Procurement and Supply Management

# Quality and availability considerations of wholesalers of maternal, newborn, and child health products in Mozambique

March 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

#### **DISCLAIMER:**

The views expressed in this publication do not necessarily reflect the views of the U.S. Agency for International Development or the U.S. Government.

## **Contents**

Contents	3
Executive Summary	4
Introduction	6
Background	6
Methodology	6
MNCH product scope	6
Mozambican pharmaceutical supply chain: mechanisms, processes, and environ	ment8
Supply chain overview for MNCH commodities	8
Registration	9
Importation	10
Ongoing quality surveillance	11
Pricing scheme for health commodities	11
Domestic pharmaceutical supplier overview	12
Wholesaler association	13
Wholesaler sourcing and procurement	13
Public and private procurement processes impact wholesaler business	13
Government payment schedules impact wholesaler business	14
Insufficient forecasting impacts wholesaler business	14
Patient preferences impact sourcing	14
Transferring stock between entities is difficult and impacts stockouts	14
Quality considerations	15
Wholesaler sourcing	15
Wholesaler storage conditions	16
Wholesaler distribution practices	16
Conclusions and considerations	17
Appendix I. Desk review	18
Appendix 2. Key stakeholders interviewed	19
References	21

#### **Executive Summary**

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project assessed the maternal, newborn, and child health (MNCH) commodities market in Mozambique to understand the capacities and quality capabilities of MNCH wholesalers. The assessment combined document review and semi-structured wholesaler and government stakeholder interviews to generate the findings. No inspections or quality audits were carried out. The assessment focused on four areas—product sourcing, storage, distribution and quality oversight—as critical to understanding the capabilities, opportunities and barriers for MNCH wholesalers. Summary findings are further detailed.

The majority of MNCH products and services are provided through the public sector. As a result, the Government of the Republic of Mozambique (GRM) is the primary client for wholesalers supplying MNCH commodities. Given the critical nature of this relationship, it was important to first understand the basic requirements and environment set by GRM, and then explore how that environment affects wholesalers' ability to provide quality commodities. The wholesaler representatives interviewed noted **challenges in the operating environment**, especially with long, complex, and sometimes confusing processes for importation and registration. Sourcing products from India seemed cumbersome particularly due to additional country of origin testing required by GRM, the cost of which is potentially passed on from manufacturers. Lack of consumer confidence in the quality of products sourced from India also poses challenges for wholesalers.

The use of Portuguese as the primary language in Mozambique impacts wholesalers. For example, translation errors can lengthen review processes, and donated MNCH commodities may require different labeling due to language requirements.

The MNCH wholesalers in Mozambique described barriers and disincentives to wholesalers due to potential **delays in payment, fixed pricing schemes, and long processes.** These issues may limit availability of MNCH commodities at health facilities, especially those further from Mozambique's largest cities.

Wholesalers did include quality as a consideration in sourcing, storage and transportation. They described their efforts to meet established quality standards and supplement manufacturer inspections and testing conducted by GRM. The few wholesalers interviewed who supply oxytocin, which must be kept cold to maintain quality, noted their cold chain capabilities such as air conditioning, cold boxes, and other temperature control mechanisms. These wholesalers were also aware of their responsibility to oversee temperature control through their distribution partners and ultimately to those who would be dispensing the product.

Finally, in light of the challenges noted by wholesalers, the assessment found that the Associação dos Importadores e Produtores de Medicamentos (Association of Importers and Manufacturers of Medical Products (AIPROMEM)) was an important piece of the MNCH supply chain landscape, helping to escalate wholesalers' issues. The Association facilitates information sharing and advocates for fair dealings between the public and private sector. Through these coordination efforts, this Association has the potential to increase wholesaler buy-in to government-led quality assurance processes. International wholesaler associations also provide a shared quality management system for sourcing and conducting manufacturer site visits.

Overall, this assessment suggests that wholesalers experience some challenges in the regulatory environment related to commodity quality. Some domestic wholesalers consider quality as a factor in sourcing, storage, and distribution. Wholesalers in Mozambique typically have the capacity to conduct or coordinate audits of manufacturers. As such, wholesalers demonstrate the internal capabilities to ensure quality from sourcing to distribution.

