



CROSS COUNTRY SUMMARY REPORT

LANDSCAPE ASSESSMENT OF HEALTH PRODUCT
WHOLESALE AND DISTRIBUTOR CAPABILITIES AND
OPPORTUNITIES IN FIVE COUNTRIES IN SUB-SAHARAN AFRICA

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Executive Summary

The Partnership for Supply Chain Management (PFSCM) and PATH, AfrX Consulting, and Strategnos, undertook a nine-month (January–September, 2019) study on behalf of the Bill & Melinda Gates Foundation to assess the landscape of health commodity wholesalers and distributors in Africa. The primary objective of the study was to understand capabilities of wholesalers/distributors that can partner with governments, pharmaceutical companies, and product developers to increase health care product availability in selected country markets.

The team interviewed 47 pharmaceutical and medical device wholesalers and distributors across the project's five study countries (Kenya, Nigeria, Senegal, Tanzania and Uganda). In these countries, of the total commodities procured across all sectors in 2017, health commodities—most of which were imported—comprised approximately \$3.4 billion (b). Pharmaceuticals were consistently the largest product area, commanding roughly 80% of the total commodities procured. The results of the study showed that Kenya, Nigeria, and Senegal have a comparatively large number of private-sector procurers of health products (e.g., private hospitals, pharmacies), and that demand from these entities determine the composition and capabilities of the wholesalers and distributors that operate there, more so than demand from the public sector. In Tanzania and Uganda, the markets are controlled mostly by the public (government and donor) sector. Private sector wholesale and distribution is moving toward greater upstream market consolidation but continue to experience downstream fragmentation.

This project found private wholesalers/distributors in every country that would make strong partners for the public and donor sectors. Throughout the study the strength, reach and capabilities of the private wholesalers/distributors in each country were directly impacted by the environment in which they were operating. Common themes that were relayed by these companies in the interviews are noted below:

Quality compliance

- Most large pharmaceutical wholesaler/distributors have defined quality management systems (QMS). Reported standards are generally high; major players are ISO 9001-certified, despite the general shortage of human resources and skills for QMS.
- The medical device companies have varying standards of QMS implementation.
- Product quality testing is rarely performed by private wholesalers because of high costs and long lead-times.
- Of the 47 companies interviewed, two wholesalers are prequalified by USAID, meaning they have passed a quality audit by a USAID contractor.
- All countries rely on their regulators for supplier prequalification and registration, and product sampling and testing, but the regulators are under-resourced.

Finance

- Cost of capital ranging from 14.5% to 34% in study countries negatively affects all companies, but durable medical device companies more so. The larger companies (those that are part of international conglomerate groups) are more shielded from interest and exchange rates. This is a major barrier for smaller companies.
- Public-sector agencies do not pay on time. This limits the interest or ability of the private sector to supply and leads to inflated product prices to cover cost that extended payment terms incur. [in Kenya the exception is KEMSA].
- Public-sector tender structure, transparency, and quality compliance hinder private wholesaler work with the public sector.

Regulatory

- Regulation and public procurement policy generally support local pharmaceutical production.
- Pharmaceutical products are highly regulated, whereas regulation for medical devices is largely non-existent.
- Regulatory scrutiny is higher in urban than rural areas; regulations encourage wholesalers and pharmacies to expand to less-served areas.
- Regulatory capacity is limited.
- Pre-shipment inspections can improve quality of pharmaceuticals and transparency in logistics but reduce availability.
- Business environment and policy in Kenya and Senegal favor parallel imports.

In addition to these themes, PFSCM encountered several small but **noteworthy market approaches** in different countries that affect the trading environment of wholesalers and distributors. These approaches, which are explored in greater depth in the market landscape and country market interventions sections, include:

- Drug store networks—like patent and proprietary medicine vendors and Accredited Drug Dispensing Outlets in Nigeria, Tanzania, and Uganda—that have limited product ranges and are one rung below pharmacies in the health care system hierarchy.
- Mobile payment as a methodology to for larger wholesalers to reach and sell to small pharmacies
- Medical device public procurement in Kenya under the Managed Equipment Services program.
- Group purchasing initiatives in Kenya.
- Multi-market wholesaling service providers in French West Africa and the East African community.
- Informed push supply model and remote monitoring of medical equipment in Senegal.
- A medical device wholesaler in Kenya providing managed equipment services for durable medical equipment alongside maintenance, reagents, training, and installation.
- The prime vendor model and its effect on the market in Tanzania.

Conclusion

Access to health commodities is predicated upon their availability, affordability, and quality. Existing literature for most countries in the study¹ indicated that the private sector had higher medicine availability at the facility level than the public sector. Based on the findings of this project, ensuring and maintaining affordability and quality throughout the supply chain and to the end user should be the focus of future interventions.

It is clear that many wholesalers/distributors have the capacity to offer high-quality services to companies that want to distribute their products in these markets. Future interventions to strengthen and support wholesalers/distributors could focus on access to affordable finance and systems to assist with assessment of credit worthiness, prequalification of medicines and in-country affordable testing facilities, and adequate regulatory capacity for pharmaceuticals and medical devices.

Opportunities to align regulatory policy with the roles and goals of private wholesalers/distributors, including thoughtful alternatives to the regulation of last-mile medicine dispensaries, many of which are unregulated and serviced via sub-wholesalers, should also be pursued.

¹ HAI / MeTa study of medicine availability found public sector availability in rural Uganda to be higher than private sector (2015) and public and private pharmaceutical availability in Kenya to be equal (2017).

1 Project Overview

1.1 Introduction

The Partnership for Supply Chain Management (PFSCM), PATH, AfRX Consulting, and Strategnos, undertook a nine-month (January–September 2019) study on behalf of the Bill & Melinda Gates Foundation to support the following strategic goals:

- Improved primary health care system strengthening, functionality, and resilience over time through more effective product distribution market.
- Accelerated scale of life-saving technologies through more effective product distribution market.

1.2 Purpose of the Study

To develop a stronger understanding of capabilities of wholesalers/distributors that can partner with governments, pharmaceutical companies, and product developers to increase health care product availability in selected country markets. Additionally, this study has the potential to:

- Strengthen collaboration between global life-sciences companies and distributors.
- Help governments select strong distribution partners when they consider outsourcing certain capabilities.
- Guide future investments from the Gates Foundation and other funders in this area.
- Contribute to more efficient distribution of health products.

1.3 Project Overview

The study reviewed and assessed:

- Wholesalers and distributors' geographic and product segment coverage, maturity, quality management systems (QMS) and their capacity to distribute and provide other services to the markets in which they operate.
- Wholesaler innovations that may be incorporated into other supply chain distribution.
- Wholesaler aspirations for growth and development that may inform future investments to close identified gaps and optimize in-country geographic reach.

1.4 Technical Approach

The technical approach, summarized below, consisted of two components: a **landscape analysis** and **in-country interviews** with key players in each market.

1.4.1 Landscape analysis

The landscape analysis consisted of a literature review including data from national regulators in the countries of interest, as well as reports generated by UN Comtrade, Asoko Insights, Indian Export Data, Advantage Pharmaceutical Ltd (Nigeria), Medpages, and Maisha Meds (Kenya) (see Appendix A for

details). The analysis facilitated the development of a wholesaler/distributor registry by country (from which the team selected in-depth interviewees) and provided information on the market dynamics in each country. The analysis also informed PFSCM's development of a standardized questionnaire for use during the interviews to gain in-depth understanding of business maturity, market dynamics, and quality compliance. This enabled consistent comparison of similarities and differences among companies co-located in the same domestic market and of trends across each of the five country markets. A priority set of pharmaceutical products and medical devices was defined to further characterize and categorize distributors by product type (see Appendix B).

A key component of the study was to examine both the pharmaceutical and medical device distributors in each country.

1.4.2 In-country interviews

The landscape analysis helped PFSCM identify at least six wholesalers and distributors in each country (between 12–15 in larger countries like Kenya and Nigeria) as potential interviewees. The team conducted in-person interviews with representatives from each to learn about market dynamics, business maturity, and ability to provide high-quality sales, distribution, and other services. In-person discussions also lent insight into organizational areas needing improvement and aspirations for investments.

After the first round of interviews in Uganda, the questionnaire was revised for completeness and clarity and in addition a secondary set of customized questions was added to enhance the team's understanding of context of the four remaining countries.

1.5 Limitations

- Study design
 - All information was self-reported by interviewees, except information that was in the public domain.
 - The team did not conduct an in-depth review of the QMS as the study was not scoped as a quality audit.
 - Differentiation of branded versus unbranded generics was unclear, but, based on market dynamics, most generics were assumed to be branded unless stated otherwise.
 - In general, the team did not interview local manufacturers or sub-wholesalers, although it did interview two sub-wholesalers in Kenya and two local manufacturers (one in Nigeria and one in Senegal).
 - Logistics and courier service providers identified throughout the study were not interviewed.
- General
 - Due to time constraints, one of the 47 companies interviewed were unable to complete the quality compliance questionnaire.
 - The lack of sufficient and up-to-date pricing, mark-up, product availability, and market share data for each country was a common constraint and there was less data available for medical devices than pharmaceuticals.

2 Market Overview

This portion of the report includes country profiles, market archetypes identified, and the market structure.

- **Country profiles:** Covers size of countries and markets for pharmaceutical and medical devices including mark-ups and pricing.
- **Market archetype:** Attributes including size, pricing policy, expenditure, ease of doing business, and how these translate to the three defined market archetypes referred to in the relevant section.
- **Market structure:** Information about wholesaler and distributor companies interviewed including the broad market, such as the number of registered companies and single vs. multi-country presence.

2.1 Country Profiles

2.1.1 Country statistics

The size, structure, and composition of a country's health commodity market can help determine the strength of its health product wholesalers and distributors. Larger private-sector markets with greater demand for high-margin branded products are more profitable, making larger wholesalers more likely to emerge. The chart below summarizes key country indicators which provides the context within which the private-sector wholesalers/distributors operate.

