



NOVEMBER 2017

PHARMACEUTICAL MANAGEMENT CONSIDERATIONS to EXPANDED COVERAGE OF ESSENTIAL HEALTH SERVICES and FINANCIAL PROTECTION PROGRAMS

By Kwesi Eghan and Megan Rauscher



USAID
FROM THE AMERICAN PEOPLE

SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

TABLE OF CONTENTS

I. Pharmaceutical Management in the Context of Expanded Coverage of Essential Health Services	1
Limited Recognition of the Role of Pharmaceuticals in UHC.....	1
II. Some Components of the Pharmaceutical System and Their Relation to UHC	4
III. Tailoring Pharmaceutical Management Efforts to Meet UHC Objectives—Practical Steps.....	13
Conclusion.....	16
References	17

Internal Reviewers and Contributors: Francis Aboagye-Nyame, Ruth Musila, Mohan Joshi, Emmanuel Nfor, and Michael Gabra

External Reviewers: Anthony Boni, Tobey Busch, Elizabeth Ludeman, and Robert Emrey

Target Audience: In-country policy makers, health insurance and financial protection program managers, development partners, and pharmaceutical system strengthening technical advisors

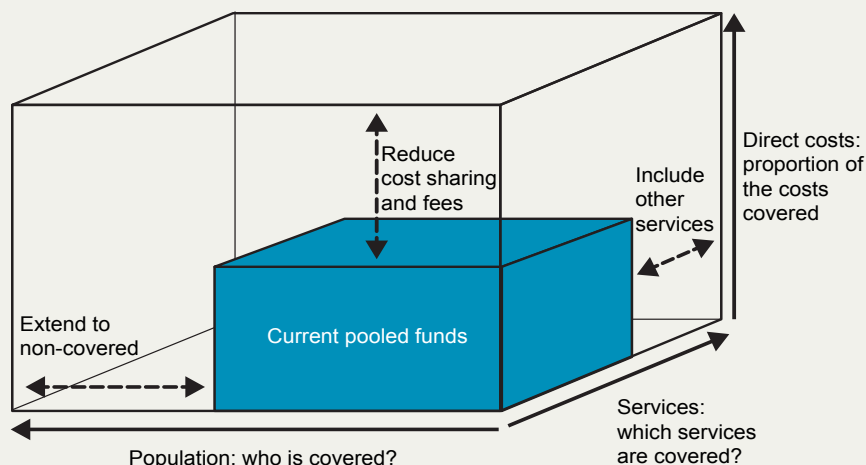
MAJOR TAKE AWAY POINTS

- As financial protection programs and the commitment to achieving the UN Sustainable Development Goals (SDGs) garner global support, the role of pharmaceutical systems has largely been missing from the discourse. The critical role that pharmaceutical products and other health technologies, including vaccines/biologics and diagnostics, and related pharmaceutical services will play in meeting Universal Health Coverage (UHC) objectives and ensuring the sustainability of a health system must be recognized.
- To ensure that people can access and use pharmaceuticals when and where they need them, a systems approach that builds on existing structures, including the private sector, to strengthening the pharmaceutical system must be adopted.
- Stronger pharmaceutical systems contribute to increased access to and appropriate use of quality-assured pharmaceutical products; related services; and improved health outcomes, including reducing and preventing maternal and child deaths, achieving an AIDS-free generation, and protecting communities from infectious diseases.
- Strategies that improve the selection, procurement, distribution, and appropriate use of pharmaceutical products by strengthening the lagging capacity of institutions or organizations (e.g., regulatory agencies, procurement agencies) and resources (e.g., human, financial, information) are critical to improving the efficiency and effectiveness of the pharmaceutical system and will aid in reducing the overall cost of health service delivery.
- Countries can choose the approach to adopt in providing financial access to medicines and protection for expanded health services to their populations. They should consider context-specific interventions that address challenges and sustainably strengthen their pharmaceutical systems to provide much-needed health services.
- Using appropriate metrics at the country level to track progress and ensure that strengthening efforts are effective will be essential for countries working toward extending coverage for essential health services and financial access to medicines.

To achieve the UN SDGs, countries can choose approaches that ensure that their populations can access health services at a cost that does not put people at risk of financial catastrophe.¹ Over the last decade, the global community has continued to push the SDGs and UHC agenda forward, including adopting specific objectives that countries can pursue as they work toward expanding health services to their

populations. Figure 1 illustrates the three primary UHC objectives defined by the World Health Organization (WHO) and the global community and introduced in the 2010 World Health Report. The objectives are to increase the availability of a wider range of high-quality health services to entire populations while reducing out-of-pocket expenses for health care.

FIGURE 1



Three dimensions to consider when moving toward UHC²

Source: WHO.

The UN adoption of the SDGs in 2015 signaled a strong commitment of member countries to the expanded access to essential health service agenda and definitively recognized the critical role of medicines in achieving UHC. The SDGs call for countries to “achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to *safe, effective, quality and affordable essential medicines and vaccines for all*”.³

This paper seeks to highlight the key functional areas of pharmaceutical management, the critical components of the pharmaceutical system, and the management considerations needed to facilitate

the attainment of UHC targets. It is organized into three sections that reflect its purpose. Section I aims to describe the critical role that pharmaceutical management and pharmaceutical systems strengthening play in realizing the objectives of all three UHC dimensions. Section II illustrates through selected cases some of the challenges low- and middle-income countries (LMICs) face in pharmaceutical management and how they have successfully addressed those challenges. Finally, Section III provides a practical guide for decision makers by explaining how to ensure that pharmaceutical systems are strengthened in a way that will enable countries to meet UHC objectives.

I. PHARMACEUTICAL MANAGEMENT IN THE CONTEXT OF EXPANDED COVERAGE OF ESSENTIAL HEALTH SERVICES

LIMITED RECOGNITION OF THE ROLE OF PHARMACEUTICALS IN UHC

Despite the expansion of financial protection programs, more than one billion people globally still lack access to basic health care, and out-of-pocket payments are very high in many countries where individuals and families are not adequately protected from financial risk.⁴ An estimated 150 million people suffer financial catastrophe each year and are often pushed below the poverty line by health care-related expenses.⁴ The severe consequences of catastrophic health expenses on individuals, communities, and countries have generated significant discussions on resource mobilization to increase health system financing, causing the UHC discourse to focus heavily on financing and revenue generation efforts. Because UHC focuses on ensuring the availability of high-quality health services for people when and where they need them, efforts to expand access to essential health services must go beyond revenue mobilization to include broader health and pharmaceutical systems strengthening approaches, such as improved governance, ensuring the right level of use of health resources, and quality of personnel. If not, the inherent inefficiencies will lead to a waste of mobilized resources.

Pharmaceutical products, other health technologies, and related services are vital to achieving UHC objectives because they are essential to high-quality health service delivery. Pharmaceuticals also contribute significantly to household health expenditures and account for 45% to 57% of out-of-pocket payments.^{6,7} Global spending on medicines is forecasted to reach USD 1.2 trillion in 2017 and account for up to 67% of total health expenditures in some countries.^{6,7} Medicines are also a primary driver of inefficiency in the health systems due to poor pharmaceutical management practices, such as faulty selection and quantification, poor procurement and distribution practices, underuse of generic medicines, use of substandard and counterfeit medicines, and inappropriate medicine use.⁸ Given the disproportionately high impact that pharmaceuticals

have on the cost and efficiency of health systems, improving pharmaceutical management practices and strengthening pharmaceutical systems to ensure the availability, affordability, and appropriate use of pharmaceutical products is imperative for achieving UHC. In addition, the substantial contributions that quality-assured pharmaceutical products make to health and well being cannot be underestimated and warrant an explicit focus on and investment in pharmaceutical management and systems strengthening in the efforts to expand health services coverage and financial protection.

