

Tackling the Triple Transition in Global Health Procurement



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Promoting Access to Essential Health Products through Aid Eligibility Changes, Epidemiological Transformation, and the Progressive Realization of Universal Health Coverage

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Preface

Over the past decades, increased access to cost-effective medicines, devices, and diagnostics has saved millions of lives. Yet a look at the data reveals an unfinished agenda. Lifesaving medicines continue to remain out of reach for many of those who need them the most. And some of the world's poorest people face the highest prices for medicines; some low- and middle-income countries pay as much as *20 to 30 times* a minimum international reference price for basic generic medicines.

For both low- and middle-income country governments and global health funders, spending on health products is big money, and spending those resources inefficiently can undermine our collective progress toward the health-related Sustainable Development Goals. That's why getting smarter on how health products are procured will play a critical role in stretching scarce health resources as far as possible.

Looking ahead, a triple transition is unfolding. Many countries that have traditionally been recipients of donor aid are transitioning away from development assistance. The global burden of disease is shifting from infectious to non-communicable conditions. And countries are increasingly undergoing health sector reforms to meet ambitious commitments to universal health coverage. Further, the global market landscape for medicines and other health products will increasingly be driven by the purchasing behavior of big players like China and India. This changing world represents both a challenge and an opportunity for low- and middle-income country governments, global health institutions, and their donors.

Within this evolving landscape, how can the global health community act now to ensure the efficiency, quality, affordability, and security of global health procurement? This question was the focus of a CGD Working Group on the Future of Global Health Procurement, which brought together a diverse range of

country policymakers, representatives from global health institutions and donors, procurement specialists, and academic experts. The Working Group aimed to elevate procurement as an important health system function—one closely linked with priority setting, product selection, and the design of health benefits packages, which are key areas of previous and ongoing CGD work. This final report draws on the Working Group's deliberations, which benefited from a rich array of background analyses conducted—and commissioned—by CGD. Collectively, this research makes a valuable contribution to the overall evidence base on global health procurement—a relatively underexamined topic—while also shedding light on the many gaps that remain.

This final report suggests that large efficiency gains can be achieved by addressing common breakdowns that lead to suboptimal procurement outcomes. To this end, the Working Group issued four actionable recommendations: (1) sustain and expand global cooperation for procurement and targeted innovation; (2) reform WHO guidance and policy to support modern and agile procurement policy and practice; (3) professionalize procurement by building capacity and driving strategic practice; and (4) support in-country procurement policy reform.

The work does not end here. While these recommendations are ambitious, the sweeping changes on the horizon create a strong imperative for the global health community to act proactively. By translating these proposed strategies into action, country governments, global health institutions, and their donors can strengthen procurement systems and ultimately improve the quality of life for millions of people. I encourage those who have the power to act on such knowledge to do so.

Masood Ahmed
President

Center for Global Development

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The report draws from Working Group discussions and background research conducted by CGD experts and commissioned from external partners, including AfRx Consulting, the Clinton Health Access Initiative, and the Toulouse School of Economics (see Appendix C

for a summary of all research inputs). Special thanks to Daniel Rosen (AfRx Consulting) for background work that greatly contributed to the analyses presented in this report. This work was also informed by a technical workshop with leading industrial organization economists, a private roundtable discussion with private-sector procurement experts, and bilateral consultations with representatives from the pharmaceutical industry. (See Appendix B for a full list of research partners, contributors, and individuals consulted.)

Jessie Lu and Julia Kaufman assisted with final preparation of the report. Emily Schabacker coordinated report production and Stephanie Brown helped with report design.

Note

This report is a product of the Center for Global Development (CGD). Its content is based on the deliberations of a Working Group and a series of background research and analyses. The Working Group was composed of low- and middle-income country policymakers, procurement specialists, representatives from global health institutions and donors, and academic experts. All members of the Working Group have had the opportunity to review and provide input to this report. However, Working Group members do not necessarily endorse all components of this report, nor do the contents of this report constitute a policy commitment by any party. All errors and omissions are those of the authors.

This CGD Working Group was funded by the Bill & Melinda Gates Foundation and individual CGD funders. CGD is an independent and nonpartisan research institution. There are no conditions or limitations on CGD's independence in research, findings, conclusions, or resulting publications. Where appropriate, CGD may welcome and consider comments or views from funders, but CGD retains total discretion and final decision-making authority regarding program and project research topics, speakers, and participants in activities, and on the content of reports.

Acronyms

ACT	artemisinin-based combination therapy	MDCs	Millennium Development Goals
AMFm	Affordable Medicines Facility–malaria	MOH	Ministry of Health
API	active pharmaceutical ingredient	MSF	Médecins Sans Frontières
ARV	antiretroviral	NGO	nongovernmental organization
CGD	Center for Global Development	NHS	National Health Service
CHAI	Clinton Health Access Initiative	OECD	Organisation for Economic Co-operation and Development
CIF	cost, insurance, and freight	OOP	out-of-pocket
CIPS	Chartered Institute of Procurement and Supply	PAHO	Pan-American Health Organization
CMS	central medical stores	PEPFAR	President’s Emergency Plan for AIDS Relief (US)
CRP	Collaborative Registration Procedure	PMI	President’s Malaria Initiative (US)
DFID	Department for International Development (UK)	PQR	Price and Quality Reporting
EU	European Union	R&D	research and development
FDA	US Food and Drug Administration	SDG	Sustainable Development Goals
Gavi	Gavi, the Vaccine Alliance	SRA	stringent regulatory authority
GDP	gross domestic product	TB	tuberculosis
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria	TRIPS	Trade-Related Aspects of Intellectual Property Rights
GNI	gross national income	TSE	Toulouse School of Economics
GPEI	Global Polio Eradication Initiative	UHC	universal health coverage
GPO	group purchasing organization	UMIC	upper-middle-income country
HHI	Herfindahl-Hirschman Index	UNFPA	United Nations Population Fund
HTA	health technology assessment	UNICEF	United Nations Children’s Fund
IDA	International Development Association (World Bank)	Unitaid	Tous Unis pour Aider
IHME	Institute for Health Metrics and Evaluation	USAID	United States Agency for International Development
INN	international nonproprietary name	V3P project	Vaccine Product, Price and Procurement project
LIC	low-income country	WHO	World Health Organization
LMIC	lower-middle-income country		



Executive Summary

There have been impressive gains in global health over the past 20 years, with millions of lives saved through expanded access to essential medicines and other health products. Major international initiatives backed by billions of dollars in development assistance have brought new drugs, diagnostics, and other innovations to the fight against HIV, malaria, tuberculosis, and other scourges. But behind these successes is an unacceptable reality: in many low- and middle-income countries, lifesaving health products are either unavailable or beyond the reach of the people who need them most. While each country's context is unique, a reliable, affordable, and high-quality supply of health products is a vital necessity for any health system. In its absence, lasting health gains will remain elusive.

Access to medicines, diagnostics, devices, and equipment is driven in large part by the efficiency of their procurement. Procurement is, therefore, central to the efforts of low- and middle-income countries to improve health, meet the Sustainable Development Goals, and achieve universal health coverage. Health product purchasing in low- and lower-middle-income countries already makes up a sizeable share of overall health spending; in fact, in just a subset of these countries, spending on health products totals an estimated \$50 billion per year.¹ Procurement is not only essential to the missions of global health entities like the Global Fund, Gavi, UNICEF, UNFPA, and PEPFAR, but it also represents big money. In the case of the Global Fund, health product procurement accounts for \$2 billion per year,² or almost half of its 2017 disbursements.³ Yet despite its importance, procurement is an underappreciated health system function. Today's procurement systems are hobbled by inefficiencies that leave some of the poorest countries paying some of the highest drug prices in the world.

Within a changing global health landscape, a forward-looking approach is needed to anticipate tomorrow's challenges and plan for the future. To this end, the Center for Global Development convened the Working Group on the Future of Global Health Procurement to review the evidence and formulate recommendations for how the global health community—international health organizations, their bilateral and foundation donors, and low- and middle-income countries—can ensure the medium- to long-term relevance, efficiency, quality, affordability, and security of global health procurement.

1. This estimate is based on a subset of 43 countries: 18 LICs and 25 LMICs where spending on global health products totals \$4.4 billion and \$45.4 billion, respectively; <https://www.cgdev.org/publication/initial-estimation-size-health-commodity-markets-low-and-middle-income-countries>.

2. The Global Fund. Procurement Strategies & Implementation with a focus on ARVs. May 2, 2017.

3. Based on \$4.2 billion annual disbursements for 2017. See <https://www.theglobalfund.org/en/financials/>.

Importantly, the group limited its focus to the procurement process: the journey of a health product from manufacturer to a centralized warehouse or other wholesaling facility. The downstream supply chain and delivery process—a product’s journey from warehouse to end user—was beyond the Working Group’s scope.

The Triple Transition in Global Health Procurement

Global health procurement needs are evolving rapidly as countries face a *triple transition*:

First, with income levels rising, low- and middle-income countries face the prospect of a *transition from donor aid*. Health products procurement, especially in low-income countries, remains heavily reliant on donors; making up for lost financing following donor exit will stretch already-strained national health budgets. Many low-income and lower-middle-income countries also have limited experience and capacity in procurement-related functions.

Second, low- and middle-income countries face an *epidemiological transition*. As countries become wealthier, disease burdens shift from infectious to noncommunicable diseases such as cardiovascular disease, cancer, and diabetes. To meet their citizens’ evolving health needs, governments will need to purchase and make available a very different set of health products from those procured today.

Third, countries face a *transition in health system organization* as they move away from siloed disease-specific programs and out-of-pocket spending toward universal health coverage. As more governments commit to protecting their citizens against catastrophic health spending, national or subnational procurement processes will be a cornerstone of equitable and universal access to health products. Achieving universal health coverage within tight budgets will require national governments and their global health partners to make procurement decisions that deliver the most value for money.

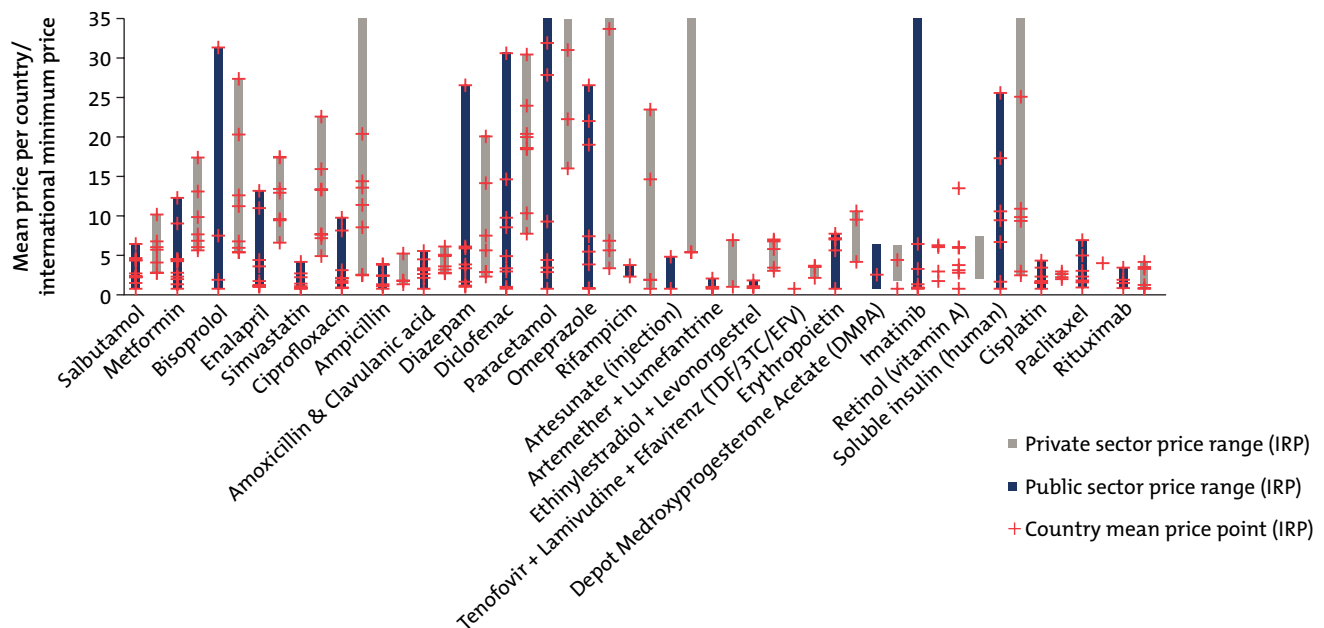
Key Insights on Health Product Markets in Low- and Middle-Income Countries

Key Insight 1: In Low- and Middle-Income Countries, Prices for Basic Generic Medicines Can Vary and Far Exceed Wealthy-Country Prices.

Purchasers in low- and middle-income countries pay as much as 20 to 30 times a minimum international reference price for basic generic medicines like omeprazole, used to treat heartburn, or paracetamol, a common pain reliever.

Price Variation Across Seven Low- and Middle-Income Countries for Generic Pharmaceutical Products

Comparison of public and private pharmaceutical procurement prices (US\$) across countries, relative to international minimum price

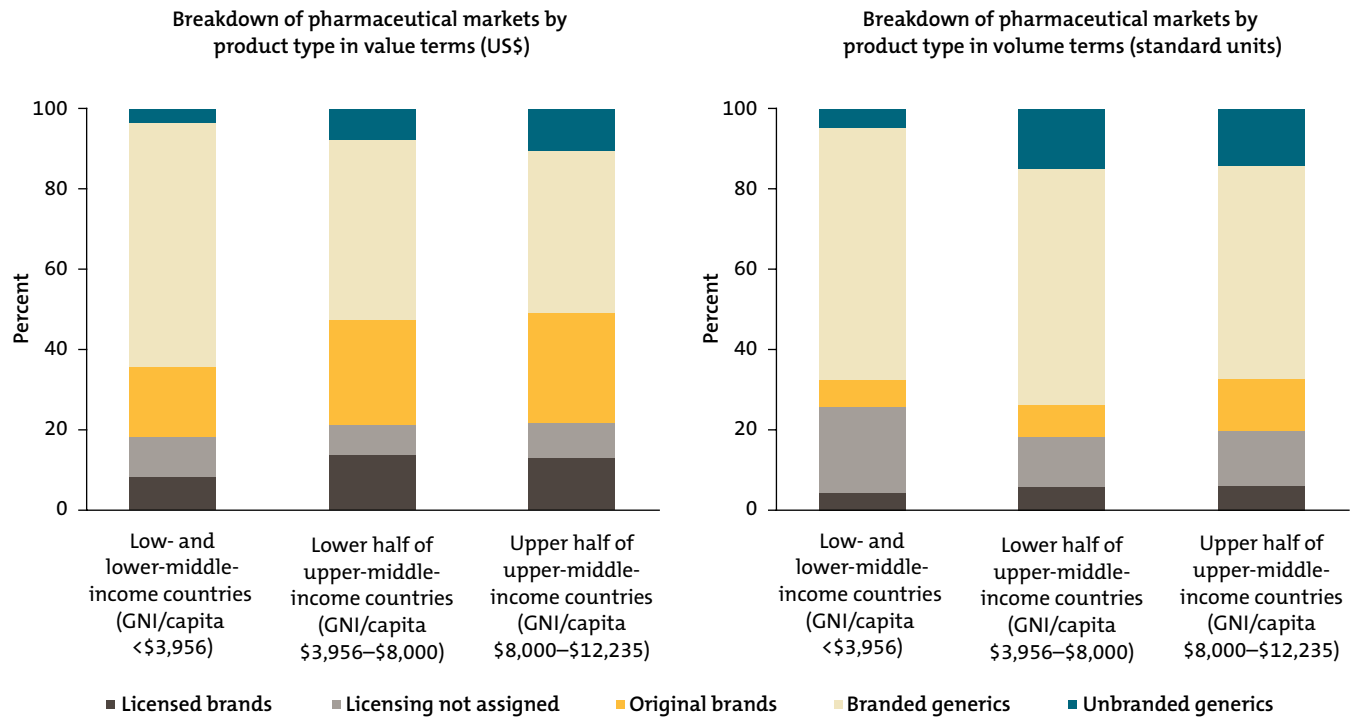


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Key Insight 2: Low- and Middle-Income Countries Disproportionately Purchase Expensive Branded Generic Drugs Rather than Cheaper Unbranded Generics.

In the poorest countries, branded generics—which command a price premium—make up about two-thirds of the market by volume and value. Unbranded generics, usually the least expensive option, are a tiny sliver: only 5 percent of the market by volume and 3 percent by value. In contrast, in the United States and the United Kingdom, unbranded quality-assured generics account for 85 percent of the pharmaceutical market by volume, but only about a third by cost.

Health Product Markets in Low- and Middle-Income Countries by Brand and Licensing Status

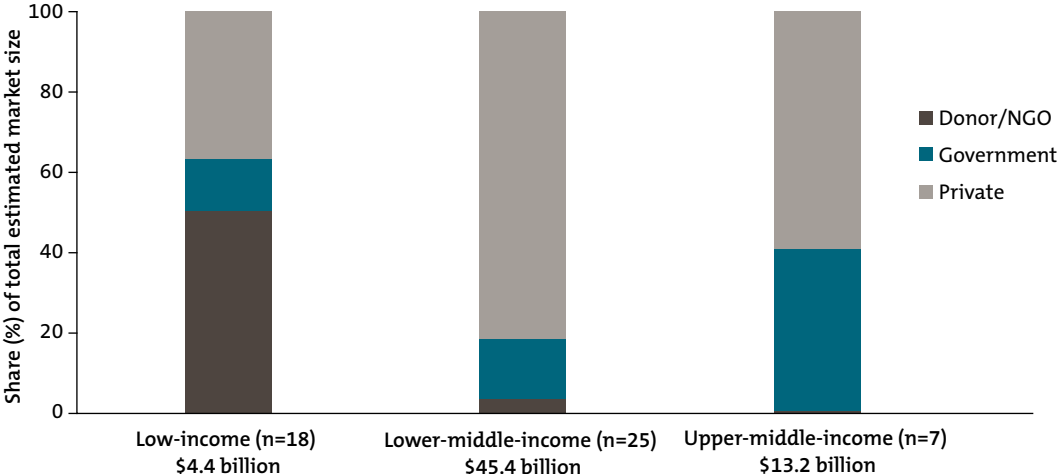


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Key Insight 3: As Countries Become Wealthier, Donor Financing for Health Products Becomes Less Important.

Donors account for half of all expenditure on health products in low-income countries; in contrast, in lower-middle-income countries, 80 percent of health products are procured through the private sector, where individuals pay directly for medicines out-of-pocket. Lower-middle-income country governments do not yet account for a large share of total purchasing in their countries for medicines and other health products.

Private, Government, and Donor/NGO Financing as a Share of the Total Estimated Market (Value) for Health Products by Country Income Groups



For source and notes see full report.

Key Insight 4: There Is Little Competition in the Supply of Essential Medicines in Low- And Middle-Income Countries— These Markets Are Dominated by a Single or a Small Number of Suppliers, Which Directly Affects the Prices Paid by Public Procurers and Consumers.

In some low- and middle-income countries, the largest seller of certain therapy and product classes accounts for upwards of 85 percent of all sales, such as contraceptives in Zambia, Philippines, Senegal, and Kerala; cancer medicines in Zambia and Kerala; diabetes medicines in Zambia; and antiparasitics in Philippines, Zambia, Tunisia, and South Africa.

One-Firm Concentration Index by Therapy Area for Selected Countries/States (Sample of 40 Molecules Only)

Area	Country (%)						
	Kerala	Philippines	Senegal	Serbia	South Africa	Tunisia	Zambia
Anemia		66.4	100.0	88.1			
Antiulcerants	44.4	44.0	18.4	72.1	61.4	50.4	81.3
Antihypertensives	62.2	62.2	69.6	43.7	76.5	75.1	91.7
Antibiotics	21.9	51.9	88.3	63.2	29.0	44.5	61.9
Antiparasitics	33.1	100.0	40.0		91.8	97.5	98.2
Arthritis immunosuppressants	37.4	57.5	31.3	57.9	61.6	63.1	90.6
Asthma/COPD	84.8	62.9	96.2	84.0	78.9	95.7	100.0
Cancer	90.6	61.7	76.0	58.8	65.0	64.4	100.0
Contraceptives & hormones	84.4	97.2	87.3		72.5	80.7	98.7
Diabetes	27.3	51.5	72.4	61.0	59.8	56.0	100.0
HIV antiretrovirals	64.7				82.2	84.4	100.0
Lipid regulators	74.1	46.7	46.4	59.8	81.2	70.3	98.8
Nervous system medications	89.1	78.2	100.0	78.2	83.3	91.4	99.5
Pain analgesics		55.0	93.2	40.6	50.0	30.8	100.0
Tuberculosis	40.0	59.7	30.7	46.5	50.4	61.5	80.6
Vitamins and minerals		99.0	88.0	97.7	99.8	26.6	

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Institutional Inefficiencies, Market Failure, and Unorganized Demand Lead to Suboptimal Procurement Outcomes

The Working Group found that a wide range of factors lead to suboptimal procurement outcomes—institutional inefficiencies, market failure, unorganized demand, supply chain and delivery challenges, and absolute resource constraints. The first three categories can be addressed, at least in part, by improved procurement policies and practices at the global, regional, and national levels.

Institutional inefficiencies include constraints related to the capacity of procurement entities and supporting institutions to create the right conditions for efficient and effective procurement. These include:

- *Institutional, administrative, and legal barriers*, such as onerous registration processes, inefficient local purchasing preferences, and legal strictures against more effective procurement modalities, which artificially constrain competition, raise transaction costs, and inflate prices
- *Inefficient product selection*, which directly affects what is purchased and can thus lead to inefficient use of scarce budgetary resources for health
- *Limited procurement capacity and expertise* across the entire procurement process, which can lead to suboptimal procurement outcomes
- *Inadequate and inconsistent tracking, monitoring, and evaluation*, which limit the ability to track and effectively manage products along the supply chain and identify effective procurement instruments and reforms
- *Parallel and duplicative supply chains*, which drive inefficiencies and undermine efforts to build national capacity

Market failure occurs when free-market forces lead to an inefficient distribution of goods and services. Several characteristics of global health commodity markets make them susceptible to market failure and create welfare losses for producers, consumers, and society as a whole. These include:

- *Imperfect information* about product quality, which may allow substandard products to enter and/or dominate the market and/or lead consumers to pay higher prices for branded generics that signal quality
- *Barriers to entry* (e.g., the costs to receive approval for a generic equivalent or register an existing generic in a new market), which may prevent new suppliers from entering the market, thereby limiting competition and potentially raising prices

- *Externalities* that shift costs and benefits beyond the user of a given product may, for example, lead to the overuse and misuse of antibiotics, undermining their efficacy, or lead to underuse of a relatively expensive vaccine with important global benefits
- *Public and common goods* in global health—such as antimicrobial efficiency and research and development on new health technologies—lead to diffuse benefits to all of society and thus actors may have insufficient incentives to invest in, purchase, conserve, and/or provide such products
- *Present bias*, whereby people undervalue preventative health measures, may contribute to low expenditure on preventive health technologies such as contraceptives, bed nets, or immunization
- *Principal-agent problem*, which occurs when purchasers (agents) face strong personal or financial incentives that do not align with the interests of end users—for example, different levels of risk aversion or the opportunity for kickbacks from suppliers
- *Anti-competitive behavior*, which can involve unilateral practices that a dominant firm uses to exclude rivals or explicit or tacit agreements between firms to set prices above market-clearing rates

Unorganized demand—including relatively low levels of pooling/high levels of procurement fragmentation coupled with uncertain and unreliable demand—can, under some circumstances, also contribute to procurement inefficiency. The high transaction costs in serving fragmented markets are oftentimes passed down to purchasers. This includes:

- Fragmentation of demand in the case of products purchased in small quantities may lead to high transaction costs, prevent suppliers from entering low-volume markets, and/or deter suppliers from offering preferential pricing
- When demand is uncertain and/or unreliable, suppliers may limit investment in research, development, and manufacturing capacity

Four Recommendations for Reform

We propose four recommendations for smarter, more strategic procurement policy and practice. Together, these recommendations offer a vision for how today's global health procurement bodies can reimagine and redefine their roles to stay relevant in a changing world.

1. Sustain and Expand Global Cooperation for Procurement and Targeted Innovation. The global community should seek to sustain and possibly expand global cooperation to address specific global challenges—particularly supply security and targeted innovation—even after most countries transition from current global health mechanisms. Avenues for continued or expanded global cooperation should include pooled demand or cooperative purchasing; targeted investments in research and development; monitoring and managing the supplier landscape; information sharing, market intelligence, and e-platforms; support to nascent and start-up private sector innovations; common standards and principles for quality assurance; and continued subsidy for specific products—that have important positive externalities or that are marginally cost-effective, for example—even after countries have largely transitioned from external aid.

2. Reform WHO Guidance and Policy to Support Modern and Agile Procurement Policy and Practice. To reassert itself as the global standard-setting body and better support modern and agile procurement policy and practice, the WHO should set and execute a prioritized guidance reform agenda, which may include expanding efforts to facilitate common or expedited drug registration at the country level; providing guidance on and working with countries to adapt the WHO essential medicines, diagnostics, and medical devices lists and technical guidance to local contexts and resource constraints; and comprehensively updating guidance for pharmaceutical policy.

3. Professionalize Procurement by Building Capacity and Driving Strategic Practice. A concerted push is needed to professionalize procurement and broaden capacity from the global to national level. A partnership or network of existing entities including procurement universities or accreditation bodies, multilateral institutions, and resource platforms could support the creation of the following components: Procurement University; mentoring and exchange, including through a community of practice or learning network; global health-specific procurement guidance including toolkits, decision trees, and other resources; standardized set of performance measures for global health procurement; and evaluation of procurement policies and approaches.

4. Support In-Country Procurement Policy Reform. Global funders interested in ensuring more efficient national procurement processes and sustainable access to essential global health products should provide dedicated support to governments leading in-country procurement policy reforms. Potentially, development policy lending from the International Bank for Reconstruction and Development or IDA could be leveraged to facilitate procurement reforms, with attention to ensuring that there is domestic leadership and commitment. Country-led procurement reforms should consider the following dimensions: purchasing and contracting modalities, procurement-related functions, industrial policy requirements, and product regulation.

1

INTRODUCTION



Global Health Procurement: Big Money, Big Impact

Health products like medicines and diagnostics can save and improve lives—but only if patients can access them in moments of need.¹ The global health community also emphasizes the transformative potential of these technologies to fight scourges like HIV, malaria, and tuberculosis (TB), and to achieve the health-related Sustainable Development Goals (SDGs). Yet these potential gains can only be realized with strong systems to prioritize and procure cost-effective lifesaving health products and ensure they are available at affordable prices to those who need them most.

Although each low- and middle-income country faces distinct health and financing challenges, effective procurement of medicines, diagnostics, devices, and vector control tools can be a shared foundation for efforts to improve health, achieve international goals, and build systems for universal health coverage (UHC).² Expenditure on health products in low- and lower-middle-income countries (LICs and LMICs) is already high—in absolute terms and as a percentage of total health expenditure—and is rising fast. In a subset of these countries, overall spending on global health products totals an estimated \$50 billion per year.³ At the same time, emerging markets like Turkey, Pakistan, and Egypt are among the countries expected to see the fastest growth in spending on pharmaceuticals between 2019 and 2023.⁴ As countries grow wealthier and increase their domestic spending on health products, donor support typically wanes. Yet in its absence, newly middle-income governments can be slow to pick up the bill, often leaving patients to go without or seek products in the private sector using their own out-of-pocket (OOP) resources.⁵

Effective procurement systems alone cannot address the entirety of the “priorities ditch” for transitioning countries, which may not have the incentives to continue providing the essential health products and services previously funded by aid.⁶ However, such systems can help stretch scarce health resources as far as possible, expanding the availability of high-quality health products, enhancing access, and reducing catastrophic financial risk for patients.

Likewise, procurement of health products is central to the mission (and expenditure patterns) of large global health institutions. Some global health entities, including UNICEF’s Supply Division, UNFPA (United Nations Population Fund) Supplies, and Unitaid, focus almost exclusively on commodity procurement, market access, and delivery. Others finance more comprehensive service delivery activities and at the same time invest heavily to ensure a steady supply of health products; for example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) spends an estimated \$2 billion per year on procurement of global health products, accounting for almost half of its overall annual disbursements in 2017.⁷ The concentration of purchasing power in the hands of a few global donors can create wide-ranging benefits. Yet these arrangements also have risks, as procurement-related shortcomings at the global level or volatile donor funding flows can have systemic and catastrophic consequences, including, for example, delays in the delivery of lifesaving products.⁸ Beyond routine procurement, many global health institutions—including the Global Fund, Gavi, the US Agency for International Development (USAID), and Unitaid—have pursued market shaping efforts to influence the market landscape for health products considered central to their

1. This report focuses solely on the procurement of health products, rather than services.

2. Wirtz et al. 2017.

3. This estimation is based on a subset of 43 countries: 18 low-income countries (LICs) and 25 lower-middle-income countries (LMICs) where spending on global health products totals \$4.4 billion and \$45.4 billion, respectively. For more, see Rosen, Chalkidou, and Madan Keller 2017.

4. “The Global Use of Medicine in 2019 and Outlook to 2023” 2019.

5. AfRx 2018.

6. For more information on the “priorities ditch,” see Glassman and Kenny 2015. For a discussion on the “priorities ditch” as applied to health products, see Rosen, Chalkidou, and Madan Keller 2017.

7. The Global Fund 2017; and “Financials” 2018.

8. “Oversight Investigation: USAID Global Health Supply Chain Contract” 2018.

core missions.⁹ And most agree that long-term stability of global health markets and sustainability of global health procurement systems are likewise central to eventual aid transition.

At both the national and global levels, health products are big money, and ensuring reliable and affordable supply is a basic prerequisite for any health system or program. How countries and global health institutions procure these products—and whether procurement processes optimize for quality, price, supply security, and efficiency—can be a matter of life and death.

What We Mean by “Global Health Procurement”

This report draws a distinction between procurement processes—the segments of the value chain that occur up to the moment a product is delivered to and accepted by a centralized warehouse or other wholesaling facility—and the downstream supply chain/delivery processes that help bring the health products to end users. It focuses on the former: the procurement segment of this broader process, encompassing product selection, regulation of health products, tendering, price negotiation, ordering, and quality assurance. The procurement segment is intrinsically embedded within the overall supply chain and must be understood as part of this broader process; nevertheless, the procurement component itself—as a rapidly evolving and relatively underexamined portion of the overall value chain in global health—merits its own focus.

Even the most effective procurement systems will fail to deliver health value without complementary downstream supply chain and delivery systems. Moreover, procurement and downstream supply chain functions are interrelated and often difficult to disentangle in practice; for example, an effective inventory management system is required to track stock levels and

prompt timely reordering. Nonetheless, the specific skills, knowledge, and capacities required to effectively manage *procurement* in and of itself are distinct and merit specialized attention, even if improved procurement alone addresses only one segment of the overall value chain.

