34 products from the CPMR. It is used for maintenance of prostate health. According to scientific reports, every male from age 45 years old and above has the potential to develop prostatic hyperplasia (enlargement of the prostate). Thus, this group of males is advised to take regular doses of these products at least twice a year for the maintenance of prostate health. A complete dose of Uro500 is four (4) containers; therefore, every male from age 45 years old and above must take about eight bottles of Uro500 annually. Ghana has approximately 2.5 million males from the age of 45 years and above (GSS report, 2021) (<https://census2021.statsghana.gov.gh/>). Therefore, it is estimated that about 20 million containers of Uro500 should be sold annually, translating into approximately \$60 million at an average cost of \$3 per bottle. However, CPMR reported an estimated meager total annual sale of \$3 million for all its herbal products. Projecting this to the West African sub-region and beyond, Uro500 has the potential to generate several million dollars for Ghana.

8.4.4 Leveraging the herbal medicine industry to create employment and support livelihoods in Ghana

According to Zamora (2016), the concept of “value chain” was introduced by Porter in 1985 to describe the full range of activities that are required to bring a product or service from conception through the different phases of production, distribution to consumers, and final disposal after use, and as the product moves from one player in the chain to another, it is assumed to gain value. Zamora further posited that, as a result, the value chain can be used as a tool to disaggregate a business into major activities, thereby allowing the identification of sources of competitive advantage. The typical value chain of the herbal industry sector is as shown in figure 3 below. As alluded to by Hishe et al. (2016), the value chain can be very long, and the various components of the value chain can be further divided.

As shown in figure 3, the value chain of the herbal industry is made up of a complex network of activities ranging from plant raw material cultivation and harvesting to retailing of herbal products, with each having the potential to create a good number of decent jobs. Every aspect of herbal medicine formulation and use value chain (i.e., cultivation harvesting, processing, formulation, packaging, sale, use, and waste disposal) has diverse socioeconomic relevance from the local to global scale. Each activity of the value chain has the potential to be developed into a company. Figure 4 represents a typical organizational structure of the Traditional Herbal Medicine Industries arm of the value chain shown in figure 3. Despite all the difficulties being faced by the manufacturers, those that were interviewed reported an average staff strength of approximately fifty (50) employees. However, the eighteen (18) companies that have been identified as big players in the industry each have the potential to directly engage at least two hundred (200) employees, ranging from collectors through production to management and administration. That will give a total of about four thousand (4,000) jobs.

Data on the number of people employed in the herbal medicine industry in Ghana is lacking. The GSS has yet to collect data on the total number of people employed in the herbal industry. This notwithstanding, Ghana’s herbal medicine industry is a major source of employment in the

country, as many people, such as traditional medicine practitioners, herbal manufacturers, local vendors, raw plant material aggregators and suppliers, and farmers, are involved in the value chain of the herbal medicine industry (Asase, 2023). The Ghana Federation of Traditional and Alternative Medicine (GHAFTRAM) is currently made up of about 40,000 traditional medicine practitioners, including all practice groups, although 25,000 practitioners are currently registered with the Traditional Medicine Practice Council (TMPC). For most of these people, traditional medicine is their main source of livelihood. The herbal medicine industry has huge prospects for youth employment and poverty reduction in the country. The Ghana Association of Medical Herbalists (GAMH) is an association of trained medical herbalists who have been awarded a Bachelor of Science degree from the Kwame Nkrumah University of Science and Technology, Kumasi. The membership currently stands at 256.

Furthermore, the justification for leveraging on the herbal medicine industry for economic growth is because a significant number of the African population, approximately 72% of 1.2 billion people, rely on it for their healthcare needs. This widespread use of African traditional medicine is not limited to the underprivileged, rural poor, or illiterate, but rather encompasses a diverse range of consumers. Traditional healers primarily rely on indigenous plants as their source of medicine. However, only a small fraction of these plants is farmed, while a large proportion are harvested from grasslands, forests, woodlands, and thickets each year. This highlights the potential for medicinal plants to be a valuable natural resource that can be collected and traded to generate income for rural communities. Thus, cultivation and collection of medicinal plants alone present an attractive business opportunity. With their low volume and high value, they offer a sustainable source of income that can support local economies.