Table 1. Summary of Country indicators

INDICATORS	KENYA	NIGERIA	SENEGAL	TANZANIA	UGANDA
Population (2018)	51.39 million (m)	195.87m	15.85m	56.32m	42.72m
Population growth	2.3% annual	2.6% annual	2.8% annual	3.0% annual	3.7% annual
Area	580,400 sq.km	923,800 sq. km	196,700 sq. km	947,300 sq. km	241,600 sq. km
GDP (2018)	US\$ 87.91b	US\$ 397.27b	US\$ 24.13b	US\$ 57.44b	US\$ 27.48b
GDP growth	6.3% annual	1.9% annual	6.8% annual	5.2% annual	6.1% annual
Health expenditure (2016)	4.55% of GDP	3.67% of GDP	5.51% of GDP	4.14% of GDP	6.17% of GDP
Domestic private exp (2016)	44.4% of health exp	76.67% of health exp	59.3% of health exp	22.96% of health exp	43.01% of health exp
Out-of-pocket exp (2016)	27.7% of health exp	75.21% of health exp	51.8% of health exp	21.89% of health exp	40.32% of health exp
Health commodity market size (2017)	\$660m	\$1,720m	\$230m	\$425m	\$360m
Local pharmaceutical manufacturing market share	25%	30%	10%	16%	10%
Local medical device manufacturing market share	10%	0%	0%	0%	0%
% split between pvt/donor/govt (2016)	50/35/15	75/15/10	60/10/30	20/70/10	35/40/20
Health spend per capita (2016)	\$66.2	\$79.3	\$52.6	\$35.5	\$37.61
Pharmaceutical spend per capita (CIF/EXW)	\$10.4	\$8.4	\$12.7	\$6.7	\$4.9
Medical device spend per capita (CIF/EXW)	\$2.2	\$0.6	\$2.1	\$0.8	\$1.1

GDP, population, area, health expenditure, out-of-pocket expenditure data source: World Bank. **Market size data source:** UN Comtrade. **Proportion of local manufacturing source:** UNIDO Country reports, UN Comtrade export data. **Split between pvt/donor/govt source:** AfRx Consulting analysis for The Future of Global Health Commodity Procurement.

2.1.2 Market sizes

To calculate the sizes of the various health commodity markets, the team used data from UN Comtrade and considered the value of local manufacturing taken from secondary literature sources.

Pharmaceuticals

India is the largest source of pharmaceuticals for the five countries in this study, accounting for 38% of imports in 2017, with France second at 29%, followed by China with 8% of pharmaceutical imports. Overall growth of the importation of medicine was slow between 2012 and 2017, with a compound annual growth rate (CAGR) of 4.2% during 2012–2017. However, there are differences at the country level. While the Nigerian market has grown at a CAGR of 7.2%, the Kenyan market has shrunk, with a CAGR of -1.5% during 2012–2017.

Figure 1. Source and Growth of Pharmaceutical Imports into the Five Countries

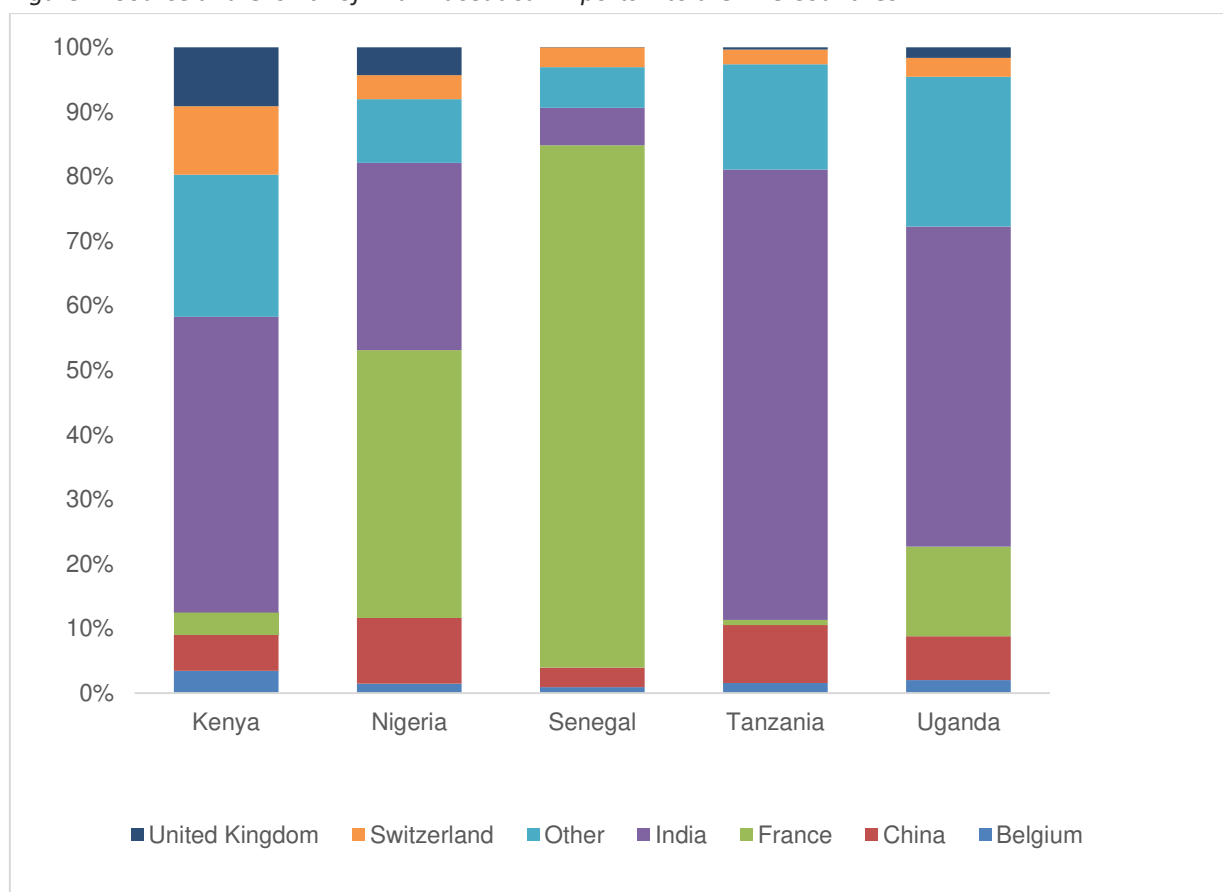
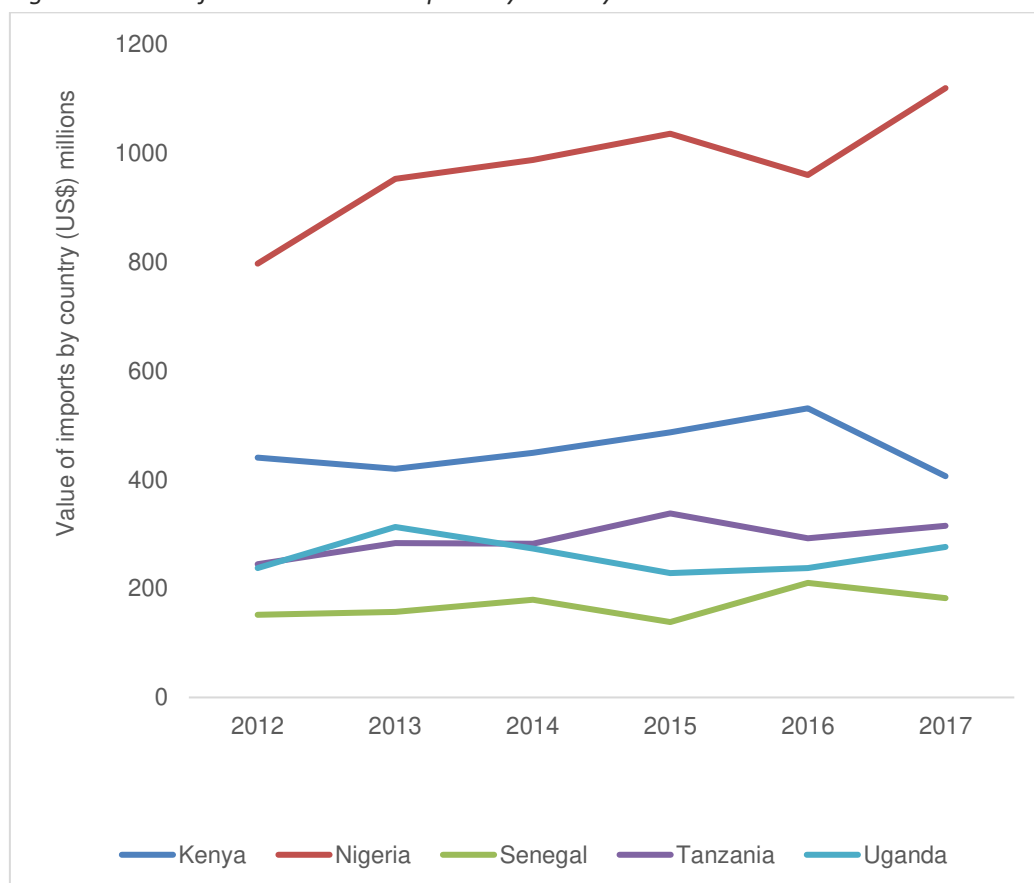


Figure 2. Value of Pharmaceutical Imports by Country



Pharmaceutical imports from India include donor-financed health products. However, examining the Indian export data also shows a significant market for India-manufactured generic medicines in the private sector. Additionally, though it is not captured in these data, there is a significant flow of active pharmaceutical ingredient (API) from India and China to the African continent for local manufacturing because no APIs are produced locally.

The Senegalese market is an exception to the Indian export dominance rule, with France accounting for 81% of pharmaceutical imports. Senegal's market is structured differently, with large Paris-based wholesalers aggregating demand across many Francophone countries. For example, EuroPharma (€1.47bn pharmaceuticals sales in 2018, 39% to French West Africa)² procures more annually than the total value of health commodities in Senegal, Cote d'Ivoire, and Cameroon combined. EuroPharma has significant aggregated buying power and can achieve price-volume savings. This procurement structure could be considered for other regions, though the question of whether price-volume savings reach the patient needs further investigation.

² <http://www.eurapharma.com/en/keys-figures> accessed 26.09.2019.

Medical devices

China, accounting for 28% of all imported medical devices in 2017, is the largest source of medical devices for the five countries in this study, with Germany second at 11% of imports, followed by India with 8%. Overall, the importation of medical devices, with an average CAGR of 1.9%, did not grow fast during 2012–2017. However, there are differences at the country level.

