

# Private Sector Pharmaceutical Supply and Distribution Chains

Ghana, Mali and Malawi

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## Acronyms

ACT	Artemisinin Combination Treatment for Malaria
AMFm	Affordable Medicines Facility - malaria
CHAG	Christian Health Association of Ghana
CFA	West African Franc (XAF) (1CFA = US\$0.0023)
CIF	Incoterm for Carriage, Insurance, Freight (paid by seller)
CMS	Central Medical Store
CSCOM	Centre de Santé Communautaire (Mali)
CSRef	Centre de Santé de Référence (Mali)
DPM	Departement de la Pharmacie et du Médicament (Mali)
FDB	Food and Drugs Board (Ghana)
GHC	Ghana New Cedi (1GHC= US\$0.7)
GHS	Ghana Health Service (under MoH)
GMP	Good Manufacturing Practices
GNDP	Ghana National Drug Program (under MoH)
HAI	Health Action International (an NGO)
HAN	Health Access Network
HCNLS	Haut Conseil National de Lutte Contre le SIDA (Mali)
ICB	International Competitive Bidding
IDA	IDA Foundation – Dutch procurement agency (not for profit)
INN	International Non-proprietary Name
MK	Malawian kwacha (1MK= US\$0.00724)
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	Non-governmental organization
NHIA	National Health Insurance Authority
NHIL	National Health Insurance Levy
NHIS	National Health Insurance Scheme
OTC	Over the counter
PMAG	Pharmaceutical Manufacturers Organization of Ghana
PPM	Pharmacie Populaire du Mali
QCL	(Drug) Quality Control Lab
RMS	Regional Medical Store
SDP	Service Delivery Point
USP DQI	United States Pharmacopeia, Drug Quality Initiative
VAT	Value Added Tax
WB	World Bank
WHO	World Health Organization

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## **Executive Summary**

Sustainable access to affordable, quality medicines is an important component of health care but in many African countries it continues to be limited. Commonly reported problems include poor supply chain management, pilfering of stock, insufficient human resources and limited financing resulting in chronic stock-outs. In the countries in this study, stocks of medicines supplied by the state-run medical stores were reported to be below recommended minimum stock levels and suffering from rampant stockouts (Andrews, Yamyollia et al. 2004; DPM 2008; Ministry of Health (Malawi) 2006; Ouattara and Ag Tachrist 2005: 5; Rao and Durgavich 2008). The trade of substandard and counterfeit medicines is also growing rapidly. In resource-poor settings where public sector services are unable to meet the demand for services, the private and voluntary sectors are increasingly being called upon. As a result, many policy makers have begun to identify mechanisms that are alternatives to state-run drug procurement and distribution systems.

The supply and distribution of medicines are a fundamental aspect of the success of any health system. Disruptions to this supply of medicines undermine health outcomes as supply chains have an impact on the availability, cost and quality of medicines available to patients.

This study aims to gain a better understanding of some of the different ways in which private sector pharmaceutical supply and distribution channels are organised in Africa. To gain a broad perspective, this study focuses on three very different country contexts: Ghana, Mali, and Malawi. These countries represent significant geographic, economic, social and historical differences. The countries in the study come from English and French-speaking Africa; West and South-east Africa; have close ties with European sources vs. links with other African and Indian pharmaceutical supply chains; draw upon common law vs. civil law legal traditions and regulatory frameworks; are dependent upon imports vs. local manufacturing capacity; and rely upon various levels of public and private health care services.

The focus of the study is medicines; it does not address reactives or pharmaceutical devices. Interviews were conducted over 1-2 week missions in each of the three countries participating in the study. The project was conducted between July and October 2009. Data were drawn from interviews with actors at each level of the private sector pharmaceutical supply and distribution chain and from secondary sources.

The study suggests potential actions that could be taken by international policy makers, government officials, donors, investors and local supply chain participants. The main suggestions are:

### **Businesses and Investors**

- Invest in *market research and data gathering organisations* and mechanisms;
- Strengthen *pharmaceutical distribution networks* by leveraging the private supply and distribution chains of other sectors (eg. Curatio in Ghana or VillageReach in Mozambique) or by creating shared specialised pharmaceutical distribution companies.

- Invest in Accredited Drug Dispensing Outlets (ADDO) based on the Tanzanian model to ensure access to affordable, quality medicines and pharmacy services.

## **National Governments**

### ***To Improve Access to Quality of Medicines:***

- *Strengthen Pharmacy and Drug Regulatory Authorities.* In all of the focus-countries, the quality of medicines available in the private market was hampered by poor government pharmacy inspection and quality testing processes. Strengthening the financial and technical means of the pharmacy and drug regulatory authorities can improve the quality of medicines in circulation by ensuring that all appropriate inspections and testing occurs at all levels of the supply chain (customs, drug registration, wholesale, distribution and retail).
- Support public or private health insurance models with drug coverage to reduce out-of-pocket spending and increase local pharmaceutical consumption.

### ***To Support Manufacturing:***

- *Make better use of existing local private sector supply and distribution channels.* Tender and donations programmes could make more use of local private sector supply and distribution networks for the procurement or distribution of products.
- *Ensure that the public tender system is designed to facilitate and provide incentives for the participation of local supply chain actors* (manufacturers, wholesalers and distributors).
- *Promote the regional harmonisation of drug registration requirements and processes and quality testing facilities.* This would facilitate and extend the entrance of good quality products into new markets and avoid duplicating registration in several small markets. The creation of regional quality testing facilities may reduce current problems with identifying and retaining trained staff and funding national quality labs.

### ***To Stimulate Consumer Demand for Quality Medicines***

- *Educate consumers about the importance of quality in medicines to stimulate consumer demand for quality medicines.* Encourage civil society groups to engage in discussion and raise awareness about the dangers of poor quality medicines and their health care options. This will stimulate consumer demand for quality medicines and good pharmacy services by making consumers aware of their choices.
- *Increase transparency of prices, quality and availability of medicines.* The Medicines Transparency Alliance (MeTA) initiative provides a useful forum to bring stakeholders (national governments, private sector, health service, vulnerable communities and civil society) together and to promote open discussion, to disclose information about issues such as the quality and registration of medicines, the price, availability and access to medicines, prescribing habits, and supply chain operations. Civil society members (patient groups, consumer societies, professional associations) are then able to build capacity to monitor and increase accountability for the prices, availability, selection and quality of medicines in the public and private sectors.

***To Improve the Business Environment:***

- *Encourage local financial institutions to lend to health care businesses. Educate banks about pharmaceutical business models and constraints.*
- *Promote alternative finance services such as cooperative pharmacy banks: Actors in the pharmaceutical supply and distribution chain complained that there were insufficient financial services for them as banks did not understand the pharmaceutical business. These services could provide lines of credit, small loans.*
- *Offer business training for pharmacists and chemical/drug store/ depot de vente either as a part of their academic training or their accreditation/licensing. In many academic pharmacy courses little time is spent on learning how to run a pharmacy business, which is how most earn a living.*

***To Improve the Regulatory Framework:***

- *Financial and political support for post-market surveillance and pharmacy inspections as a way to monitor the quality of products on the market.*
- *Encourage the consolidation of fragmented wholesale market by limiting the number of licences to wholesalers and by reducing prices of medicines by decreasing or eliminating taxes and tariffs on medicines and raw materials. Lower prices may drive consolidation by forcing companies to look for increased economies of scale.*
- *Improve regulatory frameworks to facilitate the introduction of alternative pharmaceutical business models and retail platforms. These could include buyers' cooperatives, franchises, pharmacy chains, or locations within other businesses eg. grocery stores.*
- *Review incentive structure to encourage pharmacists to dispense generics. For examples by allowing higher margins on INN generics than brand-name products or ensuring that generic products are included on reimbursement lists.*

***International Agencies***

- *Assess the impact of international financing, donations and procurement policies on local distributors and retailers. Donations bypass local supply and distribution pathways. Subsidized drugs may undermine the profitability of local distribution and therefore damage the distribution system.*
- *Channel donor funds through existing local private sector supply and distribution channels. Tender and donations programmes could make use of local private sector supply and distribution networks for the manufacture, procurement and distribution of products.*

## **1.0 Introduction: Access to Health Care in Africa: The Need for Private Sector Support?**

Health care in much of Sub-Saharan Africa remains poor. The region accounts for 11 percent of the world's population and 24 percent of the global disease burden, yet commands less than one percent of global health expenditure (World Health report 2006). Recent development targets such as the Millennium Development Goals require significant new investment and scaling up of health services. In resource-poor settings where the public sector is unable to provide all necessary services, the private and voluntary sectors are increasingly being called upon to deliver assistance. Global actors begun to identify new mechanisms to deliver assistance by operating through private sector organisations and experimented with new ways of working with recipient countries. This has led to a reinvigorated interest in adapting private sector models to achieve development goals.

Continuous access to quality medicines is an important component of health care but in many African countries continues to be problematic. Commonly reported problems include inadequate storage facilities, poor forecasting, pilfering of stock, insufficient human resources and limited financing resulting in chronic stockouts. The trade in substandard and counterfeit medicines is also increasingly prevalent. Donors have experimented with a range of approaches to strengthen in-country supply chains including building new supply chains (PEPFAR-SCMS) and strengthening public sector supply networks (Global Fund, USAID/JSI). Donors have also begun to explore how private sector supply and distribution channels can effectively complement state-run drug procurement and distribution systems (Ballou-Aares, Freitas et al. 2009; IFC 2008).

Although some of the literature on the role of the private sector in improving health services focuses on market failures affecting the private sector and the negative implications for affordability, socio-economic determinants of use, and quality (Oxfam International 2009), private sector health services are already present and becoming an increasingly important component of African health care systems. Private sector activities cover all aspects of the pharmaceutical value chain including provision, financing, manufacturing, distribution and retail. Providers of services in the formal sector may be non-public entities, including commercial for-profit companies, non-profits and not-for-profits. In the informal sector they may include traditional healers, mid-wives and individual medicine sellers. Of total health expenditure of US\$16.7 billion in 2005, about 60 percent (mainly out-of-pocket spending), was financed by private parties (IFC 2008: 5). This is due in part to the privatisation of the health professions since the late 1980s and 1990s<sup>1</sup> but also due to failures of the public health system to ensure a continuous supply of quality medicines.

It is generally assumed that the private sector targets wealthy clients and therefore has higher prices; however often the poor are the largest consumers of private sector health services. Marek (2008) and various household surveys suggest that it is the poor, due to a variety of circumstances other than price (perceived quality of care, availability of medicines, presence of health care workers, discrimination, additional payments),

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<sup>1</sup> For example, in Mali the health professions began to be privatised in 1985 (loi No. 85-41/AN RM); the first pharmacies opened in Bamako in 1989 and wholesalers were granted licences in 1992. In Malawi the government began granting licences for private pharmacies in the early 1990s.

that resort to buying medicines for cash from private sector and informal drug sellers. This places the poor at a higher risk of purchasing products of dubious quality and use. However, the private sector can also offer attractive alternatives where public services are inaccessible, unaffordable and of poor quality and it is often the only option acceptable and available to users. Private sector may also offer a range of skills, ideas, capacities and comparative advantages within private sector that can positively impact health outcomes. Re-enforcing a regulated private sector is one way to support the provision of quality medicines to rural and urban populations. For the purposes of this study, the term “private sector” is defined to include: for-profit organizations; social enterprises, and privately motivated individuals and groups of individuals.

The aim of this study is to 1) better understand the current state of private sector supply and distribution networks in three African countries: Ghana, Mali and Malawi; 2) identify some of the gaps in performance of these chains and 3) to make suggestions for reinforcing the private sector to ensure improved access to quality medicines.

## **2.0 A Comparison of Ghana, Malawi and Mali**

The focus-countries of this study (Ghana, Mali, and Malawi) represent significant geographic, economic, social and historical differences. They include countries from English- and French-speaking Africa; West and South-East Africa; with close ties to Europe vs. links with Africa and India; draw upon common law vs. civil law laws and regulatory frameworks; are dependent upon imports vs. have local manufacturing capacity; rely upon various levels of public and private health care services.<sup>2</sup>

Supply and distribution systems in the three countries have different components and are organised in different ways due to a variety of factors including needs, historical influences, power and influence of particular groups, role of the state and the private sector in providing health care services, financial incentives and national laws and regulatory frameworks.

Below, provide a brief introduction to the countries highlighted in this study in order to gain a better understanding of each country-context. The Appendices provide more details of the comparison of country development indicators (Appendix A) and Appendix B-D offer case studies of each country.

### ***Demographics***

The three countries differ considerably. Ghana (US\$670) and Mali (US\$580) are considerably better off than Malawi (US\$290) in terms of GNI per capita. All countries are primarily rural with less than half of the population living in urban areas: (Ghana 47.6%; Mali 31.6% and Malawi 16.7%). While about 90% of the population of Malawi lives on less than US\$ 2 per day, the situation is better in Ghana (53.6%) and Mali (63.8%). Ghana has a longer life expectancy (57 years) than Malawi (48 years) or Mali

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<sup>2</sup> Health care services may be provided by several sectors:

- Government or public sector;
- Faith-based or NGOs;
- Employer provided;
- Private sector.

The share of services offered by each provider depends on the country. Often, while government services are free, faith-based/NGO, employer-provided and private sector health services are delivered by the private sector. Faith-based/ NGO services and those supplied by employers (eg. plantations and mines) are often on a not-for profit basis.

(54 years). All three countries are endemic malaria regions, but the prevalence of HIV in the population between 15-19 years of age is considerably higher in Malawi (11.9%) than Ghana (1.9%) or Mali (1.5%).

### ***Public Health Insurance***

All three countries offer public health care services, which include local level clinics, regional and national hospitals. Of the three countries studied, only Ghana offers public health insurance although in Malawi many health services are provided by the public and not-for-profit sectors. Patients have high out-of-pocket spending on health care services and medicines and the use of the private sector is growing in all three countries.

In Ghana, health care services and medicines are covered by the National Health Insurance Scheme (NHIS). Wealthy individuals may also have access to a form of private or employer-based insurance that includes coverage for medicines. However, about half the population still is not covered by the NHIS and therefore pays out-of-pocket for medicines. Approximately 40 percent of the funds paid out by the NHIS are for pharmaceutical products (Seiter and Gyansa-Lutterodt 2008).

In Malawi, the public sector offers free health services and medicines although maternity care, private wards at central and district hospitals, and some outpatient departments incur patient fees. The not-for-profit private sector (mission hospitals, NGOs and Christian Health Association of Malawi–CHAM) offer services and medicines for small fees. Private sector health care is limited, but due to limited public sector resources that are spread thinly this sector is growing. The health insurance industry in Malawi is underdeveloped. There is no compulsory health insurance even for those in public formal sector employment. Since 2000, a few private sector health insurance schemes have been established (OASIZ Medical Aid and MASM). Some parastatals and some firms have small schemes of their own which they operate themselves or contract out to MASM to administer on their behalf. Spending on medicines remains low: about 10% of MASM's health expenditure was spent on drugs (2004-5) (Makoka, Kaluwa et al. 2007).

In Mali, health care services and medicines are offered by the public sector but patients must pay a small co-payment. Some public health insurance schemes exist for certain formal sector employees. In general, these require a co-payment but cover hospitalisations, primary care and medicines. In addition, private health insurance schemes are paid for through personal premiums or group insurance schemes paid for by employers. However, about 80 percent of the population has no insurance coverage other than the basic services provided by the state through public health services (Fischer, Sissouma et al. 2006: 6). They are therefore subject to "out-of-pocket" user fees such as for medicines and diagnostic tests. One study estimates that 60 percent of household spending is allocated to these two items (EDS4).

### ***Role of State***

The role of the state differs significantly in each country studied. These differences can be attributed, in part, to different regulatory approaches. In Mali, the government closely regulates issues such as the price of pharmaceuticals, whereas the governments of Ghana and Malawi do not get involved in this.

In all countries the state is a large purchaser and supplier of medicines. All countries have an essential drugs list drawn up by the national drug authority. However, the extent to which the public sector is involved in selection, procurement and distribution of medicines varies between countries. In Malawi, for example, the government purchases between 70-90 percent<sup>3</sup> of all medicines consumed in the country.<sup>1</sup> Although the CMS offers emergency tenders several times per year, these often go to foreign suppliers. Donors supply many products through parallel channels (contracting to foreign logistics companies) to national CMS, mission hospitals and NGO health centres.

One reason for the greater development of the private sector in Ghana and Mali is that it often supplies the public sector. In Ghana, in 2008, the MOH spent US\$31 million (including pooled procurement) on medicines and non-drug items or about 10 percent of total retail sales (estimated at US\$300 million) (Seiter and Gyansa-Lutterodt 2008). Procurement and distribution for the public sector are done by the CMS. However, if there are stockouts and Regional Medical Stores or Service Delivery Points do not have access to products, they are allowed to purchase from the private sector (See Public Procurement Act 663). In reality, some Regional Medical Stores buy up to 80 percent of their supplies from the private sector (Seiter and Gyansa-Lutterodt 2008).

In Mali most pharmaceutical supplies for the public sector are provided by the CMS (locally referred to as the Pharmacie Populaire du Mali or PPM). The government contracts out services to the PPM on a three-year basis, i.e. procurement, warehousing and distribution of essential medicines throughout Mali. The public drug budget in 2007 was 9.5 billion F CFA (US\$21 million) or about 14.8 percent of total national pharmaceutical consumption. The national pharmaceutical policy (2000) outlines a scheme, which all pharmaceutical importation and distribution should follow. However, in the case of stock-outs, SDP may procure products from private sector wholesalers by drawing upon small budgets, funded by patient co-payments. On rare occasions hospitals are allowed to offer tenders to the private sector; but this is an unattractive market for private wholesalers, as it takes the government a long time to pay.

### ***Business Environment***

The business environment and government regulatory frameworks play an important role in creating a favourable context for the private sector to flourish. It also serves to regulate unregulated markets.

As discussed above, government procurement policies and the availability of health insurance are important factors that determine the size of the pharmaceutical market. With health insurance and procurement policies that allow RMS and SDP to call upon private sector resources, Ghana has been able to develop a relatively large pharmaceutical market. In Mali, there is no local manufacturing sector. The dominant private sector wholesalers have close ties to France; efficient global supply and national distribution networks are able to supply public sector SDPs. Theoretically, the PPM is also able to supply private sector pharmacies, but in practice this seems to be no longer the case. Finally, in Malawi, the government offers little support to local private sector manufacturing or local wholesalers. Rather it opts for procurement and supply through international tenders and international donors.

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<sup>3</sup> Reports of these numbers vary widely.

In addition, government procurement policies also provide support to businesses. In Ghana, the government prohibits the importation of 44 basic medicines, which are supplied by local manufacturers. In contrast, Malawian manufacturers do not benefit from such policies.

At the retail level, the relatively larger size of the private sector in Ghana and Mali allows for a larger potential market for pharmacies and chemical sellers/ *depots de vente*. In Mali, the opening of new retail pharmacies is promoted and facilitated by the provision of start-up capital by large wholesalers. In Malawi, the pharmacy retail sector is limited both by a weak private sector but also the absence (until recently) of the pharmacy training in Malawi. The growth of private sector pharmacies has also been hindered by government policy to promote private sector doctor dispensing over prescribing.