#### Introduction

#### **Background**

This assessment of domestic pharmaceutical wholesalers in Mozambique describes the regulatory environment in which these wholesalers operate and the quality systems they use in sourcing and supplying MNCH pharmaceuticals. The GHSC-PSM project interviewed domestic stakeholders, including the Direcção Nacional de Farmácia (National Pharmacy Directorate, DNF), Central de Medicamentos e Artigos Medicos (Central Medical Store, CMAM), domestic wholesalers, and other key health supply chain actors.

This report evaluates the quality considerations for the domestic MNCH wholesaler market across three dimensions: quality in sourcing, quality in storage, and quality in distribution. This report also explores opportunities and offers recommendations for improving MNCH product quality when sourced by Mozambique domestic wholesalers.

#### **Methodology**

The assessment team conducted desk research and a series of in-depth interviews with key stakeholders (primarily domestic wholesalers and pharmacies in Mozambique), focusing on ten select MNCH products. Desk research included a review of publications from peer-reviewed articles, gray literature sources, policy documents, and other relevant GRM documents to inform an understanding of the wholesaler market landscape, including the regulatory policy environment. Key informant interviews were conducted in April 2019. Qualitative data were collected using semi-structured, in-depth interviews with stakeholders located in the Mozambican capital city of Maputo. The interview questions focused on supply, demand, sourcing, regulatory environment, pricing, and collaboration. Interviewees included domestic wholesalers, private sector pharmacies, and pharmacies located within private clinics. A summary of the documentation reviewed may be found in Appendix I, and a summary of key informants interviewed may be found in Appendix 2.

#### **MNCH** product scope

The assessment focused data collection and analysis on ten lifesaving MNCH commodities supplied through the public sector in Mozambique. These commodities, presented in Table 1, overlap with the recommended products identified by the UN Commission on Life-Saving Commodities.

Table I. Overview of select MNCH products supplied through the public sector

Recipient	Select MNCH product	Indication
Mother	Oxytocin 5 IU in I-mL injection	Postpartum hemorrhage
	Oxytocin I0 IU in I-mL injection	Postpartum hemorrhage
	Misoprostol 200-mcg tablets	Postpartum hemorrhage
	Magnesium sulfate 500 mg/mL in 2-mL or 10-mL ampoule, injection	Eclampsia and severe preeclampsia
Newborn	Gentamicin 40 mg/mL 2-mL ampoule, injection	Newborn sepsis
	7.1% chlorhexidine digluconate gel	Newborn cord care
Child	Amoxicillin 250-mg dispersible tablets	Pneumonia
	Amoxicillin 250-mg/5 mL oral suspension	Pneumonia
	Oral rehydration salts	Diarrhea
	Zinc sulfate 20-mg dispersible tablets	Diarrhea

#### Mozambican pharmaceutical supply chain: mechanisms, processes, and environment

#### Supply chain overview for MNCH commodities

Mozambique has an estimated population of 29.5 million, and the majority seeks care and treatment in one of the 1,579 government health facilities that all offer free medical services. <sup>2,3</sup> Depending on the severity and condition, patients may seek care at four different types of health facilities: central-level hospitals, secondary provincial hospitals, tertiary district and rural hospitals, and lastly, health centers and health posts. To support this health care delivery structure, the public health supply chain is similarly structured into four tiers, as illustrated in Figure I.

The Ministry of Health (MISAU) typically procures, stores, and distributes a large percentage of MNCH medicines in Mozambique, and most of these products are sourced through domestic wholesalers. MISAU mandates quality assurance for DNF. DNF is responsible for pharmaceutical quality oversight and carries out key regulatory functions, including medicines registration, importation inspection, and post-marketing surveillance. DNF is

Provincial Warehouses

District Warehouses

District/Rural Hospitals

District/Rural Hospitals

Figure I. Supply chain overview

also responsible for the licensing of commercial entities such as wholesalers, manufacturers, and pharmacies. MISAU provides governance, oversight and policy development for all supply chain functions undertaken by the CMAM, including:

- Forecasting and supply planning
- Procurement
- Storage and distribution

The supply chain for MNCH products is divided into two separate procurement and distribution channels: *via classica* and the kit system. It is estimated that roughly 60% of the country's essential medicines are distributed *via classica*, whereas 40% are imported and distributed through kits. *Via classica* is a standard "pull-based" system whereby supply chain managers place orders of MNCH

commodities when stock levels reach a specified threshold. Notably, oxytocin, amoxicillin dispersible tablets, and oral rehydration salts (ORS) are included in kits and are packaged with an estimated 50 other essential medicines.