Indeed, in 2016, the CPMR initiated the project for the cultivation of *Croton membranaceus* (the medicinal plant used for the production of prostate health herbal products) by private individuals. CPMR raised and sold seedlings to interested individuals. The project was very successful, as many individuals, including the youth and some employees and retirees of CPMR, went into the cultivation of the plant. Unfortunately, CPMR did not scale up the production of uro500, which the plant is used for. They therefore could not purchase the plant materials from the growers, creating a situation where supply of the plant material far exceeded demand, with some of the growers not able to find any market for their materials.

In Ghana, an estimated 951 tons of crude herbal medicines are said to have been sold at herbal markets in 2010, with a total value of around US\$7.8 million (Van Andel et al., 2012). Data from GEPA indicated that about US\$4 million of herbal products (mainly crude plant materials) were exported in 2023.

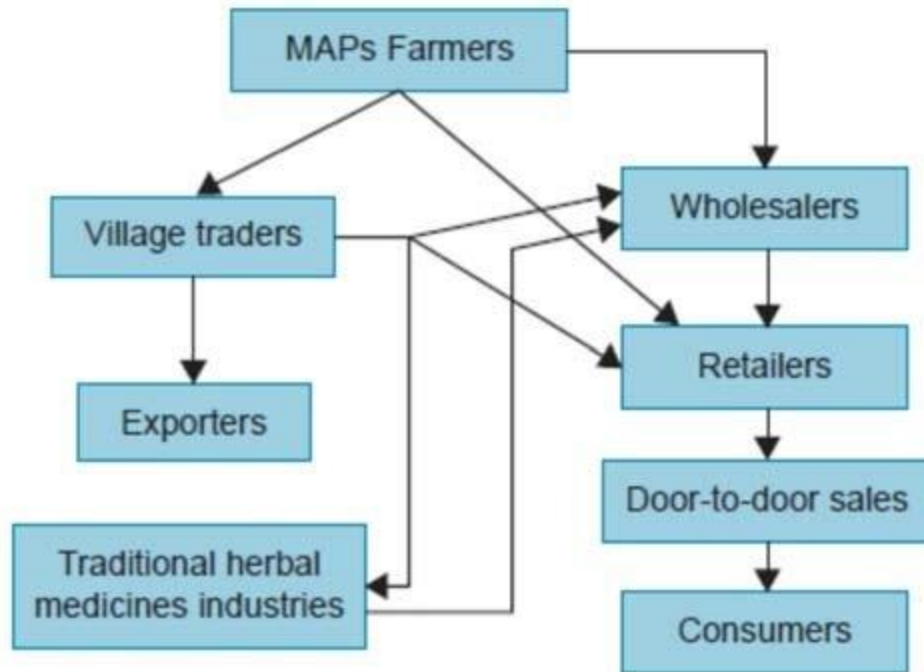


Figure 3: Herbal medicine value chain adapted from Marshal, 2011

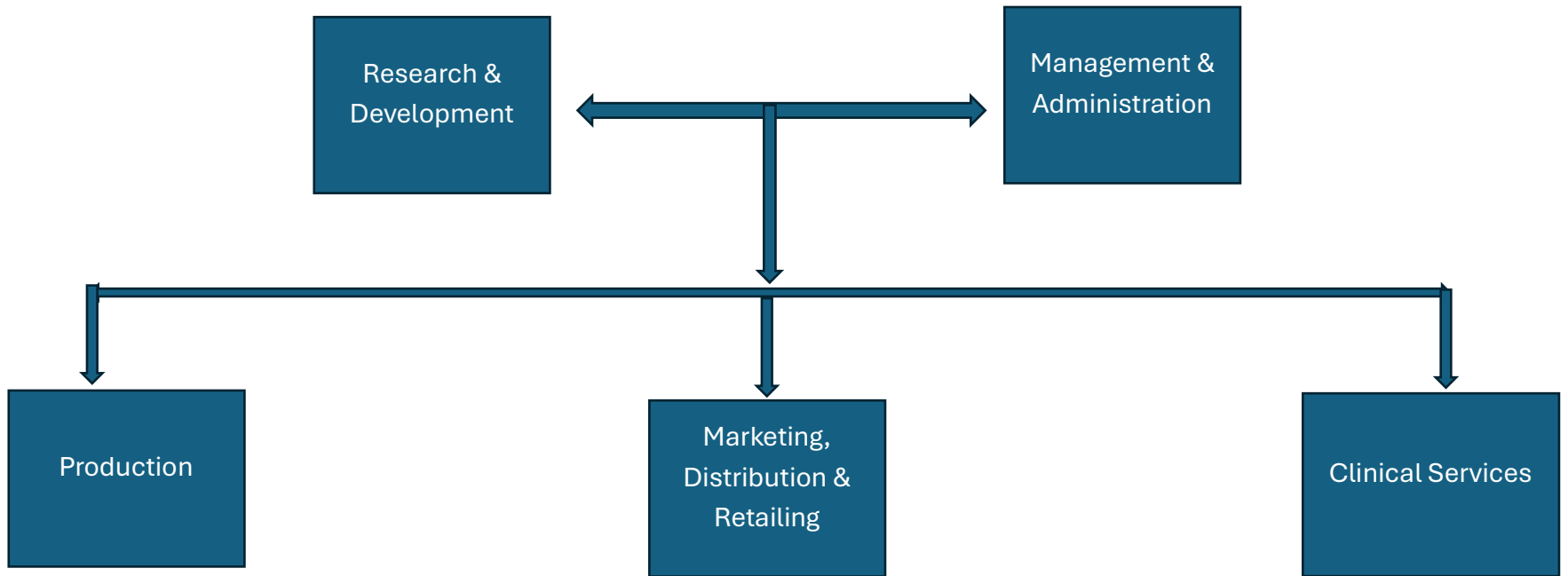


Figure 4: Organizational structure of a typical herbal medicine manufacturing company

8.5 INTERNATIONAL INVESTMENT AND TRADE OPPORTUNITIES

8.5.1 The current trends in international investment concerning Ghana's herbal medicine sector

Investment is critical for the growth of every sector (Aschauer, 1990). For instance, China is said to have invested about US\$2.6 billion to build the traditional Chinese medicine infrastructure (Sami, 2023).

There is a lack of investment (local or international) in the herbal industry in Ghana. All the manufacturers indicated that they do not have investor(s). Indeed, the CPMR has indicated that there is virtually no investment in the herbal sector, which they attributed to a lack of efforts to attract investment.

The Ghana Investment Promotion Council (GIPC) does not have accurate data on the level of international investment into the herbal medicine sector. The only data received from GIPC is the information on herbal sector-related activities from 1994 to 2024 (Table 5). As shown in Table 6, only ten (10) investment activities were recorded in the herbal sector over the last three decades. Out of the ten (10) companies, only one is in cultivation, and four (4) are in manufacturing. The remaining six (6) are into trading, which is consistent with the data from the field study, which shows that the majority of the foreign players in the sector are into services (importation and use of foreign herbal medicines for healthcare delivery services). An example is Milyash Herbs Ltd., which is established by a Ukrainian and uses products from Ukraine and was mentioned by the FDA as one of the big players in the industry.

Nonetheless, the following areas were identified during the study as areas for potential:

- Research and Development (R&D).
- GMP production facilities including stability testing facilities.
- Standardization and clinical studies.
- Commercial Cultivation and exportation of medicinal plants.
- Extraction and Sale of Active Pharmaceutical Ingredients from medicinal plants.

