USAID GLOBAL HEALTH
SUPPLY CHAIN PROGRAM
Procurement and Supply Management

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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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

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ACRONYMS AND ABBREVIATIONS

3PL	third-party logistics
FP	family planning
GBT	Global Benchmarking Tool
GDP	good distribution practice
GHSC-PSM	Global Health Supply Chain Program–Procurement and Supply Management project
GHSC-QA	Global Health Supply Chain–Quality Assurance Program
GSP	good storage practices
HSC	heat-stable carbetocin
LMICs	low- and middle-income countries
MNCH	maternal, newborn, and child health
MQAS	Model Quality Assurance System
NGO	Nongovernmental organizations
NMRA	national medicines regulatory authority
PPH	Postpartum hemorrhage
QUAMED	Quality Medicines for All
RHSC	Reproductive Health Supplies Coalition
SMO	social marketing organization
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

CONTEXT

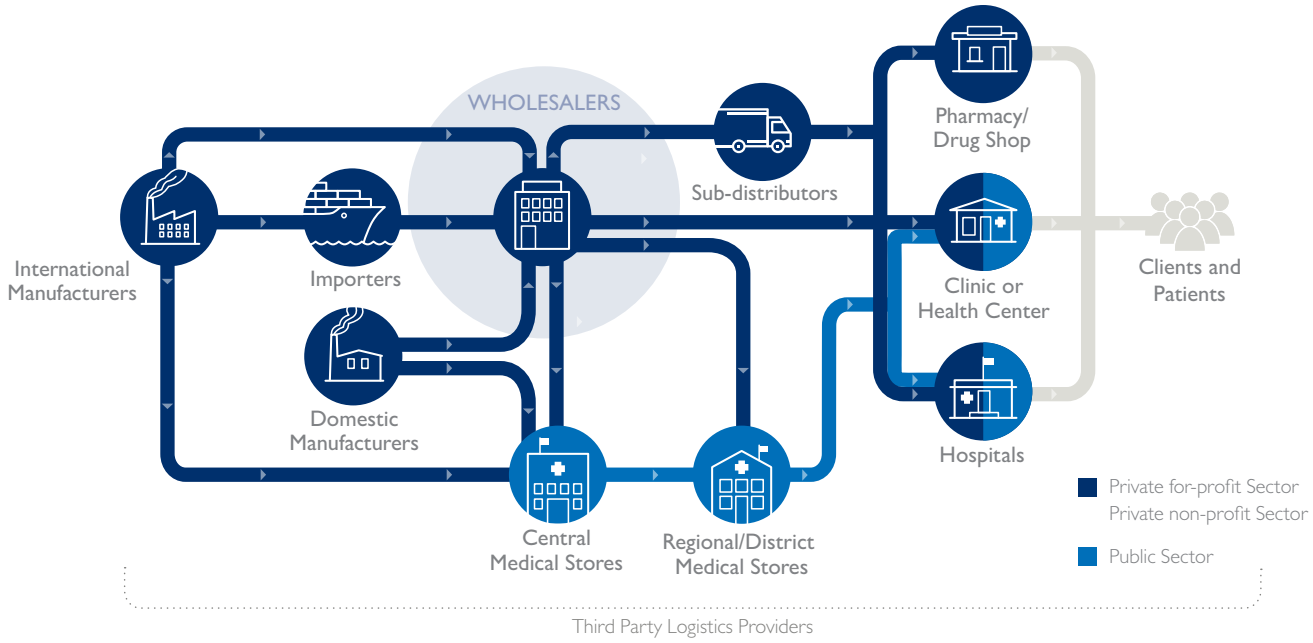
Expanding the availability of quality health commodities: domestic wholesalers

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.

Figure 1. Public, private not-for-profit, and private for-profit health supply chains in low- and middle-income countries (LMICs)



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 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 wholesaler types

Specialty wholesalers
procure and supply a particular group of products, for example, medical devices

Subsidiaries or wholly owned subsidiaries
partially or fully owned by another company (parent company) that often makes strategic decisions for the subsidiary

Traditional wholesalers
procure and supply a range of products, including pharmaceuticals, devices, and other consumer goods

Regional wholesalers
serve multiple countries and/or wholesalers with offices in multiple countries within a given region

The terms **wholesaler** and **distributor** are often used interchangeably to describe for-profit commercial entities responsible for procuring and distributing health commodities. Wholesalers may often be referred to as distributors in emerging markets; however, the term distributors is also used to describe intermediary logistics providers, providing freight services between wholesalers and retailers that interact directly with consumers.

