USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

Quality Considerations of Zambian Wholesalers and Regulatory Authorities to Increase Availability and Access to Quality Maternal, Newborn, and Child Health Products in Zambia

January 2020

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership.

GHSC-PSM is implemented by Chemonics International, in collaboration with Arbola Inc., Axios International Inc., IDA Foundation, IBM, IntraHealth International, Kuehne + Nagel Inc., McKinsey & Company, Panagora Group, Population Services International, SGS Nederland B.V., and University Research Co., LLC. To learn more, visit ghsupplychain.org

Contents

Executive Summary

The USAID Global Health Supply Chain–Procurement and Supply Management (GHSC-PSM) project conducted a rapid assessment of the maternal, newborn, and child health (MNCH) commodities market in Zambia to understand the current capabilities and roadblocks for wholesaling entities to provide quality assured products. The activity combined document review and semi-structured key informant interviews with wholesaler representatives and key government stakeholders to inform the findings. No inspection or quality audits were carried out. Four focal areas—product sourcing, storage, distribution and quality oversight—were identified as critical areas for assessment. Summary findings are further detailed.

The majority of MNCH products and services are provided through the public sector, and as a result, the Government of Zambia is the primary client for wholesalers that supply MNCH commodities. Wholesaler representatives noted challenges in their macro-operating environment, including large and often delayed government payments. Missionpharma Zambia—one of the largest wholesalers in Zambia with robust quality assurance practices—announced that they would be shifting from a fully operational subsidiary in Zambia to a representative office due to large, unpaid government invoices. This will likely result in a gap in the market and will likely have a negative impact the availability of quality-assured MNCH products in Zambia.

When sourcing MNCH products, wholesalers often noted quality as an important consideration; however, some wholesalers in Zambia may not have the capacity to conduct their own audits of manufacturers. They may instead rely upon other, less reliable quality assurance criteria and information, including achievement of WHO prequalification, self-reported certification of WHO Good Manufacturing Practices, Zambian pharmaceutical registration, manufacturer reports from the Zambia Medicines Regulatory Authority (ZAMRA), the number of other countries in which the product is registered, the number of years a supplier has been in operation, and the number and frequency of quality incidences or recalls. Wholesalers with linkages to international wholesalers, such as Missionpharma Zambia, may be better able to leverage resources and best practices that other exclusively domestic wholesalers were not.

Wholesalers interviewed recognized the importance of maintaining good storage facilities and indicated that ZAMRA provides oversight to storage facilities through licensing and inspection. To obtain a wholesaler license from ZAMRA, domestic wholesalers must demonstrate quality storage practices and pass an initial facility inspection by ZAMRA, followed by annual audits. According to wholesalers interviewed, ZAMRA examines the following during inspections: product validity, records, quarantine facilities, hygiene, security, temperature control, and other premise standards. ZAMRA has established quality systems and regulatory frameworks with the aim of ensuring quality

of medicines. In this assessment, inspections were not carried out nor were inspection reports accessed.

Wholesalers indicated that quality maintenance in distribution is a priority. For example, several indicated that products requiring refrigerated storage were transported in refrigerated vehicles and cold storage boxes. In addition, temperature monitoring and data logging equipment are either being utilized currently or prioritized for the future to assure cold chain. Beyond cold chain products, wholesalers mentioned methods to minimize temperature excursions, including destination pre-alerts, morning deliveries, and temperature monitoring.

Overall, this assessment suggests that some domestic wholesalers consider quality as a factor in sourcing. However, with some exceptions, wholesalers in Zambia may not typically have the capacity to conduct their own audits of manufacturers, and instead may rely upon other information that may be less reliable for ascertaining quality which may lead to the inclusion of lower quality products in Zambia. As such, there is significant variation in wholesalers' internal capabilities to ensure quality from sourcing to distribution.

Introduction

Background

This assessment of pharmaceutical wholesalers in Zambia describes the quality systems used by domestic wholesalers in sourcing and supplying MNCH pharmaceuticals. Utilizing Zambia as a case study, the GHSC-PSM project interviewed domestic stakeholders, including: the MOH, the Zambia Medical Regulatory Authority (ZAMRA), domestic wholesalers, and other key supply chain actors.

This report evaluates MNCH stakeholder quality considerations for the domestic MNCH wholesaler market across three dimensions: quality in procurement, quality in storage, and quality in distribution. This report also explores opportunities for continuing to improve the quality of MNCH products sourced by domestic wholesalers in Zambia.

Methodology

The assessment team conducted desk research and a series of in-depth interviews with key stakeholders (primarily domestic wholesalers and pharmacies in Zambia), focusing on eight select MNCH products included on the Zambia Essential Medicines List (ZEML) 2013.[1] Desk research included a review of publications from peer-reviewed, gray literature sources, policy documents, and other relevant Government of Zambia (GRZ) documents to inform an understanding of the wholesaler market landscape, including the regulatory policy environment. Key informant initial and follow-up interviews were conducted in Lusaka and over the phone and consisted of qualitative and quantitative questions spanning a range of topics including: quality assurance practices, supply, demand, sourcing, regulatory environment, pricing, and collaboration. See Appendix 1 for a summary of the documentation reviewed and Appendix 2 for a summary of key informants interviewed.