Table 5: Investment activities in the herbal sector between 1994 and 2024

#	Name of Company	Country of origin	Type of Activity	Type of Business	Activity
1	Arcova Healthcare Ghana Limited	United Kingdom	General Trading	Joint Venture	Manufacture and Sale of Pharmaceuticals and Herbal Remedies
2	Banger Tcm Health Service Centre Ltd	China	Service	Foreign	To Operate a Herbal Clinic
3	Chinese Trust Clinic Ltd	China	Service	Foreign	Operation Of Hospital and Herbal Shop
4	Forestry Impex Company Ltd	Denmark	Agriculture	Joint Venture	Cultivation & Processing of Herbal Plants
5	Green World Industries (Gh) Ltd	China,United States of America	Manufacturing	Foreign	Manufacturing of Herbal Products
6	Green-Extract Processing Company Ghana	United States of America	Manufacturing	Joint Venture	Medicinal Processing Plant, Export of Green Extracts & Herbal Plant & Fruit Farm
7	Greenlife Industrial Limited	China	Manufacturing	Joint Venture	Processing of Natural Food Supplement and Herbal Products
8	Kedi Healthchare Industries Limited	China	General Trading	Foreign	Trading in Pharmaceutical Products, Herbal Medicines and Medical Devices & Health Equips
9	Taiwan Herbal Clinic Ltd	Taiwan	Service	Joint Venture	Operation of a Chinese Herbal Clinic
10	Unique Naturalist Care Ltd	Nigeria	Manufacturing	Joint Venture	Manufacture of Herbal Medicine

8.5.2 Barriers to international investment in this sector

To invest in a sector, investors look out for several factors among which are: Market Potential and Growth Prospects, Competitive Landscape, Regulatory Environment, Economic Indicators, Technological Advancements, Financial Performance Metrics, Risk Factors, Management Team Quality, Valuation Levels and Social Responsibility and Sustainability (Sharma et al., 2017).

Also, to be able to attract investors, a sector or a business must be operating within a proper Legal Structure/Framework. There must be a Detailed Business Plan, Strong Management Teams, Financial Transparency, Demonstratable Market Potential and Attractive Investment Terms (Kotler, 2004; Goedhart, 2013).

Although Ghana's herbal medicine sector has great economic prospects, it is bedeviled with numerous challenges. The sector faces stiff competitions not only from orthodox pharmaceuticals industries but also from foreign herbal products especially from China and India. Indeed, our interaction with retailers revealed that the most popular products are those of **Qunloon** from China and **Himalaya Herbal Healthcare** from India. Qunloon retails a very popular aphrodisiac capsule called **Mr. Q** and Himalaya Herbal Healthcare retails a very popular cough syrup called **Koflet** that is prescribed by medical practitioners. Livolin H is another herbal preparation that is prescribed by medical practitioners in Ghana.

There is also a lack of effort to attract investment into the sector as shown by lack of data from GSS, GEPA and GIPC, the three main state institutions, that need to collaborate and come out with strategic initiatives that will attract investment into the area.

Finally, the study also revealed that the private manufacturers themselves are not amenable to the idea of allowing investment into their companies. They seem to prefer access to loan facilities as most of them stressed high interest rates rather than availability of investors as the main economic challenges that the sector faces. In fact, there seem to be ownership issues as far as investment in the sector is concerned.

The respondent from GAMH commented that:

“The herbal medicine practitioners should be willing to let go of the idea of having total ownership. By so doing there will be transparency in the industry and will encourage investors to partner in the industry”

8.5.3 The current trends in international trade concerning Ghana's herbal medicine sector and international markets that are most receptive to Ghanaian herbal products

The MoTI indicated that the GEPA is the export development unit under the Ministry. The GEPA was established in 1969 by an Act of Parliament (Act 396, 1969) to develop and promote exports

through. The Authority currently does not have a unit in charge of promoting herbal products. According to GEPA, the estimated value of herbal products exported in 2023 is a meager US\$4 million, which is just about 0.002% of the estimated value of the global herbal medicine market in 2023. Thus, the level of international trade in terms of export of Ghana's herbal products is very low.

