The Role of Domestic Wholesalers

Identifying opportunities for increasing domestic wholesaler contributions to improve availability of quality family planning and maternal, newborn, and child health commodities in Low- and Middle-Income Countries

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**ACRONYMS AND ABBREVIATIONS**

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<tr>
<td>3PL</td>
<td>third-party logistics</td>
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<tr>
<td>FP</td>
<td>family planning</td>
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<td>GBT</td>
<td>Global Benchmarking Tool</td>
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<td>GDP</td>
<td>good distribution practice</td>
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<td>GHSC-PSM</td>
<td>Global Health Supply Chain Program–Procurement and Supply Management project</td>
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<td>GHSC-QA</td>
<td>Global Health Supply Chain–Quality Assurance Program</td>
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<td>GSP</td>
<td>good storage practices</td>
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<td>HSC</td>
<td>heat-stable carbetocin</td>
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<td>LMICs</td>
<td>low- and middle-income countries</td>
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<td>MNCH</td>
<td>maternal, newborn, and child health</td>
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<tr>
<td>MQAS</td>
<td>Model Quality Assurance System</td>
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<td>NGO</td>
<td>Nongovernmental organizations</td>
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<tr>
<td>NMRA</td>
<td>national medicines regulatory authority</td>
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<tr>
<td>PPH</td>
<td>Postpartum hemorrhage</td>
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<td>QUAMED</td>
<td>Quality Medicines for All</td>
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<tr>
<td>RHSC</td>
<td>Reproductive Health Supplies Coalition</td>
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<tr>
<td>SMO</td>
<td>social marketing organization</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<td>UNFPA</td>
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<td>U.S. Agency for International Development</td>
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<td>WHO</td>
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Expanding the availability of quality health commodities: domestic wholesalers

In the past few decades, impressive progress has been made to increase the availability of important family planning (FP) and maternal, newborn, and child health (MNCH) commodities. Yet, 218 million women in low- and middle-income countries still have an unmet need for family planning and every year, more than six million women and children die from preventable illnesses in part from the lack of available commodities.¹

Many factors contribute to ensuring access to and availability of quality, affordable health commodities at service delivery points, including reliable and efficient health supply chains to facilitate the movement of products between manufacturers and consumers. In many countries, domestic wholesalers are the crucial intermediaries in public, private not-for-profit, and private for-profit (commercial) health supply chains, responsible for multiple supply chain tasks, including procurement, importation, and warehousing and distribution, as depicted in Figure 1.

A set of critically important FP and MNCH commodities have been identified by the global health community, including the United Nations (UN) Commission on Life-Saving Commodities for Women and Children. These commodities include but are not limited to short-acting and long-acting FP commodities; antibiotics to treat infections in newborns and children; and commodities for preventing and treating postpartum hemorrhage. See Annex A for a full list of these products.
Domestic wholesalers may also:

- Outsource various activities previously described.
- Be consolidated vertically throughout the supply chain through ownership of manufacturing sites and/or networks of health clinics and pharmacies.
- Have expertise in forecasting client demand and strategic sourcing.
- Undertake additional activities, such as sales, promotion, marketing, labeling, and bundling of commodities.
- Provide additional services, such as equipment maintenance and repair.

Domestic wholesalers primarily:

- Procure health commodities—from foreign manufacturers, domestic manufacturers, and importers.
- Import health commodities or work with importers that manage the customs clearance and importation of health commodities.
- Provide warehousing and storage services.
- Sell health commodities to actors/clients in the public, private not-for-profit, and private for-profit sectors, including distributors, hospitals, clinics, and pharmacies that directly serve consumers.
- Provide logistics services to deliver health commodities to clients or use distributors to provide subnational and last-mile delivery.
- Engage in quality assurance activities with the goal of ensuring clients and patients receive quality, safe medicines.
- Serve as financial intermediaries in the supply chain by retaining ownership of a manufacturer’s product on a cash or credit basis, managing contracts, and collecting payments from clients.