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

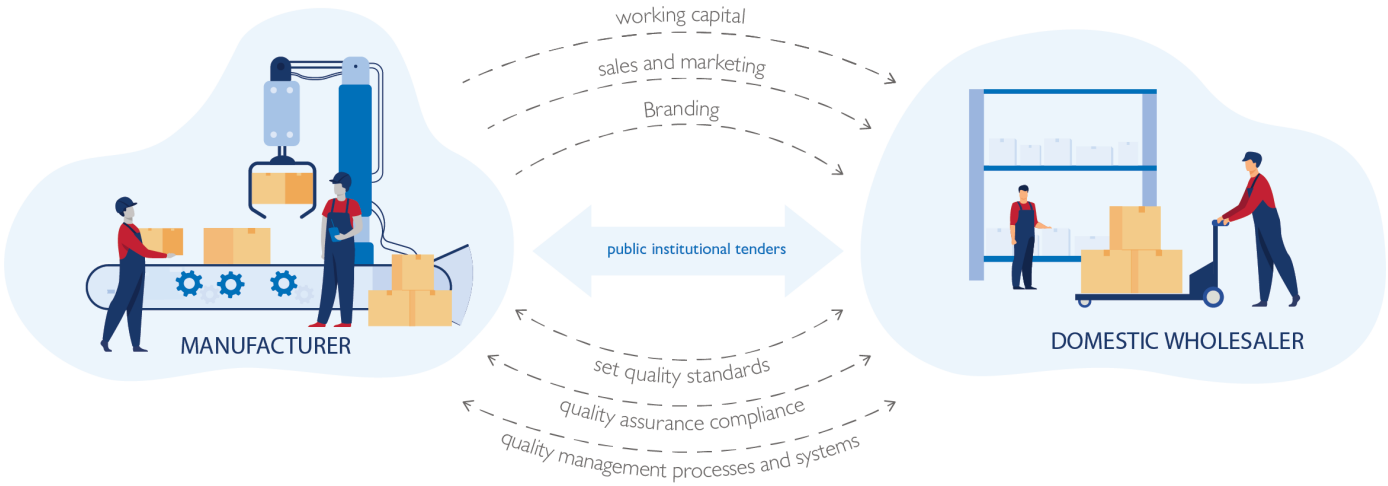
Sourcing Quality Health Commodities

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.[3] 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.[4]

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 countires. IDA Foundation is a not-for-profit organization that has a broad network of country-level wholesalers.[5] 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. [6] 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.[7] Domestic wholesalers actually borrow at even higher rates than market averages, which can impact the product price for the consumer.[8]

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 intuitions such as the United States International Development Finance Corporation.

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.[9] [10] [11] 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.[12]

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. [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.[14] To manage markups, some countries implement mark-up remuneration strategies. [15] For example, in Mozambique, commodity prices are fixed based on a preestablished percentage. [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.