Another important question relates to the set of products under the “global health procurement” umbrella. Historically, the term “global health procurement” has been associated with the subset of products procured in large quantities by global health donors and funding mechanisms—most notably vaccines; family planning products; and health products associated with the prevention, diagnosis, and treatment of HIV, TB, and malaria. Yet in an era of increasing burdens from noncommunicable conditions and the global ambition to achieve UHC, “global health” necessarily takes on a broader meaning. Rather than limiting our inquiry to a specific commodity class or disease area, we thus take a more holistic and cross-cutting view, considering the entire range of products that countries and households purchase to prevent ill health, diagnose ailments, and treat disease. These include medicines, diagnostics, devices, and vector control tools—encompassing those that are on- and off-patent; branded and generic; preventative, diagnostic, palliative, and curative; for infectious diseases, noncommunicable conditions, and injuries; and costing anywhere from a few cents to many thousands of dollars.¹⁰ In general, we do not closely analyze specific market characteristics and challenges for individual products, but instead make conceptual distinctions between product classes to guide policy choices. (The specific challenges related to vaccines are out of scope for this report, but many—though not all—of the same findings and lessons should apply.¹¹)

9. For the Global Fund, see “34th Board Meeting: Market Shaping Strategy” 2015. For Gavi, see “Gavi’s Strategy, Phase IV (2016–20) - the Market Shaping Goal” n.d. For US Agency for International Development (USAID), see “Healthy Markets for Global Health: A Market Shaping Primer” 2014. For Unitaid, see “Strategy 2017–2021” 2017.

10. Health information technologies and digital technologies are out of the scope of this report, though we acknowledge that the rapid pace of technological development will impact the future of global health procurement.

11. Notably, vaccine markets are relatively well studied and understood; one important distinction is that they are more centralized with one major funder (Gavi) and a few major buyers (e.g., UNICEF, the Pan-American Health Organization [PAHO]), and thus may not suffer from the same complexity and fragmentation present in other product markets.

Global Health Procurement Since 2000: Major Investments, an Incomplete Agenda

The “golden age” of global health kicked off in 2000–2001 with adoption of the Millennium Development Goals (MDGs); the founding of the Bill & Melinda Gates Foundation and Gavi, the Vaccine Alliance; and initial discussions about a global fund to fight AIDS, TB, and malaria.¹² In subsequent years, these mechanisms matured and grew, while the introduction of the President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI), and Unitaid further expanded the scope and reach of global health assistance. Through global upheaval and economic crises, development assistance for health grew rapidly and consistently for more than a decade, from just over \$10 billion in 2000 to about \$38 billion in 2013.¹³

As the MDG era came to a close in 2015, these investments had greatly expanded global access to life-saving health products. In 2017, for example, more than 21 million people living with HIV globally were receiving antiretroviral (ARV) therapy, compared to just 685,000 people in 2000.¹⁴ With assistance from global health institutions, new and groundbreaking products—a vaccine against meningitis A and artemisinin-based combination therapies (ACTs) to treat malaria, for example—achieved widespread distribution and uptake, saving many lives.¹⁵ In part aided by improved access to global health products, far fewer children now die before their fifth birthday; more women than ever before use modern contraception to prevent unwanted pregnancies; and malaria deaths have fallen dramatically since 2000.

12. The term “golden age” was coined by the Institute for Health Metrics and Evaluation (IHME). See Murray and Hanlon 2013.

13. “Financing Global Health 2016: Development Assistance, Public and Private Health Spending for the Pursuit of Universal Health Coverage” 2017.

14. For 2000 data, see “People Receiving ART by Region, 2000–2016” n.d. For 2017 data, see “Global HIV & AIDS Statistics – 2018 Fact Sheet” 2019.

15. On the meningitis A vaccine, see Trotter et al. 2017; “Meningitis A nearly eliminated in Africa through vaccination” 2016; and Glassman and Temin 2016. On the artemisinin-based combination therapy, see “Independent Evaluation of the Affordable Medicines Facility - Malaria (AMFm) Phase 1: Multi-Country Independent Evaluation Report: Final Report” 2012.

These are major successes, reflecting global cooperation and effective investments. Yet these good news stories coexist with an unpleasant reality: global access to essential medicines and other health products is still grossly insufficient, leaving too many men, women, and children without the health products they need to survive and thrive. In 2011, the World Health Organization (WHO) reported that “at least one-third of the world’s population [had] no regular access to medicines.”¹⁶ In many low- and middle-income countries, where progress toward UHC remains limited, essential health products may be available only in the private sector—purchased through OOP spending and at prices unaffordable for many families.¹⁷ (In LICs and LMICs, private sources of spending account for 36 percent and 81 percent of health commodity expenditure, respectively.¹⁸) Other health products—particularly innovative technologies—may be out of reach for even the wealthy few; data suggests that innovative health products often enter low- and middle-income country markets many years after they become available in higher-income countries. Of the 330 new chemical entities launched globally between 2007 and 2016, by 2017 just 6 percent (or 21 new chemical entities) were available in French West Africa and less than 20 percent (62) in South Africa; by contrast, 86 percent (285) were available in the United States.¹⁹

And while global conversations about access to medicines typically focus on pricing for originator on-patent drugs, the vast majority of spending on health products in low- and middle-income countries goes

16. Hogerzeil and Mirza 2011.

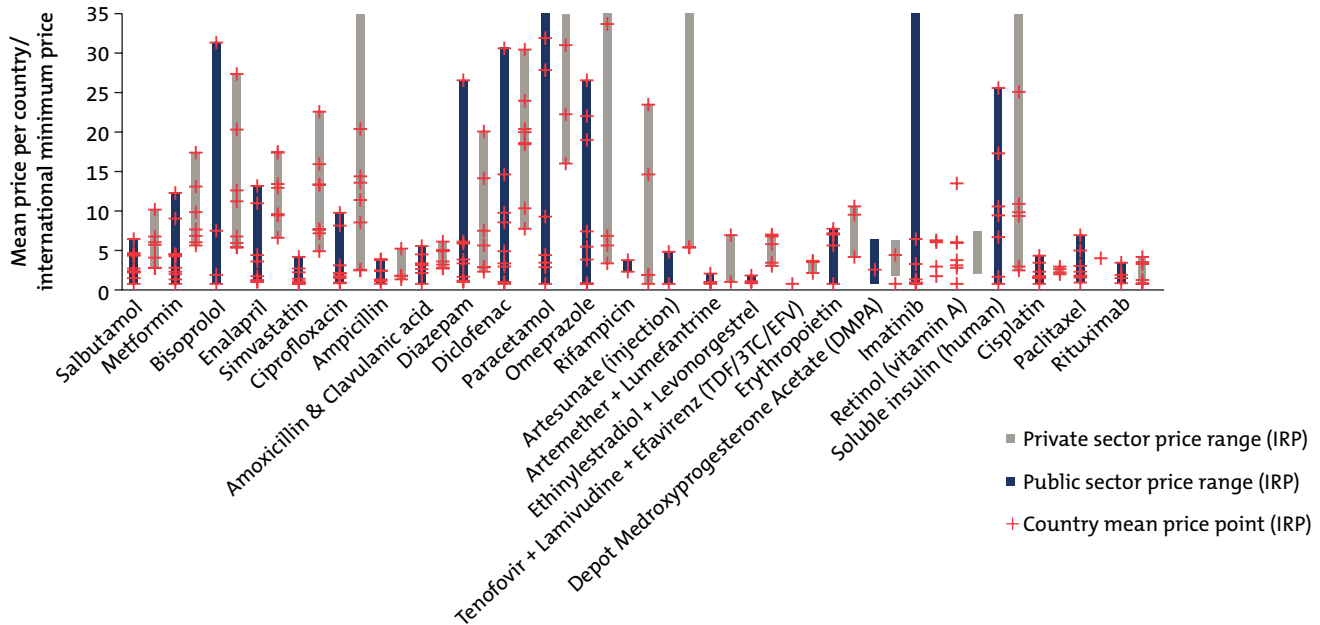
17. Ewen et al. 2017.

18. Data for 2015. The private sector here includes procurement through large hospitals or pharmacy chains (group purchasing organizations [GPOs]); private wholesalers and retailers; private distributors (e.g., Eurapharma/Laborex in French West Africa); and government hospitals, clinics, and pharmacies purchasing directly from domestic private sector distributors. AfRx 2018. See also Rosen, Chalkidou, and Madan Keller 2017.

19. Although we acknowledge that the French West Africa region has particularly slow absorptive capacity (innovation diffusion is likely to be better in Nigeria, Ghana, and in East Africa), the limited available data nonetheless illustrate the broader trend of slow diffusion of innovation. The data represent sales of all new chemical entities “launched” globally in the past 10 years. If a country had any sales of these products in the past 10 years, then it was considered to have “launched” in that country. The new chemical entities were selected according to molecule, not brand, and licensed brands were counted as launches for the purpose of the analysis. AfRx 2018.

Figure 1. Price Variation Across Seven Low- and Middle-Income Countries for Generic Pharmaceutical Products

Comparison of public and private pharmaceutical procurement prices (US\$) across countries, relative to international minimum price



Source: IQVIA Data for Indian state of Kerala (Hospital, Retail), Philippines (Private), Senegal (Private), Serbia (Private, Public Hospital, Public Pharmacy), South Africa (Private, Public Tender, Public Direct), Tunisia (Public, Private), and Zambia (Public, Private). Respondents: Kerala, Senegal. Publicly available data: Philippines. Public sector respondent data from Kerala, Senegal, and publicly available data from the Philippines. Public data n= 154 data points, Private data n=131 data points.

Note: Analysis measures price variation by molecule. IRP=International reference price.

to off-patent products.²⁰ Nevertheless, purchasers in low- and middle-income countries often face high and highly variable medicine prices.²¹ Recent data covering a basket of 25 generic pharmaceutical products in a subset of seven countries suggests that some countries pay as much as 20 to 30 times a minimum international reference price for basic generic medicines, such as the heartburn treatment drug omeprazole or the common pain reliever paracetamol (Figure 1).²² This variation is most notable in some of the poorest countries. A World Bank analysis in the Republic of the Congo, for example, found that drug prices were, on average, four times higher than international reference prices—essentially

doubling the price tag of its proposed health benefits package compared with published international reference levels.²³

Looking Forward: A Triple Transition on the Horizon

Today, health systems everywhere are struggling to make essential health products available to those in need. But the global health community cannot simply address today's problems, looking backward to the unfinished MDG agenda. Global health procurement needs are evolving rapidly and dramatically—as are the opportunities to achieve efficiencies and leverage technological innovations seen in broad use among

20. AfRx 2018.

21. Cameron et al. 2009.

22. This data point is specifically for paracetamol syrup (120 mg/5 ml). AfRx 2018.

23. Bitran 2016.

private firms and supply chains worldwide. A forward-looking approach is needed to anticipate tomorrow's challenges and proactively plan for the changing landscape. This report focuses on the simultaneous *triple transition* in global health procurement: the *transition from donor aid* as poorer countries grow wealthier, the *epidemiological transition* from infectious diseases to noncommunicable conditions, and the *transition of health system organization* from vertical disease programs to integrated UHC.

First, LICs and LMICs are facing the prospect of *transition from donor aid*. In large part, this is a good news story, prompted by widespread economic growth. However, multiple global health transitions are occurring simultaneously in newly middle-income countries, with potentially significant fiscal impact if countries take on the costs and procurement of aid-funded commodities directly. Countries gradually lose eligibility for the World Bank's International Development Association (IDA) concessional lending once their gross national income (GNI) per capita exceeds the \$1,165 threshold. They subsequently begin a five-year accelerated transition process from Gavi for vaccine support once GNI per capita exceeds \$1,580, averaged over three previous years.²⁴ Global Fund transitions typically occur far later and at much higher income levels, but its requirements for phased increases in cofinancing require increasing levels of domestic counterpart funding. Countries are also subject to changing spending patterns from those global health institutions and initiatives that do not have formal eligibility policies, including PEPFAR, UNFPA, and the Global Polio Eradication Initiative (GPEI). Analysis across multiple global health funding channels suggests that the pace of transition will soon accelerate, with Gavi and IDA transitions front-loaded between now and 2025, combined with the rapid phaseout of GPEI expenditures.²⁵ Moreover, the next cohort of transition countries will enter the transition period with worse macroeconomic, fiscal, poverty, and governance conditions than earlier

cohorts, suggesting that future country purchases of the cost-effective commodities currently procured by global health funders may be at significant risk.²⁶

Further, current patterns of health products spending suggest a potentially grim prognosis for procurement of essential medicines in countries undergoing aid transition (Figure 2). In most LICs, coded red in Figure 2, the public sector accounts for half or more of overall health products spending (indicated by the x-axis); in turn, donors and nongovernmental organizations (NGOs) comprise a large share of public-sector funding (indicated by the y-axis), based on data from 2015 or the nearest available year.²⁷ Slightly wealthier LMICs, indicated by the black dots, predictably see international aid decline in relative importance as a source of health products spending (indicated by the y-axis). Despite variation across countries in this group, emerging LMICs generally appear slow to replace the donor contribution with pooled (usually public/government) spending on health products—and in the vacuum, private-sector spending increases in relative importance as citizens seek alternative channels to meet their health product needs (most of the black dots are positioned on the left side of the x-axis).²⁸ Only the most mature systems (OECD [Organisation for Economic Co-operation and Development] countries and some upper-middle-income countries [UMICs]) see a majority of health products spending channeled through pooled sources, often allocated through framework agreements that allow for decentralized decision-making on volumes combined with nationally negotiated prices and formulary control. These findings are only indicative; this static snapshot of health products financing historically cannot necessarily predict future trends. Nonetheless, it should attract the attention of global policymakers who seek continuity of health products financing and

24. Countries Eligible for Support" n.d.

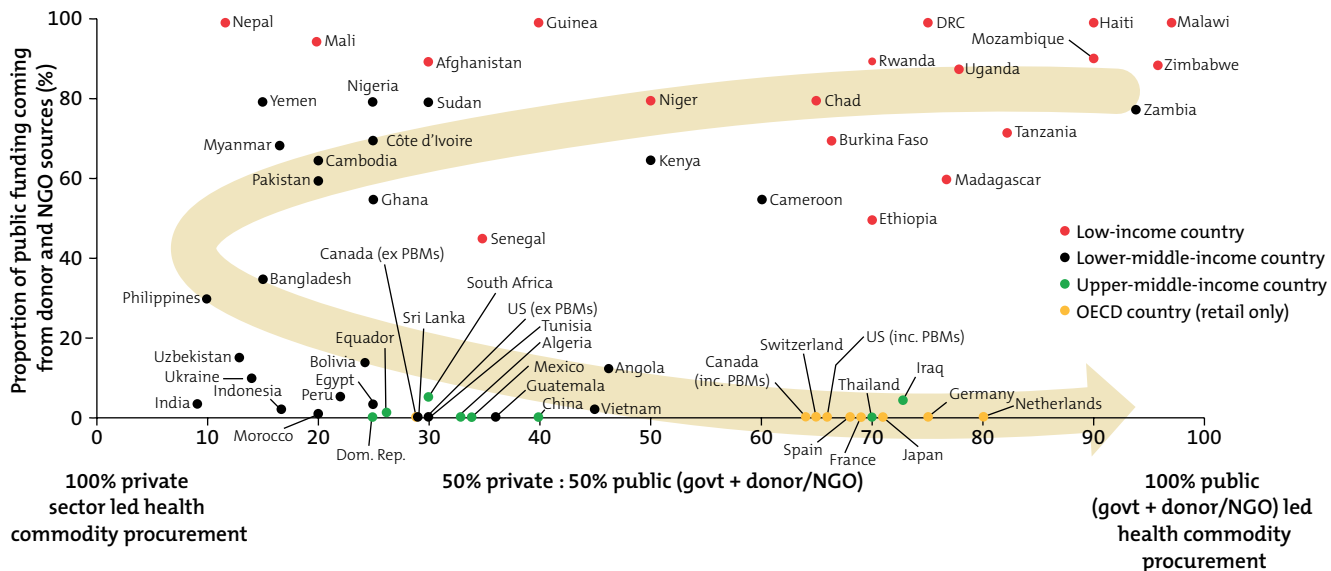
25. Silverman 2018.

26. Yamey et al. 2018.

27. Public sector here comprises expenditures by governments; social health insurance funds; and external borrowings and grants, including from international agencies and nongovernmental organizations (NGOs).

28. Private sector includes out-of-pocket (OOP) spending and private insurance, as well as private not-for-profit, charitable, and faith-based organizations.

Figure 2. Levels of Centralized Procurement by Country and Donor Dependence (2015 or nearest available year of data)



Source: UN Comtrade and secondary sources.

Note: Donor/NGO procurement includes integrated procurement within government systems; multicountry NGO global tenders (e.g., through Gavi, Pan-American Health Organization [PAHO], Global Fund). Government procurement includes central medical stores (CMS); ministries of health (MOHs); regional medical stores; state/group of hospitals; social security programs. Private procurement includes large hospitals or pharmacy chains (GPOs); private wholesalers and retailers; private distributors (e.g., Eurapharma/Laborex in French West Africa); government hospitals, clinics, pharmacies purchasing directly from domestic private-sector distributors outside of framework agreements. May be missing NGO data sources for Guinea, Afghanistan, Mali, and Nepal that would move them toward greater public procurement.

For methodology and full list of caveats, see AfRx 2018.

procurement across aid transitions, with the idea that governments simply assume responsibility for donors' previous fiscal commitments. It also implies that many LIC and LMIC governments are currently procuring health products at a relatively small scale, potentially signaling limited expertise and capacity to support procurement-related functions following donor exit.

Second, low- and middle-income countries are facing an *epidemiological transition* from infectious diseases to noncommunicable conditions, driving an evolving composition of product needs and demands.²⁹ As Figure 3 shows, the most significant drivers of nonvaccine health products spending in the public and private sectors of a sample of relatively poor countries are almost all related to infectious diseases—ARVs, antibiotics, and antiparasitics. In wealthier middle-income countries, by contrast, the pattern of spending appears

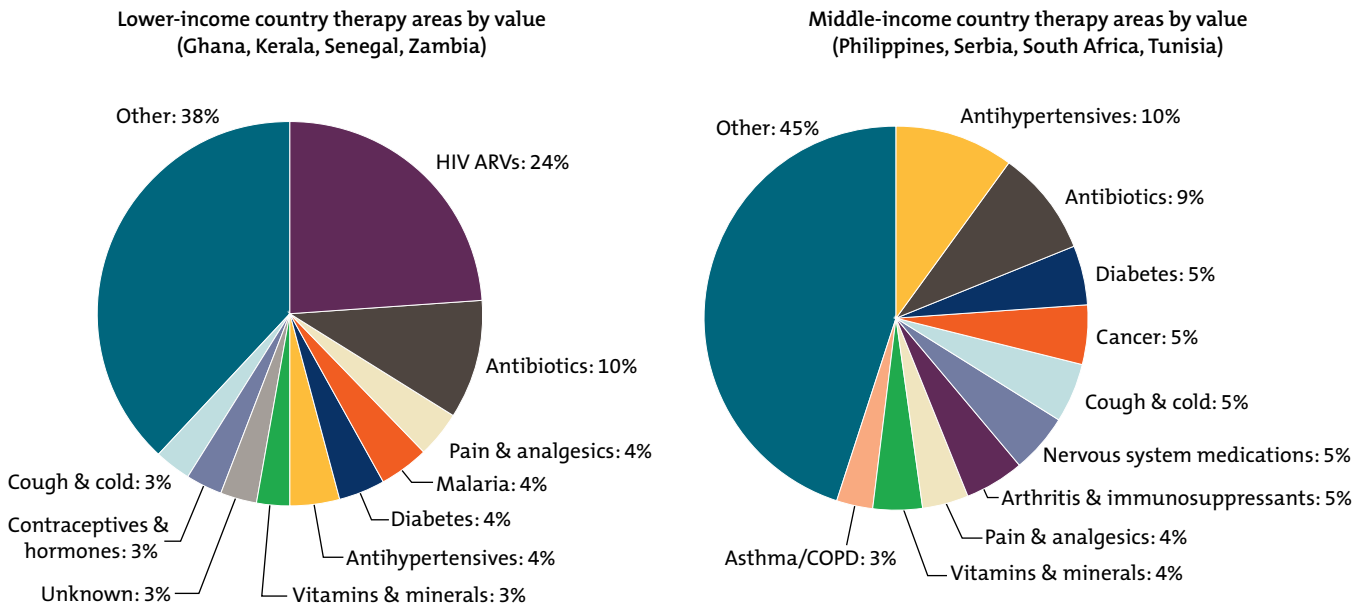
far different; antihypertensives become the leading source of expenditure, with cancer and nervous system medications also taking top slots.³⁰ To meet their populations' changing health needs, tomorrow's low- and middle-income country procurement systems will need to procure an almost entirely different portfolio of health products from those they are familiar with today. Further, countries facing a double burden of communicable and noncommunicable conditions will need to increasingly focus on managing multiple morbidities.

Finally, countries are grappling with a *transition in health system organization*—away from disease-specific programs and OOP spending toward comprehensive UHC. Citizens are increasingly demanding access to a broader range of essential health products than

29. "Findings from the Global Burden of Disease Study 2017" 2018.

30. Although South Africa, which is one of the highest-burden HIV countries, is included in this grouping, it is notable that ARVs are not among the top 10 therapy areas by value. See Appendix D.

Figure 3. Top 10 Therapy Areas as a Share of Health Product Markets (By Value, Across Public and Private Sectors, Excludes Vaccines)



Source: IQVIA Data. All countries and years weighted as equal. Average of last three years of available data.

Note: The 10 therapy areas (specified by 55 aggregated definitions) shown in each figure represent those that constitute the largest share by value of the total health commodity market for the public and private sectors, excluding vaccines. The “other” category is an aggregation of all remaining therapy areas included in the analysis. Data for Ghana is from the Ghanaian Food and Drug Administration’s import GCNet database, processed by molecule into pharmaceutical therapy areas. See Appendix D for more details.

Data copyright IQVIA AG and its affiliates. All rights reserved. 2017. For methodology and full list of caveats, see AfRx 2018.

those historically procured by donors or low- and middle-income country governments.³¹ Governments and civil society are in turn mobilizing to protect their communities against catastrophic health spending and health-related impoverishment. China, India, and Kenya are just a few examples of countries undergoing health sector reforms to drive greater medicines affordability and access as part of ambitious commitments to achieve UHC. As low- and middle-income countries progress toward UHC, procurement will be the cornerstone of equitable and universal access to health products—and achieving UHC within tight budget constraints will challenge global health institutions and country payers alike to rationalize product selection with an eye toward driving increased access to medicines and better health for all citizens. Moreover, in an increasingly global marketplace for health

products, the actions of big buyers like China and India, which are expanding and pooling procurement within emerging UHC schemes, will influence what happens in the rest of the market and the terms that smaller purchasers in LICs will face.³²

These three transitions are only a subset of the challenges likely to confront low- and middle-income countries over the coming years. Domestic and global procurement systems must also prepare to face rapid technological change and digitization, manage demographic shifts, address drug resistance, and prevent and prepare for novel outbreaks, among other changes. These trends will inevitably stress and challenge health procurement systems. Yet by looking forward—while also referencing the lessons of past decades—countries

31. Logendra, Rosen, and Rickwood 2014.

32. Xu 2019; “India’s Mega Health Reforms: Treatment for Half a Billion” 2018; and Sanghvi 2018.

and global institutions enjoy an enormous opportunity to institute proactive evidence-based reforms, with the potential for real benefits.

Why This Center for Global Development Working Group?

The Center for Global Development (CGD) is a Washington-based “think- and do-tank,” working to “change the policies and practices of rich countries and powerful institutions to reduce global poverty and inequality.”³³ Through its Global Health Policy Program, CGD seeks to apply accumulated economic knowledge to address today’s pressing global health challenges, with a particular focus on correcting market failures, creating virtuous incentives, and building institutions to equitably and efficiently allocate scarce resources for health.³⁴ Previous CGD Working Groups have identified solutions to accelerate research and development (R&D) for lifesaving innovations; address regulatory barriers to the rollout of new health technologies; increase value for money at leading global health institutions, including the Global Fund, UNFPA, and the Family Planning 2020 (FP2020) partnership; and build domestic priority-setting institutions for UHC.

Within the changing context described in the previous section, CGD and the Bill & Melinda Gates Foundation agreed that CGD’s collaborative working group model and economic lens were well-suited to help identify how global health procurement can be smarter and more efficient—a question that is top of mind for many global institutions and procurement experts. In July 2017, CGD convened a Working Group on the Future of Global Health Procurement, with the goals of applying economic insights and analysis to current and future global health procurement challenges; strengthening data and analytics to track performance and efficiencies; and evaluating how different purchasing modalities (including pooled purchasing mechanisms) can drive both value for money and increased access to

lifesaving products. The Working Group was composed of low- and middle-income country policymakers, procurement specialists, representatives from global health institutions and donors, and academic experts (see Appendix A for complete membership and profiles). The group was tasked with reviewing evidence and formulating recommendations for how the global health community can ensure the medium- to long-term relevance, efficiency, quality, affordability, and security of global health procurement.

The Working Group centered its discussions and recommendations around three primary audiences. First, it considered the role of large international global health institutions serving a direct or indirect (e.g., technical assistance or guidance) health products procurement function, particularly the Global Fund; UNFPA; UNICEF; Gavi; the WHO and its regional branches; the World Bank (including the Global Financing Facility); and US government agencies and initiatives, including USAID, PEPFAR, and PMI, through the USAID Global Health Supply Chain Program—Procurement and Supply Management, implemented by Chemonics. Second, it considered the role of bilateral and foundation donors to these institutions, including but not limited to the US government, the UK Department for International Development (DFID), and the Bill & Melinda Gates Foundation. Finally, it considered the specific challenges of low- and middle-income country governments looking to improve the performance of domestic procurement offices, particularly in the context of transition from global health assistance and concomitant commitments to achieve UHC.

This diverse group met four times: July 2017, February 2018, July 2018, and November 2018. To inform the Working Group’s deliberations, CGD also conducted and commissioned a wide range of original quantitative and qualitative background research, all of which is publicly available on the Working Group webpage.³⁵ The group benefited from research partnerships with AfRx Consulting, the Clinton Health Access Initiative

33. “About CGD” n.d.

34. “Global Health Policy” n.d.

35. Note, all background research and materials are available at: <https://www.cgdev.org/global-health-procurement-background-research>.

(CHAI), the Toulouse School of Economics (TSE), and the Office of Health Economics; bilateral consultations with representatives from the pharmaceutical industry; a small private roundtable with private-sector procurement specialists; a technical workshop with leading industrial organization economists, including Nobel laureate Jean Tirole; and several CGD-led analyses, including on the pace and magnitude of forthcoming aid transitions and the potential for technological innovation to improve global health procurement and supply chain processes (see Appendix C for all inputs).

This report—the final product of the Working Group—proceeds as follows. Chapter 2 lays out an analytical

framework for understanding global health commodity markets based on characteristics of their three constituent dimensions: products, purchasers, and suppliers. Drawing on the economic literature, it identifies several reasons why markets may fail, or where institutional inefficiencies or unorganized demand will lead to suboptimal procurement outcomes. Chapter 3 offers a snapshot of the current state of global health procurement. It focuses on the breakdowns from market to access: institutional inefficiencies, market failure, and unorganized demand. The report concludes with Chapter 4, which offers recommendations to drive procurement efficiencies at the global, regional, and country levels.

2

MAKING SENSE OF GLOBAL HEALTH PRODUCT MARKETS: AN ECONOMICS-BASED FRAMEWORK



A Disconnect Between Global Health and Economics

For at least the past decade, the global health community has increasingly recognized that the specific features of health product markets matter for ensuring affordability, access, quality, and a reliable supply of global health products.

In response to the growth in health spending and wave of procurement consolidation in the early 2000s, several global health institutions that undertake or contract for health product procurement—including the Bill & Melinda Gates Foundation, Gavi, the Global Fund, UNICEF, Unitaid, and USAID—stood up specialized units (and accompanying strategies) on “market dynamics” or “market shaping.” Their efforts aimed to address perceived problems in the market that affect procurement outcomes, such as the relationship between volume and price (addressed by volume guarantees or buy-downs in an effort to lower prices, coordinated demand forecasting, pooled procurement); supply insecurity or shortages (addressed by contracts that purposefully split total volumes between several suppliers and cost of goods studies to avoid over-negotiating/pushing margins “too” low; intentional supplier development); attracting new investment in research and development and manufacturing capacity (addressed by volume guarantees, advance market agreements, and other purchaser commitments; push funding from R&D suppliers; development of robust target product profiles to guide R&D); slow market entry of innovative products (addressed by efforts to accelerate regulatory approval and provide targeted introduction planning and support); and the ubiquity of low-quality and fraudulent health products in low- and middle-income countries (partially addressed by the WHO prequalification program and initiatives to subsidize products of assured quality).

The expansion of market shaping efforts among the global health institutions includes several notable success stories. The Affordable Medicines Facility for Malaria, which began as a pilot in eight countries in

2010, has helped expand the reach of new and more affordable ACTs.³⁶ Several high-quality competitor firms have entered the ARV market, accelerating treatment access among people living with HIV in low- and middle-income countries.³⁷ Availability of pediatric ARVs has expanded, providing lifesaving treatment for some of the world’s most vulnerable populations.³⁸ Finally, there have been quality improvements for the set of high-priority products covered by the WHO’s prequalification program—a prerequisite for purchase by the Global Fund, among others.³⁹

Yet the issues addressed to date are only a small portion of the problems that arise in procurement in imperfectly competitive markets, including markets for pharmaceuticals and other health products. These problems are the subject of industrial organization economics, a wide-ranging subfield of economics dedicated to understanding markets and improving their ability to serve the public interest through legal, institutional, and regulatory levers. This branch of economics takes a broader view of markets: it considers dimensions along which markets should be characterized, using a standard terminology; sets out how markets work, when and why market failure occurs, and how to address it; defines the limits of markets in achieving social objectives (including for global health); and considers the ways in which regulation, procurement, and institutional design can optimize outcomes. Many of these issues are also addressed by experts and schools of business focusing on operational procurement and supply chain management, with many overlapping concepts. These different communities cover similar ground, but they use different language and terminology—potentially creating confusion and constraining opportunities for mutual learning.

This chapter attempts to bridge the gap between market shaping and industrial organization economics by developing a framework to characterize global health

36. “Independent Evaluation of the Affordable Medicines Facility—malaria (AMFm) Phase I” 2012.

37. “HIV Market Report: The State of the HIV Treatment, Testing, and Prevention Markets in Low- and Middle-Income Countries, 2017-2022” 2018.

38. Lissfelt and Pasquier 2016.

39. “Healthy Markets for Global Health” 2014.

product markets, describe and classify obstacles to optimal procurement outcomes, and clearly identify the access and affordability challenges that are unrelated to “market” shortcomings. It seeks to more accurately diagnose the market challenges facing global and low- and middle-income country procurers, and to develop recommendations that build on these insights to yield better procurement outcomes. To bridge the linguistic divides, it uses standard economic terminology (see Appendix E for glossary).

Many elements of this detailed framework will be familiar to economists and seasoned procurement experts. However, in the course of the Working Group, we have come to appreciate the need to offer a comprehensive account of how these issues affect procurement outcomes and strategies, including specific health sector examples. To our knowledge, there is no existing source or literature that lays out these issues comprehensively, with a focus on health markets, and in language accessible to nonspecialists. The remainder of the report will use this framework to examine observed procurement breakdowns in the real world and to inform appropriate recommendations, mapped to country-specific procurement challenges.

Characterizing Health Product Markets

In a classical economics framework, the observed “market” for a product—the price, volume, and quality of goods sold and purchased—is a function of underlying characteristics along three dimensions: product quality, product demand, and product supply. The specific interplay among these three forces determines whether markets will effectively serve the public interest and informs the procurement, institutional, and regulatory approaches required to address market shortcomings. This section discusses essential market characteristics within each of these three categories, briefly explaining the axes of potential variation and their implications for procurement outcomes, policies, and strategies.