Domestic wholesaler types

- Specialty wholesalers procure and supply a particular group of products, for example, medical devices.
- Traditional wholesalers procure and supply a range of products, including pharmaceuticals, devices, and other consumer goods.
- Subsidiaries or wholly owned subsidiaries partially or fully owned by another company (parent company) that often makes strategic decisions for the subsidiary.
- Regional wholesalers serve multiple countries and/or wholesalers with offices in multiple countries within a given region.
For the purpose of this document, the term domestic wholesaler is used to describe commercial entities responsible for procuring and delivering health commodities.

Domestic wholesalers operate in challenging contexts, facing several barriers that limit their ability to provide affordable, quality FP and MNCH commodities. These constraints include lack of affordable financing, unknown demand for commodities, challenges to ensuring product quality throughout the supply chain, and distorted markets in countries where there is a presence of subsidized and donated commodities, limiting private sector opportunity.

Public health needs will continue to evolve, and demand will continue to grow for a range of health commodities. To equitably meet the needs of women and children, public, private not-for-profit, and private for-profit health systems need reliable, sustainable supplies of affordable, quality FP and MNCH commodities. With engagement and a supporting environment, domestic wholesalers have the capacity to efficiently support all sectors.

This brief aims to:

• Describe how domestic wholesalers operate in public, private not-for-profit, and private for-profit sector markets and their added value to each.
• Discuss wholesaler quality determinants and challenges.
• Examine specific barriers faced and opportunities for strengthening the ability of domestic wholesalers to provide quality-assured health commodities and to identify opportunities to ensure sustainable sources of supply as countries transition from U.S. Agency for International Development (USAID) and other donor assistance to country-financed procurement.
KEY FUNCTIONS AND CHARACTERISTICS OF DOMESTIC WHOLESALERS IN LMICS

Sourcing Quality Health Commodities

SOURCING AND PROCUREMENT

Domestic wholesalers procure health commodities from foreign manufacturers, domestic manufacturers, importers, and in some cases, other wholesalers. The relationship between a wholesaler and a manufacturer can take different forms. A wholesaler may limit engagement with a manufacturer to simply purchasing health commodities, or a wholesaler and manufacturer may develop a meaningful relationship, as illustrated in Figure 2.

The latter type of partnership can create opportunities and advantages for domestic wholesalers, including access to working capital, branding, sales and marketing resources. An arrangement can be made in which a manufacturer relies on a wholesaler to respond to and fulfill public institutional tenders, also known as centralized public procurements, that are typically managed at the national level. Coordination on national public procurements has the ability to benefit both the domestic wholesaler and manufacturer. Finally, a manufacturer may set quality standards for the wholesaler, encourage quality assurance compliance, and share information related to quality management processes and systems. Wholesalers that have a prequalification system to preselect suppliers and individual products, are more likely to be importers/branches of international parent/partner companies and therefore may be required to be compliant with some quality standards. ²

Figure 2. Potential interactions between a domestic wholesaler and a manufacturer
Launch of 
HEAT-STABLE CARBETOCIN
in the public sector

Postpartum hemorrhage (PPH)—excessive bleeding after childbirth—continues to be a major cause of maternal mortality, accounting for more than a quarter of maternal deaths worldwide. A number of medicines can be used to prevent and treat PPH, but an unmet need for an affordable high-quality, heat-stable uterotonic persisted in LMICs, due to challenges with cold-chain distribution. In 2018, following the successful outcome of the CHAMPION trial, the World Health Organization (WHO) updated its guidelines to include the use of heat-stable carbetocin (HSC), manufactured by Ferring Pharmaceuticals, for PPH prevention. In 2019, HSC was added to the WHO Model List of Essential Medicines.

Ferring Pharmaceuticals publicly announced its commitment to register, manufacture, and make HSC available at a sustainable access price in the public sector of LMICs. Ferring Pharmaceuticals worked with IDA Foundation and Concept Foundation to identify wholesalers to assist with the launch of HSC in the public sector in more than 80 countries. IDA Foundation is a not-for-profit organization that has a broad network of country-level wholesalers. Concept Foundation, also a non-for-profit organization, assisted with mapping out the regulatory requirements in select countries and identifying additional wholesalers to complement IDA Foundation’s network where necessary.