Pharmaceutical Systems and Pharmaceutical Systems Strengthening

While pharmaceuticals and other health technologies are recognized as critical for health service delivery, often their role is reduced to an “input”. As such, the system components around this input, such as regulations and governance arrangements; human, financial, and information resources; and the processes that ensure availability of quality-assured pharmaceuticals and their appropriate use, are often neither considered nor given the needed attention.⁹ Ensuring equitable access to quality-assured medicines and their appropriate use is a core function of the health system. However, most health systems struggle to ensure access to and the appropriate and cost-effective use of medicines. Access refers to affordability, (cultural) acceptability, (geographical) accessibility, and availability.³⁸ More often than not, the approaches to address access to quality-assured medicines are frequently fragmented and vertical in nature and have a heavy emphasis on commodity supply, which results in short-lived progress toward increasing access to medicines.⁹ Rarely do vertical, supply-oriented approaches address weaknesses within the pharmaceutical system and they are not sustainable. In reality, efforts to increase access to medicines require the implementation of interventions in the pharmaceutical system that will impact all four dimensions of access.

The pharmaceutical system is a subset of the health system. By definition, a pharmaceutical system comprises all structures, people, resources, and processes and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality-assured pharmaceutical products and related services that promote appropriate and cost-effective use to improve health outcomes.¹⁰ Pharmaceutical systems strengthening is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes.¹⁰

The components of a pharmaceutical system are its core functions and structures; the supporting health system resources; and enabling policy, legal, and governance frameworks. Although pharmaceutical systems have several other components, for the purpose of this paper we adopt seven critical components for measuring pharmaceutical system strengthening identified by Hafner et al as a basis for discussing the role and key considerations for pharmaceutical management in achieving sustainable financial protection and expansion of essential health services. These critical components are 1) policy, laws, and governance; 2) financing; 3) innovation, research and development (R&D), manufacturing, and trade; 4) pharmaceutical products and services; 5) regulatory systems; 6) human resources; and 7) information management.

Why Does Pharmaceutical Management Matter for UHC?

Improved pharmaceutical management contributes to expanding essential health services and financial access to medicines by addressing inefficiencies caused by poorly executed selection, quantification, procurement, and distribution; inappropriate use; misallocated and improperly managed human and technical resources; fragmented financing; and weak information systems within the pharmaceutical system. Improved pharmaceutical management requires cost-effective strategies and actions to select and supply medicines and other health technologies; promote their

rational use; and ultimately enhance the availability of comprehensive, affordable, quality-assured medicines and health technologies to extend coverage of health services and help countries meet UHC objectives.

As countries work to increase the number of people with access to high-quality health services, the critical role that medicines and other health technologies play must be recognized and challenges associated with enhancing access to quality-assured medicines addressed. Without medicines and other health technologies, health care providers cannot provide high-quality health services to individuals and communities, and patients may come to health care facilities with the promise of improved health care coverage and financial protection only to find that pharmacies do not have the needed medicines. Given the importance of medicines in health care, pharmaceutical systems will need to be strengthened to guarantee access to medicines. Many countries suffer from weaknesses within their political, legal, and pharmaceutical regulatory sectors; institutional and human resource capacity; information systems; financing; and service delivery. If not addressed, these will hamper progress toward UHC. Policies and laws lay the foundation for equitable care for all and need to be strengthened to ensure that people are guaranteed access to quality-assured life-saving medicines and commodities. Many LMICs already struggle to ensure a reliable supply of quality-assured medicines, particularly to the underserved. Extending financial protection and essential health services to a larger population will place additional demands on already overburdened pharmaceutical systems. Expanding the package of health care services may require that new treatment options be made available to treat both existing diseases and conditions and newer and more complex diseases. This highlights the importance of strengthening medicine selection, procurement, and distribution systems at all levels.

The demand for newer medicines and health technologies will necessitate improved manufacturing practices and increased investment in R&D. Most LMICs face a two-fold challenge: first, to increase the availability of older and well-known medicines and second, to address the demand for newer, more

costly medicines and health technologies. The recent Lancet Commission on Essential Medicines Policies identified five areas that are “crucial to essential medicines policies: paying for a basket of essential medicines, making essential medicines affordable, assuring the quality and safety of medicines, promoting quality use of medicines, and developing new and missing medicines.”³⁷

LMICs can locally manufacture older, well-known but less complex pharmaceutical molecules to increase their availability, reduce dependence, and ensure a sustainable supply. LMICs can then work with the global community to negotiate with international R&D-based manufacturers to increase access to newer medicines and health technologies at reasonable prices to their populations. Overall, decision makers need to continue balancing the increasing demand for more complex treatments with the overall cost to their health system to ensure that their efforts to expand essential health coverage are sustainable in the long term.

Currently, medicines account for a very high proportion of out-of-pocket medical expenses and comprise a significant proportion of overall health system expenditures.^{6,7} Given their high cost to individuals and the impact that this cost can have on

the health system, countries need to explicitly address the issues around pharmaceutical financing under UHC. Countries will again be challenged on two fronts: first, to increase domestic revenue and fully integrate the financial requirements on the supply (system) side and second, to address the demand (patient) side to ensure that medicines do not increase individual out-of-pocket expenses. Health insurance is one of the primary financing mechanisms that countries use to reduce catastrophic out-of-pocket health expenditures. Insurance schemes will need to include robust medicine benefits programs to manage medicines efficiently and effectively. However, in many LMICs, the systems to support medicine benefits are either emerging, fragmented, or nonexistent. Most LMIC spending on medicines is not cost effective because nearly half of all medicines are inappropriately prescribed, dispensed, or sold and patients do not adhere to the guidelines for approximately 50% of the medicines they receive.¹¹ Reducing waste across all components of the pharmaceutical system while increasing the mobilization of funding for medicines is critical to sustaining expanded access to health care services and ensuring the sustainability of financial protection programs.

II. SOME COMPONENTS OF THE PHARMACEUTICAL SYSTEM AND THEIR RELATION TO UHC

Policy, Laws, and Governance Practices

Key message: *Strengthening pharmaceutical policies, laws, and governance arrangements and practices is essential because they provide the framework, structure, and mechanisms for selection, procurement, distribution, and use of pharmaceutical products and for organizing, financing, and regulating the pharmaceutical subsystem. In the context of expanding essential health coverage and enhancing financial protection, it is important to update pharmaceutical laws, policies, and governance practices to support and align them with new financial protection policies to lay a strong foundation for UHC implementation.*

Each country travels a unique path toward UHC, and this path is often guided by its own history, culture, political environment, demography, epidemiology, existing labor, and health and financing structures. However, it is important to ensure that the appropriate legal, policy, and governance arrangements are in place so that everyone in society can access health services and quality-assured medicines at a cost that does not put people at risk of financial catastrophe. It is also important to establish, update, and implement policies and legislation that support a patient-centered approach, accountability, and transparency; reinforce organizational decision making and coordination among stakeholders; and improve authority and oversight to ensure access to quality-assured pharmaceuticals and other health technologies.