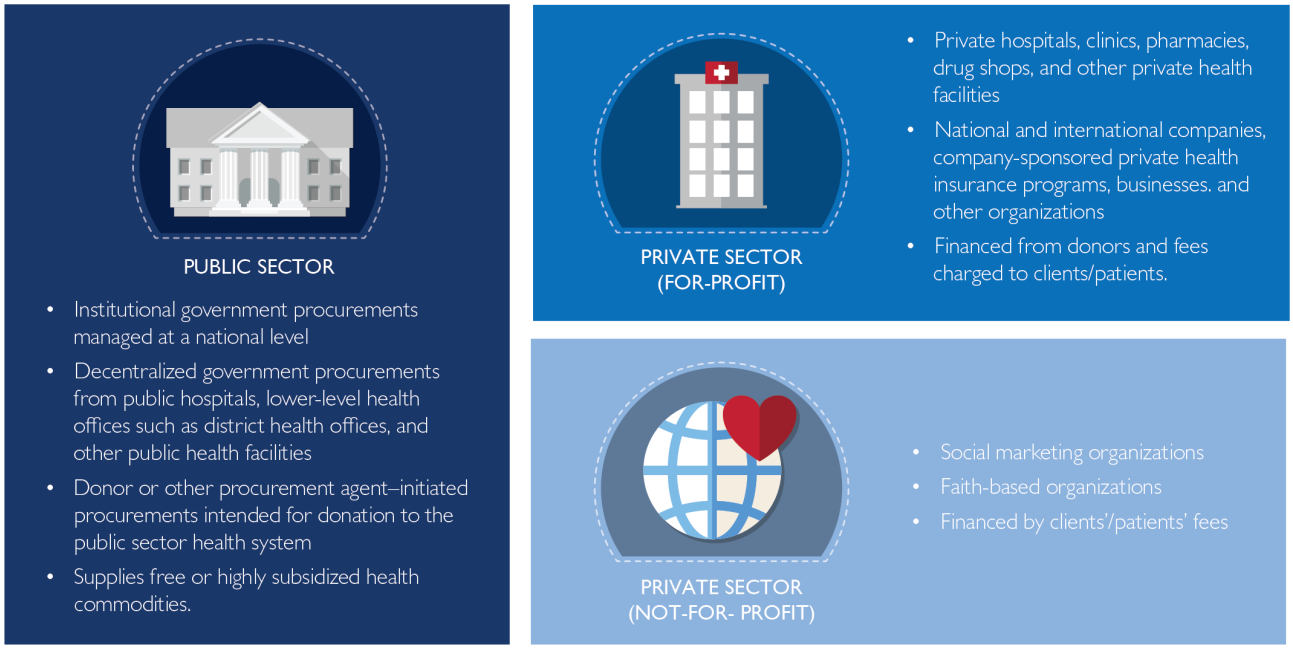
INNOVATION

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.[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.[18] 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. [19] 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.[20] 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.[21] 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.[22] 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.[23] 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.[24]

**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.*

Social Marketing Organization

Through a USAID-funded social marketing project in a USAID priority country, the social marketing organization conducted a pilot project with third-party distributors/wholesalers. In September 2020, the social marketing organization piloted using the identified domestic wholesalers in two provinces to distribute FP, chlorinated safe water solution, and oral rehydration salts products.

This resulted in

268% number of sales outlets

202% average number of orders

57% average monthly revenue

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.

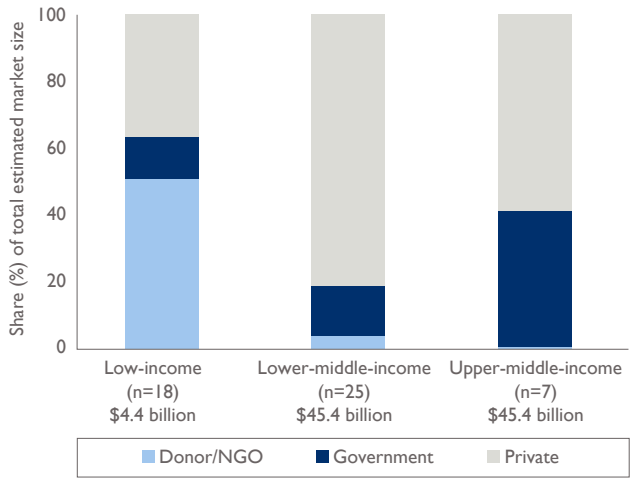
SUPPLYING THE PRIVATE FOR-PROFIT SECTOR

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]

Figure 4. Tackling the triple transition in global health procurement



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.

Figure 5. IQVIA FP and MNCH commodity data availability in USAID FP and MNCH priority countries

USAID FP and MNCH priority countries	FP data	MNCH data
Bangladesh	Retail	
Congo	Retail	Retail
India	Retail and hospital (excludes government purchases)	Retail and hospital (excludes government purchases)
Indonesia (MNCH priority country only)	Retail and hospital	Retail and hospital
Kenya	Retail	Retail
Mali	Retail	Retail
Pakistan	Retail and hospital (similar to India above)	Retail and hospital (similar to India above)
Philippines (FP priority country only)	Retail and hospital (similar to India above)	Retail and hospital (similar to India above)
Senegal	Retail	Retail