Domestic wholesalers offered support with the launch of HSC through these activities:

PRODUCT REGISTRATION
- Compilation of additional product registration dossier documentation such as translations, country-specific certificates, letters of authorization, et cetera, as per current requirements, regulations, and practices—which can change frequently.
- Submission and in-person follow-up on the status of the registration dossier.
- In select countries, hold the marketing authorization.

IMPORTATION
- Importation documentation and processes
- Monitoring and following-up on shipments

STORAGE AND DISTRIBUTION
- Receipt and storage as necessary
- Forecasting, addressing demand, and management of sub-national distribution

In some countries, entities such as government procurement agencies, nongovernmental organizations (NGOs) and global health institutions such as United Nations Population Fund (UNFPA), also may assist with one or more of the activities described above.
CONTRACTING, IMPORTING, AND FINANCIAL FLOW

To effectively source FP and MNCH commodities, domestic wholesalers require skills in supplier relationship, contract, and financial management. Managing financial flow is a particular challenge for many domestic wholesalers. Domestic wholesalers are financially responsible for the cost of products beginning with product pick up at the place of manufacture, through transportation, importation, delivery, and customer payment which can take anywhere from five to eight months for mid-size wholesalers. These funding cycle challenges are further exacerbated by lengthy payment cycles from clients, including delayed payments from public sector procurements, procurement agents, and national health insurance programs. The long financial cycle results in increased operating costs that get passed on to consumers through higher commodity prices and the preference for branded and innovator products with higher and quicker rates of return over lower-value, generic FP, and MNCH commodities.

Wholesalers report lack of affordable financing and capital as a common challenge. A study conducted by the Partnership for Supply Chain Management in five countries found average finance charges from annual percentage rates at 21 percent. Domestic wholesalers actually borrow at even higher rates than market averages, which can impact the product price for the consumer.

WAREHOUSING AND DISTRIBUTION

A significant value-add of domestic wholesalers is their ability to warehouse essential health commodities; when assured of consistent demand, they can stock products, avoiding long lead times from international manufacturers. In some countries, ministries of health and relevant government entities have leveraged private sector capabilities to outsource select supply chain management functions and operations to domestic wholesalers. These functions may include procurement, warehousing, and distribution services.

Domestic wholesalers are efficient sources of supply for distribution, as they can procure a range of products from multiple domestic and international suppliers, facilitate importation, and consolidate delivery. Wholesalers can also “kit” products procured from multiple suppliers, such as injectable contraceptives and antibiotics requiring ancillary syringes for administration. Some domestic wholesalers have in-house logistics capabilities while others maintain a complex network of third-party logistics (3PL) providers or distributors to deliver FP and MNCH commodities to dispensation points, which allows wholesalers to increase commodity access for hard-to-reach, rural consumers. It is common for multiple distributors to be involved in managing a product between the wholesaler and the retailer.

Opportunities

Expand innovative financing programs for health-related entities including domestic wholesalers in emerging-market countries, to alleviate financial strain throughout the supply chain cycles.

Provide domestic wholesalers with information on development credits and equity investing funding available from institutions such as the United States International Development Finance Corporation.

The Role of Domestic Wholesalers
An analysis of national and subnational distribution costs conducted by the International Finance Corporation shows downstream distribution drives anywhere from 30 to 60 percent—and in extreme cases, as much as 90 percent—of a product’s final cost to consumers in the poorest countries.\(^\text{13}\)

Delivery to rural areas is costly due to geographic inaccessibility, caused by distance, poor road conditions, or severe weather conditions. These challenges can be exacerbated by a still-nascent transportation sector with limited availability of 3PLs and limited capacity of domestic wholesalers to manage logistics providers. Such costs are often passed down to the consumer. In a study conducted in Ghana, markups on MNCH commodities in private sector health facilities and pharmacies averaged 74 to 164 percent with the highest-markup products being gentamicin 40 mg/mL in 2-mL vial, amoxicillin 250-mg dispersible tablets, and oral rehydration solution.\(^\text{14}\) To manage markups, some countries implement mark-up remuneration strategies.\(^\text{15}\) For example, in Mozambique, commodity prices are fixed based on a preestablished percentage.\(^\text{16}\) This fixed-pricing scheme offers some benefits, as it helps control the overall cost of health commodities and prevents high markups that may be passed on to consumers; however, with this scheme, domestic wholesalers report a disincentive to supply products outside of cities and ports.

