Guide to Tracking Pharmaceutical Expenditures in a Health System

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RESULTS FOR DEVELOPMENT

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The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Pharmaceutical expenditures; pharmaceutical financing; expenditure tracking; System for Health Accounts (SHA); National Health Accounts (NHA); out-of-pocket expenses; household health expenditure

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ACRONYMS

CMS	Central Medical Stores
CPM	Center for Pharmaceutical Management
GAVI	The Global Alliance for Vaccines and Immunizations
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
LMIC	Low- and middle-income country
ICHA	International Classification for Health Accounts
MDG	Millennium Development Goal
MOF	Ministry of Finance
MOH	Ministry of Health
MSH	Management Sciences for Health
NCU	National Currency Unit
NHA	National Health Accounts
OECD	Organization for Economic Cooperation and Development
R4D	Results for Development
SCMS	Supply Chain Management System
SHA	System of Health Accounts
THE	Total Health Expenditures
TPE	Total Pharmaceutical Expenditure
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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INTRODUCTION

Access to essential medicines is a fundamental component of a health system. It is a cost-effective systemic intervention for reducing mortality and morbidity (MDS-3), and is critical to achieving universal health coverage. However, in many low- and middle-income countries (LMICs), the high cost of medicines, together with economic instability, continued population growth, and a heavy burden of disease, makes it a challenge to ensure adequate financing for a stable and adequate supply of medicines. The emergence of diseases such as HIV/AIDS and drug-resistant strains of malaria and tuberculosis is further straining country health systems, resulting in reduced availability of medicines and rising pharmaceutical expenditures.

Resource-poor countries face numerous challenges in ensuring access to affordable medicines, including sustainable financing and optimal allocation of resources, a lack of efficient and reliable supply and distribution channels, and inequity. A lack of or limited local production of medicines in these countries can add to these challenges. In many LMICs, spending on medicines is the largest driver of out-of-pocket payments—less than one-third of pharmaceutical expenditures are publicly funded (MDS-3). In contrast, among the established economies, private spending on medicines averages about 40% of total pharmaceutical spending; the remaining 60% is paid through public budgets and social insurance.

The large role of private expenditures (mainly households) and donor financing in overall pharmaceutical expenditures in LMICs raises important concerns about equity and future sustainability. However, a major limitation in our understanding of these expenditures and overall pharmaceutical expenditures in general, is that there is no widely used or accepted methodology for fully understanding them that informs decisions about allocations, equity and/or financial sustainability and allow for cross-country comparisons and setting of benchmarks to monitor progress in achieving national goals. This guide is intended to provide a foundation for taking action to address this gap, and establish a process for systematically and comprehensively tracking pharmaceutical expenditures.

Rationale for Estimating Pharmaceutical Expenditures

Given a decrease in donor funds dedicated to health and a growing emphasis on maximizing value for money, it has become even more important for countries, donors and other partners to better understand *where* funding for pharmaceuticals is coming from and *who* spends on *what*. An essential first step in developing a systematic and comprehensive methodology for tracking and estimating pharmaceutical financial flows is reaching agreement on the products and services that should be included in pharmaceutical expenditure tracking activities. For this guide, we offer a working definition based on the System of Health Accounts[1] (SHA), a widely used health accounting approach developed by the Organization for Economic Cooperation and Development (OECD) that explicitly incorporates core management functions associated with

[1] The System of Health Accounts is an internationally standardized framework that systematically tracks the flow of expenditures in a health system. A brief produced by the USAID funded Health Finance and Governance project describing the key elements of the SHA framework can be found here: https://www.hfgproject.org/sha-2011-explained-new-brief/.

managing pharmaceuticals, namely procurement, acquisition costs, quality assurance, and distribution (including warehousing, inventory management and logistics management information systems). Working definitions associated with these functions are described in Annex A.

What do we mean by pharmaceutical expenditures?

Expenditure on pharmaceuticals and other medical non-durables comprised of pharmaceuticals such as medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives, **and the core management functions associated with the delivery of these products.**

Source: Based on System of Health Accounts (SHA), 2011

From a country's policy perspective, particularly in the context of universal health coverage or Millennium Development Goals (MDGs), a complete understanding of the costs of delivering much-needed vaccines or life-saving medicines vital for reducing child mortality, maternal mortality, and morbidity associated with—but not restricted to—HIV/AIDS, TB, or malaria is critical. Policymakers can better plan and prioritize initiatives, and make informed allocation and equity-related decisions based on an understanding of the flow of funds within a system. A complete picture of the resource envelope for pharmaceuticals provides critical information that can be used to advocate for and mobilize additional resources from the Ministry of Finance or from international donors; to improve the allocation of these resources among priorities; and to monitor pharmaceutical expenditure patterns. It also can facilitate comparisons of one country's pharmaceutical expenditures to another's, which in turn can help to inform the setting of performance benchmarks.

From a donor's perspective, resource allocation and pharmaceutical expenditure information can be used in partnership with country policymakers to make more informed decisions about funding gaps. Donors can also use this information to better manage their aid portfolios, ensuring the best value for money, and, where applicable, a plan for a future graduation of support to a given country.

At the global level, accurate and routine expenditure data on pharmaceutical spending contributes to the global public good by strengthening global databases on health spending and advancing the knowledge base. Finally, consistent estimation of pharmaceutical expenditures using a standardized methodology allows for regional and global comparisons.

Need for an Approach for Tracking Pharmaceutical Expenditures

Summary of Existing Resource Tracking Tools

To begin this work we conducted a review of existing tools for tracking pharmaceutical expenditures using the search terms described in Annex B to understand what currently exists

and where there may be gaps in the type of information collected. We included all tools with a health sector resource tracking component. In addition to the search terms, our review targeted a list of international organizations and implementing agencies involved in the pharmaceutical sector (Annex B).

Using this methodology we identified a total of 16 resource-tracking tools. Two of these tools were relevant to the broader health system, six were relevant to the pharmaceutical sector, and eight had a specific disease or health intervention focus. A detailed summary of the tools is provided in Annex C.

The *One Health Tool*, which targets the overall health system, had been applied in 25 countries as of October 2014, and is designed to identify the costs of key national disease programs and those of the health system components. Its focus is on the important issues of costing and budgeting, but allows only for limited analysis of financing and resource gaps. Furthermore, while it incorporates costing of medicines and supply chains, it does not track pharmaceutical resource flows through core pharmaceutical functions and activities.

The *System of Accounts* (SHA) framework, also relevant to the broader health sector, has been applied in more than 100 countries. The framework is designed to provide a systematic and standardized compilation of health expenditures—tracking where resources go, how and for whom they are spent, trends in spending, and how this compares to other countries. The framework can be customized to allow for country-specific pharmaceutical expenditure tracking; however, resource-tracking activities based on this methodology are tied to the SHA schedule, which can pose limitations.

Tools such as the *Enhancing Contraceptive Security Through Better Financial Tracking* tool developed by the USAID-funded DELIVER project or the *National AIDS Spending Assessment* have a specific focus on a disease area or health intervention, and do not allow for a detailed tracking of a complete range of pharmaceutical expenditures.

While there are several tools that are relevant to the pharmaceutical sector, most have limited—if any—focus on pharmaceutical financing. The *WHO Tools for mapping financial flows for medicines procurement and distribution, and for rapid assessment of medicines supply management systems* offer an exception. These tools, which include data entry sheets for mapping partners and financial flows, are designed to quantify pharmaceutical financing by partner, donor support for procurement, and financing for functions associated with distribution and warehousing. However, the tools do not comprehensively track the flow of resources from one level of the pharmaceutical system to the next—that is, from selection and procurement down to the provider or household levels.

Toward a Methodology for Tracking Pharmaceutical Expenditures

From this review, we learn that there are no existing tools that comprehensively quantify pharmaceutical expenditure flows at all levels of the pharmaceutical system, in particular at the provider and household levels. Additionally, the tools do not capture expenditures associated

with the core functions of pharmaceutical supply systems: procurement, acquisition costs, quality assurance, pre-storage distribution and distribution of drugs.

Of the 16 tools reviewed, the WHO tools for mapping financial flows and the *System of Health Accounts* offer the best starting point for tracking pharmaceutical expenditures. Although the WHO tool does not capture pharmaceutical expenditures at the provider or household level, it includes a qualitative component that can be used to assess pharmaceutical supply and management systems, and help inform financial estimates. The SHA methodology, which facilitates resource-tracking from the sources of funds through intermediaries to final recipients or users, offers a potential way to operationalize and build on the Center Pharmaceutical Management (CPM) pharmaceutical financing framework (Figure 1) developed by Management Sciences for Health (MSH). SHA results are targeted to national-level policymakers such as Ministries of Health and Finance, international donors and partners, and civil society organizations and members, and can be used to help answer questions related to resource mobilization, allocation, efficiency, and finally equity. The WHO tools, while targeted to similar users, are designed to provide a better understanding of stakeholders and partners with the aim of improving resource mobilization, information sharing, and coordination. The tools, however, do not allow for a detailed analysis of provider-level or private expenditures.