Supply Chain Overview for MNCH Commodities

The MOH provides governance, oversight and policy development for all supply chain functions undertaken by Medical Stores Limited (MSL), including forecast and supply planning (FASP). The MOH also mandates quality assurance for ZAMRA, the primary pharmaceutical regulatory authority. The supply chain for MNCH products is a hybrid push-pull system, whereby health center kits are procured by the MOH and allocated to health facilities based on population size within the catchment area for each health facility. Health center kits are stored and distributed by MSL to local health centers on a bi-weekly cycle. In addition to health center kits, MNCH products are also procured in bulk. The MOH uses FASP data to inform bulk stock procurements of MNCH products to fill supply needs not met through health center kits.

The MOH maintains lists of essential medicines and tracer medicines. The list of essential medicines guides the prioritization of critical products procured by the MOH. Similarly, the list of tracer medicines supports the monitoring of stock levels by identifying key commodities for facilities and supervisors to monitor stock levels. These key commodities serve as indicator products that, if stocked out, indicate a wider stock out of other products. Table 1 lists the eight MNCH products selected for the purposes of this assessment, indicating which are included on the essential medicines list,[1] in health center kits and on the tracer list.[2] Of the eight selected MNCH products, seven are included on the essential medicines list. Of those seven, five are included on the tracer list and three are included in the health center kits.

Table 1. Overview of Select MNCH Products Supplied through the Public Sector

Select MNCH Product	Essential Medicines List[1]	Health Center Kits	Tracer List[2]
amoxicillin	X (tablets/capsules 250 mg, syrup 125 mg/5 ml)	X 1,000 tablets (non-dispersible tablets, 250 mg)	X 1,000 tablets (dispersible tablets, 250 mg)
7.1% chlorhexidine digluconate solution or gel			
gentamicin injection 40mg/mL in 2-mL ampoule	X		X
magnesium sulfate (injection 500 mg/mL in 2-mL and 10-mL ampoule)	X		
misoprostol tablets, 200 micrograms	X		
oral rehydration salts	X	X (100 sachets)	X
oxytocin 10 IU/mL, 1-mL ampoule	X		X
zinc sulfate tablets 20 mg	X	X (100 tablets)	X

MSL is a parastatal company, established in 1976 under the Companies Act. The MOH grants MSL the mandate to warehouse and distribute health commodities to all hospitals and health centers down to the last mile.[3] In recent years, significant investments have been made to improve MSL's infrastructure, including: the extension of MSL's central warehouse and the construction of regional MSL hubs aimed at addressing last-mile inefficiencies in the supply chain, insufficient storage space, and commodity security. Further, in 2019, the Zambia Medicines and Medical Supplies Agency Bill 13 was ratified by Parliament to establish MSL as the Zambia Medicines and Medical Supplies Agency (ZAMSA) and transfer procurement and supply chain functions from the MOH to MSL. At the time of this assessment, the bill had not been enacted to law.

ZAMRA was established in 2013 by the National Medicines and Allied Substances Act (No. 3) of Zambia. The MOH grants ZAMRA the mandate to regulate and control the manufacturing, importation, storage, distribution, supply, sale, and use of medicines and allied substances.[4]
The MOH procures the majority of public sector MNCH commodities from local and international wholesalers. MNCH commodities are contained in health center kits procured through framework contracts. MNCH commodities are also sourced from local wholesalers and local manufacturers through bulk stock procurements. Beginning in 2020, the MOH plans to adopt an updated kit composition which will contain 39 essential medicines and 20 consumable products, including three of the select MNCH products (amoxicillin, oral rehydration salts, and zinc sulfate). In 2015, the MOH executed a three-year contract with Missionpharma to secure delivery of 90,000 health center kits. As of November 2019, only 58,242 health center kits out of a contracted amount of 90,000 health center kits had been delivered due to outstanding unpaid invoices by the MOH as a result of ongoing funding contraints (interview with Missionpharma Zambia General Manager, Jakob de Rosbo-Sestoft, December 2, 2019; unreferenced). Table 2 below illustrates the annual procurements of health center kits by the MOH from 2016 to 2019. Since 2016, the volume of annual procurements of health center kits have not been sufficient to meet the quantified annual needs of 30,000 health center kits.

Table 2: Health Center Kits Received by MSL, 2016–2019[5]

Calendar Year	# of Health Center Kits
2019	1,739 (donations)
2018	19,941
2017	22,494
2016	20,440

Funding constraints and delays in payment by the MOH to wholesalers have led to stock shortages of health center kits and the accrual of debt owed to wholesalers. Since January 2019, the Ministry of Finance has been unable to disburse funding to the MOH. As such, in May 2019, the GRZ issued a directive prohibiting procurement of health center kits until resources become available, resulting in zero health center kit procurements in 2019. According to one wholesaler interviewed, the Pharmaceutical Business Forum is currently collecting information on the amount of MOH debt owed to wholesalers; it is expected to exceed $150 million by January 2020. In 2019, wholesalers Missionpharma Zambia and Sheline Pharmaceuticals donated a total of 1,739 health center kits to the MOH. This donation represents less than 10 percent of previous annual procurement levels and is not sufficient to meet the planned monthly distributions of 2,500 health center kits.