What Is the Product?

From an economics perspective, the characteristics that determine the efficiency with which a product is produced, sold, and used go beyond its chemical and physical properties. The following six characteristics affect market behavior and outcomes.

1. Degree of Product Homogeneity or Differentiation:

In economics, products can be categorized according to their degree of homogeneity (the extent to which all products are the same across suppliers) or differentiation (the extent to which different suppliers make products with somewhat different characteristics, such that they cannot be easily substituted). Fully homogeneous products have identical physical and reputational characteristics across suppliers; in theory, purchasers should have no preferences for one supplier or another. In the context of health products, unbranded quality-assured generics and some basic medical supplies can be considered homogenous products. If profit margins for existing suppliers exceed the opportunity cost of capital—and if there are no structural barriers to market entry—new suppliers will have an incentive to seize on the opportunity by entering the market. Higher degrees of homogeneity therefore tend to increase competition, helping to lower prices.

Suppliers have several strategies to differentiate their products, potentially helping increase profit margins and maintain market share. First, patents offer suppliers the exclusive, time-limited right to sell a specific molecule or product configuration. Patented products may still face competition from other substitute products in the same therapeutic/functional class, but producers are able to differentiate their product from other suppliers based on its physical characteristics. The patent-holder’s degree of market power will therefore depend on the extent to which physically differentiated competing products—molecules, diagnostics, or devices—are available. Access to on-patent health

products, particularly in low- and middle-countries, will largely depend on the extent to which companies can price discriminate across different countries; whether purchasers can threaten compulsory licensing to break the monopoly protection; and whether large or influential purchasers can negotiate concessional pricing on behalf of particular countries or patient groups.

Even for off-patent products—which may be physically and/or chemically identical to each other—association with a well-known, easily recognizable “brand” can increase product differentiation and affect purchasing behavior. Branding may signal to consumers that the product is of high quality—which may or may not be the case. Branded products may command a significant price premium over unbranded products, particularly in settings where regulatory regimes have limited capacity to ensure consistent quality, leading consumers (and health workers) to seek alternative quality and safety indicators. In some cases, originator companies can establish a well-known, easily recognizable “brand” during the patent period, enabling the originator to command a significant price premium over unbranded products even after the product has expired.

Product differentiation through branding is particularly important in LIC and LMIC drug markets. Branded generics dominate these markets, comprising about two-thirds of the market by both value and volume (Figure 4). Unbranded generics are a sliver of the overall market size. Originator products become increasingly important (in value terms) at higher levels of national income, but remain a relatively small source of overall spend (<20 percent) in the poorest countries. Furthermore, across low- and middle-income countries, originator products continue to be bought long after the patent has expired. Available data from a subset of countries (India, the Philippines, South Africa, Thailand, Tunisia, and a group of 10 countries in French West Africa) indicates that less than 10 percent of the pharmaceutical market comprises on-patent products; the remainder of originator products

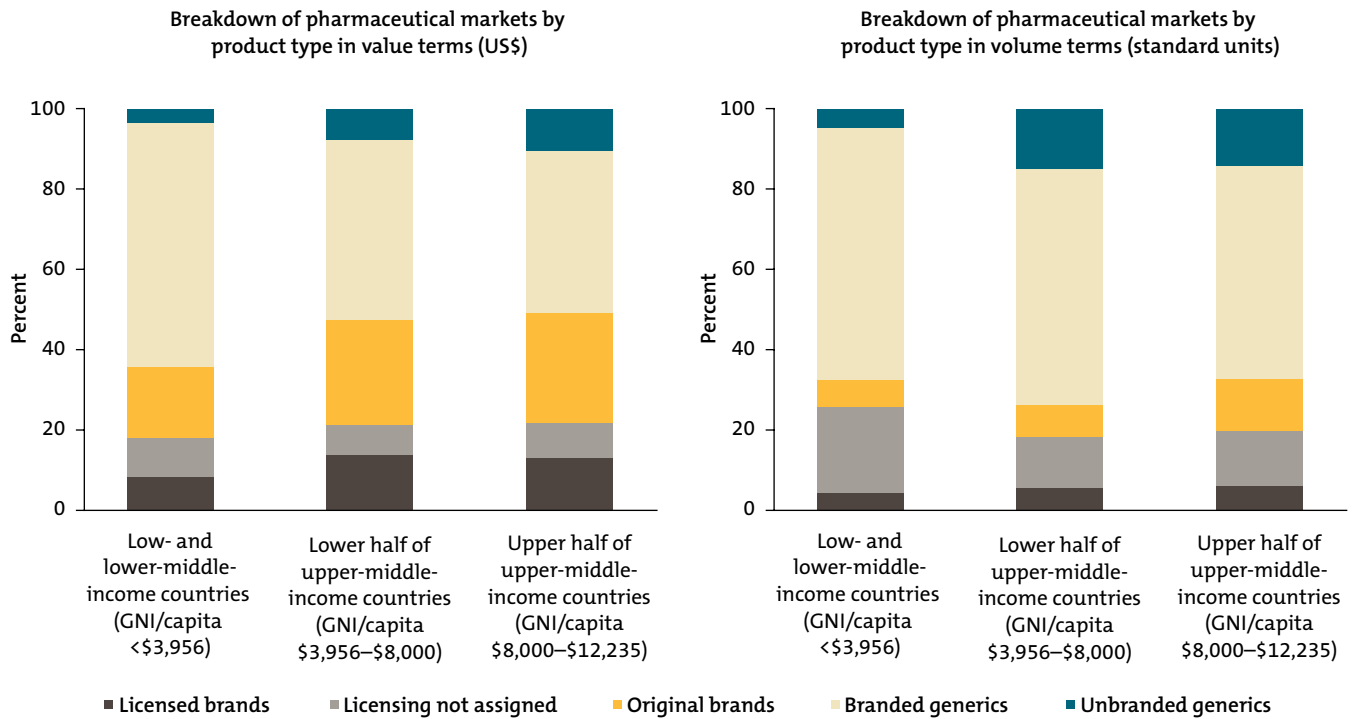
purchased are older and off-patent, launched globally over 20 years previously. In OECD countries, by contrast, unbranded generics—the least expensive option in most cases—are a far larger share of health product volumes and expenditure (see Figure 10 in Chapter 3). The relative scarcity of procurement of quality-assured unbranded generics in low- and middle-income countries often reflects limited capacity of and trust in regulatory regimes or other factors that influence product choice, such as rent-seeking or corruption. Consumers therefore pay a price premium for branded products, which serve as a proxy for quality and authenticity.

2. Cost Structure: The underlying cost structure to produce a product influences the price at which the product is offered, the potential scope of price reductions, and the relationship between total volumes and price. Most generic medicines, for example, have high fixed costs (to invest in manufacturing capacity and regulatory approval) but very low marginal costs. Potential new entrants are unlikely to start producing for the generic market if they believe that total market value will be too low to recover the fixed costs. Such a dynamic can limit competition and thereby prevent prices from converging to marginal cost.

A second set of products have high fixed costs with moderate to high marginal costs; these include biologics, medical devices, and drugs with relatively expensive active ingredients (e.g., ACTs used to treat malaria). The potential scope of price reductions for these products is intrinsically limited, as suppliers will not offer the products at a price point below marginal cost except under exceptional circumstances, such as for excess stock that is about to expire.

A final set of products (originator drugs) have high fixed costs *plus the sunk costs of research, development, and marketing*—but, similar to generic medicines, most also have low marginal costs unless they are biologics. These products benefit from patent protection for a time, which allows companies to set legally condoned monopolistic pricing. When there are no good substitute products, these monopolistic prices are often well

Figure 4. Health Product Markets in Low- and Middle-Income Countries by Brand and Licensing Status



Source: IQVIA Data (MIDAS database).

Note: Low- and lower-middle-income countries = French West Africa, India, Philippines. Lower half of upper-middle-income countries = Serbia, South Africa, Thailand, and Tunisia. Upper half of upper-middle-income countries = Brazil, Malaysia, Mexico, Romania, and Turkey. French West Africa is an aggregation of 10 Francophone countries from the West African region: Benin, Burkina Faso, Cameroon, Chad, Côte d'Ivoire, Guinea, Mali, Niger, Senegal, and Togo.

Licensed brands = products that are licensed by an originator company to a company located in another region or country. Licensing not assigned = products specific to that country or region (e.g., locally manufactured branded generic medicines) where the global IQVIA system does not recognize the brand or the data have not been recorded properly by the distributors supplying IQVIA with data. Original brands = products developed by originator/innovator companies. Branded generics = off-patent medicines sold under a brand name. Unbranded generics = off-patent medicines marketed as the international nonproprietary name (INN) of the active ingredient(s). See Appendix D for more details.

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above marginal cost, potentially enabling the originator to recoup R&D costs.

3. Observability of Quality: Perfectly functioning markets rely on both parties to a transaction having full and equal information about the product in question, particularly about its quality. When consumers can readily observe the quality of a product, the prices will reflect the quality of goods, enabling consumers to avoid substandard, low-quality products. But when quality is not observable to the consumer, poor-quality products can crowd out high-quality products. This phenomenon, known as the “market for lemons,” results from an

information asymmetry between consumers, who cannot observe quality, and suppliers, who take advantage of the asymmetry by supplying lower-cost, lower-quality products and deceiving purchasers about the quality of their products.⁴⁰ (See Box 3 for further details.) To avoid this suboptimal outcome, consumers are forced to rely on reputational signaling, such as more expensive branded generics or off-patent originator products, to ensure quality. This is a particular problem for many low- and middle-income countries, which have weak regulatory capacity to enforce quality standards.

40. Akerlof 1970.

Economists distinguish between three types of products, differentiated by the observability of quality.⁴¹ For “search goods,” consumers can accurately compare and shop between products and directly observe their quality before purchase. In contrast, the quality of “experience goods” is unknown before purchase—but consumers often can accurately judge their quality after use, informing future purchasing decisions for repeat customers. For a final category, “credence goods,” consumers can *never* directly observe the quality. The latter two categories are vulnerable to market failure arising from asymmetric information, requiring regulatory and institutional interventions to resolve the failure. Such interventions, however, may be quite difficult in practice.

Most global health products fall into the latter two categories, allowing substandard and fraudulent products to enter and sometimes dominate the market. Consumers cannot directly observe the chemical contents of a pill or bed net without specialized laboratory equipment, and may thus gravitate toward either cheaper, poor-quality products or recognizable brands that signal higher quality (whether or not quality is indeed higher). Curative or pain medications are often experience goods; consumers cannot judge their quality before ingestion, but they may know after the fact whether their discomfort is relieved, even if they have no recourse against the vendor or manufacturer. (There are exceptions, of course: the placebo effect may make a patient feel better without actually treating the condition, or substandard antibiotics may offer temporary relief but lead to both infection recurrence and drug resistance.) For the individual consumer, most preventive health products—vaccinations, vector control tools, and preventative medications—will be of completely unobservable quality, both before and after administration. (At the population level, however, it may be possible to observe the overall effectiveness of preventative health interventions.)

4. Quality: Beyond *observability*, *quality* in and of itself varies between health products and is of core importance

⁴¹ Darby and Karni 1973.

to both market and public health outcomes. A first set of products are considered *certified* high quality; they are approved by a recognized national regulatory authority and/or the WHO’s prequalification program, and thus command a price premium under conditions of asymmetric information about product quality. A second set of products are also high quality—and thus may have the same underlying cost structure needed to produce a high-quality product—but have not obtained certification of their quality. If quality is unobservable, and a product does not have branding or other forms of quality signaling, it is likely to be crowded out by low-quality products, which are cheaper to produce and may be indistinguishable from non-certified high-quality products to purchasers.

5. Substitutability: Products vary in their degree of substitutability—the extent to which other products can substitute for the product in question. Substitutability is often closely tied to the degree of product homogeneity versus differentiation (see discussion above). Substitutability exists along a spectrum and is a function of both a product’s physical properties (e.g., chemical makeup, quality, efficacy) and nonphysical properties (e.g., reputation, acceptability, availability). For some products, a chemically equivalent and equally effective, acceptable, and cost-effective alternative is available; the purchaser can easily switch between the two. Other products may be more difficult to substitute; perhaps an equally effective and cost-effective product exists, but the purchaser will incur significant transaction costs (e.g., retraining physicians) to make the transition. Further along the spectrum, purchasers can only substitute less effective and/or cost-effective products, or there are no substitute products at all. Substitutability can influence procurement outcomes because it affects a purchaser’s negotiating power and the relative price it will pay for a product. Within a group of substitute products, a rise in the price of one increases the demand for the others.

6. Complementarity: Some products are most useful—and may *only* be useful—when used together. In economics, such products are described as “complementary”—the

existence of one product *complements* the other. For example, a diagnostic is of limited utility without products to treat or cure the disease in question. Likewise, an intrauterine contraceptive device requires specialized medical equipment for insertion, and many vaccines rely on electricity, solar power, and refrigeration technology to maintain the cold chain that preserves their efficacy. In practical terms, procurement policy should thus optimize for a “suite” of complementary products, rather than for the price of individual products. Within a group of complementary products, a rise in the price of one reduces the demand for the others.



Who Is Supplying the Product?

For any given product, a market is created by the interplay of supply and demand. Suppliers are the

actors that manufacture the product and offer it for sale to potential purchasers. The supplier landscape—comprising the number and characteristics of suppliers for a given product—helps to determine market outcomes (e.g., price, volume, quality) but is also itself a function of market dynamics.

Two characteristics of the supplier landscape are particularly important for procurement outcomes: the location of the supplier (local vs. multinational manufacturing) and the level of competition. Unlike the immutable characteristics of a product itself, the supplier landscape can change and evolve based on forces elsewhere in the market, as well as deliberate policy choices by purchasers and regulators. To promote optimal procurement outcomes, policymakers can thus consider direct action to influence and maintain a favorable supplier landscape for affordable, high-quality, and sustainable health products.

1. Location of Supplier: Purchasers can choose between procuring products that are manufactured locally (“domestic manufacturing”) or procuring products from multinational suppliers. In theory, domestic manufacturing can have several advantages: close

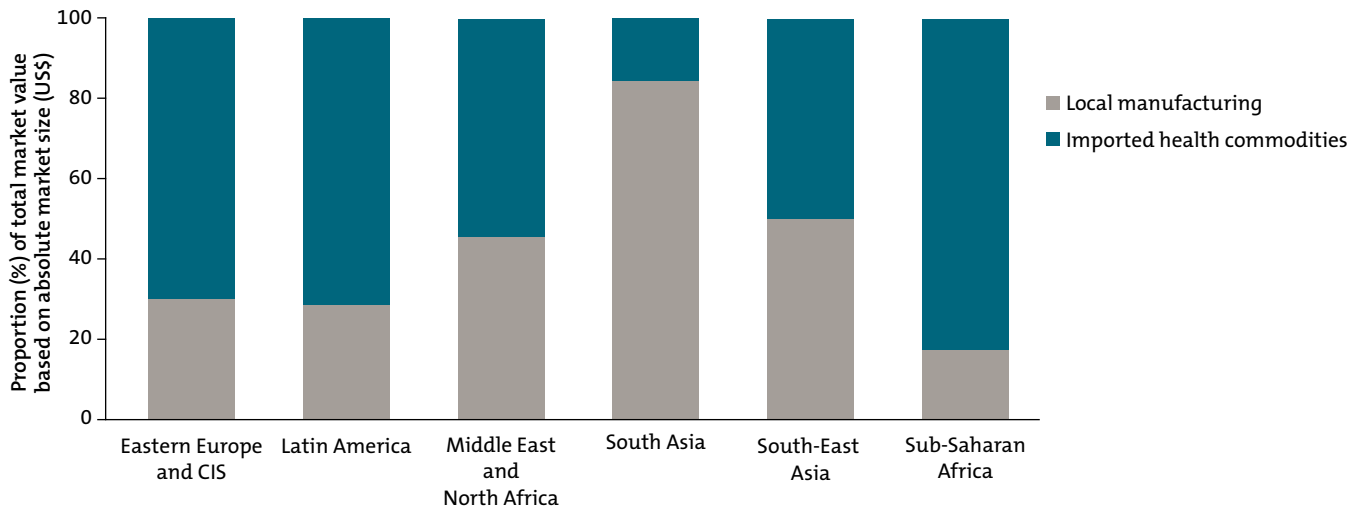
proximity between purchaser and supplier can limit shipping costs and reduce lead times, a common currency and/or language can help contain transaction costs and minimize risk related to exchange rate volatility, and use of local manufacturing can help promote national economic growth and development. Primarily for this last reason, many low- and middle-income countries have procurement laws or regulations that offer explicit procurement preference to local manufacturers. However, explicit preferences for domestic manufacturing can also come with downsides, particularly where the domestic pharmaceutical industry is immature (not operating at an efficient scale) or poorly regulated. By limiting competition, purchasers may pay significant premiums over international market rates for basic generics or may receive substandard products. Empirical evidence on the effects of local manufacturing remains limited and will always be dependent on context.⁴²

In practice, the use of locally manufactured products varies dramatically by region (Figure 5). In South Asia, where countries like India and Bangladesh have developed an extremely strong generic pharmaceutical industry, more than 80 percent of pharmaceuticals and vaccines (by value) are sourced from local manufacturers. Sub-Saharan Africa stands out for its relatively high reliance on imported health products, primarily from Indian suppliers, with local manufacturing comprising under 20 percent of health product expenditure. In other regions, locally manufactured products comprise 30 to 50 percent of the health product market by value.

2. Level of Competition: For markets to work efficiently in the public interest, multiple suppliers are required to compete for purchasers’ business on both price and quality. Economic theory predicts and empirical evidence has shown that more competitive markets tend to clear at lower prices (closer to marginal cost). Importantly, the level of competition does not always increase in proportion to the *number* of suppliers; rather, their

42. “Local Production and Access to Medicines in Low- and Middle-Income Countries: A Literature Review and Critical Analysis” 2011.

Figure 5. Average Proportion of Local Manufacturing and Importation of Pharmaceuticals and Vaccines (US\$)



Source: Analysis based on secondary research. See Appendix D for definitions and sources.

Note: CIS = Commonwealth of Independent States.

For methodology and full list of caveats, see AfRx 2018.

market shares (or market concentration) and degree of anticompetitive behavior (cartels and collusion) also play a role.⁴³ In addition, the level of competition *globally* may differ substantially from the level of competition within a given country or market. Four types of markets—organized by decreasing levels of competition—are common for global health products.

In a *competitive* or *commoditized* market, many different producers offer the same product type, with little to no differentiation between them. If the purchaser knows that the products meet minimum quality standards, the purchaser should, in theory, have no preference between different manufacturers. As a result, manufacturers compete almost exclusively on price, offering progressively lower prices to attract purchasers' business. Suppliers thus are likely to converge around a single international price point that approaches the marginal cost of production. Well-functioning generic medicines markets—observed in most OECD markets—typically can be characterized as competitive/commoditized.

43. Dubois, Lefouili, and Straub 2019.

In a *concentrated* market, at least two suppliers are competing for market share, but just one or a handful of producers control a large share of the overall market. *Ex ante* market concentration, whereby only a handful of producers are available to supply a product, is likely to affect procurement outcomes; this should be distinguished from *ex post* market concentration observed as the *outcome* of a successful procurement process—for instance, if two suppliers win a highly competitive, long-term government tender. Individual countries may have concentrated markets even when there is ample global-level competition, such as in situations where production requires high local fixed costs and the local market is small, or when there are local regulatory or political barriers to entry. Economic evidence from low- and middle-income countries (see Table 1 in Chapter 3) shows that country-level market concentration can be very high. More concentrated markets are often associated with higher prices and shortages because limited competition allows the leading firms to charge higher prices without losing market share to competitors (Box 1).

Box 1. Evidence on the Relationship Between Level of Competition and Price for Pharmaceutical Companies

Even in globally competitive pharmaceutical markets—for example, markets for most common generic molecules—the level of *local* competition can vary dramatically between countries. One way to measure the local level of competitiveness is the Herfindahl-Hirschman Index (HHI), a common economic metric defined as the sum of each seller's squared market share. An HHI equal to 1.0 indicates a single seller with 100 percent market share: a perfect monopoly. Lower HHIs, by contrast, indicate increasingly competitive markets.

CGD used proprietary procurement data from IQVIA—drawn from seven countries for 40 representative generic drugs, spread over three years—to calculate the HHI for each local drug market. (A “local market” here is defined as the market for one molecule in each country in a given year, and for a specific type of purchaser: public sector pooled, public sector decentralized, or private sector.) Within our sample, 25 percent of markets had an HHI of 0.17 or lower, which describes a market in which less than

20 percent of sales are from the largest supplier. At the other end, 25 percent of markets had an HHI of 0.44 or higher, which describes a market in which the largest seller accounts for somewhere between 50 percent and 60 percent of all sales.

We then used statistical analysis to explore whether a hypothetical increase in the level of competition for a local market—represented by a reduction in the HHI from the 75th to the 25th percentile—would substantially affect procurement prices. The analysis predicts that this increased competition would reduce public-sector procurement prices by more than a third. Surprisingly, this finding applies only to public-sector procurement; private-sector prices appear to rise slightly at lower levels of supplier concentration. A potential explanation is that suppliers are able to exploit private-sector buyers' hypersensitivity to superficial distinctions relative to quality by differentiating their products slightly, so that each supplier can retain market power and charge higher prices in its own market niche.

Source: This box is based on Mead Over's (2019) extension of the analysis in Dubois, Lefouili, and Straub (2019). See Appendix F for extended discussion and methodology. Caveats as outlined in AfRx 2018.

Cartels are a third category of supplier competition. On paper, a cartelized market may appear competitive; several different companies may operate in a given country and respond to tenders. However, in practice the firms cooperate (“collude”) to limit effective competition, splitting market volumes and setting prices above the levels found in a truly competitive market. Cartelized markets can result from explicit or tacit agreements between firms and may not be readily apparent to purchasers without specialized anti-trust expertise. Collusion and similar anticompetitive behaviors are often illegal, but many global health

procurers and low- and middle-income country purchasers are ill-prepared to spot or effectively police these practices (see discussion in Chapter 3). In addition, purchasing by large multinational institutions on behalf of low- and middle-income countries may fall into jurisdictional gray zones, with unclear lines of legal authority to identify and enforce appropriate punitive measures.

At the anticompetitive extreme are *monopolies*, where only a single supplier produces the product in question. For health products, the most common form

of monopoly is created by patent protection, which is intended to incentivize innovation by offering a time-limited, exclusive right to sell a specific molecule or product design. These markets may essentially function as monopolies if there are no substitute products competing for market share. In addition, individual local or regional producers of off-patent products might operate like monopolies at the country level if there are regulatory barriers to entry or potential competitors lack commercial viability, as in the case of French West Africa. Monopolists are generally expected to price their products at profit-maximizing levels, typically far above the marginal cost of production.

Governments and international organizations have various policies and procedural instruments available to affect the level of competition in a given market. In some cases, country governments can exploit TRIPS (Trade-Related Aspects of Intellectual Property Rights) flexibilities to compel originator companies to license on-patent products for local sale.⁴⁴ Efforts to reduce regulatory barriers to entry can also help expand the number of in-country suppliers of high-quality generics, which comprise the bulk of health product expenditure in low- and middle-income countries. Innovative procurement mechanisms, including appropriate auction design (discussed in Chapter 4), can also help purchasers maintain a robust and diverse supplier base while minimizing opportunities for anti-competitive behavior.



Who Is Purchasing/ Demanding the Product?

Purchasers—the parties considering and/or executing procurement of a health product—are the “demand” side of health product markets. Purchasers vary along several dimensions, such as their goals/objective functions, ability to secure favorable pricing and other procurement terms, and capacity to counteract information asymmetry on

product quality. A subset of these variations is most important from a health procurement perspective.

1. Type of Purchaser: Purchasers can be placed into categories based on their institutional type and motivation. *Public-sector* purchasers are governments or parastatal institutions, purchasing on behalf of their local, subnational, or national constituents. In theory, public-sector procurement offices should be operating in the public interest, optimizing public health and budgetary outcomes for their catchment populations. They also may incorporate industrial policy and local development objectives, such as support for local industry. In practice, however, public procurement offices are run by individuals with personal interests and motivations beyond their official job descriptions, introducing principal-agent conflicts that can affect procurement outcomes. Such conflicts include kickbacks, personal relationships with suppliers, risk aversion, or lack of effort and/or external or senior oversight to run a thorough procurement process. In higher-capacity contexts, public procurement bodies (supported by competent independent regulators) will have relatively high capacity to evaluate and regulate product quality throughout the procurement process, both during the preprocurement period of supplier qualification and bid appraisal and following receipt of procured products. Less mature procurement offices may have lower capacity to assess and assure product quality across the procurement cycle.

Global institution or international NGO purchasers operate at the supranational level, with mission statements that explicitly reflect the *global* public interest. Like public-sector purchasers, these bodies theoretically operate in the public interest but may be vulnerable to principal-agent conflicts. However, whereas public-sector procurement groups optimize for their own constituents, international purchasers should in theory optimize for global outcomes; for example, a lower price for the Global Fund specifically would not be considered a “good” procurement outcome if it was directly offset by higher prices for government purchasers in low-income countries. Because of their

44. “TRIPS and Health: Frequently Asked Questions, Compulsory Licensing of Pharmaceuticals and TRIPS” 2018.

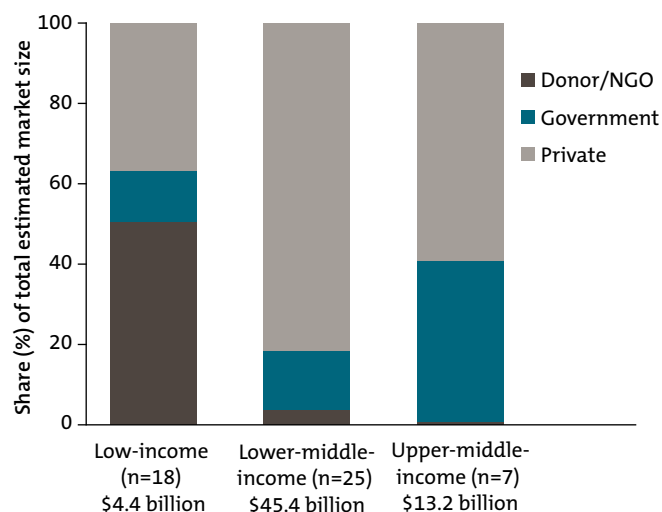
mission statements and often high-volume purchases, international purchasers are responsible for considering the systemic market impacts of their purchasing decisions, with implications for all potential purchasers and end users. With access to the best international expertise and laboratory capacity, international purchasers should have the capacity and capability to ensure the quality of purchased products. In addition, international procurers often serve the poorest and most vulnerable patients, and may, as a result, receive preferential (tiered) pricing for some products.

Private-sector importers or distributors purchase at wholesale levels but intend to resell the drugs for profit at subnational, national, or regional levels. As private firms, their primary objective is to maximize profits, not necessarily to improve public health outcomes. The extent to which their profit motivation will align with public health objectives may depend on whether a country has sufficient regulatory capacity or can develop reputational incentives to ensure that private-sector providers stock only quality-assured products, and whether competition constrains prices.

At lower levels of purchasing, individual product preferences become more significant and information asymmetries become larger. Depending on health system organization, *hospitals* and other *health centers* (both public and private) may buy for use within their own facilities. Facilities are likely to have some expertise about product quality but little independent capacity for quality assurance; they may also have strong brand or configuration preferences based on habit and comfort. Finally, *households* or *individuals* will purchase health products on their own behalf, typically through retail outlets stocked by private-sector importers or distributors, trading off personal health objectives against budgetary constraints. These purchasers are most vulnerable to information asymmetries; in the absence of effective regulation, individuals have no independent capacity to evaluate or verify the quality of a health product and may gravitate toward familiar brands.

In the poorest countries, data suggests that most health products are purchased by donors/international NGOs or through the private sector where households often pay OOP; government (public-sector) purchasing comprises just 10 percent or so of overall expenditure on health products (Figure 6). In LMICs, donor expenditure is mostly replaced by additional private purchasing, without a substantial increase in government expenditure. UMIC governments demonstrate somewhat higher expenditure (as a percent of all health product financing), but private purchasing still accounts for a majority of all purchasing.

Figure 6. Private, Government, and Donor/NGO Financing as a Share of the Total Estimated Market (Value) for Health Products by Country Income Groups



Source: Analysis based on UN Comtrade and secondary research. Data sources and definitions listed in Appendix D.

Notes: Donor/NGO procurement includes integrated procurement within government systems; multicountry NGO global tenders (e.g., through Gavi, PAHO, Global Fund). Government procurement includes CMS; MOHs; regional medical stores; state/group of hospitals; social security programs. Private procurement includes large hospitals or pharmacy chains (GPOs); private wholesalers and retailers; private distributors (e.g., Eurapharma/Laborex in French West Africa); government hospitals, clinics, pharmacies purchasing directly from domestic private-sector distributors outside of framework agreements.

For methodology and full list of caveats, see AfRx 2018.

Box 2. Economic Evidence on the Relationship Between Pooling and Price for Pharmaceuticals

To better inform the Working Group's deliberations and findings with rigorous economic evidence, CGD partnered with TSE to investigate whether national pooled (or centralized) procurement offers price advantages over decentralized public purchasing. The research team first derived a theoretical framework suggesting that pooled procurement should indeed result in lower procurement prices; they subsequently used econometric techniques to test their proposition in a sample of seven countries, working with the proprietary data described in the previous box. Their findings offer empirical support for their theoretical derivation: centralized public-sector procurement appears to result in lower pharmaceutical prices than decentralized public- or private-sector procurement, suggesting that large and powerful public purchasers can effectively negotiate lower prices. The magnitude of the effect is large; compared to uncoordinated purchasing, savings from pooled (or centralized) national public procurement can be as high as 50 to 75 percent of total prices. However, the advantages of pooled procurement decrease

and eventually disappear at higher levels of market concentration, where suppliers' local monopoly power can at least partially offset the negotiating power of a pooled buyer.

In an extension of TSE's analysis, described in further detail in Appendix F, Mead Over controls for transaction size and finds that the effect of pooling remains significant. Pooled public procurement still appears to offer price advantages over decentralized purchasing, even for purchases of an equally large quantity. This suggests that the buyer's exercise of negotiating/purchasing power—not just large transaction sizes—is helping drive the lower prices observed in this analysis. Further, for large transactions, the advantages of pooled procurement may endure even in highly concentrated markets.

Together, these findings suggest a strong rationale for pooled purchasing at the national level. Additional analysis is needed to explore whether these country-level findings also apply to supranational pooling arrangements.

Source: Dubois et al. 2019; and Over 2019. Data copyright IQVIA AG and its affiliates. All rights reserved. 2017. Caveats as outlined in AFRx 2018.

2. Level of Pooling: Pooling refers to the degree to which a single purchaser or agent aggregates demand across multiple end users. At one extreme, an individual can purchase a single dose of a drug for personal or household use; at the other, an international purchasing body can pool the vast majority of demand for a product across countries through a single procurement mechanism. Between the two extremes, pooling can occur within informal patient buying groups, at the facility level, among networked private providers/

hospitals or private-sector distributors/intermediaries, at subnational or national levels by or on behalf of governments, or at a regional level among a set of cooperating countries.