Based on these observations of the tools reviewed, we recommend the SHA framework as the more practical and robust methodology for systematically and comprehensively tracking pharmaceutical expenditures in a pharmaceutical system. The SHA approach can be combined with household expenditure or facility surveys to generate additional analysis aimed at better understanding who uses pharmaceutical services and products, how much is used, and how much different socioeconomic groups pay for goods and services.

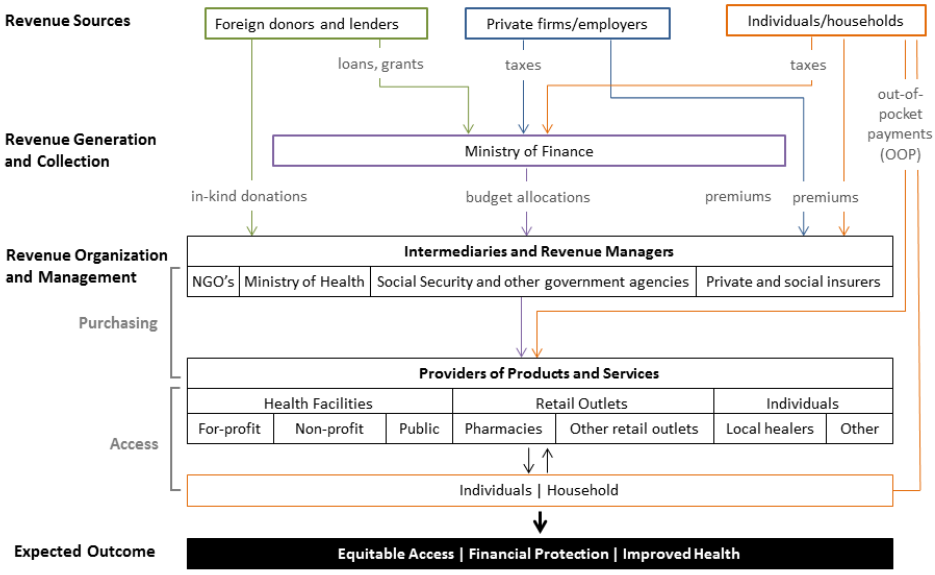

Figure 1: CPM Pharmaceutical Financing Framework

Using Pharmaceutical Expenditure Information to Inform Decisions and Policies

Information produced by pharmaceutical expenditure tracking activities can be used by Ministries of Health (MOH), Ministries of Finance (MOF), donors and other international partners to help bring greater accountability and improved transparency to financial transactions in the pharmaceutical system. Some of the recommendations that can evolve from tracking pharmaceutical expenditures can be policy-based or can suggest specific actions to address problems along the pharmaceutical supply chain. On the policy side, pharmaceutical expenditure tracking information can help to ensure that resource allocation decisions are based on recent trends and requirements, and improve alignment of spending with policy priorities. Recommended actions that flow from pharmaceutical expenditure-related findings can include restructuring procurement practices, enhancing donor coordination, the re-allocation of resources to address a specific disease priority, and improvements in pharmaceutical management information systems. Finally, routine collection of accurate pharmaceutical expenditures helps to build databases on international public goods expenditures, facilitating research and innovation as well as cross-country comparisons and the setting of benchmarks to monitor progress in achieving national goals.

While initial findings relating to pharmaceutical financial flows can also be used to estimate out-of-pocket payments and other fees borne by households for the purchase of pharmaceutical commodities, additional surveys are needed to better understand how health spending is distributed among populations and to more deeply assess the equity implications of these types of payments.

OBJECTIVES OF THIS GUIDE

This guide is designed to take country-level pharmaceutical and financing experts through the SHA framework as a potential approach that can be adapted to track pharmaceutical expenditures. The SHA model has been identified through the literature review as a promising methodology. The guide also reviews important first steps that must be considered to operationalize pharmaceutical expenditure tracking. It is intended to serve as a foundation for a wider conversation about pharmaceutical expenditure tracking approaches and to bring attention to key normative issues including expenditure definitions and boundaries that will need to be addressed before full-scale implementation guidelines for pharmaceutical expenditure tracking can be fully adopted.

USING THE GUIDE

There are 4 sections to the guide:

Section 1: Key considerations in the adoption of the SHA model for tracking pharmaceutical expenditure at the country level reviews important expenditure definitions, boundary considerations and indicators for monitoring progress.

Section 2: Mapping the flow of pharmaceutical expenditures from initial sources to end users presents a series of SHA-based matrices for tracking pharmaceutical expenditures from funding sources. Donors, national public resources, and households to financing agents/intermediaries such as the Central Medical Stores (CMS) represent Matrix 1; points of warehousing or insurance agencies that procure and manage the resources form Matrix 2; and service providers, such as health facilities or independent pharmacies, constitute Matrix 3.

Section 3: Mapping expenditures related to key pharmaceutical management functions presents an SHA-based matrix (Matrix 4) that allows for the estimation of expenditures associated with various pharmaceutical management functions.

Section 4: Data collection needs for estimating pharmaceutical expenditures provides guidance on data collection.

Section 5: Using pharmaceutical expenditure data to develop indicators for decision-making presents a list of core indicators that can be used to assess and monitor pharmaceutical expenditures at different levels of the pharmaceutical supply chain system and describes how they can be used for decision-making.

Section 6: Recommended next steps offers suggestions for a way forward in operationalizing an approach for tracking pharmaceutical expenditures.

SECTION 1: KEY CONSIDERATIONS IN THE ADOPTION OF THE SHA MODEL FOR TRACKING PHARMACEUTICAL EXPENDITURES AT THE COUNTRY LEVEL

To ensure proper accounting and minimize the possibility of double counting, it is important to reach agreement on key definitions prior to engaging in any expenditure mapping or tracking activity. Buy-in from country-level stakeholders and experts is critical to determining the feasibility and relevance of the approach and to ensuring that definitions, boundaries and indicators capture country-specific contexts and priorities. A country-level technical expert working group should be convened to discuss and agree on the pharmaceutical expenditure tracking approach, expenditure definitions, boundary considerations as well as indicators for monitoring progress.

Who should be included in a country-level technical expert working group?

Multi-stakeholder representation is important.

- Experts from multilateral and bilateral organizations with in-depth expertise in pharmaceutical expenditures and pharmaceutical systems
- Country-level representatives with expertise in pharmaceutical supply systems and government accounting systems
- Representatives from non-governmental organizations with expertise in medicines expenditures

While not an exhaustive list, critical issues to consider in pharmaceutical expenditure tracking are highlighted below:

1. **Agreement on the approach**: The proposed pharmaceutical expenditure tracking approach is based on SHA methodology. It is the first attempt to operationalize the MSH/CPM pharmaceutical financing framework and more comprehensively quantify financing flows along the pharmaceutical supply chain. Expert consultation is recommended to adapt and ensure buy-in and agreement on this approach.

2. **Scope:** Important decisions about scope, including the types of questions raised below, should be reached among key stakeholders:

    - Should supplementary medicines such as natural herb supplements or alternative medicine therapies be included?

    - Should every single drug be tracked or should only a more limited list such as specific categories that will cover 80% of the pharmaceutical expenditures, including the National Essential Medicines List and the vertical programs be considered?

    - Should in-patient drug costs be included?

    - What types of pharmaceutical products should be included (e.g. drugs, vaccines, reagents)?

3. **Public vs. private:** It is important to define upfront the criteria that will be used to determine the type of private or quasi-public spending that will be included in tracking activities. Clear rules of distinction are needed to limit confusion. Many health systems have a complex mix of "public" and "private" roles spanning different functions and institutions, and ranging across the core functions of pharmaceutical supply systems. With the rise in public-private partnerships in pharmaceutical supply and management systems, the duties of the public and the private in these partnerships are sometimes unclear, meaning clarification is necessary in advance of expenditure-tracking activities.

4. **Assessing private-sector expenditures**: Detailed expenditure data from the private sector may be hard to obtain given the multitude of players in most countries, the added complexities of decentralized health systems, and the sometimes tenuous relationships with the public sector. Thus it may be necessary to consider additional primary data collection for tracking private sector pharmaceutical expenditures. However, in some countries data might be captured by the Ministry of Trade for imported pharmaceuticals, or by the Ministry of Finance or industry associations and cartels that track the production of pharmaceuticals.