#### **Registration**

For products to be imported into Mozambique, a registration or registration waiver from DNF must be acquired by the importing entity. An importing entity tends to be either a manufacturer or wholesaler. There are several options for wholesalers to register a product in Mozambique. DNF accepts the Common Technical Dossier (CTD) and Collaborative Registration Procedure (CRP) for WHO-Prequalified products, and recognizes registrations from European Union, Southern African Development Community members states, and Brazil. Registration of a product can also be obtained through ZAZIBONA. DNF is a member of ZAZIBONA, a collaboration between national regulatory authorities in Angola, Botswana, DRC, Mozambique, Namibia, South Africa, Zambia, and Zimbabwe. This collaboration aims to facilitate work-sharing in assessment of products and inspection of manufacturing facilities across member countries. However, Mozambique's participation in ZAZIBONA has been challenging for DNF due to the differences in stringency of national drug regulatory authorities and the differences in official languages among participating countries. Mozambique is one of the few countries in southern Africa that has recognized Portuguese as the official language. As such, all dossiers must be translated into Portuguese. According to the wholesalers GHSC-PSM interviewed, DNF feedback on submitted dossiers is frequently related to translation errors. They also expressed confusion with the various registration format options.

Once obtained, registrations are valid for 5 years. Barriers for wholesalers to obtain product registrations include: limited visibility and feedback from DNF on the status of dossiers and lack of incentives to register products with low profit margins. In Mozambique, only one domestic wholesaler or manufacturer may register a specific product from a specific manufacturer. Registration waivers are commonly granted when non-registered health commodities are deemed urgent. However, the frequent use of waivers has the potential to undermine the regulatory process for maintaining quality medicines.

Of the ten MNCH commodities selected for this assessment, there were 59 active product registrations with DNF as of December 2019. There are 49 registrations for misoprostol, gentamicin, amoxicillin oral suspension, and ORS. The remaining six commodities share a total of ten registrations.<sup>4</sup> A product only needs to be imported once every two years in order for the importer to maintain an active status for the product. Generally, the demand for the injectable products (gentamicin, magnesium sulfate, oxytocin) was concentrated within the public sector because these products are mainly found in public hospitals and not in private sector health outlets.

Table 2. DNF product registrations (December 2019)4

Health product	Registrations
Oxytocin 5 IU in 1-mL injection	3
Oxytocin 10 IU in 1-mL injection	I
Misoprostol 200-mcg tablets	8
Magnesium sulfate 500 mg/mL in 2-mL or 10-mL ampoule, injection	0
Gentamicin 40 mg/mL 2-mL ampoule, injection	8
7.1% chlorhexidine digluconate gel	I
Amoxicillin 250-mg dispersible tablets	2
Amoxicillin 250-mg/5 mL oral suspension	22
Oral rehydration salts	П
Zinc sulfate 20-mg dispersible tablets	3

As illustrated in the table above, oxytocin is mainly registered in 5 IU/mL injections. Since the study was conducted, Missionpharma, a leading global wholesaler for health commodities with a local presence in Mozambique, has been supplying kits (which supply the majority of the country's oxytocin) with oxytocin 10 IU/mL. Missionpharma is seeking registration of the 10 IU/mL presentation and is currently importing the 10 IU/mL presentation with a registration waiver.

#### **Importation**

The importation process in Mozambique can be long and complex. MISAU requires importers to:

- Obtain an importation bulletin (Boletim de Importação de Especialidade Farmacêutica (BIEF));
- Ensure pre-shipment inspections in the country of origin;
- Ensure pre-shipment testing for products originating in India;
- Notify DNF of importation before the shipment arrives in country; and
- Pass DNF inspections at the port of entry.