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

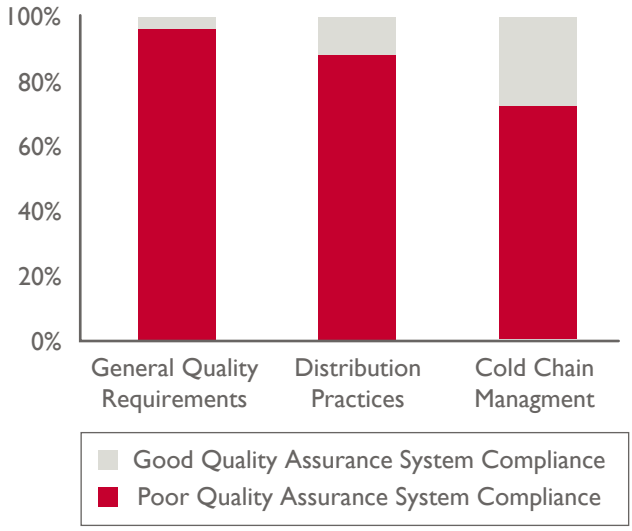
Assessing Wholesaler Quality

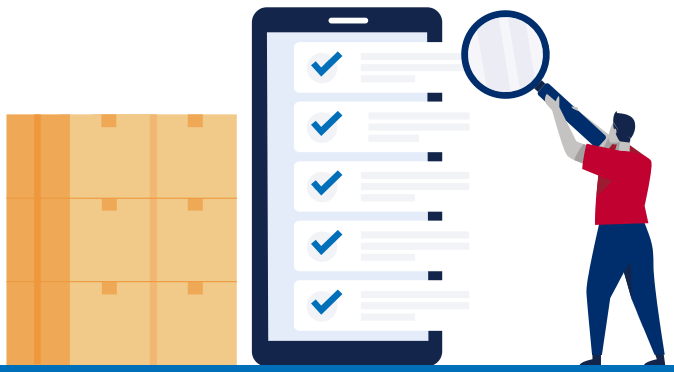
Wholesalers must have the capacity to source quality products and ensure product quality during storage and distribution. In 2005, the WHO published the first *Model Quality Assurance System for Procurement Agencies* (MQAS) manual to set quality standards for procurement agents, including wholesalers, 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.[32] [33] 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.[2]

Figure 7. Percentage of LMIC private pharmaceutical distributors at each level of MQAS compliance





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.

FHI 360 and Quality Medicines for All (QUAMED) Quality Assurance Collaboration

In November 2018, a group of donors under the Interagency Supply Chain Group developed Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities to harmonize quality standards in procurement practices, including outlining agreed-upon standards for wholesalers. To date, donors have not made progress in harmonizing quality assurance standards. However, FHI 360, the prime contractor for the USAID Global Health Supply Chain-Quality Assurance (GHSC-QA) Program, responsible for product quality oversight for the Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project, independently developed a collaboration with QUAMED. FHI 360 became a member of QUAMED and recognized the results of QUAMED audits. Since the start of the collaboration in 2021, FHI 360 subcontracted QUAMED to conduct six pharmaceutical wholesaler or distributor audits to assess supplier compliance with WHO's Model Quality Assurance System (MQAS), GDP, and GSP. Future collaborations in audits of wholesalers are planned in three additional countries.

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.

NRMAs also regulate importers, wholesalers, and distributors; however, many NMRAs 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

	Product
Maternal Health	Oxytocin
	Misoprostol
	Magnesium sulfate
	Methyldopa, nifedipine, hydralazine, and labetalol
Newborn Health	Gentamicin injection
	7.1% chlorhexidine digluconate solution or gel
	Newborn resuscitation equipment
Child Health	Amoxicillin dispersible tablets
	Oral rehydration solution
	Zinc sulfate, dispersible tablets

FAMILY PLANNING COMMODITIES

	Product
Short-acting contraceptives	Combined oral contraceptive
	Progestin-only pill
	Emergency contraceptive
Long-acting contraceptives	Two-rod implantable contraceptive
	One-rod implantable contraceptive
	Nonhormonal intrauterine device
	Hormonal intrauterine device
Condoms	Male condoms
	Female condoms

ANNEX B. ENDNOTES

1 Sully EA, Biddlecom A, Darroch JE, Riley T, Ashford LS, Lince-Deroche N, et al. (2020). Adding It Up: Investing in Sexual and Reproductive Health 2019.

2 Giralt AN, Bourasseau A, White G, Pouget C, Tabernero P, Assche KV, et al. (2020). Quality Assurance Systems of Pharmaceutical Distributors in Low-Income and Middle-Income Countries: Weaknesses and Ways Forward. *BMJ Glob Health, 5*(10), e003147.

3 World Health Organization. (2018). WHO Recommendations on Uterotonics for the Prevention of Postpartum Hemorrhage [Internet]. Retrieved March 5, 2021, from https://apps.who.int/iris/bitstream/handle/10665/277276/9789241550420-eng.pdf

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

5 Ferring Pharmaceuticals. (2019). Ferring Statement on Subsidized Pricing of Heat Stable Carbetocin for the Prevention of Postpartum Hemorrhage in Low- and Lower-Middle Income Countries.

6 Salient Advisory. (2021). Accelerating Improvements in Health Product Distribution | Examining Opportunities for Blended Financing in Sub-Saharan Africa.

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.

8 John Snow Inc. (2016). Getting Products to People: How Private Sector Solutions Can Strengthen Supply Chains for Public Health.