Higher levels of pooling will naturally create larger volumes. Under some (but not all) conditions, economic evidence suggests that higher levels of pooling may also be associated with preferential pricing and negotiating power (Box 2). Pooling may also reduce transaction

costs by reducing the number and complexity of tenders and individual transactions. However, increased pooling can also concentrate procurement risk; a single procurement failure by a monopsonist buyer can have systemic and catastrophic effects on global supply and access. As the level of pooling increases, purchasers must remain aware of how their individual purchasing behavior will affect market conditions more broadly.

3. Purchaser Negotiating Power: For purchasers, “negotiating power” refers to conditions that help them secure favorable pricing and other contractual terms. Negotiating power is often considered synonymous with volume; greater volumes can indeed contribute to a purchaser’s overall negotiating power when there is sufficient manufacturing capacity to meet overall need. Yet this narrow view elides other forms of leverage that may substantially affect the overall balance of power within a given negotiation (see Box 2 above).

Beyond volume, a second category of negotiating power is derived from a purchaser’s ability and willingness to “walk away” from a deal without purchasing the product—whether this is real or perceived. This can take several forms, depending on specific circumstances. For some product classes, purchasers can easily switch to a substitute drug or device (see above), increasing their ability to drive a hard bargain. If the product offers only marginal health value or cost-effectiveness, purchasers may be willing to go without it entirely. A subset of purchasers can credibly threaten backward integration, such as by creating their own dedicated supply facilities, potentially obviating the need for an outside supplier. Within the global health context specifically, the threat of compulsory licensing for essential public health products (as allowed under TRIPS) may induce suppliers to offer concessional pricing for on-patent drugs.

Finally, some purchasers may be able to affect negotiations by exerting systematic reputational, legal, or regulatory pressure on suppliers. Public interest groups such as Médecins Sans Frontières (MSF)

regularly publicize access gaps in low- and middle-income countries. These groups argue that such gaps are driven at least in part by patent and pricing policies, potentially challenging the entire intellectual property infrastructure that drives industry profits.⁴⁵ High-profile pharmaceutical firms may seek to avoid negative press coverage that could inspire legal or regulatory constraints against their business models, and, as a result, may offer concessional pricing for on-patent products below profit-maximizing levels. Such companies also sometimes seek to attract positive press coverage through high-profile access partnerships with foundations or international organizations. Some government purchasers can also use regulatory levers to improve their negotiating position, including priority review vouchers for regulatory approval or regulated price reductions.

4. Purchaser Credibility: A purchaser’s credibility determines the overall “cost of doing business” for the supplier and thus influences procurement outcomes. Factors such as delayed payments and onerous registration processes may limit a purchaser’s ability to secure favorable pricing (discussed further in Chapter 3). In instances where the “cost of doing business” is perceived as particularly high, suppliers may be unwilling to enter new markets or continue selling their product.

5. Quality Assurance Capacity: Finally, purchasers vary in their capacity to exercise independent control over the quality of purchased products, affecting the extent to which information asymmetries affect procurement outcomes. Mature purchasers may have sophisticated quality assurance systems and advanced laboratory capacity, enabling them to ensure that purchased products meet stringent quality standards. Others—particularly low-income governments, retail shops, and individuals—may have little or no capacity to independently evaluate product quality.

45. See, for example, Mpulo 2018; “MSF Joins Europe-Wide Action Challenging Patent on Key Hepatitis C Drug” 2017; Tomlinson et al. 2016; and “Access: MSF Launches Challenge to Pfizer’s Patent on the Pneumonia Vaccine in India, to Increase Access to More Affordable Versions” 2016.

Why Procurement Falls Short: Institutional Inefficiencies, Market Failure, and Unorganized Demand

For any given market, the specific mix of characteristics described in the previous section can create widely different market and procurement outcomes, with direct knock-on effects for public health. This section considers three major reasons why global health product procurement often falls short of achieving the best possible outcomes for affordability, access, security, and sustainability. These shortcomings fall into three broad categories: institutional inefficiencies, market failure, and unorganized demand (though there is some overlap between the three). Each of these three challenges can be at least partially addressed by better, more strategic procurement policy and practice at the global, national, and regional levels. The next chapter will explore how these shortcomings manifest in the real world, constraining procurement outcomes and holding back international public health objectives.

Institutional Inefficiencies

Institutional inefficiencies are a broad set of constraints related to the capacity of procurement entities and supporting institutions to create the right conditions for efficient and effective procurement. They include:

- ***Institutional, Administrative, and Legal Barriers*** that artificially constrain country-level competition, introduce excessive transaction costs, and/or inflate prices. These include:
 - ❑ Onerous registration processes;
 - ❑ Inefficient local purchasing preferences;
 - ❑ Outdated procurement systems;
 - ❑ Payment delays;
 - ❑ Legal strictures against more effective procurement modalities;

- ❑ Inability to forecast needs (leading to over-reliance on spot tenders and emergency ordering);
- ❑ Country-specific labelling requirements; and
- ❑ Tariffs.

- ***Inefficient Product Selection***, which directly affects what is purchased and can lead to inefficient use of scarce budgetary resources for health. Selection must be based on clear criteria, including quality and effectiveness, affordability, and disease burden, to ensure that the right products are purchased to meet patients' needs and payers' resource constraints. National essential medicines lists based on the WHO model list are typically used to guide product selection.
- ***Limited Capacity and Procurement Expertise*** across the entirety of the procurement process, including tendering, bid appraisal, contracting, supplier management, and quality assurance, which can lead to suboptimal procurement outcomes.
- ***Inadequate and Inconsistent Tracking, Monitoring, and Evaluation***, which limit an institution's ability to track and effectively manage products across public and private supply chains. This also constrains reordering and accurate forecasting, the ability to consistently evaluate procurement performance, and the identification of effective procurement instruments and reforms.
- ***Parallel and Duplicative Supply Chains***, which include siloed purchasing and delivery channels across diseases, programs, and donors, and can create inefficiencies and undermine efforts to build national capacity.

Market Failure

Market failure occurs when free market forces lead to a suboptimal allocation of goods or services, creating welfare losses for suppliers, consumers, or society as a whole. Several characteristics of health product

markets make them particularly vulnerable to specific types of market failure. A few of the most important market failures for health products (further detailed in the next section) include:

- **Imperfect Information:** Imperfect information occurs when one or both parties to a transaction lack important information, such as information related to the quality or value of a product. Under conditions of imperfect information, substandard or poor-quality products can enter and ultimately dominate the market, as they are cheaper to produce and indistinguishable to consumers at the point of purchase (see Box 3 on the “market for lemons”). As discussed earlier, most health products are either credence or experience goods, and so the degree of imperfect information is typically quite high and can be problematic in the absence of effective regulation and pharmacovigilance.
- **Barriers to Entry:** Barriers to entry limit competition and can inflate the prices paid by institutional procurers and consumers. Even for off-patent drugs, which predominate in low- and middle-income country markets, onerous and costly local processes can prevent additional generic companies from registering their products in small low- and middle-income country markets, allowing incumbent local firms to continue extracting rents. Monopoly markets—when arising from time-limited patents—represent an intentional distortion of market forces to encourage investments in R&D. Monopolies enable profit-maximizing prices to be set at levels well above marginal costs. Tiered pricing can reduce welfare losses associated with a single price monopoly but allows the supplier to capture a greater proportion of the total surplus. Under perfect tiered pricing, the monopolist would supply a product to everyone willing to pay more than marginal cost—but every consumer would face a price exactly equal to his or her willingness to pay, implying that the

monopolist would capture the entirety of the social surplus. However, in the absence of perfect tiered pricing, many consumers will not be able to purchase a product even though their willingness to pay exceeds the marginal cost of production. Thus, tiered pricing increases the numbers of patients who are able to access a medicine; economists regard it as an approach that increases social value as compared to a single price monopolist.

- **Externalities:** Products create value for individual consumers and costs for individual suppliers, but some products also create wider benefits or costs to the broader society. These knock-on effects are known as “externalities” because they are *external* to the transaction between individual sellers and purchasers, and their cost (or value) to society is not incorporated into the purchase price. In global health, substandard or inappropriate use of antibiotics, for example, can spread resistance in the population. This is a *negative* externality, implying that antibiotics will be *overused* if their allocation is left to the free market. On the other side, infectious disease treatment or prevention has society-wide benefits known as *positive* externalities; for example, a malaria net directly protects an individual, but also contributes to lower transmission and endemicity rates in the community. This implies that malaria nets will be *underused* relative to their social benefit if individuals must pay the full cost of the net.
- **Public and Common Goods:** Some goods offer diffuse benefits to all of society, with large aggregate impact. Yet because the benefit is spread across many individuals or firms, no single actor will have a sufficient economic incentive to purchase or conserve the good—a market failure that prevents the good from being produced or sustained at a socially efficient level. Collective action, typically through a government or supranational body, is thus required to mobilize resources across society and invest in the

Box 3. The Market for Lemons and Implications for Health Product Markets

In 1970, economist George Akerlof published a seminal paper, one that eventually earned him the Nobel Prize in Economics. Entitled “The Market for ‘Lemons’: Quality Uncertainty and the Market Mechanism,” the paper describes how asymmetric information between buyers and sellers can impede effective market functioning.^a Akerlof illustrates his point with the example of used cars, which may be either of good or bad quality (the latter are known as “lemons” in American slang). In this market, the seller has driven the car, dealt with its maintenance, and thus knows whether or not the car is indeed a “lemon.” The would-be purchaser, however, has no way to distinguish between “lemons” and good-quality cars. Since the consumer is unable to differentiate between the two, the market will converge to a single price for both products. But since that price is above the real value of a “lemon” but below the real value of a good-quality car, only owners of “lemons” will offer their used cars for sale. Through this mechanism, high-quality cars are pushed out of the market entirely, leaving a used-car market composed exclusively of “lemons.”

The “market for lemons” phenomenon has an obvious parallel in health product markets. When the quality of a pill is unobservable to consumers, the purchaser has no way to distinguish between high- and low-quality generics. Consumers therefore make purchase decisions based on price alone. If high-quality generics are more expensive to produce (e.g., higher costs for APIs [active

pharmaceutical ingredients], quality controls), they will, in the long run, be unable to compete on price with the lower-quality producers. Over time, the high-quality generic products will be pushed out, leaving a generics market dominated by poor-quality drugs.

As Akerlof notes, there are several potential responses to counteract the “market for lemons,” many of which are observed in health product markets. Through certification, a third party—often a government regulator (such as the US Food and Drug Administration [FDA]), or even a nonprofit or industry group—can test and validate the quality of a product to consumers, helping to overcome the information asymmetry. However, the fixed costs of certification can be high, and in the absence of government/public-sector intervention those costs are likely to be passed on to consumers. This dynamic can create a highly segmented and inequitable market, with certified products for those willing and able to pay, and uncertified products for those who are not.^b When regulatory control/certification is weak or unavailable, consumers may also rely on branding to signal product quality. As anticipated by theory, branded generics comprise a large portion of the total health product market in low- and middle-income countries and command a significant price premium over their unbranded counterparts (see Chapter 3).

a. Akerlof 1970.

b. Auriol and Schilizzi 2014.

production and conservation of the shared good on behalf of its constituents. In economics, these goods are known as either “common goods” (if their use by one individual can reduce the overall supply, like forested land) or “public goods”

(if an individual’s consumption of the good does not impact its availability to others, like national defense). In global health, common goods include antimicrobial and insecticide efficacy. Public goods include scientific and operational

research, including for the development and deployment of new health technologies; regulation and enforcement; disease eradication; standards, norms, and guidelines; disease surveillance; epidemic prevention and response; and vaccine and drug stockpiles to respond to outbreaks.⁴⁶

- **Present Bias:** In economics, present bias refers to the human tendency to overvalue short-term gratification relative to long-term payoff, leading to underinvestment.⁴⁷ Within the context of global health, present bias can manifest as underinvestment in or underuse of preventative technologies or behaviors such as vaccinations or healthy diets, underinvestment in the maintenance of capital medical equipment, underinvestment in outbreak preparedness, or underinvestment in R&D.
- **Principal-Agent Problem:** In development assistance for health, the “principals” can be thought of as either the end users of health products in low- and middle-income countries or the bilateral or private donors that finance the purchase of these products. Yet the specific individuals making the purchases on behalf of the beneficiaries or donor (the agents), at least for institutional procurement, are staff within international NGOs or public procurement offices. These agents may be operating in the public interest, but they also face incentives, priorities, and interests that may differ from those of the principals. For example, procurement agents and end users may have different views about what counts as a “safe” or “high-quality” product; the appropriate prioritization across multiple objectives (quality, price, access, and supply security); or the trade-off between short-term and long-term benefits. Likewise, external purchasers may purchase capital health technologies without considering the life-cycle costs

of their use, leading to underutilization. When agents face strong personal or financial incentives that do not align with the public interest—for example, the opportunity for kickbacks from suppliers or the promise of a lucrative job with a supplier after leaving public service—their decision-making on behalf of the public good also may be compromised in the absence of robust policies and enforcement to counter corruption and/or conflicts of interest.

- **Anticompetitive Behavior:** Anticompetitive behavior can involve (1) unilateral practices that a dominant firm uses to exclude rivals or block market entry; and (2) explicit or tacit agreements between firms to set prices above market-clearing rates, leading to a cartelized market (discussed in the previous section) and welfare losses for consumers. Cartels and anticompetitive behavior by an individual company, such as pricing below cost to drive competitors out of the market and then increasing prices once they are gone, may not be readily apparent to purchasers without specialized expertise. Collusion and similar anticompetitive behavior are illegal in many contexts, and increasingly in low- and middle-income countries, but many global health procurers and low- and middle-income countries are ill-prepared to spot or effectively police these practices (see discussion in Chapter 3).

Unorganized Demand

Unorganized demand—including relatively low levels of pooling and high levels of procurement fragmentation, coupled with uncertain and unreliable demand—can, under some circumstances, decrease procurement efficiency. In addition to foregoing potential preferential pricing derived from greater volumes (as described in previous sections), unorganized demand can increase transaction costs and limit investment in R&D and manufacturing capacity by increasing market risk, especially when suppliers lack demand visibility. It also

46. Moon, Röttingen, and Frenk 2017.

47. O’Donoghue and Rabin 1999.

may deter suppliers from registering in small-volume or small-margin markets. Conversely, demand that is overly consolidated also may lead to suboptimal outcomes. For example, a monopsonist purchaser may drive down prices to the point where one or more suppliers exit the market, as happened with UNICEF and the market for pentavalent vaccines.⁴⁸

Why Better Procurement May Not Always Improve Access: Supply Chain, Delivery, and Absolute Resource Constraints

As described in the previous section, failures of procurement policy and practice can dramatically affect access to essential health products. But even with perfect procurement, many people still will not be able to access the health products they need to survive and thrive because prices that reflect efficient levels of cost are beyond their means. Some challenges to universal and affordable access remain outside the scope of procurement policy, requiring institutional, capacity-building, and financing approaches to fully address and overcome.

Supply Chain and Delivery Constraints

In most cases, good procurement policy will result in more timely delivery and more affordable, high-quality, cost-effective, and locally appropriate products for the purchaser. Sometimes, these products may be supplied directly to an end-use facility, such as a hospital, but they are often delivered to a national port, centralized warehouse, or other storage facility. Yet the journey from warehouse to patient is long and complicated, including multiple intermediaries and requiring sophisticated supply chains and logistics; cold chain maintenance; and effective inventory management to prevent expiration, degradation, diversion, or stock-outs. In the private sector, national and subnational

distribution costs drive anywhere from 30 to 60 percent—and in extreme cases, as much as 90 percent—of products' final cost to patients in the poorest countries (Figure 7).⁴⁹ Further analysis on final price to patient in a subset of 43 LIC and LMIC countries showed that \$50 billion worth of health products procured would end up costing \$80 billion by the time they reach end users, owing to a combination of supply chain mark-ups and distribution costs.⁵⁰ Moreover, depending on the structure of subnational distribution systems, economic theory suggests that reductions in private-sector import prices will not necessarily be passed on to consumers.⁵¹ As a result, even efficiently procured products may be unaffordable by the time they reach the end user.

Questions of effective *delivery* and *prescription* further complicate the *physical* challenge of moving products from place to place. Doctors, nurses, and other health professionals may lack training, motivation, or incentives to offer appropriate treatment to patients in need. Absenteeism, under- and overprescribing, and poor adherence to clinical guidelines are endemic in some settings, representing further barriers to effective access. Procurement policy alone can do little to address systemic barriers to care and effective prescribing in underresourced, low-capacity health systems.

Even so, some potential procurement interventions or improvements to procurement policy can help ease or mitigate supply chain and delivery constraints elsewhere in the system. For example, a centralized procurement office could adopt standard nomenclature and serialization, with potential follow-on benefits across the supply chain, including more accurate demand forecasting that can improve negotiating

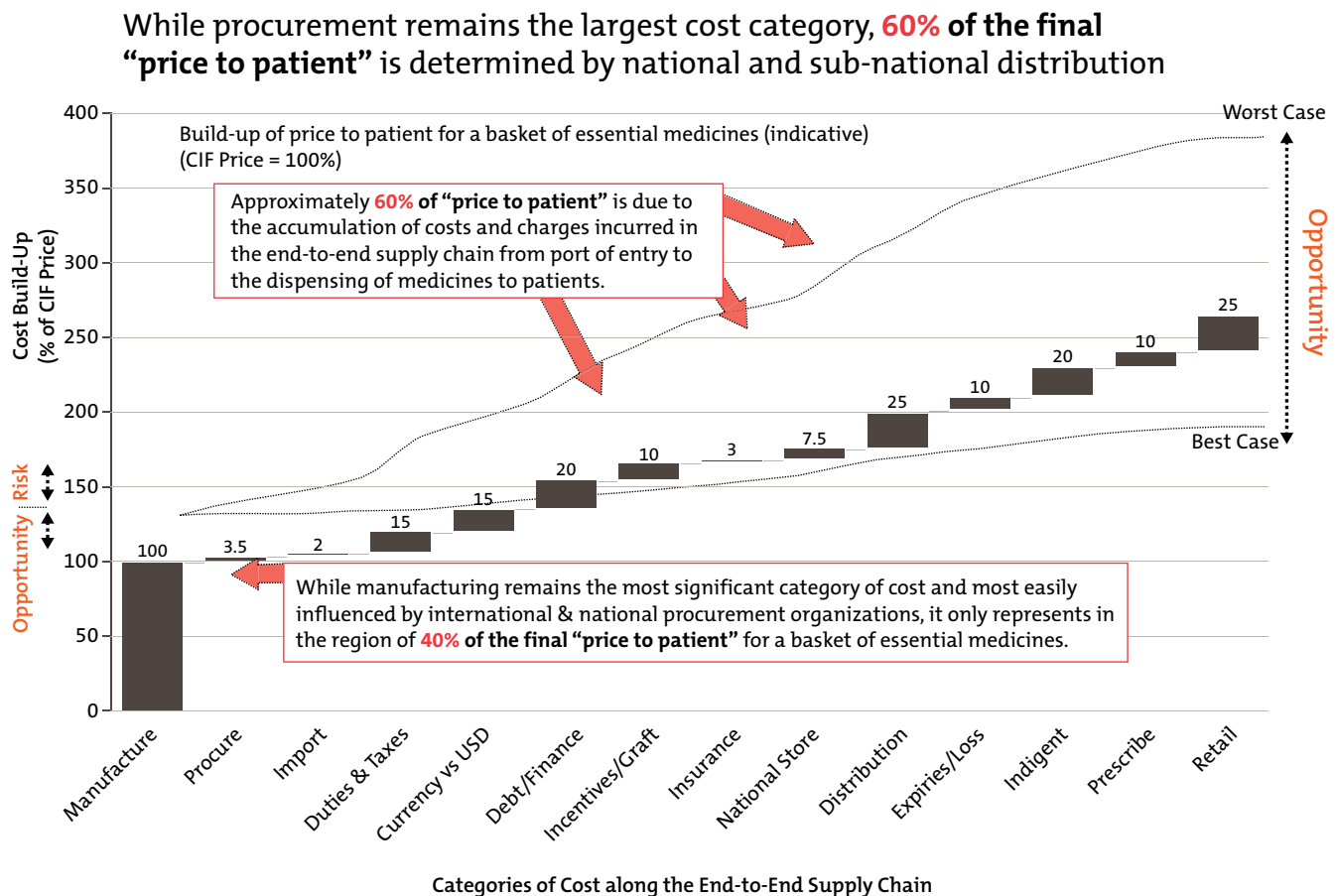
48. "Gavi's Strategy, Phase IV (2016–20) - the Market Shaping Goal" n.d.

49. See also Ball 2011 and "Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets: Making the Case for Investment" 2017. Note that the proportion of distribution costs in the final price to patient tends to be lower as distributors and public supply chains gain scale and competition increases; this explains, at least in part, why the share of the final cost to patient driven by distribution costs is lower in LMICs and UMICs, compared to LICs.

50. AfRx 2018.

51. Over 2019.

Figure 7. Illustrative Representation of Mark-Ups for Health Products Along the Distribution Chain



Source: Prepared by SmartChain (Richard Holmes and Nuno Alves) as input to the CGD Working Group.

Note: CIF = cost, insurance, and freight. For other sources on mark-ups see also Ball 2011 and “Private Sector Pharmaceutical Distribution and Retailing in Emerging Markets: Making the Case for Investment” 2017.

The figures here are illustrative in nature and draw in large part on SmartChain’s operational experience, including fieldwork commissioned by the Global Fund and DFID over the period 2014–2018. The analysis draws on a review of in-country supply chains in Nigeria, Ghana, the Democratic Republic of the Congo, and South Africa, and focuses primarily on products for HIV, TB, malaria, and other essential medicines. The estimations are based on information gathered through various informants across the in-country supply chains and through primary sources, including operational budget data from hospitals, clinics, national public- and private-sector warehouses, wholesalers, and distributors across the in-country health commodity supply chains. A limited degree of cross-checking with IQVIA data was conducted, particularly on import volumes, prices, and cost of goods.

power and procurement outcomes.⁵² Likewise, some aspects of procurement policy, particularly product selection, can help to better match local delivery constraints with available products, lowering the risk that products will go unused and be wasted at the point of delivery.

52. Pisa and McCurdy 2019.

Absolute Resource Constraints

In the poorest countries or among the poorest living in relatively wealthier countries, absolute resource constraints remain a difficult reality. Such resource constraints may be inevitable given the depth of poverty, but they can be exacerbated by ineffective government resource mobilization; low budgetary priority to the

health system generally; or insufficient allocation to the health products procurement budget specifically.

Even after addressing market failures, many products will not be locally cost-effective in low- and middle-income countries at an efficient market-clearing price given available resources. Therefore, these products may not be recommended for purchase given competing, potentially better (i.e., more health maximizing) uses for very scarce funds. The great challenge facing low- and middle-income countries during transition is that many health products can deliver significant health improvements, but not all health-improving products will be affordable within highly constrained government budgets.

Procurement policy in itself cannot overcome the accessibility challenges arising from absolute resource constraints. Nonetheless, the potential savings from better procurement of locally cost-effective products can and should be reinvested in the health system, effectively expanding its budget and creating fiscal space for additional products to become locally cost-effective and affordable. Donors can also make a policy decision to subsidize or purchase such products on behalf of low- and middle-income countries, particularly products that are marginally cost-effective or have a compelling global or public health rationale for wider adoption—for instance, to combat drug resistance or to eliminate or eradicate a particular disease (see discussion in Chapter 4).

3

BREAKDOWNS FROM MARKET TO ACCESS IN THE REAL WORLD: INSTITUTIONAL INEFFICIENCIES, MARKET FAILURE, AND UNORGANIZED DEMAND



Introduction

Since the early 2000s, low- and middle-income country governments, international procurement entities, and global health donors have been able to expand access to essential health products. However, global access to lifesaving health technologies remains grossly insufficient. At present, global health procurement in these countries is plagued by inefficiencies and waste, limiting patient access and siphoning scarce resources from elsewhere in the health system. Looking ahead, existing procurement challenges at the country and global levels also will face a “triple transition”: the drawdown of donor aid, the epidemiological transition, and the evolution of health systems organization.

This chapter draws from existing literature, background research commissioned by CGD, and Working Group discussions to describe major “breakdowns” within global health procurement. Drawing on the economics-based framework outlined in Chapter 2, this analysis identifies key constraints to efficient and effective procurement of health products at the global, national, and subnational levels. It is not an exhaustive accounting of all procurement challenges, but instead focuses on three broad categories of breakdowns: institutional inefficiencies, market failures, and unorganized demand. Better procurement policy can help address—if not fully solve—many of these issues.

Institutional Inefficiencies

Institutional, Administrative, and Legal Barriers

Institutional and Administrative Challenges

Many low- and middle-income countries continue to use procurement procedures that are not fit-for-purpose, including:

- Purchasing on an annual basis for a fixed volume, drawing on inflexible and inaccurate demand forecasts.⁵³ This practice is associated with long

lead times and more frequent stock-outs; when stock-outs occur, purchasers must resort to more expensive emergency orders. (A growing literature points to longer-term framework agreements as a more flexible and potentially attractive alternative.⁵⁴)

- Cumbersome tendering procedures, requiring bidders to endure lengthy processes with high transaction costs.
- Manual, paper-based procurement systems, creating high administrative burdens.⁵⁵ Some low- and middle-income countries have started automating their procurement processes, as in the case of online tendering and e-platforms used by Chile (CENABAST & ChileCompra), Brazil (ComprasNet), Indonesia (Lembaga Kebijakan Pengadaan Barang Jasa Pemerintah), and South Africa—but others (e.g., multiple states in Nigeria) continue to rely on manual, paper-based systems.

Onerous tender procedures, long processing times, and payment delays to suppliers also contribute to inefficient procurement. Cash flow limitations or administrative and public financial management constraints within ministries of finance may delay the release of funds, resulting in delivery delays and higher prices to offset the “cost of doing business.”⁵⁶ In South Africa and Nigeria, for example, many stakeholders believe that payment delays result in higher supplier prices.⁵⁷ Late payments also make it difficult for national purchasers to enforce other contract terms. In Uganda, for example, the CMS contracts often have penalty clauses for late deliveries, yet these provisions are rarely enforced because of payment delays from the CMS itself.⁵⁸ For relatively small-scale suppliers, delayed payments can

53. Yadav 2015; and Dowling 2011.

54. Arney et al. 2014, p. 298. Countries like Chile and Mexico have moved toward negotiating long-term framework agreements; global procurers like UNFPA, UNICEF, and the Global Fund also negotiate framework agreements with multiple suppliers for key products.

55. CHAI 2018.

56. Dickens 2011, p. 12; Roberts and Reich 2011, p. 125.

57. CHAI 2018.

58. Ibid.

impact supply operations and cash flow.⁵⁹ In Ghana, a local company supplying intravenous fluids recently issued a call to the National Health Insurance Scheme to repay about 10 million Ghana cedis (\$2 million) in back payments at an annual percentage rate over 30 percent; the company feared that banks would cut off lending as its debt mounted.⁶⁰ In Angola, some provincial hospitals have designated budgets to purchase supplies on their own, but payments are managed by the central government and may take up to eight months to process.⁶¹

Complex and Lengthy Product Registration Processes

To register drugs and other health products, suppliers must often surmount institutional, administrative, and legislative obstacles. Resource and capacity constraints among LIC and LMIC regulatory authorities often result in inefficient, lengthy, and delayed registration processes. One study identified a lag of four to seven years, on average, between initial submission of a drug or vaccine for regulatory approval (typically in a high-income country) and final approval in 20 sub-Saharan African countries.⁶² Further, registration requirements vary across countries and are unnecessarily duplicative, with national regulatory authorities typically failing to leverage prior reviews by external and potentially more mature regulatory authorities. From the manufacturer's perspective, these factors raise transaction costs to enter low- and middle-income country markets. The African Medicines Regulatory Harmonization Initiative aims to address some of these challenges; however, progress to date has been mixed.⁶³

Legal Barriers to Efficient and Effective Procurement

Public procurement legislation and related policies can significantly constrain the ability of procurement agents to adopt more strategic procurement processes and practices. In Mozambique, for example, a decree

prevents the CMS from using framework agreements.⁶⁴ In Nicaragua, Peru, and the Dominican Republic, the legal framework offers no option for international tendering, although there are exceptions for tendering via UN agencies.⁶⁵ In Indonesia, the winning price of an auction cannot exceed a ceiling; moreover, until recently, there could be only one winner.⁶⁶ Industrial policies that support local industry or promote the consumption of locally produced goods can also impede optimal procurement. For example, Uganda's "Buy Uganda Build Uganda" policy requires exclusive procurement of locally manufactured products, limiting the potential scope of competition.⁶⁷ Legislation may also impose value-added taxes and tariffs, potentially limiting competition and driving up prices.⁶⁸

Inefficient Product Selection

A critical and foundational step in the procurement process is selecting the most clinically effective and cost-effective product. When purchasers fail to consider value for money in deciding which products to list or make eligible for coverage, scarce budgetary resources for health are used inefficiently. Even though product selection should be linked with, and inform, relevant health system functions, including procurement decisions and pricing negotiations, efforts in many low- and middle-income countries fall short. In Vietnam, for example, a 2015 review found that 13 medicines, mostly antibiotics and cancer drugs, were consuming more than a quarter of the total public budget for drugs. Yet most public expenditure on those medications was used for inappropriate (51 percent) or cost-ineffective (27 percent) indications—a waste of the country's scarce resources.⁶⁹

Product selection and/or listing also often fails to systematically incorporate cost-effectiveness and affordability criteria, with important knock-on budget

59. Ibid.

60. "Intravenous Infusion Company Calls on NHIS to Pay GH¢10m Debt" 2018; and Ibrahim 2017.

61. Eisenhammer 2018.

62. Ahonkahi et al. 2016. This study focused on registration timelines for vaccines and drugs that are used to treat and prevent communicable diseases and are eligible for WHO prequalification in low- and middle-income countries.

63. Ndomondo-Sigonda et al. 2018.

64. Arney et al. 2014, p. 302.

65. Dickens 2011, p. 13.

66. Pisani et al. 2019; and Ursu and Rabovskaja 2017.

67. CHAI 2018; see also: "BUBU-BUY UGANDA BUILD UGANDA POLICY" 2017.

68. Dickens 2011, p. 13.

69. Thiboonboon et al. 2017.

impacts. Many low- and middle-income countries draw on the WHO's Essential Medicines List, which specifies medicines that "satisfy the priority health care needs of the population," to define their own national medicines lists and determine what products national procurement entities should purchase. They also look to the WHO's diagnostics and medical devices lists to drive these national-level decisions. However, global guidance does not incorporate local cost-effectiveness considerations or account for variations in resource availability in different countries. Therefore, countries may not fully consider whether a given product is locally affordable before its inclusion on national medicines lists.⁷⁰ Further, donors often fund the most cost-effective products—leaving governments to purchase less cost-effective items. As countries transition from donor support, there is a risk that national governments will fail to pick up procurement of the most cost-effective health technologies.