At all levels of the private sector supply and distribution channels actors in the three countries complained about problems of indebtedness and a lack of trust, the impact of which reverberates throughout the chain. For example, the failure of health insurance companies to pay pharmacists has an impact on retailers' ability to settle debts with their suppliers. Many business people expressed a desire to adopt alternative business models (cooperatives, franchises, chains, hiring additional staff, entering business relationships with partners beyond family members), but feared that they would be unable to trust their business partners or employees not to steal or take advantage of their arrangements.

### ***Growing Informal Sectors***

The informal sector (*pharmacie par terre* in Mali) appears to be growing in all of the countries visited during this study. There is no solid data on the size or value of the sector. Locals estimate the value of the informal sector at 30 percent of the value of the Malian market at about US\$42 million<sup>4</sup> and suggest that in Ghana illegally circulating drugs comprise 10-20 percent of all medicines in circulation (Seiter and Gyansa-Lutterodt 2008). The informal sector can be defined as the market in which unregulated medicines are sold to patients. Medicines in this sector may be counterfeit, substandard or quality products, but as they are exchanged in an unregulated market their origin, price and quality cannot be assured.

The drivers of the counterfeits and the informal sector are:

- Poverty – the informal sector allows customers to buy medicines by the pill, which is cheaper than buying a whole box or blister;
- Lack of education and illiteracy;
- Lack of knowledge about drug quality;
- Stock-outs in the public sector;
- High cost of medicines in the formal sector;
- Limited proximity to public or private sector sales/dispensing points.

These factors are all commonly found in the three countries examined. The informal sector requires significant political will to address – some actors may have good

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<sup>4</sup> In 2005, Dr. Cissé Djita Dem, the president of the Malian Order of Pharmacies estimated that this was about 10 billion FCFA (US\$ 23 120 000) Marsaud, O. 2005. "Le pharmacien africain en première ligne: Entrevue avec Dr Cissé Djita Dem, présidente de l'Ordre des Pharmaciens du Mali" 13 mai 2005 <http://www.afrik.com/article8392.html> Accessed 03.07.2009.

political connections. Apparently, not everybody sees the informal market as a problem. Some may view it as a source of employment and as contributing to access to medicines.

### **3.0 Effective Pharmaceutical Supply and Distribution Chains**

The supply and distribution of medicines are a fundamental aspect of the success of any health system. Fundamentally, they ensure access to medicines to local populations. However, they also provide information on the supply and demand of products and transfer money to finance the system. Disruptions to this supply of medicines undermine health outcomes as supply chains have an impact on the availability, cost and quality of medicines available to patients. Developing countries face a number of challenges that limit access to medicines. These include:

- Regulating the quality and flow of medicines into and within the country;
- Geographic access to medicines;
- Financial access to medicines;
- Supply chain forecasting and planning;
- Limited warehousing.

A Rockefeller Foundation report (Ballou-Aares, Freitas et al. 2009) suggests that effective supply chains provide positive health care outcomes, such as:

- Consistent availability of the right type and quality of medicine;
- Access to safe, authentic, efficacious and unexpired products;
- Medicines that the patients and the health system are able to afford and to sustain;
- Geographic Access to Medicines: Provision of medicines within a reasonable distance to the patient.

The report suggests that successful pharmaceutical supply chains should be:

- Sustainable;
- Adapted to the local context;
- Cost effective;
- Have financial integrity;
- Able to rely upon the continuous presence and enforcement of the regulatory framework;
- Have access to appropriate financing.

The private sector can play a variety of roles in the supply and distribution of medicines.

- Sell medicines, supplies and equipment;
- Sell supply chain contractual services (procurement, transport, warehousing and logistics, information and financial services);
- Provide a private sector supply, distribution and retail channel;
- Advisory services in supply chain best practices.

In formulating policies to support the private sector, suitability to the local context is critical. Private sector market forces alone cannot ensure improved service or efficiencies. The incentive of competition, appropriate and enforced regulatory frameworks and social and cultural context are also crucial.

In many African countries (eg. CFW pharmacy franchises in Kenya and Rwanda), pharmacy franchises have been successful business models by standardising practices within the supply and distribution chain. They aim to support access to quality medicines at low prices (cost savings through greater volumes), standardise pharmaceutical products and pharmacy practices (supply management, warehousing of products, accounting) and improve access to medicines in underserved areas.

Franchises are not always an ideal business model, as they require:

- Very good understanding of the local market;
- Locally relevant business model;
- Substantial investment in the monitoring of franchises;
- Supportive local regulatory frameworks;
- Pharmacist and customer culture that is amenable to the adoption of franchising.

Franchises seem to have little traction in Mali in the short term. In Mali, inquiries into the potential of franchising or opening pharmacy chains were met with scepticism. Malian pharmacy regulations do not support the central procurement required by the franchise model. Given the limited awareness about the quality of medicines, it would be difficult to build a pharmacy brand on this basis. At a cultural level, Malian pharmacists see themselves as independent business people. Pharmacists felt it would be difficult to adhere to franchisor rules and to accept that their businesses would be independently monitored. Fundamentally, Malian pharmacists were concerned about trusting their business partners and having to conform to someone else's rules. There do not seem to be enough incentives for pharmacists to enter into a franchise model.

In Ghana, CareShop was a pharmacy franchise model that struggled and ultimately collapsed (Segré and Tran 2008 provide a detailed review of this project). The main reasons for the failure were the inability of the franchise to maintain franchise discipline and difficulties in encouraging franchisees to transform their business practices. The franchise struggled to maintain a balance between its franchisees' demands and its own financial needs for sustainability. The pharmacists interviewed for this study that had been CareShop franchises complained that the model did not quite fit the local market needs as prices were too high, they did not offer sufficient stock or a desirable product mix and that the delivery service did not allow them to go to Accra to pick up stock, which they enjoyed. The initiative however, did provide valuable training in records keeping and business training, which they still use.

Other business models such as pharmacy chains or cooperatives seem promising under the right circumstances. In Malawi's small private sector, pharmacy chains are beginning to appear. Buyers' cooperatives are relatively easier to establish as they require little regulatory or financial investment. However, the potential for discounts on large volumes are an important incentive. Large discounts are less likely in some contexts (Malawi) where wholesalers claim they operate at low prices. This concept already has some traction in Mali as several pharmacies sometimes join together to take advantage of wholesalers' promotions. Similarly, pharmacies in more rural areas sometimes join together to benefit from joint deliveries to their community. However, this cooperation has not been extended to purchases. This may be because pharmacists

seem to order stock almost every day, making it more difficult to coordinate with others.

Other reports have highlighted the potential benefits of greater use of technology (such as bar codes, RFID, e-procurement or e-payments). However, such technological initiatives seem to be difficult to implement in the three country contexts explored in this report because many of the retail outlets were too small. Many wholesalers and some pharmacies in this study used computer systems to monitor their business' stock and sales, but none of the chemical sellers/drug stores/*depots de vente* visited did. Only some retail outlets monitored their monthly sales electronically, while most opted for paper notebook methods. Similarly, none of the retailers visited had a system to keep track of batch numbers in case of recalls. Some wholesalers also indicated that, although the products have batch numbers, they do not keep track of their destinations.

#### **4.0 Private Sector Supply and Distribution Channels in Ghana, Mali and Malawi**

This section compares private sector supply and distribution channels in the three focus-countries by looking at each segment of the supply channel: product manufacturing, flow of goods into a country, flow of goods within a country and retail. The analysis highlights substantial differences between the three countries. There are significant contrasts between English- and French-speaking Africa but also between countries within English-speaking Africa. Each country has varying strengths and weaknesses in pharmaceutical manufacturing, supply chain management (forecasting, stock management and warehousing), distribution networks and retail strategies.

#### **4.1 Product Manufacturing**

Product manufacturing refers to the production of finished pharmaceutical products (final formulators). In 2006, the IFC estimated the Sub-Saharan Africa pharmaceutical market to be worth US\$3.8 billion. Local final formulators created 25-30 percent of this value, or approximately US\$1 billion. While 37 Sub-Saharan African countries have some pharmaceutical production, South Africa dominated the sector with over 70 percent of the region's annual pharmaceutical production. Nigeria, Kenya, and Ghana together represent another 20 percent. Nigeria and Ghana's production focuses more on local consumption whereas Kenya exports 35-40 percent of manufacturer's sales. The sector is also growing: The IFC (2008) estimated that 40 percent of the cumulative US\$1.6- US\$2.9B projected investment in health care in the region between 2007 and 2016 will be invested in generic final formulation manufacturing.

Despite these positive indicators, African countries, and those in this study, vary considerably in the strength and potential of their domestic manufacturing sectors. While Ghana has about 32 pharmaceutical manufacturers (of which 22 are active), Malawi has 4 (of which 3 are struggling) and Mali had 1, which has closed down.

Several factors explain the relative strength of the Ghanaian pharmaceutical manufacturing sector and its relative weakness in Malawi and Mali. These are:

**Government incentives:** Ghanaian government law forbids import of about 44 medicines, which are locally manufactured. Locally produced products include anti-infectives, paracetamol, aspirin, antacids, antibiotics tablets, syrups and creams, vitamins and anti-malarials. In addition, 66 of the 200 basic materials required for

production are exempt from VAT (12.5 percent) and the national insurance levy (2.5 percent). In addition, local manufacturers have benefited from the introduction of the national health insurance scheme (NHIS), which increases the volume of prescriptions filled. As a result, local manufacturers supply about 30 percent of local production while the remainder is imported. This policy also has a downside: almost all the local manufacturers produce the same products and have yet to begin to move up the product value chain.

**Limited private sector consumption:** In Malawi, the largest consumer/ purchaser of medicines is the CMS, which procures between 70-90 percent of all medicines consumed in the country.<sup>ii</sup> Government tenders are often awarded to foreign procurement agents that procure cheap generics from India. There are often emergency tenders (4 per year), which have been awarded to local wholesalers and on occasion to local manufacturers (PharmaNova - 1 last year, SADM - 1 last year). Local manufacturing is therefore focused on supplying the small private sector, which includes private clinics, wholesalers, pharmacies, and private hospitals.

### ***Challenges Procuring Manufacturing Materials on the Global Market***

APIs and other materials required for the manufacture of final pharmaceutical formulations are sourced mainly from India and China and to a lesser extent United States, Italy and other European countries.<sup>5</sup> Most African manufacturers purchase their supplies (APIs, excipients, glass bottles, blister packages, paper carton and manufacturing machinery) through a procurement agent rather than directly from API manufacturers. Procurement agents have access to a wide variety of prices from many suppliers in various countries. If quantities are too small, agents may procure supplies through a broker (e.g. Helm AG, Indukern Chemie AG or GMP Pharma Trading AG), for example in Hamburg, who purchases large quantities of supplies and warehouses them in Hamburg. Brokers are able to put together smaller amounts of materials into a container and ship it to African manufacturers.

As African manufacturers often have ***poor access to lines of credit***, they have to pay the value of their orders up-front. Because this is difficult for them, brokers often also extend payment terms (90-120 days). Sometimes API manufacturers want final formulators to pay upfront, which can be difficult if ***African manufacturers have cash flow problems*** and need to sell products to access funds. Brokers therefore also provide financing and arrange shipping. Brokers add these costs, plus the agent's margins to the final bill. Margins can be between 10-15 percent of FOB: financing 3 percent, large broker 7 percent, and smaller broker 1-3 percent. In cases, in which large brokers price themselves out of the market, smaller agents intervene and arrange the financing themselves.

African manufacturers can have ***difficulties forecasting demand, dealing with fluctuating costs and managing their manufacturing pipeline. Thus, the quantities of supplies of their finished products can fluctuate dramatically.*** Due to a lack of continuous orders, in-bound transport difficulties and problems accessing credit, manufacturers may be unable to stock raw materials. As a consequence, when they run out they are unable to manufacture. For pharmaceutical manufacturers in West Africa, where shipments from China take 4-6 weeks, an ideal product pipeline requires a

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<sup>5</sup> Although South Africa produces APIs (such as acetaminophen, acetylsalicylic acid and other fine chemicals), waxes, gums, and maize-based products (starch, glucose and dextrose), their output is small and their prices are too high to sell in other African countries.

shipment of APIs in stock, one in port, one at sea, one in port in China and one at the API manufacturer's factory.<sup>iii</sup> Throughout this process, prices of APIs may fluctuate. Local agents then pay clearing costs and clear materials at the closest ports and arrange transport to factories. Sometimes there are serious delays in port clearance and transport. Brokers courier documents before they arrive to local agents or manufacturers that obtain insurance on the goods, which costs about 1 percent of CFI. Delays in port and in transport set back production and eventual sales, returns on investment and therefore payment of suppliers.

As African final formulators source almost all of their materials abroad they face similar problems (See Harper and Gyansa-Lutterodt 2007 for a study of Ghanaian manufacturing). These include:

1. **Poor access to foreign exchange:** Purchases on foreign markets are transacted in US dollars. However, manufacturers often complain of difficulties accessing dollars or of poor exchange rates due to devaluations of currency. In Malawi, at certain times of the year (after harvests of commodity crops are sold and when donors release funds) the government and the national banks have better access to foreign currency. At other times, the supply is limited. Given Malawian manufacturers are paid in kwacha (MK-local currency) they are sometimes unable to pay bills from abroad.
2. **Rapidly fluctuating API prices and in supply of raw materials:** Reports (World Bank 2009) have highlighted the volatility of API prices and supplies. APIs prices may fluctuate on a monthly or even a daily basis. Interviews with procurement agents suggested that prices for raw materials always have an expiration date and are usually only good for 3 months. Prices and supplies may fluctuate due to shortages of materials (eg. Amoxicillin) or increases in prices of raw materials such as petroleum. Countries may also impose limits on exports, for example the Indian government occasionally prohibits exports of maize products. Recently, as sugar and maize have been used to make biofuels, there have been shortages of these products in global markets.
3. **Taxes and tariffs on medicines:** Imports of APIs may be subject to VAT and tariffs. In Malawi and Ghana, raw materials are subject to taxes (VAT: 6.5 percent in Malawi and 12.5 percent in Ghana; 2.5 percent health insurance levy), which they are theoretically able to claim back. However, local manufacturers claim that procedures are complicated, often there are delays and sometimes they do not get this money back. Local manufacturers often have to pay a percentage of CIF to (7.5 percent in Malawi) to clear goods locally.
4. **Unreliably and expensive cost of utilities:** The high cost and erratic supply of water and electricity make manufacturing difficult. However, sometimes equipment is old and inefficient, which increases costs dramatically.
5. **Poor transport infrastructure:** In a land-locked country, Malawian manufacturers face certain problems that Ghana and other countries with easy access to large ports do not. For raw materials to arrive in Ghana from India it takes 4 weeks and from China 6 weeks. In contrast, for goods to arrive in Malawi it requires about 8 weeks and potentially more if products are stuck in the port (as is reportedly often the case) in Beirira, Mozambique.<sup>iv</sup> If goods arrive in Durban, South Africa or in Mozambique they are then transported by truck overland. This process is sometimes delayed by the lack of trucks.
6. **Poor forecasting: Manufacturers complain that** because of stock-outs and/or emergency tenders in the public sector, African manufacturers often run out of

product and materials. They therefore are unable to hold large inventories and often manufacture in short time frames.

7. **Limited access to credit:** Banks do not understand the pharmaceutical business and are not interested in providing lines of credit or loans at reasonable interest rates.
8. **High cost of meeting quality standards:** Some observers have suggested that African formulators should be better trained to assess quality of APIs (World Bank 2009). However, even if formulators understand how to assess APIs and institute quality assurance systems, some suggest that higher costs undermine their competitiveness in the markets they serve.

#### **4.2 Impact of Multilateral Donations and Funding for Medicines**

Multilateral and bilateral donor policies and activities can also have an impact on African manufacturing and supply and distribution channels. In recent years, in response to health crises in developing countries, multilateral donors have focused considerable attention on supporting health systems and improving access to medicines. New mechanisms have been developed and significant funding has been allocated to finance the purchase of medicines, aid has been provided in the form of drug donations, policy advice has been directed to improve procurement practices and new quality standards have been devised and implemented. Despite their laudable objectives of improving access to quality medicines, some of these initiatives seem to have a potentially detrimental impact on local manufacturing and private sector supply and distribution channels. Some aspects of these policies are described in greater detail below.

##### ***1. Internationally Negotiated Price Reductions***

While drug or product price reductions negotiated by multilateral agencies provide improved financial access to quality medicines, these arrangements also can have a detrimental impact on local manufacturers' product portfolios. One new financing mechanism launched by the Global Fund, called the Affordable Medicines Facility (AMFm), will potentially have a very negative impact on Ghanaian manufacturers. This initiative is designed to expand access to the most effective current treatment for malaria, artemisinin-based combination therapies (ACTs). It aims to reduce the use of less-effective treatments to which malaria parasites are becoming increasingly resistant and preserve ACT's effectiveness.

The Global Fund will reduce the manufacturer sales price of ACTs to public, private and not-for-profit sector buyers. The Global Fund will do this by negotiating a lower price for ACTs and then paying a large proportion of this directly to manufacturers on behalf of buyers (a buyer "co-payment"). Buyers will pay about US\$0.05 for each course of ACTs. This is expected to result in a significant reduction in the price of ACTs from about US\$6-10 per treatment to about US\$0.20-0.50. Of the countries in this study, only Ghana will be impacted by the initial roll-out of this project in 2010.

For Ghanaian manufacturers, whose main products are anti-malarials, this will potentially have a negative impact on their businesses. Local manufacturers doubt that they will be able to compete with high-quality foreign ACTs if they are sold at a fraction of their usual price.<sup>v</sup> In order to participate in the scheme, local manufacturers would have to meet quality standards (as defined by the Global Fund) and lower their

production costs to levels of large international companies. Lower margins would have an impact on manufacturers and the rest of the distribution chain - wholesalers and retailers.

## **2. *International Quality Certification***

Donor support to CMS can involve financial support and the reform of national tender policies. This can introduce new tender requirements and quality standards that present challenges to local manufacturers and result in the award of many annual tenders to foreign agencies. In interviews with African manufacturers and procurement agents, several noted that international quality standards, such as WHO or UNICEF prequalification and World Bank procurement guidelines, have a detrimental effect on local industries. Manufacturers argue that once they have obtained local cGMP standards, additional requirements add extra costs and barriers to already low margin businesses. For final formulating manufacturers these hurdles include, the cost of bringing factories up to standard (this can cost hundreds of thousands of dollars), and the attempts to get WHO inspectors to visit African facilities (reportedly often ending in failure). Although, some African manufacturers that are financially able to invest in refurbishing their factories to standard, they say that they prefer not to because they are not confident of a return on their investments.

A World Bank report (2009) suggests that pharmaceutical manufacturers in Ghana only source about 30 percent of their supplies from pre-approved WHO suppliers. This was also confirmed by interviews with a procurement agent with a strong presence in English-speaking Africa. He suggested that prices for APIs from WHO approved sites are often too expensive for African manufacturers. For example, the top quality acetaminophen from the best American supplier with complete drug registration files costs about US\$6 per kilo whereas cheap sources in China cost US\$4 per kilo.<sup>vi</sup> In other words, a 50 percent increase in price. Furthermore, high quality suppliers may be unwilling to supply African manufacturers in the small quantities that they purchase.