Figure 3. Source and Growth of Medical Device Imports into the Five Countries 2012–2017

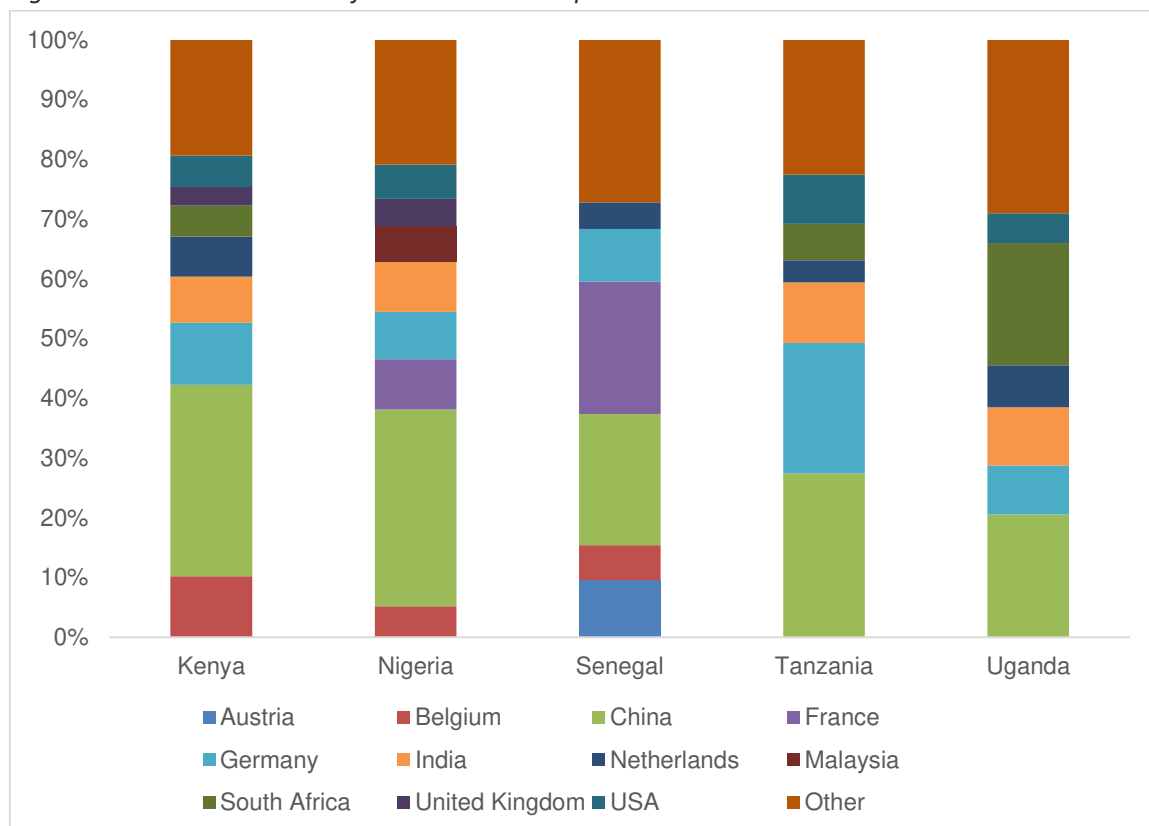
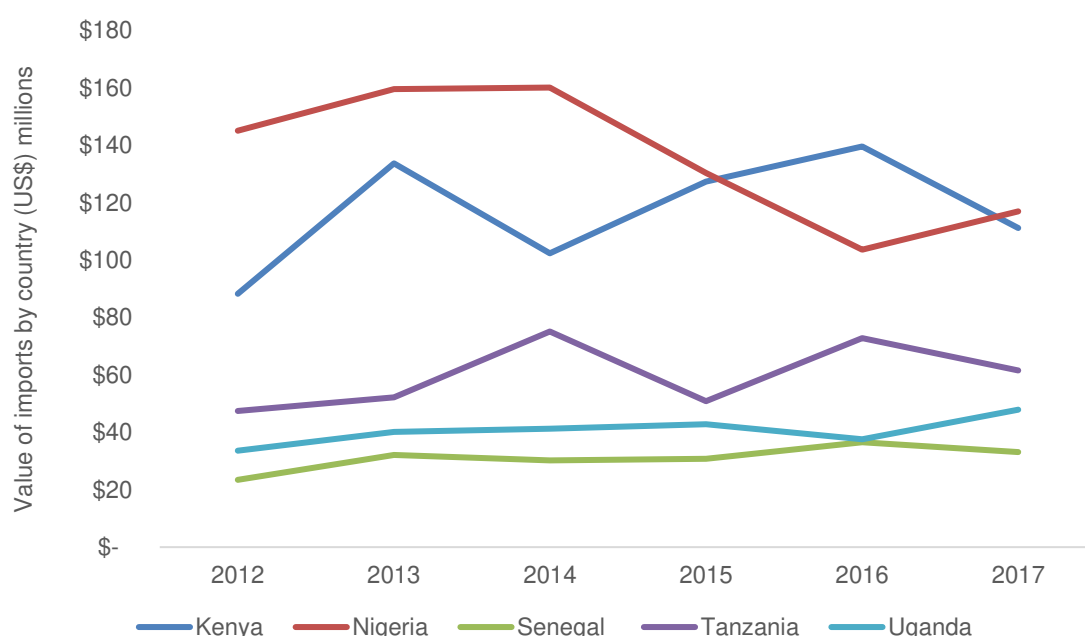


Figure 4. Value of Medical Device Imports by Country



2.1.3 Pricing and mark-ups

Market structure and level of consolidation in the private sector determine economies of scale and levels of efficiency that are achievable by private wholesalers. The team used secondary literature reviews of pricing and mark-ups for pharmaceuticals to estimate the average cost of the private supply chain for pharmaceuticals in the countries examined. In each case, the total mark-up of the private supply chain is largely a function of the level of consolidation in the market, with Senegal having the lowest average for-profit supply chain mark-ups and Nigeria the highest. There was no secondary literature on the average supply chain mark-ups for the medical device wholesale and distribution sector.

While Senegal has legislated fixed mark-ups on pharmaceutical products, the other four countries in this study do not set fixed mark-ups at the point of health commodity retail and wholesale. In effect, there is a free pricing environment regulated by competition between the wholesalers, manufacturers, and retailers. It is therefore difficult to estimate the final price to patient, though the literature review indicated that supply chain mark-ups in the private sector of all these countries are higher than they are in Senegal.

Table 2. Per Capita Assumed Average Private Sector Mark-up

Country	Kenya	Nigeria	Senegal	Uganda	Tanzania
Value of private sector health commodity market at CIF/import price^{3,4}	\$330m	\$1,290m	\$140m	\$126m	\$85m
Level of consolidation in the pharmaceutical for-profit-private sector supply chain⁵	Medium	Low	High	Medium	Low
Estimated average for-profit-private sector mark-up for imported pharmaceuticals	126% ⁶	227% ⁷	60.5% ⁸	164%	202% ⁹
Per capita private expenditure on health commodities assuming average for-profit-private sector mark-up	\$14.18	\$22.20	\$14.22	\$7.79	\$4.56

Typical for-profit mark-ups in the supply chain help explain why such a large proportion of total health care expenditure is added to the cost of health products in these countries. This observation is born of information obtained during the desk review in which data from the National Health Insurance Fund in Kenya and the National Health Insurance System in Ghana show that medicines account for 40% and 50% of total health insurance claims, respectively.¹⁰

Though regulation of private-sector mark-ups can control prices, it can also have undesired effects. Fixed mark-ups encourage the dispensing of more expensive branded medication to maximize profits at the point of wholesale and retail. For example, if mark-ups are fixed at 18%, a wholesaler would be incentivised to sell a \$20 product over a \$10 product. Alternatively, tiered price mark-up systems in South Africa and Morocco have been shown to promote low-cost generic medicines over higher-cost branded generics or innovator product alternatives.

Similarly, fixing medicines prices at the point of importation may encourage prices to be set higher. With the fluctuation in API prices, fixing price at the point of registration will not allow for adjustment in medicine cost. This may encourage companies to set their prices higher to avoid becoming unprofitable if API costs increase.

Based on the desk research conducted, the team determined that certain market factors, indicated in the table below, influence the affordability, availability, and quality of health products in the private sector.

³ UN Comtrade, UNIDO country reports on local manufacturing capacity.

⁴ Split between pvt/donor/govt sourced from AfRx Consulting analysis for working group on the Future of Global Health Commodity Procurement.

⁵ See 2.2.1 for evaluation of market consolidation in the private pharmaceutical sector.

⁶ Report by IMS Institute and IFPMA found average private sector mark-ups in Kenya for pharmaceuticals to be 400% (Understanding the Pharmaceutical Value Chain 2014). HAI report from 2004 found average mark-up to be 322% for a locally manufactured medicines and 227% for an imported generic in the private sector (HAI medicine prices in Kenya 2004). This project used a more conservative estimate based on reported mark-ups from wholesalers, importers, and sub-wholesalers, as well as average mark-ups from Maisha Meds data.

⁷ Due to a lack of more recent studies on the supply chain mark-ups of Nigeria's private sector, this report used figures from Medicine Prices in Nigeria: The Prices People Pay For Medicines.

⁸ Senegal legislates fixed health commodity prices with fixed retailer and wholesaler mark-ups.

⁹ Unfortunately, there is no recent literature on medicine price composition in Tanzania. A paper from 2004 specified that "For an imported generic medicine, the cost price in the private sector represents 42% of the final price with wholesale and retail mark-ups accounting for 16% and 23% respectively. Clearance costs account for 4% and import tariffs represent 15% of the final price charged to patients." (HAI medicine prices in Tanzania). Now that medicines in Tanzania are VAT- exempt, the team removed import tariffs from cost structure.

¹⁰ Notes of meeting DFID informal technical discussion, 17 October 2019 (Barriers and opportunities for improving access to medicines in developing countries).