As policy makers develop new laws, policies, and governance structures to support UHC, misalignment between old and new laws and policies must be resolved. For example, health insurance guidelines, which are often selected as a key financing strategy to help fund expanded health care coverage and reduce out-of-pocket payments, may recommend that health facilities at all levels undertake therapeutic substitution of medicines.¹² However, existing pharmaceutical laws and policies may prohibit therapeutic substitutions and place restrictions on the types of facilities or personnel that can dispense certain medicines and provide pharmaceutical services. Policy makers will need to carefully examine existing pharmaceutical policies

and laws to ensure consistency with UHC objectives to promote efficiency and cost savings and to expand access to medicines and related pharmaceutical services to a wider group of people.

Financing

Key Message: *Efficiently managing financial resources for pharmaceuticals and other health technologies and related services is a key step toward sustaining UHC efforts. It is important for countries to effectively estimate the financial implication of the medicine benefit component of expanded essential health services coverage and align the allocation and use for essential medicines appropriately. Strengthening pharmaceutical divisions and ministries of health to make appropriate use of recurrent budgets for medicines can make a significant difference in increasing coverage, medicines, and services provided. It may be useful to engage civil society to monitor agreed-upon medicine prices.*

Countries that are expanding essential health coverage to their populations need to identify a prioritized group of medicines to procure or reimburse at fair prices. Pharmaceutical financing efforts must include mobilizing both domestic and international resources to ensure efficient resource allocation for and use of pharmaceutical products and services. Countries often fail to consider the funding implications for the group of medicines they seek to cover and the funds needed to support the management and regulatory functions needed to operate and provide oversight to the pharmaceutical system. A mix of cost sharing and risk pooling strategies is available to reduce financial access to medicines. Countries must build performance standards into provider contracting, regardless of whether they adopt provider-payer splits or follow traditional financing models, and monitor the cost and quality of pharmaceutical services by introducing robust systems to track spending and reduce waste within the pharmaceutical system. In the case of provider-payer splits, the type of mechanism for paying providers can incentivize positive or negative behaviors for dispensing high-priced pharmaceuticals, which may lead to high out-of-pocket payments or threaten the sustainability of expanded health service coverage.

Efforts to prevent catastrophic health care spending must address the high cost of medicines and out-of-pocket payments by addressing medicine pricing issues and financial barriers to access at the system and individual levels.

Existing tools and approaches, including the use of health technology assessments in decision making and priority setting processes, can help ensure the inclusion of safe, efficacious, cost-effective, and quality-assured medicines as part of benefit plans. There are a number of pricing and purchasing options that LMICs can use to help drive down the cost of medicines. Pricing strategies may target manufacturer, wholesale, retail, or reimbursement prices.²³ Countries may engage and capacitate civil society to act as a watchdog for monitoring prices and promoting transparency of procurement information, particularly in the public sector. Small seed grants will be considered to support groups with the necessary equipment to facilitate their role, including gathering data and conducting operational research to inform or evaluate pricing policy reforms. A number of countries,

including Angola, Botswana, Democratic Republic of the Congo (DRC), and South Africa, are using pooled procurement mechanisms to bring down the price of medicines.²³ It is important for policy makers to consider the various options available to them when deciding how to purchase medicines and related pharmaceutical services to balance the needs of patients and the overall cost to the health system.

Finally, countries need to introduce robust systems to track spending and reduce waste within the pharmaceutical system. There is a void in the UHC conversation on the importance of improving pharmaceutical dispensing and use. Improving dispensing practices and use of medicines has the potential to improve the use of resources, positively impact clinical care provision, and improve patient outcomes, as shown in a case study from Jordan (box 1).

Strategies similar to those employed in Jordan can be used to generate cost savings, which can in turn be reallocated or reinvested in other areas of the health system.

BOX 1

Improving Appropriate Use of Antibiotic Prophylaxis Decreases the Cost of Medicines in Jordan¹⁴

Inappropriate medicine use can have harmful effects on the health of individuals, increase antimicrobial resistance, and raise the cost of health care provision. In Jordan, approximately one-third to one-half of all antibiotics used in hospitals are for surgical prophylaxis; however, 30% to 90% of this use is inappropriate. To address this problem, the US Agency for International Development (USAID)-funded Strengthening Pharmaceutical Systems (SPS) Program and its follow-on, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, provided technical assistance to help strengthen practices regarding antibiotic prophylaxis for cesarean sections at three Ministry of Health (MOH) hospitals in Jordan. A 2010 study indicated that local practices at the participating hospitals did not match the current best international evidence and recommendations in terms of the choice of antibiotic and dose, the timing of administration, or the duration of prophylaxis. Using the latest international evidence on antibiotic prophylaxis for women undergoing cesarean sections, teams at each hospital developed customized antibiotic prophylaxis protocols and procedures and established ongoing quality control plans.

Positive changes were observed across all three hospitals, and each now provides better pharmaceutical care for women undergoing cesarean sections. Prior to the program intervention, no women undergoing cesarean sections received an antibiotic prophylaxis dose prior to incision, whereas after the program, the majority of women received the first dose at the appropriate time. In addition, all three hospitals demonstrated a decrease in both the number of doses of antibiotic prophylaxis given and the prescribing of other unnecessary antibiotics. The pilot study also showed major cost savings in one month across all three hospitals of roughly 10,905 Jordanian Dinars (JD) (approximately USD 15,397). If scaled nationally, the newly developed antibiotic prophylaxis protocols and procedures have the potential to save significant funds. In its Annual Statistics Book of 2010, Jordan's MOH reported 17,823 cases of cesarean section in its hospitals. If the new protocols with their cost reduction potential were to be extrapolated to these cases, an estimated savings of JD 84,396 (approximately USD 119,160) per month would be realized.

Innovation, Research and Development, Manufacturing, and Trade

Key Message: *More people will have access to health care services as UHC efforts expand and reduce out-of-pocket payments. As population coverage and access expand, the demand for new, sometimes rare, and often untreated diseases and conditions will increase. Countries will need to employ innovative strategies to improve the availability of older medicines, incentivize R&D, and bring down the overall cost of new medicines. Taking advantage of international trade agreements will facilitate technology transfer and help build local manufacturing capacity for older medicines. These efforts will increase the range of treatments available for all diseases and conditions and support UHC objectives.*

According to the SDGs, UHC efforts must “support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries”.³ In addition to targeting diseases and conditions that primarily affect those living in LMICs, R&D and innovation will play a critical role in improving access to treatment for rare and untreated diseases and pharmaceutical product formulations, such as those for children under the age of five. While the positive benefits of improved

treatments cannot be denied, countries will have to balance these benefits with high costs.²⁰ Bringing a new medicine or health technology to market is expensive—estimated at up to USD 2.8 billion—and as a result, the pharmaceutical industry in high-income countries has traditionally driven R&D efforts.^{15,16} However, revenue requirements to pay off upfront R&D costs and obligations to shareholders provide minimal R&D incentives for diseases and conditions that primarily affect people living in low-income settings.¹⁷

Some LMICs have taken advantage of flexibilities granted by TRIPS.¹⁸ Brazil and Thailand both issued compulsory licenses to allow the domestic manufacturing of AIDS treatments currently under patent protection, while other countries, including Zambia and Mozambique, used the possibility of compulsory licensing to negotiate medicine prices with pharmaceutical companies.¹⁸ Several LMICs, including Rwanda, Ghana, and Uganda, have started to implement policies and laws to incentivize the local production of and good manufacturing practices for much-needed generics as part of their efforts toward UHC. Box 2 details Ethiopia’s strategy for increasing local pharmaceutical manufacturing as the country looks to its own domestic pharmaceutical industry to increase access to medicines and generate domestic revenue.