5. **Time:** A decision should be reached early on about the timing of expenditures. Decision-makers should consider whether the country-specific financial year is more policy-relevant or whether expenditures should be reported on the basis of a calendar year, which would allow for international comparability. At the country level, there may be some inconsistencies in financial-year boundaries between government and non-government agencies, which should also be harmonized.

6. **Space:** In classifying health expenditures, norms dictate that both public and private expenditures (including pharmaceuticals) incurred by a country's citizens within its borders, as well as those incurred overseas by citizens temporarily abroad, are included in health accounts. Expenditures incurred by foreign nationals in a given country are excluded.

7. **Cash- or accrual-based accounting:** Typically, SHA methodology uses accrual accounting; however, this issue should be reviewed in the context of pharmaceutical finance resource-tracking. Accrual accounting implies that expenditures are recorded for the time period in which the activity takes place and not when payment is made. Most government pharmaceutical systems operate on a cash basis and do not track donated medicines or equipment, medicines issued for free or on credit, or losses—all important components of pharmaceutical expenditures.

8. **Cost-sharing between inputs:** As there are often overlaps in the inputs required for the production of goods and services in a health system, decisions should be made about how to best apportion expenditures to appropriate functions. To accurately capture costs, norms on how to distribute shared inputs, such as personnel who carry out multiple functions, will need to be established. For example, if a hospital nurse dispenses medicines to in- and outpatients, allocation rules will need to be established to apportion

her time between inpatient and outpatient pharmaceutical costs. Allocation rules also can be defined in a pilot phase.

9. **Taxes:** Taxes such as value-added tax are often levied on pharmaceutical products, including in-kind pharmaceutical support from donor agencies. Consensus on whether these types of taxes should be included in pharmaceutical expenditure tracking is needed.

10. **Levels of prices and volumes:** Pharmaceutical expenditures consist of price and volume components. Prices may be indicated at different levels: key price types include the ex-factory price (manufacturer level), the pharmacy purchasing price (wholesale) and the pharmacy retail price (pharmacy). Additionally, different price types apply in the hospital sector (official hospital price and actual hospital price). Prices can also vary within a year through price adjustment policies, in addition to variations between private- and public-sector prices. Volume, in turn, may be expressed in sales units, prescriptions, or defined daily doses. To accurately estimate total expenditures, it is important to be cognizant of the different units of analyses.

11. **In-kind assistance and technical support.** Rules should be established on how in-kind and technical support for vaccines, drugs and commodities should be valued. These could be valued from the donor perspective of the costs incurred to provide the resources or amounts that would be received if the resources were sold, or they could be valued differently from the recipient's perspective.

12. **Exchange rate conversions:** It is important to agree on the exchange rate that will be used for conversion between the National Currency Unit (NCU) and currency in which drugs are imported. This consideration is particularly pertinent in cases where the NCU is highly volatile.

13. **International Classification System:** To ensure that expenditure transactions and pharmaceutical functions follow an internationally accepted classification norm, pharmaceutical expenditure tracking tools should be aligned with OECD's International Classification for Health Accounts (ICHA), which is used to categorize each expenditure.

14. **Indicators:** It is important to agree on indicators that can be used to measure and monitor key aspects of pharmaceutical expenditures. These indicators should be relevant to country-level policy and decision-making processes and will inform the expenditure data that are collected. In the next section, we show how SHA data can be used to compute select indicators. A more detailed list of potential indicators to consider in monitoring pharmaceutical expenditures is provided in Section 3.

SECTION 2: MAPPING THE FLOW OF PHARMACEUTICAL EXPENDITURES FROM INITIAL SOURCES TO END USERS

Once boundaries and indicators have been agreed on, an important next step is to classify the key actors in a pharmaceutical system using SHA classification standards as guidelines and to map pharmaceutical expenditure flows. The principal ICHA classification categories are: financing sources, financing agents, health providers and health care functions.

Key Dimensions to Consider in Pharmaceutical Expenditure Tracking

Financing Sources: institutions or entities that provide funds

- Private sector – corporations and households
- Donors/foreign aid
- Government – tax/revenues

Financing/Procurement Agents: entities including insurance and pharmacy benefit schemes that pool and channel funds provided by financing sources to pharmaceutical procurement or management

Point of Warehousing: point at which pharmaceuticals and medical commodities are stored

Providers: entities that deliver pharmaceutical products

Functions: activities related to procurement, distribution and use of pharmaceuticals such as warehousing, supply chain management, staff training and logistics information systems

The process for mapping financial flows presented in this guide builds on the flows outlined in the CPM Pharmaceutical Financing Framework (Figure 1), and is based on the matrix-based approach used in the System of Health Accounts, by which expenditures are tracked from sources of funds through intermediaries to final recipients or users for a given year. The matrix approach is designed to organize health expenditure information, disaggregating a vast amount of data into a simple series of tables that respond to policy priorities, facilitating comparisons between different sources and helping to point out gaps and overlaps. Data sources for the matrices typically include records from national, regional and local authorities, donor reports, provider records, insurance records and household surveys. A detailed list of potential data sources for each matrix is included in Annex E. A data collection approach for the matrices is described in Step 3 of this section.

SHA matrices make a distinction between financing sources, financing/procurement agents, points of warehousing, and pharmaceutical functions, and providers. The flow of funds across the matrices is linked, with row headings (recipients/users) of one table becoming column headings (originators) for the next table.

In this section we provide an illustrative walk-through of three different matrices[2] based on these four dimensions. While countries can choose to fill the matrices in an order that makes most sense for the policy questions they are seeking to address, most begin with Matrix 1, which maps financing sources by financing agents. The matrices can be adapted to reflect country context and policy or decision-making needs. It is important to emphasize again, that the matrices are designed to showcase the SHA methodology; they are not necessarily the final tables that should be used in a country's estimations.

Matrix 1 - Sources of Funding to Financing/Procurement Agents

The sources of funding matrix maps actors who provide funds for the financing of pharmaceuticals and medical commodities in a health system. Funds flow from these actors to financing/procurement agents, where they are pooled and used to purchase pharmaceuticals and commodities. In some pharmaceutical systems, funders also play a role in procurement activities, serving both as a procurement/financing agent and a financing source. For example, UNICEF finances vaccines and is often the procuring agent. The matrices can be customized to map sources of funding by type of program such as HIV, TB, malaria or family planning. In this case, current row headings in Matrix 1 would be replaced by program type.

Matrix 1: Sources of Funding to Financing/Procurement Agents

	Sources of Funding							
Financing/ Procurement Agents		Government	Private Sector	Rest of the World/Donors				**TOTAL**
				USAID	GFATM	GAVI	UNICEF	
	CMS	$ U		$ V				**$ U+V**
	MOH							
	SCMS				$ W			**$ W**
	Crown Agents							
	UNICEF					$ Z	$ Y	**$ Z+Y**
	Private		$ M					**$ M**
	TOTAL	**$ U**	**$M**	**$ V**	**$ W**	**$ Z**	**$ Y**	**Σ $U+V+W+Y+Z+M**

The government category—typically the Ministry of Finance—denotes all funds generated through tax revenues at various levels of government, including, central, regional, and provincial. The tool can be expanded to accommodate sub-national levels of government financing for pharmaceutical supplies, as relevant to countries. This type of information would be useful for regional comparisons at the country level.

The private sector typically encompasses private, for-profit corporations, non-profit organizations, and households. Financing from private companies can be in the form of benefits provided through their own facilities, reimbursements to local providers for the provision of services, or contributions to insurance for employees. The private sector also encompasses

[2] For all tables, the letters U, V, W, Y, Z, Y and M represent illustrative dollar amounts. They are not acronyms.

household payments for pharmaceuticals and medical commodities, and insurance premiums, if the benefits include pharmaceuticals. These payments include direct payment to vendors or facilities where drugs are procured for full price or co-payment of an insurance mechanism. This category should also include funds used to make under-the-table or "gray market" payments to providers.

The private sector includes both commercial and local nonprofit organizations such as charities that provide medical care and disburse medicines to the poor. Nonprofit organizations can be used as a catch-all category to ensure all sources of financing of pharmaceutical care are captured.
The rest of the world/donors[3] category is reserved for funds that come from outside the country for use in the current year. This includes external resources received from international donor partners, including bilateral and multilateral organizations.

A cross tabulation of financing sources and financing /procurement agents is useful in depicting transactions between them, and can help assess the financial sustainability of the pharmaceutical sector. Understanding who pays for and procures pharmaceuticals can help policymakers assess whether financing and procurement mechanisms are optimal, the extent of donor dependence, and the role of the government. Table 1 shows examples of basic indicators that can be computed using information from Matrix 1.