Pharmaceutical Wholesalers Overview

The primary importers of the eight select MNCH products to both the public and private sectors are wholesalers and domestic manufacturers that also hold importation licenses. In 2019, there were 49 pharmaceutical wholesale outlets included on ZAMRA's published registry.[6] Prior years' published lists contained more than 200 registered wholesalers. In 2017, a new legislation was enacted, requiring wholesalers to reapply for importation licenses. Officials at ZAMRA noted that many wholesalers are in the process of updating their licenses and are not yet included in the 2019 published list.

The majority of wholesalers and pharmacies are based in Lusaka, with the remainder based in the urban centers of the Copperbelt Province and Livingston. In 2019, there were 393 hospitals and retail pharmacies included on ZAMRA's published registry.[6] While the number of hospitals and retail pharmacies is growing, the largest client for wholesalers in Zambia continues to be the MOH. Other primary clients include: public sector hospitals, district health offices, and mining industry facilities.

Supplemental bulk stock MNCH products are also procured by the MOH to fill supply needs not met through health center kits. As illustrated in Table 3, the volume of bulk stock procurements is not enough to fulfill the annual quantified need. From January 2017 to May 2019, data from MSL indicates that amoxicillin, chlorhexidine gluconate solution, magnesium sulfate, misoprostol, oral rehydration salts, gentamicin sulfate and oxytocin were procured in bulk stock. Supply of these products was concentrated among 11 wholesalers. Additionally, small quantities of amoxicillin, oral rehydration salts, oxytocin and zinc sulfate were supplied by donors and local manufacturers. During January through May 2019, $319,266 in supplemental bulk stock MNCH products was procured by the MOH from three wholesalers: International Drug Company, Horizon Pharmaceuticals, and Fongda Corporation. In 2018, $1,037,934 in supplemental bulk stock MNCH products was procured by the MOH from three wholesalers: International Drug Company, Intermed Pharmaceuticals Ltd and Yash Pharmaceuticals Limited. In 2017, $1,145,489 in supplemental bulk stock MNCH products were procured by the MOH from seven wholesalers: Phillips Pharmaceutical, Triple Medicals, Yash Pharmaceuticals, Unimed International, Sterelin Medical, V.L. Pharmaceuticals Healthnet and Missionpharma.[7] Bulk stock procurement of MNCH products were relatively stable in 2017 and 2018. However, bulk stock MNCH procurements in the first half of 2019 represent a decline from 2017 and 2018 levels.

Table 3: Comparison of MNCH Bulk Stock Forecasted Quantities versus Procurement Quantities, 2018[7,8]

Bulk Stock MNCH Product	2018 Forecast (units)	2018 Bulk Stock Procurements (units)
amoxicillin, dry powder for suspension, 125 mg/5 mL	3,170,352	926,800
chlorhexidine gluconate solution	Not forecasted	0
gentamicin injection, 40mg or 80 mg/mL (2-mL ampoule)	1,449,600	21,000
magnesium sulfate, injection, 500mg/ml inj	62,400	0
misoprostol tablets, 200 micrograms	Not forecasted	0
oral rehydration salts	5,000,000	10,000
oxytocin, 10 IU/mL, 1-mL ampoule	532,620	16,030

From January 2017 to May 2019, MSL procured bulk stock products from 11 wholesalers; however, a large percentage of the value of MNCH procurements was supplied by two wholesalers. Notably, from January to May 2019, International Drug Company supplied 47 percent of the value of MNCH products supplied to MSL—the remaining 53 percent was split between Horizon Pharmaceuticals Limited and Fongda Corporation Limited. In 2018, International Drug Company supplied 93 percent of the value of MNCH bulk products supplied to MSL. In 2017, Unimed International Limited supplied 80 percent of the value of MNCH products supplied to MSL. Wholesaler interviews indicated that Unimed International Limited has since pulled out of the Zambian market.

Table 4. Wholesalers Supplying to MSL by Bulk Stock MNCH Product, January 2017–March 2019[7]

Bulk Stock MNCH Product	Wholesaler	
amoxicillin, dry powder for suspension, 125 mg/5 mL	• Yash Pharmaceuticals Ltd. • Intermed Pharmaceuticals Ltd.	• International Drug Company • Horizon Pharmaceuticals Ltd.
chlorhexidine gluconate solution	• Phillips Pharmaceuticals (Zambia) Ltd.	
gentamicin injection, 40 mg/mL (2-mL ampoule)	• Triple Medicals Ltd. • Yash Pharmaceuticals Ltd. • International Drug Company	• Fongda Corporation Ltd. • Unimed International Ltd.
magnesium sulfate, injection, 50% (10-mL ampoule)	• Unimed International Ltd.	
magnesium sulfate, injection, 50% (10-mL vial)	• Yash Pharmaceuticals Ltd.	
misoprostol tablets, 200 micrograms	• Sterelin Medical/Diagnostics	
oxytocin, 10 IU/mL, 1-mL ampoule	• V.L. Pharmaceuticals Healthnet	• Missionpharma • International Drug Company

In addition to responding to tenders conducted by the MOH, interviews indicated that wholesalers monitor and respond to supply gaps at lower-level health facilities, including public sector hospitals and district health offices. Lower-level procurements are intended to respond to supply gaps in emergency situations if products are not available at MSL. Data was not available on the quantities procured through this mechanism.