BOX 2

Incentivizing Local Manufacturing of Pharmaceutical Products in Ethiopia

Steady economic growth, improvements in the delivery of health care services, and increased domestic revenue generation through the introduction of social health and community-based insurance coverage in Ethiopia has led to a growing demand for medicines and pharmaceutical products. The Ethiopian Industrial Development Strategy (2013–2025) is designed to mobilize resources and allocate them to the manufacturing sector. With the primary objective of improving access to essential medicines through quality local production, the strategy calls for the creation of incentives to move companies along the pharmaceutical value chain.¹⁹ It also calls for upgrading and promoting the pharmaceutical sector and includes technology transfer and technology diffusion among its objectives.

Specific efforts to increase local production under this strategy include providing zero-interest loans for up to 70% of new investments and up to 60% for upgrading projects during the first five years and significantly reducing the amount of upfront capital needed.¹⁹ In addition, the Government of Ethiopia will grant customs and duty exemptions of up to 15% of the total value of imported investment capital goods, including manufacturing machinery, equipment, construction materials, and spare parts.¹⁹ The overall strategy aims to promote local pharmaceutical manufacturing, increase the availability of medicines for prioritized diseases, and create an environment conducive to the growth of the pharmaceutical industry as a whole.¹⁹

As countries expand domestic manufacturing, technological challenges must be addressed. Safety and quality must be prioritized, and countries need to build local manufacturing capacity and strong surveillance systems to ensure that only high-quality, safe, and efficacious medicines are produced. One strategy that countries have used is collaborative partnerships among governments and private companies.²⁰ For example, an Indian generic manufacturer and a Ugandan company undertook a joint venture to establish a manufacturing plant to produce antiretrovirals in Uganda.²⁰ Under this venture, Indian experts provided training to local staff.²⁰ The plant has received certification from WHO for compliance with good manufacturing practices and has obtained WHO prequalification for two products.²⁰ Other opportunities include utilizing innovative patent partnership models to leverage existing intellectual property. For example, UNITAID founded the Medicines Patent Pool (MPP) to reduce the price of HIV and TB medicines and increase R&D for better treatment. The MPP encourages patent holders, including governments, pharmaceutical companies, researchers, and universities, to voluntarily offer their related intellectual property to the pool so that it can be licensed out royalty free to companies who want to produce or develop treatments for use in LMICs.²¹

Innovation, R&D, manufacturing, and trade comprise the entry points for medicines and health technologies into the system, and countries have the option to leverage existing R&D efforts and build local pharmaceutical manufacturing capacity to help improve access to medicines and health technologies. Efforts to incentivize R&D efforts globally and develop local production capacity will be critical to achieving the UHC objective of expanding access to treatment for those living in LMICs.

Selection, Procurement, and Distribution of Pharmaceutical Products and Related Services

Key Message: *Pharmaceutical products and services are at the center of the pharmaceutical system and are enabled through the selection, procurement, distribution, and appropriate use of quality-assured pharmaceutical products and related services. As countries expand their package of health care services to more people, improving the dispensing and use of medicines offers an additional point of intervention*

that will help improve health outcomes and reduce wastage within the health system.

The processes adopted and types of medicines selected have significant influence on the quality and cost of pharmaceutical services and therefore represent a key area where strategic interventions can help promote access to high-quality health care services while reducing out-of-pocket payments. However, with the removal of financial barriers to access through the introduction and/or expansion of risk pooling schemes, a reduction in the proportion of costs paid for medicines may lead to increased demand for and use of medicines. To address these potential increases in demand, the processes for selection, procurement, distribution, and use of medicines will need to be more efficient, robust, and evidence based. In addition, policies and interventions that encourage the appropriate use of medicines will need to be promoted to ensure safety and effectiveness within the health system as a whole.

The process of selecting medicines often begins with the definition of a list of common diseases that are treated at each level of the health system.⁸ This list is the foundation for selecting the medicines to be included in national essential medicines lists, formularies, and standard treatment guidelines.⁸ When sound clinical evidence is paired with information on the cost of medicines and other health technologies, the most cost-effective medicines are selected. **Box 3** illustrates how improvements in selection processes can save money for the entire health system while still guaranteeing high-quality, efficacious medicines for consumers.

It is important that evidenced-based product selection is accompanied by transparent procurement practices, efficient distribution systems, and appropriate use of medicines to ensure that people can access quality-assured pharmaceutical products at an affordable cost when and where they need them.

As health care coverage under UHC is expanded, improving the dispensing and use of medicines offers an additional point of intervention that will help improve health outcomes and reduce wastage within the health system. Improving dispensing practices among providers will be critical under UHC, and countries need

BOX 3

Improving the Medicine Selection Process in South Africa Promotes Cost Savings²²

In South Africa, pharmaceuticals comprise the second-largest spending category of the national health budget, which highlights the importance of containing pharmaceutical costs to ensure the overall sustainability of the health system. Delays in reviews of essential medicines lists in three South African provinces led to uninhibited adoptions of new medicines in provincial and hospital medicine formularies, resulted in the misalignment of essential medicines lists and national procurement contracts, and increased medicines expenditures.

In a collaborative initiative, South African provincial health authorities and USAID's SIAPS program worked with the provincial Pharmacy and Therapeutics Committees to conduct two analyses to inform a review of the essential medicines list selection process. The first was an ABC analysis, which typically aims to examine the annual medicine consumption data and develop a ranking of those medicines into tiered categories based on percentages of annual expenditure. The second analysis was a medicine utilization evaluation, which is a review of prescribing, dispensing, and using medicines at the provincial level in South Africa. As a result of these analyses, recommendations were made to use enalapril as the preferred ACE inhibitor and amlodipine as the preferred calcium channel blocker. Based on their prices, a reduction in the number of medicines, and the overall incidence of hypertension, a cost saving of USD 646,000 and USD 955,000 respectively for every 100,000 hypertensive patients is anticipated

to invest in quality improvement measures that target job performance among pharmaceutical professionals. Different capacity-building interventions, such as job-specific participatory and interactive learning methods, have been employed successfully in LMICs to improve dispenser performance.²⁴ The success of ongoing education as a quality improvement strategy highlights the need for building local capacity within training and university settings to develop and deliver high-quality pharmaceutical training.²⁴ Changing prescribing and dispensing behaviors to increase adherence to clinical guidelines and improve patient outcomes will require long-term investment in local education and capacity development, but without this investment, inappropriate prescribing and dispensing will continue to threaten patient health and waste already scarce resources.