Limited Capacity and Procurement Expertise

Design, management, and execution of an effective procurement process requires specialized, technical knowledge across several specific domains. Below is an illustrative description of the expertise required at different steps in the procurement process.⁷¹

- For *procurement planning*, procurement offices require processes and expertise to ensure effective product specification and selection; accurate forecasting of expected needs; appropriate budgeting; and timely availability of requisite financing.
- For *tender preparation*, procurement offices require a deep understanding of compliance standards for national legislation and donor requirements. Tender preparation also requires staff capacity to adequately understand and translate clinical considerations into tender specifications, helping to ensure that potential

bidders are responsive to clinical needs. Effective tendering can drive transparency in supplier selection; increase competition by expanding the pool of potential suppliers; increase supply security; and ensure that high-quality products are ultimately purchased, among other benefits.⁷²

- For the *bidding process*, procurement offices must effectively manage the actual tendering process and select the winning bidder based on appropriate evaluation criteria. Often, tendering processes and evaluation criteria will need to meet compliance guidelines laid out in national legislation or regulations, or those set by an international donor or lending institution such as the World Bank. Bid evaluation may also require a substantive understanding of products' technical specifications, costs of deployment, and quality; for example, evaluation of bids for capital medical equipment should consider the life-cycle costs for each alternative technology.
- For *contract preparation and finalization*, procurement offices must have legal and negotiation capacity to set advantageous contract terms, including payment schedules. The contract serves as the legally binding agreement between the purchaser and vendor.
- For *contract management*, procurement agencies require capacity to meet contractual/legal obligations (e.g., timely payment) and monitor supplier performance (e.g., on-time shipment and compliance with quality standards). When suppliers do not meet their contractual obligations, procurement offices should also have legal capacity to determine and pursue appropriate consequences for breach of contract.

Beyond the technical expertise required to design and execute a procurement process, an understanding of strategic sourcing should inform the entirety of the procurement cycle. Strategic considerations include determining when pooled purchasing offers benefits,

70. Glassman et al. 2012.

71. Rao, Mellon, and Sarley 2006.

72. CHAI 2018.

including price reductions and lower transaction costs; the conditions under which to outsource procurement to a private entity; or the selection of appropriate procurement tools and approaches for different product categories and underlying market dynamics, including when to use framework agreements or procurement auctions to achieve supply security at lower prices. Certain market characteristics—including market size, number of formulations in active use, whether the market is growing or shrinking, and the relative market share of leading suppliers—should also inform procurement approaches.⁷³

At the global level, global health procurement bodies are staffed with highly trained employees—yet anecdotal evidence nonetheless suggests a potential mismatch between in-house expertise and optimal procurement practice. Global health procurement professionals tend to have technical health backgrounds and/or experience in the pharmaceutical industry. By contrast, private-sector procurement and sourcing experts (outside global health) suggest that expertise in procurement processes, strategies, and approaches may be more important than product- or market-specific knowledge—or at least an essential complement to domain-specific experience.⁷⁴

At the country level, health procurement capacity is often highly constrained. Many countries lack trained and experienced staff to draft effective, high-quality tenders. In Bangladesh, for example, lack of knowledge among procurement staff of how to apply procurement guidelines and standards meant that the procurement process, lasting from product selection to delivery, could take up to two years.⁷⁵ High turnover among staff who seek higher-paid jobs in the private sector can also create or exacerbate capability gaps, as observed in Uganda.⁷⁶ Public procurement bodies also may struggle to deploy efficient or innovative tendering procedures; enforce regulatory standards; and ensure the quality

of medicines and other health products.⁷⁷ Finally, suppliers' limited understanding of national procurement regulations could result in low-quality bids and raise transaction costs for the purchasing entity.⁷⁸ As low- and middle-income countries assume an increasingly large role in purchasing health products for local use, early observations from domestic procurement in specific product markets point to suboptimal outcomes. For example, 29 low- and middle-income countries purchased TB medicines of unknown quality and 8 saw failed tenders for TB medicines, lab consumables, and reagents between 2016 and 2018.⁷⁹ These governments will require greater capacity and specialized expertise to effectively manage procurement procedures in the future.⁸⁰

Inadequate and Inconsistent Tracking, Monitoring, and Evaluation

Failure to “Track and Trace” Health Products Across the Supply Chain

Standard nomenclature, labelling norms, and serialization are the foundation for systems that “track and trace” health products across the supply chain. Among other benefits, the flow of timely information across the supply chain can provide data on inventory and use to help improve inventory management and demand forecasting—key functions for effective procurement.⁸¹ Yet at present, many products in low- and middle-income countries lack standardized barcodes with cross-country interoperability, and some lack barcodes altogether. In their absence, few low- and middle-income country governments or international agencies can effectively track product movement and stock levels, constraining prompt reordering and creating vulnerability to stock-outs and diversion.

In response to these challenges, a subset of national governments and global health agencies have advanced

73. CHAI 2018.

74. Based on discussions at a private roundtable with private sector procurement and sourcing experts, May 2018.

75. Rao, Mellon, and Sarley 2006.

76. CHAI 2018.

77. Yadav 2015.

78. CHAI 2018.

79. Waning 2018.

80. Dickens 2011, p. 9; see also Rao, Mellon, and Sarley 2006.

81. Pisa and McCurdy 2019.

nascent efforts to improve supply chain traceability. Pilot initiatives to roll out standardized barcodes for pharmaceuticals and medical devices are under way in Ethiopia and Pakistan.⁸² Likewise, the Indian government now requires barcoding per GSI common standards on Indian pharmaceutical exports, a leading source of generic drugs and vaccines around the world.⁸³ On the donor side, USAID recently issued a memorandum formally adopting GSI global standards for its health products by 2022.⁸⁴ In the context of ARV drugs, PEPFAR, the Global Fund, and the government of South Africa—the three largest purchasers of these products—are also working to align their procurement systems to GSI standards.⁸⁵ Yet these efforts remain in their infancy and the path forward may be long and challenging. The United States and the European Union (EU) are both phasing in track-and-trace requirements over a decade, but limited political will, connectivity, data literacy, and incentives to record transactions and product movement in low- and middle-income countries can further slow or hinder efforts to increase supply chain traceability.⁸⁶

Inadequate and Inconsistent Performance Measurement

The lack of consistent and standardized performance measurement, including globally accepted standards for best practice, is a critical impediment to improving procurement practice. Done well, performance measurement allows for tracking of progress and benchmarking across different procurement entities, which increases collective knowledge about effective practice and informs efforts to improve procurement.⁸⁷

At the country level, performance benchmarking across public and private procurement entities is almost nonexistent. At the global level, procurement entities report publicly on a limited set of metrics, including order lead times and on-time in-full delivery. However, data on rolling forecasts of consumption and the volume and value of inventory levels—essential figures for measuring performance, and common in private-sector procurement practice—typically is unavailable.⁸⁸ Further, basic metrics such as order lead times and on-time in-full delivery vary in scope, definition, reporting period, and targets/thresholds, undermining their relevance and utility.⁸⁹ As a result, the Working Group (and in-country budget appropriators or aid evaluators) could not conduct even simple analyses of procurement performance, for example to explain differences in the prices obtained or compare order lead times achieved by a US government supply chain project to those of the Global Fund for the same product.

Limited Evidence About What Does and Does Not Work

Finally, procurement practitioners face a highly limited evidence base to help inform their procurement strategies. Despite a wealth of anecdotal and gray literature on procurement experience, rigorously evaluated studies of procurement strategies and performance are rare. A deep dive into the peer-reviewed literature found that most studies are descriptive in nature, with only a few empirical evaluations.⁹⁰ The few empirical studies tend to focus on the Global Fund, leveraging its price and volume database.⁹¹ Other analyses, like the 2017 systematic review by Gabriel Seidman and Rifat Atun, focus more narrowly on a specific approach, such as pooled procurement.⁹²

82. Hara et al. 2017; Berihun and Shiferaw 2018; and “Traceability in Ethiopia’s Health Sector: Piloting GSI Barcodes with Global Trade Item Number Serialization to Track Health Commodities from Supplier to Health Facility” 2016.

83. Sinha n.d.

84. “Global Standards for Supply Chain Data Visibility” 2018; and “Business Case for the Implementation of Global Standards” 2018.

85. Jallow 2017, see slide 66.

86. Pisa and McCurdy 2019.

87. Yadav 2015, p. 150; Dickens 2011.

88. CHAI 2018.

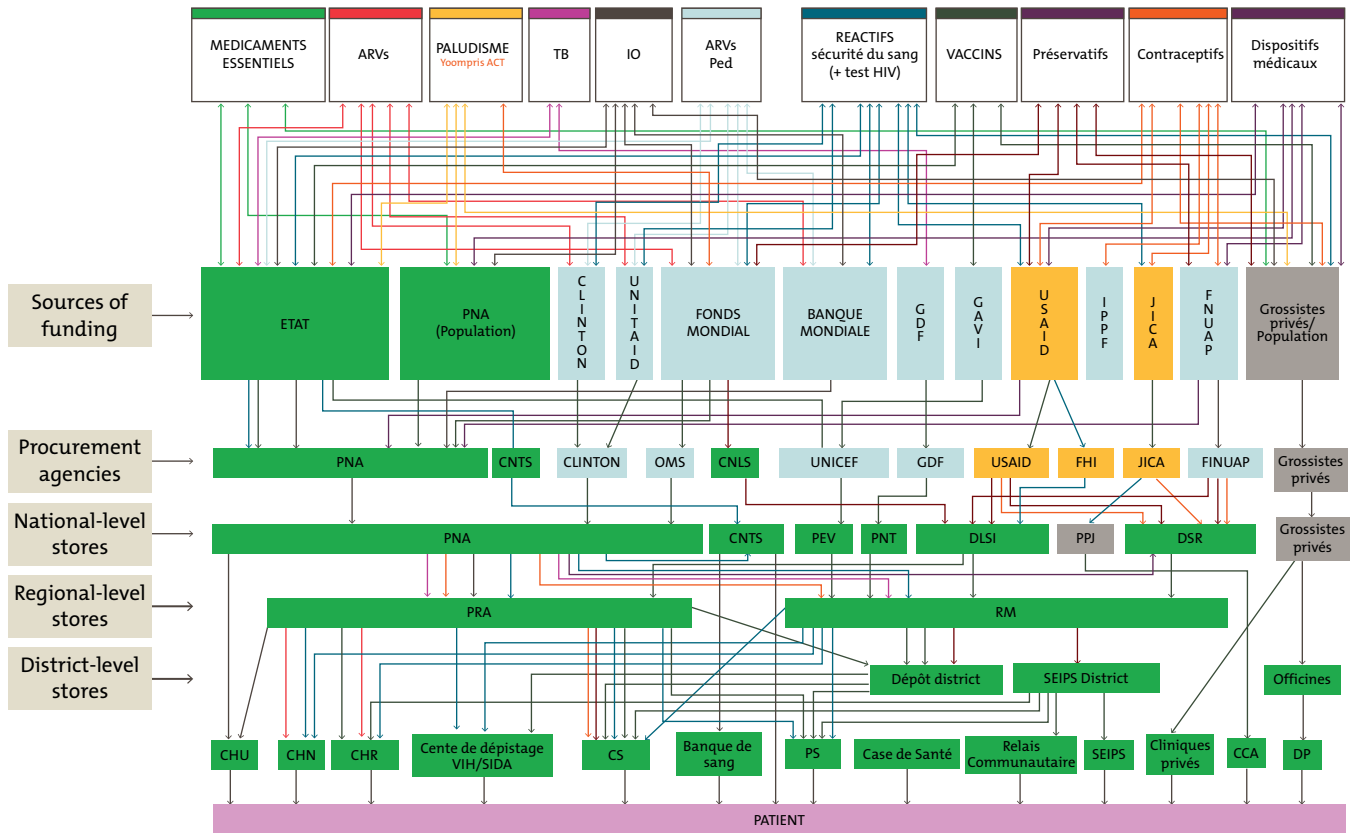
89. Ibid.

90. Oroxom 2017, 2018.

91. Nguyen et al. 2015; Arney et al. 2014; and Seidman and Atun 2017.

92. Seidman and Atun 2017.

Figure 8. Fragmented Procurement Processes and Supply Chains in Senegal



Source: Senegal MOH/CMS; cited in “Cartographie et évaluation approfondie des systèmes d’approvisionnement et de distribution des médicaments essentiels et autres produits de santé au Sénégal” 2009.

Parallel and Duplicative Supply Chains

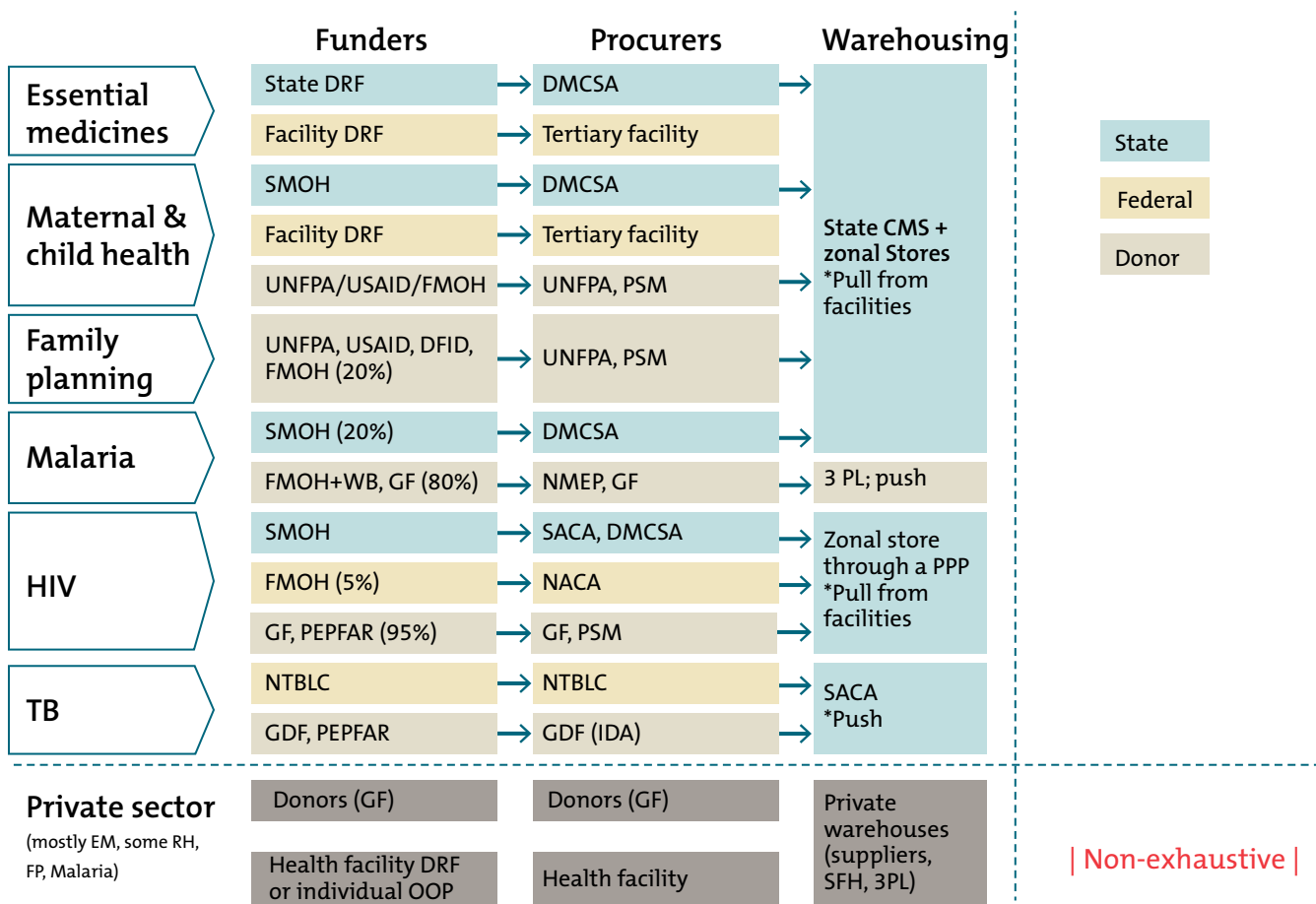
At the country level, procurement processes and supply chains are often highly fragmented, with purchasing and delivery functions siloed across donors, diseases, and program areas. In Senegal, for example, public-sector procurement processes and supply chains have at least 13 different sources of funding (Figure 8). The example of Kano state, Nigeria, illustrates how donors often set up parallel purchasing processes and distribution channels for the specific commodity groups they support (Figure 9). This duplication undermines efforts to build national capacity to plan, organize, and manage core health system functions. Acknowledging this reality, the Nigeria Supply Chain

Integration Project has been making efforts to integrate the different supply chains managed by donors and other partners.⁹³ Some parallel supply chains have been established specifically to bypass public-sector procurement agencies that are seen as low-performing. In Uganda, for example, family planning donors (except UNFPA) responded to perceptions of public-sector mismanagement and corruption by establishing and channeling their commodities support through a parallel system managed by a nonprofit. While this may be an understandable donor reaction, investments in privately run supply chains raise concerns about neglect of the public sector.⁹⁴

93. CHAI 2018.

94. Silverman and Glassman 2016.

Figure 9. Fragmentation in Public and Private Sectors in Kano State, Nigeria



Source: CHAI 2018. Interviews with government officials, donors, and implementing partners (UNFPA, National AIDS and STDs Control Programme, National Malaria Elimination Program, Nigeria Supply Chain Integration Project, National Product Supply Chain Management Program, Kano State Drugs and Medical Consumables Supply Agency, Kano State Logistics Management Coordination Unit, MOH Lagos).

Market Failure

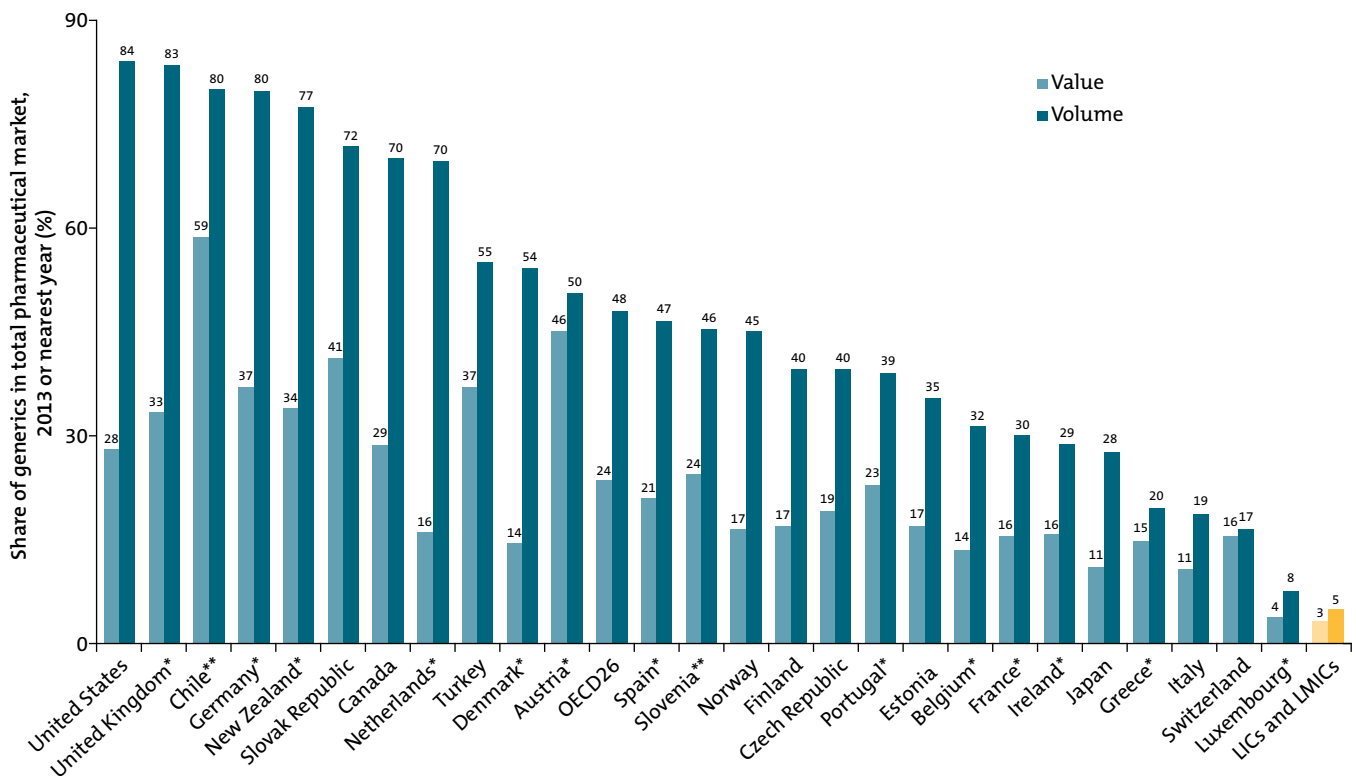
Imperfect Information

Imperfect Information on Product Quality

As discussed in Chapter 2, purchasers are often unable to directly observe the quality of health products—and in the absence of robust regulatory and quality assurance systems, this information asymmetry between suppliers and purchasers can create market failure. In high-income countries, most patients use unbranded generic drugs for off-patent molecules. In most cases, this is the least expensive option; at the same time, high-income country patients can be confident that

their government’s well-functioning regulatory system assures that generic medicines meet quality standards. By contrast, patients in low- and middle-income country settings often cannot rely on regulatory systems to keep poor-quality drugs off the shelves; as a result, use of and expenditure on cheap unbranded generics is relatively low (Figure 10). Instead, LIC and LMIC health commodity markets are dominated by more expensive branded generics, comprising about two-thirds of the market by both value and volume (see Figure 4 in previous chapter). Patients rely on the branding to (potentially) signal reputation and better quality. As a result, high-quality generic suppliers that want to enter markets where an established name brand holds sway may

Figure 10. Relative Underuse of Unbranded Generics Across Countries, by Value and Volume



Source: OECD Health Statistics 2015, <http://dx.doi.org/10.1787/health-data-en>.

Note: * Reimbursed pharmaceutical market; ** Community pharmacy market. The data points for the LICs and LMICs category are from Figure 4.

find it difficult to compete if they lack a way to assure customers that their product is of equal quality. By limiting effective generic competition, consumers are likely to pay higher prices for drugs.⁹⁵

In countries that have weak regulation and enforcement of quality standards, substandard and falsified medicines, devices, and other health products may enter the market (the “market for lemons”; see Chapter 2). Although accurate data is limited, estimates suggest the prevalence of substandard and falsified medicines in low- and middle-income countries ranges from 10 to 13.6 percent, and may be as high as 18 percent in some sub-Saharan African countries.⁹⁶

95. Auriol and Schilizzi 2014.

96. “1 in 10 Medical Products in Developing Countries Is Substandard or Falsified” 2017; and Ozawa et al. 2018.

In practice, however, the prevalence may be higher. These products are a significant threat to public health. Substandard and falsified malaria medications, to take one example, are estimated to cause 116,000 deaths in sub-Saharan Africa each year.⁹⁷

Imperfect Information on Pricing and Market Structure

Full and accurate information on pricing and market structure helps buyers to budget, execute, and evaluate procurement processes. When purchasers can see prices paid by peer countries for specific (off-patent) commodities, they can input appropriate price parameters into health technology assessments (HTAs) to inform priority-setting, ensure that commodity budgets

97. “A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products” 2017.

are appropriate to match population demand, and conduct informed price negotiation with suppliers. The information provided by comparative pricing can also allow purchasers to benchmark procurement performance against peers, helping to identify and diagnose the underlying causes of high prices, which may reflect inefficient procurement, an uncompetitive supplier landscape, corruption, or the local “cost of doing business.” Opaque pricing can impede all these processes, making it difficult or impossible to evaluate and improve procurement outcomes.

Limited availability of market intelligence may also impede efficient supplier entry and investment, potentially leading to supply shortages, suboptimal competition, or underinvestment in R&D. Suppliers rely on market intelligence, such as market size and purchasers’ willingness to pay, both in aggregate and for specific commodity classes and drugs. They use this information to inform investments in R&D and additional manufacturing capacity, allocate existing manufacturing capacity to specific products, and prioritize market entry across countries and products. However, overly granular data on competitors’ pricing may facilitate anticompetitive behavior among suppliers—a potentially important downside to full price transparency. In addition, price transparency for on-patent products—in the absence of global norms and agreement around tiered or differentiated pricing—may deter suppliers from offering concessional pricing to countries with less ability to pay.⁹⁸

The development community now tracks and releases prices and volumes for a subset of health products procured directly by donors.⁹⁹ Yet even for donor-procured goods, the data is fragmented across a complex and often contradictory set of data sources, plagued by double counting, inconsistent nomenclature, and incomplete or missing data.¹⁰⁰ Nondonor repositories also have limited coverage and constrained access. Taken together, the full range of sources cover only a

subset of products—mostly in donor-supported disease and program areas like HIV, malaria, TB, and maternal and child health—leaving little to no visibility into growing commodity areas like diabetes, heart disease, and cancer.

For example, the Global Fund’s Price and Quality Reporting (PQR) mechanism, which has provided data for HIV, TB, and malaria products since 2005, has informed many empirical studies yet still suffers from incomplete, missing, and poor-quality data.¹⁰¹ Other databases cover only a single geographic region or small group of countries, such as the WHO Western Pacific Regional Information Exchange (PIEMEDS).¹⁰² A few country-level databases offer public procurement data, sometimes including tender details, but their databases are limited to national *public* procurement; examples include the Philippines, South Africa, Indonesia, Jordan, Chile, and Kazakhstan.¹⁰³ Privately led efforts like IQVIA (formerly IMS Health and Quintiles) collect, standardize, and sell proprietary data across the private and public sectors, but its coverage prioritizes private market wholesales over government procurement and it is often sold at prices that are prohibitive for the poorest purchasers. ECRI Institute—an independent not-for-profit membership-based organization—provides access to price benchmarking data for pharmaceuticals, medical devices, and other products, but it has limited coverage of information pertaining to low- and middle-income countries.

Barriers to Entry

Barriers to entry prevent new suppliers from entering the market and may allow existing manufacturers to keep prices above market-clearing levels. In global health, there are three distinct categories of entry barriers: patent-enforced exclusivity rights; fixed costs of entry; and limited country-level competition, potentially caused by administrative barriers to entry.

98. Berdud et al. 2019.

99. “Medicine Price Information Sources” n.d.

100. See Chalkidou, Madan Keller, and Rosen 2018.

101. Oroxom 2017; “Price & Quality Reporting” n.d.; “Strategy, Investment and Impact Committee: Market Shaping Strategy” 2015, p. 29; and “Procurement and Supply Chain Management at the Global Fund” 2015, p. 20.

102. “PIEMEDS: Price Information Exchange for Medicines” n.d.

103. See Chalkidou, Madan Keller, and Rosen 2018.

Patent-enforced exclusivity rights serve as *intentional* barriers to entry for a specific molecule or device specification. They are designed to protect originator margins, enable originator companies to recoup fixed costs of R&D, and therefore incentivize global innovation.¹⁰⁴ In wealthy countries such as the United States, patent-enforced exclusivity is associated with very large price premiums, which fall dramatically once generic competition is permitted.¹⁰⁵ In low- and middle-income countries, on-patent drugs represent only a small portion of health commodity expenditure (see Figure 4 in Chapter 2). Many countries receive concessional or tiered pricing tied to local affordability, and under some circumstances countries can exploit TRIPS flexibilities, including compulsory licensing, to access lower-priced generics for on-patent drugs.¹⁰⁶ Patents also are only one of several barriers to the diffusion of pharmaceutical innovation in low- and middle-income countries.¹⁰⁷ Nonetheless, patent protection can significantly raise prices for drugs or preclude patient access to them. In Thailand, for example, one study found that patented oncology drugs demanded a 144 to 206 percent price premium compared to medicines without a patent.¹⁰⁸

Even for off-patent products, the fixed costs of market entry and challenges related to developing and receiving approval for a generic equivalent may deter or delay new suppliers from entering a market. As such, incumbent firms may extract high rents above marginal cost, at least for a limited time.¹⁰⁹ Perhaps the most infamous example of this phenomenon is

Daraprim, a highly effective drug used to treat toxoplasmosis in HIV patients. The drug served a relatively small and niche market and the price was relatively low, limiting potential profit margins; consequently, no generic competitor had emerged to challenge the originator company's effective monopoly. Under the leadership of then chief executive officer (CEO) Martin Shkreli, Turing Pharmaceuticals acquired the drug and promptly raised the price by 5,500 percent—from \$13.50 a pill to \$750. Turing also strictly limited access to the molecule, preventing would-be generic competitors from running the bioequivalence trials required for FDA approval of a generic equivalent. (Turing's conduct was also a form of anticompetitive behavior, discussed below.¹¹⁰) Two years later, despite national outrage, the price remained roughly unchanged, and the FDA had not approved an equivalent generic competitor.¹¹¹

At the country level, administrative and regulatory barriers to entry (discussed above) can prevent robust local competition, even when the global marketplace is highly competitive. Economic evidence from low- and middle-income countries (Table 1) shows that barriers to entry, along with other factors that may impede competition, can lead to very high levels of market concentration at the country level—in this case, measured by the one-firm concentration ratio.

Studies suggest that limited country-level competition may directly affect the prices paid by consumers and public procurers. In the United States, a 2005 study showed that a first generic competitor is priced at a modest discount from the originator brand, but additional entrants push down average generic pricing substantially—from 94 percent of the originator price for the first generic entrant to 52 percent after the second entrant, 33 percent after the fifth entrant, and as low as 6 percent once there are 19 generic products competing in the marketplace (Figure 11). More recent analysis confirms steep and rapid price reductions (80 percent or more) in the United States following loss

104. Note that for medical devices, patents are based on a specific design for model device that may compete with other products with their own patents where the products are each sold for the same basic indication. For instance, different model CT scanners will have unique patents but are used for the same general purpose.

105. "Price Declines after Branded Medicines Lose Exclusivity in the U.S." 2016.

106. Hoen et al. 2018.

107. Other factors, discussed throughout this report, include slow and burdensome registration and approvals processes; limited perceived profitability in small or low-income markets; limited stewardship capacity for antimicrobials; and human resource/transition costs of product introduction, including health worker retraining.

108. Yamabhai and Smith 2015.

109. Moreover, for some drugs, lack of competition may be more acute at the active pharmaceutical ingredient (API) level as compared to the downstream drug manufacturing level.