Table 3: Factors that Influence Pricing and Mark-ups

Consolidation	Across all sectors, efficient distribution favors consolidation and vertical integration. ^{11,12} Economies of scale in procurement, warehousing, logistics, and last-mile distribution reduce costs. With competition, if cartels can be avoided, lower prices should be passed to the patient. In most developed markets, the private sector is responsible for all health commodity distribution.
Competition	Healthy competition is essential to ensure that cost-savings are passed down the supply chain; too much competition results in fragmentation of the market and higher prices, thus striking a balance is important. Data collected as part of this project show that pharmacies operating in smaller towns are more likely to charge higher mark-ups, likely due to less competition and bigger % mark-ups on lower-priced generics.
Regulation	Regulation has controlled patient price and mark-up in the private sector in some countries, including South Africa and Morocco. It has also contributed to supply shortages in others, particularly in more remote areas. Policy can facilitate or stifle private-sector competition and consolidation. In Tanzania, policy has led to consolidation of the private wholesale market. In Kenya, consolidation is more difficult to achieve due to wholesalers being unable to sell to unregulated (hence illegal) market vendors.
Finance	Access to affordable finance affects the final price of health commodities, especially durable medical devices; factors include the cost of capital and the speed of the credit cycle. Finance can also inhibit competition. Established wholesalers that have more working capital or are part of an international conglomerate have an advantage over newer, smaller firms.
Availability	Health commodity shortages (public or private markets) increase prices; thus better demand forecasting and data are needed to reduce national- and facility-level stockouts. Better inventory and consumption data at all levels of the supply chain is required.
Quality	Private wholesalers view quality assurance/monitoring as the responsibility of regulators and civil society. Though many have adopted formal quality management systems, it does not extend to regular quality testing.

Through the interviews, the team learned that durable medical device manufacturers are more likely than non-durable medical device and pharmaceutical manufacturers to appoint an exclusive wholesaler/distributor for each country. As a sector, the durable medical device market may be harder to consolidate if companies don't want partners to distribute competitors' products.

The average durable medical device wholesaler/distributor also has fewer customers than the pharmaceutical wholesaler/distributor. These wholesalers/distributors sell only to hospitals and clinics, while pharmaceutical wholesalers must reach thousands of pharmacies. Durable medical device suppliers typically have fewer warehousing requirements, as most stock is made and shipped to order. Thus, a smaller wholesaler/distributor with an exclusivity agreement incurs fewer inefficiencies than a similar pharmaceutical wholesaler/distributor, and there is less benefit in consolidation.

Another factor that influences the affordability, availability, and quality of durable medical devices is that most of the equipment requires specific technical skills for installation and maintenance. Interviews with

¹¹ Yadav P; Barton I. "53" - Strengthening of Pharmaceutical Wholesalers in Africa. Working paper; 2012.

¹² Carlton D, Perloff J. Modern industrial organization. Harlow: Pearson; 2014.

durable medical device distributors revealed a large co-investment between distributors and manufacturers to develop in-country technical skills to install and maintain these devices.

These factors result in little downstream fragmentation in durable medical devices, because the distributor is responsible for final delivery and installation so no sub-distributors are used. The exception may be the supply of consumables, but even this is mostly undertaken directly by the distributor. The lack of fragmentation because of the downstream ownership by the distributor, as well as the full services required to be offered by the distributor, result in higher mark-ups. However, because devices are not sold to sub-wholesalers, the delivered product price remains competitive.

2.2 Market archetypes

The study compared the similarities and differences across five country markets and determined which factors affected the private wholesale/distributor sector in each. Using the outputs from the country assessments, the team classified the five focus countries into three subsets of market archetypes, indicated in the table below.

While recognizing the unique attributes of each country's health commodity supply chain, the archetypes enable broad categorization and discussion on the challenges faced across market type, based on the findings from the in-country visits. These archetypes are not exhaustive and do not capture all market types in Africa. The archetypes apply to both pharmaceutical and medical device products with one exception; the medical devices wholesalers in Senegal are closer to archetype 2 than archetype 3.

	Archetype 1 [Kenya, Nigeria]	Archetype 2 [Uganda, Tanzania]	Archetype 3 [Senegal]
Market Structure	Large, developing markets (private sector-driven)	Emerging markets (donor-dependent)	Centralized markets (Europe-based sources)
	High QMS standards and scale	A handful of wholesalers with the capabilities and geographic reach to distribute products	Highly professionalized wholesalers with limited competition and high entry barriers for competitors
	Significant consolidation of the private sector (importation)	Human resources for supply chain management need strengthening	Regulated fixed mark-ups encourage the sale of more expensive, branded medication
	Fragmented as product moves to the last mile (lack of traceability)		Fixed medicine prices at the point of importation may encourage prices to be set higher
	Maturing regulatory environment		Regulators only register products that have been approved by a stringent regulatory authority
	High levels of local production, compared to other African peers		Limits on the establishment of corporate pharmacies in urban areas result in lack of chain pharmacies and focus on urban areas by existing pharmacists means rural areas are underserved
Partnership Potential	Multiple partners for governments and manufacturers	Limited partners for governments and manufacturers	Limited but highly developed partners for governments and manufacturers

The only exception to the table above, is for durable medical devices in Senegal. These wholesalers/distributors have more of the characteristics of Archetype 2 rather than Archetype 3. These durable medical device wholesalers/distributors are far less developed than the pharmaceutical wholesalers/distributors interviewed. One major difference between the two is that the medical device wholesalers/distributors are locally owned and operated while pharmaceutical counterparts are multi-national.

Common challenges across all archetypes include:

- Access to affordable **financing** was a common challenge across all market archetypes except corporate-financed pharmaceutical wholesalers. Finance has a direct effect on the price of medicines to patients through high interest rates and protracted credit cycles that increase the operating costs of both importers and wholesalers.
- The **regulatory environment** was a common challenge across markets, though often for different reasons. Regulation affects the quality of medicines in the market and the rules for importation, wholesale, and retail, which are capable of affecting the structure of the market and incentives for wholesale.
- Poor private-sector **market data visibility** limits supportive policy development and contributes to market uncertainty, which potentially increases the cost of doing business. In Kenya and Senegal, the company IQVIA has established a private-sector audit of the pharmaceutical wholesalers, but more data visibility is needed to improve private-sector transparency on products, price, availability, and quality.

2.3 Market Structure

2.3.1 Market landscape

Most pharmaceuticals are imported by a small subset of companies that control the market at the point of importation. As observed through the interviews, these companies primarily sell to sub-wholesalers and lose visibility of their products once they move beyond the first level of the supply chain. It is in the last mile of delivery that the private supply chain often fails and where large mark-ups are added, limiting access to these products in harder to reach, and less profitable areas.^{13,14,15}

Except for Senegal, each country investigated in this report had hundreds of registered pharmaceutical and medical device wholesalers. The low barriers to registering a wholesaler/distributor came up consistently as a potential explanation for the large number of wholesalers. Low registration fees may also limit the ability of regulators to visit wholesalers, particularly those outside major urban areas. Table 4 shows the number of wholesalers and distributors identified through this study.

Most medical devices are imported by a larger subset of companies that control the market at the point of importation. These companies primarily sell directly on to clinics and secondary and tertiary hospitals. As they are often responsible for the installation and maintenance of equipment they do not lose visibility of the product in the market. We observed that during the last mile the failures in the supply chain are more likely caused by lack of trained staff to operate the machinery, maintenance issues, reagents, a lack of spare parts and inadequate budget allocations by health facilities for the running costs of machinery.

¹³ Based on Maisha Meds data showing higher mark-ups in small pharmacies outside major urban areas.

¹⁴ Making the Pharmaceutical Market Work For The Poor. P. Yadav (2018). TANZANIA.

¹⁵ Distribution of wholesale pharmacies in Uganda and Tanzania when mapped against geography shows significant clustering around major urban areas.

Table 4. Wholesalers/Distributors, by Country

Country	Number of pharma wholesalers	Number of medical device wholesalers	Source
Kenya	404	324	Pharmaceuticals: Pharmacy and Poisons Board of Kenya (PPB) interview in 2018 Medical devices: Medpages data
Nigeria	577 importers 1,298 wholesalers	Unknown 35 in Medpages data	Primary care network (PCN) Nigeria: Shared for top line use only Medical devices: Medpages has limited coverage in Nigeria
Senegal	6	64 identified	Pharmaceuticals: Interviews and literature review Medical devices: manual search of corporate database
Uganda	455	19 identified	Pharmaceuticals: National Drug Authority Website 2019 Medical devices: Medpages data and Asoko data
Tanzania	177 (down from 292 in 2009)	331	Pharmaceuticals and medical devices: Tanzanian Food and Drug Authority – though some may have expired licences

Not all wholesalers/distributors have an equal role in the market. In Tanzania, “over 40 of the 300 registered pharmaceutical wholesalers/distributors contributed to 80% of the market share”.¹⁶ Based on the revenues reported by the largest pharmaceutical wholesalers interviewed in Kenya, the top six importers account for 60–70% of the private market at ex-works/customs insurance and freight prices. Senegal is the most concentrated market of those assessed, with only five operating pharmaceutical wholesalers, of which the top two, Laborex and Cophase, held a market share of 71% in 2014. In Nigeria, a 2008 report showed that Worldwide Commercial Ventures had “an 80% market share of the ethical pharmaceutical (original branded products) market,” though today there appears to be more competition and fragmentation, particularly in the generic market segment. A USAID report from 2016 observed that, “Uganda has 16 large distributors and an equivalent number of warehousing entities. Many of them are part of the donor supported private ARV supply chain such as Medical Access Uganda Limited and the Uganda Health Marketing Group.”¹⁷ They procure, store and distribute essential medicines and health supplies for all sectors.”¹⁸

The project team was unable to calculate the market concentration of the largest wholesalers in Nigeria, due to a lack of available information and because some of the larger players were less forthcoming about their market share or revenues. Nigeria has 577 medicine importers, in addition to 1,298 registered wholesalers. Visits to Nigeria indicated that the market is more fragmented at the point of importation than the other markets studied. In the 2018 Indian export data, there were more than 1,000 unique Nigerian consignee companies importing medicines and medical devices, indicating fragmentation and the likelihood that many companies import medicines illegally.

¹⁶ Making markets work for the poor - P Yadav 2018 for Global Financing Facility and MM4H

¹⁷ In 2018, USAID terminated funding to Uganda Health Marketing Group over fraudulent activities.

¹⁸ Exploring partnership opportunities to achieve universal health access 2016 - Uganda private sector assessment in health.

Generic medicines accounted for 93% (Tanzania) and 76% (Uganda) of pharmaceuticals respectively in 2017.¹⁹ Conversely, Nigeria, Senegal, and Kenya have larger private sectors with a higher proportion of sales generated from originator brands. European- or U.S.-manufactured generic medicines hold a market share of 66%, 60%, and 71% respectively.