Many of the manufacturers indicated that they do not export their products, although they know that individuals buy their products and send them to other countries. Only a few countries have been mentioned as the official destinations of Ghana's herbal products. CPMR mentioned Barbados and Cote d'Ivoire, while Taabea Herbal mentioned Liberia.

Furthermore, according to GEPA, most of Ghana's herbal products are exported as crude extracts or dried raw plant materials to China, India, and other parts of Europe. Although the exportation of raw medicinal plant materials without value addition is not recommended in the long term, the increase in global demand for crude medicinal plant materials offers an opportunity for foreign exchange generation in the short term.

8.5.4 Barriers to international trade in the sector

Two main barriers to international trade were identified during the study: (a) unharmonized regulatory regimes, which vary from region to region and, in some cases, from country to country; and (b) the low quality of Ghana's herbal products or the inability of the local herbal products to meet international standards in terms of packaging and scientific data.

According to the FDA, unlike the regulation of orthodox medicines, which is harmonized under the Common Technical Documentation platform, the regulation of herbal medicines varies from region to region and country to country. Thus, for an herbal medicine manufacturer to be able to enter a new market, the product must not only be produced to meet international standards, but the manufacturer must also have the resources to meet the regulatory requirements of the country of interest in addition to meeting the requirements of the country of origin. This does not only create logistic challenges for the manufacturers but also adds to their financial burden.

Some of the manufacturers commented as follows:

"We know individuals informally send our products to other countries, but we do not have the money to go through the registration processes in those countries, therefore, we do not export our products."

"I have completed all the forms and paid the registration fees to register my products in Nigeria. Now, they said I should pay \$11,000.00 for them to visit Ghana and inspect my facility. Where am I going to get that money from?"

8.5.5 Positioning the Ghanaian herbal medicine products to attract more international investors and enter new markets

The main issue that emerged from the study regarding the positioning of the Ghanaian herbal medicine products to attract more international investors and enter new markets is improvement in the overall quality of the local herbal products. GMP, efficacy testing, standardization, and packaging issues must be completely resolved. Almost all the stakeholders indicated that improvement in the quality and standard of the local products was the main activity that could position the Ghanaian herbal medicines to attract international investors and enter new markets.

The GMDC and the CPMR mentioned the need to ensure that Ghanaian herbal medicines meet international standards in terms of scientific data and quality of the products (packaging and nomenclature). GAMH and GHAFTRAM also highlighted the same.

Interestingly, the GEPA remarked as follows: *“The issue to deal with would be to standardize our products to increase the demand from our local market and then promote it on the international market.”*

9. INTERVENTION SUGGESTIONS AND RECOMMENDATIONS

9.1 INTERVENTION STRATEGIES THAT COULD BE IMPLEMENTED TO ADDRESS THE CHALLENGES IN GHANA’S HERBAL MEDICINE SECTOR

Short-term

1. The nineteen (19) big players in the local herbal medicine industry could drive the growth of the sector if their individual needs are properly assessed and interventions are targeted. It is therefore recommended that JET should provide additional financial support to the consultants to carry out in-depth analysis of these companies in order to fully understand their individual needs.
2. Currently, Ghanaian herbal medicinal products are exported largely as raw plant materials. Ghana should take advantage of the global demand for medicinal plant materials and position itself as a major exporter of crude raw medicinal plants. This initiative should be led by the GEPA.
3. The implementation of the “*Basic Procedures for Assessing Efficacy and Safety of Herbal Medicine Products*” in response to WHO’s call to all member states to establish separate guidelines for conducting clinical trials on herbal medicines from orthodox medicines will pave the way for local herbal medicines to be registered for certain disease conditions that they are not currently registered for. However, interaction with the manufacturers revealed that they are not even aware of the development of the guidelines. We recommend that the FDA hold dissemination workshops for all stakeholders. The FDA should also publish the guidelines on their website. It is further recommended that the implementation should start at least six months after submission of this report.