**Opportunities**

**Conduct research on pharmaceutical pricing regulations** such as those related markups, and their impact on pricing and product availability.

**Understand drivers of subnational distribution costs** in addition to the capacity and interest of third- and fourth-party logistics companies to provide pharmaceutical logistic services.

**INNOVATION**

Domestic wholesalers are improving the way health commodities are delivered to dispensation points and consumers. Innovators are emerging in developing markets in countries such as South Africa, Kenya, Nigeria, and Ghana. These new agents are commonly small in size, self-financed, and often driven by the use of an improved technology aimed at increasing availability and access to health commodities through more competitive prices, product visibility through the supply chain, digital ordering systems, and applications for direct consumer sales.\(^\text{17}\) As a result, these new models have a high potential to create positive health impacts.
Supplying Quality Health Commodities

Domestic wholesalers supply essential health commodities to public, private not-for-profit, and private for-profit sector markets. Additional information on each sector is provided in Figure 3.

Figure 3. Supplying the three sectors

SUPPLYING THE PUBLIC SECTOR

Domestic wholesalers supply governments through centralized and decentralized procurement mechanisms. Centralized public procurements are typically managed by a country’s central medical stores or by the authorized government procurement and supply division at the Ministry of Health.

Domestic wholesalers may also supply subnational government structures, such as district health offices and public health facilities. Domestic wholesalers vetted for quality through a decentralized system can have a significant influence on product availability, price, and quality. A decentralized public supply chain can exist as part of a structured mechanism, often with framework contracts or selected suppliers established at a national level, or it can operate in an unregulated, independent context.

Examples of decentralized procurement include the Jazia Prime Vendor System (Jazia PVS) in Tanzania and the Procurement Act of 2003 in Ghana. Through the Jazia PVS in Tanzania, one wholesaler is selected per region as the supplier for public health facilities when health commodities are unavailable through the country’s Medical Stores Department. In Ghana, the Ghana Health Service establishes long-term agreements with suppliers known as National Framework Contracts for select essential medicines to enable economies of scale and supply to Regional Medical Stores. If the Regional Medical Stores do not have commodities available, the Procurement Act of 2003 allows hospitals and health facilities to source from private sector suppliers, often domestic wholesalers. In these examples and in other decentralized models,
if domestic wholesalers have supplies available, they can contribute to increased product availability at lower levels of the health system.

In some LMICs, FP and MNCH commodities in the public sector are supplied by global health institutions such as USAID, United Nations Children’s Fund (UNICEF), and UNFPA. These entities and related procurement agents source FP and MNCH commodities directly from manufacturers that produce products with stringent regulatory authority approval or WHO prequalification. Donors and procurement agents also source commodities from select international wholesalers. These wholesalers maintain stringent quality management systems and they generally serve multiple markets, giving them the ability to leverage economies of scale to negotiate competitive pricing.

Domestic wholesalers are often unable to offer comparable pricing for FP and MNCH products financed by global health institutions, as the products offered by domestic wholesalers frequently include freight, importation taxes, and other costs associated with sourcing and importing. Global health institutions are exempt from select importation costs such as value-added taxes and tariffs. While global health institutions are able to ensure quality products and can achieve economies of scale through bulk procurements, domestic wholesalers face specific operational challenges to working with donors, procurement agents and governments. These challenges are categorized as institutional procurement inefficiencies and include product selection, complicated tender procedures, lengthy sourcing timelines, and opaque award and procurement preferences, among others. Global health institutions also have stringent quality standards that domestic wholesalers are often not able to achieve.

Despite these barriers for donors and domestic wholesalers, donors have a growing interest in working with domestic wholesalers to contribute to goals of supporting market-shaping efforts.