Tanzania is the only country in which the number of wholesalers is decreasing. This is a result of regulatory changes, including the adoption by the government of a prime vendor model (PVM), that have severely limited the ability of private wholesalers to sell to the public hospitals and clinics. The PVM allows public facilities to buy from only one supplier, meaning that the remaining wholesalers are only able to serve 20% of the market, resulting in a rapid consolidation of the market. Due to the Tanzanian government's revised policies, Tanzania experienced an increase in the importation and consumption of generic medicine, according to the 2017 UN Comtrade trade data. Greater control over decentralized procurement through the PVM seems to have reduced the opportunity for inefficient procurement of original brands at the district level.

The literature review indicated prevalence of private wholesalers selling to the public sector in Kenya, Nigeria, and Uganda. This is a concern in Nigeria, where public-sector health commodity prices in studies have been found to be similar to private sector prices and there is little international tendering for health commodities by the State Ministries of Health.^{20,21,22}

Although no literature on the market concentration of the durable and non-durable medical device sector was available, it was observed that in countries with large pharmaceutical wholesalers (Kenya and Nigeria) there were large and developed medical device wholesalers. Often these larger wholesalers were responsible for selling both pharmaceuticals and medical devices. The one exception was Senegal, where the large wholesalers of pharmaceuticals were not involved in the sale of medical devices, and the sector had more small and fragmented players as a result. In Tanzania and Uganda, the revenues and QMSs of medical device wholesalers were less developed, in line with their status as emerging regions for private wholesale.

2.3.2 Regional market players

The following health commodity wholesalers were identified as having a presence in one or more countries in sub-Saharan Africa. Because business turnover is indicative of reach, companies are listed according to their approximate annual revenue. Estimated revenues, geographic reach, and portfolio are based on findings from Asoko Insights, Indian export data, and secondary desk research. Data from interviews were triangulated with those from the literature review to produce the below table. Not all these companies were interviewed as part of this project, so the strength of all their QMS is not known, though higher revenues correlated with better QMS systems.

¹⁹ UN Comtrade data.

²⁰ Indian export data show little public procurement of medicines direct from India.

²¹ World Health Organization & Federal Ministry of Health, Nigeria. (2010). Access to and Rational Use of Medicines at the Facility Level.

²² Medicine prices in Nigeria: the prices people pay for medicine (2006). DfID, WHO and GoN.

Table 5. Regional Wholesalers/Distributors

Company name	Revenue band	Countries with direct operations	Core portfolio
Europharma (Laborex)	\$500m+	Mauritania, Mali, Burkina Faso, Gambia, Cote d'Ivoire, Ghana, Benin, Togo, Nigeria, Niger, Chad, Cameroon, Equatorial Guinea, Gabon, Rep. of Congo, DRC, Angola, Zambia, Tanzania, Rwanda, Burundi, Kenya, Uganda, and Mozambique	Branded and generic pharmaceuticals
Imperial Health Sciences	\$500m+	South Africa, Botswana, Zambia, Malawi, Kenya, Nigeria and Ghana. Rwanda, and Uganda indirectly via Surgipharm subsidiary.	Branded and generic pharmaceuticals
Ubipharm (Cophase)	\$500m+	Owner of 15 subsidiaries in Africa including Congo, Senegal, Gabon, Mali, Burkina Faso, Niger, Cameroon, Togo	Branded (Planet Pharma) and generic (Ubigen) pharmaceuticals, non-durable medical devices (Labell)
Clicks Group Limited	\$500m+	South Africa, Namibia, Botswana (United Pharmaceutical Distributors), Swaziland, and Lesotho	Core business is retail pharmacy but also wholesale of branded and generic pharmaceuticals
Dis-Chem Pharmacies Limited	\$500m+	South Africa, Namibia, and Botswana	Core business is retail pharmacy but also wholesale of branded and generic pharmaceuticals
CERP (Bretagne Atlantique)	Not available	Mali, Senegal, Guinea, Mauritania, Chad, Niger, Cameroon, Cote d'Ivoire, Benin, Togo, Congo, Gabon, Burkina Faso	Branded and generic pharmaceuticals and medical equipment all French approved
Phillips	\$50–100m	Dubai corporate office owns operations in Kenya, Tanzania, Uganda, Rwanda, Zambia, and Nigeria.	Branded and generic pharmaceuticals
Harleys	\$50–100m ²³	Direct operations in Kenya, Tanzania, and Uganda	Branded and generic pharmaceuticals, durable and non-durable medical devices
Crown	\$50–100m	Direct operations in Kenya, Tanzania, Uganda, Rwanda, Nigeria	Durable medical devices, non-durable medical devices, and unbranded generics
Shalina	\$25–50m	Nigeria, Ghana, CAR, Rep. of Congo, DRC, Benin, Kenya, Liberia, South Sudan, Zambia	Branded and generic pharmaceuticals, non-durable medical devices
Avacare	\$25–50m ²⁴	Kenya, Senegal, Zimbabwe, Namibia, Botswana, Zambia, South Africa, Tanzania, Ethiopia, Nigeria (Healthline)	Branded and generic pharmaceuticals, durable and non-durable medical devices
Abacus	\$10–25m	Also a manufacturer but has wholesaler operations in Uganda, Kenya, Tanzania, Burundi, and Rwanda	Branded and generic pharmaceuticals, non-durable medical devices
Prince	\$10–25m	Angola, Tanzania, Congo, DRC, and Guinea	Branded and generic pharmaceuticals
Artemis Pharma	\$10–25mn	Tanzania (KAS Medics Ltd.), Rwanda Swaziland, Zambia, Central African Republic	Branded and generic pharmaceuticals, durable and non-durable medical devices

²³ Revenue estimate not available from Asoko Insight or Indian export data, revenue estimate extrapolated from <https://www.devex.com/organizations/harley-s-limited-83687> accessed 23.10.2019.

²⁴ Estimate based on number of corporate acquisitions.

Company name	Revenue band	Countries with direct operations	Core portfolio
Astra Pharma	\$10–25m	Tanzania, Uganda, Kenya	Branded and generic pharmaceuticals, non-durable medical devices
Medhold Medical (Pty) Limited	\$10–25m	South Africa, Zambia, Mozambique	Durable medical devices and non-durable medical devices
Guinee Pharma S.A.	\$10–25m	Guinea, Guinea Bissau, Senegal, Gambia, Mali, Sierra Leone, Cote d'Ivoire, and Ghana	Branded and generic pharmaceuticals
Opham Limited	\$10–25m	Madagascar and Mauritius	Branded and generic pharmaceuticals, non-durable medical devices
Bluepharma	\$10–25m	Angola and Mozambique	Branded and generic pharmaceuticals, non-durable medical devices
Kamoso Distribution	\$10–25m	Botswana, South Africa, Mozambique, Namibia, Zambia, and Zimbabwe	Branded and generic pharmaceuticals, non-durable medical devices
Tecmed Africa	\$10–25m	South Africa, Kenya, Namibia, Zimbabwe	Durable medical devices and non-durable medical devices

Source: Asoko Insights data, Indian export data, secondary desk review.

2.3.3 Regulatory and policy

While specifically reviewing national regulators was beyond the scope of this project, it became clear through the interviews that regulators, regulations, and national policy affect the five focus countries. The observed factors were diverse across the countries. One key theme is that pharmaceuticals are overwhelmingly more regulated than medical devices in every country, with only Kenya advancing medical device regulations.

Other cross-country themes include strong support from regulators for local manufacturing, wholesalers in major urban areas subjected to more regulatory scrutiny than rural-based wholesalers, and ongoing regional and continental regulatory harmonization efforts. The following are key regulatory and policy elements that influence the market:

- Kenya: PPB actively supports parallel imports. Pharmacists may own more than 1 pharmacy but must be on the license. Policy encourages opening pharmacies in rural areas.
- Nigeria: Nigeria National Drug Agency (NAFDAC) focuses on product quality initiatives for testing and pharmacovigilance. Doctors can legally dispense. Importing certain finished products is restricted to support local manufacturing. Seven years ago, the government introduced legislation to establish regional “mega-distributors.” While this has not been enacted, it concerns the local market players.
- Senegal: From a policy perspective, Senegal is the most regulated market of the five focus countries, with prices and mark-ups regulated by the government and established at point of product registration. The market largely self-regulates because the national regulatory authority capacity is low. There is an informal (“gray”) private market for pharmaceuticals.
- Tanzania: Rigorous and lengthy regulatory pathway for pharmaceuticals is not transparent. The Medical Stores Department (MSD) is the exclusive supplier to all public facilities. MSD buys directly from the manufacturers (no wholesalers sell anything to MSD). In addition, MSD has

mandated that should it be unable to supply products, so health facilities must buy through a government-nominated prime vendor (PV). Each region has an appointed PVs, but a company can be the PV for up to five regions. Two of the companies interviewed are PVs.

- Uganda: “Buy Uganda Build Uganda” drives wholesalers to manufacture. Product registration is tightly controlled.

While this study did not focus on regulations or regulators, the team received consistent feedback from all interviewees of their effect on business. The above factors have shaped the private wholesalers/distributors’ strategies in several ways, including which product categories they focus on representing (branded vs. generic); their commercial relationships with the government medicine procurement agencies (a smaller part of their business than initially anticipated and overall not a desirable client); the use of sub-distributors to “remove” private wholesalers/distributors from the process of delivering to unregulated dispensaries, which results in less product traceability; and the exit of commercial players from products that are locally produced and supported by government medicine procurement agencies.

2.3.3 Finance

A common theme throughout the interviews was the effect of finance on businesses, specifically the cost of capital, and the fact that public-sector clients do not pay in a timely manner.

Finance charges from annual percentage rates range from 14.5% in Kenya to 34% in Nigeria. The companies most affected by these costs are small and lacking cash reserves to finance imports from their own treasury and so must borrow from commercial banks. Most wholesalers interviewed leverage the credit terms secured from their overseas suppliers. Wholesalers that belong to larger groups, such as those described in Senegal, are less affected by this issue as most of the procurement takes place overseas where interest rates are much lower. This means that companies that can fund procurement of imported goods with their own money have a significant advantage over those that need to borrow money commercially.