Medium-term

1. To be able to enter the international market, the quality of the Ghanaian herbal medicine must be improved to international standards. This will depend partly on the local regulatory requirements. Although the regulation of the sector (registration and issuance of market authorization) started with the inception of the Food and Drugs Board in 1997, the initial regulatory requirements were relaxed and are gradually being tightened, leading to frequent changes. The overall goal is to assist the herbal medicine manufacturers in attaining international standards. It is recommended that the FDA should strengthen the regulatory regime within the next five (5) years. The herbal medicine manufacturers should be categorized, and those that are close to achieving international standards should be supported technically by the FDA to attain the required standards.
2. Although none of the local herbal medicine manufacturers meets the GMP requirements, eighteen (18) companies and the CPMR have been identified to have some GMP processes in place. It is recommended that the FDA should support these companies to attain GMP status within the next five years.
3. The inability to comply with GMP was also attributed to a low level of education among the indigenous manufacturers, inadequate technical support by the FDA, and a lack of local expertise. It is recommended that the companies that would be earmarked to benefit from the low-interest rate loan facility should be supported to recruit the required manpower with the needed skill set. The FDA should also resource their technical support unit to be able to provide the needed support to the manufacturers. This should be led by the FDA and could be done within one (1) year after submitting this report.
4. Standardization and quality control of herbal medicines begin from the source of plant raw material. Sourcing medicinal plants from that wild makes standardization and quality control and assurance processes difficult to maintain, resulting in batch-to-batch differences in products. It is therefore recommended that commercial cultivation of essential medicinal plants be promoted. The FDA should lead this policy change and ensure strict compliance. The Forestry Commission and the Ministry of Food and Agriculture should incorporate the cultivation of medicinal plants in their agriculture and afforestation strategies. The commercial cultivation of any medicinal plant must be matched with scaling up of the production of the product for which the plant is used. This is to avoid what happened in the past, where individuals were encouraged to cultivate the medicinal plant used to produce the herbal medicine used for the management of prostate enlargement without the corresponding investment in scaling up of the production facility, resulting in the supply of the plant material exceeding demand, leading to most of the farmers losing their investment.

5. To be able to enter the international market, Ghana's herbal medicines must be produced and packaged to meet international standards. This can only be achieved if the regulatory environment is strengthened to ensure that the quality of Ghanaian herbal medicines is improved and on par with the foreign products. It is therefore recommended that the FDA strengthen and stabilize the regulatory environment.
6. To be a big player in herbal medicine in Africa and globally, there is the need to invest in the development of a few herbal medicines for specific disease conditions to international standards and aggressively promote them. It is therefore recommended that there should be investment in, e.g., the Uro500 produced by the Centre for Plant Medicine Research for the management of prostate enlargement.

Long-term

1. The local herbal medicine manufacturers are not able to meet regulatory requirements mainly because of inadequate resources, especially financial resources, which are compounded by high interest rates. It is therefore recommended that (a) the government of Ghana, through its development partners, support the sector by giving the herbal medicine manufacturing companies loans at relatively low interest rates. A special fund could be created at the Ministry of Finance for it. The nineteen (19) companies that have been identified in the study to have some GMP structures in place can be targeted, and the process must be made easy and transparent. This process should be led by the MoTI. (b) Alternatively, international investors could invest in setting up GMP-compliant production facilities across the region to offer contract production services to the herbal medicine manufacturers. This must be led by the Ghana Investment Promotion Centre in collaboration with the FDA.
2. In addition to the lack of financial resources by manufacturers to pay for scientific studies on their products, almost all testing laboratories do not have state-of-the-art equipment. It is therefore recommended that the government of Ghana, through its development partners, support the laboratories, which are mainly located in the universities across the country, with research grants to be able to acquire the required equipment to support the industry. This should be led by the MoH and in collaboration with the Ministry of Education. Alternatively, international investors could invest in the establishment of ISO-certified testing and analysis laboratories to support the industry. This should be led by GIPC in collaboration with the FDA.
3. The growth of the herbal sector will depend largely on the governance structure. The current governance structure, which involves four independent agencies, does not support growth and development. It is recommended that the herbal sector be reorganized and