Table 1: Examples of Pharmaceutical financing sustainability indicators

Indicators	Computations from Matrix 1
Percentage of total pharmaceutical financing from donors	Funds from USAID + GFATM + GAVI + UNICEF+/total financing *100
Percentage of total pharmaceutical financing from government	Funds from MoH/total financing*100
Percentage of total pharmaceutical financing from private sector	Funds from private sector/total financing*100
What percentage of total pharmaceutical financing flows to the Central Medical Store?	Funds from Government + USAID/total financing *100

Matrix 2 - Financing/Procurement Agents to Point of Warehousing

The financing/procurement agents' matrix depicts the subsequent step in resource flows in the pharmaceutical supply chain from Financing/Procurement Agent to points of warehousing. This matrix is intended to help track where pharmaceuticals (value of) are distributed by procurement/ financing agents. In a pharmaceutical supply system where there are no leakages,[4] row totals of the sources of funding matrix would match the column totals of the financing/procurement agents' matrix. The stakeholders in a country will need to determine the level of warehousing they want to obtain.

[3] "Rest of the world" is a term of used in health accounts globally.
[4] Leakages may result from fraud, corruption or wastage, among other causes.

The information collected in this matrix can be further customized to glean regional patterns in pharmaceutical expenditures – to ascertain whether and to what extent any particular region, such as an urban or capital area, is being served better than rural or marginalized areas. Such a matrix could map point of warehousing to geographical regions, with current row headings becoming column headings and row headings becoming geographical regions. When matched against forecasted amounts information provided in these matrices will provide an understanding of the gap between demand and supply of drugs and medical commodities. However, this analysis will be only as good as the (often flawed) forecasts produced by the CMS. For a complete picture, two similar matrices could be produced: one to track expenditures on pharmaceuticals and the other to track the flow of volumes of pharmaceuticals. Table 2 lists examples of indicators that can be computed from Matrix 2 to assess whether appropriate financing is reaching warehousing and distribution points.

Matrix 2: Financing/Procurement Agents to Point of Warehousing

	Financing/Procurement Agents							
Point of Warehousing		CMS	MOH	SCMS	Crown Agents	UNICEF	Private Sector	**TOTAL**
	CMS	$ U		$ W				$ U+W
	Regional Medical Store	$ V						$ V
	District MS							
	Tertiary[5] Hospitals					$ Z		$ Z
	Health Facility					$ Y		$ Y
	Private Sector						$ M	$ M
	TOTAL	**$ U+V**		**$ W**		**$ Z+Y**	**$M**	**$ U+V+W+Z+Y+M**

Table 2: Examples of indicators to track where pharmaceuticals are distributed by financing agents

Indicators	**Computation from Matrix 2**
Donor financing for tertiary hospitals as a percentage of total financing	Funds from SCMS+UNICEF+Crown to tertiary hospitals/total financing *100
CMS financing for warehousing/distribution as a percentage of total financing	Funds from CMS to regional medical stores+CMS warehouse/total financing *100
MOH financing for district medical stores as a percentage of total financing	Funds from MoH to district medical stores/total financing *100

Matrix 3: Point of Warehousing to Providers

The point of warehousing to providers matrix tracks expenditures at the point of service or point of dispensation by providers in a health system. It depicts one of the last stages in the flow of funds and pharmaceutical goods from the point of warehousing to providers and seeks to identify who the money goes to in the pharmaceutical system. Providers are the entities that deliver pharmaceutical products. Examples include private and public hospitals, clinics, and health care facilities.

[5] In some countries, Centers of Excellence or large tertiary hospitals have their own procurement mechanisms.

Matrix 3 shows that pharmaceutical financing from CMS is distributed to tertiary hospitals, district hospitals, health facilities and public pharmacies, which can be captured as an indicator as illustrated in Table 3. This information can be used to assess how big a role CMS plays in the pharmaceutical system. Again in the absence of leakages, row totals of the point of warehousing in Matrix 2 would match the column totals in Matrix 3. Similarly, the grand total in each matrix would always be consistent.

Matrix 3: Point of Warehousing to Providers

		Point of Warehousing						
		CMS	Regional MS	District MS	Tertiary hospitals	Health Facility	Private Sector	**TOTAL**
Providers	Tertiary hospitals	$ U_1			$ Z			$ U_1+ Z
	District Hospitals	$ U_2	$ V_1					$ U_2+V_1
	Health Facilities	$ W_1	$ V_2			$ Y		$ W_1+V_2+ Y
	Public Pharmacies	$ W_2	$ V_3					$ W_2+ V_3
	Pvt. Pharmacies						$ M	$ M
	TOTAL	**$ U+W**	**$ V**		**$ Z**	**$ Y**	**$M**	**$ U+V+W+Z+Y+M**

Table 3: Examples of indicators to assess who the money goes to in a pharmaceutical system

Indicators	**Computation from Matrix 3**
Pharmaceutical financing from CMS to all providers as a percentage of total financing	Funds from CMS to tertiary hospitals + district hospitals + health facilities +public pharmacies/ total financing *100
Pharmaceutical financing from private sector to private pharmacies as a percentage of total financing	Funds from private sector to private pharmacies/total financing *100

SECTION 3: MAPPING THE FLOW OF PHARMACEUTICAL EXPENDITURES TO KEY PHARMACEUTICAL MANAGEMENT FUNCTIONS

Matrix 4 - Financing/Procurement Agents to Pharmaceutical Functions

In the context of health accounts, "functions" refer to the delivery of health care services and goods. Examples include curative care, long-term nursing care, medical goods (e.g. pharmaceuticals), preventive services, and health care administration. However, in the context of pharmaceutical resource tracking, functions refer to components or activities along the supply chain. An understanding of the distribution of costs associated with these components or activities among the different financing/procurement agents can help policymakers determine which agents are producing or implementing services at lower costs (see Table 4 for sample indicators). However, cost information will have to be weighed against other factors like geographical access and quality to determine the best value for money.

Matrix 4 maps the financing agents identified in Matrix 1. These have programmatic responsibility for pharmaceutical financing by core pharmaceutical functions. Financing agents play an important role in a country's resource allocations and thus are indicated in three of the four illustrative matrices presented in this guide. Operationally, it is challenging to fill in Matrix 4 without first collecting information on financing agents as outlined in the earlier matrices.

Expenditure data on functions in a health system are typically challenging, but not impossible to capture. There are no discrete data points or sources and expenditures for these activities, so they often require primary data collection at the agent level and an aggregation of costs. Likewise, it may be complicated trying to assign or break down the pharmaceutical management functions and the expenditures associated with each function. Decisions need to be made regarding which costs should be allocated, and to what functions should they be allocated in order to obtain a comprehensive tally of expenditures, for the system, as a whole. For example, is the accounting for pharmaceutical expenditures for public sub-sector or social insurance sub-sector or both? Depending on country context, there is a need to ensure comprehensiveness while not "double counting."

Key pharmaceutical management functions are listed in Matrix 4. These include:

- Procurement, which encompasses a range of functions, among them selection of medicines; quantification of pharmaceutical requirements; preparation of product specifications and quality standards; approval of suppliers (pre-qualification or post-qualification); adjudication; award of tender.

- Acquisition costs, which are the net costs of all pharmaceutical purchases, including shipping and insurance charges from the manufacturer and any duty or customs fees.

- Quality assurance functions, including the cost of sampling, transportation of samples, and laboratory analysis.

- Pre-storage distribution activities, including functions such as port clearing (for imported products), receipt and inspection.

- Other associated distribution-related functions, such as warehousing and storage; inventory control; and information systems and reporting.

Normative functions addressing pharmaceuticals and their appropriate use (medicines and therapeutics committees, selection committees, and medicines utilization review programs) may also need to be accounted for.

Matrix 4: Financing/Procurement Agents to Pharmaceutical Functions

	Financing/Procurement Agents							
Pharmaceutical Functions		CMS	MOH	SCMS	Crown Agents	UNICEF	Private Sector	**TOTAL**
	Procurement	$ U_1		$ W_1		$ Z_1	$ M_1	**$ $U_1+W_1+Z_1+M_1$**
	Acquisition costs	$ U_2		$ W_2		$ Z_2	$ M_2	**$ $U_2+W_2+Z_2+M_2$**
	Quality assurance	$ V_1		$ W_3		$ Z_3	$ M_3	**$ $V_1+W_3+Z_3+M_3$**
	Pre-storage distribution			$ W_4		$ Y_1		**$ W_4+Y_1**
	Distribution • Warehousing and storage • Inventory management • Transportation • Information system and reporting	$ V_2		$ W_5		$ Y_2	$ M_4	**$ $V_2+W_5+Y_2+M_4$**
	Distribution • Within facility	$ V_3		$ W_6		$ Y_3	$ M_5	**$ $V_3+W_6+Y_3+M_5$**
	TOTAL	**$ U+V**		**$ W**		**$ Z+Y**	**$M**	**$ U+V+W+Z+Y+M**

Table 4: Examples of indicators to assess financing for core pharmaceutical functions

Indicators	**Computation from Matrix 2**
CMS financing for procurement as a percentage of total financing	Funds from CMS to procurement/total financing *100
UNICEF financing for procurement as a percentage of total financing	Funds from UNICEF to procurement/total financing*100
Donor financing for all pharmaceutical functions as a percentage of total financing	Funds from SCMS+Crown+UNICEF/total financing *100

SECTION 4: DATA COLLECTION NEEDS FOR ESTIMATING PHARMACEUTICAL EXPENDITURES

Once key actors and flows of funding have been identified, and a framework or matrices for capturing these flows have been developed the next step is to identify pharmaceutical expenditure data sources. Countries should develop a data collection plan that identifies existing secondary data and where primary surveys are needed to fill in gaps.