Regulatory Systems

Key Message: *As countries expand health care services, population coverage, and financial protection, pharmaceutical regulatory systems will play an important role in ensuring the delivery of quality-assured medicines and related services. Weak regulatory systems put people at risk of receiving counterfeit or substandard medicines. Countries will need to strengthen registration and licensing practices while ensuring that robust postmarket surveillance systems are put in place to guarantee patient safety as UHC programs increase access to pharmaceuticals and related services.*

While medicines can contribute substantively to health outcomes, poor quality and substandard medicines threaten the overall health of individuals, families, and communities. In addition, counterfeit medicines are a significant risk in LMICs, where they are estimated to represent between 10% and 30% of medicines sales.²⁵ Poor quality, substandard, and counterfeit medicines waste resources and hinder the sustainability of the health system as a whole, which highlights the importance of strengthening regulatory and surveillance systems within the pharmaceutical sector.^{5,26}

The pharmaceutical sector must be regulated at all stages of the value chain. Manufacturing processes for medical products must ensure that products are safe and effective for patient consumption, and safety and quality must be further guaranteed throughout the entire distribution and supply chain process. For example, licensed and regulated distributors, wholesalers, and retailers must comply with good storage and distribution practices and should be inspected by appropriate national regulatory authorities to help ensure quality.²⁷ In addition, regulatory policies, procedures, and sanctions should be made public and applied consistently to supply chain stakeholders.²⁷ Box 4 describes how DRC introduced medicine registration and its influence on improved transparency and patient safety.

BOX 4

Strengthening Regulatory Systems in DRC to Improve Access to Safe, Effective, and Quality Medicines²⁸

Chronic underfunding of the health sector coupled with long-term civil unrest in DRC has resulted in insufficient regulatory capacity to effectively manage the complexity of registering and approving new medicines.

Weakeness in the governance of the registration process were also noted. In partnership with SIAPS and its predecessor program, SPS, the Directorate of Pharmacy and Medicines (DPM) (part of the MOH) carried out a number of activities to strengthen the pharmaceutical regulatory system in DRC. In 2010, the DPM developed guidelines and standard operating procedures for product registration and trained staff to implement them. These efforts contributed to the establishment of the first national medicine registration committee. With SIAPS support, the DPM has continued to improve these standard operating procedures to ensure their alignment with international guidance and good governance recommendations.

In 2012, the first list of registered medicines in DRC was published and disseminated with SIAPS support. The list was used to improve the regulation of medicines. For example, customs officers used it to check for unregistered medicines at border posts, and provincial pharmacists used it to track and confiscate unregistered products during inspections of pharmaceutical premises. With support from SPS and SIAPS, the number of registered medicines increased from 200 in 2010 to more than 3,000 in 2014; 72% of the medicines included on DRC's essential medicines list currently have at least one product registered, up from 44% in 2011. The MOH can now systematically evaluate and approve medicines for registration in a timely manner using processes that are more transparent and less vulnerable to corruption. These efforts have created a stronger product registration system that helps ensure that medicines in the country are safe, effective, and of acceptable quality.

Registration systems, such as those introduced in DRC, help protect populations by providing patients with high-quality, efficacious medicines and health technologies. It is also important to ensure that strong surveillance systems are in place to protect patients after licensing and approval occurs. Pharmacovigilance (PV) aims to detect, assess,

understand, and prevent adverse effects related to medicines and health technologies, and this type of rapid reporting of adverse effects contributes to improved medicine use.²⁷ Box 5 describes how actions to strengthen Bangladesh's PV surveillance system improved reporting of adverse effects of medicines.

BOX 5

Strengthening Bangladesh's National Pharmacovigilance System

In Bangladesh, more than 97% of the domestic demand for medicines is met by Bangladeshi pharmaceutical companies, and approximately 30 companies export a significant quantity of medicinal products to more than 113 countries. It is fairly easy for pharmaceutical companies in Bangladesh to obtain marketing authorization for the sale of medicines in the country. However, it is becoming increasingly crucial for the Directorate General of Drug Administration (DGDA) to strengthen regulations and surveillance systems to ensure that medicines and commodities provided to patients and the public are safe, effective, and meet approved quality standards.

WHO defines PV as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse reactions to medicines.³⁵ The ultimate goal of PV is to improve the safe and rational use of medicines, thereby improving patient care and public health.³⁵ Although Bangladesh initiated PV activities in 1999, the lack of legislation and strategic leadership, limited motivation, and uncoordinated communication among DGDA staff stalled progress, and as a result, many adverse drug reactions were not reported at all or were reported incorrectly.

In 2012, the DGDA and SIAPS partnered to revive the national PV program and establish an Adverse Drug Reaction Monitoring (ADRM) cell. This cell is responsible for collecting adverse event reports from health care facilities, hospitals, and pharmaceutical companies; maintaining and analyzing adverse event databases; and sharing adverse event information with WHO's International Drug Monitoring Center. As a result of the revival of the PV program and the establishment of the ADRM cell, the number of adverse drug event reports increased four-fold, and all public medicine college hospitals, local manufacturing companies, and pharmaceutical importers received an executive order from the DGDA to monitor the adverse drug events of the products.

Finally, in addition to protecting patients against substandard medical products, regulatory systems play an important role in ensuring that people with the right training and qualifications are dispensing medicines at licensed pharmacies and private medicine outlets. Pairing pre- and post-qualifications for professionals who dispense medicines with appropriate regulations and sanctions against those who are not licensed to dispense will help protect patients and ensure that high-quality pharmaceutical services are delivered.

Human Resources

Key Message: *As coverage of health care services is expanded under UHC initiatives, the demand for pharmaceuticals and related services will also expand as more people are able to access health care services. To meet this increase in demand, countries will need to increase the number of pharmaceutical service providers through robust training and contextually relevant educational programs to cultivate new skillsets and build a pipeline of qualified pharmaceutical personnel. In addition, countries can adopt task-shifting strategies to support UHC implementation. Innovative strategies will need to be employed to better leverage existing human resources and build the capacity of new pharmaceutical service professionals.*

As countries implement UHC initiatives and expand health service coverage, the critical role of pharmaceutical service professionals and providers and the importance of their geographic distribution cannot be underestimated. In many LMICs, pharmaceutical system improvements are already constrained by insufficient personnel, imbalances in their distribution, and a limited skill mix of personnel to respond to current population needs.^{29,30} To meet the

growing demand for pharmaceutical services under UHC, efforts to strengthen human resource capacity and ensure the availability of adequate numbers of appropriately trained staff to manage the selection, procurement, supply, of products and supply of products and delivery of pharmaceutical services.

Efforts to address growing pharmaceutical service needs will require competency-based trainings for all roles and at all levels within the pharmaceutical workforce, from researchers to facility-level pharmacists and dispensing technicians, to ensure that pharmaceutical cadres deliver safe, high-quality, and efficacious medicines and other health technologies.³⁰ Countries will need to increase local capacity to deliver pharmaceutical preservice and in-service training programs to build a pipeline of qualified pharmaceutical personnel and work with regulatory bodies to ensure that staff adhere to best practices and standard treatment guidelines. Continual education and on-the-job training have been shown to be effective in improving the quality of care provision in the health sector, which highlights the importance of employing diverse capacity building strategies that meet local needs.²⁴

Countries may also need to apply other strategies such as task shifting, which has been used to help increase access to medicines and pharmaceutical services. [Box 6](#) describes how the accredited drug dispensing outlet (ADDO) model—an innovative public-private sector partnership—used task-shifting strategies to increase access to medicines in rural Tanzania. Similar strategies to improve access could be used in other locations to help countries expand health care coverage under UHC.