## **3. *Donations and Procurement Guidelines***

In some cases, multilateral and bilateral donor support involves the donation of medicines either to the CMS or through parallel channels that by-pass the CMS. Parallel channels may be private sector wholesalers (eg. World Bank MAP Project Mali) or foreign logistics companies that supply, warehouse and distribute products to public or mission sector health institutions, eg. Unicef and SDV in Malawi.

In countries with local manufacturing capacity (such as Ghana and Malawi), local manufacturers complain that basic products that can be manufactured locally should be sourced within the country rather than manufactured and supplied by foreign producers. In Malawi, for example, the newly formed manufacturers association PhaMAM, has advocated that the government allocate a portion of CMS annual procurement to local manufacturers for basic products such as Paracetamol, Aspirin, quinine sulphate, amoxicillin and cotrimoxazole.<sup>vii</sup>

***Box 1: World Bank MAP Project: Mali***

One way in which donors can use local private sector supply and distribution chains more effectively is by contracting private sector suppliers to procure, warehouse and distribute products for the public good. In Mali, through the MAP project, the World Bank funding and private sector procurement and supply expertise are able to extend access to anti-retrovirals by making products available in private pharmacies. The World Bank provides funds to the national AIDS Council (Haut Conseil National de Lutte Contre le SIDA or HCNLS), which then opened a national competitive tender to select a private procurement agent and wholesaler. In 2008, Laborex was selected to procure stock in accordance with World Bank procurement guidelines, warehouse and distribute products to private sector pharmacies throughout Mali.

Laborex receives a 5.46 percent margin to cover their costs. For this project, Laborex has created a special section in their warehouse and they ensure that each delivery package is individually sealed and transported in appropriate conditions. After initial problems in adhering to World Bank procurement guidelines, Laborex has selected two Indian generics manufacturers (Matrix Laboratories Ltd. and Cipla) to supply 10 products.

Pharmacists have also been recruited to participate in the scheme. They are required to receive training in the pharmacology and dispensing of anti-retrovirals and to renovate their pharmacies to ensure a discrete place for patients to talk with the pharmacist. For their services, pharmacists are paid a small amount (1800 CFA or US\$4.16) for every patient they see.

Some problems have arisen during this project such as the desire for public sector doctors to maintain control over the dispensing of anti-retrovirals, difficulties adhering to World Bank procurement guidelines and following Malian import procedures and the desire for the PPM to continue to procure and distribute products to the private sector.

### **4.3 Flow of Goods into and within a Country**

This research suggests that English and French-speaking countries in sub-Saharan Africa historically have different models for pharmaceutical imports. Each approach has implications for the type, quality and source of products, the effectiveness of distribution networks and warehousing and transport capacity. Comparing Ghana and Malawi with Mali highlights the importance of consolidated importation and distribution channels with transparent prices, so that competition is on the basis of product quality, warehousing and product supply management, and delivery services.

In Mali, pharmaceuticals sold in the private sector are mainly brand-name medicines. They are imported from France by two wholesalers (Laborex and CoPharma) that belong to international large conglomerates that have about 80 percent of the Malian wholesale market share. The goods imported by both companies are similar and the prices are known as they are set in agreement between manufacturers, the government and wholesalers. The supply chain is therefore highly consolidated and competition is on the basis of wholesale customer services, i.e. finance services, availability of stock and delivery networks and schedules.

Because the wholesale market is consolidated, the supply chain management systems are far more sophisticated in Mali than in Ghana or Malawi. The two large wholesalers have formalised and well-established distribution networks. Laborex, for example, has 8 shuttles within Bamako. For delivery to the regions they contract out to specialised pharmaceutical distribution companies, individual deliverymen or send

products by plane (to Tombouctou), depending on the route. Both companies offer same day delivery in Bamako. In rural areas, companies have delivery circuits and deliver within 1 or 2 days depending on the location. In total, they service 400 pharmacies, located in all regions of the vast country.<sup>viii</sup>

In contrast, the importation and distribution channel in Ghana and Malawi is much more fragmented and chaotic. In these two countries, importers are often also wholesalers, pharmaceutical manufacturers, or pharmacists. In Ghana, there are about 60 importers, 12 manufacturer/wholesalers, 166 wholesalers, 328 wholesaler/retailers, 700 retail pharmacies and 11 159 chemical sellers. In Malawi there are about 22 importer/wholesalers, 4 importer/manufacturers and about 4 importer/pharmacies. In Ghana, there are many levels in the supply chain as importer/wholesalers often sell to one-stop-shop wholesalers, which sell to individual drug salesmen that sell to pharmacies or chemical sellers. Sometimes supply chains are vertically consolidated. Ernest Chemists Ltd., for example, is an importer, wholesaler and runs a retail pharmacy.

These systems are characterised by weak distribution networks and fragmented competition. Large wholesalers provide delivery services in large cities but customers in peri-urban or rural areas often have to pick up supplies at wholesalers' offices in the capital or in regional hubs. In Malawi, distribution networks are informal. As there are few pharmacies outside of Blantyre and Lilongwe there is limited demand for regular supply routes. Distribution may be through national bus routes or company vans on an ad hoc basis. In Ghana, this gap in the market has been filled by individual drug salesmen who buy enough products to fill their vans and travel around the countryside selling their products to rural pharmacists and chemical sellers, who would rather not spend time and money on travelling to wholesaler offices.

This practice is detrimental to the quality of products, the supply chain is unregulated and the distribution business partially operates outside the formal market. Individual salesmen have no training in pharmaceuticals, products could be purchased from anywhere and transport conditions are not optimal. Some consolidation of importers/wholesalers could improve efficiencies and quality of service in particular in the area of distribution.

#### **4.4 Retail and Health Care Services**

The retailing of pharmaceuticals in the private sector is offered by an array of actors including wholesalers, pharmacies, private doctors clinics, chemical sellers/ drug stores/ *depots de vente*, or grocery stores. Government policies determine which drugs can legally be sold at each type of outlet.

All countries in this study have attempted to extend access to medicines by allowing those with no or limited training in healthcare or pharmaceutical dispensing to sell certain limited selection of medicines (usually anti-malarials, analgesics and other OTCs), such outlets are referred to as chemical sellers (Ghana), drug stores (Malawi) and *depots de vente* (Mali). Often these outlets are small single owner-run businesses with high overheads. The owners of chemical shops are often farmers, teachers, nurses or pharmacists with pharmacies in urban areas, who use their stores to supplement their income. This proves problematic as it can diminish pharmacy services: knowledgeable staff are not present to advise patients. The increased use of quality generics through

the substitution of brand-name products for lower cost generics requires the presence of knowledgeable staff.

## 5.0 Strengths and Gaps in Performance

Drawing from Ballou-Aares et al. (2009), private sector supply chain performance can be assessed on the basis of how well they achieve positive health outcomes. Successful supply chains are those that ensure: 1) geographic access, 2) consistent availability of medicines, 3) affordable products, and 4) quality products. See Table 1.0 provides an overview of a comparison of the private sector supply chains in Ghana, Mali and Malawi.

**5.1 Geographic access to medicines in rural areas remains a challenge for all the countries in the study.** Geographic access is determined by the costs and modes of product transport and the location of product dispensing points (pharmacies, drug stores or private clinics). In the three countries in the study a range of service delivery points offer medicines to consumers in the private sector: pharmacies, chemical sellers/depots de vente/drug stores and private clinics. ***Despite various types of dispensing outlets, geographic access (especially in rural areas) to quality medicines is limited for several reasons.***

1. ***There is a lack of service delivery points offering medicines.*** In Mali, there is a waiting list of 580 pharmacists hoping to be granted a licence to practice in rural and urban areas.<sup>ix</sup> In Malawi, the absence of local pharmacy training programmes has resulted in a lack of trained practitioners available to open pharmacies.
2. ***Wholesalers do not provide last mile distribution.*** In Malawi and Ghana pharmacists and chemical sellers often must pick up products from wholesalers. Because this is time consuming and can be expensive, this creates a market for individual drug salesmen who sell from door-to-door a range of products to pharmacists and chemical sellers. However, in Mali wholesaler distribution networks supply products to rural areas on regular and dependable schedule.
3. ***Chemical sellers/ drug stores/ depots de vente and pharmacies often sell medicines that are not on the general sales list or that are not registered with the national drug authorities.***
4. ***Lack of trained staff present in drug dispensing outlet. Because chemical sellers/ drug stores/ depots de vente and pharmacies are often second jobs trained staff are often not present.*** This leads to an absence of medical/pharmacist supervision running shops; inappropriate dispensing of medicines; and potentially irrational use of drugs.
5. ***Poor business environment and high rates of failure.*** In all the countries examined, the business environment for pharmacists was difficult and many pharmacy councils spoke of high rates of undeclared pharmacy failures.<sup>x</sup> Retailers complained of high overheads, excessive taxes and poor financial services for pharmacists. Overall, there are few incentives to open pharmacies in underserved areas. In Mali, pharmacists are largely dependent on wholesalers to finance new businesses.
6. Most of the ***pharmacists and chemical sellers in this study have little knowledge or prior training of how to run a business.*** They use unsophisticated methods of pricing aiming to sell products for “a bit more” than the purchase price. All retailers relied on the sale of linked products, such as

traditional medicines, shampoos, diapers, vitamins, and even machetes to generate revenue.

Some local initiatives have been undertaken to improve access improve pharmacy services. To facilitate access to financing relevant to pharmacies, the association of women pharmacists in Mali is trying to create a cooperative bank, which would provide small loans to member pharmacists. In Malawi, however, the few existing pharmacists are experimenting with retail formulas to generate increased customer traffic. These include: opening pharmacies in grocery stores, pharmacy chains, and pooled procurement. Another potential solution is to improve the quality of services offered by drug shops. This can be accomplished through accreditation schemes, training, community mobilisation and improving regulations. One example is the Tanzanian Accredited Drug Dispensing Outlet project (See Box 2).

**Box 2: Accredited Drug Dispensing Outlets (ADDO)**

Tanzania suffers from many similar problems as those found in Mali, Ghana and Malawi. The accredited drug dispensing outlet (ADDO) project aims to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or periurban areas where there are few or no registered pharmacies. The project hopes to change the behaviour and expectations of individuals and groups who use, own, regulate, or work in retail drug shops. For shopowners and dispensing staff, this was achieved by combining training, incentives, consumer pressure, and regulatory coercion with efforts to affect client demand for and expectations of quality products and services.

The activities undertaken to support these aims are:

- Developing Tanzania Food and Drugs Authority (TFDA) accreditation based on Ministry of Health/TFDA-instituted standards and regulations
- Developing business skills and supervising ADDO owners
- Changing behavior of dispensing staff through training, education, and supervision
- Changing behavior of ADDO owners by providing commercial incentives (e.g. access to loans, authorization to sell some prescription medicines);
- Improving awareness of customers regarding quality and the importance of treatment compliance through marketing and public education;
- Improving legal access to a limited list of basic, high-quality prescription and nonprescription essential medicines;
- Focusing on regulation and inspection and improving local regulatory capacity.

This initiative has had measurable positive impact on access to and the availability of quality medicines, the quality of dispensing services, the affordability of medicines and the financial sustainability of local drug dispensing shops.

Source: Management Sciences for Health SEAM Program Tanzania: Accredited Drug Dispensing Outlets—*Duka la Dawa Muhimu*

## 5.2 Availability of Medicines

The availability of medicines is least problematic in Mali and Ghana and most difficult in Malawi. The factors that influence the availability of medicine include:

- ***The effectiveness of supply chains in the private sector is linked to their performance in the public and mission sector.*** In all the countries visited, the supply chains of the public, private and mission sectors were closely intertwined. This was particularly problematic in Malawi and less so in Ghana and Mali. In Malawi, regular CMS emergency tenders, problems with in-bound supply chains and limited access to foreign exchange resulted in fragile domestic supply chains. When there is demand (usually large volumes) in the public or mission sector, wholesalers divert resources away from the private sector resulting in stockouts in the private sector. Because of the presence of relatively few wholesalers, limited access to foreign currency and long delivery times of products, restocking the private sector can be difficult.
- ***Access to supplies of medicines:*** Malian wholesalers that are supplied by French intermediaries have well-established vertically integrated international networks and are able to access products for next day delivery if necessary. However, for low value products transit links to Mali often present problems. In Ghana, the multiplicity of wholesalers and importers and vertically integrated supply chains means that pharmacists are often able to source products from one of the many Ghanaian suppliers. In Malawi, wholesalers are less numerous, lacking vertically integrated global supply networks and challenged by fragile in-bound supply routes.
- ***Access to working capital.*** All actors in the supply chains assessed had problems in maintaining working capital due to customer debt. In Mali, large wholesalers seem to be able to absorb pharmacy debt and pharmacy financing. In Ghana and Malawi wholesalers and manufacturers have a poor working capital ratio whereby inventory or money that customers owe often prevent the company from paying of their obligations or purchasing more stock.
- ***Financing gaps, delays and leakages:*** Related to the previous point, large wholesalers are able to absorb the financial cost of frequent delays in product delivery and loss of products.
- ***Warehousing and transport capacity:*** Storage and logistics are expensive. Smaller scale wholesalers have less scope to manage these costs. The fragmented character of the Ghanaian and Malawian market makes it more difficult to provide sufficient storage of supplies and adequate distribution networks.

## 5.3 Quality and Affordability of Medicines

### ***Storage and Delivery Practices***

Good storage practice (GSP) and Good distribution practice (GDP) are not a priority for actors in the supply chain in any of the countries visited. Wholesale distribution practices in Malawi and Ghana often require retailers to pick up supplies themselves. In Ghana, the complex supply chain environment and the desire to maintain control over distribution has resulted in vertical integration of supply chains. In all of the countries in this study, efforts made to track and trace products are limited. Wholesalers undertake measures to ensure that stock is not stolen in transit by keeping records of quantities of goods shipped. However, batch numbers are not registered and tracking devices are not used.

Some ways to improve storage and distribution practices would be to support the creation of specialist pharmaceutical delivery companies or to make use of shared private sector product delivery platforms eg. Curatio in Ghana and VillageReach in Mozambique, VillageReach. The Curatio business model aims to reduce the logistics cost of delivering to rural pharmacies in Ghana. The business plans to leverage the fine mesh distribution network of Unilever to reduce costs, ensure quality and extend deliveries to franchised dispensing points throughout the country. The initiative plans to carry out primary distribution from a warehouse near Accra using private distributors who currently distribute consumer products (i.e. Unilever Ghana). The secondary distribution will use the distribution capabilities of these private distributors utilizing their fine mesh network to reduce secondary distribution costs. The strategy will also use margin mix management within the portfolio of drugs (through private label, generic and branded products) is used to ensure recovery of fixed and variable costs.

At the retail level, often the quality of the conditions in which products are stored is poor. In Ghana and Mali, air-conditioning is often reserved to the pharmacy owner's office but not present in storage areas, resulting in potential product deterioration (See Appendix B for a list of products that have stability problems under tropical conditions).<sup>xi</sup>

### ***Generics vs. Brand Name Products***

The quality and affordability of medicines varies in each country. In Malawi, 90 percent of medicines are generics, mostly low cost from India. Private sector retailing is a high volume, very low margin business. In Ghana, low prices are very important to the consumer but there is a broad array of choice in terms of quality and price. In Mali, because most of the products in the private sector are sourced from European brand-name manufacturers, most drugs are brand-name. However, lower cost generics are gaining some market share and currently make up about 30 percent of the market.<sup>xii</sup> Overall in all of the countries studied, the cost of generics is considerably lower than brand name products. However in Ghana, cases where there is a low availability of generics, these products are equally or more expensive than brand name alternatives (Andrews, Yamyollia et al. 2004).<sup>xiii</sup>

### ***Prescribing Habits and Consumer Choice***

In part, the quality and affordability of medicines is determined by government policy, doctors' prescribing habits and patient preferences. In all countries visited, originator brands continue to be considered better quality because trust in the regulatory agency is lacking. In a village in Mali, the *depots de vente*, situated close to the local public health centres had a successful business offering branded products because patients had little faith in the generics offered by the public health services. In the private sector, irrational prescribing habits are a source of expensive medicines: about 80 percent of prescriptions are for brand name products and about 67 percent are for medicines not found on the national essential medicines list (Maiga, Diawara et al. 2007). A similar situation occurs in Ghana where about 56 percent of prescriptions use INN names (Seiter and Gyansa-Lutterodt 2008). Due to a lack of financial incentives for pharmacists, a lack of faith in the quality of generics and doctor prescribing habits, substitution rates are often low.

### ***Transparency and Market Choice***

Transparency of medicine prices and quality are important factors in stimulating competition. At the retail level, prices are displayed in Malawi but not in Mali. However, further up the supply chain the situation is reversed: Malian wholesale prices are known but wholesaler and government tender results are not. In Mali, patients lack information about their treatment options, product prices and availability in the private sector.<sup>xiv</sup> Therefore, all countries in this study could benefit from increased transparency of prices, quality and availability of medicines. Such information stimulates public information and debate, pressure on supply chain actors to stock products and increased market competition. Initiatives such as MeTA can serve as a catalyst for this process See Box 3.

#### **Box 3: Medicines Transparency Alliance (MeTA)**

MeTA is an initiative that aims to increase transparency about the quality, availability, pricing and use of medicine in order to improve accountability. When such information is available in the public domain it provides the public with an opportunity to understand the information and to act upon it. This information allows stakeholders to build a rational approach to regulation, procurement, supply and data gathering related to medicines and leads to public debate about medicines, to place increased pressure to improve public and corporate policy.

MeTA works toward the public disclosure of information concerning:

- Quality and registration of medicines;
- Availability of medicines;
- Medicine pricing;
- Policies on the ethical pricing of medicines;
- Supply chain operations;
- Access to medicines;
- Prescribing and use of medicines.

In order to achieve this, the MeTA model proposes the creation of a forum in which stakeholders from national governments, private sector, health service, vulnerable communities and civil society. Civil society members (patient groups, consumer societies, professional associations) are able to build capacity to monitor and increase accountability for the prices, availability, selection and quality of medicines in the public and private sectors.

The table below provides a summary of the strengths and challenges of private sector supply chains described above.