MISAU has contracted a private company, Intertek, to conduct product inspections at the country of origin. Additionally, MISAU recently contracted Quntrol, an Indian-based laboratory, to sample and

conduct testing on pharmaceuticals manufactured in India. Quntrol's testing lead times vary from two to four weeks, and testing can be conducted concurrently with shipping; however, most wholesalers do not risk shipping products until testing is complete. Quntrol's product testing poses some challenges: (i) lack of clarity regarding alignment of testing practices with international quality standards; (ii) testing being paid by the commodity manufacturer, which may create conflicts of interest. The cost of product testing incurred by manufacturers may be passed on to the wholesaler and, ultimately, the wholesaler's client. Some manufacturers no longer supply products to Mozambique reportedly due to these testing requirements. The final step in the importation process, DNF's physical inspection of products at the port of entry, was noted as often being delayed. As long as the correct, temperature-controlled containers are used, product quality should not be impacted by short delays at the port of entry.

### Ongoing quality surveillance

DNF is responsible for assuring the quality, safety and efficacy of medicines made available to the Mozambican public in part through post-marketing surveillance and pharmacovigilance activities. DNF receives and processes reports of adverse drug reactions, adverse drug events and other drug-related problems and is responsible for follow-up and reporting to the WHO Programme for International Drug Monitoring. DNF has plans to introduce an electronic reporting system to facilitate reporting. However, the rollout of this system has been delayed.

Limited government post-marketing surveillance activities are acknowledged, but may not be carried out consistently. Since government post-marketing surveillance activities are not consistent, some wholesalers conduct their own product testing, report adverse events to DNF, and conduct audits of private pharmacies. These audits may be the only active market surveillance initiatives at times. Limited market surveillance initiatives may allow some commercial entities to operate illegally and source commodities through unapproved means, and thus allow non-quality commodities into the country.

#### Pricing scheme for health commodities

Commodity prices in Mozambique are fixed, based on preestablished percentage markups and calculated based on a wholesaler's BIEF documentation. The BIEF document is completed by the wholesaler with the cost, insurance, and freight (CIF), Incoterm unit price, and additional costs for transportation, warehousing, wholesaler profit margin, and retail profit margin, according to fixed percentages established by DNF in under Ministerial Diploma 21/2017. Once the BIEF is approved, wholesalers are responsible for labeling the product's primary packaging with the unit price, inclusive of the allocated profit margin for retailers. Wholesalers may cover the cost of distribution of

products to clients, except for expedited requests from retail outlets that require extra deliveries or air shipments.

This fixed pricing scheme offers some benefits as it helps control the overall cost of health products and prevents high markups that have the potential to be passed on to patients. However, wholesalers noted several challenges with the pricing scheme. Transportation cost is fixed, regardless of destination, which creates a disincentive for importers to supply products outside of the three main port cities of Maputo, Beira, and Nampula. The volatility in the Mozambican metical currency leads to higher financial risk among wholesalers and pharmacies, discouraging them from maintaining a sufficient stock of products.

#### Domestic pharmaceutical supplier overview

The primary suppliers of the ten select MNCH products to both the public and private sectors are wholesalers. In 2018, there were 161 registered private wholesalers and distributors, with 150 located within Maputo city and the surrounding area. The number of registered wholesalers has significantly increased, from 30 registered suppliers in 2009 to 161 registered suppliers in 2018.<sup>5</sup> Despite the number of officially registered wholesalers, wholesalers interviewed estimated that only 15-20 are currently active and supplying MNCH commodities. All Mozambican wholesalers are fully private commercial entities, with the exception of Medimoc, SA. Founded in 1977, Medimoc is one of the oldest and largest wholesalers operating in Mozambique. Prior to 1999, Medimoc was a fully government-owned entity responsible for importing a large proportion of government products. In 1999, Medimoc was restructured into a parastatal organization, with the government owning 64.72% of the company.<sup>6</sup>

The pharmaceutical manufacturing industry is nascent in Mozambique, therefore the majority of MNCH commodities are imported. Sociedade Moçambicana de Medicamentos, SA (SMM), was the first pharmaceutical factory established in Mozambique in 2008. SMM was established from a partnership between the governments of Brazil and Mozambique and remains a government-owned entity that produces a limited number of essential medicines in tablet and capsule form. Strides Pharma Mozambique, SA, a subsidiary of the Indian-based company, is the second pharmaceutical manufacturer established in Mozambique. Strides produces tablets, as well as oral suspensions, for amoxicillin, co-trimoxazole, erythromycin, azithromycin, and metronidazole for the public sector. Both SMM and Strides operate as importers of active pharmaceutical ingredients in support of their production of finished pharmaceutical commodities. Additionally, these manufacturers may act as wholesalers of finished pharmaceutical products.