110. Carrier and Kesselheim 2015.

111. Johnson 2017; and "Daraprim Prices Still an Obstacle for Patients" 2018.

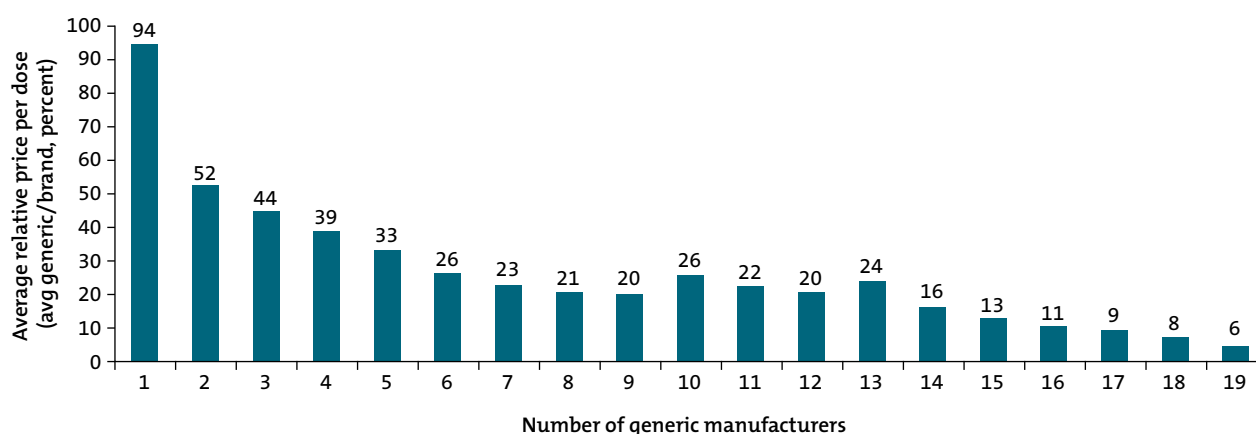
Table 1. One-Firm Concentration Index by Therapy Area for Selected Countries/States (Sample of 40 Molecules Only)

Area	Country (%)						
	Kerala	Philippines	Senegal	Serbia	South Africa	Tunisia	Zambia
Anemia		66.4	100.0	88.1			
Antiulcerants	44.4	44.0	18.4	72.1	61.4	50.4	81.3
Antihypertensives	62.2	62.2	69.6	43.7	76.5	75.1	91.7
Antibiotics	21.9	51.9	88.3	63.2	29.0	44.5	61.9
Antiparasitics	33.1	100.0	40.0		91.8	97.5	98.2
Arthritis immunosuppressants	37.4	57.5	31.3	57.9	61.6	63.1	90.6
Asthma/COPD	84.8	62.9	96.2	84.0	78.9	95.7	100.0
Cancer	90.6	61.7	76.0	58.8	65.0	64.4	100.0
Contraceptives & hormones	84.4	97.2	87.3		72.5	80.7	98.7
Diabetes	27.3	51.5	72.4	61.0	59.8	56.0	100.0
HIV antiretrovirals	64.7				82.2	84.4	100.0
Lipid regulators	74.1	46.7	46.4	59.8	81.2	70.3	98.8
Nervous system medications	89.1	78.2	100.0	78.2	83.3	91.4	99.5
Pain analgesics		55.0	93.2	40.6	50.0	30.8	100.0
Tuberculosis	40.0	59.7	30.7	46.5	50.4	61.5	80.6
Vitamins and minerals		99.0	88.0	97.7	99.8	26.6	

Source: IQVIA Data. Reproduced from Dubois, Lefoulli, and Straub (2019), Table C.2.

Note: Data represent one-firm concentration index—the proportion of domestic market share of the largest seller. Sample of 40 molecules with available data; see working paper for full details and caveats. Means over 2015–2017 for all countries except Philippines (2013–2016). Private sector only for Kerala and Senegal. Data copyright IQVIA AG and its affiliates. All rights reserved. 2017. For methodology and full list of caveats please see Afrx 2018.

Figure 11. Price Effects of Additional Generic Entrants, United States (2004)



Source: “About the Center for Drug Evaluation and Research - Generic Competition and Drug Prices” 2017.

Note: FDA analysis of retail sales data from IQVIA, IQVIA National Sales Perspective (TM), 1999–2004, extracted February 2005.

of exclusivity.¹¹² In Europe, prices for select biologics dropped substantially following the introduction of biosimilar competition (up to 55 percent for Epoetin in Germany), though the effect varied dramatically across products and countries.¹¹³ In Russia, the entry of a second bidder into public procurement auctions for pharmaceuticals has been associated with a 15 to 18 percent decrease in prices.¹¹⁴ And in Thailand, entry of an additional competitor is associated with a 13 to 30 percent reduction in the price of oncology drugs.¹¹⁵

Externalities

In the absence of state or international intervention, products with negative spillovers (“negative externalities”) are likely to be misused or overused. Among global health products, the negative externalities with the greatest impact come from the overprescription, misuse, and substandard quality of antimicrobials, undermining global antimicrobial efficacy. For example, in the early 2000s, experts recognized that many malaria patients were still being treated with less-effective, antiquated drugs, while widespread use of artemisinin monotherapies put artemisinin efficacy at risk—a negative externality threatening the global fight against malaria. This challenge prompted international intervention through introduction of the Affordable Medicines Facility—malaria (AMFm), a global initiative that subsidized superior (and efficacy-preserving) ACTs at the factory gate.¹¹⁶

For products that generate positive externalities—that is, when the product benefits wider society beyond the direct purchaser—subsidies may be required to achieve optimal and efficient levels of use within communities, counties, or across international borders. For example, global adoption of the more expensive inactivated poliovirus vaccine is essential to achieving the global public good (see below) of polio eradication, but may

not be cost-effective on a country-by-country basis. Without subsidies, many countries would not rationally invest additional resources in the more expensive vaccine. (The inactivated poliovirus vaccine and other vaccines are currently subsidized by GPEI, channeled through Gavi, for use in low- and middle-income countries.)

Public and Common Goods

Global health is characterized by extremely high-value public and common goods, paired with chronic underinvestment in their provision and conservation. Successful global collective action for global public goods for health has offered enormous net payoffs. For example, smallpox eradication cost just \$298 million in total combined investments from donors and endemic countries, spread over 13 years, yet has generated an estimated \$1.35 billion per year in savings and economic benefits.¹¹⁷ Likewise, a Bill & Melinda Gates Foundation-supported product development partnership brought an affordable and effective meningitis A vaccine to market for just \$70 million, helping address a deadly scourge at an affordable (and potentially cost-saving) price.¹¹⁸

However, many public and common goods remain underfunded and underprovided. For example, erosion of antimicrobial efficacy—a critical common good—is expected to cause 10 million deaths per year by 2050, causing \$100 trillion in cumulative global GDP (gross domestic product) loss.¹¹⁹ To help avert this grim projection and maintain shared access to antimicrobials, one estimate suggests that total public-sector investments of \$800 million to \$1.2 billion per year through 2022 are needed to replenish the antibiotic pipeline—well above the estimated \$550 million currently spent.¹²⁰ Likewise, low-likelihood but extremely high severity global pandemic risk translates to 700,000 expected deaths per year, generating an expected \$570 billion per year in

112. “Price Declines after Branded Medicines Lose Exclusivity in the U.S.” 2016.

113. “Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets” 2016.

114. Jascisens 2017.

115. Yamabhai and Smith 2015.

116. “Independent Evaluation of the Affordable Medicines Facility—malaria (AMFm) Phase 1” 2012.

117. Seymour 2014.

118. Bishai et al. 2011; and LaForce and Okwo-Bele 2011.

119. “Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations” 2014.

120. Ardai et al. 2018.

mortality and economic losses.¹²¹ Investments in health technologies to prevent or reduce global risk therefore represent critical public goods. Nevertheless, R&D for 11 high-risk pathogens remains critically underfunded despite a relatively modest price tag (\$1.17 billion per pathogen).¹²²

Global health aid, particularly when channeled through multilateral institutions, can in theory offer an appropriate collective action vehicle to provide critical global public goods, including disease eradication, R&D, and stewardship. The Lancet Commission on Investing in Health has argued that investments in global public goods, paired with leadership/stewardship and management of cross-border externalities, are the “core functions” of international collective action.¹²³ In practice, however, relatively little health assistance goes toward global public goods. One study estimates that just 14 percent of donor financing for health goes toward global public goods; an additional 7 percent is directed toward other “global functions,” including management of cross-border externalities and efforts to foster leadership and stewardship.¹²⁴

Present Bias

Present bias is a behavioral economics phenomenon that leads individuals to overvalue short-term gains and undervalue long-term investments. In global health, this bias can lead to unhealthy behavioral choices at the individual level where gratification is instant and the impact far in the future—for example, smoking, poor diet, or sedentary lifestyle. In low- and middle-income countries, it may also contribute to

relatively low expenditure on preventive health technologies such as contraceptives, immunization, bed nets, or sexual prophylaxis, despite relatively high expenditure on curative treatments.¹²⁵ Underinvestment in and underuse of capital medical equipment is another example of present bias.¹²⁶ Governments, responding to aggregated individual preferences, may be more likely to spend resources on acute treatment and curative medicines, leading to relative underinvestment in preventive technologies, R&D, antimicrobial stewardship, pandemic preparedness, and other public health functions.¹²⁷ Present bias in health is often cited as a justification for government intervention through subsidy, nudging, or messaging; it may also merit global intervention if individual and governmental present biases lead to systemic underinvestment in cost-effective health technologies.¹²⁸

Principal-Agent Problem

Most large purchasers—within global health institutions, country or subnational governments, procurement agents, or large hospital/pharmacy networks—act as agents of their citizens, clients, or potential beneficiaries (the “principals”). These purchasers are tasked with serving the best interests of their principals but also face their own set of incentives that may be misaligned with the ultimate social objectives of their agencies.

At the relatively benign (but still potentially impactful) end of the spectrum, procurement agents may hold different beliefs and priorities than the government recipients of their donations or the end users of health products. For example, procurement agents at international NGOs typically insist on stringent quality standards for the products they buy, such as by requiring WHO prequalification. At times, government procurers or individual patients may not share that insistence on prioritizing prequalified products; they may prefer

121. Fan, Jamison, and Summers 2016.

122. “An R&D Blueprint for Action to Prevent Epidemics: Funding & Coordination Models for Preparedness and Response” 2016. The Commission on a Global Health Risk Framework for the Future of the National Academies of Medicine has also proposed that just \$1 billion per year in additional R&D investments (in addition to \$3.5 billion per year in health systems strengthening) would substantially offset this risk by “provid[ing] a strong foundation for the development and production of an armamentarium of medical tools, including diagnostics, vaccines, drugs, equipment, and techniques, to build and sustain R&D preparedness capacity for rapid response to global infectious disease outbreaks.” See “The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises” 2016.

123. Jamison et al. 2013.

124. Schäferhoff et al. 2015.

125. Dupas 2011.

126. Perry and Malkin 2011.

127. Schmidt, Gostin, and Emanuel 2015.

128. Ashraf 2013; Trujillo et al. 2015; Buttenheim and Asch 2013; and Taylor and Buttenheim 2013.

“The availability of jobs in industry can have a subtle, but debilitating effect on an officer’s performance during his tour of duty in procurement management assignment. If he takes too strong a hand in controlling contractor activity, he might be damaging his opportunity for a second career following retirement. Positions are offered to those officers who have demonstrated their appreciation for industry’s particular problems and commitments.”

J. Ronald Fox (Former Assistant of the Secretary of Defense, US) 1974 (Laffont and Tirole, 1993).

broader access to nonprequalified products purchased at a lower price point. Beyond competing priorities and beliefs, even procurement agents with the best intentions face subtle organizational incentives that affect their professional conduct. For example, procurement agents may shy away from potential opportunities to increase procurement efficiency, out of either hesitation to expose poor past performance or a strong personal and professional risk aversion—namely, fear of superior scrutiny and professional consequences if things go wrong. Limited rotation of staff and ineffective oversight can exacerbate these natural tendencies.

Further along the spectrum, suppliers may leverage personal relationships with procurement agents to exercise influence outside standard competitive processes. Many global health procurement professionals have been recruited from the for-profit pharmaceutical industry; they may have extensive networks within industry, natural sympathy toward industry’s perspective and concerns, investments (e.g., stock options) tied to the pharmaceutical industry’s success, or a desire to return to the private sector after their service is complete. Even subconsciously, these forces could drive a prosupplier demeanor and favorable treatment. This “revolving-door” phenomenon is common and widely

discussed across sectors and countries, as in the case of military procurement in the United States. Further, governments (agents of all citizens) looking to increase their popularity may act in their own self-interest by investing in high-cost health products demanded by powerful groups rather than those that might benefit poorer segments of the population.

At an extreme, misaligned incentives between the principals (ultimate end users or donors) and agents (procurement bodies or agents) can create opportunities for corruption and diversion—for example, by preferential selection of specific suppliers or wasteful and unnecessary purchases.¹²⁹ A 2013 survey of health sector managers across 95 countries ranked procurement of drugs and supplies as the health system function with greatest vulnerability to corruption. Examples include kickbacks and bribes, nontransparent tendering and procurement processes, and overpricing of drugs and supplies.¹³⁰ In OECD countries, public procurement processes are notoriously vulnerable to corruption; the large volume of transactions, coupled with opaque processes and cozy relationships between suppliers and public officials, creates many windows for kickbacks or bribery.¹³¹ Estimates are out of date, but have previously suggested that 10 to 25 percent of global spending on health procurement is lost to corruption.¹³²

Corruption, waste, and misuse can also affect access to lifesaving health products. A 2015 study analyzed the relationship between the amount of ARV drugs entering a country and the number of people surviving longer with HIV due to ARV treatment. Countries with higher levels of corruption experienced a smaller drop in AIDS deaths for the same quantity of ARVs imported.¹³³ The efficiency of procurement and supply chain processes plays an important role in enabling countries to translate procurement of health products into improved health outcomes.

129. Petkov and Cohen 2016.

130. “Corruption in Health Sectors of Low- and Middle-Income Countries” 2013.

131. “Preventing Corruption in Public Procurement” 2016.

132. “Pharmaceuticals & Healthcare Programme” n.d.

133. Friedman 2015.

Anticompetitive Behavior and Collusion

Anticompetitive behavior refers to a range of firm conduct used to limit market competition and extract artificially high prices. In health product markets, anticompetitive practices such as the following are commonly used to limit effective generic competition, even after the initial expiration of patent exclusivity:

- **Anticompetitive Mergers and Acquisitions:** At the local or global level, a tactic where one supplier seeks to acquire or merge with its competitors or an API manufacturer to decrease competition and increase its market power.
- **Predatory Pricing:** A tactic where a dominant firm sets an artificially low price in the short term to drive competitors out of business or prevent new competitors from entering the market. In the long run, the dominant firm faces less competition and can substantially raise prices.
- **Patent “Evergreening”:** A variety of tactics used by originator companies to extend patent protection for lucrative drugs and prevent generic entry. In the United States, a 2017 study found that 80 percent of the 100 best-selling drugs were able to extend their patent protection at least one time, with Oxycontin receiving 13 different extensions.¹³⁴
- **Restricted Distribution:** To receive regulatory approval, generic entrants must prove their bioequivalence to the originator formula. In some cases (as for Daraprim, described above), originator companies may tightly control distribution of their product, preventing would-be generic competitors from acquiring sufficient quantities to prove bioequivalence and enter the market.¹³⁵
- **Pay-for-Delay:** An increasingly common tactic where an originator brand pays a cash settlement to a would-be generic competitor to delay generic market entry. In the United States, the

Federal Trade Commission estimates that American consumers and taxpayers lose \$3.5 billion each year because of these pay-for-delay deals.¹³⁶

- **Product Hopping:** A tactic where an originator yanks its product off the market just before patent expiration, replacing it with a slightly tweaked (and therefore patent-extended) formulation. So long as doctors continue to prescribe the originator’s reformulated variant, pharmacies cannot automatically substitute a generic competitor. Examining data from 1995 to 2009, a 2011 US study identified almost \$40 billion in originator revenue tied to suspect reformulations—that is, minor reformulations or extended release/combination products released just before patent expiration.¹³⁷

Cartels—a form of anticompetitive behavior where multiple suppliers work together to hold prices at artificially high levels—often appear in public procurement and health commodity markets.¹³⁸ Cartels raise the prices of products, benefiting suppliers and directly harming consumers and procurers. Though far from perfectly predictive, economic theory and evidence suggest that cartels are more likely to form under a specific set of favorable conditions. Cartels are easier to form when there are a limited number of competitors, all providing homogenous products with small and frequent purchases. Other risk factors include barriers to entry, the ability to police and enforce the cartel through the availability of information on price, and limited government enforcement. Formation of cartels is well documented at the national level but may also affect large-scale purchasing by global health institutions. Several global health markets have specific characteristics that may facilitate or incentivize collusion, and even markets that appear “low risk” may be vulnerable, demanding purchaser vigilance.¹³⁹

134. Feldman 2017.

135. Carrier and Kesselheim 2015.

136. “Pay for Delay” 2013.

137. Carrier and Shadowen 2017; and Shadowen, Leffler, and Lukens 2010.

138. “Policy Roundtables: Collusion and Corruption in Public Procurement 2010” 2010; Danzon 2014.

139. Vistnes 2018.

Investigators have detected many large-scale instances of collusion in pharmaceutical pricing and bidding. In the United States, for example, a recent antitrust investigation implicated 16 companies and 300 generic drugs as part of a massive price-fixing scheme—including a 3,400 percent price hike for albuterol, a common drug to help control asthma.¹⁴⁰ In Mexico, data from public procurement auctions for generic pharmaceuticals showed suspiciously similar bids across suppliers, indicating potential bid-fixing. Subsequent reforms of the auction design to reduce incentives for anticompetitive behavior resulted in price reductions averaging 20 percent for 18 of the 20 most important products (by total value).¹⁴¹ In South Africa, antitrust authorities reached a 55 million rand (close to \$4 million) settlement with local suppliers of intravenous solutions after the parties admitted to bid-fixing when supplying public hospitals.¹⁴² In Chile, the three largest retail pharmacy chains colluded to raise consumer-facing prices of branded pharmaceuticals.¹⁴³ However, without in-depth investigation and routine analytics, it is impossible to distinguish collusion from rational, competitive responses to market and tender incentives.¹⁴⁴

Collusion among firms is common, but regulatory and oversight authorities often lack the resources or capacity to identify, police, and consequently deter anticompetitive behavior. In addition, as Patricia Danzon notes, “the absence of powerful payers that regulate or negotiate drug prices with manufacturers and pharmacies as part of their drug reimbursement processes may” increase the risk of horizontal price-fixing at retail pharmacies.¹⁴⁵ Exacerbating these problems, purchasing by large multinational institutions on behalf of low- and middle-income countries may fall into jurisdictional gray zones, with unclear lines of

legal authority to identify and enforce appropriate punitive measures.

Unorganized Demand

Demand for health products is often fragmented across purchasing entities in different countries. Fragmentation is particularly acute for certain health products, especially those that are purchased in small volumes in countries that have a low disease burden or a small population. Product categories with multiple formulations for the same regimen also show high levels of fragmentation. Country-specific regulatory approval processes and distinct packaging and labeling requirements can exacerbate fragmentation, increasing suppliers’ transaction costs to enter each additional market.

Pediatric ARVs are one example of a fragmented global health commodity market. Countries were placing low-volume orders for different regimens, which vary by a child’s age and weight. At times, orders were so small that they failed to meet the minimum batch size that the manufacturers required for production.¹⁴⁶ Due, in large part, to this fragmentation, the supply of pediatric ARVs at the global level has been extremely unreliable. In some cases, manufacturers had to hold off on production of certain regimens until they could aggregate enough orders to meet minimum batch sizes. These challenges resulted in lead times of more than a year, leading to stock-outs that interrupted life-saving treatment for HIV-infected children while also preventing those not yet on treatment from accessing the drugs. Starting in 2006, a Unitaid-CHAI project aimed at coordinating global demand has helped overcome these challenges. Global cooperative efforts, including coordinating orders and rationalizing product selection, are now carried out under the auspices of an ARV Procurement Working Group, with funding for pediatric ARVs in many countries provided in large part by the Global Fund and PEPFAR.¹⁴⁷

140. Rowland 2018.

141. “Policy Roundtables: Collusion and Corruption in Public Procurement 2010” 2010.

142. Ibid.

143. Chilet 2017.

144. Vistnes 2018.

145. Danzon 2014.

146. CHAI 2018.

147. “Antiretrovirals” n.d.

Table 2. Price Ranges Reported to the V3P (Vaccine Product, Price and Procurement) Database by Self-Procuring Non-Gavi, Non-PAHO Lower-Middle-Income and Upper-Middle-Income Countries

Vaccine	Indicative multiyear supply agreement price via UNICEF	Price per dose for non-Gavi LMIC* (n)	Price per dose for non-Gavi UMIC** (n)
PCV	\$3.05–3.30 (2017)	\$12.51–19.83 (4)	\$9.85–49.99 (14)
Rota	\$3.20 (2017–2021)	\$3.57–7.36 (2)	\$3.34–15.76 (7)
HPV	\$4.50 (2017)	\$13.96 (1)	\$7.38–113.30 (9)

Source: Authors, recreated from <https://lnct.global/wp-content/uploads/2018/02/Vaccine-Pricing-for-GAVI-Transitioning-Countries-1.pdf>; data from the V3P database, available at: https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/en/.

Notes: * GNI per capita between \$1,006 and \$3,955; ** GNI per capita between \$3,956 and \$12,235. (n) = number of countries reporting price data.

The high transaction costs to serve fragmented markets are often passed down to purchasers and may ultimately be borne by patients. This can also result in limited bargaining power for purchasers (see discussion in Chapter 2). Gavi’s support for vaccines provides one example where organizing demand through institutional negotiations can help address high transaction costs. Many countries undergoing “accelerated transition” from Gavi (plus others that have fully transitioned from Gavi support) can still benefit from prenegotiated, multiyear price commitments from specific suppliers—but only if they procure through UNICEF’s Supply Division or PAHO.¹⁴⁸ In 2017, the multiyear supply agreement prices for pneumococcal conjugate vaccine ranged from \$3.05 to \$3.30 per dose; the price agreement for Merck’s rotavirus vaccine was \$3.20 per dose. In contrast, a sample of self-procuring countries all paid higher prices for the same product, with some paying up to six times the price for Gavi-funded vaccines (see Table 2). The lower Gavi price could be indicative of lower transaction costs from consolidating demand or other manufacturer incentives, as well as industry efforts to tier prices (or price discriminate) according to GNI levels.¹⁴⁹ Conversely,

the higher price paid by self-procuring countries may also reflect differences in physical delivery conditions, specific labelling and registration requirements in specific countries, or emergency ordering, among other factors.

In addition to fragmentation, uncertain and unreliable demand can also lead to procurement inefficiencies. In some cases, suppliers may not have visibility into demand, which is needed to help organize manufacturing capacity and plan production lines. Even available estimates of demand may be highly unreliable—as in Indonesia, where actual procured quantities for some health products can vary by up to 130 percent of the demand specified in public contracts with suppliers.¹⁵⁰ In the long run, unreliable and uncertain demand also deters investment in dedicated manufacturing capacity. In the absence of interventions to align incentives, the transaction costs associated with fragmented, uncertain, or unreliable demand may disincentivize suppliers from investing R&D resources to serve low- and middle-income country markets, choking off potentially lifesaving innovations.

148. “Vaccine Pricing: Gavi Transitioning Countries” 2017.

149. Note that in addition to demand consolidation, Gavi uses tools to reach the lowest prices in the market (e.g., longer-term tenders, guarantees, advance purchase commitment, prepayments), derisking the manufacturers’ demand predictability in exchange for more favorable pricing.

150. Socialine 2018.

4

THE WAY FORWARD: A COMPREHENSIVE AGENDA FOR PROCUREMENT REFORM



Introduction

Looking ahead, procurement will be central to the efforts of low- and middle-income countries to meet their citizens' evolving health needs and achieve UHC, with or without global health assistance. To be most effective, better procurement policy and practice must be embedded within an end-to-end approach, from market access and product regulation to supply chain and delivery processes, to ensure that appropriate and high-quality health products reach end users. Procurement outcomes will depend in large part on policies and decisions made across this continuum, but procurement itself is an essential and underappreciated health system function that merits its own focus. The evolving global health landscape offers stakeholders a valuable opportunity to address existing constraints to improved procurement while taking proactive steps to sustain access to essential medicines and other health products through anticipated changes.

Based on the findings in Chapter 3, this report lays out four recommendations for smarter, more strategic procurement policy and practice. These recommendations move from the global to country level, building an enabling international environment that can facilitate country-level reform. The proposed recommendations are the first steps in addressing many—though not all—of the breakdowns in health product markets as identified by the Working Group. These recommendations also can help lay the groundwork for more ambitious, transformational reforms across a longer time horizon. For example, many but not all Working Group members expressed a long-term ambition to develop a global e-marketplace for medicines, diagnostics, devices, and other supplies.

Recommendation 1: Sustain and Expand Global Cooperation for Procurement and Targeted Innovation

In most cases, the transition from donor aid is global “good news.” Countries are growing wealthier and increasingly self-sufficient, requiring less external support to secure essential health products for their populations. Yet global health procurement entities play important global roles beyond mere “purchasing”; they also aggregate demand, provide market signals to “pull” targeted innovations, ensure product quality, monitor and manage the supplier landscape, and subsidize products that may not be locally cost-effective in all countries but provide important global benefits. In the absence of other interventions, rapid devolution of procurement functions from the global to national or subnational levels may threaten the global health community's collective capacity to promote and sustain these health-related global public goods.

Looking forward, the global community should therefore seek to *sustain* and possibly *expand* global cooperation to address specific global challenges—particularly supply security and targeted innovation—even after most countries transition from current global health mechanisms. A forward-looking global health cooperation strategy will need to engage emerging middle-income countries as partners rather than recipients, reframe the mission and criteria for intervention or subsidy, and leverage an evolving set of tools to address a changing landscape. Potential avenues for continued or expanded global cooperation include the following:

- ***Pooled Demand and Cooperative Purchasing:*** Pooled or other forms of cooperative purchasing across countries may be an appropriate strategy to address fragmented demand or high transaction costs in low-volume or fragile product markets. Pooling could occur at the regional or global level; it could cover a subset of “strategic”

products or the entire portfolio of health product needs. Other forms of collaboration could include globally or regionally negotiated price agreements accessible to multiple procurers. (However, decentralized purchasers may have less capacity to signal joint demand, which could undermine their ability to secure favorable prices.)

- **Targeted Investments in R&D:** Over the past two decades, global health agencies have helped bring important new products to market, for example the Meningitis A Vaccine for Africa (MenAfriVac) and the GenXpert TB diagnostic. Donors have funded targeted “push” investments in new R&D through basic research grants and product development partnerships. They have also helped “pull” new products through the pipeline by aggregating and signaling demand, and in one case (the pneumococcal conjugate vaccine) through an explicit advance market commitment. Moving forward, traditional donors will need to engage emerging MICs as partners to identify and advance R&D priorities that could be purchased by country payers and delivered at locally cost-effective prices, particularly where market failures limit private-sector investments through normal channels. For example, the proposed Market-Driven Value-Based Advanced Commitment (MVAC) offers a country-led model to channel private-sector R&D resources to better TB therapies—a priority for emerging markets.¹⁵¹ There may be a rationale to sustain donor “push” funding at early stages of basic research, but global efforts should focus on signaling and aggregating national demand for locally cost-effective innovative products to spur private investment and create a more sustainable long-term innovation model.

- **Monitoring and Managing the Supplier Landscape:** Global stakeholders could continue monitoring and managing the supplier landscape for strategic or globally important products and API, even if procurement itself is highly decentralized. In the long run, one of the global agencies could potentially host a supply security function with a mandate to monitor the supplier landscape, interface with strategic suppliers around production and pricing, and alert payers to potential threats to supply security.
- **Information-Sharing, Market Intelligence, and E-Platforms:** Countries should continue to collect and share relevant information at the regional and global levels, particularly with respect to product pricing and quality. The Global Fund’s e-procurement platform, known as Wambo.org, was launched in 2012 to help streamline procurement processes. Currently, it remains limited to HIV, malaria, and TB products, although a wider scope was initially envisioned.¹⁵² Another recent example is the Global Family Planning Visibility and Analytics Network platform, launched in 2018, which gives governments and global procurers insight into planned orders, shipment progress, and country-level inventory and demand data for contraceptives.¹⁵³ As a longer-term goal, one or more donors may explore options to build up existing initiatives into a more comprehensive global data and market intelligence platform, potentially including an e-marketplace function.
- **Support to Nascent and Start-Up Private-Sector Innovations:** Global stakeholders could also support start-up innovators focused on the supply and distribution of health products with promise to reduce prices (and price variability), improve quality, and increase availability, among other benefits. These emerging efforts

151. Chalkidou et al. 2019.

152. See “wambo.org - Sourcing & Management of Health Products” n.d.
153. “Global Family Planning Visibility and Analytics Network” 2019.

have the potential to impact the procurement and broader supply chain landscape for national payers, wholesale and retail pharmacies, and individuals paying OOP.¹⁵⁴

- **Adopting Common Standards and Principles for Quality Assurance:** Donors should ensure consistency in quality standards across medicines and other health products, whether procured by countries themselves or through bilateral, multilateral, and third-party procurers using donor funds. A recent effort, led by the Interagency Supply Chain Group, aims to encourage donors to adopt and implement a standard set of guiding principles around quality standards.¹⁵⁵
- **Subsidy:** In some cases, there may be a powerful rationale for donors to offer continued subsidy for specific products even after countries have largely transitioned from external aid. Donors could make a policy decision to subsidize specific products that meet one or more of the following criteria:
 - **Products Have Important Positive Externalities:** Some health products, particularly those addressing infectious diseases, can have positive spillovers with regional or global implications. ACTs, for example, have fewer externalities with regard to artemisinin resistance, and are preferred to monotherapies; likewise, vaccines can help control the spread of disease across borders. Products that help address global challenges may merit continued subsidy even in a post-aid paradigm.
 - **Time-Limited Subsidy Can Offer Lasting Benefits:** In some cases, targeted and time-limited subsidies may offer lasting benefits. For example,

some products (e.g., specific devices or diagnostic tools) may require substantial introductory costs (e.g., physician retraining) that could be prohibitive in the poorest countries, yet may be highly cost-effective once they are introduced. Donors could consider offering upfront subsidy to introduce new products if there is compelling evidence that products will be locally cost-effective or self-sustaining within some parts of the population in the long-run.

- **Products are Marginally Cost-Effective:** Donors may wish to sustain a humanitarian role in global health by subsidizing access to life-saving or health-improving products that do not meet local cost-effectiveness criteria and affordability constraints. To do so, they may subsidize a product down to the level that it becomes cost-effective in a given country's health system, and require cofinancing for the rest of the cost.

Recommendation 2: Reform WHO Guidance and Policy to Support Modern and Agile Procurement Policy and Practice

Many low- and middle-income countries look to WHO guidance as their lodestar for procurement and pharmaceutical policy, particularly when national regulatory and purchasing functions suffer from capacity constraints. WHO guidance covers a broad range of related topics, including standards for drug importation and donation; essential medicines, diagnostics, and medical device lists; and pharmaceutical pricing. In addition, many global health institutions and country payers have adopted the WHO's prequalification standards as a prerequisite for purchase of certain product classes.

Yet despite the centrality of the WHO in global pharmaceutical policy, and the rationale for an assertive global standard-setting institution, much of its

154. A landscaping assessment of innovative companies in Nigeria, Kenya, Ghana and South Africa, conducted by Impact for Health, with support from the Bill & Melinda Gates Foundation, identified 30 companies offering services to improve the supply of products to providers and to consumers directly. See Nemzoff, Rosen, and Chalkidou 2018; and "Disrupting Health Product Distribution: The Emergence of Digital Innovators in Africa" 2018.

155. See the Interagency Supply Chain Group memo dated November 2018 "Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and Other Health Care Commodities" (on file with the authors).

guidance is out-of-date, inflexible, and inappropriate for modern contexts. For example, the WHO's guidance on the development and implementation of a national drug policy was first released in 1988 and last updated in 2001.¹⁵⁶ Further, the World Bank's guidance on imported pharmaceuticals and vaccines, based off WHO guidelines dating back to 1996, states that at least three-fourths of the specified shelf-life should be remaining when products arrive at the port of entry.¹⁵⁷ This procurement requirement, defined as a percentage rather than a threshold expressed as a fixed number of months, can affect flexibility and efficiency, complicating supply chain planning and undermining efforts to respond to stock-outs.¹⁵⁸

To reassert itself as the global standard-setting body and better support modern and agile procurement policy and practice, the WHO should set and execute a prioritized guidance reform agenda. Its Roadmap on Access to Medicines and Vaccines 2019–2023, presented at the World Health Assembly in May 2019, rightfully acknowledges the need for regulatory system strengthening, building competencies in procurement and supply chain management, and evidence-based selection (including HTAs) of health products to guide procurement and reimbursement.¹⁵⁹ However, WHO's future efforts should consider adding the following components:

- ***Expand Efforts to Facilitate Common or Expedited Drug Registration at the Country Level:*** The Working Group identified time-consuming and burdensome drug registration processes as a major barrier to entry, both for innovative (on-patent) products and for generic competition that could help drive down prices. Robust regulatory oversight is essential to ensure product quality and prevent fraudulent or substandard

drugs from entering the market. Nonetheless, country-by-country review of a product dossier, each with slightly different processes and requirements, is often unnecessarily duplicative and slow, potentially keeping prices artificially high and diverting resources from desperately needed pharmacovigilance functions.