**Table 1: Challenges of the Private Sector Pharmaceutical Supply Chain**

	<b>Geographic Access</b>	<b>Availability</b>	<b>Affordability</b>	<b>Quality</b>
<b>Ghana</b>	Limited in Northern and rural areas. Poor distribution networks outside of urban centres. Chemical sellers limited stocks.	Good. Many wholesalers. Stockouts in public sector have a limited impact on private sector.	Wide range of products and prices. Public health insurance. Taxes?	Limited inspections and government drug testing facilities. No pre-qualified manufacturers.
<b>Mali</b>	Fair. Wholesalers have a good delivery network. Limited number of pharmacists in rural areas.	Good. Within the distribution network wholesalers are able to deliver products to rural areas within 2 days. Able to order high value products from international suppliers for next day deliver.	Expensive. Mainly brand name products. Generics segment growing. Limited pharmacist substitution of brand-name for generic products.	Brand name products good quality but generics more dubious. Poor inspections capacity and government testing facilities. Good wholesaler but poor pharmacy storage facilities.
<b>Malawi</b>	Few pharmacies and those that exist are in 2 urban centres. Drug stores and private clinics serve rural areas. Wholesaler delivery is generally limited to urban areas although special arrangements can be made.	Stockouts in the public sector exhausts private sector supplies. Malawi's geographic location, delays in port and poor transport make inbound supply links tenuous.	Mainly generics. Private sector pharmacies are a low volume, high margin business. Private clinics are reportedly cheaper.	Can be poor. Poor government inspections and testing facilities. No pre-qualified manufacturers. Privilege price over quality.
<p><b>Common Challenges</b></p> <ul style="list-style-type: none"> <li>• Lack of pharmaceutical and supply chain market data</li> <li>• Lack of knowledge about and limited demand for quality medicines</li> <li>• Poor government quality control testing</li> <li>• Fragmented supply chains</li> <li>• Limited access to capital and financial service tailored to pharma sector</li> <li>• Limited competition on product price and transparency in product pricing</li> <li>• Small markets and limited consumer purchasing power</li> <li>• Multilateral financing, donations and procurement policies can have a harmful impact on the local private sector</li> </ul>				

## 6.0 Options for Reinforcing Private Sector Pharmaceutical Supply and Distribution Chains in Ghana, Mali and Malawi

This report aims to provide a more detailed understanding of the private sector pharmaceutical supply and distribution chain in three diverse African countries. It highlights some of the strengths and challenges faced by actors in each country.

Overall, the recommendations aim at:

- Stimulating consumer/patient knowledge of and demand for quality products;
- Improving the regulatory environment for new businesses and new business models;
- Supporting access to financial services appropriate for the pharmaceutical sector

Specifically, national and international actors could implement the following actions:

### Businesses and Investors

- Invest in *market research and data gathering organisations* and mechanisms;
- Strengthen *pharmaceutical distribution networks* by leveraging the private supply and distribution chains of other sectors (eg. Curatio in Ghana or VillageReach in Mozambique) or by creating shared specialised pharmaceutical distribution companies.
- Invest in Accredited Drug Dispensing Outlets (ADDO) based on the Tanzanian model to ensure access to affordable, quality medicines and pharmacy services.

### National Governments

#### *To Improve Access to Quality Medicines:*

- *Strengthen Pharmacy and Drug Regulatory Authorities.* In all of the focus-countries, the quality of medicines available in the private market was hampered by poor government pharmacy inspection and quality testing processes. Strengthening the financial and technical means of the pharmacy and drug regulatory authorities can improve the quality of medicines in circulation by ensuring that all appropriate inspections and testing occurs at all levels of the supply chain (customs, drug registration, wholesale, distribution and retail).
- Support public or private health insurance models with drug coverage to reduce out-of-pocket spending and increase local pharmaceutical consumption.

#### *To Support Manufacturing:*

- *Make better use of existing local private sector supply and distribution channels.* Tender and donations programmes could make more use of local private sector supply and distribution networks for the procurement or distribution of products.
- *Ensure that the public tender system is designed to facilitate and incentivise the participation of local supply chain actors* (manufacturers, wholesalers and distributors).
- *Promote the regional harmonisation of drug registration requirements and processes and quality testing facilities.* This would facilitate and extend the entrance of good quality products into new markets and avoid duplicating registration in several small markets. The creation of regional quality testing

facilities may reduce current problems with identifying and retaining trained staff and funding national quality labs.

***To Stimulate Consumer Demand for Quality Medicines***

- *Educate consumers about the importance of quality in medicines to stimulate consumer demand for quality medicines.* Encourage civil society groups to engage in discussion and raise awareness about the dangers of poor quality medicines and their health care options. This will stimulate consumer demand for quality medicines and good pharmacy services by making consumers aware of their choices.
- *Increase transparency of prices, quality and availability of medicines.* The Medicines Transparency Alliance (MeTA) initiative provides a useful forum to bring stakeholders (national governments, private sector, health service, vulnerable communities and civil society) together and to promote open discussion, to disclose information about issues such as the quality and registration of medicines, the price, availability and access to medicines, prescribing habits, and supply chain operations. Civil society members (patient groups, consumer societies, professional associations) are then able to build capacity to monitor and increase accountability for the prices, availability, selection and quality of medicines in the public and private sectors.

***To Improve the Business Environment:***

- *Encourage local financial institutions to lend to health care businesses.* Educate banks about pharmaceutical business models and constraints.
- *Promote alternative finance services such as cooperative pharmacy banks:* Actors in the pharmaceutical supply and distribution chain complained that there were insufficient financial services for them as banks did not understand the pharmaceutical business. These services could provide lines of credit, small loans.
- *Offer business training for pharmacists and chemical/drug store/ depot de vente either as a part of their academic training or their accreditation/licensing.* In many academic pharmacy courses little time is spent on learning how to run a pharmacy business, which is how most earn a living.

***To Improve the Regulatory Framework:***

- *Financial and political support for post-market surveillance and pharmacy inspections* as a way to monitor the quality of products on the market.
- *Encourage the consolidation of fragmented wholesale market* by limiting the number of licences to wholesalers and by reducing prices of medicines by decreasing or eliminating taxes and tariffs on medicines and raw materials. Lower prices may drive consolidation by forcing companies to look for increased economies of scale.
- *Improve regulatory frameworks to facilitate the introduction of alternative pharmaceutical business models and retail platforms.* These could include buyers' cooperatives, franchises, pharmacy chains, or locations within other businesses eg. grocery stores.
- *Review incentive structure to encourage pharmacists to dispense generics.* For examples by allowing higher margins on INN generics than brand-name products or ensuring that generic products are included on reimbursement lists.

**International Agencies**

- *Assess the impact of international financing, donations and procurement policies on local distributors and retailers.* Donations bypass local supply and distribution pathways. Subsidized drugs may undermine the profitability of local distribution and therefore damage the distribution system in the longer term.
- *Channel donor funds through existing local private sector supply and distribution channels.* Tender and donations programmes could make use of local private sector supply and distribution networks for the manufacture, procurement and distribution of products.

## Appendix A

**Table 1: Health and Demographic Indicators for Selected Countries**

<b>Indicators</b>	<b>Ghana</b>	<b>Malawi</b>	<b>Mali</b>
Population, total (millions)*	23.4	14.28	12.71
Population Growth Rate (annual %)*	2.1	2.5	3.0
Surface Area, sq, km (thousands)*	238.5	118.5	1240.2
Urban population (as % of total), 2006†	49	18	31
Population living below the national poverty line (%)	28.5	65.3	63.8
GNI per capita Atlas method, current US\$ (billions)*	670	290	580
Life expectancy at birth†	57	48	54
Infant mortality rate (per 1000 live births), 2006†	76	76	119
Maternal Mortality rate (per 100 000 births), 2005†	560	1100	970
Prevalence of HIV (% of total population 15-49)†*	1.9	11.9	1.5
Years lost to communicable diseases (%), 2002†	16	6	8
Percentage of Population living on < \$US 1.25 per day	30	73.9	51.4
Percentage of population living on < \$US 2 per day	53.6	90.4	63.8

Source: \*World Development Indicators, \*\*UNDP Development Indicators, †WHO Statistical Information.

**Table 2: Drugs Found to Have Stability Problems under Tropical Conditions**

<b>Oral Solids (tablets)</b>	<b>Oral liquids (syrups)</b>
Acetylsalicylic acid	Paracetamol
Amoxicillin	
Ampicillin	<b>Injections/ injectables</b>
Penicillin V	Ergometrine
Retinol	Methylethergometrine

Source: (Management Sciences for Health 1997: 274).

**Table 3: Comparison of Private Sector Supply and Distribution Channels in Ghana, Mali and Malawi**

<b>Issue</b>	<b>Ghana</b>	<b>Mali</b>	<b>Malawi</b>
<b>Impact of multilateral pharmaceutical and donations policies</b>			
<b>Price reductions</b>	AMFm reduces prices of anti-malarials which is the largest seller for manufacturers and wholesalers and retailers	N/A	N/A
<b>Donations</b>			Donations of products that can be manufactured locally. Bypass local supply and distribution networks.
<b>Prequalification manufacturing and API standards</b>	Expensive and undesirable to implement because not cost effective.	N/A	Expensive and undesirable to implement because not cost effective.
<b>Business Environment</b>			
Financial Services	Limited access to credit, financial services for pharma sector	Reliance on large wholesalers for financing. Limited access to credit, financial services for pharma sector	Limited access to credit, financial services for pharma sector
Market information	Limited	Limited	Limited
Trust	Poor. Lack of trust results in vertically integrated supply chains and fragmentation of market.	Ok. Some localised Malian business collaborations, eg. Between pharmacies for discounts, wholesaler linkages.	Poor. Manufacturer suspicion of governments, donor community and wholesalers. Accusations of corruption. But collaboration between manufacturers.
Debt	NHIS slow to pay back. Pharmacists in debt to wholesalers.	Pharmacists in debt to wholesalers.	Pharmacists in debt to wholesalers.
<b>Local Manufacturing</b>			
Local Manufacturing	Yes, several small firms. Government policies to support.	No. Reliance on imports.	Yes but struggling due to small private sector, limited CMS tenders and no government support
<b>Products into Country</b>			

Wholesaling	Fragmented. Many small players.	Consolidated. Dominated by 2 large firms competing on delivery services and financing	Fragmented. Many small players.
Equality of warehousing	Ok. In some cases lack of storage space and poor storage conditions.	Good amongst large wholesalers.	Poor. Limited of storage space. Poor storage conditions.
Supply Management	Ok.	Poor. Poor transport infrastructure results in delays.	Poor. Poor transport infrastructure results in delays. Difficulties forecasting demand.
Government regulation of prices	No	Yes	No
Quality testing	Yes to grant product market approval. Limited post market surveillance.	Yes to grant market approval. Limited post market surveillance.	Yes to grant market approval. Limited number of tests able to be done. Limited post market surveillance.
<b>Products within Country</b>			
Distribution	Limited, provides market for travelling traders.	Overall Good.	Limited. Only in 2-3 main cities.
Cost of medicines	Mainly generics. Can have high margins at retail level. Numerous middlemen increase consumer prices.	Limited generics. Mainly brandname and expensive.	Relatively inexpensive. 90% low cost generics.
Availability	Public sector stockouts. Fair poor distribution in rural areas limits access to medicines. Rural chemical sellers struggling financially.	Public sector stock outs. Private sector good but impacted by poor transport infrastructure and stockouts in public sector.	Public sector stock outs. Private sector fair but impacted by poor transport infrastructure and stockouts in public sector.
<b>Retail</b>			
Retail outlets	Pharmacists, chemical sellers. Limited in rural areas.	Pharmacists, depot de vente mainly in urban areas. Limited in rural areas.	Few pharmacists or drug stores. Mainly private clinic dispensing.
Problems	High margins. Indebtedness to wholesalers. Limited presence of qualified pharmacist – Limits pharmacy services.	Financial difficulties. Supported by wholesalers. Indebtness to wholesalers.	Little competition. High margins. Limited of customer volumes.

## **Appendix B: Ghana Case Study**

### **Analysis of the Private Sector Supply and Distribution Chains for Medicines in Ghana**

#### **1.0 Overview of Ghana**

Located in West Africa, Ghana is bordered by the Ivory Coast, Togo, and Burkina Faso. The population of 23.35 million and is growing at an annual rate of 2.1 percent. The country is divided into 10 regions and 166 districts. The population density is highest in the southern and central zones and is lowest in the northern zones.

Ghana has a per capita gross national income of US\$590 in 2007 (World Bank 2007). As of 2005, poverty stood at 28.5 percent, down from 52 percent in 1992. However, this poverty reduction has not been equitably distributed across the county, and in both the Upper East and Upper West regions over 70 percent of the population remain impoverished (World Bank 2008). Ghana's economy is predominantly agricultural (small scale peasant farming) and absorbs 60 percent of the adult labour force, followed by a small capital intensive mining sector and a growing informal sector (small traders and artisans, technicians and businessmen) (WHO n.d.).

Ghanaians have a life expectancy of 57 years, an infant mortality rate of 68 per 1 000 live births and a maternal mortality rate of 540 per 100 000 live births (WHO 2006). Ghana ranks 152th (of 182) in the 2009 UNDP Human Development Index. Ghana is on track to meet the Millennium Development Goal of halving poverty by 2015.

Malaria accounts for 40 percent of outpatient attendances with high mortality rate (13 percent). Upper respiratory tract infections, tuberculosis, diarrhoea (including cholera), yellow fever and meningococcal meningitis are common. Tuberculosis is a major public health problem; HIV prevalence is under the general epidemic threshold of 5 percent and has been fluctuating between 2.2 percent and 3.6 percent since 2001. Hypertension, diabetes, chronic renal diseases, cancer and mental diseases are increasing due to economic development and life style changes, including a rise in alcohol and tobacco use, and substance abuse (WHO n.d.).

#### **2.0 Health Services**

Health services are provided by the public sector, the not-for profit mission sector (Churches Health Association of Ghana (CHAG) and the Muslim Ahmadiyya Movement) and the private sector. The public sector provides about 40 percent of all health services in Ghana and the mission sector about 30 percent (Ballou-Aares, Freitas et al. 2009).

##### ***Medicine Procurement***

In Ghana, in 2008, the MOH spent US\$ 31 million (including pooled procurement) on medicines and non-drug items or about 10 percent of total retail sales (estimated at US\$ 300 million) (Seiter and Gyansa-Lutterodt 2008). Public sector procurement and distribution for the public sector are provided by the CMS. However, in the case of stockouts or limited access to medicines at regional medical stores and service delivery points, they are permitted to purchase products from the private sector (See Public Procurement Act 663). Because the CMS operates at 50 percent of their

capacity, buying products from the private sector can occur up to 80 percent of the time (Seiter and Gyansa-Lutterodt 2008).

The mission sector also has their own medicine supply and distribution network. The CHAG runs a central warehouse in Accra, the Catholic Distribution Centre (CDC). The mission sector is supplied mainly by IDA (60-70 percent of products procured annually) and from local wholesalers (30 percent of products procured annually).<sup>xv</sup>

## 2.1 Health Insurance

Ghana introduced national public health insurance, the National Health Insurance Scheme (NHIS) in 2005. The NHIS covers health care services and medicines. The goal is to provide universal coverage to affordable high quality healthcare. Subsidies are available to certain economically disadvantaged groups. Wealthy individuals also have access to a form of private or employer-based insurance that includes coverage for medicines. Despite the introduction of the NHIS, about half the population still is not covered by the NHIS and therefore pays out-of-pocket for medicines. The programme has a limited impact on the poor as only 2.3 percent of those covered are classified as indigent and only 40 percent of those in the lowest quintile were registered. In contrast, 70 percent of those in the highest quintile were enrolled (Ballou-Aares, Freitas et al. 2009). In some cases, NHIS card holders still have to pay for medicines. Approximately 50 percent of the funds paid out by the NHIS are for pharmaceutical products (Seiter and Gyansa-Lutterodt 2008).

Some question the long-term viability of the NHIS. Many pharmacists, chemical sellers, and wholesalers complained that the NHIS are often more than 2 months late paying reimbursements and as a result retailers are unable to pay for their stock on time. Retailers are threatening to stop accepting NHIS patients. Wholesalers are threatening to stop providing the sale on credit.

## 3.0 Overview of National Pharmaceutical Market

Data on the Ghanaian pharmaceutical sector and market are quite weak. No formal market research has been undertaken. Some local actors conduct their own informal market studies (by visiting competitor establishments, tracking types of prescriptions and evaluating where products are sold) but they are often unwilling to share information about their own businesses. The data provided here are estimates from various market participants.

The total market value is estimated at US\$300 million (Seiter and Gyansa-Lutterodt 2008). This equals an annual per-capita pharmaceutical consumption of about US\$12. OTC sales are about 30 percent of total retail sales in value or about US\$ 90 million.

**Table B1: Estimated Market Data on Ghanaian Pharmaceutical Industry, 2008**

<b>Data</b>	<b>Figures (in US\$ millions)</b>
Total market at retail value	300
Prescription drugs total (70% of total)	210
Growth rate (%)	6-8%
Pharmaceutical consumption per capita	US\$ 12
Retail sales of domestic manufacturers (30% of total)	90

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sales)

Market share of generic products (value)<sup>xvi</sup> 80%

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Source: (Seiter and Gyansa-Lutterodt 2008). No solid market research. Data gathered from market participants.

### 3.1 Regulation of the National Pharmaceutical Market

The Food and Drugs Board (FDB) control the manufacture, import, export, distribution, use and promotion of pharmaceuticals in Ghana. The FDB has a staff of 235 and carries out inspections of: pre-licensing of manufacturers; annual premise inspections; post-marketing surveillance; and advertising monitoring. The FDB maintains a quality-testing laboratory, which employs about 35 technical people. The lab reportedly operates according to Good Laboratory Practice (GLP) standards. The lab tests random batches of high risk consignments of imported medicines, samples taken in GMP inspections, post-market surveillance testing and samples provided for the market registration process. Testing is also conducted on. The lab suffers from a shortage of space (they are currently building new facilities), qualified staff and funds for operations, equipment and staff.

An important aspect of their work is to monitor the quality of pharmaceutical products entering and circulating within the country. However, sometimes importers are able to “influence” customs officials so that goods are cleared before they can be tested. **Substandard and counterfeit products also enter the market through poorly controlled borders and entry points where the FDB has no presence and where customs officials are more interested in collecting revenue** than about the quality of products. The FDB claims that Ghana has less of a problem with counterfeits than other countries in the sub-region.

The **agency conducts few post-market surveillance studies** due to limited budgets. However, one study was recently conducted on anti-malarials (2009). They found 15 percent of all anti-malarials were substandard but did not find any counterfeits. Several products did not have valid drug registration. However, in July 2009 fake Coartem tablets, with no active ingredients, were discovered in Kumasi.<sup>6</sup> The FDB reports highlight **poor transport and inappropriate warehousing and retail storage facilities as major reasons for substandard medicines**. There are also reports of a decline in quality between product registration tests and general product retail sales. These are difficult to identify without continual inspection and quality testing.

The FDB does not have a system for the regulation of pharmaceutical distribution and there is an absence of national legislation governing this aspect of the supply chain. The **traceability of drugs is very poor**. Some drugs are shipped without a waybill and go astray. Throughout the distribution chain, wholesalers and distributors maintain records of quantities of medicines but not their batch numbers. Product recall announcements are made on TV and radio but because batch numbers are not kept retailers do not know if they have sold the suspect product batches.

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<sup>6</sup> Hope, Kingsley E. 2009. “Beware Of Fake Co-Artem Malaria Tabs On The Market” Ghanaian Times, July 10, 2009 <http://www.newtimesonline.com/story/254> Accessed 6 August 2009.