The public sector was identified as the largest client for eight of the 15 wholesalers interviewed. MISAU/CMAM contracts for *via classica* products were a primary source of revenue for several wholesalers; additional contracts were obtained from the Ministries of Agriculture, Defense and Interior. In addition to responding to tenders conducted by MISAU, interviews indicate that wholesalers respond to procurement requests from central and provincial-level public hospitals. District and lower-level facilities are not permitted to conduct procurements.

Health center kit procurement contracts have historically been awarded to large, international wholesalers. Cost, registration, and technical advantages are conferred to larger wholesalers when procuring and packaging so many different health commodities at acceptable levels of quality. Missionpharma and IDA Foundation are two predominant suppliers of health center kits in Mozambique. In recent years, the contracts for health center kits have been awarded on an annual basis.

#### Wholesaler association

The Mozambican wholesaler association AIPROMEM was established to advocate for fair and transparent dealings between public health authorities and the private sector to address challenges. These include delayed government payments and difficulties navigating the regulatory process. AIPROMEM has the potential to create healthier markets by smoothing the process for market impediments to be addressed. AIPROMEM influenced Mozambique's Law of Medicines 12/2017 by successfully advocating for the increase of wholesaler profits while maintaining prices for patients. The association facilitates information sharing from the DNF with private sector wholesalers and has coordinated with the Confederação das Associações Económicas (Confederation of Economic Associations (CTA)) at times to petition DNF on the behalf of its members. Despite AIPROMEM's successes, some wholesalers may still default to direct communication with MISAU for their issues.

#### Wholesaler sourcing and procurement

#### Public and private procurement processes impact wholesaler business

The public and private sectors are two major procurement avenues for MNCH products to enter the Mozambican market. Public sector procurements account for the majority of MNCH commodity volumes and are largely sourced through domestic wholesalers. Private sector procurement for supplies to private health shops, pharmacies, and hospitals constitute a smaller volume of MNCH commodities and are also sourced through domestic wholesalers. In order to ensure the quality of MNCH products sourced through the public or private sector, CMAM requires product registration or a registration waiver as well as the following documentation: Certificate of Pharmaceutical Product (COPP); Certificate of Analysis; and documentation detailing Good Manufacturing Practice.

Once commodities arrive in country, samples may be collected and sent to the GPHF-Minilab™, which is a mobile mini-laboratory for rapid drug quality verification and counterfeit medicines detection. GPHF-Minilab™ has the capability to test three MNCH products: amoxicillin, gentamicin, and chlorhexidine.<sup>7</sup>

## Government payment schedules impact wholesaler business

Government payment schedules impact wholesalers' ability and willingness to supply MNCH products to the public sector. Wholesalers interviewed indicated that funding disbursements from the Ministry of Finance are routinely delayed and are insufficient, impacting MISAU's ability to pay wholesalers on time. Additionally, CMAM may prioritize payments to wholesalers supplying critical products, such as vaccines. Several wholesalers interviewed indicated that they no longer respond to CMAM tenders due to challenges posed by delayed payments.

#### Insufficient forecasting impacts wholesaler business

Longer lead times associated with commercial sector demand planning was noted by wholesalers as a challenge. Wholesalers are typically unwilling to keep large stocks of MNCH commodities on hand for the commercial sector because they do not have very much visibility into client needs, and private pharmacies tend to be unable or unwilling to keep stocks on hand. Additionally, private pharmacies do not typically share forecasted demand with wholesalers, and this insufficient forecasting may limit the wholesaler's ability to aggregate demand and unlock economies of scale in procurement.