Operational Challenges

Access to capital was the most significant challenge for wholesalers of MNCH products described during the interviews. Since 2017, payments made by the GRZ have been delayed, or all together halted, resulting in mounting debt owed by the GRZ to domestic wholesalers. No acceptable solution has been reached to reconcile the parties involved. Late payments and non-payments from the GRZ pose an imminent threat not only to smaller, capital-constrained wholesalers, but also to larger, established wholesalers. Without liquid cashflow, wholesalers are unable to procure products for the Zambian market without assuming debt of their own. Such challenges are further exacerbated by currency fluctuations and the continued depreciation of the Zambian kwacha, with a particular impact on international suppliers, typically financed in U.S. dollars. These cash flow constraints, induced by the lack of payments made by the GRZ, have compelled some wholesalers to reevaluate their business models. For example, in November 2019, Missionpharma Zambia announced a reorganization from a fully operational subsidiary in Zambia to a representative office as a direct result of the MOH's unpaid invoices of $12.5 million and the lack of commitment to an organized reimbursement plan for the outstanding balance (interview with Missionpharma Zambia General Manager, Jakob de Rosbo-Sestoft, December 2, 2019; unreferenced). As the primary supplier of health center kits in Zambia, Missionpharma Zambia's reorganization is likely to leave a gap in the market.

In response to the stock out of health center kits resulting from unpaid invoices to Missionpharma Zambia, the MOH initiated an emergency procurement of health center kits in October 2019. Awards were made to three smaller companies: Artemis Pharmaceuticals Limited, Honey Bee Pharmacy, and Pharmanova. These companies have no previously demonstrated experience in supplying health center kits to the GRZ. Additionally, they each quoted ambitious lead times of 16 weeks or fewer, raising concerns regarding their capacities to supply quality products in quantities sufficient to reestablish an adequate and continuous supply of health center kits.

Zambia's limited local pharmaceutical manufacturing base, which consists of six domestic manufacturers, impacts procurement options available to wholesalers. High importation tariffs on active pharmaceutical ingredients (API) have disincentivized domestic manufacturing of finished

pharmaceutical products (FPP). According to Zambia's fee schedule, importation rates are one percent for each API versus 1.5 percent for FPP.[9] From January 2017 to May 2019, the only bulk MNCH products procured from local manufacturers were oral rehydration salts supplied by Pharmanova (Zambia) Limited and zinc sulfate supplied by Pharmanova (Zambia) Limited and Baxy Pharmaceuticals Manufacturing Company.[7] The remaining MNCH products are largely manufactured by international manufacturers and sourced through wholesalers as part of health center kits or bulk stock orders.

Finally, labeling requirements can inhibit capital-constrained wholesalers' purchasing power. ZAMRA's labeling requirements mandate that all imported pharmaceutical products have a product license number printed on the packaging. Since the product license number is specific to Zambia, wholesalers are not able to source partial-batches of medicines with standard labeling. There is, however, some discussion among Southern Africa Development Community (SADC) countries to have a regional registration numbering system to address this challenge. Until there is a resolution, the requirement to procure full batches, even when private sector demand is low, will continue to reduce wholesalers' purchasing power and the availability of products on the market in Zambia.

Regulatory Landscape for Pharmaceutical Wholesalers

The MOH grants ZAMRA the responsibility to regulate imported pharmaceutical products through three mechanisms: wholesaler licensing, product registration, and post-marketing surveillance/pharmacovigilance.

Wholesaler Licensing

ZAMRA is responsible for licensing pharmaceutical wholesalers. Licensing requirements for wholesalers include: application and inspections fees of approximately $500–$1,000;[9] staffed part-time or full-time licensed pharmacist(s); documented standard operating procedures for expired products, recalled products, and distribution; facilities inspection; and demonstrated systems for good distribution practices. Interviews revealed that wholesalers in Zambia operate at varied levels of quality and some entities importing MNCH products into Zambia may not meet the licensing requirements. Large, international wholesalers do meet these requirements and additionally implement processes and systems such as a quality management system, vendor prequalification programs, and sourcing strategies. However, these additional processes and systems are not required to obtain a wholesaler license.

Additionally, for wholesalers to repackage products, they must be granted a pharmaceutical repackaging license by ZAMRA.

Product Registration

For products to be imported into Zambia, ZAMRA, mandated by the MOH, requires that either a registration or a registration waiver be acquired by either the manufacturer or wholesaler. Waivers are granted only on an emergency basis, typically when life-saving products are not available from registered sources. Therefore, the registration process is the primary avenue for products to be imported into the country.