### **Limited Inspection Capacity**

The national Pharmacy Council is responsible for licensing and inspecting licensed pharmacies and chemical sellers. However, the Pharmacy Council only has about 32 inspectors nationwide with 12 in head office. There are 7 offices throughout the country with 2-3 inspectors and 1 vehicle per region. As a result coverage is minimal and inspectors cannot inspect all of the facilities in 1 year. **The Pharmacy Council inspects about 190 of a total of 1000 establishments per year.**<sup>xvii</sup>

## **4.0 Private Sector Pharmaceutical Market**

### **4.1 Manufacturing**

Ghana has a small pharmaceutical manufacturing sector with about 38 companies. 11 are active manufacturers, of which 6 are significant national producers. The most prominent players are Danadams, Ernest Chemists, LaGray and Kinapharma. The sector employs 5000 people and supplies about 30 percent of Ghana's total pharmaceutical consumption. The private sector suppliers are growing at an estimated 6-8 percent in line with population growth. They are expanding their market by supplying a growing private sector and providing products to public sector health facilities on a more regular basis.

**Most manufacturers focus on producing basic OTCs although a few companies manufacture specialised products.** Kama Group manufactures syrups, Danadams has the ability to produce ARVs, several companies produce anti-malarials. However, none have diversified product lines that include TB drugs, neglected tropical diseases or cardiovascular illnesses. **Government policy encourages local manufacturing by protecting** forty-four drugs from imports. Also, 66 of the 200 basic materials required for production are exempt from value-added tax (12.5 percent) and the NHIS levy (2.5 percent). With all local manufactures producing the same basic OTC products, this segment is highly competitive. One study from (2005) suggests that manufacturers' profit margins range from 10-40 percent. Insiders suggested that this number was closer to 50 percent.

**Although there is a relatively active local manufacturing sector, imported products from China and India are more price competitive. Local manufacturers have difficulty moving up the product value chain and obtaining GMP and prequalification standards.** This is for several reasons (See also Harper and Gyansa-Lutterodt 2007):

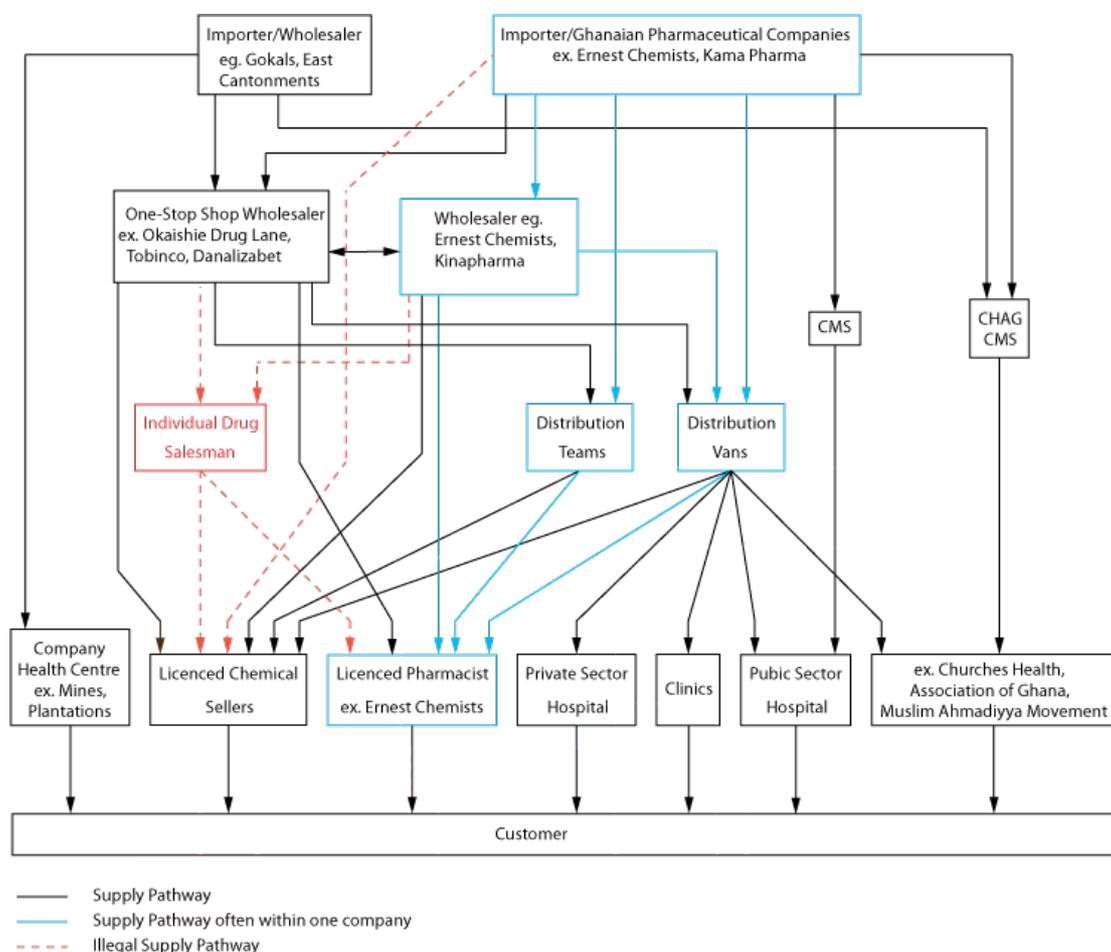
- VAT on many manufacturing materials and on those products that are exempt, time consuming bureaucratic procedures to claim back taxes;
- High cost of borrowing (interest rates up to 30 percent) and limited access funds to invest in industrial upgrading;
- High utility costs (electricity, water and transport)
- Inconsistent supply of utilities (water and electricity failures);
- Difficulties sourcing APIs (fluctuating prices,
- Problems in complying and documenting adherence to GMP standards and protocols, providing documentation of validation and calibration of machinery and documenting the traceability of raw materials and to point of sale.
- Limited market research and unsophisticated business strategies (usually based on what they have always done and what seems to work in the market rather than patterns of disease or market research data.<sup>xviii</sup>
- Limited availability of qualified staff;

- Limited transport infrastructure and administrative barriers to access regional markets;
- Anti-malarial drug portfolio threatened by AMFm (see section 4.2).

#### 4.2 Flow of Goods into and within Ghana

The supply and distribution network in Ghana is chaotic and fragmented (See Figure B1). In addition to manufacturer/ wholesalers there are about 60 importers/wholesalers that import and sell to one-stop-shop wholesalers and about 166 national wholesalers.<sup>7</sup> Often multinational companies use several agents, which have non-exclusive distribution rights. For example, Eli Lilly uses both Kama Pharma and Reiss and Co. to distribute their products. Agents may also be manufacturers or wholesalers. Some wholesalers may also be importers, manufacturers, distributors and retail pharmacies. Often businesses begin as retail outlets and then apply for wholesale licences and eventually act as an importer and then move into manufacturing.

**Figure B1: Flows of Pharmaceutical Products within Ghana**



<sup>7</sup> Wholesalers must apply to the Pharmacy Council to obtain a wholesaler licence. To obtain a licence companies must register with the registrar general, have a pharmacist to manage the distribution facilities and have a total floor space of more than 36 square meters. Licences must be renewed every January.

The high number of small pharmaceutical trading businesses with a limited market share (see Table B2) and intermediaries in the supply and distribution chain, limits transparency and makes it difficult to ensure product integrity. It also suggests low efficiencies in private sector distribution. In 2008, Gokals-Laborex (a Ghanaian wholesaler of Indian descent in a joint venture with Laborex (part of the French-group Eurapharma) purchased several local competitors. This caused uproar as local wholesalers complained that Gokals unfairly acquired exclusive licences with European companies from local manufacturers who had maintained these relationships for years. Local wholesalers complain that Gokals-Laborex has an unfair advantage because they have access to a continuous supply of quality European products. Using companies, such as TNT or DHL, they are able to receive products within 24 hours whereas other wholesalers/importers receive products transported by sea and must establish lines of credit with local banks, which takes time. The Ghanaian wholesalers' complaints reflect the acknowledgement of their weak competitive position and may encourage them to take measures to become more efficient.

**Table B2: Estimated Annual Sales and Market Share for Major Wholesalers**

<b>Wholesaler</b>	<b>Estimated Sales (US\$ million)</b>	<b>Market Share (%)</b>
Ernest Chemists	13	11
Kama	8	7
Unichem	5	4
Gokals	5	4
Osuns	4	3
Western Pharmacy	2	2
Kinapharma	3	3
Geo Pharmacy	2	2
Baseline	1	1
Other*	74	<1
Total Market	117	100

**Source:** (Management Sciences for Health 2003: 13). \*Each of the other wholesalers have less than 1% market share.

#### *Price Structure*

Some wholesalers position themselves as a one-stop shop (e.g. Class Pharma, Tobinco) and buy from several other importer/wholesalers such as Kinapharma, Ernest Chemists, Litap, or MNG. One-stop shop wholesalers also buy products directly from importer/agents (e.g. Gokals, Osuns) and local manufacturers. Their main criteria for purchasing products from suppliers are price; they do not have long-term contracts with suppliers. Importer/wholesalers sell to one-stop-shop wholesalers at 5-10 percent discount on the importer/wholesaler price. One-stop-shop wholesalers then add 5-10 percent to their purchase price for sales to retailers. Importer/wholesaler and one-stop-shop wholesaler prices may be the same or in some cases one-stop-shop prices may be more expensive.

**Table B3: Summary of Private Sector Supply Chain Margins in Ghana**

<b>Actor</b>	<b>Margin</b>
Manufacturer	10-50%
Wholesaler	10-30%
One-stop-shop Wholesaler	5-10%*
Retailer	30-200%

\* Wholesaler sells to One-stop-shop wholesaler at a discount of 5-10%. Often the One-stop-shop wholesaler then adds 5-10% to the importer/wholesalers price for sales to retailers.

When there is a large amount of product in stock that needs to be liquidated, wholesalers offer deals to retail customers such as buy 10 of product X and receive 1 of Y free. When products near their expiry date wholesalers push sales by offering a 50 percent discount.<sup>xxix</sup> Wholesalers often offer discounts to customers that buy in bulk. For example, if customer buys 5-10 cartons they receive a 10-15 percent discount.<sup>xxx</sup>

Wholesalers and manufacturers promote their products by advertising on television and radio but since patients are interested in inexpensive products, most marketing efforts are targeted at doctors. Many wholesalers and manufacturers have representatives that promote their business to hospitals, pharmacists and chemical sellers. Retailers may receive promotional material (eg. Pens, brochures, radios, TVs and refrigerators) if they buy by large quantities (i.e. orders of more than 1000 – US\$ 700).<sup>xxxi</sup> Wholesalers and manufacturers also host workshops with for doctors, pharmacists and chemical sellers. **Kickbacks are such a common practice** that when various wholesalers were asked how they could improve their business, they suggested that they should be more proactive in “public relations”. This means providing doctors with more incentives (payments) to prescribe their products.<sup>xxxii</sup> Hospitals inflate prices in the tendering process. The difference between the wholesaler’s invoice and the tender purchase price goes to doctors as a payment for prescribing the wholesaler’s products. A similar process reportedly occurs with hospital procurement agents.

#### *Distribution*

Importer/wholesalers and manufacturer/wholesalers have integrated distribution businesses with fixed distribution points in several regions. One-stop-shop wholesalers buy from several importer/wholesalers and manufacturer/wholesalers. Small specialised wholesalers such as those located in Okaishe area of Accra do not offer delivery services and retailers pick up products themselves. Large wholesalers of all types deliver products via distribution vans, teams or customers pick up stock from the wholesaler themselves. Vans only distribute products to customers. ‘Teams’ refers to vans with a driver and wholesaler representative that sell various brands carried by the wholesaler on credit or a cash and carry basis mainly in rural areas. The employees earn a salary and earn a commission if they achieve their targets. Orders can be placed to the vans. For one branch of a large wholesaler located in Takoradi, teams sell about 70 percent of the total sold.<sup>xxxiii</sup>

#### **4.3 Retail: Pharmacies and Chemical Sellers**

There are about 700 licensed pharmacies and 11 159 chemical sellers in Ghana (end of 2007 numbers). There are also 328 wholesalers with a licence to retail products. All retailers are required to obtain a licence to operate in Ghana.

Chemical sellers sell a limited range of products including anti-malarials and analgesics and they must keep a minimum distance of 1 km in radius from any other existing retail outlet. Both of these rules are usually ignored as several chemical sellers are often found located near pharmacies and chemical sellers are known to stock products not on their approved list of products (i.e. antibiotics). To obtain a licence chemical sellers must have a basic education level (GSCE), have passed a basic knowledge and skills test and have a minimum room size of 12 square metres.

Often pharmacists and chemical sellers ran their businesses alongside their regular jobs. Some pharmacists worked full-time in hospitals and visited their pharmacies only in the evening. Chemical sellers were farmers, teachers, former nurses and housewives. As a result, often the person with knowledge of the pharmacy business and profession is not present to provide the necessary pharmacy services to customers. This has an important impact on substitution of generics but also the value of the service provided by pharmacies. In rural areas it is difficult to find people with basic education qualifications and often stores are run not by the licence holder but by local staff. As a result, the Pharmacy Council intends to introduce the District Pharmacy Programme in which one pharmacist can supervise more than one pharmacy shop. Pharmacy technicians can be employed to run each store.

**Table B4: Regional Distribution of Private Sector Pharmaceutical Outlets in Ghana**

Region	Type of Institution				Total	LCS
	MW	W	W&R	R		
Ashanti	1	35	62	152	250	1712
Brong Ahafo			28	2	30	1723
Central		1	14	13	28	1479
Eastern	1	1	29	14	45	1822
Greater Accra	10	114	165	481	634	1822
Northern		5	3	2	10	723
Upper East			2	2	4	167
Upper West			3	2	5	178
Volta			7	10	17	992
Western		10	15	22	47	1485
Total	12	166	328	700	1206	11 159

Source: Ghana Pharmacy Council as of 31 December 2007. MW – Manufacturing Wholesale Pharmacy, W- Wholesale Pharmacy, W&R – Wholesale & Retail Pharmacy, R- Retail Pharmacy, LCS- Licensed Chemical Seller.

#### *Price structure*

Typical margins in pharmaceutical retail (pharmacists and chemical sellers) range from 30-40 percent but can also be 30-200 percent depending on the product, its price and its volume of sales. In order to increase customer traffic, all pharmacies and chemical sellers in this study sold complementary products including machetes, mosquito nets, cosmetics (shampoos and soaps), diapers, sanitary pads, etc. A contact at the Pharmacy Council suggested that many chemical sellers and pharmacies have suspended business activities because they found that it was not profitable.<sup>xxiv</sup>

#### **Chemical Sellers**

Rural chemical sellers are often the only source of medicines in their town. They obtain their supplies from a variety of sources. They may obtain stock from the wholesaler in the nearby town, they travel to Okaishe (a place in Accra where many wholesalers are located) or they buy from the travelling drug salesman. Sometimes because some wholesalers have minimum orders that are larger than what chemical sellers can buy, pharmacies become wholesalers catering to small orders. Chemical sellers often shop around for the best prices and buy as much stock as they can afford at the moment. One chemical seller in a village one hour from Accra explained that he bought stock for about \$US100 per month. Chemical sellers in more rural areas buy

stock about once per month from up to 6 wholesalers. In contrast, pharmacists in urban areas (Cape Coast) may order stock every week for a total of about 10 000 GHC (or US\$7070): 60 percent from wholesalers, 30 percent from manufacturer, 10 percent from independent drug salesman) per month.<sup>xxv</sup>

All the chemical sellers mentioned that they bought stock from travelling salesmen. Since wholesalers do not deliver outside of their towns and retailers (pharmacists and chemical sellers) buy from several wholesalers, it is more convenient to buy from a salesman even though they are more expensive. Travelling salesmen are quite profitable. One told that he made about 800-1200 GHC (US\$560- US\$840) in profit per month.<sup>xxvi</sup> He loads his van with goods he buys from wholesalers in Okaishe and makes about 3 week long trips to the Central and Western regions per month. Like other suppliers and retailers, they sell on credit and their biggest problem is collecting debts. They resort to tactics such as taking indebted retailer's medicine stocks or televisions as collateral until their debts are paid.

Often the price setting process in rural areas seems quite arbitrary and chemical sellers say they aim to just sell the products for more than they bought them.<sup>xxvii</sup> Pricing seems to take into account the purchase price (from supplier) and how much the market will bear but not their additional variable and fixed costs (rent, electricity, transport). For example, one village chemical seller explained that he just ensures that he sells his product for more than he buys it. "If I buy the product for 1 GHC then I sell it at 2 GHC. If I buy it at 0.5 GHC then I sell it at 0.65 GHC".<sup>xxviii</sup> Another said that if he buys a drug at 1 GHC he sells it for 1.20 GHC. However, the most expensive medicine in the store is the blood tonic, which he buys at 6 GHC and sells at 8 GHC.<sup>xxix</sup> Thus, cheaper products he sells at 20 percent profit and more expensive ones he sells at 33 percent profit. Another explained that he just tries to make a 40 GHC (US\$ 28) profit: he tries to sell his 400 GHC of stock for 440 GHC.

### **Overview of Challenges**

1. Chaotic and inefficient distribution networks, which gives rise to individual drug salesmen and limited access to medicines in rural areas;
2. Multiple layers of supply chain increases consumer prices;
3. Poor storage and delivery practices;
4. Manufacturing: Limited added value products and problems meeting GMP or prequalification standards;
5. Pharmaceutical sector businesses have poor access to financing;
6. Limited support for drug testing and pharmaceutical business inspections.

### **Interviews**

Dr. Paul Lartey, President and CEO, LaGray Pharmaceuticals

Dr. Alexandra Graham, COO, LaGray Pharmaceuticals

Mr. T.T.L Bernasko, Executive Chairman, The Bernswett Co. Ltd.

Mrs. Martha Gyansa Lutterodt, Head of Ghana National Drugs Programme

Rev. J.Y. Martey, Deputy Chief Executive, FDB

Mr. E.Y. Opoku-Adjei, Manager of Education and Training, Pharmacy Council

Dr. Mike Addo, President of Kama Pharmaceuticals and President of PMAG

Mr. Lebene Soga, Pharmaceutical Representative, Krka Pharmaceuticals of Slovenia

Mr. Charles Allotey, Health Access Network

Ms. Doris Attafua, Managing Director, Vicdoris Pharmaceuticals Ltd.  
Mr. Nelson Offei-Kumi, Independent Drug Salesman

Representatives of the following wholesalers:

Ernest Chemists Wholesalers, Greater Accra

Class Pharma, Swedru

Kinapharma, Takoradi

Kojach Pharma, Takoradi

Tobinco, Takoradi

Pharmacists in Cape Coast

Chemical Sellers in Accra, Ajumako, Entumbil, Swedru, Accracama and Takoradi

## **Appendix C: Malawi Case Study**

### **Analysis of the Private Sector Supply and Distribution Chains for Medicines in Malawi**

#### **1.0 Overview of Malawi**

Located in South-eastern Africa, Malawi is bordered by Zambia, Tanzania and Mozambique. The population is currently estimated at 13.6 million people and has been growing at an annual rate of 2 percent. Malawi has a relatively high inequality in income distribution, with a Gini coefficient of 0.38. Poverty was measured at 54 percent of the population in a household survey (2004-2005) and has remained largely unchanged since the previous household survey was undertaken in 1997-1998. HIV/AIDS coupled with poverty and food insecurity constitute the major long-term human development challenges in Malawi.