**Opportunities**

**Examine donor, procurement agent, and public sector sourcing processes and streamline tender procedures for suppliers including domestic wholesalers.**

**Develop common standards and quality requirements for domestic wholesalers.**

**Develop strategies and commitments to source a percentage of procurements from domestic sources, including wholesalers by working with the global health community, including donors and procurement agencies.**

**Conduct a value analysis of sourcing FP and MNCH products and consumables from domestic wholesalers to meet agreed-upon commitments to source products from domestic sources.**

Investing in domestic wholesalers may have a positive impact on the health of the domestic market and the ability of domestic suppliers to also be sustainable supply sources for the public, private not-for profit, and private for-profit health sectors.
SUPPLYING THE PRIVATE NOT-FOR-PROFIT SECTOR

The private not-for-profit sector, including NGOs, social marketing organizations (SMOs), and faith-based organizations, plays a small but important role in the availability of FP and MNCH commodities in some contexts. The private not-for-profit sector combines financing from donors with fees charged to clients and patients to reduce the burden on the public sector by shifting clients and patients who can pay a typical nominal fee for services and commodities.

NGOs and SMOs source products directly from manufacturers or international wholesalers due to quality and cost considerations. NGOs and SMOs may partner with domestic wholesalers in other ways. For example, the Agence pour le Développement du Marketing Social in Senegal has used domestic wholesalers for promoting and distributing health commodities for more than 20 years. In countries such as Burkina Faso, Mali, and Senegal, SMOs are prohibited from selling medical abortion commodities and therefore rely on domestic wholesalers to sell these commodities on their behalf. SMOs report domestic wholesalers are interested in distributing SMO-branded products, as they are often distinguishable from generics with unique branding and more marketable, giving domestic wholesalers the opportunity to increase sales and thus profits.

Ghana’s Total Family Health Organisation partners with wholesalers to increase the availability of 7.1 percent chlorhexidine digluconate gel

Recognizing an unmet need for 7.1 percent chlorhexidine digluconate gel* in the Ghanaian market, in 2019 the Total Family Health Organisation identified a supplier of 7.1 percent chlorhexidine digluconate gel and partnered with eight domestic wholesalers to conduct a range of specialized services, including warehousing, transportation, bulk breaking of supplies into smaller quantities, and distributing products to last-mile retailers, such as pharmacies and corner shops in designated sales zones across the country.

*Daily application of 4% chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) to the umbilical cord stump in the first week after birth is recommended only in settings where harmful traditional substances (e.g. animal dung) are commonly used on the umbilical cord.
Historically, overbranding, also known as repackaging, of commodities has been an important component of social marketing. Repackaging commodities with a recognizable brand designed to be accepted by and meet the needs of a specific target group enables SMOs to strengthen their market position—particularly in underdeveloped commercial markets—to achieve health impact. Repackaging can be done in the country of intended distribution by the SMO.

However, in recent years, regulatory authorities in countries such as Madagascar, Malawi, Senegal, and Tanzania have become increasingly stringent, making it difficult for SMOs to repackage products domestically. At times, this has led manufacturers to no longer permit overbranding by SMOs, raising concerns around supply security. Some generic FP manufacturers offer trade packaging services to overbrand products at their own facilities with SMO-provided artwork and packaging specifications. This allows the manufacturer to retain control of branding and quality assurance by reducing the number of “touch points.”

However, lack of standardization in SMO branding and packaging configurations vis-a-vis relatively low SMO volumes may also lead manufacturers to discontinue trade packaging services. These same manufacturers may also supply the same FP commodities to the commercial sector at higher prices, unsubsidized price points, further disincentivizing manufacturers to continue offering trade packaging services.

As the landscape is evolving, SMOs, too, must evolve and adopt new strategies and models that create space for FP commercial markets to develop. Such evolution presents new opportunities for domestic wholesalers.

- **Opportunities**

SMOs and manufacturers may consider partnering with domestic wholesalers to supply trade packaged brands across multiple countries.