There are several options for wholesalers to register products in Zambia. ZAMRA accepts the Common Technical Dossier, Collaborative Registration Procedure for WHO-prequalified products and is a member of ZAZIBONA. ZAZIBONA is a collaboration between national medicines regulatory authorities in Angola, Botswana, Democratic Republic of Congo, Mozambique, Namibia, South Africa, Zambia and Zimbabwe, established to facilitate access to quality-assured medicines through work-sharing in the assessment of medicines and the inspection of medicine manufacturing and testing facilities.[10] Barriers to product registration of select MNCH products include extended registration approval timelines and limited profit potential given the low unit price of products, associated fees, and small market size. Fees range from $1,700–$2,800 per registration, with annual retention fees of $800 per year. Additionally, full-site good manufacturing practices (GMP) inspection fees for foreign-based manufacturers can range from $1,500 to $7,500.[9]

ZAMRA maintains an up-to-date registry of all registered products, product dosages, and associated marketing authorization holders. Both manufacturers and wholesalers are permitted to hold marketing authorization for a given product.[11] Notably, once a product is registered in Zambia, the product registration does not expire. As such, products that were registered when regulations were less stringent maintain a non-expiring registration and this may allow for substandard products to carry registration. Wholesalers cannot simply rely upon Zambia registration as an indication of product quality since the quality standard conferred by a registration may not be uniform.

Post-marketing Surveillance and Pharmacovigilance

ZAMRA is also responsible for assuring the quality, safety, and efficacy of medicines made available to the Zambian public through post-marketing surveillance and pharmacovigilance activities. ZAMRA receives and processes reports of all adverse drug reactions, adverse drug events, and other drug-related problems and is responsible for follow-up. ZAMRA maintains a schedule for post-market

surveillance, whereby periodically samples are randomly selected for testing. At the time of the assessment, ZAMRA was only testing antimalarials, antiretrovirals and antibiotics for routine post-marketing surveillance because it did not have the in-house capability to test all medicines. The GRZ, with support from the European Union, has invested in a modern, national quality control laboratory that, once operational, will enable more streamlined quality inspections inside the country. Further, interviews suggested that ZAMRA has taken actions to strengthen pharmacovigilance activities in recent years through: the promotion of a public awareness campaign against unregistered products; increased inspection at the borders; auditing products on the market; and auditing records to confirm import authorization.

In 2019, ZAMRA piloted the use of Global Pharma Health Fund Minilabs (GPHF-Minilabs) for testing pharmaceuticals in three provinces. GPHF-Minilabs are rapid field test kits used to verify drug identity and content and to detect substandard and falsified medicines. Samples that do not pass testing are sent to the National Drug Quality Control Laboratory for full pharmacopeia testing. From January 1, 2019 to December 10, 2019, 417 quality tests were performed on 740 medicine samples, across product categories. The GPHF-Minilab system is expected to fully launch in the first quarter of 2020; however, it should be noted that the GPHF-Minilab is limited in the products that it can test.[12] While recent efforts to increase pharmacovigilance are promising, interviews with wholesalers suggested that pharmacovigilance remains a challenge and illegal imports continue to appear in the market.

In January 2019, ZAMRA received 32 suspected reports of ADR to gentamicin injection. ZAMRA sampled suspected stock gathered in-country and sent samples to South Africa for quality analysis. Pending the results of the analysis, ZAMRA quarantined stock at MSL and recalled all stock already distributed. The analysis determined that there were impurities in the product beyond the acceptable range and the product was recalled from the market. ZAMRA's actions leading to the recall of gentamicin injection demonstrates its commitment to assuring the quality, safety, and efficacy of medicines through pharmacovigilance.[13]

While the above are examples of positive actions that ZAMRA has taken to address pharmacovigilance, interviews with the Pharmaceutical Business Forum, as well as wholesalers, revealed that pharmacovigilance needs to be further prioritized. Since ZAMRA does not have a modern quality control laboratory for pharmaceutical testing, ZAMRA does not have the capability to routinely test all pharmaceutical products in country, including MNCH products. This current inability to test for all MNCH products may mean it does not resolve quality issues for MNCH products, including the presence of substandard and falsified medicines.

Quality Considerations

To ensure patient safety and treatment efficacy, the global community acknowledges the importance of quality across the supply chain, from raw materials to distribution. To assess quality in domestic wholesalers within this international ecosystem, three elements of quality were considered.

1. Do the domestic wholesalers source quality products?
2. Do the domestic wholesalers have the storage facilities and quality assurance practices in place to maintain quality while products are in their care?
3. Do the domestic wholesalers verify that quality is maintained in distribution to client entities?

Pharmaceutical products require particular attention for each of these elements. Some MNCH products are WHO-prequalified or approved by a standard regulatory authority, which provides a straightforward, internationally recognized quality benchmark for procurement organizations. In the absence of these approvals, wholesalers indicated that product quality is less certain and requires quality to be assured by other means including national registrations, documentation of WHO GMP, and quality auditing.[14]

Wholesaler Sourcing Decisions

Quality assurance demonstrated by product registration and adherence to GMP was cited by many wholesalers during interviews as a requirement for sourcing. Some wholesalers in Zambia are international wholesaler organizations able to leverage established global quality management systems to source quality products from prequalified suppliers. For example, Missionpharma Group maintains a global team of highly trained auditors who perform over 60 GMP inspections of manufacturers annually. Prior to its reorganization, Missionpharma Zambia received support from Missionpharma Group (Denmark) throughout the procurement process to ensure quality, safety, and efficacy of products sourced. Other domestic wholesalers interviewed do not have the same degree of quality management infrastructure in place. These wholesalers must rely upon a more limited set of evaluation criteria and indicators for the evaluation of products. Such indicators may include: achievement of WHO prequalification, self-reported GMP, Zambian registration, ZAMRA manufacturer reports, the number of other countries in which the product is registered, the number of years a supplier has been in operation, and the number and frequency of quality incidences or recalls. While it is clear that these wholesalers do consider quality as a factor in sourcing, with some exceptions, wholesalers in Zambia may not typically have the capacity to conduct their own audits of

manufacturers, and instead may rely upon other information that may be less reliable for ascertaining quality which may lead to the inclusion of lower quality products in Zambia.