Table 6: Cost of Finance

Country	Annual Percentage Rate
Kenya	14.5
Nigeria	27–34
Senegal	16.3
Tanzania	18
Uganda	26

Local government medical stores pay to suppliers is unreliable and poor. On average, wholesalers wait 180–360 days to receive payment from government customers. As a result, most of the companies interviewed limit their involvement in government tenders or increase margins to compensate for delayed payments. Late public-sector payments therefore increase public-sector procurement prices.

3 Wholesaler Assessments

3.1 Market Players

Representatives from 47 companies across all five countries were interviewed using questionnaires designed to obtain in-depth understanding of business maturity, market dynamics, and quality compliance. The questionnaires contained closed and open-ended questions and were interviewer-led. Interviewees were permitted to skip questions that they deemed confidential. With interviewee permission, the team sent follow-up emails requesting copies of product catalog or financial information.

BUSINESS MATURITY AND CAPABILITIES CATEGORIZATION PFASCM assessed a variety of factors, including years in business, revenue, number of employees, customer profile, interest in expansion, attitude toward overall quality, and ability to absorb investment, and used the results to place each company in one of the three following categories:



Maturity Level 3 - Performing with a stable, well-functioning, and profitable wholesaler business. Typically, these companies have a strong understanding of regulatory requirements, demonstrated commitment to quality, and capacity to achieve required certifications. They are represented in all regions within their country or working toward expanding geographic reach both within their country and those in the region, often with multiple warehouses or offices across the country. These companies have the potential to absorb investments and scale-up in a short timeframe to become leaders in their market.



Maturity Level 2 – Evolving with an effective and functioning wholesaler business. These companies have sound business principles and good understanding of the market. They have made substantial investments in their infrastructure and technology to streamline their business processes and improve service quality. They handle most distribution in the capital and may outsource for other regions in the country. They are confronted by internal and external challenges that hamper business expansion. Nevertheless, these companies show steady growth, prioritize value-added services, and are prepared to invest to improve the quality of their service.



Maturity Level 1 – Developing with limited elements of business processes in place and significant room for improvement, specifically in infrastructure and compliance with regulatory requirements. Procedures for key operations need to be established and personnel to oversee implementation and manage risks hired. While they focus on increasing profits, they lack initiatives to offer additional services and engage with other parties/sectors to reach underserved areas. While their business models are successful, they need coherent well-integrated systems and tools to expand geographically, improve service quality, and achieve cost efficiencies and financial sustainability.

Table 6 categorizes all 47 companies that participated in the survey. As agreed with all participants, each company name was anonymized and assigned a simple internal key that lists each wholesaler/distributor by country (i.e., Kenya = KE; Nigeria = NG; Senegal = SN; Tanzania = TZ; Uganda = UG) and number. Of the 47 companies interviewed, 24 (51%) were categorized as Level 3 and 11 (23%) were categorized as Level 2. Level 3 companies were identified in all countries with the highest number being in Nigeria.

Table 6: Wholesalers/Distributors Categorized by Level and Country

Country	Number of companies interviewed	Level 3	Level 2	Level 1
Kenya	12	KE3, KE7, KE8, KE11, KE12	KE1, KE2, KE5	KE4, KE6, KE9, K10
Nigeria	14	NG3, NG4, NG5, NG6, NG7, NG8, NG9, NG10, NG12, NG13, NG14	NG2	NG1, NG11
Senegal	6	SN2, SN5	SN1, SN4	SN3, SN6
Tanzania	8	TZ1, TZ3, TZ8	TZ2 TZ4 TZ5	TZ6, TZ7
Uganda	7	UG3, UG4, UG6	UG1, UG2	UG5, UG7

3.2 Priority Products

A set of 11 priority products were identified. These products (Table 7) were of interest to both the Gates Foundation and PFSCM, which had specific procurement experience of these products sourced from some of the interviewed wholesalers. Priority pharmaceutical products were selected based on price/unit, data availability in number of observations, median price ratio, therapy area, financing, level of use in the health system, and acute vs. chronic condition. Priority medical devices were selected based on price/unit, electricity requirements, durability, level of use in the health system, personnel who can operate/administer, financing, and consumables.

Table 7. Priority Products

Pharmaceutical products	Medical devices
<ul style="list-style-type: none"> • Amoxicillin • Artemether lumefantrine • Metformin • Co-trimoxazole • Atorvastatin • Oxytocin 	<ul style="list-style-type: none"> • Latex gloves • Glucometer • Oxygen concentrator • Ultrasound machine • Malaria rapid diagnostic test kit (RDT)

Each interviewee was asked if his/her company stocked these priority products on a regular basis. Companies that were primarily pharmaceutical wholesalers were likely to stock some or all the non-durable medical devices, while companies that distributed durable medical devices primarily were unlikely to stock any pharmaceuticals. The companies were grouped by primary product (pharmaceuticals, non-durable, and durable medical devices) and secondary product, based on the cost of the durable and non-durable medical devices (high- or low- and medium-cost).

Table 8. Companies that carry priority pharmaceutical products

Country	# of companies by country	# of companies by product					
		Artemether + lumefantrine	Amoxicillin	Metformin	Atorvastatin	Co-trimoxazole	Oxytocin
Kenya	8	7	8	7	6	6	5
Nigeria	8	8	5	6	5	4	4
Senegal	2	2	2	2	1	2	2
Tanzania	7	5	7	7	6	5	3
Uganda	4	4	4	4	3	3	2
Total	29	26	26	26	21	20	16

Table 9. Companies that carry priority medical devices

Country	# of companies that carry medical devices / by country	# of companies that carry low- and medium-cost non-durable and durable medical devices			# of companies that carry high-cost durable medical devices	
		Latex gloves	Malaria RDTs	Glucometers	Oxygen concentrators	Ultrasound machines
Kenya	9	7	4	9	4	5
Nigeria	6	5	5	6	2	6
Senegal	3	2	0	3	3	3
Tanzania	4	3	4	4	2	2
Uganda	4	4	2	3	2	2
Total	26	21	15	25	13	18

Of the 47 companies interviewed, 26 carry durable and non-durable medical devices. No companies in Senegal carry malaria RDTs.

3.3 Differences in Durable Medical Device and Pharmaceutical Wholesalers

According to information from interviews, non-durable medical devices like latex gloves are often sold in a similar manner to pharmaceuticals. However, there are significant differences in the supply of durable medical devices:

- Gross mark-ups of durable medical device wholesalers tend to be higher than pharmaceutical mark-ups because of aftersales costs, maintenance, and possibly finance costs.
- Customers for pharmaceuticals are different than medical devices:
 - In Kenya, there are about 500 major clinics and hospitals and more than 5,000 pharmacies. Managing the supply of medicines across this number of clients is a significant logistical challenge.
 - Facility-based medical device use is still nascent and home-based medical device use is practically non-existent. Pharmaceuticals are sold to health facilities and pharmacies that sell directly to individuals.
 - Medical devices are sold to a smaller number of customers in part because the total number of customers is lower (most devices are used on multiple patients rather than a

1:1 relationship as with drugs). The market is still developing, and uptake remains limited with less potential customers.

- Distributors benefit from buyers having a poor understanding of the total cost of medical devices and mark-ups are at times a dramatic reflection of this asymmetric knowledge.
- Individual-use durable medical devices (like glucometers) could be sold at pharmacies given their low cost/direct to consumer sales.

“Selling pharmaceuticals and medical devices is like selling petrol and cars. You need both to treat a patient, or to drive, but the way you sell them is totally different.” –Kenyan medical device wholesaler

- Medical device manufacturers are more likely to contract exclusively with a wholesaler in a market, while pharmaceutical suppliers might have an exclusive distribution deal but also use a multitude of wholesalers to distribute. A key distinction is that brand manufacturers tend to engage in exclusive contracts, whereas “me-too” medical device manufacturers (generic equivalent) work with several wholesalers to increase volume.
- Regulation of medical devices across all markets was much weaker than pharmaceuticals. While product registration may be required, regulatory oversight including quality assurance review was not observed in the project focus countries.
- Literature, market studies, and survey data on medical devices were much weaker than those on pharmaceuticals.
- Financing is more of a problem for Small Medium sized Enterprises (SME) clinics looking to purchase durable medical devices. Due to the high upfront cost of the products that take years to pay for themselves, the financing needs for durable medical devices are very different than for pharmaceuticals. This makes it difficult to compete with (large) companies that don’t have this constraint.

3.4 Access and Human Resources

Human resources for wholesalers was called out as an issue in a few countries and in some contexts. In Tanzania, the literature and interviews with regional and local companies indicated that finding qualified staff was a challenge.

A reoccurring theme across all markets was the limited number of qualified pharmacists, which often resulted in private-sector outlets like pharmacies being concentrated in urban areas. To fill this gap in demand, market traders sell pharmaceuticals to underserved communities. In Nigeria, Uganda, and Tanzania there are programs—the Accredited Drug Dispensing Outlets (ADDO) and patent and proprietary medicine vendors (PPMV)—to formalize, license, and control these “chemical sellers.” However, in Kenya and Senegal, similar programs do not exist, and informal market vendors are referred to as “quacks.”

As the larger, reputable wholesalers comply with local legislation, they do not sell directly to these “chemical sellers” but rather to sub-wholesalers, who in turn supply other wholesalers or pharmacies that

supply grey market pharmacies. During this informal process, product quality and price becomes less visible and risks associated with unregulated markets increases, potentially allowing sub-standard and counterfeit medicines to enter the supply chain. PFSCM's study identified various market interventions to remedy this problem; these are discussed in Section 6.

Another significant risk for entry of counterfeit and sub-standard product is parallel trade of health commodities. Parallel trade is legal in these countries under the TRIPS agreement and can drive down drugs prices, particularly for high-cost original brands. However, it can also lead to unforeseen consequences in the private sector, such as overstocking and expiry, and can compromise the security of the supply chain and introduce perverse incentives into the system. In more developed regulated markets, track and trace systems to prevent the insertion of falsified medicines into the supply chain have been implemented. Regulators in Kenya and Ethiopia are investing in the introduction of product barcode technology to mitigate this problem.