overseen by one agency (an Authority and a Commission). The government of Ghana should solicit financial support from development partners to achieve this.

9.2 LEVERAGING ON PUBLIC-PRIVATE PARTNERSHIPS TO SUPPORT THE ABOVE INTERVENTIONS

Public-Private Partnership should be explored in the establishment of GMP-compliant production facilities for contract production and establishment of state-of-the-art standardization laboratories.

9.3 RECOMMENDATIONS TO ENHANCE THE SECTOR'S APPEAL TO INTERNATIONAL INVESTORS AND TRADERS

To enhance the sector's appeal, there is the need to develop a few Ghanaian brand of herbal medicinal products for certain disease conditions that meet international standards. The government, through development partners, must invest in the important areas of the sector. Thus, the need to create herbal medicine development authority to spearhead this effort since current governance structure looks a little chaotic.

9.4 LEVERAGING TECHNOLOGY AND INNOVATION TO BOOST THE SECTOR'S GROWTH AND GLOBAL COMPETITIVENESS

Creation of a digital database of local herbal medicines will unearth the nature and types of products that are being sold by the over 40,000 GHAFTRAM members. It will contribute to creation of the Ghanaian brand of herbal medicinal products leading to getting rid of quacks who are operating in the space.

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11.APPENDIX

Research Questionnaire on Ghana's Herbal Medicine Sector

1. Regulatory Environment in Ghana

- a. What are the current classifications for herbal medicine in Ghana, and which regulatory bodies oversee them?
- b. How does the Food and Drugs Authority (FDA) of Ghana regulate the herbal medicine sector, and what are the specific requirements for product registration?
- c. What are the main challenges faced by herbal medicine producers in complying with regulatory standards in Ghana?
- d. Are there any recent changes or proposed amendments in the regulatory framework that could impact the herbal medicine sector?
- e. What opportunities exist for improving the regulatory environment to support the growth of the herbal medicine industry?

2. Governance of the Sector

- a. Which associations and organizations are key players in the governance of Ghana's herbal medicine sector?
- b. Who are the leading companies and influential individuals in this sector, and what roles do they play?
- c. What challenges do these entities face in terms of sector governance, market dynamics, and industry collaboration?
- d. Are there opportunities for strengthening sector governance through partnerships, policy interventions, or other means?

3. Economic Growth: Opportunities and Challenges

- a. How does the herbal medicine sector contribute to Ghana's economic growth?
- b. What are the main economic challenges faced by stakeholders in this sector?
- c. What are the potential opportunities for economic growth within the herbal medicine industry?
- d. How can the sector be leveraged to create employment and support livelihoods in Ghana?

4. International Investment and Trade Opportunities

- a. What are the current trends in international investment and trade concerning Ghana's herbal medicine sector?
- b. Which international markets are most receptive to Ghanaian herbal products, and why?
- c. What barriers exist to international investment and trade in this sector?
- d. How can Ghanaian herbal medicine products be positioned to attract more international investors and enter new markets?

5. Intervention Ideas and Recommendations

- a. What intervention strategies could be implemented to address the challenges in Ghana's herbal medicine sector?
- b. How can public-private partnerships be formed to support these interventions?
- c. What recommendations can be made to enhance the sector's appeal to international investors and traders?

d. How can technology and innovation be leveraged to boost the sector's growth and global competitiveness?