Wholesaler Storage Conditions

To obtain a wholesaler license from ZAMRA, domestic wholesalers must demonstrate quality storage practices and pass an initial facility inspection by ZAMRA, followed by annual audits. According to wholesalers interviewed, ZAMRA examines the following during inspections: product validity, records, quarantine facilities, hygiene, security, temperature control, and other premise standards. Wholesalers interviewed noted that some manufacturers may also conduct their own facility audits on an ad hoc basis. Audits by ZAMRA and manufacturers are positive indicators that stakeholders across the supply chain are taking responsibility to ensure quality.

Wholesalers typically hold inventories, sometimes up to three months. Inventory stock enables wholesalers to create logistics efficiency and to have a competitive edge in quoting shorter lead times to clients. Moreover, the health center kit packing process requires product sourcing with multiple suppliers and storage of supplies prior to kitting. Therefore, MNCH products supplied in bulk or through health center kits are stored for some amount of time by wholesalers and require quality storage facilities, including temperature management and cold storage for oxytocin specifically. Quality storage systems are essential to maintain product quality after sourcing.

Wholesaler Distribution and Traceability Practices

To obtain a wholesaler license from ZAMRA, domestic wholesalers must also demonstrate quality distribution practices. Wholesalers make deliveries to retail pharmacies and private hospitals in urban centers. Some wholesalers report handling delivery entirely in-house with their own fleet of vehicles, while others contract out to delivery partners. Wholesalers indicated that quality maintenance in distribution was asserted as a priority. The cold chain is reported to be maintained through refrigerated vehicles and cold storage boxes. In addition, temperature monitoring and data logging equipment are either being utilized currently or prioritized for the future to assure cold chain. Beyond cold chain products, wholesalers have other methods to minimize temperature degradation, including destination pre-alerts, morning deliveries, and temperature monitoring.

Wholesalers also ensure that their client pharmacies and hospitals comply with quality assurance guidelines to various degrees. Many wholesalers ensure private pharmacies are licensed and possess appropriate storage capabilities. Again, this is a positive sign that wholesalers are assuming responsibility for this facet of quality assurance, supplementing the efforts undertaken by ZAMRA.

Conclusions and Considerations

To ensure excellence in complex, multi-stakeholder pharmaceutical supply chains, robust systems are required to ensure that quality products are procured, quality is maintained in storage, and quality is maintained through distribution. The assessment suggests that, historically, while some domestic wholesalers have developed systems to ensure quality from sourcing to distribution, there is considerable variation in wholesalers' internal capabilities to ensure quality. Resource constraints and lack of proximity to manufacturers (to enable audits of manufacturers) likely contribute to this variability. For example, international wholesaler organizations are able to leverage additional, global resources with regard to quality. Without a connection to a larger international quality assurance system, other wholesalers rely upon ZAMRA, other regulatory systems (a stringent regulatory authority or WHO PQ), and shared audit information to ascertain quality.

Efforts to strengthen ZAMRA's ability to assess pharmaceutical quality is an essential part of assuring drug quality in Zambia. ZAMRA, as mandated by the MOH, has established quality systems and regulatory frameworks with the aim of assuring quality. However, more robust systems, funding consistency and routine enforcement of regulations at scale are required to ensure that all entities importing products into Zambia meet the minimum licensing and product registration requirements, and that all imports and medicines in the supply chain are routinely monitored.

Appendix 1. Desk Review

The assessment team conducted a review of publications from peer-reviewed, gray literature sources to gain an understanding of various activities related to improving the availability and quality of private sector health services and products. Limited documentation exists on private sector wholesalers and distributors specifically.

Below is a summary of the documentation reviewed.