In recent years, the WHO has set up the Collaborative Registration Procedure (CRP) to help address this problem, as an intermediate step toward strengthening in-country regulatory capacity. Under the CRP, national medicines regulatory bodies can voluntarily elect to receive the WHO's product assessment data in lieu of conducting primary assessment based on a country-specific dossier; in turn, the regulatory bodies agree to make and communicate their registration decision within 120 days. At the time of writing, 36 countries (mostly from Asia and sub-Saharan Africa) were participating in the CRP for prequalified products.¹⁶⁰ Twenty-two of those countries, almost all from sub-Saharan Africa, also had enrolled in a pilot project to expand the CRP to products approved by a stringent regulatory authority (SRA).¹⁶¹

Building on these efforts, the WHO should fully fund, expand, and endorse expedited and aligned registration for prequalified and/or SRA-approved products as the norm in smaller low- and middle-income countries. To help the CRP become self-sustaining, the WHO and member countries could consider charging small submission fees for each country of registration, on top of country-level registration fees; alternatively, this could be an area for sustained donor subsidy as a global public good.¹⁶² WHO guidance should further encourage countries to adopt national laws and regulations that enable

156. "Guidelines for Developing National Drug Priorities" 1988; and "How to Develop and Implement a National Drug Policy" 2001.

157. "Annex 12: Guidelines on Import Procedures for Pharmaceutical Products" 1996; and "Technical Note: Procurement of Health Sector Goods" 2006.

158. CHAI 2018.

159. "Medicines, Vaccines and Health Products: Access to Medicines and Vaccines" 2018.

160. "Accelerated Registration of Prequalified FPPs" n.d.

161. "Accelerated Registration of FPPs Approved by SRAs" n.d.

162. In the United States, the Prescription Drug User Fee Act of 1992 authorized the FDA to collect fees from drug manufacturers, which have helped expedite the drug approval process. See Office of the Commissioner 2019.

expedited registration procedures for quality-assured medicines (such as the CRP), including allowing quality-assured but unregistered products to compete for public tenders under an expedited registration process.

- ***Provide Guidance on and Work with Countries to Adapt the WHO Essential Medicines, Diagnostics, and Medical Devices Lists and Technical Guidance to Local Context and Resource Constraints:*** The WHO lists and other technical guidance documents are often used to guide country-level lists and policy decisions—and, consequently, the formulary and related lists of national purchasers. Yet the WHO lists and guidance are typically one-size-fits-all, and thus do not account for country-by-country variation in disease burden, resource availability, prioritization, or cost-effectiveness. Though the WHO itself is poorly placed to evaluate country-by-country cost-effectiveness, it should ensure that technical guidance and the lists are written to encourage appropriate modification and adaptation based on local context, including consideration of local cost-effectiveness, budgets, and disease priorities. Where appropriate, WHO country offices could help countries adapt the list to suit the local context.
- ***Comprehensive Update of Guidance for Pharmaceutical Policy:*** The Working Group recommends that the WHO undertake a comprehensive review of all guidance related to pharmaceutical policy and procurement to support more agile and effective purchasing. However, before a more specific recommendation can be made, the priorities, capacities, and relative roles of international agencies and expert entities in this domain need to be reviewed in full.

Recommendation 3: Professionalize Procurement by Building Capacity and Driving Strategic Practice

Limited capacity and expertise within procurement and regulatory agencies are at the root of many institutional inefficiencies in the current global health procurement landscape. Country-level procurement entities (especially in larger middle-income countries that have achieved procurement efficiencies), global procurement organizations, and donors should raise collective awareness and build much-needed recognition of procurement as an integral health system function.

A concerted push is needed to professionalize procurement and broaden capacity from the global to national level along two tracks: procurement *process* capacity and procurement *strategy* capacity. Procurement process capacity encompasses product selection/HTA; regulatory approval and quality assurance; price negotiation; tendering and contracting; and monitoring and evaluation of procurement performance. Procurement strategy capacity, by contrast, includes increased know-how of best practices, including when, where, and how to use a wider menu of procurement tools and approaches, such as pooling to maximize efficiencies or use of specific auction formats to achieve cost savings while maintaining supply security. (See Box 4 on auction-based procurement as a tool to ensure efficient and sustainable purchasing.) Efforts to develop a cadre of dedicated procurement professionals could also lead to greater recognition of, and demand for, reform of national legislation and regulation governing procurement and related processes, as described under recommendation 4 below.

Efforts could be led by a partnership or network of existing entities such as procurement universities or accreditation bodies, including the Chartered Institute of Procurement and Supply (CIPS), multilateral institutions, and platforms like the Africa Resource

Box 4. Adding Auction-Based Procurement to the Toolbox to Promote Efficient and Sustainable Purchasing

Applying innovative auction designs as part of a bigger, more sophisticated toolbox for global health procurement mechanisms may hold promise in certain instances. For procurement of health products, ensuring affordable and sustainable prices while maintaining supply security are key objectives. Many other sectors that prioritize supply security, including telecommunications, electricity, and offshore wind energy, have applied auctions to drive competition while assuring supply security.^a

A limited number of pilot efforts point to the potential to apply auction designs to global health.^b A 2014–15 study conducted by Power Auctions LLC for the Bill & Melinda Gates Foundation designed, evaluated, and simulated auction mechanisms for vaccine procurement. Results suggested that in markets with adequate supply (i.e., the total supply that can be produced by manufacturers meets demand) and sufficient competition (i.e., no single supplier is essential for satisfying demand), nontraditional auctions may drive down prices and maintain supply security. Using cost data, the study concluded that, compared to the status quo tendering procedure, an appropriately designed multiround auction could obtain significantly lower prices for pentavalent vaccine. The study also concluded that the relatively newer and less mature market for rotavirus vaccine did not have sufficient competition to allow for an appropriate auction design. Based on the findings, UNICEF and Gavi used a phased approach in their 2016 pentavalent tender, where certain quantities of the total forecasted volume were awarded in multiple rounds. This resulted in purchase agreements with

six suppliers and close to a 50 percent price drop (the weighted average price fell from \$1.65/dose to \$0.84/dose).^c

Uptake of auction designs in global health procurement remains relatively low, due, in part, to concerns that they may negatively impact market structure and supply security. Some observers attribute such concerns to misconceptions, emphasizing that auctions can potentially be more effective than negotiations because they institutionalize competition to reduce procurement costs, while taking account of other procurement objectives. However, empirical studies also point to potential challenges. One study comparing auctions and negotiations, for example, shows that although auctions are publicly executed, they may not always be less prone to favoritism.^d

Nevertheless, innovative design elements, carefully applied in appropriate contexts, could help advance specific objectives such as supply security. Such options may include setting aside a portion of the demand for certain bidders, favoring bidders with a long history of reliability, or allocating quantities across a minimum number of suppliers (known as the two-stage scalar clock format). Selecting the appropriate auction design ultimately depends on the stated procurement goals and metrics, which may include minimizing cost or achieving supply security. Doing so requires a combination of auction theory expertise and a deep understanding of the candidate product's market characteristics (e.g., cost structure) and current procurement processes.

(continued)

Box 4. Continued

Global procurement entities and their funders should systematically pilot and further evaluate different, novel auction approaches for other health products that meet the required market conditions. Such approaches might consider whether auction-based procurement could achieve supply security and lower prices compared to existing tendering approaches. Improved evidence about the potential benefits and challenges of applying innovative auction designs is one important step toward

expanding the toolbox of effective approaches and increasing know-how on applying best practices to global health procurement.

Source: Based on Aperjis and Ausubel 2019 and other publicly available sources as cited above.

a. McAfee, McMillan, and Wilkie 2010; and Ausubel and Cramton 2010.

b. See Baranov et al. 2017.

c. See “Supply of Children’s Five-in-One Vaccine Secured at Lowest-Ever Price” 2016.

d. Gretscho and Wambach 2016.

Centre.¹⁶³ One or more interested funders could support the creation of such an international partnership, including dedicated resources to produce global public goods related to health products procurement.

The global push to professionalize health products procurement could be achieved by advancing the following components:

- **Procurement University:** CIPS, in partnership with academics and private-sector procurement experts beyond the health sector, and drawing inspiration from the World Bank Flagship Course, should develop and finance an intensive short course on best practice and skills-building in health products procurement, focused on process and strategy capacity. The course would be offered to a carefully selected group of representatives from national and international procurement agencies. Upon successful completion, participants would receive a diploma accredited by CIPS. A distance-learning version of the course could be developed in future years.

- **Mentoring and Exchange:** In addition to support through the Procurement University, there should be opportunities for national procurement professionals to enhance their skills and competencies and to share knowledge of strategic best practices through targeted mentorship and exchange programs. These could include learning “internships” within peer procurement agencies; or targeted *in situ* mentorship from an embedded public- or private-sector sourcing and procurement expert. Specifically, establishing a joint learning network or community of practice dedicated to procurement could facilitate greater opportunities for knowledge exchange and learning among procurement professionals across low- and middle-income countries.
- **Global Health-Specific Procurement Guidance, Including Toolkits, Decision Trees, and Other Resources:** The guidance should include:
 - Affordability guidelines calibrated to local budgets;
 - Costing toolkits;
 - A repository of HTA models by disease and technology;

163. The World Bank has been taking steps to put greater attention on procurement of health products, under its new Procurement Framework; in 2017, for example, it launched the Industry Engagement Program to tackle procurement challenges for large medical diagnostic equipment, among products in other sectors. See “Industry Engagement Program” 2017.

- ❑ Decision trees and guidance on when and how to adopt different tendering modalities, including nontraditional auctions and framework agreements;
- ❑ Links to existing resources and pricing databases (e.g., the International Medical Products Price Guide published by Management Sciences for Health, the ECRI Institute Price-Guide, the WHO V3P project);¹⁶⁴
- ❑ Dedicated guidance and toolkits to drive greater use and better analyses of market and pricing data.

These resources should be publicly available and used to support the reform programs described below. Compliance with a core set of procurement guidelines could also be incorporated as a requirement for all global health procurement supported by international financing, including the Global Fund, UN agencies, and the World Bank.

- **Standardized Set of Performance Measures for Global Health Procurement:** Global health procurement entities should align behind a single set of key performance indicators for global health procurement, creating a common framework for assessing performance across institutional procurement entities and national procurement agencies. Using these metrics, global health institutions should offer regular public reporting on procurement performance.
- **Evaluation of Procurement Policies and Approaches:** Financial and technical assistance is needed to help support countries, global health agencies, and independent researchers to rigorously evaluate innovative procurement reforms and build an evidence base of strategic practices for health products procurement. For example, the global health procurers should systematically pilot and

evaluate auction-based procurement for appropriate global health products to understand the specific market conditions and product characteristics where applying this strategic practice could result in lower prices and more information on manufacturers' actual costs, while also enabling supply security and greater competition (see Box 4). Support from one or more donors could also help establish a peer-reviewed journal on global evidence and best practices related to health products procurement.

Recommendation 4: Support In-Country Procurement Policy Reform

As countries, particularly middle-income countries, transition away from donor-supported mechanisms, health products procurement will increasingly become nationally financed and managed. However, country-level policy, legal, and regulatory environments often present significant impediments to effective health procurement. National procurement reforms to address such barriers are needed to improve procurement performance and accelerate progress toward UHC.

Several countries—notably, larger middle-income countries—have launched expansive policy reforms to improve affordability of and expand access to medicines and other health products. For example, the government of China recently launched ambitious procurement reforms—centralizing purchasing of generic medicines in select cities—as part of its UHC scheme (see Box 5). Indonesia, under its new health insurance scheme, is using an e-Catalogue and national formulary to guide its medicine reimbursement policy—though several challenges persist, including a lack of harmonization between the two lists.¹⁶⁵

Global funders interested in ensuring more efficient national procurement processes and sustainable access

164. "How to Use" n.d.; "Pricing - Supply & Implant" n.d.; and "WHO | MI4A: Vaccine Purchase Data" n.d.

165. Wasir et al. 2019.

Box 5. China's "4+7" Drug Procurement Reform

In June 2018, China's national government announced plans to centralize procurement to curb rising drug prices within its UHC scheme. Under the "4+7" drug procurement reform pilot plan, four municipalities and seven cities will pool purchases of guaranteed volumes of generic pharmaceuticals. The reform, which has strong political backing, aims to facilitate greater use of quality, cost-effective generics. With the 11 pilot jurisdictions constituting 30 percent of the country's pharmaceutical market by volume, these complex reforms will significantly affect how generic drugs are priced and procured, with implications for China's pharmaceutical sector.

Multiple waves of procurement centralization efforts have been initiated since the early 2000s, but they claimed modest achievements and differ from the "4+7" reforms in notable ways. First, because previous efforts were initiated at the provincial levels, tendering processes and criteria were fragmented across provinces, limiting the benefits of consolidation. By contrast, the latest reforms are led by the State Council and are slated to be rolled out nationwide. Second, earlier efforts did not emphasize drug quality, whereas the latest reforms include product quality criteria enforced by the National Drug Administration. Third, predefining quantities and offering a 30 percent prepayment—elements not included in previous reforms—could help achieve favorable pricing. Finally, originator firms that supply products whose patents have expired will now compete with generic manufacturers.

In November 2018, the Joint Procurement Office, an alliance with representatives from each pilot

city, initiated an open tendering process for 31 quality-assured generic drugs. Bidding took place through a two-stage process resembling an auction, though price was the primary selection criteria and there was only one winning supplier per product. Contracts for guaranteed quantities of 25 generic drugs were awarded to 23 domestic Chinese and 2 multinational companies (tenders failed for 6 products). This stark differential is broadly explained by the gap in prices offered by multinational versus domestic firms.

The initial bidding resulted in significant price drops. Compared to 2017, prices for the 25 drugs in the 11 jurisdictions fell by 52 percent on average; the highest price cut was 96 percent. According to the bid result announcement, the prices of some drugs, like entecavir to treat hepatitis B, are significantly lower in China (\$0.09) compared to the US market (\$32.72). Recognizing that prices were already low, the National Health Insurance Bureau stated that further reductions of 10 to 20 percent could in fact be achieved. Estimates suggest procurement savings from the initial pilot effort for 25 generic drugs could be as much as \$0.85 billion, with the prospect of much larger savings following scale-up to non-pilot cities.

It is still too early to fully assess the effectiveness of these reforms. Nevertheless, initial results point to far-reaching effects on China's pharmaceutical sector. One indication is the \$44 billion in losses experienced by the pharmaceutical industry on the domestic stock markets in the days following the bidding.

(continued)

Box 5. Continued

This initial experience raises several considerations for the future. First, products selected for this pilot plan should be systematically informed by evidence from the newly established HTA agency. Second, the success of the scheme will depend on close collaboration across multiple policymaking bodies to manage contracts and payment arrangements, enforce accountability, and assess performance in public hospitals. Finally, the reforms signal the potential market dominance of domestic Chinese

generics manufacturers—small, inferior firms are expected to be driven out of the market—with subsequent consequences for how multinational pharmaceutical companies operate in China. Nevertheless, the government must proactively build up alert systems to identify possible monopolistic and anticompetitive behavior.

Source: Based on Yue 2019.

to essential global health products should provide dedicated support to governments leading in-country reforms. Prioritizing those countries that are projected to transition from one or more global health financing mechanisms and informed by data and analytics, global health institutions and international procurement entities should work directly with national procurement agencies/offices and other relevant national institutions to reform and strengthen procurement policies and practice.

The reforms, which will necessarily be led by countries themselves and could be supported by global funders, should target the specific constraints to effective country-level procurement. These constraints may include limited competition, inadequate attention to quality assessment, and legal restrictions against more effective procurement modalities. Over time, these reforms would reduce transaction costs for suppliers, especially for small volume products, thus encouraging entry of quality generics suppliers and potentially driving increased competition in these markets. Overcoming existing barriers to collaborative purchasing arrangements could also allow national procurement bodies to pool demand through regional and international mechanisms, where appropriate, or organize demand

more effectively in decentralized settings (see recommendation 1 above).

Multilateral development institutions like the World Bank can play an important role in facilitating government-led reform efforts, but they must be careful to *support* rather than *dictate* the terms of procurement policy reforms. Policy-based lending, for example, could offer conditional financing to support a bespoke diagnostic assessment of procurement outcomes and barriers, followed by codevelopment of an agenda for policy and institutional changes across different sectors. Development policy lending from IDA or the International Bank for Reconstruction and Development also could be leveraged to facilitate procurement reforms, while ensuring that there is domestic leadership and commitment.¹⁶⁶

Country-led procurement reforms should consider the following dimensions:

- **Purchasing and Contracting Modalities:** Legal and/or regulatory changes to allow a wider range of appropriate tendering and contracting approaches, including long-term framework

166. For more on the World Bank's Development Policy Financing, see "Products and Services" n.d.

agreements, appropriate auction designs, or joint purchasing via regional or international pooling mechanisms. Governments, particularly in smaller countries, should analyze the benefits and costs of self-procuring compared to seeking an external procurement agent or end-to-end supply chain agent as a service provider. Preliminary evidence from Kaduna state in Nigeria and Ukraine, among others, suggests potential substantial savings and other benefits for procurement of quality-assured medicines and other products.¹⁶⁷ It should be acknowledged that there is a difficult political economy and multiple non-health policy objectives (local development, employment, etc.) beyond value-for-money that motivate existing procurement modalities. Reform efforts should therefore include consideration of phased approaches and more efficient strategies to achieve additional policy objectives.

- **Procurement-Related Functions:** Legal and/or regulatory changes to ensure HTA, evidence-based, budget-conscious product selection, and quality assurance are integrated within the procurement process.
- **Industrial Policy and Related Requirements:** Legal and/or regulatory changes to amend particularly burdensome or problematic local purchasing requirements, including rules around cash flow and local currency for tenders. Reduced market entry barriers and increased market entry incentives for quality-assured generics manufacturers will enable an increased number of suppliers and greater competition, thereby reducing price while increasing supply security.
- **Product Regulation:** Reforms to streamline registration procedures for new products without compromising quality assurance. These reforms

could link with and build on WHO's CRP and Global Benchmarking Tool, which evaluates national regulatory systems using a systematic methodology and identifies areas of improvement (see recommendation 2).¹⁶⁸

Conclusion

The recommendations in this chapter (see Table 3)—building on the conceptual framework and diagnosis developed in Chapters 2 and 3—have wide-ranging implications for how the global health community conceptualizes, facilitates, and organizes the procurement of global health products. Together, they offer a vision for how today's global health procurement bodies can reimagine and redefine their roles to stay relevant in a changing world: by sustaining and potentially expanding global health cooperation to address issues of global concern, by facilitating competitive quality-assured generic markets, and by supporting country payers to professionalize and reform procurement practices.

The Working Group is well aware that it will be difficult to implement these recommendations, and that implementation will have to be spread over many years and across a broad range of stakeholders. Yet the opportunity—proactive action to address predictable global change, sustaining and expanding global access to lifesaving health products—cannot be ignored. The authors of this report urge all global health stakeholders to review these recommendations, understand their relevance, and chart a path toward the long-term relevance, efficiency, quality, affordability, and security of global health procurement.

167. On Kaduna state in Nigeria, see Abdulkadir and Tafuri 2017; and "Expression of Interest for the Supply of Essential Drugs and Medical Consumables for Drugs Revolving Fund (DRF) Scheme by the Government of Kaduna State" 2018. On Ukraine, see "Ukraine Is Struggling with Corruption, Sometimes Successfully" 2017.

168. "WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory Systems" n.d.

Table 3. Mapping the Proposed Recommendations to the Identified Breakdowns

Recommendation	Proposed action	Related breakdown and identified challenge	Response to the breakdown
1. Sustain and expand global cooperation for procurement and targeted innovation	Pooled demand and cooperative purchasing	<i>Unorganized demand:</i> fragmented, uncertain, and unreliable demand	Reduces fragmented demand and curbs high transaction costs
	Targeted investments in R&D	<i>Market failure:</i> public and common goods.	Channels private-sector R&D investments to develop new, improved health technologies
	Continued subsidy for specific health products	<i>Market failure:</i> externalities; public and common goods; <i>Absolute resource constraints</i>	Enables provision of lifesaving, health-improving products that have positive externalities and/or are marginally cost-effective
	Information-sharing, market intelligence, and e-platforms	<i>Institutional inefficiencies:</i> limited capacity and procurement expertise; inadequate and inconsistent tracking, monitoring, and evaluation	Drives better decision making and improved procurement practice
	Common standards for quality assurance	<i>Market failure:</i> imperfect information	Ensures consistent, quality standards for procured health products
2. Reform WHO guidance and policy to support modern and agile procurement policy and practice	Common or expedited drug registration	<i>Institutional inefficiencies:</i> institutional, administrative, and legal barriers; <i>Market failure:</i> barriers to entry	Lowers transaction costs, eases barriers to entry, and potentially increases competition among quality-assured generics suppliers
	Guidance to adapt WHO lists to local context and resource constraints	<i>Institutional inefficiencies:</i> inefficient product selection; limited capacity and procurement expertise	Facilitates improved processes for the selection of clinically effective and cost-effective health products
3. Professionalize procurement by building capacity and driving strategic practice	Procurement University, and mentoring and exchange programs	<i>Institutional inefficiencies:</i> limited capacity and procurement expertise	Promotes specialized and technical expertise on procurement as a key health system function
	Global health-specific procurement guidance, standardized performance measures, and evaluation of procurement policies and approaches	<i>Institutional inefficiencies:</i> limited capacity and procurement expertise; inadequate and inconsistent tracking, monitoring, and evaluation	Drives more efficient, evidence-informed practice
4. Support in-country procurement policy reform	Reforms to purchasing modalities, contracting procedures, and other procurement-related functions (e.g., HTA)	<i>Institutional inefficiencies:</i> institutional, administrative, and legal barriers; limited capacity and procurement expertise; <i>Market failure:</i> barriers to entry; principal-agent problem; anticompetitive behavior and collusion	Overcomes constraints to efficient country-level procurement by enabling the use of appropriate procurement and contracting modalities
	Reforms to streamline registration procedures and reduce onerous purchasing requirements	<i>Institutional inefficiencies:</i> institutional, administrative, and legal barriers; <i>Market failure:</i> barriers to entry	Reduces transaction costs for suppliers, encourages market entry of quality-assured products, and potentially promotes increased competition

APPENDICES



APPENDIX A.

PROFILES OF WORKING GROUP MEMBERS

Michael Anderson, MedAccess

Michael Anderson is chief executive officer (CEO) of MedAccess, a social finance company increasing access to medical supplies in Africa and South Asia. He was previously CEO of the Children's Investment Fund Foundation, the British prime minister's special envoy for international development goals, director general for policy and global programmes at the UK Department for International Development (DFID), founder and manager of Bazian, and director of studies at the British Institute of International and Comparative Law. Anderson was a Rhodes Scholar, and in 2016 was made a Companion of the Order of the Bath for his services to international development.

Amie Batson, formerly PATH

Amie Batson is currently the acting executive director for the Women Leaders in Global Health Initiative at Stanford University. Her 25-year career in global health includes positions with the World Health Organization (WHO), UNICEF, the World Bank, the US Agency for International Development (USAID), and PATH, where she most recently served as chief strategy officer and vice president of applied analytics and learning. Throughout her career in global health, she has been a leader in innovation and partnership. Her contributions to immunization and vaccine financing at the World Bank resulted in billions of dollars in new funding for global health; the establishment of Gavi; and the vaccination of millions of children against polio, pneumonia, diarrhea, and other vaccine-preventable causes of death. She has a BA in economics from the University of Virginia and an MBA from the Yale University School of Management.

Christa Cepuch, Médecins Sans Frontières (MSF)

Christa Cepuch has worked as a clinical pharmacist in MSF programs, and in medicines research and policy with HAI Africa. She joined the MSF Access Campaign in 2017 as pharmacist coordinator. Her current interests include medicines quality, pricing, and noncommunicable conditions.

Clinton de Souza, Imperial Logistics

Clinton de Souza joined Imperial Logistics in 1994 as a part of the South African transport business before moving to the healthcare division in 2010. He has held several senior management positions, including sales director, general manager for organizational development, and most recently director of the public health consulting unit. He has a 25-year career in supply chain strategy, business development, operations and deployment management throughout the African continent. He has an MBA from the Henley Management College, University of Reading (UK).

Todd Dickens, PATH

Todd Dickens provides technical assistance to public health procurement and supply agencies to help strengthen their capacity to plan for, procure, and supply quality assured medicines and medical equipment in a cost-effective manner.

James Droop, UK Department for International Development

James Droop is responsible for over £1 billion of DFID programming that supports the procurement and supply of essential health commodities. This includes DFID's funding of Unitaid, United Nations Population Fund (UNFPA) Supplies, and the Clinton Health Access Initiative (CHAI). He has been involved in the design, implementation and oversight of a range of large-scale innovative financing and market shaping interventions for antiretrovirals, vaccines, and contraceptives in global health, including the Advance Market Commitment for vaccines, the International Financing Facility for Immunisation, the UNFPA Bridge Funding Mechanism, MedAccess, and ATscale.

Akthem Fourati, UNICEF

Akthem Fourati, MD, is the chief of Medicines and Nutrition Centre in the UNICEF Supply Division. He leads a team responsible for the procurement of medicines and nutrition products in support of maternal and child health programs. He joined UNICEF in 2006 and has mainly been working on immunization, HIV/AIDS, and maternal and child health programs.

Sarah Garner, World Health Organization

Sarah Garner, PhD, BPharm, is the coordinator for the Innovation, Access and Use Team in the Essential Medicines and Health Products Department at the WHO. Sarah is a pharmacist specializing in innovation, with previous work focusing on development strategies and the interface between health technology assessment, regulation and payers. Sarah is an honorary professor at University College London and Manchester University. Her previous roles have included the associate director for science policy and research at the UK's National Institute for Health and Care Excellence and pharmacist lead for the UK Government's Special Advisory Committee on Antimicrobial Resistance.

Eduardo González-Pier, formerly Ministry of Health, Mexico and Center for Global Development

Eduardo González-Pier is a non-resident visiting fellow at the Center for Global Development (CGD). For more than 20 years, he has held senior positions and has promoted policy changes in the health and social security sectors in Mexico. Recently, he served as deputy minister of health; executive chairman of FUNSALUD, a leading health policy think tank; and chief financial officer of the Mexican Institute of Social Security. He has a Ph.D. in economics from the University of Chicago.

Martha Gyansa-Lutterodt, Ministry of Health, Government of Ghana

Martha Gyansa-Lutterodt is the director of technical coordination at the Ministry of Health Ghana and holds leadership positions in a wide range of pharmaceutical-related institutions in Ghana. She has coordinated several assessments of the pharmaceutical sector in Ghana with meaningful contributions to health sector dialogue. She is an expert member of United Nations (UN) Interagency Coordinating Group on Antimicrobial Resistance. Martha has a doctorate in pharmacy from Kwame Nkrumah University of Science and Technology, Ghana, and has studied at Leeds University and the Ghana Institute of Management and Public Administration School of Governance and Leadership.

Lisa A. Hare, US President's Malaria Initiative/USAID

Lisa Hare leads the US President's Malaria Initiative (PMI)/USAID global procurement and supply chain program, which procures and delivers malaria products and supports in-country supply chain strengthening. She was formerly the task order malaria director under the USAID | DELIVER PROJECT and has led efforts to tailor traditional supply chain approaches to malaria. Previously, she focused on building the capacity of individuals and institutions to sustain health program impact, including institutionalizing Egypt's National Control of Diarrheal Disease program, building nongovernmental organization sustainability, and expanding access to private health services in Ghana and Nigeria.

Beverly Lorraine Ho, Department of Health, The Philippines

Beverly Lorraine Ho is the chief of the Health Research Division of the Philippine Department of Health's Health Policy Development and Planning Bureau, where she designs innovative research grants and builds institutional capacity for policy research. She was recently designated Special Assistant to the Secretary of Health for Universal Health Coverage. She cofounded the Alliance for Improving Health Outcomes and is a fellow of the Equity Initiative, an IAMP Young Physician Leader, and a Fulbright scholar. She has an M.D. from the University of the Philippines and a M.P.H. in health policy and management from the Harvard T. H. Chan School of Public Health.

Christine Jackson, Crown Agents Ltd.

Christine Jackson has more than 30 years of procurement experience supporting national governments, the European Union (EU), World Bank, African Development Bank and other bilateral donors. She has been at Crown Agents since 1987, managing and implementing procurement programs and reforms in the health, power and water and sanitation sectors. She currently leads a team of experts to support procurement activities of the Ministry of Health, Ukraine. Since 2015, they have supplied medicines and medical devices for 16 programs from the central budget, including adult and child oncology, cardiovascular, HIV testing, blood donation testing, dialysis and substitution therapy.

Mariatou Tala Jallow, Global Fund to Fight AIDS, Tuberculosis and Malaria

Mariatou Tala Jallow is a senior manager in the Sourcing and Supply Chain Department of the Global Fund. She established the Global Fund Pooled Procurement Mechanism in 2009 and has successfully managed the mechanism to its current state. She has more than 25 years of experience in sourcing, procurement and supply management of health products, spanning across national, regional and global levels. She previously served as the chief pharmacist and registrar of the Medicines Board in the Ministry of Health of The

Gambia. She holds a Ph.D. in Pharmacy from the University of Oslo as well as an M.Sc. and an M.A. in pharmacy and health administration respectively.

Biljana Kozlovic, Ministry of Health, Serbia

Biljana Kozlovic leads the Second Serbia Health Project financed by the World Bank through the Ministry of Health. She is a medical doctor with more than 20 years of experience in management and consulting in the pharmaceutical industry. She has acted as an advisor to a number of organizations, including the World Bank, USAID, the Canadian International Development Agency, the Pharmaciens Sans Frontières Comité International, and ministries of finance and health in a number of countries in Europe and Central Asia.

Wesley Kreft, i+ solutions

Wesley Kreft is the global supply chain director for i+ solutions. He has more than 15 years of professional experience in procurement and supply chain management and specializes in project management, contracting, supplier selection, prequalification procedures, and vendor rating systems. He has worked with USAID, various country governments, and the Global Fund, and is highly knowledgeable in antiretrovirals, tuberculosis medicines, malaria treatments, medicines against infections and bed nets. Kreft is the co-chair of the ARV Procurement Working Group Consortium.

Melissa Malhame, Independent Advisor and formerly Gavi, the Vaccine Alliance

Melissa Malhame led the design and implementation of Gavi's market shaping efforts from 2013 until late 2017, where she ensured supply of vaccines, set long-term access strategies and led relationships with the vaccine industry. Before that, she had nearly 20 years of industry experience, where she led late-stage vaccine development, business and commercial development, marketing and sales. She currently consults independently with clients, including Gavi, the Bill & Melinda Gates Foundation, PATH, and vaccine manufacturers. She has an M.B.A. from the Johnson Graduate School of Management, Cornell University.