- Start by mapping type of information needed, time period and level of detail to conduct the estimates as shown in Table 5.
- Develop a timeline for collecting the data
- Identify the key country and international experts who can help identify secondary data sources
- Use the worksheet shown in Table 6 to review secondary data sources to collect information as identified above and also to determine further data gaps to be filled by primary data collection.
- Use the worksheet shown in Table 7 to identify primary data sources and where existing or ongoing surveys can be leveraged.
- Identify if and where freestanding primary surveys are needed, design and implement survey instruments

As a starting point, Annex D suggests potential data sources for information on national and international financing, procurement agents and providers.

Table 5: Worksheet for mapping information needs and possible sources

Actor	Data needed	Possible sources	Contact information	Web links/contact information
MoH				
MoF				
Donors				
Providers				

Table 6: Worksheet for documenting secondary data

Document/source	Year data collected	Description and comments	Assessment of strengths/weaknesses	Web links/contact information

Table 7: Worksheet for identifying existing or ongoing primary data sources

Type of Survey	Year Data Collected	Description and Comments	Assessment of Strengths/Weaknesses	Web links/Contact Information
Donor Survey				
NGO Survey				
Demographic Health Service Survey				
Provider Survey				

Depending on sources mapped in Table 7, additional data may need to be collected for more in-depth analyses, for example to determine whether public financing for pharmaceuticals is reaching the poor, and at what level of the health system. This type of analysis requires household data information describing demographics, health status, and information on private expenditures which is typically collected for Matrix 1. A sample household survey that can be used to collect additional data required for estimating household out of pocket expenditures on pharmaceuticals is included in Annex D.

Once data needs and gaps are identified, countries can begin to implement a plan for primary data collection, first seeking approval to conduct the survey, then designing survey instruments, identifying and training data collectors, and finally analyzing data.

General Data Collection Checklist

☐Develop survey sampling frame

☐Develop survey instruments

☐Identify and train data collectors and data collection supervisors

☐Collect Data

☐Enter/Clean Data

☐Analyze Data

Typically SHA is a country-led process that is carried out by national teams in the MoH, with technical support provided by the WHO or other partners as needed. If a decision to add a pharmaceutical expenditure component to SHA is made, the team could be expanded to include an expert from the Ministry's pharmaceutical division.

SECTION 5: USING PHARMACEUTICAL EXPENDITURE DATA TO DEVELOP INDICATORS FOR DECISION-MAKING

Pharmaceutical expenditure indicator based assessments can be a useful way for countries, donors and international agencies to track and monitor complex pharmaceutical financing flows at the system level, and around the core functions of pharmaceutical supply systems. They can be used to identify problems, critical gaps and opportunities for containing costs in pharmaceutical supply systems. They also can be used to monitor the effects of new policies, demonstrate resource needs, self-report on progress and facilitate cross country comparisons.

Table 5 lists several potential expenditure indicators that can be tracked in a pharmaceutical supply system. While some of the indicators are tied to the matrices in the previous section, many are illustrative indicators can be developed to monitor pharmaceutical expenditures. Most of the indicators can be developed from the data that are collected already as a part of standard reporting on health sector using in SHA matrices. Several require customized matrices (for example financing agents by disease group or National Essential Medicines List) and will need to draw on supplementary secondary and primary data sources. Countries should select indicators that are relevant, easily understood, measurable and useful.

Table 8: Indicators for Monitoring Pharmaceutical Supply Systems

System Level Indicators – can be used to assess financial sustainability
Total Pharmaceutical Expenditure (TPE) Total pharmaceutical expenditure estimated
TPE as a proportion of Total Health Expenditure *(TPE as % of THE) =* $Estimated\ TPE \div Total\ Health\ Expenditure$ Source for THE: Most recent national health accounts estimation or the WHO-SHA database. Note that year of estimation should be the same for both TPE and THE
TPE as a percentage of GDP $Estimated\ TPE \div Gross\ Domestic\ Product$ Source for the GDP can be the Federal/national bank, MOF, or the World Bank macro database. Note that year of estimation should be the same for both TPE and GDP
TPE as a percentage of total national (public) health budget $Estimated\ TPE \div public\ health\ budget$ Source for the public health budget: MOH Finance/Accounting department for the same year.
Total TPE per capita $Estimated\ TPE \div total\ population$ Source for the total population: national bureau for census or UNDP.
Proportion of publicly funded TPE $Sum\ of\ the\ public\ sources\ of\ funding\ \div TPE$ Source for the public sources of funding: sum of total of public sources in Funding sources/Financing Agents table

Proportion of publicly funded PE by quintile or urban/rural or by adults/children or by males/females or other target groups
Proportion of donor funded TPE $Sum\ of\ the\ donor\ funding\ \div TPE$ Source for the donor funding: sum total of donor sources in Funding sources/Financing Agents table
Proportion of TPE funded by Out of Pocket payments. $Sum\ of\ the\ Out\ of\ Pocket\ payments\ \div TPE$ Source for the OOP funding: Colum total of households in Funding sources/Financing Agents table
TPE percentage of top (5) donor contributions to key vertical programs (HIV, TB, Malaria, Vaccines, Reproductive Health) e.g. *Estimated donor contributions* $for\ HIV \div Estimated\ TPE$
TPE by vertical program (MCH, HIV, Malaria, etc.)
Selection – can be used to assess a country's commitment to cost containment
Proportion of generic drugs or commodities of the TPE (versus brand name ones) *Estimated pharmaceutical expenditure for generic÷ TPE*
Proportion of expenditures on drugs included in the National Essential Medicines List *Estimated pharmaceutical expenditure on drugs included in National Essential Medicines List* $\div TPE$
Procurement – can be used to assess how well resources are be used
Proportion of hidden costs *Estimated hidden costs ÷Total costs*
Proportion of pharmaceuticals procured by public, international, or private procurement agents *Value of pharmaceuticals procured by public agent* $\div Value\ of\ all\ pharmaceuticals\ procured$
Proportion of value of drugs domestically produced versus value of drugs imported. *Value of domestically produced pharmaceuticals* $\div value\ of\ all\ pharmaceuticals$ *compared to Value of drugs imported Value of all domestically produced pharmaceuticals* $\div value\ of\ all\ pharmaceuticals$
Proportion of value of drugs managed by the Central Medical Stores
Proportion of value of publicly funded drugs purchased through competitive tender *Value of publicly funded drugs purchased through competitive tender* $\div Value\ of\ all\ drugs\ purchased$
Financing/Use – can be used to assess extent to which private expenses on pharmaceuticals act as a barrier to pharmaceutical access for poor and vulnerable populations
Proportion of TPE channeled through insurance or pre-payment schemes
Proportion of private/out of pocket funding of TPE
Distribution of total pharmaceutical spending by demographic characteristics - If a robust household health expenditure and utilization survey is available TPE by age and sex TPE by socio-economic status TPE by health status TPE by disease TPE by geographical region TPE by urban/rural
Proportion of value of drugs offered for free at primary public health facilities *Value of drugs offered for free* $\div total\ value\ of\ drugs\ offered$
Proportion of out of pocket PE by quintile or urban/rural or by adults/children or by males/females

The estimation of pharmaceutical expenditures and financing flows provides a solid indicator of the "financial health" of a health system, and can be used as a strategic planning tool. The value

of developing and monitoring indicators is not only in the results but also in the "so what" questions that the results can help to answer and the policies and programs that these results can help shape (PHRplus 2003). These results should be analyzed in a broader health policy context including quality and epidemiological factors, government policies and initiatives; and availability of human resources for health.

The primary audiences for the results include national level policy makers and other national and international stakeholders involved in the pharmaceutical system. Secondary audiences include non-governmental organizations (NGOs), the commercial private sector, providers and patients. A data dissemination plan that delineates where data will be stored, which groups will have access to data and when this data will be available is critical to ensuring effective use of results and indicators in decision-making processes.