- *Total market assessments for condoms and contraceptives:* Three assessments on condoms and contraceptives have been conducted in Zambia between 2017 and 2019. Common themes and recommendations center on the need to improve the understanding of total market approaches, the urgency to identify champions within the government to lead public-private engagements, and the need to include the private sector in government strategies. All three reports highlighted the need to improve the collection of and use of data from the total market.[15]
- *Analysis of malaria market data in Zambia:* ZAMRA in collaboration with IMS Health established an additional database to collect information on pharmaceutical imports across the public, private, and not-for-profit health providers. The data collected were comprehensive and allowed the researchers to develop a full picture of the anti-malarial medical market in Zambia, including from the private sector. With the data, the researchers were able to identify bottlenecks and drivers that impact the availability of quality medicines. Detailed findings of this activity are available in the publication *A New Approach to Gathering Pharmaceutical Market Data to Support Policy Implementation and Access to Medicines: As Demonstrated by Malaria Medicines in Zambia*. Unfortunately, this data collection was conducted for a limited period and did not continue beyond the end of funding and staff support from IMS Health.[16]
- *Accreditation and regulation of drug shops and pharmacies:* Specifically related to improving the quality of private sector entities, several countries have developed regulations and policies for pharmacies and drug shops. Notably, there is significant documentation on Tanzania's accredited drug dispensing outlet (ADDO) program. The ADDO program model was developed more than 10 years ago to increase the number of high-quality private-sector drug sellers and is still successful to date. Challenges with this program include economic stability and maintaining regular supervision of the drug shops.[17,18]
- *Social marketing models:* Across various countries, social marketing organizations such as DKT International and Population Services International (PSI) work with private sector wholesalers to expand the distribution of their products through existing commercial channels. The model of working with private sector entities is often part of a sustainability

plan for the socially marketed products. The primary challenges of transitioning socially marketed products is to shift from highly subsidized products while maintaining prices at acceptable levels for targeted low-income populations.[19]

Government Documents

The assessment team also reviewed policy documents and other relevant GRZ records and documents to gain an understanding of the regulatory and policy environment.

A list of the relevant documents reviewed is given below.

- *National Health Strategic Plan 2017–2021*
- *Zambia Medicines Regulatory Authority Guidelines for Health Shops*
- *Zambia Medicines Regulatory Authority Guidelines for Wholesale and Retail Outlets*
- *Zambia Medicines Regulatory Authority Guidelines for ZAZIBONA and the Common Technical Dossier*
- *Zambia Medicines Regulatory Authority Guidelines on Applications for Registration of Vaccines and Other Biological Products for Human and Veterinary Use*
- *Zambia Annual Forecasting and Quantification Report for Essential Medicines, Medical Supplies and Family Planning Commodities (2019–2021)*
- *Zambia Essential Medicines List (EML) 2013*
- *Zambia Ministry of Health Tracer List*
- *Zambia Ministry of Health Registers of Pharmaceutical Premises*
- *Zambia Medicines Regulatory Authority Schedule of Fees as per SI No. 38*
- *Zambia Medicines Regulatory Authority Register of Human Medicines (2019)*

Appendix 2. Key Stakeholders Interviewed

One group of key informants interviewed was domestic wholesalers and pharmacies. To inform the sample size, the assessment team obtained the most up-to-date information on domestic wholesalers in Zambia. Given that the majority of wholesalers are within the capital, the assessment was focused in Lusaka. To further narrow the list of assessment participants, the assessment team received importation data from ZAMRA and prioritized outreach to wholesalers who have imported at least two shipments of one or more of the MNCH focus products since 2017. Finally, the team contacted established Zambian wholesalers with significant market presence to participate in the assessment. Several wholesalers declined the opportunity to be interviewed.

The assessment team also interviewed a small number of private pharmacies. These were selected at random among the list of registered entities in Lusaka. Lastly, out of the six registered domestic manufacturers in Zambia, two were selected for interviews based on products manufactured and interest in participating in the activity.

In additional to commercial sector entities, the assessment team interviewed the Zambian Pharmaceutical Business Forum and the Pharmaceutical Society of Zambia, two important civil society groups within the pharmaceutical sector in Zambia. Among relevant GRZ officials, the assessment team held several meetings with ZAMRA and the MOH. The team additionally interviewed GHSC Zambia Field Office staff in order to gain a nuanced understanding of the environment. Finally, the team met with donors, including USAID and the United Nations Population Fund.

Table A1: Key Informants Interviewed

Name of Entity	Type of Entity	Interview Status
Zambia Ministry of Health	Key stakeholder entity	Initial interview
Zambia Medical Regulatory Authority	Key stakeholder entity	Initial interview, follow-up interview
USAID	Key stakeholder entity	Initial interview
United Nations Population Fund (UNFPA)	Key stakeholder entity	Initial interview
Ms. Nchobeni Luundu	Key informant, USAID GHSC Zambia Field Office	Initial interview, follow-up interview
Missionpharma Zambia	Wholesaler	Initial interview, follow-up interview
Sterelin Medical and Diagnostics	Wholesaler	Initial interview
Pharmanova	Manufacturer	Initial interview
Yash Pharmaceuticals	Wholesaler, manufacturer	Initial interview, follow-up interview
NRB Pharma Zambia Ltd.	Manufacturer	Initial interview
Phillips Pharmaceuticals Ltd.	Wholesaler	Initial interview, follow-up interview
Cairo Chemist Ltd.	Pharmacy	Initial interview
Vikay Pharmacy	Pharmacy	Initial interview
Jubilee Chemist	Pharmacy	Initial interview
Zambian Pharmaceutical Business Forum	Key stakeholder organization	Initial interview
Pharmaceutical Society of Zambia	Key stakeholder organization	Initial interview
Melcome Pharmaceuticals	Wholesaler	Initial interview requested
International Drug Life Company	Wholesaler, manufacturer	Initial interview requested; follow-up interview requested
Vyking Pharmaceuticals	Wholesaler	Initial interview requested
Tata Zambia	Wholesaler	Initial interview requested