This strategy creates more harmonization in SMO branding and packaging configurations and allows manufacturers to leverage greater economies of scale.
SUPPLYING THE PRIVATE FOR-PROFIT SECTOR

Individuals and families are increasingly seeking health services and commodities in private for-profit sector hospitals, clinics, pharmacies, and drug shops, and domestic wholesalers are the primary suppliers to those facilities. Domestic wholesalers may also provide products directly to international and national businesses and private company-sponsored health insurance programs.

A recent secondary analysis carried out by the USAID-funded SHOPS Plus Project found among all caregivers who seek treatment outside of the home in 24 USAID priority countries, an average of 43 percent seek treatment or advice from private sector sources.25

Domestic wholesalers have enabled tremendous and rapid growth in the availability of FP and MNCH commodities in the private sector in many LMICs, given increased levels of household spending on health care and greater consumer ability to pay.26 Over 80 percent of health products are purchased in the private for-profit sector as shown in figure 4 below.27

Most of the growth can be attributed to the increase in affordable generics to treat chronic diseases, and branded commodities, rather than MNCH commodities, which are primarily generic and have already low price points. For family planning products, 73 percent of private sector users rely on pills, injectables, condoms, and other short-term methods compared to 67 percent of users in the public sector that rely on long-acting reversible contraceptives, such as intrauterine devices and implants.28 Wholesalers report consistent demand for STMs in the private for-profit sector because they are consumer-facing products that can benefit branding versus clinician-administered long-acting reversible contraceptives and may provide greater returns on profits due to the need for continual resupply. Also, some government policies prohibit pharmacists and lower-level health workers from administering long-acting reversible contraceptives.29

Commercial entities routinely cite the private for-profit sector’s limited ability to attract clients and patients, even those with the ability to pay due to the dominance of free and subsidized FP and MNCH products in the public and private not-for-profit sectors. Efforts have been made, however, to stimulate interest among wholesalers in supplying some health commodities, for example, oral rehydration salts and zinc. In Tanzania, the Social Marketing Plus for Diarrheal Disease Control: Point-of-Use Water Disinfection and Zinc Treatment Project aided the promotion of zinc supplementation by supporting a domestic manufacturer in providing wholesalers with 90 days of credit for their first supply while simultaneously implementing a vigorous demand creation campaign.30

Overall, domestic wholesalers report a general lack of incentives to supply FP and MNCH commodities and cite specific challenges around limited profit margins and unknown demand. Aggregated pharmaceutical market data are not commonly available in many LMICs.
except for select data for purchase from companies such as IQVIA. See Figure 5 below.

Some domestic wholesalers conduct their own formal and informal market intelligence through communications with retailers and facilities. However, gathering comprehensive market intelligence data requires significant time and investment. Without consistent known demand, wholesalers are not motivated to keep products in stock.

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<tr>
<th>USAID FP and MNCH priority countries</th>
<th>FP data</th>
<th>MNCH data</th>
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<tr>
<td>Bangladesh</td>
<td>Retail</td>
<td>MNCH</td>
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<td>Congo</td>
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<td>India</td>
<td>Retail</td>
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<tr>
<td>Indonesia (MNCH priority country only)</td>
<td>Retail and hospital (excludes government purchases)</td>
<td>Retail and hospital (excludes government purchases)</td>
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<tr>
<td>Kenya</td>
<td>Retail</td>
<td>Retail</td>
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<td>Mali</td>
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<td>Pakistan</td>
<td>Retail</td>
<td>Retail</td>
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<tr>
<td>Philippines (FP priority country only)</td>
<td>Retail and hospital (similar to India above)</td>
<td>Retail and hospital (similar to India above)</td>
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<tr>
<td>Senegal</td>
<td>Retail</td>
<td>Retail</td>
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</tbody>
</table>

Data are unavailable for Afghanistan, Ethiopia, Ghana, Haiti, Liberia, Madagascar, Malawi, Mozambique, Nepal, Nigeria, Rwanda, South Sudan, Tanzania, Uganda, Yemen, and Zambia.

Opportunities

**Increase market information**

by conducting new market intelligence activities and research.