BOX 6

Accredited Drug Sellers in Tanzania Increase the Availability of and Access to Life-saving Medicines

In low-resource settings, people often seek care and purchase medicines from small retail shops. In some rural settings, up to 80% of people seek care at these shops because there are very few licensed pharmacies or pharmacists outside of urban areas.^{31,32} To address this, the Tanzanian government piloted the ADDO program in 2003 and later adopted it as a policy to bring it to scale nationally.¹³ The ADDO program is a public-private partnership that aims to build the capacity of owners, dispensers, and institutions that own or work in retail drug shops.¹³ The program uses a combination of extensive training, business incentives, and regulatory enforcement to increase community-level demand for affordable, high-quality, life-saving medicines in Tanzania.¹³

Early evaluations demonstrated that the ADDO program was improving accessibility to and availability of medicines to Tanzanian communities. For example, the program increased the availability of high-quality medicines, particularly in peri-urban and rural locations, and improved dispensing practices.³³ The availability of unauthorized medicines decreased significantly, which contributed to efforts to decrease antimicrobial resistance.³³ Overall, the ADDO program has been shown to be scalable, sustainable, and transferable as it has been rolled out nationally in Uganda and adapted and implemented in Liberia.¹³

While much of the conversation around pharmaceutical human resource requirements has centered on those who provide services to patients, progress toward UHC will require diverse, increasingly complex skill sets. For example, many countries lack the skilled personnel needed to regulate and monitor the quality of medicines, manufacture medicines, and design and manage complex medicines benefits management programs within their health systems.¹² As countries introduce innovative financing schemes to support the expanded coverage of health services skills in technical areas such as pharmacoeconomics, health technology assessment actuarial analyses will be needed to determine which new medicines will be included and how new medicine benefits packages will be financed, developed, revised, and expanded.¹² A new push for domestic manufacturing will require staff with skills in good manufacturing practices and experience in quality control and pharmacovigilance. Overall, countries will need to adapt and strengthen their pharmaceutical human resource management systems to adapt to the changing HR needs under UHC.

Information

Key Message: *As countries work to expand health care services under UHC, pharmaceutical and logistics systems that provide relevant, quality, and timely data for decision making will be required. In particular, supply chain systems will need to be responsive to increased demand and shifting needs that require infrastructure that captures, aggregates, analyzes, and validates data and information in a timely and*

accurate manner. Strong information systems will also be needed to support regulatory processes and postmarket surveillance, financial protection coverage, and routine utilization of medicines. Readily available data and an enhanced capability to analyze those data are essential requirements for evidence-based decision making within the supply chain and pharmaceutical system more broadly and will be crucial to the success of UHC.

At the country level, many LMICs lack accurate, relevant, and timely data to inform pharmaceutical management decision making. As countries expand coverage to include a wider range of quality health services for more people, strong and robust information systems will be required to capture data that will enable the pharmaceutical system to function effectively and efficiently. To ensure that people can access medicines and health technologies when and where they are needed, information systems must be able to accurately predict medicine needs, support quality assurance and regulatory processes at all levels of the health system, and protect patient safety. First, information systems will need to capture information on demand, including the profile of populations covered under UHC. Second, data on supply—including information on prescribers, suppliers, and medicine registration—will be required as insurance providers expand financial protection under UHC. Only by ensuring that increased demand for health care services is met with equitable increases in supply can UHC programs prevent gaps in health service provision.

To improve distribution processes, many countries have introduced electronic and paper-based logistics management information systems (LMIS). box 7 describes the positive effects of an LMIS in Bangladesh, including the reduction of stock-outs at various levels of the health system. Creating an electronic LMIS in Bangladesh was a strong first step

toward strengthening the pharmaceutical information system. Countries working toward UHC can use similar strategies as they analyze the best options for collecting information related to medicines and strengthen their supply chain processes to help meet a growing demand for life-saving medicines and other health technologies.

BOX 7

LMIS in Bangladesh Improves Efficiency in the Supply Chain System³⁴

In 2011, with the support of SPS, Bangladesh introduced a web-based LMIS that included two electronic tools: the Upazila Inventory Management System (UIMS) and the web-based Supply Chain Information Portal (SCIP). The system allows central, regional, and upazila (subdistrict) managers of the Directorate General of Family Planning (DGFP) to enter logistics data, including information on consumption and current stock levels, into the UIMS, which are then consolidated and uploaded to the web-based portal. A key feature of the portal is an interactive dashboard that presents easy-to-understand charts, alerts, maps, and tables on stock levels throughout the country.

The introduction of the LMIS had positive effects. First, the number of stock-outs decreased after the introduction of the LMIS. For example, potential stock-outs decreased by more than 85% at both upazila stores and service delivery points. Understocking of these commodities decreased by 60% at both levels of the system. All stock-outs (i.e., stock-out, potential stock-out, and under-stock) of injectables and intrauterine devices decreased from 2009 to 2013. The availability of logistics data contributed to improved decision making at several levels of the system. At the national level, SCIP data enabled the DGFP to adopt an improved, evidence-based approach to quantification that considers different policy scenarios to produce a more accurate forecast of needs. The SCIP provides logistics information that gives a clear picture on actual consumption and whether appropriate levels of commodities are available.

The strength of health information systems varies widely across LMICs. In settings where electronic and automated systems are available and reliable, the process of monitoring services and utilization and measuring performance is simplified. Robust information systems, particularly those that are electronic, can facilitate improved pharmaceutical system functioning as they promote the use of good quality data and information in decision making processes and allow managers to monitor and detect over and/or underutilization, adverse events, fraud, and other problems in real time.

While many LMICs struggle to create systems that will routinely capture information, some may have a different challenge—getting systems to talk to one another.³⁵ For example, one country may have two or three different information systems that operate independently, including a health management information system that captures information on

health care service utilization, a separate logistics and pharmaceutical management system, and a claims processing system that was set up for health insurance. Countries will need to address issues surrounding information system interoperability to ensure that decision makers can use information from different sources in a cohesive manner. Within the pharmaceutical system, information is often limited to supply and logistics information, and actual patient and health system medicine expenditures are often not captured or measured.²⁶ Systems to capture and integrate expenditure data into existing information systems and architecture will be required to track overall medicine spending and utilization and help safeguard the sustainability of the financial protection program. The interventions targeted at achieving UHC goals must include incremental efforts toward integrating and harmonizing existing health information systems and developing new systems to fill current gaps.

III. TAILORING PHARMACEUTICAL MANAGEMENT EFFORTS TO MEET UHC OBJECTIVES—PRACTICAL STEPS

Tailoring pharmaceutical management efforts to meet UHC objectives can be complex and may follow different trajectories depending on country-specific needs and contexts. The readiness of the pharmaceutical system to support UHC efforts is dependent on not only the strength of each pharmaceutical functional area but also how cohesively these areas work together. Decision makers in all contexts must make choices to determine how to rollout UHC, but those in resource-limited settings will need to pay even greater attention to prioritization efforts. Existing strengths and resources within the pharmaceutical system, include the use of the private sector, will need to be leveraged while identifying and strengthening weak areas.