#### Patient preferences impact sourcing

Patient preferences were noted as a key driver for wholesaler sourcing decisions for the private sector. Reported patient preferences included perception of quality, price, and geographic source (e.g., preference for European and Brazilian sources). According to the pharmacy personnel interviewed, patients seem disinclined to products from India. This preference impacts the sourcing preferences for pharmacies which filters up to the sourcing decisions made by wholesalers and even to manufacturers responding to bids. Some wholesalers indicate that Indian manufacturing partners no longer respond to Mozambican tenders. Generally, products from India are less expensive than those from Europe, and therefore private sector patients must evaluate if the price differential is sufficient to overcome customer preference.

#### Transferring stock between entities is difficult and impacts stockouts

Although stock transfers of donated commodities with some remaining shelf life from wholesalers to MISAU are relatively infrequent, several wholesalers interviewed noted the process of transferring

these commodities can be lengthy and complicated. Delays may lead to more donated commodities expiring and needing to be disposed of, rather than reaching patients. Wholesalers must work with the Provincial Health Directorates, which coordinate with the Department of Hospital Pharmacy, to identify interested public health facilities and coordinate receipt of donated products. DNF and CMAM are consulted for large donations.

Wholesalers must generally source products from manufacturers in full production batch sizes, which are frequently larger than the volume required by a wholesaler's private sector clients. Since Portuguese is the required packaging language in Mozambique, and this is relatively uncommon amongst neighboring countries, sharing production batches is difficult.

#### **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 system, three elements of quality were considered.

- I. 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 stringent 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 Good Manufacturing Practices (GMP), and quality auditing.8 These mechanisms require the support of a strong regulatory system within the country.

#### Wholesaler sourcing

Wholesalers in Mozambique assess the quality of pharmaceutical commodities based on various processes ranging from manufacturer audits to dossier reviews and more unstructured assessments of manufacturer reputation. Certain product documentation, as referenced above, and adherence to GMP are requirements for product registration in Mozambique. Many wholesalers are members of

international wholesaler organizations or have partnerships with international organizations. They leverage these relationships to benefit from shared global quality management systems and manufacturing site visits or audits to further assure the quality of commodities being sourced. Several of the wholesalers not connected to international organizations also visit or audit manufacturers when considering submitting their products for registration. These site audits constitute an assumption of responsibility by the wholesalers to ensure that quality commodities are being sourced.

#### Wholesaler storage conditions

During this assessment, storage and distribution practices were not assessed, nor were facilities inspected—however, qualitative, self-reported information is presented as follows. For private sector commodities, wholesalers typically hold small inventories of stock, usually no more than three months due to risks—such as product expiry—associated with holding larger quantities. For public sector essential medicines kit procurements, international wholesalers are responsible for product sourcing across multiple suppliers and storage and kitting of products prior to international shipment. Current kit suppliers, such as Missionpharma, have reputable quality management systems in place. Of the focus MNCH products, only oxytocin requires cold chain storage. Air conditioning, cold boxes, and other temperature control capabilities were reported by a minority of wholesalers who did actively report supplying temperature-sensitive commodities.

#### Wholesaler distribution practices

The majority of wholesalers are responsible for distribution of MNCH commodities either to government central warehouses or to private retail locations. Wholesalers often make deliveries to destinations near Maputo with their own fleets of vehicles. For destinations outside of Maputo, some wholesalers manage transportation by themselves, while others partner with transporters. Cold chain products were reportedly maintained in the cold chain through distribution by five of the 15 wholesalers interviewed. Some concern was expressed regarding infrastructure and capacity to maintain refrigeration in both the public and private sector health facilities, which could impact the quality of oxytocin in the market.

Wholesalers may also ensure that their client pharmacies and hospitals comply with quality assurance guidelines to various degrees. Some wholesalers do not supply temperature-sensitive products to private pharmacies because they do not generally have the cold storage capabilities. It is a positive sign that wholesalers are cognizant of the quality capabilities of their retail partners.

#### **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 ensured throughout distribution. The assessment suggests that wholesalers providing MNCH commodities in Mozambique are aware of quality standards and the resources required to meet them, and generally have systems in place to maintain commodity quality in each of these areas. However, the wholesalers interviewed cited several challenges to providing quality-assured commodities. These include the presence of illicit pharmaceutical entities that take advantage of the limited nature of post-market surveillance conducted by the Mozambican government. Further challenges include the burden often assumed by the wholesalers in testing, manufacturing site visits, and other steps in procurement, importation and post-market phases.