3.5 Distribution

The use of courier services of third-party logistics (3PLs) enables wholesaler/distributor to increase geographic reach. 3PL services are particularly important in Kenya and Nigeria, where they don't just carry pharmaceutical and medical device products but also ship goods across the country. In Kenya, the 3PL geographic reach of G4S, Wells Fargo, and DHL ensures that the entire country can receive deliveries within 24 hours. By distributing a wide range of commodities, they are able to offer cheaper and more regular deliveries of goods across the country, though cold chain products often need to be shipped in a cold box and as 3PL trucks are rarely equipped with refrigeration. Cultivating 3PL partners in developing markets like Uganda and Tanzania could reduce logistics costs across all sectors, not just health care. In addition, the use of 3PLs allow centrally operated wholesalers/distributors to deliver directly to their end customer which removes the need to sell product through sub-wholesalers and increases overall supply chain visibility. Durable medical device wholesalers are required to install and commission machines directly at their customers' sites, they make use of 3PLs, especially in areas outside of the cities.

4 Quality Management Systems

Although a full quality audit was not part of the study scope, the interview questionnaire had a quality assurance component. Specifically, interviewee compliance with national regulatory requirements was reviewed, quality manuals examined, and, where permitted, operating facilities were toured. In general, all organizations in or near the capital city, and therefore within proximity of the national regulator, met the local quality requirements. This was not always the case for companies with primary operations outside the capital. The degree to which the interviewees exceeded the local standards was related to size, how long they had a quality management system in place (i.e., its maturity), whether they distributed pharmaceuticals and/or medical devices, and the financial position of the organization. Table 10 shows how the grading methodology ranked each organization's QMS.

Table 10. Country Assessment of QMS Maturity

Country	Key factors	# of companies interviewed for quality compliance	Overall QMS maturity		
			Level 1	Level 2	Level 3
			Developing	Evolving	Performing
Kenya	Varying levels of QMS; some are ISO 9001-certified, including most of the larger players	11 (1 company not interviewed)	2	2	7
	Rely on PPB for supplier prequalification; occasional on-site inspection of manufacturers				
	Quality control testing a challenge because of high costs and long wait times				
	Conversant with GDP requirements				
Nigeria	Quality units in place, regulatory authority well equipped to enforce compliance	14	0	12	2
	Two wholesalers have reached high enough levels of QMS standards to work with USAID				
Senegal	Quality units in most companies with pharma quality standards consistently high and ISO certified	6	1	3	2
	Varying standards of QMS implementation in medical device companies				
Tanzania	Varying levels of QMS; some are ISO 9001-certified and others are now working towards ISO certification	8	1	3	4
	Rely on Tanzania Food and Drug Authority (TFDA) for supplier prequalification and registration, and product sampling, testing				
	Recent requirement to have pharmacovigilant qualified person on staff				
	Shortage of HR and skills for QMS systems				
Uganda	Variable quality; some are ISO 9001-certified	7	0	5	2
	Rely on NDA for supplier prequalification- no system for prequalifying customers				
	Conversant with GDP requirements				
	Growing importance of pharmacovigilance				

5 Country Market Interventions

Table 11. Market interventions

Intervention	Description	Kenya	Nigeria	Tanzania	Senegal	Uganda
Organizing/legalizing drug shops	A network of legal medicine shops to which wholesalers may sell their products have increased access to medication in rural areas. Currently there are over 6,000 registered ADDOs in Tanzania; 5,000 out of a possible 21,000 drug shops registered are registered in Uganda, and 200,000 PPMVs operating in Nigeria.			✓		✓
Mobile payment	Mobile money platforms (e.g., M-PESA) make the transfer of payment between customer and distributors easy and efficient. This has resulted in wholesalers being able to take orders from smaller pharmacies and extend credit to a wider client base.	✓				
Group purchasing and point-of-sale business management systems	Downstream coordination of demand across medicine shops that procure through the same wholesaler(s) at higher volumes. This model has led to lower medicine prices for pharmacies, better understanding of credit risk, lower rates of medicine stockout, better data visibility and improved business management skills.	✓				
Above-market wholesaling	Regional wholesaler that aggregates demand from country wholesalers and provides bonded warehousing for manufacturer(s). This model has been successful because it: a) offers manufacturers one commercial transaction across multiple geographies; b) carries a bond store allowing for single import from manufacturers and export to multiple markets; and 3) improves the overall visibility of sales across multiple markets from manufacturers.	✓			✓	
Medical device supplier financial TA	Distributors provide technical support to hospitals and clinics to complete bank loan applications and create business case for purchasing durable medical devices. This reduces the credit risk associated with SME health care commodity loans.	✓				
Medical device pool of bioengineers	A firm in Senegal is servicing durable medical devices with a pool of biomedical engineers who are trained on a variety of machinery from different manufacturers. This reduces the operating costs of wholesalers and could improve maintenance response times.				✓	
Remote monitoring of medical equipment	Sensors on medical devices allow long-distance monitoring of functional status and timely service provider response in the case of device failure. This has reduced device downtime.				✓	
Manufacturer-led distribution	Companies develop direct sales models to end-users for specific products in selected markets to promote uptake, often used for high-value, low-volume products such as oncologics.		✓		✓	

Of these innovations, the team highlighted four that appear to have had a positive effect on the markets where they are prevalent and could be expanded in their countries or adopted in other countries. Further research is required.

- **ADDO program:** A recurring problem across countries is that there are not enough pharmacies or medical facilities in rural communities. Creating a formal program and giving vendors basic training has potential to set and monitor quality standards. Furthermore, giving these facilities

legal status allows larger and more reputable wholesalers to sell to these outlets, which they previously could not do legally.

- Group purchasing or supra-national private sector pooled procurement: As highlighted in the recent Center for Global Development procurement report,²⁵ pooling procurement can ensure product quality, lower costs, and provide manufacturers with aggregated demand, which would be especially useful in smaller markets. This has traditionally only been applied to public procurement but private wholesalers may also benefit.
- Above-market wholesaling: This model aims to be a “one-stop shop” for manufacturers that wish to have their products available in smaller markets but cannot justify establishing or maintaining an in-country presence. The above-market wholesale model allows manufacturers to contract one organization that will procure the product from the manufacturer, appoint multiple in-country wholesalers to sell the products, manage the financial transactions, and take the risk, in exchange for each country wholesaler providing its product sales data to the above-market wholesaler. The contractor also provides in-country demand-creation services to clients that require it and incentivizes downstream distributors to provide data on a regular basis. Currently, the model is intended to represent a multi-national pharmaceutical manufacturer across six East African markets, with ambitions to expand to Western and Southern Africa in 2020.
- Managed Devices Equipment Services: This Kenyan program used private contractors to supply durable medical equipment, reagents, maintenance services, and aftersales to 98 hospitals. In addition, these companies assumed the risk and responsibility of procuring, installing, maintaining, and replacing equipment, and were to be held accountable to a performance monitoring system to guide payments.

²⁵ Tackling the Triple Transition in Global Health Procurement. Centre for Global Development (2019).

6 Implications and Opportunities

While respecting the nuance and complexity of the different countries, this project has identified a number of opportunities for intervention that could improve access to medicines and medical devices. These interventions, which are explored in more depth in the country reports, aim to improve access to health products via the private sector and facilitate opportunities for importers and wholesalers to support public health goals across all markets.

Finance: Most companies interviewed for this project, with the exception of those that were part of large international conglomerates, said that the cost of capital was a major challenge to their operation and a hindrance to growth. Favourable debt financing has the potential to influence private wholesaler behaviour. A possible structure for this would be if lower-cost debt was availed for importation of low-cost unbranded generics. Debt financing could then be linked to a quality testing and a pharmacovigilance program to increase faith in unbranded generic quality in the market and drive sales. Alternatively, lower-cost debt could be extended to small- and mid-sized hospitals and clinics for the purchase of durable medical devices, possibly through an existing vehicle such as Pharmaccess' Medical Credit Fund. Currently, the way that many importers and wholesalers validate the credit worthiness of new clients is to discuss their operations on informal communication channels such as WhatsApp. A credit reference bureau to track late payment and default by facility across wholesalers would reward facilities that pay bills on time and might accelerate the credit cycle and reduce credit-based overheads. With the penetration of mobile money in these markets, there is an opportunity to use new technologies to achieve this and lower barriers to credit.

Regulation of medical devices: Developments in advanced economies including the U.S., European Union, and India in recent years indicate the need for streamlining the registration and regulation of medical devices. The absence of a policy or regulation defining the required QMS for medical devices limits a country's ability to manage the quality of devices and the operations of distributors that supply these devices. Local lessons from managing pharmaceutical product licensing and quality management must be applied alongside global trends to inform the classification, registration, and distribution requirements for medical devices.

Public procurement reform: Across all the markets investigated, with the exception of KEMSA in Kenya, wholesalers remarked that working with the public sector was difficult because the government almost always fails to pay bills on time. Many expressed that they were not that interested in working with the government and that the cost of services to the public sector must be inflated compensate for likely late payment.

Senegal and Tanzania have already undergone some level of public procurement reform with the introduction of the IPM and PVM, respectively, though these initiatives did not focus on on-time payment. The remaining countries could benefit from measures to support public health commodity

procurement. More transparent tenders, on-time payments, shorter tendering cycles, and longer contract lengths could all help entice more private wholesalers to participate in public tenders.

Pre-wholesale and bonded warehousing: A way to reduce the cost of financing across sub-Saharan Africa is for manufacturers to increase levels of vendor-managed inventory. If manufacturers, particularly in pharmaceuticals, are willing to store more product in the region or country, levels of credit required to import shipping containers of product might reduce and shorten the credit cycle, while taking advantage of the fact that corporate bond interest rates in Europe and the U.S. are far below the 14.5%–28% local and 7%–8% US\$ interest rates. In Kenya, PFSCM interviewed Imperial Logistics, which recently acquired a bond store operation and is running a pharmaceutical bond store on behalf of several pharmaceutical manufacturers. Imperial Logistics is running a similar operation in Ghana, where its operation is located in the Free Trade Zone, enabling bonded imports and exports.

Supra-national procurement: Wholesalers like Europharma and Ubipharm are able to aggregate the demand for the private sectors of francophone West African countries. There might be savings available in the private sector if private wholesalers could aggregate the demand for health commodities and move away from distribution-exclusivity deals. This will require shifting the market from a focus on entrenched brands to accepting unbranded or different branded health commodities and would likely need to be linked to a quality assurance program to drive sales.