**Improve the dissemination of existing data**

to domestic wholesalers to reduce uncertainty in demand and assist them in making informed decisions on future product purchases, promotions, and other activities. Existing information might encompass government-funded forecasts and supply plans, landscape analyses, and changes within the health system, such as updates to national standard treatment guidelines.
DOMESTIC WHOLESALER QUALITY DETERMINANTS AND CHALLENGES

Product Quality

Ensuring product quality is a priority in any health supply chain. Prevalence of substandard and falsified medicines is a challenge among several types of commodities including, generic FP and MNCH commodities. Specifically, for MNCH commodities, several postmarketing surveillance studies have highlighted commodity quality concerns. A recent systematic review found that over 50 percent of uterotonic samples collected in low-resource countries failed quality testing, which is a major threat to pregnant women. 31

Product quality starts with the manufacturer using high-quality raw materials and following current good manufacturing practices throughout production. Product quality must then be maintained throughout transportation, storage, and distribution systems. As such, the risk of substandard products moving through the supply chain often can originate from two sources: (1) low-quality raw material or poor manufacturing processes or (2) poor transportation, storage, or distribution practices that cause degradation through inappropriate environmental conditions, such as high temperatures.

These two sources of risk point to the critical role domestic wholesalers play in ensuring the quality of medicines circulating in the supply chain—first, by selecting high-quality manufacturers from which to source their products, and second, by maintaining those products within the defined environmental conditions to prevent exponential degradation before their stated expiry date.

Figure 6. Two critical sources of risk of substandard products in a health supply chain 2019
Assessing Wholesaler Quality

Wholesalers must have the capacity to source quality products and ensure product quality during storage and distribution. In 2005, the WHO published the first *Model Quality Assurance System for Procurement Agencies (MQAS)* manual to set quality standards for procurement agents, including wholesalers, and reduce the risk of substandard products in the supply chain. MQAS addresses the two sources of product quality risk by emphasizing the use of supplier prequalification as a primary risk-mitigation tool for preventing the introduction of substandard products into the supply chain and reinforces quality management system and (GSP) and good distribution practice (GDP) concepts for products within the wholesaler’s chain of custody.

Three studies have documented distributor and wholesaler compliance with WHO’s MQAS in LMICs. In all three studies, quality systems of LMIC distributors and wholesalers were found not to be in compliance with MQAS standards. Figure 7 depicts findings from Assche et al. in detail and highlights low levels of compliance among private sector distributors.

The prevalence of substandard and falsified medicines in health supply chains requires domestic wholesalers to maintain adequate quality systems in procurement and distribution to fully ensure the quality of medicines they source and distribute. Improving elements of a quality system, such as GDP, requires wholesalers to make a significant resource and financial investment. Most domestic wholesalers are commercial entities and therefore are inherently driven by the market. While investments to increase quality standards can be implemented, wholesalers must be able to justify the business case for investing in their quality systems and have access to affordable financing to make those improvements, unless they are required by their own customers to be compliant with some quality standards. However most customers are often uninformed of product quality risks.

### Opportunities

**Develop accessible, risk-based assessment tools** for wholesalers to complement MQAS, to improve their compliance with MQAS with a focus on selecting suppliers and ensuring quality control of products.
National Regulatory Authorities

Ultimately, verification of the manufacturer’s ability to consistently produce quality products depends on the capacity and competency of the National Medicines Regulatory Authority (NMRA) in each country where the product will be used. Over the past five years, FHI 360 has performed 34 wholesaler audits in high-, middle-, and low-income countries. This experience has shown that many wholesalers rely exclusively on the market authorization licenses issued by their NMRA to determine the manufacturers from which they will procure. While the wholesalers are legally operating within the framework of their domestic regulations, the existing capacity of these regulatory authorities raises questions about the quality of products that have received market authorization.

NRMAAs also regulate importers, wholesalers, and distributors; however, many NRMAAs have limited capacity to regulate these supply chain actors. The limited regulatory focus on wholesalers in particular is exemplified in gaps such as lenient wholesaler licensing requirements and limited ability to monitor wholesaler pharmacovigilance. Limited regulation of wholesalers encourages a proliferation of wholesalers, including many that are low performing and poor quality. Poor-quality wholesalers that do not comply with national regulatory standards or MQAS standards lack the capacity to detect, evaluate, and prevent medicine safety issues that can contribute to harming individual and public health.