SECTION 6: RECOMMENDED NEXT STEPS

This paper recognizes that several key steps are necessary before an expenditure-tracking approach can be fully operationalized at the country level. These steps can be summarized as follows:

1) Reach an agreement on an approach that is best suited to country policy and decision-making needs. This involves reviewing challenges in tracking expenditures; reviewing and agreeing on an expenditure-tracking approach; establishing a working group to 1) review and establish potential indicators, expenditure definitions, and boundaries and 2) explore approaches/tools to capture expenditures; and finalizing and documenting a framework or methodology for tracking expenditures.

2) Pilot implementation of the methodology in countries with pharmaceutical supply management systems in varying stages of development and with varying experience with SHA. This involves drafting implementation guidelines and data collection tools and refining and finalizing the approach post-piloting.

3) If SHA methodology is the agreed approach, liaise with SHA/WHO-OECD teams to further develop the methodology/approach and agree on the International Classification for Health Accounts system for pharmaceutical expenditure tracking and a way forward for making it a formal part of SHA. This would involve establishing a multi-stakeholder expert technical working group to finalize normative definition and cost categories issues agreed on by countries; finalizing implementation guidelines and data collection tools; and establishing a capacity-building strategy for countries and conduct pharmaceutical expenditure training workshops in various regions.

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ANNEX A: WORKING DEFINITIONS

1) Total Pharmaceutical Expenditure

As defined by the System of Health Accounts

HC.5.1 Expenditure on pharmaceuticals and other medical non-durables: Total expenditure on pharmaceuticals and other medical non-durables comprises pharmaceuticals such as medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives **and the core management functions associated with the delivery of these products.**

HC.5.1.1 Expenditure on prescription medicines: Prescription medicines are medicines exclusively sold to customers with a medical voucher (prescription), irrespective of whether it is covered by public or private funding and include branded and generic products. In the SHA, this includes the full price with a breakdown for cost-sharing.

HC.5.1.2 Expenditure on over-the-counter medicines: Over-the-counter medicines (OTC medicines) are classified as private households' pharmaceutical expenditure of non-prescription medicines.

HC.5.1.3 Other medical non-durables: This item comprises a wide range of medical non-durables such as bandages, elasticized stockings, incontinence articles, condoms and other mechanical contraceptive devices.

Source: System of Health Accounts 2011 Edition.
http://www.who.int/nha/sha_revision/sha_2011_final1.pdf

As defined by OECD

"Pharmaceutical expenditure covers spending on prescription medicines and self-medication, often referred to as over-the-counter products. For some countries, other medical non-durables such as syringes, bandages, etc. may be included in the total. It also includes pharmacists' remuneration when the latter is separate from the price of medicines. Pharmaceuticals consumed in hospitals are excluded (on average they account for around 15% of total pharmaceutical spending). Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax."

Source: Health at a glance 2011 – OECD Indicators; https://www.oecd.org/els/health-systems/49105858.pdf

As defined at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

Pharmaceutical expenditure consists of price and volume components. Prices may be indicated at different levels: key price types are ex-factor price (manufacturer level), pharmacy purchasing price (wholesale), and the pharmacy retail price (pharmacy). Taxes, such as the value added tax, are likely to be added. In the hospital sector, different price types, e.g. official hospital prices and actual hospital price may apply. Volume may be expressed in sales units, e.g. Standard Units; prescriptions, or Defined Daily Doses. Pharmaceutical policies, e.g. reference price system, prescription monitoring, discounts and rebates, influence prices or volume and thus pharmaceutical expenditure.

Source: http://gabi-journal.net/understanding-the-components-of-pharmaceutical-expenditure-overview-of-pharmaceutical-policies-influencing-expenditure-across-european-countries.html

2) Procurement

"The procurement cycle includes most of the decision and actions that determine the specific medicine quantities obtained, prices paid, and quality of medicines received. *Procurement* is defined here as the process or purchasing supplies directly from national or multinational private of public suppliers; purchasing through global agencies and procurement mechanisms or regional procurement systems; or purchasing from international procurement agents. These sources may be used individually or in combination to meet the entire range of pharmaceutical needs."

The Procurement Cycle includes the following:

- Determining and quantifying needs
- Reconciling needs with available funding
- Determining and selecting procurement method
- Identification and selection of suppliers
- Contracting suppliers and executing work orders
- Monitoring orders
- Receiving order
- Paying supplier
- Distribution of pharmaceuticals to medicines
- Collect data on consumption

Procurement Methods: Procurement of pharmaceuticals can be done at the national or sub-national level by governments or by organizations. The methods used (arrangements and mechanisms) for pharmaceutical procurement varies by country and by health system and will affect the timing, pricing, and administrative processes used to deliver pharmaceuticals. Organizations may use a combination of methods to procure pharmaceuticals. The major types of procurement methods are as follows:

- **Open tender:** Suppliers respond to an invitation for bids from the procurement agency and submit quotes. Qualifications and requirements are specified by the procurement agency in the invitation. The open tender process used by institutions and organizations varies based on their competitive bidding policies.

- **Restricted tender:** Suppliers go through a prequalification process to assess past performance and quality of service.

- **Competitive negotiation:** The buyer approaches severs firms and conducts negotiations. (This was the approach used by UNICEF to negotiate lower ARV prices).
- **Direct procurement:** The buyer procures goods from a single supplier.

- **E-procurements and reverse auction:** Bids from suppliers are posted online, usually anonymously, to encourage competitive bidding among suppliers.

Factors influencing pharmaceutical prices and total costs: Overall costs incurred by a country, or program, includes both explicit and hidden costs. Key categories of costs are the unit price of pharmaceuticals, the reorder frequency, and hidden costs.

- **Unit prices (explicit costs incurred during procurement)**: The price of medicines is usually established by the manufacturers or distributors and varies greatly. Some major contributor factors that influence the unit price of pharmaceuticals include market competitiveness and government policies (registration, manufacturing, and distribution, price regulation)

- **Reorder frequency (other costs incurred during procurement):** The frequency of procurement (interval between orders) and the purchasing model (formula used to calculate order quantity, other) affects other costs incurred during procurement, including costs of holding inventory, costs to operate the purchasing system, and costs incurred to address shortages and stock-outs.

- **Hidden costs:** costs paid during service delivery (not usually paid to supplier) associated with quality and supply chain issues.

List of illustrative costs, presented by cost category

A. Procurement and acquisition:

- Unit price
- Taxes and tariffs
- Operating and administrative costs (personnel and staff time, utilities, overhead, IT and communication costs)

B. Inventory holding costs (carrying costs):

- Storage costs (rental, maintenance, equipment)
- Operating and administrative costs (personnel and staff time, utilities, overhead, other)
- Quality control and inspection costs
- Losses due to waste and theft
- Opportunity costs
- Other?

C. Distribution

- Startup/investment costs (initial costs for infrastructure, equipment)
- Operating costs
    - Salaries, personnel
    - Costs incurred for management or oversight
    - IT system (includes inventory control, records and forms, consumption reports)
    - Communication costs
    - Utilities and overhead
    - Other supplies (packing, unpacking)
- Storage (rental, maintenance costs, other)
- Transportation (international and domestic fees, insurance, fuel other)
    - Fixed costs: cost of vehicle, interest, taxes and fees, insurance, wages and overhead for drive
    - Variable costs: fuel, preventative maintenance, repairs, per diem payments for drivers, parking and other fees incurred
- Quality assurance (inspections, other)
- Losses due to waste and theft

D. Replacement: costs incurred when gods are damaged due to poor quality or issues that arise during transportation. This category also includes costs incurred to ship and replace damaged goods.

3) Distribution

The distribution cycle includes the following steps: clearing or port/airport (if applicable), receipt of goods, inventory control and inspection, storage, allocation of goods, delivery of goods, dispensing to patients, and reporting consumption of goods.

ANNEX B: TOOL REVIEW METHODOLOGY

Research Question: What methodologies and tools exist to estimate and track expenditure for the pharmaceutical sector?