Given the high market share of domestic wholesalers who supply MNCH products to the public sector, improvements to the public procurement process could support domestic wholesalers in supplying quality MNCH products. Increased visibility and clarity on public procurement plans could be provided to assist domestic wholesalers in planning and forecasting, positioning them better to respond to public procurement tenders.

Additionally, significant opportunities exist to expand the wholesaler association AIPROMEM into a proactive, solution-oriented and standard-setting organization. Association members interviewed expressed interest in improving the organizational structure and learning from successful regional wholesaler organizations. By providing technical assistance that promotes best practices and standards to improve the availability of quality MNCH commodities and facilitating a regional exchange with other wholesaler associations, public-private coordination—to the benefit of all involved—could be improved greatly.

Finally, opportunity exists to tailor the MNCH pricing scheme to the reality of health commodity distribution in country. Wholesalers highlighted that the actual cost profiles are higher for products retailed at rural outlets as compared to urban outlets, limiting their ability to supply rural populations. The pricing scheme could be bifurcated to address product costs for rural locations. AIPROMEM and other key stakeholders could be consulted for input for establishing an equitable pricing scheme which allows adequate incentives for rural coverage of MNCH commodities.

# Appendix I. Desk review

The assessment team conducted a review of publications from peer-reviewed, gray literature sources to develop 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 identified.

- Total Market Assessment for Family Planning in Mozambique: PSI/Mozambique completed a landscape analysis of the family planning market in Mozambique in 2015.
- Regulation of Drug Shops and Pharmacies Relevant to Family Planning: A Scan of 32 Developing Countries. Specifically related to improving the quality of private sector entities, several countries have developed regulations and policies for pharmacies and drug shops.<sup>9</sup> Notably, there is significant documentation on Tanzania's accredited drug dispensing outlet (ADDO) program. The ADDOs program model was developed 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.<sup>10</sup>
- Moving Toward Sustainability: Transition Strategies for Social Marketing Programs: Across various countries, social marketing organizations such as DKT and 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 the shift from highly subsidized products while maintaining prices at acceptable levels for targeted low-income populations.

#### **Government documents**

The assessment team also reviewed policy documents and other relevant GRM documents to shape its understanding of the regulatory and policy environment. Below is a list of the relevant policy documents.

Health Sector Strategic Plan 2014–2019

Mozambique Ministry of Health 2013–2023 Strategic Plan for Pharmaceutical Commodities Logistics

Diploma 21/2017. Boletim da República; Publicação Oficial da República de Moçambique [Pricing Regulations for Medicines]

# Appendix 2. Key stakeholders interviewed

The primary activities of the assessment were a series of in-depth interviews with key stakeholders in Mozambique. The interviews consisted of qualitative questions focused across a range of areas including supply, demand, sourcing, quality assurance, regulatory environment, pricing, and collaboration. A follow-up quantitative questionnaire was sent to participants requesting information on importation and sales data.

The primary informants were domestic wholesalers, private sector pharmacies, and pharmacies located within private clinics. Given the majority of wholesalers are within the capital, the assessment was focused in Maputo. To further narrow the list of assessment participants, USAID/Mozambique coordinated with DNF to prioritize a list of wholesalers that have imported MNCH commodities. Of 18 wholesalers contacted to be interviewed, 15 wholesalers responded positively and participated in the activity.

The assessment team interviewed managers at a total of seven private pharmacies. The private pharmacies were selected at random among the list of registered entities in Maputo. No domestic manufacturers were included in the activity. Table 2 provides a list of private sector participants.

Table 2. Commercial entity participation

Name of entity	Type of entity	Interview status
Medafrica	Wholesaler	Interviewed
MEDIS Farmaceutica	Wholesaler	Interviewed
Well Worth	Wholesaler	Interviewed
Maputo Health Care	Wholesaler	Interviewed
MEDIMOC	Wholesaler	Interviewed
Mission Pharma	Wholesaler	Interviewed
Shani, Lda	Wholesaler	Interviewed
ACE Health Care	Wholesaler	Interviewed
NaturPharma	Wholesaler	Interviewed