Recognizing the need for a standard way to measure the capacity of regulatory systems, WHO developed the Global Benchmarking Tool (GBT). The GBT is designed to assess regulatory frameworks and functions of a national regulatory system through standard indicators and scores the system in terms of maturity level, ranging from one to four. GBT is organized by nine categories and eight core functions, including components related to the licensing and monitoring of domestic wholesalers.

Using the GBT to identify gaps and areas for strengthening could improve the regulation of wholesalers that would lead to a smaller concentration of quality wholesalers operating in the market.

Opportunities

Support the strengthening of the national regulatory authority and regional and continental harmonization efforts like African Medicines Regulatory Harmonization initiative to develop improved wholesaler licensing requirements and effective oversight systems for wholesalers to ensure the safety of medicines within the supply chain.
CONCLUSION

Domestic wholesalers are critical actors in many health supply chains and are essential for providing consistent availability of affordable, quality FP and MNCH commodities. From insights and lessons presented in this report, the following opportunities provide suggested approaches to address common challenges that limit the effectiveness of domestic wholesalers.

- Expand innovative financing programs and provide domestic wholesalers with information on development credits and equity investing funding
- Conduct research on pharmaceutical pricing regulations and understand drivers of subnational distribution costs
- Examine donor, procurement agent, and public sector sourcing processes and streamline sourcing processes
- Develop common standards and quality requirements for domestic wholesalers
- Conduct a value analysis of sourcing FP and MNCH products and consumables from domestic wholesalers
- Develop strategies and commitments to source a percentage of procurements from domestic sources
- Explore partnering with domestic wholesalers to supply trade packaged brands across multiple countries
- Increase market information by conducting new market intelligence research and improve the dissemination of existing data
- Develop accessible, risk-based quality assurance system tools and resources to compliment MQAS
- Support the strengthening of the national regulatory authority and regional and continental harmonization efforts

Through important engagement to address these challenges and a supporting environment, domestic wholesalers have the capacity to equitably meet the commodity needs of women and children.
# ANNEX A.
## LIST OF PRIORITY COMMODITIES FOR WOMEN AND CHILDREN
### MATERNAL, NEWBORN, AND CHILD HEALTH COMMODITIES

<table>
<thead>
<tr>
<th>Product</th>
<th>Maternal Health</th>
<th>Newborn Health</th>
<th>Child Health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Oxytocin</td>
<td>Gentamicin injection</td>
<td>Amoxicillin dispersible tablets</td>
</tr>
<tr>
<td></td>
<td>Misoprostol</td>
<td>7.1% chlorhexidine digluconate solution or gel</td>
<td>Oral rehydration solution</td>
</tr>
<tr>
<td></td>
<td>Magnesium sulfate</td>
<td>Newborn resuscitation equipment</td>
<td>Zinc sulfate, dispersible tablets</td>
</tr>
<tr>
<td></td>
<td>Metyldopa, nifedipine, hydralazine, and labetalol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### FAMILY PLANNING COMMODITIES

<table>
<thead>
<tr>
<th>Product</th>
<th>Short-acting contraceptives</th>
<th>Long-acting contraceptives</th>
<th>Condoms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Combined oral contraceptive</td>
<td>Two-rod implantable contraceptive</td>
<td>Male condoms</td>
</tr>
<tr>
<td></td>
<td>Progestin-only pill</td>
<td>One-rod implantable contraceptive</td>
<td>Female condoms</td>
</tr>
<tr>
<td></td>
<td>Emergency contraceptive</td>
<td>Nonhormonal intrauterine device</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hormonal intrauterine device</td>
<td></td>
</tr>
</tbody>
</table>
ANNEX B.
ENDNOTES


4 Ferring Pharmaceuticals. (2019). Heat-Stable Carbetocin has been Added to the WHO Essential Medicines List for the Prevention of Excessive Bleeding after Childbirth.


7 Partnership for Supply Chain Management. (2019). Landscape Assessment of Health Product Wholesaler and Distributor Capabilities and Opportunities in Five Countries in Sub-Saharan Africa.