Definition of "Tool": instruments used to forecast or track expenditure of medicines/pharmaceuticals

General Search Terms (Google)

Pharmaceutical expenditure tracking
Pharmaceutical sustainability plans
Health sector financing tools pharmaceuticals
Pharmaceutical spending
Pharmaceutical expenditure tool
Pharmaceutical financial management
Measuring pharmaceutical expenditure
Pharmaceutical budget tracking
Pharmaceutical tracking excel
Vaccine expenditure tracking
Resource tracking pharmaceutical
Pharmaceutical expenditure questionnaire
Essential medicines expenditure tracking
Pharmaceutical spending management system
Pharmaceutical sector country profile
Pharmaceutical oversight tool
SIAPS pharmaceutical expenditure tool
Pharmaceutical "resource tracking"
National pharmaceutical "resource tracking"
Forecasting pharmaceutical spending
Drug supply budget tool
Drug forecast tool

Organization Search

WHO** = yielded results
Futures Institute*
EU*
Global Fund*
GAVI
Clinton Foundation*
UNAIDS*
UNDP
PEPFAR*
Clinton Foundation*
K4Health*
IHME
MSH*

ANNEX C: REVIEW OF EXPENDITURE TRACKING TOOLS

Expenditure Tracking Tool	Description	Intended Users	Strengths	Weaknesses
Health Sector				
1. One Health Tool, Futures Institute, 2012 http://www.futuresinstitute.org/onehealth.aspx	• National health sector with a focus on focus on public sector health interventions • Planning, costing, budgeting, financing, of strategies for all major disease and health system components	• Experts involved in national health planning, including government health planners, UN agencies, nongovernmental organizations, donors, researchers and consultants	• Focus on public sector, although activities in the private sector can be incorporated • Limited analysis of resource gaps, pharmaceutical resource flows are not tracked across core functions	• Limited analysis of resource gaps, pharmaceutical resource flows are not tracked through core pharmaceutical functions and activities
2. System of Health Accounts (SHA)[6], WHO et al, 2011 http://www.who.int/health-accounts/methodology/en/	• Internationally standardized framework for systemically tracking expenditures in a health system	• Ministries of Health, Ministries of Finance, donors	• A universally accepted, rigorous and comprehensive methodology endorsed by the WHO and used in more than 100 countries for tracking different types of health expenditures[7] • Classifies type, purpose and all actors in a health system • Technical support and resources are available to support country implementation • Countries carry out SHA estimations routinely so including pharmaceutical expenditure tracking pharmaceutical expenditure tracking would only add a marginal cost • SHA expertise /capacity already exists in many countries	• Pharmaceutical expenditure tracking would be tied to SHA timing/schedule • Household survey data is a necessary input because of the high proportion of private expenditures

[6] First published in 2000, SHA was adapted in 2003 to a developing country context in a version called National Health Accounts (NHA). OECD, EUROSTAT and WHO recently updated SHA to SHA 2011 (OECD et al 2011). Going forward the SHA 2011 framework will be used by all countries. Source: https://www.hfgproject.org/wp-content/uploads/2014/03/SHA-Brief.pdf

[7] https://www.usaid.gov/news-information/fact-sheets/health-systems-2020-hs-2020

Expenditure Tracking Tool	Description	Intended Users	Strengths	Weaknesses
			• Sources of data for pharmaceutical expenditure tracking are similar to SHA – particularly, at donor, household and national government levels	
Pharmaceutical Sector				
3. Core indicator package to monitor and evaluate country pharmaceutical situations, WHO and the Global Fund, 2007 http://www.who.int/medicines/areas/policy/monitoring/en/ http://apps.who.int/medicinedocs/documents/s14877e/s14877e.pdf	• Indicators to monitor and evaluate country pharmaceutical situations • Level I measures national level processes and structures • Level II assesses outcomes, including access, quality and safety, and rational use of essential medicines at public health facilities and pharmacies • Level III is designed to assess specific aspects of the pharmaceutical sector, such as medicines prices, the supply system, or traditional medicines	• Ministries of Health	• A systematic way to gather data for monitoring and assessment of pharmaceutical activities and objectives at the national and facility levels and for key components of the pharmaceutical sector	• Limited focus on financing and expenditures
4. Tools for mapping financial flows for medicines procurement and distribution, and for rapid assessment of medicines supply management systems, WHO , 2012 http://www.who.int/medicines/areas/access/supply/en/index6.html	• A two stage assessment designed to: 1) map funding sources for medicines and medical products in pharmaceutical system; 2) rapidly assess medicines procurement and supply management systems	• Ministries of Health, donors	• Mapping of funding flows helps to strengthen coordination. Rapid assessment of procurement and supply systems is a way to identify strengths and weaknesses and inform strategies for improving them	• Specific focus on mapping financing by pharmaceutical products, expenditures at provider or household level are not quantified
5. Pharmaceutical Sector Country Profile Questionnaire, WHO, The	• Consolidates data on pharmaceuticals available through the	• Administrators at WHO and Global Fund; other decision makers, health	• Data collected can be used to highlight overall strengths and weaknesses in the	• Tool is designed to provide information on structures, processes and outcomes

Expenditure Tracking Tool	Description	Intended Users	Strengths	Weaknesses
Global Fund, 2010 http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf	National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.		pharmaceutical sector and is meant to available in a national database for use by decision makers, pharmaceutical experts and the donor community	and does not allow for an analysis of resource gaps • Limited data collection on pharmaceutical expenditures, financing and household use
6. WHO Data Collection Tool for the Assessment of Drug Regulatory Systems, WHO, 2007 http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/	• Assessment for quality assurance and M&E of the drug regulatory system.	• Regulatory authorities	• Practical guidance and tools for assessing regulatory systems	• Specific to data collection for WHO Drug Regulatory Review
7. Rapid Pharmaceutical Management Assessment: an indicator based approach, MSH, 1995 http://www.msh.org/resources/rapid-pharmaceutical-management-assessment-an-indicator-based-approach	• Country-level assessment of pharmaceutical systems operations • A step-by-step manual that describes 46 indicators for function and activity within a pharmaceutical system.	• Ministries of Health	• Provides 46 performance indicators, grouped into eight topics of pharmaceutical management: policy/ regulation; essential drug information; national budget; national pharmaceutical procurement; national pharmaceutical logistics; patient access to drugs; quality assurance; private sector pharmaceutical activity	• Does not specifically track or forecast expenditure on pharmaceuticals
8. Price and Quality Report Tool (PQR), The Global Fund, Voluntary Pooled Procurement Programme, 2012 https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting/	• When quantifying and budgeting country-level TB, malaria and HIV/AIDS drug requirements	• Global Fund Principal Recipients and Local Fund Agents	• Publically available database with drug prices paid by grant recipients; complements internal Global Fund PQR processes used by recipient countries	• Full PQR reporting/ forecasting tools not publically available online • Specific focus on monitoring procurement
Disease/Health Intervention				
9. Global Drug Facility Drug Calculation Tool, Global Drug Facility, 2011 http://www.stoptb.org/gdf/drugsupply/psmtools.asp	• Quantification and budgeting of TB drug requirements	• National-level health decision maker or program administrator	• Can be used to compare costs of different TB regimens and calculate costs per patients using different cost scenarios	• Specific focus on TB; does not allow for comprehensive analysis of pharmaceutical expenditures

Expenditure Tracking Tool	Description	Intended Users	Strengths	Weaknesses
10. ARV Procurement Forecast Tool 1.4, Clinton Health Access Foundation, Updated in 2011 http://www.who.int/hiv/amds/CHAI_forecasting/en/	• Quantifying and budgeting ARV demands during the first 12 months of a program.	• Program managers working on HIV/AIDS	• Tool for forecasting demand for ARVs and generating purchase orders	• Specific to ARV procurement only
11. PEPFAR Expenditure Analysis Initiative, PEPFAR, 2012 https://www.pepfar.gov/documents/organization/195700.pdf	• Assessment of expenditures for PEPFAR; forecasting of program expenditures	• National-level program administrator for PEPFAR	• Effective methodology for strategic planning for national HIV/AIDS response.	• No explicit or detailed tracking of pharmaceutical expenditures; includes line items referred to as "cost categories" for ARVs, test kits, etc.
12. National AIDS Spending Assessment, UNAIDS, 2009 http://www.unaids.org/en/dataanalysis/datatools/nasapublicationsandtools/	• National-level assessment of HIV/AIDS spending	• Country-level decision makers in health; international experts; donors	• Provides indicators of the financial country response to HIV and AIDS and to support monitoring of resource mobilization.	• Specific focus on HIV/AIDS
13. Family Planning Advocacy Toolkit, K4H, 2011 https://www.k4health.org/toolkits/family-planning-advocacy/gap-tool-gather-analyze-and-plan	• Planning and budgeting of costs associated with family planning	• Policymakers, ministry and health officials, donors, other experts	• Provides information on country's funding gaps for a national FP program and for FP commodities	• Specific focus on costs associated with expanding family planning
14. Forecasting and Costing of Medicines – Module for HIV/AIDS Commodities, mediCT, 2009 http://www.psmtoolbox.org/en/export-tool%7CQuantification%7CFoCaMed%7C75.pdf	• Forecasting and budgeting for adult HIV/AIDS medicines	• Health program administrators; health experts	• Calculates supply needs and budget implications of patients (adults and children) with a chronic disease (AIDS) who are on different treatment regimens and using different formulations	• Designed to be used at the health facility level
15. Enhancing Contraceptive Security Through Better Financial Tracking, USAID DELIVER Project–JSI, 2013 https://www.k4health.org/sites/default/files/enhacsfin_0.pdf	• Designed to help family planning stakeholders to map and track financing flows for contraceptives	• Governments, donors, technical assistance agencies	• How-to guide for "following the money" for contraceptive financing to enable monitoring of trends, understanding of funding gaps and mobilization of needed resources	• Specific focus on expenditure tracking for contraceptives (commodities) and not supply chain management