Better use of technology: Most of the wholesalers interviewed did have an enterprise resource planning system. However, most orders are still taken by telephone, email, or SMS. Their clients have little ability to forecast demand or compare prices on a large basket of goods, and repayment cycles are long, which increases the cost of credit in the system. Systems to link wholesaler enterprise resource planning to facility ordering and stock levels could create a private-sector e-marketplace for pharmaceuticals, helping to reduce stockouts and prices and increase information transparency. In addition, the use of new technologies such as point-of-sales systems can help create real-time consumption data that will have uses beyond the private health commodity supply chain.

Weak capacity for quality assurance: All wholesalers interviewed rely on approval from the national regulator for product quality assurance. Due to the high costs or lack of high-quality facilities in the country, no wholesaler interviewed runs its own quality testing mechanism. If it were possible to reduce or subsidise the cost of batch-testing for health commodities, local wholesalers might invest more in quality assurance that they could use to drive sales. A possible mechanism to increase medicine screening at a lower cost is pre-export quality assurance. Because 80%+ of pharmaceuticals consumed across sub-Saharan Africa come from only six markets, if these countries could test products before export, it would reduce the quality assurance requirements on all 47 sub-Saharan African regulators.

Access to health commodities includes their availability, affordability, and quality. Existing literature for most countries indicated that the private sector had higher medicine availability at facility level than the public sector. Based on the findings of this project, affordability and quality should be the focus of future interventions.

It is clear that many wholesalers/distributors have the capacity to offer high-quality services to companies that want to distribute their products in these markets. In order to strengthen and better support wholesalers/distributors areas future intervention could include access to affordable finance and systems to assist with assessment of credit worthiness, prequalification of medicines and in-country affordable testing facilities, as well as adequate regulatory capacity for both pharmaceuticals and medical devices.

In addition, opportunities exist to better align regulatory policy with the roles and goals of private wholesalers/ distributors, including thoughtful alternatives to the regulation of last mile medicine dispensaries, many of whom are currently unregulated and are serviced via sub-wholesalers, which results in less traceability of the overall supply chain.

Acknowledgement

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Kenya:

- Phillips Pharmaceuticals Limited
- Imperial Health Sciences (IHS)
- Laborex Kenya
- Chemoquip Limited
- Nairobi Enterprises Ltd

Nigeria

- Phillips Pharmaceuticals Nigeria LTD
- World wide Commercial Ventures LTD
- Advance Medisystem
- ISN Products Nigeria Ltd

Senegal:

- AMES

Tanzania:

- Artemis
- Astra Pharma (T) Ltd
- Phillips Pharmaceuticals (Tanzania) Limited

Uganda:

- Surgipharm
- Laborex Uganda

Abbreviations

ADDO	Accredited Drug Dispensing Outlets
API	active pharmaceutical ingredient
ARV	antiretroviral
CAGR	compound annual growth rate
CIF	cost, insurance and freight
DFID	Department for International Development
EXW	ex works
GDP	good distribution practices
GDP	good document practice
GDP	gross domestic product
HAI	Health Action International
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IMS	Institute
ISO	International Organization for Standardization
KEMSA	Kenya Medical Supplies Authority
MSD	Medical Stores Department
NAFDAC	National Agency for Food and Drug Administration and Control
NDA	new drug application
PCN	primary care network
PPB	Pharmacy and Poisons Board
PV	prime vendor
PVM	prime vendor model
QMS	quality management system
RDT	rapid diagnostic test
SME	Small Medium sized Enterprises
TFDA	Tanzania Food and Drug Authority
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
VAT	value added tax
WHO	World Health Organization

Appendices

Appendix A – Reference for Country Landscape and Wholesaler/Distributor Identification

A variety of sources of information were used for each country landscape and identification of wholesalers/distributors. The list below indicates the sources used by country. Some of the specific organization sources used are also indicated.

1. Country Landscape

1.1. Kenya –

PFSCM collected relevant data from the PPB, UN Comtrade, Asoko, Medpages, and Maisha Meds.

- a) Literature review and secondary research to identify large wholesalers in the market.
- b) Input from AfRx based on experience in the Kenyan pharmaceutical market.
- c) Input from PATH on the medical device wholesalers of the Kenyan market.
- d) Asoko Insights input (described below in section 2) for medical device wholesalers came through at the last minute and helped to direct enquiries for medical device wholesalers once the team was in country.
- e) Processed Indian export records to identify largest importer/wholesalers.
- f) Maisha Meds input and secondary research

1.2. Nigeria

PFSCM collected data from the NAFDAC, UN Comtrade, Asoko, and Medpages.

- a) Landscape reviews, to identify significant distributors in the pharmaceutical and medical devices sectors.
- b) Asoko Insights input to identify pharmaceutical and medical devices wholesalers.
- c) Access to leadership based on previous working relationships with PFSCM and its partners.
- d) Verified and prioritized medical device companies based on feedback from PATH and its contacts.
- e) A study conducted by Advantage Health identified key wholesalers/distributors in the market, which enabled the team to cross-check information gathered from other sources, as well as assisting with setting up interviews.

1.3. Senegal

- a) Landscape reviews to identify significant distributors in the pharmaceutical and medical device sectors. This was successful in the pharmaceutical but not in the medical device sector.
- b) Asoko Insights input for medical device wholesalers.

- c) Size and geographic reach of firm, importance of suppliers, product portfolio (whether priority products were carried).
- d) Verified and prioritized medical device companies based on feedback from PATH-Senegal contacts.
- e) Medpages did not have any available contact data for Senegal so was not involved.

1.4. Tanzania

PFSCM collected relevant data from the TFDA,²⁶ UN Comtrade, Asoko, and Medpages.

- a) Number of registered wholesaler premises in Tanzania, and wholesalers with multiple locations outside of Dar es Salaam.
- b) Review of priority wholesalers and importers previously audited by the PFSCM.
- c) Asoko Insight input for pharmaceutical and medical device wholesalers, including some data on estimated revenues and suppliers.
- d) Important wholesalers in previous studies, as highlighted in secondary research.
- e) Indian export data, since 70% of imported commodities originated from India; however this data was less useful for the medical devices sector.
- f) PATH team input on medical devices suppliers, based on their work.

1.5. Uganda

PFSCM collected data from the Ugandan NDA, UN Comtrade, Asoko, and Medpages.

The team identified six companies to interview and designated three as backup (Table 2). The team arrived at this set of nine companies based on:

- a) Number of registered wholesale premises in Uganda.
- b) Number of registered dossiers in the name of the parent company, and the number of dossiers for priority products in-country.
- c) Asoko Insights input for medical device wholesalers came through at the last minute (and thus does not appear in the table below) but helped direct enquiries for medical device wholesalers once the team was in-country.
- d) Following the visit, Indian export data confirmed which companies were the most prolific. This information was not available before the in-country interviews.

2. Specific organizations used for information:

- 2.1. **Advantage Health** is a Nigerian consultancy with a core mandate to address performance improvement in the health care sector with an emphasis on pharmaceuticals. Their services include business plan and market research, training and capacity development, HR management support and recruitment and location analysis.

²⁶During the course of this analysis, TFDA was renamed TMDA, Tanzania Medicines and Medical Devices Authority; removing food and cosmetics from its scope. Its reconfiguration and impact on current operations and processes is yet to be determined. It is referred to as TFDA in this report.

- 2.2. **Asoko Insights** collects private company information for businesses across Africa through a variety of frontline data acquisition channels. Its main clientele are private equity and impact investment companies. Asoko routinely updates its data, including revenue estimations. PFSCM did not publish the Asoko information, but incorporated its findings into the other data sources, which collectively can be used for future validation.
- 2.3. **Maisha Meds**, a point of sale technology company working with clinics, pharmacies, or drug shops and supporting business and inventory management. The system was designed to support offline use, work in power unstable environments, track credit given to patients, facilitate reimbursement and support the pharmacy with demand forecasting and re-ordering.
- 2.4. **Medpages**, a South African company that specializes in collecting and curating lists of contact details for a variety of medical areas across sub-Saharan African markets. Through them, the team accessed contact details and location for a large number of companies, which proved useful.
- 2.5. **PFSCM** -list of priority wholesalers and importers previously audited by PFSCM.

Appendix B

Table 12: Pharmaceuticals

Attributes	Artemether/ lumefantrine (120/20mg)	Amoxicillin	Metformin	Atorvastatin	Co- trimoxazole	Oxytocin
Price/day daily defined dose	Medium	Low	Low	Medium	Medium	High
Number of data observations	High	High	High	High	High	Low
Therapy area	Malaria	Anti-infective	Diabetes	Lipid regulator	Anti-infective	Postpartum hemorrhage
Financing	Subsidized by AMfM (Affordable Medicines Facility – malaria)	Limited public financing for Essential Medicines List (EML)	OOP (out-of- pocket payments) financed	OOP- financed	Public EML /private	Private/ Global Financing Facility financed
Level of use in health system	Health posts	Health posts	Health centers/ pharmacies	Health centers/ pharmacies	Health posts	Hospital
Chronic vs acute	Acute	Acute	Chronic	Chronic	Acute	Acute
Unique characteristics	AMfM funding recently removed for private sector	N/A	N/A	High-priced credence good	Large physical volume/likely locally manufactured	Cold chain required

Table 13: Medical Devices

Attributes	Latex gloves	Malaria rapid diagnostic test kit	Glucometer	Oxygen concentrators	Ultrasound machine
Price/unit	Low <\$5	Low <\$5	Medium (\$5–1,000)	Medium (\$5–1,000)	High >\$1,000 and/or medium (\$5–1,000)
Electricity requirements	No electricity or batteries	No electricity or batteries	Charging required but battery operated	Continuous electricity required	Continuous electricity required OR charging required but battery-operated
Durability	Non-durable/single use	Non-durable/single use	Durable	Durable	Durable
Level of use in health system	Hospitals, health centers and posts	Hospitals, health centers and posts	Hospitals, health centers, health posts	Hospitals, health centers	Hospitals
Personnel who can operate or administer	Lay worker/ community health worker (CHW); nurse/ midwives; clinical officer/ physician	Lay worker/CHW; nurse/ midwives; clinical officer/ physician	Nurse/ midwives; clinical officer/ physician	Nurse/ midwives; clinical officer/ physician	Nurse/ midwives; clinical officer/ physician
Consumables required	No	No	Yes	No	Yes
Financing	Supported by national health and hospital/district budgets	Typically donor-driven; some support from national health budget	Supported by national health and hospital/district budgets	Typically donor-driven; supported by national health budget	Typically donor-driven; supported by national health and hospital/ district budgets