To ensure that UHC policies, strategies, and defined actions are introduced and implemented in a way that compliments current pharmaceutical system strengthening efforts, a tried and true approach that aims to map relevant stakeholders, understand the current state of the pharmaceutical system's functional areas, and thoroughly analyze the options is recommended. The step-wise approach that follows is a high-level guide for decision makers who are developing, revising, or implementing UHC programs. While not inclusive of all steps required for strengthening the pharmaceutical system to meet UHC objectives, it acts as a good starting point to ensure that pharmaceutical system needs are taken into account.

BOX 8

Additional Stakeholders

- National medicines regulatory agencies
- Medicine pricing commissions
- Pharmaceutical manufacturers
- Regional and provincial medical stores
- Wholesalers
- Pharmacies
- Drug shops and accreditation and licensing councils for pharmacists and other pharmaceutical cadres

Step 1. Advocate for the inclusion of pharmaceutical system stakeholders in the expanded coverage of the health services strategy development process to ensure buy-in and ownership of a common UHC vision.

A critical first step for any policy process is to engage stakeholders across different groups within the pharmaceutical system and ensure buy-in prior to implementation. The stakeholder engagement process should clarify UHC objectives and desired outcomes and ensure the alignment of goals across all stakeholders. It is important to include representatives from the pharmaceutical sector in the broader UHC strategy development to ensure that pharmaceutical system needs are adequately addressed. Pharmaceutical-sector stakeholders may vary from country to country. Box 8 provides a suggested list. Given the importance of guaranteeing the availability of medicines as

health service coverage expands under UHC, these pharmaceutical-sector stakeholders must be engaged from the beginning. One potential strategy for ensuring that all stakeholders are engaged appropriately is to complete a stakeholder mapping. Preliminary research, including a high-level analysis of existing country-specific literature and publications, can help identify appropriate pharmaceutical system agencies and organizations for the UHC planning processes.

Step 2. Assess and describe the current functionality of the critical areas of the pharmaceutical system.

In collaboration with the identified stakeholders, the functionality of the pharmaceutical system's critical areas should be assessed. The strengths and weaknesses that are identified will enable decision makers to evaluate the pharmaceutical system's readiness to contribute to UHC objectives.

Table 1 provides a list of guiding issues to consider when assessing pharmaceutical system readiness. The table is not exhaustive, but it includes illustrative

sets of questions for each functional area to aid decision makers through the high-level assessment process, as well as suggested resources.

Table 1. Key Pharmaceutical Management Issues

Pharmaceutical system functional area	Key pharmaceutical management issues	Resources
Policies, laws, and governance	<ul style="list-style-type: none"> – Are there specific pieces of legislation and policies to support health financing and UHC efforts? – Are national medicines policies consistent with UHC and health financing policies? – Are there policies to enhance equitable access to medicines for underserved populations (e.g., if significant segments of the population cannot access licensed pharmacies, what changes in laws and regulations are needed to allow non-pharmacy outlets to dispense a limited range of public health priority medicines)? 	<p>Recent pharmaceutical management assessments</p> <p>WHO country profiles; USAID and donor partners</p> <p>Routine MOH reports and other rapid assessments</p> <p>Country health information system reports</p>
Financing	<ul style="list-style-type: none"> – What are the current sources of funding for medicines and pharmaceutical services? – What proportion of government pharmaceutical expenditure is recovered through user out-of-pocket fees? – Has a comprehensive estimate been made of the pharmaceutical financing needs based on forecasted demand under the UHC program? – How much does the lowest population quintile pay out of pocket for a set of essential tracer medicines? 	<p>Country total health expenditure and total pharmaceutical spending reports</p> <p>Ministry of Finance budget allocations for pharmaceutical products and services</p>
Innovation, research, and development	<ul style="list-style-type: none"> – What percentage of the total medicines needed is manufactured locally vs imported? – Are there trade laws that enable partnerships and technology transfers for local manufacturing of medicines for priority diseases? – Are there policies that guide local manufacturing and protect innovations? 	<p>Current essential medicines forecasting and quantification reports</p>
Pharmaceutical products and related services	<ul style="list-style-type: none"> – What are the barriers and constraints to utilizing private-sector pharmaceutical service providers? – What is the national and subnational availability of essential tracer medicines? – What is the level of adherence to treatment guidelines? 	<p>Health-sector financing and strategy documents</p> <p>MOH and local regulatory authority guidelines and documents</p>
Regulatory systems	<ul style="list-style-type: none"> – What regulations exist to ensure safe, effective, and high-quality pharmaceutical products and services on the market? – Is there a system for registering medicines in the country, and how efficient is that system? – Are there systems to regulate the licensing and accreditation of pharmaceutical service personnel and premises for dispensing medicines? 	<p>Local Ministry of Trade and/or commerce strategies, guidelines, and other documents</p>
Human resources	<ul style="list-style-type: none"> – What is the current distribution (types, numbers, geographic) of pharmaceutical cadres per capita and per insured person? – What pre- and post-qualification pharmaceutical service training programs exist? – Is there a strategy to address the deficit in available pharmaceutical professionals, and is task shifting included? 	<p>MOH and local regulatory authority guidelines and documents</p> <p>Health and pharmaceutical human resource strategy documents</p>
Information	<ul style="list-style-type: none"> – Are there robust systems to generate and disseminate timely information on product registration, quality and safety, pharmaceutical financing, and medicine prices? – Are supply chain and logistics information management strategies and systems in place? – To what extent are the existing health, financing, and logistics information systems integrated? 	<p>National health sector plans and strategies</p> <p>National health status indicator-based survey reports (e.g., DHS and MICS surveys)</p>

Table 1 provides a high-level overview and requires more granular and detailed indicator-based assessments and analyses to inform the potential pharmaceutical system strengths and challenges.

Step 3. Identify functional area gaps and prioritize interventions for impact.

Stakeholders should collaborate on a comparison of options that include current system considerations to assess the viability of potential interventions based on operational characteristics, existing legal and regulatory frameworks, and potential cost implications.³⁶ Decision makers should consider investing in and implementing pharmaceutical system interventions with the greatest benefit to the health system as a whole and to the UHC goals.

Step 4. Develop robust monitoring and evaluation systems that promote learning, adapting, and continual improvement.

Countries will need to strengthen data and information systems and carefully monitor access to medicines—defined by their affordability, availability, accessibility, and acceptability—and their effective use to ensure that as coverage of health services expands under UHC, individuals and families are able to get the life-saving medicines that they need.

CONCLUSION

As the global community works to expand coverage of high-quality health services and decrease catastrophic health care-related expenses, countries must recognize that all components of the pharmaceutical system can and must be strengthened to achieve these objectives. Countries must explicitly recognize that medicines contribute significantly to the overall cost of health service delivery and that they account for a sizeable

proportion of out-of-pocket payments. Given the critical role that medicines play in quality health service provision and the disproportionately high impact that they have on the cost and efficiency of the health system, strengthening pharmaceutical systems and management practices to improve access to and affordability of medicines is imperative for achieving UHC.