9 Global Health Supply Chain Program – Procurement and Management Project. (2021). Contracting for Transportation of Public Health Commodities to the Private Sector. United States Agency for International Development.

10 Results for Development. (2009). Public Stewardship of Private Providers in Mixed Health Systems: Synthesis Report from the Rockefeller Foundation-Sponsored Initiative on the Role of the Private Sector in Health Systems in Developing Countries.

11 Center for Global Development. (2020). When Fewer Is Better: Pharmaceutical Wholesaling and Distribution in Low- and Middle-Income Countries.

12 International Finance Corporation. (2017). Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets: MAKING THE CASE FOR INVESTMENT.

13 Global Health Supply Chain Program – Procurement and Management Project. (2022) Supply Chain Assessment of Maternal, Newborn and Child Health Commodities in Ghana's Private Sector Facilities, Wholesalers, and Retail Pharmacies: Findings from a Mixed-Methods Assessment. United States Agency for International Development.

14 Health Access International. (2014). The Regulation of Mark-ups in the Pharmaceutical Supply Chain.

15 Global Health Supply Chain Program – Procurement and Management Project. (2020). Quality Considerations of Wholesalers and Regulatory Authorities to Increase Availability and Access to Quality Maternal, Newborn, and Child Health Products in Mozambique. United States Agency for International Development.

16 Impact for Health. (2021) Innovations in Health Product Distribution in Emerging Economies.

17 Nepomnyashchiy L, Yadav P. (2022). Decentralized Purchasing of Essential Medicines and Its Impact on Availability, Prices, and Quality: A Review of Current Evidence. Center for Global Development.

18 Wiedenmayer K, Mbwasi R, Mfuko W, Mpuya E, Charles J, Chilunda F, et al. (2019). Jazia Prime Vendor System- a Public-Private Partnership to Improve Medicine Availability in Tanzania: From Pilot to Scale. *J Pharm Policy Pract*, 12(1), 4.

19 Ghana Health Service & Global Health Supply Chain Project-Procurement and Management Project. (2020). Ghana National Supply Chain Assessment: Capability and Performance [Internet]. Retrieved from https://pdf.usaid.gov/pdf_docs/PA00WJPC.pdf

20 Center for Global Development. (2019). Tackling the Triple Transition in Global Health Procurement.

21 Hurkchand H. (2019). Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities. Interagency Supply Chain Group (ISG).

22 Global Health Supply Chain Program – Procurement and Management Project. (2021). Interview Guide for Private Sector Domestic Wholesaler White Paper: ASMO, ATMS, ADEMAS.

23 Sanabria A. (2019). Landscape Assessment: Leveraging the Role of National Distributors to Increase Access to MA Combi-Packs in Africa. Mann Global Health.

24 SHOPS Plus Project. (n.d.). Contracting Third Party Distributors to Increase ASMO's Retail Coverage Cost-Efficiently.

25 Global Health Supply Chain Program – Procurement and Management Project. (2021). Interview Guide for Private Sector Domestic Wholesaler White Paper: TFHO.

26 Bradley SEK, Rosapep L, Shiras T. (2018). Sources for Sick Child Care in 24 USAID Priority Countries. Abt Associates [Internet]. Retrieved from https://shopsplusproject.org/sites/default/files/resources/Sources%20for%20Sick%20Child%20Care%20in%2024%20Priority%20Countries.pdf

27 Reproductive Health Supplies Coalition. (2019). Commodity Gap Analysis.

28 Armand F, Warren A, Shayo S. (2021). Improving Access to Implants through the Private Sector: Lessons from Tanzania. Shops Plus Project.

29 Goh N, Yobo J. (2016). Progress over a Decade of Zinc and ORS Scale-up. Clinton Health Access Initiative.

30 Torloni MR, Bonet M, Betrán AP, Ribeiro-do-Valle CC, Widmer M. (2020). Quality of Medicines for Life-Threatening Pregnancy Complications in Low- and Middle-Income Countries: A Systematic Review. *PLOS ONE, 15*(7), e0236060.

31 Nebot Giralt A, Schiavetti B, Meessen B, Pouget C, Caudron JM, Marchal B, et al. (2017). Quality Assurance of Medicines Supplied to Low-Income and Middle-Income Countries: Poor Products in Shiny Boxes? *BMJ Glob Health, 2*(2).

32 Assche KV, Giralt AN, Caudron JM, Schiavetti B, Pouget C, Tsoumanis A, et al. (2018). Pharmaceutical Quality Assurance of Local Private Distributors: A Secondary Analysis in 13 Low-Income and Middle-Income Countries. *BMJ Glob Health, 3*(3), e000771.