Shalina Pharmaceuticals Ltd.	Wholesaler	Initial interview requested
Sonjay LLC.	Wholesaler	Initial interview requested

References

1. Zambia Essential Medicines List (ZEML) 2013 [Internet]. Lusaka: Zambia Ministry of Health; c2019 [cited 2019 Dec 4]. Available from: https://www.who.int/selection_medicines/country_lists/zam/en/

2. Zambia Essential Medicines Tracer List. Lusaka: Zambia Ministry of Health (Unpublished).

3. Medical Stores Limited. About Us [Internet]. Lusaka: Medical Stores Limited; c2017. [cited 2019 Dec 3]. Available from: https://www.medstore.co.zm/about-us/company-histroy/

4. Zambia Medicines Regulatory Authority. Functions [Internet]. Zambia Medicines Regulatory Authority. c2016 [cited 2019 Dec 3]. Available from: https://www.zamra.co.zm/functions/

5. Medical Stores Limited. MACS Warehouse Management System [MACS]. Lusaka: Medical Stores Limited (Unpublished).

6. Zambia Medicines Regulatory Authority. Registers of Pharmaceutical Premises [Internet]. Lusaka: ZAMRA; c2019. [cited 2019 Dec 3]. Available from: http://www.zamra.co.zm/registers/

7. Medical Stores Limited. MSL Receipt Data 2017 to date for Selected Products [Excel]. Lusaka: Medical Stores Limited (Unpublished).

8. Zambia Ministry of Health. Zambia Annual Forecasting and Quantification Report for Essential Medicines, Medical Supplies and Family Planning Commodities (2019-2021). Lusaka: Zambia Ministry of Health; 2018.

9. Zambia Medicines Regulatory Authority. Zambia Medicines Regulatory Authority Schedule of Fees as per SI No. 38 [Internet]. Lusaka: Zambia Medicines Regulatory Authority; c2019. [cited 2019 Dec 3]. Available from: http://www.zamra.co.zm/wp-content/uploads/2017/09/ZAMRA-FEES-STRUCTURE-SI-38-2017-.pdf

10. Medicines Control Authority of Zimbabwe. ZAZIBONA Collaborative Medicines Registration Process [Internet].Harare: Medicines Control Authority of Zimbabwe; c2019. [updated 2019 Oct 18, cited 2019 Dec 3]. Available from: https://www.mcaz.co.zw/index.php/latest-news/16-zazibona-collaborative-medicines-registration-process

11. Zambia Medicines Regulatory Authority. Register of Human Medicines (2019) [Internet]. Lusaka: Zambia Medicines Regulatory Authority; c2019. [cited 2019 Dec 3]. Available from: http://www.zamra.co.zm/registers/

12. Zambia Medicines Regulatory Authority. Internal Progress Report 2019 [PDF] (Unpublished).

13. Dr. Chilufya, CH. Status of the Quarantined Gentamed Injection [Internet]. Lusaka: Government of Zambia; c2019. [cited 2019 Dec 4]. Available from: http://www.parliament.gov.zm/publications/all-ministerial-statements

14. World Health Organization. Quality assurance of pharmaceuticals 2019. WHO guidelines, good practices, related regulatory guidance and GXP training materials [Internet]. Geneva: World Health Organization; c2019. [cited 2019 Dec 19]. Available from: http://apps.who.int/medicinedocs/en/m/abstract/Js17659en/

15. Pandit-Rajani T, Cisek C, Dunn C, M. Chanda, and Zulu H. Zambia TMA Landscape Assessment. Boston, MA: USAID DISCOVER-Health Project, JSI Research &Training Institute, Inc. 2017.

16. Coghlan R, Stephens P, Mwale B, Siyanga M. A new approach to gathering pharmaceutical market data to support policy implementation and access to medicines: as demonstrated by malaria medicines in Zambia. Malaria Journal [Internet]. c2018 [cited 2019 Dec 13];17(1). Available from: https://www.ncbi.nlm.nih.gov/pubmed/30497504

17. Riley P, Callahan S, Dalious M. Regulation of Drug Shops and Pharmacies Relevant to Family Planning [Internet]. Bethesda, MD: Abt. Associates; c2017. [cited 2019 Dec 13]; Available from: https://www.shopsplusproject.org/resource-center/regulation-drug-shops-and-pharmacies-relevant-family-planning-scan-32-developing

18. Rutta E, Liana J, Embrey M, Johnson K, Kimatta S, Valimba R et al. Accrediting retail drug shops to strengthen Tanzania's public health system: an ADDO case study. Journal of Pharmaceutical Policy and Practice [Internet]. c2015 [cited 2019 Dec13];8(1). Available from: https://www.ncbi.nlm.nih.gov/pubmed/26413304

19. O'Sullivan G, Cisek C, Barnes J, Netzer S. Moving Toward Sustainability: Transition Strategies for Social Marketing Programs [Internet]. Bethesda, MD: Abt. Associates; c2007. [cited 2019 Dec13]. Available from: https://www.shopsplusproject.org/sites/default/files/resources/4070_file_Sustainability_report.pdf