REFERENCES

1. WHO. Sustainable health financing, universal coverage and social health insurance. World Health Assembly; April 2005. Available at: http://apps.who.int/iris/bitstream/10665/20302/1/A58_20-en.pdf?ua=1
2. World Health Organization, Etienne C, Asamoah-Baah A, Evans DB, editors. The World Health Report: Health Systems Financing: the Path to Universal Coverage. Geneva: World Health Organization; 2010. 96 p.
3. United Nations. Transforming Our World: The 2030 Agenda for Sustainable Development. 2015. Available at: <https://sustainabledevelopment.un.org/post2015/transformingourworld/publication>
4. WHO. Universal Health Coverage: Report by the Secretariat. January 2013. Available at: http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_22-en.pdf
5. Medicines in Health Systems: Advancing access, affordability and appropriate use. World Health Organization; 2014. Available at: http://apps.who.int/iris/bitstream/10665/179197/1/9789241507622_eng.pdf
6. Xu K, Saksena P, Jowett M, Indikadahena C, Kutzin J, Evans DB. Exploring the thresholds of health expenditure for protection against financial risk. World Health Rep. 2010;328–333.
7. IMS Institute for Healthcare Informatics. The Global Use of Medicines: Outlook through 2017. IMS Institute for Healthcare Informatics; November 2013. Available at: http://apps.who.int/iris/bitstream/10665/44371/1/9789241564021_eng.pdf
8. Management Sciences for Health. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health; 2012.
9. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to medicines from a health system perspective. Health Policy Plan. 2013 Oct;28(7):692–704.
10. Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. Defining pharmaceutical systems strengthening concepts to enable measurement. Health Policy and Planning, 2016;1–13.
11. Leisinger KM, Garabedian LF, Wagner AK. Improving Access to Medicines in Low and Middle Income Countries: Corporate Responsibilities in Context. South Med Rev. 2012 Dec 27;5(2):3–8.
12. Rankin J, Gremillion M, Eghan K. Management of Medicines Benefit Programs in Low- and Middle-Income Settings: Adapting Approaches from High Income Countries. Arlington, VA, USA: Management Sciences for Health; 2015.
13. Rutta E, Liana J, Embrey M, Johnson K, Kimatta S, Valimba R, et al. Accrediting retail drug shops to strengthen Tanzania's public health system: an ADDO case study. J Pharm Policy Pract. December 2015;8(1). Available at: <http://www.joppp.org/content/8/1/23>
14. Gammouh S, Joshi M. Improving Antibiotic Prophylaxis in Cesarean Section in Jordanian Hospitals: SIAPS Technical Report. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health; March 2013.
15. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016 May;47:20–33.
16. Weilbaecher A. Diseases Endemic in Developing Countries: How to Incentive Innovation. Ann Health Law. 2009;18:281.
17. Banerjee A, Hollis A, Pogge T. The Health Impact Fund: Incentives for improving access to medicines. The Lancet. 2010 Jan 9;375(9709):166–9.
18. Reichman JH. Compulsory licensing of patented pharmaceutical inventions: evaluating the options. J Law Med Ethics J Am Soc Law Med Ethics. 2009;37(2):247–63.
19. Federal Ministry of Health and Ministry of Industry of Ethiopia. National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025). Addis Ababa, Ethiopia; 2015.
20. Bartels HG, World Health Organization, World Intellectual Property Organization, World Trade Organization, editors. Promoting access to medical technologies and innovation: Intersections between public health, intellectual property, and trade. Geneva, Switzerland: World Health Organization; World Intellectual Property Organization; World Trade Organization; 2013. 257 p. (WIPO Publication).
21. Bermudez J, Hoen E 't. The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good. Open AIDS J. January 19, 2010;4(1). Available at: <http://benthamopen.com/FULLTEXT/TOAIDJ-4-37>

22. Systems for Improved Access to Pharmaceuticals and Services. Systems for Improved Access to Pharmaceutical Services Annual Report: Project Year 3, October 2013–September 2014. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health; 2014.
23. Nguyen TA, Knight R, Roughead EE, Brooks G, Mant A. Policy options for pharmaceutical pricing and purchasing: Issues for low- and middle-income countries. *Health Policy Plan*. 2014 Jan 13;cz1105.
24. Dieleman M, Gerretsen B, Wilt GJ van der. Human resource management interventions to improve health workers' performance in low and middle income countries: A realist review. *Health Res Policy Syst*. 2009 Apr 17;7(1):1–13.
25. United Nations Office on Drugs and Crime. Counterfeit goods: A bargain or costly mistake? Available at: www.unodc.org/toc/en/crimes/counterfeit-goods.html
26. Wagner AK, Quick JD, Ross-Degnan D. Quality use of medicines within universal health coverage: Challenges and opportunities. *BMC Health Serv Res*. 2014;14(1):1.
27. World Health Organization. WHO | Post market surveillance. WHO. Available at: <http://www.who.int/medicines/regulation/ssffc/pms/en/>
28. Systems for Improved Access to Pharmaceuticals and Services. Systems for Improved Access to Pharmaceutical Services Annual Report: Project Year 4, October 2014–September 2015. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA, USA: Management Sciences for Health; 2015.
29. World Health Organization. Tackling the crisis of workforce shortages in the pharmaceutical sector. World Health Organization; 2011.
30. Wuliji T, Taylor O, Crommelin D, Stolk P, Bradley H, Gal D. The World Medicines Situation 2011: Pharmaceutical Human Resources. Geneva, Switzerland: World Health Organization; 2012. Available at: <http://apps.who.int/medicinedocs/documents/s21407en/s21407en.pdf>
31. McCombie SC. Self-treatment for malaria: The evidence and methodological issues. *Health Policy Plan*. 2002 Dec 1;17(4):333–44.
32. Chalker JC, Vialle-Valentin C, Liana J, Mbwasia R, Semali IA, Kihyo B, et al. What roles do accredited drug dispensing outlets in Tanzania play in facilitating access to antimicrobials? Results of a multi-method analysis. *Antimicrob Resist Infect Control*. August 20, 2015;4. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4545914/>
33. Valimba R, Liana J, Joshi MP, Rutta E, Embrey M, Bundala M, et al. Engaging the private sector to improve antimicrobial use in the community: Experience from accredited drug dispensing outlets in Tanzania. *J Pharm Policy Pract*. September 17, 2014;7(1). Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4177420/>
34. Technical Brief. Systems for Improved Access to Pharmaceuticals and Services. Design, Implementation, and Use of Pharmaceutical Logistics Management Information Systems (LMIS). Arlington, VA: Management Sciences for Health; 2016 .
35. Ritz D, Althausen C, Wilson K. Connecting Health Information Systems for Better Health: Leveraging Interoperability Standards to Link Patient, Provider, Payor, and Policymaker Data. Seattle: PATH and Joint Learning Network for Universal Health Coverage; 2014.
36. Brown M, Lee D. Analyzing Options for Strengthening Pharmaceutical Systems. Arlington, VA, USA: Management Sciences for Health; January 2016.
37. Wirtz V, et al. Essential Medicines for Universal Health Coverage. The Lancet Commission on Essential Medicine Policies. November 2016.
38. Penchansky R, Thomas JW. The Concept of access: definition and relationship to consumer satisfaction. *J. Med Care* 1981. February (2);127–140/