Human development indicators remain very weak. The 2007/2008 Human Development Index ranks Malawi as 164th out of 177 countries. The maternal mortality rate is currently 984 per 100,000 live births and remains one of the highest in the world. Adult literacy for males is 75 percent while that of females is only 54 percent. A third of the population still only has access to unsafe water.

Estimates indicate that 12 percent of adults (15-49 years) in the country are currently living with HIV infection. Tuberculosis prevalence has doubled largely due to HIV infection, with high mortality rates. Malaria is the most common reported cause of morbidity and mortality in both adults and children. Schistosomiasis, trypanosomiasis, onchocerciasis, leprosy and bacterial pneumonia are also common. The health sector previously focused its attention on communicable diseases. There is, however, a growing awareness of the increase of non-communicable diseases such as hypertension, diabetes, cancer, asthma, mental health problems and oral health. Currently, there is insufficient information on non-communicable diseases on which to determine trends in magnitude and to monitor morbidity and mortality. However, there are indications from clinical settings that cases of diabetes, hypertension and cancer are on the increase.

#### **2.0 Health Services**

The health care delivery system consists of services provided by the Ministry of Health (60 percent), the Christian Health Association of Malawi (CHAM) (37 percent) and the Ministry of Local Government (1 percent). Other providers, such as private practitioners, commercial companies, army and police provide 2 percent of health services (WHO 2005). The overall per capita expenditure on health is only US\$ 15 (in 2006) (WHOSIS) and there is no social security system for health care.

Malawi has a good coverage of health facilities with 80 percent within a 5-km radius. Unfortunately, most Malawians have difficulty accessing these facilities due to poor road networks, especially in rural communities and poor communication systems (WHO 2005). In addition, just 9 percent (54 out of 585) government and mission health facilities are capable of providing the essential package of health services on-site. This arises because of supply stock-outs, a lack of basic utilities (adequate water, electricity, phone or radio communication), and especially a lack of trained health workers (Ministry of Finance - Malawi 2006).

CHAM receives annual financial support from the Ministry of Health for the payment of salaries. CHAM also obtains funding from a variety of local and foreign sources, including charging user fees for a wide range of its health services and from drug sales. Private hospitals and clinics are emerging as a significant provider of health services. They are increasing in number and are an important source of medicines in rural areas. Around 18 percent of all consultations are being done outside MOH and mission facilities (Ministry of Finance - Malawi 2006). More than half of patients who go to government facilities first and do not receive adequate drugs or treatment end up going to private providers (Ministry of Finance - Malawi 2006).

A large share of Malawi's health expenditures is covered by development partners. The share of externally funded expenditures on health is around 70 percent (Ministry of Finance - Malawi 2006). In terms of drug procurement, health service providers procure essential medicines from varying sources from both developed and developing countries. Funding agencies largely determine where the essential medicines will be procured, in line with their set conditions. In terms of volume, the majority of drugs consumed in the public and private sectors appear to be sourced from generic manufacturers in the developing world.

### ***2.1 Human Resources***

A lack of qualified human resources is a significant problem in all areas of the health system. This has a serious impact on the private sector pharmaceutical supply chain as there are currently only 30 practicing pharmacists in Malawi. Most are concentrated in Lilongwe and Blantyre. Until recently, there was no national pharmacy-training programme. 2010 will be the first graduating class of 8 pharmacists trained in Malawi. Prior to this Malawians had to seek training abroad or employ foreign pharmacists. Many local pharmacists are Zimbabwean or Indian.

### ***2.2 Health Insurance***

In Malawi, the public sector offers free health services and medicine although maternity care, private wards at central and district hospitals, and some outpatient departments incur patient fees. The not-for-profit private sector (mission hospitals, NGOs and Christian Health Association of Malawi-CHAM) offer services and medicines for small fees. Private sector health care is growing but due to limited public sector resources that are spread thinly, this sector is growing. The health insurance industry in Malawi is underdeveloped. There is no compulsory health insurance even for those in public formal sector employment. Since 2000, a few private sector health insurance schemes have been established (OASIZ Medical Aid and MASM). Some parastatals and some firms have small schemes of their own which they operate themselves or contract out to MASM to administer on their behalf. Spending on medicines remains low: about 10 percent of MASM's health expenditure was spent on drugs (2004-5) (Makoka, Kaluwa et al. 2007).

### **3.0 Overall Pharmaceutical Market**

There is little data available on the size of the pharmaceutical market in Malawi. It is clear that the CMS is the largest purchaser of medicines in the country. However,

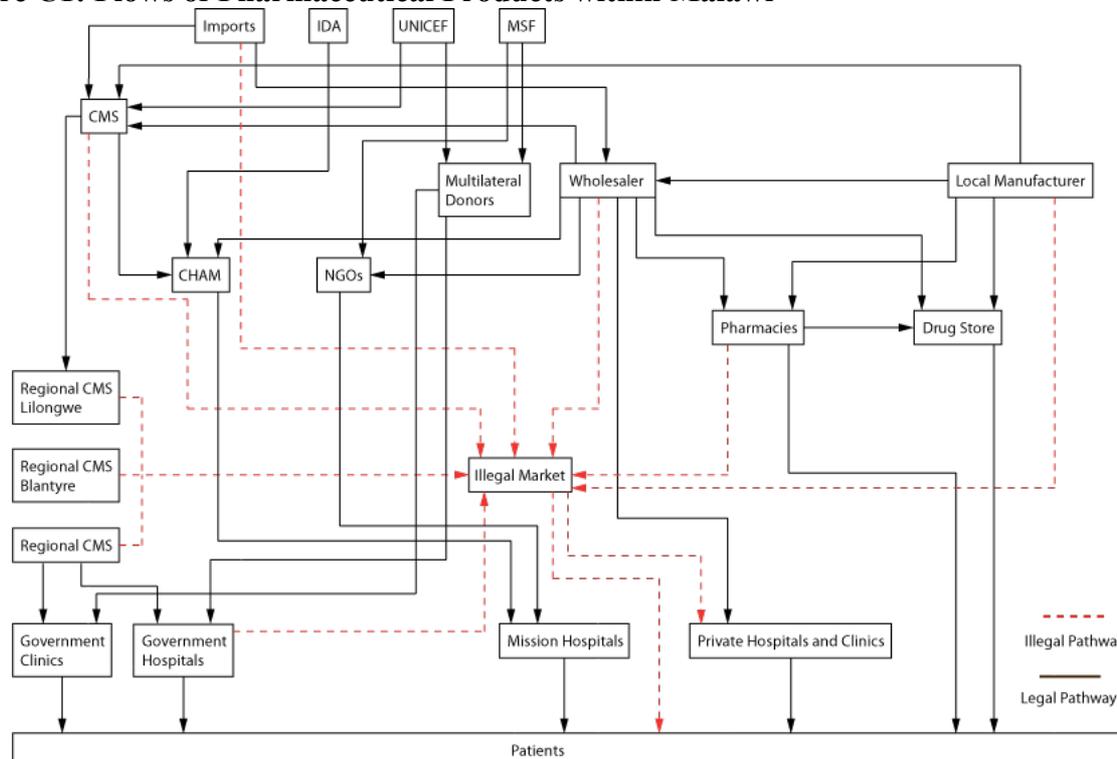
reports on the amount they purchase vary from US\$10-11 million to US\$100 million.<sup>8</sup> This may account for somewhere between 70-90 percent of total annual pharmaceutical consumption.

### Public and Mission Sector Procurement

The CMS supply public sector health services (See Figure C1). It is well known that the CMS is plagued by institutional, management and financing problems. Government facilities operate on an “IOU” basis because of the unpredictable release of funds by the Treasury. The CMS is often in arrears. The CMS also suffers from a lack of qualified staff, poor planning, poor logistics and weak support systems (Ministry of Finance - Malawi 2006). As a result the health system suffers from chronic stock-outs whose effects also reverberate in the private sector.

Annual public procurement is done through International Competitive Bids. Annual tenders are usually granted to Mission Pharma (a Danish logistics and medicines supplier; 50 percent of tenders) and to local wholesalers (eg. Worldwide, Pharmavet) that have links with Indian generics companies. There are also about 3-4 emergency tenders per year, which are granted to local wholesalers and on occasion to local manufacturers (eg. PharmaNova). The Public Procurement Act reflects a deliberate government policy to encourage domestic manufacturers or suppliers to supply goods to the government. However, in practice local manufacturers complain that this is not applied.

**Figure C1: Flows of Pharmaceutical Products within Malawi**



In addition to public sector procurement, several parallel pathways exist. These include: UNICEF, the Global Fund, USAID and PEPFAR. Products purchased by

<sup>8</sup> A wholesaler that regularly supplies to the CMS estimates it at US\$ 75 million medicines for annual and emergency tenders, TB medicines and the under-5 vaccine programme.

these multilateral donors such as for TB, malaria (at least US\$10 million), HIV (about US\$30 million) and vaccines (US\$5 million) are not procured by or delivered to the CMS.<sup>xxx</sup> Instead these products are procured by logistics and supply companies such as UNICEF, IDA and warehoused and delivered to the CHAM and other mission hospitals via logistics and transport companies such as SDV. On occasion, the CMS procures medicines (essential medicines, vaccines, anti-malarials, HIV medicines) from UNICEF.

The CHAM-affiliated health facilities, private hospitals and nongovernmental organizations (NGOs) are not bound by the Government procurement regulations. CHAM procures the bulk of its essential drugs through the International Dispensary Association (IDA) and the CMS. NGOs either procure from local wholesale distributors or import directly. Médecins Sans Frontières (MSF Luxembourg), for example, sources about 90 percent of its drugs from Europe and has been very restrictive in buying medicines from the developing world (Lewis-Lettington and Banda 2004).

Private hospitals, on the other hand, procure medicines from the private sector. They do not usually abide by MOH policies in procurement of medicines, i.e. procurement through tenders or procuring generic medicines.

### **Value of Pharmaceutical Sector**

By adding together the estimated CMS (US\$20-75 million: medicines for annual and emergency tenders, TB medicines and the under 5 vaccine programme), the parallel pathways (US\$45 million) and the private market (US\$4-5 million), we can estimate the total pharmaceutical market to be worth about US\$110 million. This suggests that annual pharmaceutical consumption is about US\$5-9 per person. Local manufacturers suggest that there are about 3 million economically active people.<sup>xxxii</sup> Local actors report that national pharmaceutical consumption is growing, although at a very slow rate.<sup>xxxiii</sup> We can estimate this at the rate of annual population growth: 2.5 percent.

**Table C1: Estimated Market Data on the Malawian Pharmaceutical Sector, 2009**

<b>Data</b>	<b>Figures</b>
Total CMS budget on pharmaceuticals	US\$ 20-75 million
Value of parallel pathways	US\$ 45 million
Value of private market	US\$ 4-5 million
Per-capita annual pharmaceutical consumption	US\$ 5-9
Market share of generics in national pharmaceutical market	95-99%

### **Reliance on Imports**

Although there is some local pharmaceutical manufacturing, Malawi relies on imported products: 90 percent of pharmaceutical products. They are mainly imported from India but are also sourced from within the region (South Africa, Zimbabwe, Tanzania, Kenya and Zambia). Most products on the market are generics – 99 percent.

### **Regulation of the National Pharmaceutical Market**

The Medicines and Poisons Board (MPB) regulates the pharmacist profession and the manufacture, import, sale and use of medicines in Malawi. The MPB has a staff of 12 inspectors that licence and carry out inspections of private sector pharmaceutical premises including new foreign suppliers, pharmacies, drug stores, wholesalers,

doctors' clinics with dispensing licences and manufacturing plants. The MPB maintains a quality control lab that conducts tests for product market registration and some post market surveillance.

The MPB faces numerous difficulties including:

- **A lack of resources available to properly test all samples.** In Malawi, the drug registration process requires six tests, however, the lab can only do four.<sup>xxxiii</sup> Government labs report that they test between 600 and 800 samples per year.<sup>xxxiv</sup> Only about 2 percent of all drugs tested are rejected.<sup>xxxv</sup>
- **A lack of sufficient funds for post-market surveillance.** However, in 2008 MPB began random batch testing at entry points with the assistance of MSH. There are reports of imported medicines with market registration of poor quality because the manufacturing facilities have been changed since registration and inspection or because of a decline in quality of APIs.
- **Donated products and products procured via multilateral pathways are not registered or regularly quality tested.** Prior to July 2009, the CMS imported products without market registration. These products were never submitted for quality testing. This practice is supposed to be phased out this year.
- **Pharmacists regularly order and sell products without market approval from abroad** for clients. Doctors prescribe or patients ask pharmacists for products that are not registered. This is in part because Malawi is a small market for which it is not cost effective for companies to register products.

These problems raise concerns that the MPB is not able to control the type or quality of products for sale in Malawi.

### ***Growing Informal Sector***

The informal sector in Malawi is reportedly growing, although no reliable data is available. The reasons for this are numerous and include poverty in rural areas and lack of knowledge about the effects of substandard medicines. In addition, stock-outs in the public sector, which some observers suggest is about 40 percent of the time,<sup>xxxvi</sup> and a high cost of medicines in the private sector are drivers of demand in the informal sector. Leakages from the CMS are common. They seem to occur at the level of CMS warehouses or public health facilities. A MOH report (2006) noted that leakages occur at various levels including the MOH, CMS, regional medical stores, district hospitals, health centres, in transit between these points and at ports of entry into Malawi (Ministry of Health (Malawi) 2006: 53-57). Products marked for government use have been found in private clinics and markets.<sup>xxxvii</sup>

Products also move from the private sector into the informal sector as small wholesalers use their import licenses to supply illegal drug sellers. Employees at pharmacies and private clinics may also sell products to informal sector traders. Fines on illegal drug vendors (MK50 000 or US\$362) are reportedly too low to be a deterrent.

### **4.0 Private Sector Pharmaceutical Distribution Chain**

As the CMS purchases such a large portion of the total pharmaceutical consumption, the private sector is small and underdeveloped. The market is very price sensitive and businesses are high volume, low margin. The private sector is estimated to be worth about US\$ 4-5 million including the CHAM.<sup>xxxviii</sup>

#### 4.1 Local Manufacturers

Malawi has 4 local manufacturers: PharmaNova Ltd., Kentam Pharmaceuticals Ltd., Malawi Pharmacies Ltd. and SADM Pharmaceuticals Ltd. Local manufacturers produce about 140 products, including essential medicines, however local manufacturers produce less than 5 percent of the country's needs.<sup>xxxix</sup> Most of their business is limited to the private sector although they are occasionally granted small CMS emergency tenders worth about US\$10 million.

Although recently manufacturers have made investments into their factories (US\$ 7 million), none have attained prequalification standards and 3 of the companies are mostly idle. Malawian manufacturers face similar problems to those of other African manufacturers:

- Difficulties forecasting demand and managing manufacturing pipeline due to CMS stockouts and tender process;
- Limited access to credit and foreign exchange;
- Inland country reliant on poor transport infrastructure from Mozambique or South Africa and long delays in ports;
- Fluctuating costs of APIs;
- High cost of meeting product manufacturing quality standards;
- High total costs (raw materials, transport, storage) invested in anticipation of receiving tenders.

Local manufacturers are also very critical of current government and multilateral donor policies, which they claim hinder their business. In order to address these concerns, local manufacturers have created a national (PhaMAM) and a regional (SADEC) pharmaceutical manufacturers association.

Specifically, they make the following criticisms that:

- CMS procurement procedures are not transparent and unfairly discriminate against local manufacturers. Local manufacturers complain that tenders are not well advertised, they are often granted to foreign suppliers or local wholesalers through backhand deals and once granted, the terms of tenders are not on public record.<sup>x1</sup> Tenders are granted to foreign suppliers for products that can be manufactured locally, such as, quinine sulfate, amoxicillin, and co-trimoxazole.
- Although the Malawian Public Procurement Act reflects a deliberate government policy to encourage domestic manufacturers/suppliers to supply goods to the government<sup>9</sup> and offers them a price preference of about 15 percent, in practice local manufacturers claim this is not adhered to.
- Local manufacturers are not generally awarded annual tenders but do sometimes receive emergency tenders. These often have a short time to delivery. This short notice coupled with poor transport links to ports, make it difficult to manufacture for tender.
- Government and donors should better support local industry by allocating a certain portion of annual and emergency tenders to their companies.

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<sup>9</sup> Section 31(17) of the Public Procurement Act stipulates that “in the evaluation of tenders, a procuring entity may apply the margin of price preference in favour of domestic bidders.”

- Some policy-makers, CMS and multilateral donors advocate the use of long-term tender contracts in which the international tender price is firm for 2 years. Local manufacturers argue this is impossible due to fluctuations in API price.
- Complaints that WHO inspectors do not visit local factories;
- Malawian manufacturers are not offered the same terms as foreign suppliers: local suppliers are paid in kwacha after 30-60 days while foreign suppliers are paid up-front in US dollars. The Malawian government clears imported products for tender at customs and suppliers do not pay charges, while local manufacturers have to clear own goods and pay charges (7.5 percent of CIF).

The Malawian pharmaceutical association calls for greater multilateral and government support for local manufacturers so that they may improve their capacity to manufacture essential medicines. The association has proposed some practical initiatives to support the local industry, including an opening up regional markets and the harmonisation of regional the regulatory system.

In addition, support in the areas of financing (access to credit and foreign exchange) and technical support to improve their manufacturing and quality standards would allow them to expand their production capacity and lower prices. There are some advantages to supporting local industry rather than relying on imports. These are:

- Just in time production avoids products sitting in ports;
- Delivery of products on a monthly basis as needed. Avoids shipment delays and storage costs;
- Improved ability to monitor quality of product and manufacturing;
- Increased volume would lower costs of local production;
- Local employment;
- Increased tax revenue;
- Technology transfer and increased skill base.

## **4.2 Wholesalers**

In recent years (since 2005), there has been a rapid increase in the number of wholesalers. Currently, there are about 22 wholesalers in Malawi of which 6 are active. The active companies focus either on supplying the CMS (eg. Worldwide) or on targeting the private sector (pharmacies, drug stores, private clinics and hospitals) (eg. Pharmavet, Chemicals & Marketing Ltd.). They mainly supply generic products from India and other African manufacturers (in Kenya, Tanzania and Zimbabwe), but a few focus on branded products from Europe Chemicals & Marketing Ltd.). The smaller, less active companies import products for specific business deals and emergency tenders.

Because Malawian consumers' purchasing power is limited and the CMS policy is to buy cheap generics, wholesaling is a high volume, low margin business. The main products traded are generics and consumables (eg. gloves, syringes). Wholesalers, previously focused on brand-name products (eg. Chemicals & Marketing Ltd.), are now looking to import new lines of generic products from India. Many local wholesalers and manufacturers would like to grow their business with the CMS as a way to increase volumes.