Susan Nazzaro, Bill & Melinda Gates Foundation

Susan Nazzaro is a senior program officer at the Bill & Melinda Gates Foundation. She sits in the Global Delivery Program where she leads the market dynamics strategy that focuses on ensuring sustainable and affordable access to essential health products including pharmaceuticals, diagnostics, vector control tools, and devices. She manages several initiatives aimed at creating and maintaining a healthy marketplace, including demand forecasting, pricing analyses, product costing and cost effectiveness, and procurement strategies. She is part of the team that manages the foundation's engagement with the Global Fund, and served as the senior advisor to the vice-chair of the board from 2010 to 2012. She also served on the Unitaid Board as the foundation's alternate board member from 2010 to 2016. An economist by training, she has an M.Sc. in Development Economics from the London School of Economics and a B.A. from Wellesley College.

Aurélia Nguyen, Gavi, the Vaccine Alliance

Aurélia Nguyen is the managing director for vaccines and sustainability at Gavi, the Vaccine Alliance. She leads the design of how Gavi's resources are turned into impactful and financially sustainable vaccine programs. Prior to joining Gavi in 2011, she held a variety of posts within GlaxoSmithKline (GSK), where she led the development of GSK's policies on access to medicines and vaccines in the developing world. She has also undertaken research for the WHO on generic medicines policies.

Ed Rose, formerly NHS England

Ed Rose was senior adviser to Simon Stevens, the chief executive of NHS England, from 2015 to 2018. Prior to this, he worked for the Cabinet Office Implementation Unit, advising on the prime minister's top health policy priorities. He has worked in a variety of front-line management roles within the NHS, including developing the United Kingdom's first Proton Beam Therapy center at University College London Hospitals and managing surgical specialties at Barts and the London NHS Trust. He has recently relocated to New Delhi,

working on a mix of healthcare projects across both the private and government sectors.

Rajeev Sadanandan, Government of Kerala, India

Rajeev Sadanandan works in managing and transforming public health systems at the state and federal level in India. In the State of Kerala, he has set up various high-performing disease control programs, redesigned the procurement and inventory management and the primary care programs, and set up the first digital health program in an Indian state. Previously, he headed the Indian National Social Health Insurance Programme Rashtriya Swasthya Bima Yojana at the state and federal level. Currently, he is a member of the editorial board of the WHO Global Report on Cancer.

Eugene Schneller, W. P. Carey School of Business, Arizona State University,

Eugene Schneller's consulting and research focus on healthcare policy, best practice adoption, supply chain purchasing strategy design and governance, human resource development, and supply chain integration. His principal interests include medical supply chain design and integration, physician preference management, medical human resources design, and group purchasing models. He is currently principal investigator for the Model Use of Innovative Medical Logistics Data Management Technologies and Industry Best Practices project with the Department of Defense. He holds a Ph.D. from New York University.

Andreas Seiter, The World Bank

Andreas Seiter is the global lead for the private sector in the World Bank's Health, Nutrition and Population Global Practice, where he works with World Bank teams and clients to strengthen private-sector participation in the pursuit of Universal Health Coverage. His areas of interest are access to medicines, quality of care, and digital health solutions that can disrupt traditional, low-performing service delivery models. Before joining the World Bank in 2004, he spent 18 years at Novartis in various positions in medical affairs, marketing, global policy and communications. He is a German national and was trained as a physician.

Paul Stannard, Population Services International

Paul Stannard has over 30 years' experience in public-sector procurement, supply chain, and project management in east, west, and southern Africa as well as in southeastern Europe. His specialties include project management of large multidisciplinary projects in Africa and Eastern Europe, international trade finance and practice, public-sector procurement procedures, multilateral and bilateral donor procurement procedures, and extensive procurement and project management experience in the procurement and supply of health sector products, most recently as director of procurement with Population Services International.

Netnapis Suchonwanich, Health Intervention and Technology Assessment Program, Thailand

Netnapis Suchonwanich is the former deputy secretary-general of National Health Security Office in Thailand and has played a key role in the Universal Coverage Scheme in Thailand since 2002. In 2009, she collaborated with the Government Pharmaceutical Organization to establish the Central Procurement with Vendor Managed Inventory Program for High-Cost Medicines. She has been nominated as member of the National Essential Drug Subcommittee and chairs the price negotiation working group for competitive medicines submitted to be essential medicines in Thailand. She has a B.Pharm. and a master's degree in information technology management.

Gregory Vistnes, William Davidson Institute, University of Michigan

Gregory Vistnes specializes in analyzing how changes in conduct or market structure affect competition and market outcomes in healthcare. He has held senior positions at the Antitrust Division (US Department of Justice) and the US Federal Trade Commission. He now

works with the William Davidson Institute to analyze competition and market dynamics in international healthcare markets and acts as a consultant to both private firms and government agencies on competition matters. He has a Ph.D. in economics from Stanford University and a B.A. in economics from the University of California at Berkeley.

Brenda Waning, Global Drug Facility

Brenda Waning is Chief of Stop TB Partnership's Global Drug Facility (GDF) at the United Nations Office for Project Services. Prior to leading GDF, she led Unitaid's technical team responsible for monitoring trends in HIV/AIDS, TB, and malaria markets; identifying strategic opportunities to intervene in these markets; and assessing the public health and market impact of Unitaid's interventions. Dr. Waning serves on many expert advisory groups, including the Market Dynamics Advisory Group of the Global Fund and the Access and Delivery Advisory Committee of the Medicines for Malaria Venture. She has a Ph.D. in pharmaceutical policy from Utrecht University and a master's degree in public health from Boston University.

Tommy Wilkinson, University of Cape Town, South Africa

Tommy Wilkinson, a health economist and clinical pharmacist, is a lecturer at the University of Cape Town, South Africa; health economics lead for the International Decision Support Initiative in sub-Saharan Africa; and a consultant to the Data and Decision Sciences Team, Health, Nutrition and Population Global Practice at the World Bank. He previously worked in the international team at National Institute for Health and Care Excellence in the United Kingdom and at New Zealand's Pharmaceutical Management Agency. He has a M.Sc. in health economics from the University of York and a B.Pharm. from the University of Otago.

APPENDIX B. RESEARCH PARTNERS, CONTRIBUTORS, AND INDIVIDUALS CONSULTED

Research Partners

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Other Individuals Consulted

In addition to the individuals listed above, several other individuals also offered comments, suggestions, and critiques over the course of this project. They are listed below but bear no responsibility for the content or recommendations of this report. Institutional affiliations are provided for identification purposes only. We apologize for any omissions.

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APPENDIX C.

SUMMARY OF WORKING GROUP INPUTS

Meetings and consultations	
Working Group Meetings	July 2017 (Washington); February 2018 (Zurich); July 2018 (London); November 2018 (Washington)
Pharmaceutical Industry Consultations	June 2017–January 2019
Technical Workshop on Applying Lessons from Economics to the Procurement of Global Health Commodities	April 2018 (Toulouse)
Private Roundtable with Private Sector Procurement Experts	May 2018 (Seattle)
Research partnerships	
Original data analysis on procurement arrangements and flows in a selection of low- and middle-income countries; breakdown of purchasing by product class, purchaser type, and branding; determinants of price variation; diffusion of innovation	AfRx Consulting
Landscaping of current global health procurement arrangements at the global level; assessment of global health procurers and benchmarking of performance; overview of supply-side market dynamics in key product categories	Clinton Health Access Initiative
Empirical research drawing on industrial organization economics to assess effects of different procurement mechanisms on drug prices; uses IQVIA data from public and private sectors in 7 lower-middle-income countries with diverse drug procurement systems	Toulouse School of Economics
Research on price transparency policies	Office of Health Economics
CGD working papers and policy papers	
Pooled Procurement of Drugs in Low and Middle Income Countries	Pierre Dubois, Yassine Lefouili, and Stéphane Straub
Projected Health Financing Transitions: Timeline and Magnitude	Rachel Silverman
The Future of Global Health Procurement: Issues around Price Transparency	Mikel Berdud, Kalipso Chalkidou, Emma Boswell Dean, Jimena Ferraro, Lou Garrison, Cassandra Nemzoff, and Adrian Towse
Improving Global Health Supply Chains through Traceability	Michael Pisa and Denise McCurdy
Imagining the Alternative Worlds of 2030: Policy Implications for the Future of Global Health Procurement	Janeen Madan Keller and William Savedoff
Impacts of Pharmaceutical Price Controls in India	Emma Boswell Dean
The Impact of Pooled Purchasing and Local Market Concentration on Pharmaceutical Prices in Low- and Middle-Income Countries: Comment on Dubois, Lefouili and Straub [forthcoming]	Mead Over
Other	
Annotated Bibliography of Relevant Literature	Roxanne Oroxom
Procurement Approaches and Policies in Low- and Middle-Income Countries	Roxanne Oroxom
Aggregating Demand for Pharmaceuticals Is Appealing in the Wake of Transition, but “Pooling” Is Not a Panacea	Cassandra Nemzoff, Kalipso Chalkidou, and Mead Over
Institutionalizing Auction-Based Procurement to Ensure Efficient and Sustainable Purchasing	Christina Aperjis and Lawrence Ausubel (Power Auctions)
4+7 Drug Procurement Reform in China	Xiao Yue (China National Health Development Research Center)

APPENDIX D.

NOTES ON DATA AND ANALYSES ON HEALTH PRODUCT MARKETS IN LOW- AND MIDDLE-INCOME COUNTRIES

Country income level classification	In Figures 2 and 6, countries are classified by the World Bank Atlas method according to gross national income (GNI)/capita in absolute dollar terms. Due to limitations in the number of countries with data, it was necessary to create some alternative income level definitions in certain figures (e.g., Figures 3 and 4).
Countries/states included	<ul style="list-style-type: none"> ■ Figure 1: Indian state of Kerala (Hospital, Retail), Philippines (Private), Senegal (Private), Serbia (Private, Public Hospital, Public Pharmacy), South Africa (Private, Public Tender, Public Direct), Tunisia (Public, Private), and Zambia (Public, Private). Respondents: Kerala, Senegal. Publicly available data: Philippines. Public sector respondent data from Kerala, Senegal, and publicly available data from the Philippines. ■ Figures 2 and 6: Countries with a population > 10 million are included. Syria, Somalia, North Korea, and other countries are excluded due to lack of available GNI and other macroeconomic data. <ul style="list-style-type: none"> □ Low-income countries (n=18): Afghanistan, Burkina Faso, Chad, Dem. Rep. of the Congo, Ethiopia, Guinea, Haiti, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Senegal, Uganda, Tanzania, Zimbabwe □ Lower-middle-income countries (n=25): Angola, Bangladesh, Bolivia, Cambodia, Cameroon, Côte d'Ivoire, Egypt, Ghana, Guatemala, India, Indonesia, Kenya, Morocco, Myanmar, Nigeria, Pakistan, Philippines, Sri Lanka, Sudan, Tunisia, Ukraine, Uzbekistan, Vietnam, Yemen, Zambia □ Upper-middle-income countries (n=7): Algeria, Dominican Rep., Ecuador, Iraq, Peru, South Africa, Thailand ■ Figure 3: Ghana, India (state of Kerala), the Philippines, Senegal, Serbia, South Africa (subset of 3 states: KwaZulu-Natal, North West, Eastern), Tunisia, and Zambia ■ Figure 4: Brazil, French West Africa (Benin, Burkina Faso, Cameroon, Chad, Côte d'Ivoire, Guinea, Niger, Mali, Senegal, and Togo), India (state of Kerala), Malaysia, Mexico, the Philippines, Romania, Serbia, South Africa (subset of 3 states: KwaZulu-Natal, North West, Eastern), Thailand, Tunisia, Turkey.
Product basket and health products included in analysis	<p>A data collection sheet was circulated to the procurement departments of 40 different countries. It requested procurement data (price, volume, manufacturer, price level) on a basket of 39 products, all taken from the 2017 WHO Essential Medicines List, that included both pharmaceuticals and medical devices. Few countries provided data on medical device procurement, whether through oversight, lack of procurement, or medical devices falling to a different department. We requested data from IQVIA on 29 pharmaceutical commodities for countries where both public- and private-sector data was available.</p> <p>The macro-level country analyses include pharmaceuticals, hospital consumables, diagnostic devices, long-lasting insecticide-treated nets, and biologics (including vaccines). The IQVIA data focused more on pharmaceuticals but did include hospital solutions, some diagnostic devices and reagents, biologics, and in some cases vaccines. However, most of the data on therapy area and pricing is based on pharmaceutical commodities.</p>
Health commodity procurement channels	<p>In Figures 2 and 6, the various sectors are defined as follows:</p> <p>Government sector includes:</p> <ul style="list-style-type: none"> ■ Central medical stores (CMS), ministries of health ■ Regional medical stores, state/group of hospitals ■ Social security programs <p>Donor/nongovernmental organization (NGO) sector includes:</p> <ul style="list-style-type: none"> ■ Integrated procurement within government systems ■ Multicountry NGO global tenders (e.g., Gavi, Pan-American Health Organization) <p>Private sector includes:</p> <ul style="list-style-type: none"> ■ Large hospitals or pharmacy chains (group purchasing organizations) ■ Private wholesalers and retailers ■ Private distributors (e.g., Eurapharma/Laborex across French West Africa) ■ Government hospitals, clinics, pharmacies purchasing directly from domestic private-sector distributors

(continued)

Timeframe	The country-level analyses and pricing analyses generally cover 2015. A lack of regularly available figures on public-private sector split, procurement, and market share of local manufacturers required extrapolation from historical data points. For export data (used in Figures 2 and 6), we used an average of 2014–2016 data to account for year-on-year fluctuations. The therapy area analysis (Figure 3) is based on the three most recent years of available data.
Price levels	Prices are at Customs Insurance Freight or Freight on Board price, procurement price or CMS price, which are comparable within a few percentage points. The IQVIA data for Kerala State, Philippines, Senegal, South Africa, and Serbia is taken at the distributor sale price and as such include distribution and mark-up prices (with the exception of the South African public depot data, which do not include distribution costs). We have removed an average mark-up in these cases to account for the distribution costs.
Volume units	For the analysis in Figures 3 and 4, the primary unit of measurement is standard units. A standard unit is defined by IQVIA as “determined by taking the number of counting units sold divided by the standard unit factor which is the smallest common dose of a product form.” For the pricing analysis, we used counting units, normalizing volumes to the lowest common unit (e.g., tablet, gram, milliliter, inhaler, vial).
Therapy areas	<p>In Figure 3, therapy area data is based entirely on IQVIA data, with the exception of Ghana, and on disease definitions built up from Anatomical Therapeutic Classification 3 level. The Anatomical Therapeutic Chemical (ATC) Classification System is used to classify active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological, and chemical properties. These ATC3 codes are aggregated into 55 therapy area definitions. The top 30 therapy areas by value in the public and private sectors are listed below. (The top 10 are included in Figure 3; the remaining areas listed here are part of the “other” category.)</p> <p>Lower-income grouping:</p> <p><i>Top 10:</i> HIV Antiretrovirals, Antibiotics, Cough & Cold, Pain & Analgesics, Diabetes, Malaria, Antihypertensives, Vitamins and Minerals, Contraceptives & Hormones, and Unknown</p> <p><i>Examples of areas in the “other” category:</i> Cough & Cold, GI (Gastrointestinal) Medication, Diagnostics, Arthritis & Immunosuppressants, Antiulcerants, Vaccines, Cardiac Stimulants and Protectors, Asthma/Chronic Obstructive Pulmonary Disease, Ophthalmic Medications, Nervous System Medications, Anemia & Red Blood Cell Synthesis, Lipid Regulators, Obstetrics and Gynecology, Topical Anti-infectives, Nutrition, Antiparasitics, Antiepileptics, Blood Thinners, Allergy, Musculoskeletal Products, and Cancer</p> <p>Middle-income grouping:</p> <p><i>Top 10:</i> Antihypertensives, Antibiotics, Diabetes, Cancer, Cough & Cold, Nervous System Medications, Arthritis & Immunosuppressants, Pain & Analgesics, Vitamins and Minerals, Asthma/Chronic Obstructive Pulmonary Disease</p> <p><i>Examples of areas in the “other” category:</i> Blood Thinners, Contraceptives & Hormones, Antiulcerants, GI Medication, Nutrition, Ophthalmic Medications, Lipid Regulators, Vaccines, Cardiac Stimulants and Protectors, Antiepileptics, HIV Antiretrovirals, Anemia & Red Blood Cell Synthesis, Topical Anti-infectives, Musculoskeletal products, Allergy, Hospital Solutions, Antidepressants and Mood Stabilizers, Obstetrics and Gynecology, and Nonreproductive Hormones</p>

Note: A full list of secondary sources used for the public-private split in Figures 2 and 6 and for estimation of local manufacturing capacity in Figure 5 are available in AfRx 2018.

Illustrative examples of data quirks and oddities

- In one country in our sample, the government's CMS did not record brand names in their systems. The regulator of this country collects this data. However, some volumes that go into the CMS are not declared to the regulator (mostly donor drugs, plus one major Indian manufacturer). This makes it impossible to get manufacturer details for a large segment of the market.
- In another country, the volumes of eye drops and other ophthalmic preparations was almost 20 percent of total national commodity consumption. This may have been caused by the misattribution of volume units. This was normalized out.
- In one country, there appears to be enough importation of deworming medicine to treat the entire region, not just a single country, so it is possible that it was the hub for a regional treatment program.
- The value of diuretic drugs jumped tenfold for one country between 2016 and 2017 from a very small base; it was still able to distort the perspective of the entire antihypertensives market for low-income countries.

APPENDIX E.

GLOSSARY OF SELECTED ECONOMICS TERMS

Average Cost: A producer's total cost of production divided by the total number of stocking units sold. A producer makes a profit if it sells a product at a price greater than its average cost.

Cartel: A (typically illegal) arrangement in which firms cooperate ("collude") to limit effective competition, splitting market volumes, setting prices above the levels that would appear in a truly competitive market, and conspiring to prevent the entry of competitors.

Commoditized Market: A market in which many different producers offer the same undifferentiated product, such that the buyer can see no distinction between the products of different producers.

Common Good: A good that is *nonexcludable* (i.e., cannot be denied to individual members of society) and *rivalrous* (i.e., an individual's use of the good diminishes the overall supply or prevents its use by another individual).

Complementarity: The degree to which one or more products is useful only with other products. Within a group of complementary products, a rise in the price of one reduces the demand for others.

Concentrated Market: A market dominated by one or a few large suppliers.

Consumer Surplus: The total net value consumers (as a group) derive from a market, defined as the difference between the price they would be willing to pay for the product and the cost of purchasing the product.

Credence Good: A product for which quality is never directly observable by consumers—either before or after purchase.

Experience Good: A product for which quality is directly observable by consumers—but only after purchase and use.

Externality: A side effect stemming from an individual's or firm's use or production of a product—either *positive* or *negative*—that is experienced by a third party or by the broader society, and therefore not incorporated into the purchase price of the product.

Fixed Cost: That portion of a supplier's cost of production that does not vary in the short run with the number of units produced. In the long run, no costs are fixed.

Herfindahl-Hirschman Index (HHI): A measure of market competitiveness (concentration) defined as the sum of each seller's squared market share. (Because the sum of market shares across all suppliers is one and each share is less than one and since squaring a proportion reduces its magnitude, the HHI cannot exceed 1.)

Imperfect Information: A state in which one or both parties to a transaction lack important information about a product, such as its underlying cost structure, quality, or value.

Industrial Organization: A wide-ranging subfield of economics dedicated to understanding markets and improving their ability to serve the public interest through legal, institutional, and regulatory levers.

Marginal Cost: A supplier's additional cost to produce one additional stocking unit (e.g., one additional bottle of pills).

Monopoly: A market with only a single producer.

Monopsony: A market with only a single purchaser.

Negotiating Power: Conditions that help a supplier or purchaser to secure favorable pricing and other contractual terms.

Objective Function: A weighted sum of the goals or interests that a supplier, consumer, or procurement agent is attempting to maximize. The weights represent the relative values of the various goals or interests.

Pooling: The degree to which a single purchaser or agent aggregates demand across multiple end users.

Present Bias: The human tendency to overvalue short-term gratification relative to long-term payoff—leading to underinvestment in long-run objectives.

Principal-Agent Problem: A situation that arises when an “agent”—an individual or organization acting on behalf of a “principal”—has interests or incentives that differ from those of the principal, and thus makes different choices than the principal would choose with the same information.

Producer Surplus: The total net value that producers (as a group) derive from a market, defined as the difference between the price they receive for a product and the price at which they would be willing to sell it.

Public Good: A good that is nonexcludable (i.e., cannot be denied to individual members of society) and non-rivalrous (i.e., one individual’s use of the good does not diminish the overall supply or prevent use by others).

Rents: Unearned income derived from control over resources, economic inefficiency/market failure, anti-competitive behavior, or corruption.

Search Good: A product for which consumers can directly observe quality before purchase.

Social Surplus: The total net benefit to consumers and producers from a market, defined as the sum of consumer and producer surplus.

Substitutability: The degree to which one or more products can be substituted for another. Within a group of substitute products, a rise in the price of one increases the demand for the others.

Tiered Pricing: A pricing strategy under which different consumers pay different prices for the same product, often related to ability or willingness to pay.

Variable Cost: That portion of a supplier’s cost of production that increases in the short run with the number of units produced. In the long run, all costs are variable.

Welfare Gain/Loss: The positive or negative change in overall social surplus created by a change in policy or market structure.

Willingness to Pay: A consumer’s maximum price point at which they will be willing to purchase a product or service.

APPENDIX F. DETAILED ECONOMIC ANALYSES

by Mead Over

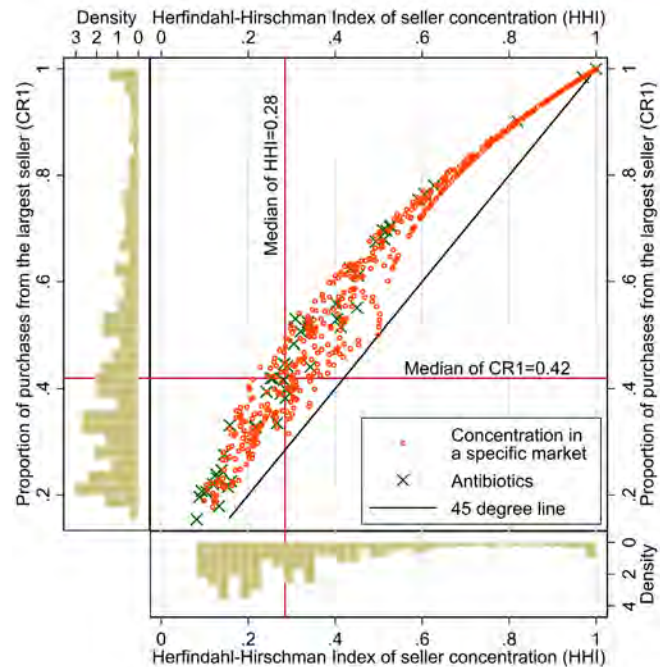
The Relationship Between Level of Competition and Price for Pharmaceutical Companies

The level of competition varies widely in local low- and middle-income country pharmaceutical markets. Appendix Figure F-1 shows this variation in a sample of 6,000 transactions for 40 representative drugs, occurring in seven countries over three years.¹⁶⁹ Each dot represents the level of competition in a single market measured in two different ways. The vertical axis plots the one-firm concentration ratio, which is defined as the proportion of all sales for a given molecule, country, year, and type of buyer from a single supplier. The horizontal axis plots the Herfindahl-Hirschman Index (HHI) for the same market, which is defined as the sum of the squared market shares of all sellers in that market. One of the therapeutic areas in the analysis, antibiotics, is highlighted to show that the same drug category is purchased under different competitive conditions in different countries. The figure shows that the two measures of concentration are almost identical for low and high values but diverge in the middle, where the HHI captures more information regarding less-dominant suppliers. The statistical analysis reported here uses the HHI to measure concentration.

Statistical analysis suggests that the level of competition is a statistically significant determinant of price paid, but the impact of competition on purchase price varies dramatically by type of purchaser. Appendix Table F-1 presents the estimated price change that would result from reducing market concentration—measured by the HHI—from the 75th to the 25th percentile of our

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Appendix Figure F-1.
Relationship between Two Measures of Seller Concentration in a Seven-Country Sample



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sample (0.44 to 0.17). An HHI of 0.44 describes a market in which the largest seller accounts for somewhere between 50 percent and 60 percent of all sales; an HHI of 0.17 describes a market in which less than 20 percent of sales are from the largest supplier.

For both types of public purchasers, reducing market domination by a single seller reduces prices by more than a third. However, the same reduction in market concentration does not appear to benefit private-sector purchasers.

Appendix Table F-1. Estimated Price Impact of a Reduction in Supplier Concentration from HHI 75th Percentile (0.44) to 25th Percentile (0.17) for Large Transactions

Type of buyer	Estimated % change in purchase price resulting from reduction in market concentration	p-value
Private	5.2%	0.6580
Public decentralized	-38.1%	0.0130
Public centralized	-34.6%	0.0170

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As discussed below, a possible explanation for the resistance of private-sector prices to improved market competition is the ability of pharmaceutical suppliers to differentiate their products slightly from one another, so that each supplier can retain market power and therefore charge higher prices in its own market niche. Public-sector buyers, being better informed regarding the substitutability of the versions of the same molecule by different suppliers, may be in a better position to disregard artificial product differentiation.

The Relationship Between Pooling and Price for Pharmaceuticals

An original economic analysis—using data from approximately 6,000 transactions for 40 off-patent molecules within seven countries, occurring over a three-year period—reveals the impact that pooled public purchasing can have on the price paid for pharmaceutical products.¹⁷⁰ Appendix Figure F-2 shows the estimated average unit price disaggregated by purchaser type (e.g., private, decentralized public, pooled public). The figure shows how the price paid for the same molecule varies across purchaser types and depending on the degree of local market concentration.

170. This annex is based on Mead Over's (2019) extension of the analysis in Dubois, Lefouilli and Straub (2019). Data copyright IQVIA AG and its affiliates. All rights reserved. 2017. Caveats as outlined in AFRx 2018.

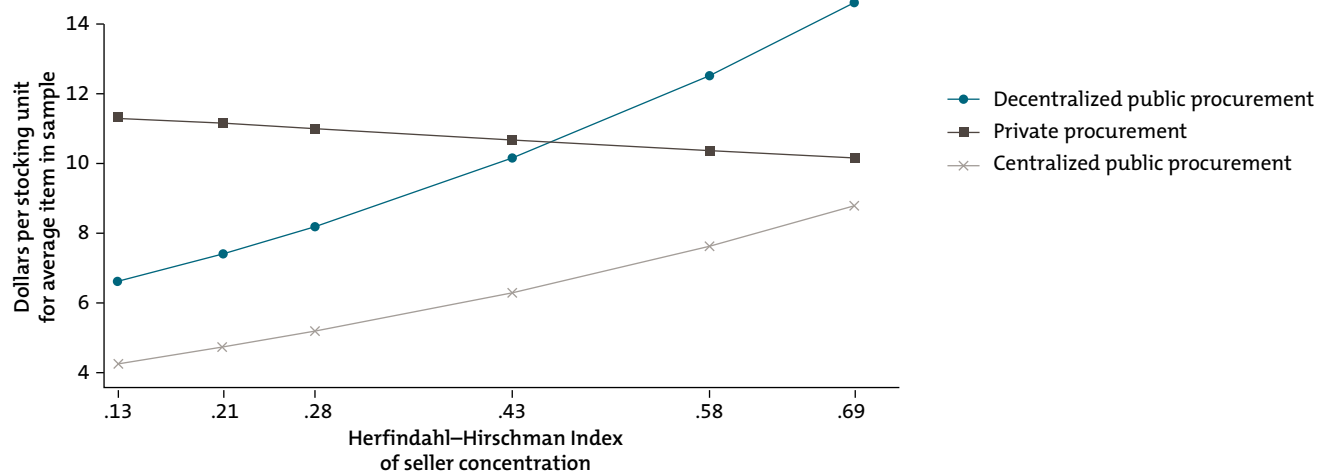
A theoretical advantage of pooled procurement is the hope that suppliers will give a volume discount. This statistical analysis therefore controls for transaction size, interacted with market concentration and type of procurement. The figure is constructed holding transaction size constant at the 75th percentile in the sample, which is for a purchase of 327,748 units. Most pharmaceutical expenditure occurs at large transaction sizes.

The horizontal axis measures the market concentration for a given molecule, country, and year combination. Market concentration is measured by the HHI, defined as the sum of the squared market shares for each molecule in a given country-year. An HHI equal to 1.0 indicates a single seller with 100 percent market share: a perfect monopoly. The median (or typical) value of the HHI in this sample is 0.28.

Compare the prices at low values of HHI, when there are many competing suppliers, to those at high HHI, with only a few suppliers. When there are enough suppliers to ensure competition (around HHI = 0.13), the price paid for an “average molecule” by a decentralized public-sector purchaser (e.g., a hospital) is almost twice as high as when the same molecule at the same transaction size is purchased by a pooled public procurement agent. The average price in the private sector is even higher. These price differences suggest that both types of public-sector purchasers are effectively deploying their purchasing power to negotiate substantially lower prices than are paid by the average private purchaser.

As the market concentration increases to the 75th percentile of HHI, 0.44, the prices paid by public-sector buyers rise; eventually, the public decentralized price exceeds prices in the private sector. At high concentration levels, the purchasing power of public-sector purchasers appears to be at least partially offset by the countervailing monopoly power of the sellers. Even though both types of public-sector purchasers lose ground to suppliers at higher concentration levels,

Appendix Figure F-2. Relationship between Market Concentration and Price Per Stocking Unit, by Type of Purchaser



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Notes: Transaction size is held constant at the 75th percentile to produce this figure. Tick marks on the horizontal axis range from the 10th percentile (0.13) to the 90th percentile (0.69).

these estimates suggest that public decentralized purchasers are more vulnerable to supplier market power than pooled purchasers. At higher levels of market concentration, the advantage of pooled over decentralized public procurement is accentuated, as shown by the divergence of the two lines with increasing HHI.

To summarize, the public sector appears to pay substantially less than the private sector when market concentration is low. Further, as detailed in Appendix Table F-2, public pooled procurement pays about half the price as public decentralized procurement for the same molecule at the same transaction size.

Appendix Table F-2. Estimated Percentage Reduction in the Price of Large Volume Transactions by Degree of Seller Concentration

HHI: Index of seller concentration (percentile)	Estimated percentage by which pooled purchase price is less than decentralized public price	p-value
0.13 (10th)	-43.7%	0.084
0.17 (25th)	-44.3%	0.046
0.28 (50th)	-45.7%	0.001
0.44 (75th)	-47.8%	< 0.0001
0.58 (85th)	-49.6%	0.01
0.69 (90th)	-51.0%	0.069

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The question arises: why does market concentration not seem to affect the prices paid by private-sector purchasers in the same way it does for the public sector? Regardless of market concentration, the private sector pays a consistently high price for large transactions. For small transaction sizes (not shown), the private sector actually pays *more* at low supplier concentrations in this sample than at high supplier concentrations. Product differentiation is one possible explanation; oligopolistically competitive producers may attempt to aim their branded products at various small niche markets, charging a high price in each. According to this theory, the average price of artificially differentiated products might be higher when there are more competing suppliers than when there are fewer.¹⁷¹

171. See Chen and Riordan 2006, 2008; and Gabaix, Laibson, and Li 2016.

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