MedImport	Wholesaler	Interviewed
Ceres Pharmaceuticals	Wholesaler	Interviewed
MDS	Wholesaler	Interviewed
Afri Farmacia	Wholesaler	Interviewed
Farma Holding, SA	Wholesaler	Interviewed
Moz In	Wholesaler	Interviewed
Farmacia Amiga	Pharmacy	Interviewed
Farmacia Rotunda	Pharmacy	Interviewed
Biofarma	Pharmacy	Interviewed
Farmacia Socorro	Pharmacy	Interviewed
Sommerschield Clinic	Clinic Pharmacy	Interviewed
Maputo Private Hospital	Clinic Pharmacy	Interviewed
Clinicare	Clinic Pharmacy	Interviewed
Prosmed	Wholesaler	Interview requested
Prosmed  Eveready Pharma	Wholesaler	Interview requested Interview requested

Among relevant government officials, the assessment team held several meetings with DNF, including with the DNF Director, and also met with Central de Medicamentos e Artigos Medicos (Central Medical Store, CMAM). In addition, the assessment team interviewed leadership of AIPROMEM. Finally, the team met with NGOs and donors including Population Services International, USAID, and the UN Population Fund (UNFPA). UNICEF was unavailable to meet given hurricane relief priorities. Follow up interviews with the GHSC-PSM Mozambique field office were conducted.

## References

- UN Commission on Life-Saving Commodities for Women and Children. Commissioners'
  Report: September 2012 [Internet]. United Nations, 2012 Sep [cited 2020 Feb 17]. Available
  from: <a href="https://www.unfpa.org/publications/un-commission-life-saving-commodities-women-and-children">https://www.unfpa.org/publications/un-commission-life-saving-commodities-women-and-children</a>
- Bradley SE, Rosapep L, Shiras T. Sources for Sick Child Care in 24 USAID Priority Countries
  [Internet]. Rockville, MD: Abt Associates, 2018 [cited 2020 Jan 24]. Available from:
   https://www.shopsplusproject.org/resource-center/sources-sick-child-care-24-usaid-priority-countries
- 3. World Bank Open Data [Internet]. United Nations Population Division; 2019. Mozambique; 2019 [cited 2020 Feb 20]. Available from: https://data.worldbank.org/country/mozambique
- 4. Mozambique DNF. Register of Pharmaceutical Products. 2019 Dec 31 [cited 2020 Feb 17]. Available from: <a href="http://www.arm.co.mz/medicamentos-2/">http://www.arm.co.mz/medicamentos-2/</a>
- 5. Mozambique DNF. List of Authorized Importers [Internet]. 2018 Jul [cited 2020 Feb 17]. Available from: http://www.arm.co.mz/licenciamento-de-entidades/
- 6. Medimoc SA. About Us [Internet]. 2019 [cited 2020 Feb 17]. Available from: <a href="http://www.medimoc.co.mz/about-us/">http://www.medimoc.co.mz/about-us/</a>
- 7. The Global Pharma Health Fund (GPHF) [Internet] Germany: Global Pharma Health Fund e.V. (GPHF); c2020. The GPHF-Minilab™—Focusing on Prevalent Medicines against Infectious Diseases; c2020 [cited 2020 Feb 18] . Available from: https://www.gphf.org/en/minilab/wirkstoffe.htm
- 8. 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/|s17659en/
- 9. Riley P, Callahan S, Dalious M. Regulation of Drug Shops and Pharmacies Relevant to Family Planning: A Scan of 32 Developing Countries. Bethesda, MD: Abt Associates Inc. 2017 [cited

- 2020 Jan 24]. Available from: https://www.shopsplusproject.org/resource-center/regulation-drug-shops-and-pharmacies-relevant-family-planning-scan-32-developing
- 10. Rutta E, Liana J, Embrey M, et al. Accrediting Retail Drug Shops to Strengthen Tanzania's Public Health System: An ADDO Case Study. Journal of Pharmaceutical Policy and Practice [Internet]. 2015: –37. [updated 2015 Nov 15, cited 2020 Jan 24];8(23). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4582893/
- 11. O'Sullivan G, Cisek C, Barnes J, et al. Moving Toward Sustainability: Transition Strategies for Social Marketing Programs [print]. Bethesda, MD: Private Sector Partnerships-One Project, Abt; 2007.