Wholesalers face **significant supply chain management challenges**. As the CMS is the largest purchaser of medicines in Malawi, CMS stock-outs and emergency tenders have a significant impact on other actors in the supply chain system. For Malawian manufacturers and wholesalers the award of emergency tenders is potentially lucrative but also make the management of supply chains difficult. CMS emergency tenders have a 4-week time to delivery. Given transport delays to Malawi (up to 8 week transit times from port in Beira, Mozambique), wholesalers and manufacturers must invest in anticipation of being awarded tenders. Uncertainty in demand forecasting results in high costs. Holding stock is expensive. One successful wholesaler claimed that they maintained stock worth between US\$500-600 thousand in the warehouse. However, of the 300 products stocked between 50-60 were short in supply.<sup>xli</sup> Wholesalers may have no stock available for sale or stock held for too long without a buyer may expire. In these cases, wholesalers often sell goods to each other and may divert sales from the private sector to the public sector.

**Other challenges include managing customer debt.** Wholesalers sell on 30-day credit, however, this is often extended to 60, 90 or 120 days. Many wholesalers complain about the failure of customers to pay on time.

Since most pharmacies are located in urban areas **delivery networks to rural regions are limited**. Most wholesalers have established two offices one in Blantyre and the other in Lilongwe. Wholesalers in Blantyre use their own vans to supply their Lilongwe branches and to make deliveries within urban areas. Pharmacists in urban areas order stock two to three times per month. Monthly orders are worth about MK200 000 to MK400 000 (US\$1448- US\$2896). Customers in rural areas either pick up supplies from the wholesaler directly or wholesalers ship products using Fedex or the local bus service.

### **Price Structure**

Wholesalers' margins range from 10-30 percent depending on the products. For sales to mission hospitals their margins are 10-12 percent and for sales to the CMS and CHAM they reduce their margins to 2-3 percent. Although one wholesaler of branded products suggested their margins to the CMS were 15%. Sometimes wholesalers sell to each other. In such cases, they offer each other discounts of 5-10 percent of the wholesale price. For retail sales, wholesalers expect to add 10-35 percent margin (10-25 percent on generics and 30-35 percent on brand name products) and do not usually offer any discounted prices for large volumes or promotions.

**Table C2: Price Structure of Malawian Pharmaceuticals**

<b>Wholesaler Sales to</b>	<b>Margins</b>
Other wholesalers	5-10% discount off wholesale price
Mission hospitals	10-12%
CMS and CHAM	2-3%
Private Sector	10-25% (generics) 30-35% (brand name)

### 1.3 Retail Outlets Pharmacies

The lack of trained staff in the health services is particularly acute in the pharmacy profession. Until recently,<sup>10</sup> there has been no pharmacy training in Malawi. Pharmacists in Malawi are either Malawians who received their training abroad or foreign pharmacists. As there are few trained pharmacists in Malawi (30), there are also few pharmacies. Pharmacies are concentrated in urban areas and there are no pharmacies in rural areas. Drug stores, licenced outlets offering a limited range of pharmaceutical products and run by staff without pharmacy training, are present in rural areas (See Table C3). Since 2002 the Medicines and Poisons Board has encouraged private doctors clinic dispensing in rural areas. They have granted about 330 dispensing licences to private clinics (See Table C3).

**Table C3: Number of Establishments Dispensing Medicines in Malawi**

Location	Drug Stores	Pharmacies	Private Hospitals/ Clinics	Wholesalers*
Lilongwe	15	15	80	13
Blantyre	14	11	67	19
Mzuzu	7	2	14	1
Other	25	0	160	0
Total	61	28	324	34 (22)

Source: Pharmacy, Medicines and Poisons Board 2009. \*Some of these include the same company in different locations.

In the absence of trained pharmacists and pharmacies in rural areas and the preponderance of generic products available from wholesalers, dispensing rather than prescribing has some advantages. These are:

Convenience (one-stop-shop) for patient;

- Forces prescriber to explain treatment to patient and gives him more control over treatment;
- Prescribers have some knowledge about pharmaceutical quality.

There are also some disadvantages:

- Dispensing may serve as a source of income to used to offset low doctors fees, leading to un-rational prescribing;
- Doctors cannot stock a full range of drugs. They are only able to stock what they like to use frequently, thereby narrowing the therapeutic range;
- Temptation to dispense what's in stock rather than ideal drug;
- Stocking drugs on the basis of deals from manufacturers;
- Possibility of developing and selling their own drugs or mixtures, which might not be regulated.

The **major challenge of pharmacists is managing their supply of medicines**. Like the other actors in the supply chain, pharmacists also have problems managing stock. In part, this is due to the forecasting and supply problems of the CMS and wholesalers. Stockouts at the CMS level result in shortages at the wholesaler and pharmacy level. This is compounded by **limited access to foreign exchange**. The largest pharmacists report that they try to maintain two months worth of stock (MK10 million or US\$72

<sup>10</sup> This year the first graduating class of eight students will graduate from the University of Malawi College of Medicine.

400) but they also aim to avoid purchasing too much because of the cost and the need to sell stock prior to the expiration dates. In cases of supply chain stockouts, pharmacists report that they travel to South Africa to pick up stock at three times the price of goods in Malawi.

### ***Price Structure***

Many suggested (including pharmacists) that prices offered by private clinics were variable and not necessarily more expensive than private pharmacies. In fact many indicated that prices of medicines were cheaper at private clinics than in private pharmacies. This is mainly because pharmacies charge high margins: between 50-100 percent. Pharmacies generally make most of their revenue (70-80 percent) from the front of store i.e. cosmetics, shampoos, diapers etc rather than pharmaceutical products. Often less than 20 percent of their customers wanted to fill a prescription. One pharmacist suggested that he filled about 5 prescriptions out of 150 customers per day.<sup>xlii</sup>

### ***Private Sector Initiatives***

Despite the small size of the private pharmaceutical market, some pharmacies are already experimenting with private sector initiatives. Current initiatives include: doctors consultations in the pharmacy (Mudi Pharmacies), pharmacy chains (One Stop Community Pharmacy and Michiru Pharmacy), private clinics dispensing medicines and one pharmacist is looking at the possibility of putting his pharmacies in grocery stores.

The fact that there are a growing number of private sector for-profit and not-for-profit clinics in Malawi, where patients pay for services and medicines, suggests that there is some disposable income in urban and rural areas. Exactly how much and where was not within the scope of this project.

#### **Box 4: Medical Aid Society of Malawi (MASM)**

A national health insurance company set established a pharmacy chain with branches in Lilongwe and Blantyre. Since then they have also started private doctors clinics (located in the country's largest urban centres: Blantyre, Lilongwe, Mzuzu and Zomba) and a pharmaceutical wholesaler business and are part-owners of a local private hospital. This allows MASM to provide a complete service to clients. Patients may visit any pharmacy but they earn a 20 percent discount on medications purchased from Michiru pharmacies.

The organisation procures products through the wholesale business and sell to the businesses within the MASM network as well as other wholesalers and pharmacies. MASM offer special prices to the businesses within their group. Due to the scarcity of foreign exchange, they receive a consignment every six months. Michiru pharmacies receive about 40 percent of the total consignment and about 15 percent is sold to MASM clinics. MASM clinics buy at cost price plus 20 percent and MASM retail pharmacies cost price plus 50-60 percent.

## **Challenges**

- Lack of trained pharmacists; lack of competition between pharmacies;
- High margins in pharmacies
- Lack of medicine outlets in rural areas
- Lack of market research on the Malawian private pharmaceutical sector
- Emphasis on dispensing rather than prescribing: pharmacy business is mainly OTC
- Limited number of pharmacies and drug stores especially in rural areas
- Limited government drug quality testing
- Relative high cost of pharmaceuticals in private sector and poor availability in public sector drives patients to informal sector
- Difficulties forecasting demand and managing stock
- Low purchasing power and lack of public or private health insurance
- Irregular national distribution network
- Small private sector
- Emphasis on low cost, low quality generics
- Poor in-bound transport links and delays in port: need to hold large quantities of stock

## **Interviews**

Mr. Steven Chapima, Pharmacy Medicines and Poisons Board

Mr. Caesar Mudondo, Procurement Officer, UNICEF

## **Wholesalers**

Mr. Kumar, Pharmacist Manager, Worldwide Pharmaceuticals

Mrs. Caroline Marufu Mwombedzi, Pharmacist, Chemicals and Marketing Co. Ltd.

Mr. Mehul Shah, Executive Director, PharmaVet

## **Pharmacies**

Mr. Fergus Maswaya, Pharmacy Manager, Michiru Pharmacies

Mr. Mataya, CEO, Onestop Community Pharmacy

Mr. Richman James Mwale, Managing Director, Livingstone Pharmacy Ltd.

## **Malawian Manufacturers**

Mr. David Bisnowaty, Chief Executive, SADM

Mr. Anup Panchal, General Manager, SADM

Mr. Colin Patrick, Group Managing Director, Pharma Nova

Mr. Dumisani Chisala, Malawi Pharmacies Ltd.

## **Appendix D: Mali Case Study**

### **Analysis of the Private Sector Supply and Distribution Chains for Medicines in Mali**

#### **1.0 Context**

Located in West Africa, Mali is bordered by Senegal, Guinea, the Ivory Coast, Burkina Faso, Niger, Algeria and Mauritania. Mali's economic growth has been favourable in recent years, averaging 5.1 percent per year for the 2003-07 period, driven primarily by gold mining and transport and telecommunications services. The population is estimated at 13.5 million; it is predominantly rural with a growth rate of approximately 3 percent a year. Between 2001 and 2006, it is estimated that the share of the population in poverty fell nationally from 55.6 percent to 47.5 percent. However, there is a growing disparity of wealth and geographic differences in poverty are widening.

In 2008, the UNDP Human Development Index ranked Mali 168 out of 179 countries. Literacy rates are about 26.3 percent (2005). The maternal mortality rate of 1200 per 100 000 live births (2000), is very high. Mali is not expected to meet all of the MDGs by 2015, particularly in the health area.

Data suggests that 1.5 percent of the population (15-49 years) are currently living with HIV infection. Malaria is one of the principal causes of morbidity and mortality in Mali and is responsible for over 30 percent of outpatient visits. The population has reasonable access to health services as 50 percent live within 5 km of medical facilities and about 75 percent live within 15 km. 68 percent of the population has access to safe drinking water.

#### **2.0 Health Services**

Health services in Mali are offered through the public, not-for-profit and private sector. The public sector provides essential health care at the central (university hospitals and a foundation hospital), regional (public hospitals) and district or *cercle* level (Centre de Santé Communautaire or CSCOM and Centre de Santé de Référence or CSRef). Since 2002, the CSCOM and CSRef are considered not-for profit private sector services as users pay a co-payment (ticket modérateur) and some are managed by local health associations. CSCOM and CSRef, the co-payments are about 1000 CFA (US\$ 2.30) at the CSRef and 600 CFA (US\$ 1.39) at the CSCOM. This covers a doctor's consultation but not all medicines. Medicines are usually available to purchase at health facilities. Many patients use public health facilities (51.9 percent), however many also forgo treatment (6.8 percent), buy medicine without going to a health practitioner (10.6 percent) or visit a traditional healer (13.3 percent) (Maiga, Traore et al. 2003:29).

#### ***Health Insurance Coverage***

Some health insurance schemes exist such as the Institut national de la prevoyance sociale (INPS, National Social Protection Institute) and mutual health organisations such as the Union Technique de la Mutualité Malienne. However, the formal health insurance system covers less than 20 percent of the economically active population (Fischer, Sissouma et al. 2006: 6). About 80 percent of the population has no insurance coverage other than the basic services provided by the state through public health services. They are therefore subject to "out-of-pocket" user fees such as for medicines, and diagnostic tests. One study estimates that 60 percent of household spending is

allocated to these two items (EDS4).

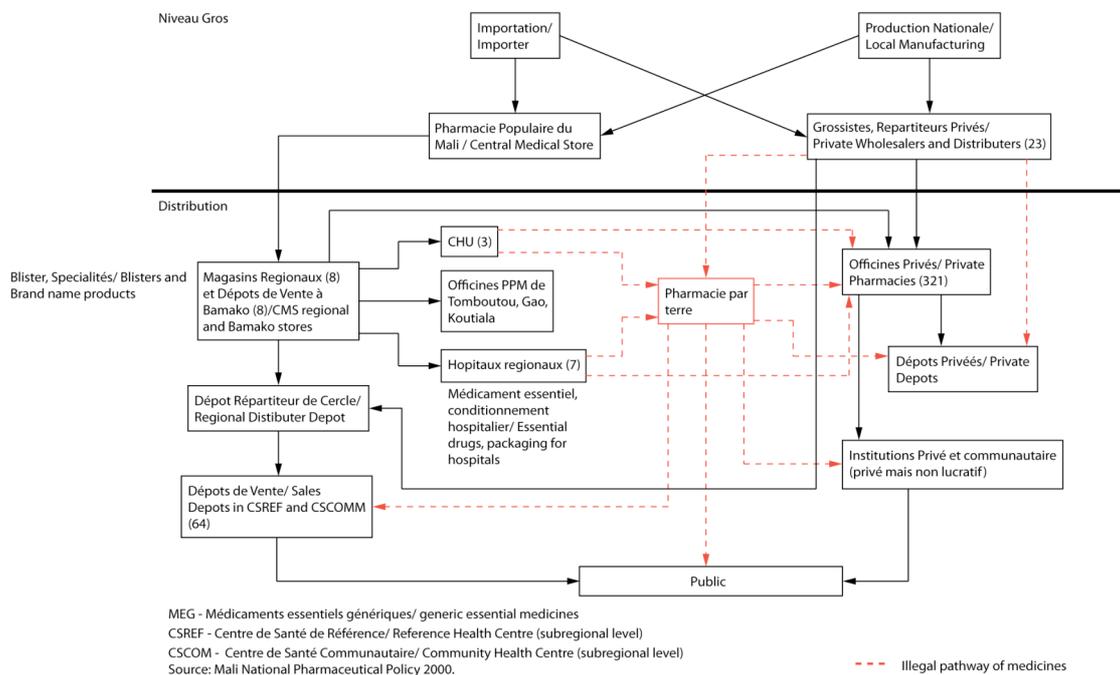
### Regulation of the Pharmaceutical Sector

The Pharmacy and Medicines Department (Departement de la Pharmacie et du Médicament DPM) was created in 2001 in order to formulate and implement drug policies, such as the national medicines policy (*politique pharmaceutique nationale*) and tools for the rational use of medicines. It also defines the regulation of pharmaceuticals and grants market approval for medicines. The National Public Health Laboratory Drug monitors the quality of medicines in the country. Quality testing is required at the time of drug market approval.

### Pharmaceutical Supply in the Public Sector

Mali's CMS or PPM (Pharmacie Populaire du Mali) is a parastatal organization responsible for the purchase and national distribution of medicines. According to the schema of importation and distribution (*schema d'importation et distribution*) described in the national pharmaceutical policy, the PPM is the sole supplier of the public sector. It provides medicines to regional medical stores (*magasin regional de la PPM*), which in turn supply the district depot (*dépôt répartiteur de cercle -DRC*) (See Figure D2). The DRCs are located within the CSREF for a specific Cercle. DRCs then distribute products to the CSCOM.

**Figure D1: Flows of Pharmaceutical Products within Mali**



The PPM faces problems at each level of the supply system. These include cases of limited resources, poor forecasting, inadequate management of stocks, limited and poor warehousing capacity and practice (misplaced products and expired and substandard products), and pilfering of products (DPM 2008). Chronic stockouts are one result from these problems in the supply chain. In one rural CSREF, the local pharmacist orders products for his CSREF and 14 rural clinics from the regional CMS depot. He complained that in most of the rural clinics the staff were poorly educated and

they were unable to measure stock levels or to forecast effectively. Storage conditions in the CSREF were poor. The CSREF suffered from regular power cuts, which left the pharmacy stockroom unbearably hot. Due to these problems, the CSCOM and CSRef are often obligated to source their supplies from the private sector and/or send patients to nearby private sector pharmacists. As a result, public sector doctors reportedly often contact private sector pharmacists for information on products, stocks levels and to send patients to fill prescriptions for medicines that are not available in the public sector (ie. brand name products).

### **Prices and Accessibility to Medicines**

Prices in the public sector remain low but availability is limited by stock-outs (Maiga, Diawara et al. 2007). On the other hand, prices in the private sector are higher but availability is also much better. In order to make medicines more accessible to patients, the government introduced legislation to set prices and reduce taxes on 107 INN essential medicines in the public and private sectors.<sup>11</sup> In addition, the government has initiated several policies (*politique sectorielle de la santé*) to provide medicines free of charge through the public sector.

Most medicines provided in the public sector are INN generics. A DPM (2007) study found that INN generics constituted about 79 percent of prescriptions in the public sector and about 20.4 percent in the private sector (DPM 2007). Although pharmacists reported that they substitute generics for brand-name products, rates of substitution remain low: between 1.1 - 3.3 percent (DPM 2007). This is in part because there is little financial incentive for pharmacists to substitute generics for branded products, given that they earn a higher margin from the sale of branded products. Substitution also requires the pharmacist to consult with the prescribing doctor, which requires an on-duty pharmacist to dispense the prescription and is a process which pharmacists find time consuming.

### **3.0 Private Sector Supply and Distribution Chains**

The revenue of the PPM in 2007 was 9.5 billion F CFA (US\$ 22 million) (DPM 2008). The largest wholesalers with 60 percent and 25 percent of the market respectively have an annual revenue of 20 billion F CFA Laborex (in 2008) and 9.5 billion F CFA (in 2008) for Copharma.<sup>xliiii</sup> This suggests that the value of the wholesale market is about 40 billion F CFA and the total Malian pharmaceutical market (public and private) at retail prices is about 54.64 billion F CFA or about US\$125.7 million and a pharmaceutical consumption rate of US\$ 7.5 per capita.<sup>12</sup>

**Table D1: Estimated Market Data on the Malian Pharmaceutical Sector**

<b>Data</b>	<b>Value</b>
Revenue of PPM (2007)	9.5 billion F CFA (US\$ 22 million)
Wholesaler market value (2008)	40 billion F CFA (US\$ 96 million)
Retail market value	54.64 billion F CFA (US\$125.7 million)
Pharmaceutical consumption per capita	US\$ 9.3
Market share of generics	30%

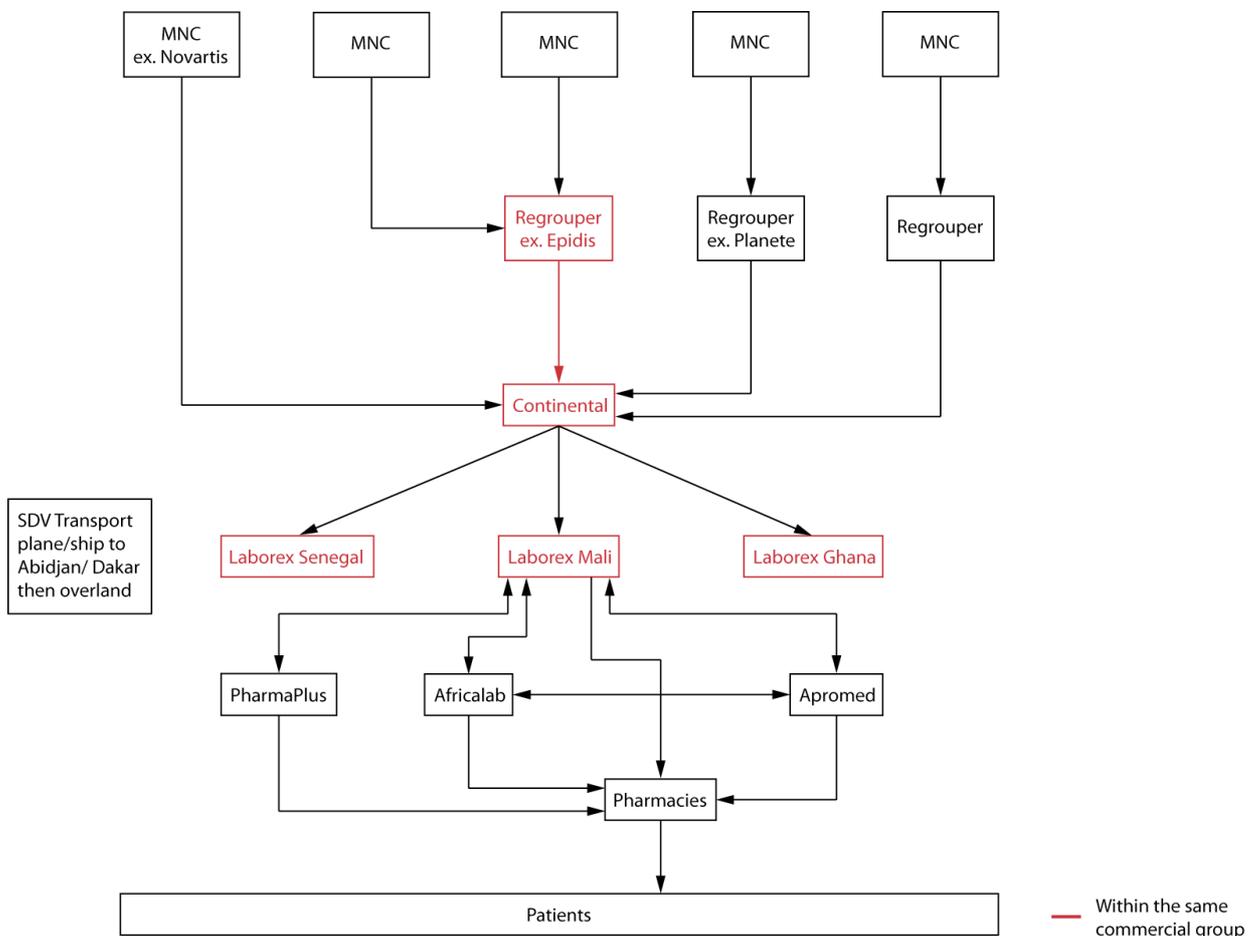
<sup>11</sup> Decret no 03-218/ P-RM which regulates the price of INN generics on the national list of essential medicines and Decret 07-087/ P-RM which sets the price of INN generics on the national list of essential medicines in the private pharmaceutical sector.

<sup>12</sup> Wholesale revenue is estimated at 40

### 3.1 Pharmaceutical Supply Chains into Mali

In Mali, almost 100 percent of the pharmaceutical supply is imported and of this amount, up to 85 percent is imported by 2 companies: Laborex and CoPharma. Laborex<sup>13</sup> is part of a large French group, called Eurapharma, that includes supply and logistics companies and pre-wholesalers or *regroupers* (See Figure D3). Much of the distribution of medicines destined for Mali (and much of French speaking Africa) occurs within Eurapharma. Eurapharma is in turn a subsidiary of CFAO<sup>14</sup> and represents a group of 55 federated companies. It constitutes the largest distribution and pharmaceutical services group in Africa (present in 20 countries) and French overseas territories (present in 7) and has 37 percent of the global share of pharmaceutical retailing.<sup>15</sup>

**Figure D2: Global Supply Chain for Finished Products into West Africa**



Laborex (Mali) places product orders with Continental Pharmaceutique (part of the Eurapharma group), which then orders products directly from mainly European MNCs and/or pre-wholesalers or *regroupers*, such as Epidis (also in the Eurapharma

<sup>13</sup> Laborex is owned partly by local pharmacists and in part by Eurapharma, which is the largest shareholder.

<sup>14</sup> CFAO a world leader in the distribution of pharmaceuticals, cars, and information technologies in Africa.

<sup>15</sup> "Letter to the shareholders. 2004.

[http://www.ppr.com/DataUploadFiles/632379368263750000\\_Lettre22GB.pdf](http://www.ppr.com/DataUploadFiles/632379368263750000_Lettre22GB.pdf)

Group) or Planete. Pre-wholesalers provide distribution platforms for pharmaceutical manufacturing companies to contract out their logistics and export business for sales in the Africa. Continental then consolidates consignments, organises shipment (via boat or plane depending on the value and the shipping requirements of the product) to their destination. Continental also provides financial services. Laborex Mali pays suppliers via Continental and Laborex (Mali) pays Continental a “forfait” equal to a percentage of the value of the products it ships. Continental uses transport company, SDV of the French Groupe Bolloré, to transport (via truck or rail) goods from France to African ports (Abidjan or Dakar) and inland destinations and to clear products through customs and to deliver them to Laborex’s warehouse in Bamako.

Most products are sourced from the world’s largest pharmaceutical manufacturers and are imported from France. As a result, 90 percent of Laborex’s products are brand-name products. Laborex receives 90 percent of its supplies from Eurapharma via Continental. It also has contracts with Malian wholesalers from which it obtains products and also supplies products. Laborex’s main competitor, Copharma, operates under a similar business model. In this case, Planete is Copharma’s principal *regroupeur*.

### 3.2 Supply and Distribution within Mali

There are 32 wholesalers in Mali of which about 5 are viable businesses (Data from CNOP 2009). Of these 5 companies, 2 (Laborex and CoPharma) dominate the market. See Table D2. Wholesalers focus on specific types of products. Brand name products are imported by Copharma, Laborex, and Africalab, whereas generics are imported by Camed, Multi-M, CAG, PPM and to some extent Laborex and Copharma. Generics wholesalers are benefiting from the recent growth in market share of generics.

**Table D2: Market Share of Wholesalers in Mali**

Wholesaler	Market Share
Laborex	55-60%
CoPharma	20-25%
Africa Lab	11-12%
CAMED	7-8%
MultiM	4%

Although prices are free in principal, since the devaluation of the F CFA in 1994 there has been a “harmonisation of prices” through a gentleman’s agreement between the government, wholesalers and retailers. As a part of the drug registration process, foreign manufacturers propose retail prices, which are approved by the DPM. In time prices are readjusted and local supply chain actors agree upon coefficients (margins) that should to be added by each actor in the chain. As Laborex and Copharma are the most powerful actors in this chain, they determine the wholesale price. As the retail price is fixed, wholesalers also effectively determine the margin of pharmacists.

Manufacturers set prices that are approved by the DPM during the market approval process. Although, the DPM should be informed when the prices of products already on the market change, this rarely occurs. Laborex and CoPharma reportedly agree amongst themselves upon sales prices and therefore pharmacists’ margins. The estimated coefficients employed by supply chain actors are listed below.

### **Coefficients For Branded Products<sup>xliiv</sup> (Ouattara and Ag Tachrist 2005)**

Wholesale Price before tax (PGHT) x 1.97 = Pharmacy price

Suggested pharmacy price x 0.75 = Wholesaler transfer price

### **Coefficients For Branded Products**

Wholesale Price before tax (PGHT) x 2.05 = Pharmacy price

Pharmacy price x 0.65 = Wholesaler transfer price

Wholesale margins on brand name products are between 13-30 percent and pharmacists' margins are about 25 percent. For generic products margins are slightly higher at 19-34 percent for wholesalers and 28-45 percent for pharmacists.<sup>16</sup>

Although the Malian wholesale and distribution market is quite consolidated, a change in legislation in 2003 now allows wholesalers to sell products to each other. The establishment of smaller players adds another layer of middlemen, which suggests there is some inflation of prices. Africa Lab, a relatively small wholesaler imports generic products from Egypt and Morocco and sells to other wholesalers such as Laborex, Camed and Copharma. Wholesalers offer a 10-12 percent discount off the wholesale price on products sold to other wholesalers.

Wholesalers often offer promotional deals to "motivate" clients. They provide discounts to high volume customers or free units ("buy 100 get 110"). Some wholesalers offer trips to France, or free breakfasts to good customers.

The **main difficulty of wholesalers is managing their stocks**. Because Mali is a lack-locked country, goods arrive in the ports of Abidjan, Lomé or Dakar and are then sent by train or truck to Bamako. Unexpected delays can occur due to products held in port, poor road conditions, train derailments or a lack of train cars available to transport goods. It can take up to three months from shipment by manufacturer or European wholesaler to receive goods in Bamako. Large wholesalers aim to receive a container per week. As a result of potential delays, wholesalers maintain between 3-5 months of supplies in their warehouses and must absorb these storage costs.

### ***Retail Outlets***

In Mali, pharmaceutical retail outlets include pharmacies and *depots de vente*. Depots de vente are licenced but are not staffed by trained pharmacists and stock a limited range of products. Currently, there are about 401 pharmacies and 109 *depots de vente* in Mali (See Table D3). By regulations, *depots de vente* should only be located in areas where there are no pharmacies within 40 metres. More than half of all pharmacists are located in the capital Bamako. However, there is a waiting list of about 580 pharmacists hoping to be granted pharmacy licences in Bamako and rural areas.

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<sup>16</sup> These were supported by a DPM report (2004) and were confirmed by my findings.

**Table D3: Number of Licensed Drugs Dispensaries in Mali by Region**

Region	Depot de Vente	Pharmacy	Wholesaler	Pharma company	Biomedical Laboratory	Total
Kayes	15	33	1	0	1	50
District of Bamako	2	201	29	1	9	242
Koulikoro	25	68	0	0	0	93
Sikasso	22	36	1	0	0	58
Segou	21	33	0	0	0	54
Mopti	7	17	1	0	0	25
Tombouctou	11	5	0	0	0	16
Gao	4	8	0	0	0	12
Kidal	2	0	0	0	0	2
Total	109	401	32	1	10	553

Source: CNOP 2009. N.B. numbers for *depots de vente* are only for currently existing entities.

Almost all pharmacists have ties with either Copharma or Laborex who are their long-term suppliers and often provide about 80% of their supplies). They also purchase products from other wholesalers. Successful pharmacies in Bamako have approximately 200 clients per day and the have revenues of about 1 320 000 F CFA per year (US\$36 432). These pharmacists often order stock every day and receive delivery the same day. In rural areas, pharmacies may see 50 patients per day and have revenues of 6 million F CFA (US\$13 800). Here, pharmacists order stock every few days. Delivery vans travel in circuits and orders are received in 1-3 days.

Pharmacists complain that they have financial problems. A **reported 60-70% of pharmacies are in financial difficulty and many are bankrupt** although they do not officially close down their businesses. They have trouble managing their business, buying stock on credit and often incur substantial debts. Pharmacists use their profits to finance their personal lives rather than channel income back into the business.

Pharmacists claim that the business environment hinders their business. They report that the **cost of their business is too high due to high taxes and annual pharmacy licence fees** or *patente*. Pharmacists **have problems accessing credit** because they claim that the banking system does not understand the pharmaceutical sector. **Interest rates are high (12-15 percent) and** banks require substantial guaranties for loans or lines of credit, which are difficult to provide. This is particularly a problem for pharmacists entering the profession. As a result, the **large wholesalers have become a defacto financial service provider**. Wholesalers have an incentive to provide pharmacies with financing as new pharmacies are a source of growth in wholesale volumes. Large wholesalers provide start-up capital (*crédit de départ*) for new pharmacists in addition to their monthly orders (*compte normale*). The terms of payment for the start-up capital and the value of maximum monthly orders is determined for each pharmacist and is outlined in their contract with the wholesaler. For example, a new pharmacist may receive 3 million F CFA (US\$6 900) worth of stock plus a maximum monthly order of 200 000 F CFA (US\$460). It is reported that Laborex has extended credit to the extent that they are reported to have 500 million F CFA (US\$ 11 500 000) in outstanding debts.

Pharmacists also describe problems with pharmacy **theft of cash from the register, staff stealing products for resale in the informal market or employees purchasing stock from the informal market** (either shell wholesalers, the market or from hospitals) and selling it in the pharmacy. This thereby deprives pharmacists of their own sales and distorts their balance sheet.

### **Challenges**

- Limited number of pharmacists in rural areas. Constrained by access to financing and allocation of pharmacy licences;
- Pharmacies in financial difficulty;
- Limited use of generics and prices of medicines remain relatively high;
- Difficulties managing stock levels at wholesale and retail levels

### **Interviews**

#### **Wholesalers**

Dr. Boukassoum Haidara, Directeur Général, Africa-Lab Mali S.A.

Mr. Mamadou-Seydou Kone, Responsables des Achats, Laborex

Mr. Alfred Dembele, Directeur, Central d'Achat des Generiques

#### **Pharmacists**

Dr. Halima Sokona Gakou, Pharmacie V2M

Dr. Nouhum Coulibaly, President, Conseil National de l'Ordre des Pharmaciens du Mali

Dr. Check Oumar Dia, Président du SYNAPPO

#### **NGO**

Mr. Stéphane Besançon, Directeur des programmes, ONG Santé Diabète Mali

#### **Government**

Dr. Youssouf Diallo, Haut Conseil pour la Lutte Contre le SIDA

Mr. Ousmane Traore, Responsable Unité Prise en Charge, Cellule du Comite Sectoriel de Lutte Contre le SIDA CSLS/ MS

Dr. Aliou Sylla, Coordinateur, Cellule de Coordination du Comite Sectoriel de Lutte Contre le SIDA, Ministère de la Santé

CSCCom Oulussebouougou

CSRef Oulussebouougou

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## Endnotes

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- <sup>i</sup> Interviews with Caesar Mudondo, Unicef, Mehul Shaw, Pharmavet, Malawi.
- <sup>ii</sup> Reports vary widely as to the annual budget of the CMS.
- <sup>iii</sup> Interview with F.D.A. Chemexport Ltd., UK.
- <sup>iv</sup> Interview with F.D.A. Chemexport Ltd., UK, London, UK. Interviews with SADM and Pharmanova, Malawi.
- <sup>v</sup> Interview with Dr. Alexandra Graham, LaGrey Pharmaceuticals, Ltd. Ghana.
- <sup>vi</sup> Interview with F.D.A. Chemexport Ltd., UK.
- <sup>vii</sup> David Bisnowaty and Anup Panchal, SADM, and Dumisani Chisala, MPL Ltd., Malawi.
- <sup>viii</sup> Interview with Mamadou-Seydou Koné, Laborex, and Dr. Hamidou Traoré, CoPharma, Mali.
- <sup>ix</sup> Interview with Dr, Nouhoum Coulibaly, President of Conseil National de l'Ordre de Pharmaciens du Mali, Mali.
- <sup>x</sup> Interview with Ghana Pharmacy Council, Dr. Check Oumar Dia, President of SYNAPPO, Dr. Gakou, Pharmacie V2M, Dr, Nouhoum Coulibaly, President of Conseil National de l'Ordre de Pharmaciens du Mali, Mali.
- <sup>xi</sup> Interview with Stéphane Besançon, ONG Santé Diabète, Mali.
- <sup>xii</sup> Interviews with Dr. Koné, Laborex, Dr. Traoré, CoPharma, Dr. Haidira, AfricaLab, Dr. Demebe, CAG, Mali.
- <sup>xiii</sup> Interviews with Charles Allotey, HAN, Lebene Songa, Krka Pharmaceuticals, Ghana.
- <sup>xiv</sup> Interview with Stéphane Besançon, ONG Santé Diabète, Dr. Souleymane Guindo, Pharmacien, Mali.
- <sup>xv</sup> Interview with Charles Allotey, HAN, Ghana.
- <sup>xvi</sup> Interview with Dr. Addo, PMAG, Ghana.
- <sup>xvii</sup> Interview with E.Y. Opoku-Adjei, Pharmacy Council, Ghana.
- <sup>xviii</sup> Interviews with Vicdoris, PMAG, La Grey, Ghana.
- <sup>xix</sup> Interview with pharmaceutical wholesaler, Takoradi, Ghana.
- <sup>xx</sup> Interview with chemical seller in Swedru, Ghana.
- <sup>xxi</sup> Interview with pharmaceutical wholesaler, Swedru, Ghana.
- <sup>xxii</sup> Interview with pharmaceutical wholesaler, Takoradi, Ghana.
- <sup>xxiii</sup> Interview with pharmaceutical wholesaler, Takoradi, Ghana.
- <sup>xxiv</sup> Interview with E.Y. Opoku-Adjei, Pharmacy Council, Ghana.
- <sup>xxv</sup> Interview with pharmacist in Cape Coast, Ghana.
- <sup>xxvi</sup> Interview with independent drug salesman, Ghana.
- <sup>xxvii</sup> Chemical sellers in Ajumako, Entumbil and Accracama, Ghana.
- <sup>xxviii</sup> Chemical seller in Accracama, Ghana.
- <sup>xxix</sup> Chemical seller in Ajumako, Ghana.
- <sup>xxx</sup> Interview with Caesar Mudondo, Unicef, Malawi.
- <sup>xxxi</sup> Interview with Colin Patrick, Pharmanova, Malawi.
- <sup>xxxii</sup> Interview with Dumisani Chisala, MPL, Malawi.
- <sup>xxxiii</sup> Interview with Steven Chapima, Medicines and Poisons Board, Malawi.
- <sup>xxxiv</sup> Interview with Steven Chapima, Medicines and Poisons Board, Malawi.
- <sup>xxxv</sup> Interview with Steven Chapima, Medicines and Poisons Board, Malawi.
- <sup>xxxvi</sup> Interview with Caesar Mudondo, Unicef, Malawi.
- <sup>xxxvii</sup> Interview with Steven Chapima, Medicines and Poisons Board, Malawi.

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- xxxviii Interview with Mr. Shaw, PharmaVet, Malawi.
- xxxix Interview with Colin Patrick, Pharmanova, Malawi.
- xl Interviews with SADM and MPL, Malawi. See also “A Strategy for the Empowerment of the Local Pharmaceutical Manufacturing Industry in Malawi” PhaMAM.
- xli Interview with pharmaceutical wholesaler, Malawi.
- xlii Interview with pharmacist, Malawi.
- xliii Interview with Mr. Koné, Laborex Mali, Mali.
- xliv Interviews with Mr. Koné, Laborex Mali, Africa Lab, CAG, Mali.

This study aims to gain a better understanding of some of the different ways in which private sector pharmaceutical supply and distribution channels are organized in Africa. To gain a broad perspective, this study focuses on three very different country contexts: Ghana, Mali, and Malawi. These countries represent significant geographic, economic, social and historical differences. The study suggests potential actions that could be taken by international policy makers, government officials, donors, investors and local supply chain participants.

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