Expenditure Tracking Tool	Description	Intended Users	Strengths	Weaknesses
16. Comprehensive Multi-Year Plan for Immunization CMYP, WHO/UNICEF/GAVI, 2005 http://www.who.int/immunization/programmes_systems/financing/tools/cmyp/en/	• Designed to answer questions about resources needs of immunization programs–source funding and resource gaps–to prioritize activities based on available funds	• Country-level immunization program managers in the MoH, donors	• Estimates past costs and financing of immunization, and projects future costs, future resources requirements, and future financing needs to achieve program objectives. Also facilitates analysis of corresponding financing gap.	• Specific focus on immunization costing and financing only

ANNEX D: HOUSEHOLD HEALTH EXPENDITURE QUESTIONNAIRE – MODULE ON PHARMACEUTICAL SPENDING

Rationale: The objective of this module on household pharmaceutical spending is to estimate the out of pocket expenditures incurred by households on medicines; where the medicines are purchased; how they are paid for; and the typical types of medicines that are being purchased to address acute and chronic illnesses.

This module should be administered as a module included within the comprehensive household health expenditure and utilization survey, following the same research protocol, sampling framework, and ethical considerations. If administered on its own, then, all of the issues mentioned earlier need to be addressed. The module is a list of illustrative questions and not formatted as a survey.

Caveats/Assumptions:

1) These set of questions are categorized based on nature of illness – Acute or Chronic, to better understand the nature of illness and the pattern of seeking medication. It can be adopted to capture in-patient and out-patient care based on how the main household survey is structured.
2) This list of questions is not an exhaustive list, but a starting point, and the language and structure of the questions will have to be redrafted accordingly.
3) Questions on wealth/income quintiles for equity analysis are not included in this module, as it is assumed they are a part of the main household survey.
4) The recall period should be same as that stipulated in the main survey. If the main survey uses variable recalls, then these questions should use a two-week recall period.
5) Questions are adapted from existing household health expenditure surveys.

Some key indicators on access, use, and affordability:

- Expenditures on pharmaceuticals as % of total health expenditures
- % of households which experienced catastrophic payments related to medicines
- % of households who cannot afford to buy the medicines they need
- % of households with acute illness who fail to take prescribed medicines because they cannot afford them
- % of households with chronic illness who fail to take prescribed medicines because they cannot afford them
- % of households who bought medicines from public facility
- % of households who bought medicines through health insurance
- % of household who bought medicines at a private facility

Respondent: Head of the Household or Household Informant should be the person in the household who is the main health care decision maker. This is usually the person who is the most knowledgeable about the health, health care expenditures, and health care utilization of members of the household.

Questions on attributes of the household such as how many members, their ages, gender, etc. are not included here because they would have already been captured in the main section of the household survey.

1) Has anyone in this household been ill in the past two weeks with an acute illness? An acute illness is a condition that appears suddenly: the person did not have it immediately before becoming ill.

   Yes: ___
   No: ___
   Do not know: _____ If No, or Do not Know skip to Question 4

2) Include name, gender, and age for each person in who has experienced an episode of acute illness and fill out Questions 2-14 for <u>each</u> household member who experienced an acute episode.

3) What type of health problems/symptoms did ***(first name)*** have during this illness? Tick all that apply.

   a. Cough, runny nose, sore throat, ear ache
   b. Thirst, sweating
   c. Difficulty breathing, fast breathing
   d. Pain, aches
   e. Fever, headache, hot body
   f. Bleeding, burn, accident, broken bone(s)
   g. Convulsions, fit
   h. Do not know
   i. Could not sleep
   j. Diarrhea, vomiting, nausea, could not eat
   k. Other

4) Has anyone in the household been diagnosed with a chronic disease? A chronic disease is an illness that will not go away or takes a long time to go away, even when treated. For example, blood pressure, diabetes, arthritis,

   Yes:____
   No:_____
   Do not know: _____

   If response to both Q.1 and Q.4 is No, then there are no more questions for the respondent in this module, move on to the next section.

5) Include name, gender, and age for each person who has experienced chronic illness and fill out questions 15-24 for <u>each</u> household member who experienced chronic illness.

ACUTE ILLNESS

6) At any point did (first name) or anybody else on his/her behalf seek care for this episode outside home?

   Yes:___
   No: ___, if No, skip to Question 15

7) Where did (first name) receive care at any time during the episode? Tick all that apply.

   a. Public hospital
   b. Mission or NGO hospital
   c. Public health care center or dispensary
   d. Private hospital or clinic
   e. Traditional healer
   f. Private pharmacy
   g. Drug seller
   h. Friend or neighbor

8) How much total (tests, doctor's fees, medicines etc.) did the household pay for this episode? (Note: Some version of this question is likely to be included elsewhere in the main questionnaire)

   Enter amount in local currency _____

9) How did you pay for it? Check all relevant responses.

   a. Health insurance *(use country relevant appropriate term to capture the essence of risk pooling)*
   b. Out of pocket (full amount or co-pay)
   c. Free treatment
   d. Borrowed
   e. Other - specify

10) Did you have to take any medicines for this episode?

    Yes_____
    No_____, If No, go to Question 16

11) If yes, what type of medicines? List them all (Please include the specific name of the medicines; the medicines can then be coded to reflect whether they are a specific brand name or generic).

    a. _____
    b. _____
    c. _____
    d. _____
    e. _____

12) Where did you buy or procure the medicines from? Check all relevant responses.

a. Pharmacy based in a public health facility/hospital
b. Mission or NGO facility
c. Pharmacy based in a private health facility/hospital
d. Private (stand-alone) pharmacy
e. Traditional healer
f. Drug seller
g. Friend or neighbor

13) Why did you choose to buy or procure the medicines from this particular (see response from Q.12) outlet? Check all relevant responses.

a. Distance to the pharmacy
b. Perceived quality of medicines
c. Availability of medicines
d. Free
e. Stipulated by insurance network
f. Store credit with the particular pharmacy
g. Relationship with the pharmacist

14) How did you pay for the medicines? Check all relevant responses.

a. Health insurance *(use country relevant appropriate term to capture the essence of risk pooling)*
b. Out of pocket (full amount or co-pay)
c. Free treatment
d. Borrowed
e. Other, specify

15) If answer to Question 6 was No, then follow up with the following question. Possible reasons for not seeking medical care.

a. Did not perceive the illness to be serious enough
a. Nearest medical facility too far
b. No time
c. No transportation means
d. No money
e. Other, specify

16) If the answer to Question 10 was No, then follow up with the following question. Possible reasons for not taking medicines.

a. Symptoms got better
b. Someone in the household decided medicines were not necessary
c. Allergic reaction to the prescribed medicines
d. Severe side effects (medication not tolerated well so discontinued)
e. Medicines were not available at public health care facility

f. Medicines were not available at the nearest outlet (pharmacy, drug seller)
g. Could not afford to buy medicines
h. No time to obtain medicines
i. Other, specify

CHRONIC ILLNESS

17) Which chronic diseases does (first name) have? Tick all that apply.

a. Hypertension, high blood pressure
b. Heart disease
c. Diabetes mellitus
d. Asthma
e. HIV/AIDS
f. Epilepsy
g. Ulcer, chronic Gastro Intestinal related issues
h. Stroke consequences
i. High cholesterol
j. Cancer
k. TB
l. Liver disease
m. Depression, other mental
n. Other, Specify

18) At any point did (first name) or anybody else on his/her behalf seek care for this illness outside home?

Yes:___
No: ___,
Do not know: ____if No, skip to Question 27

19) Where did (first name) receive care at any time during this episode. Check all that apply

a. Public hospital
b. Mission or NGO hospital
c. Public health care center or dispensary
d. Private hospital or clinic
e. Traditional healer
f. Private pharmacy
g. Drug seller
h. Friend or neighbor

20) How much total (tests, doctor's fees, medicines etc.) did the household pay for this illness (in the last one year?)? (Note: Some version of this question is likely to be included elsewhere in the main questionnaire).

Enter amount in local currency _____

21) How did you or your family pay for it? Check all relevant responses.

a. Health insurance
b. Out of pocket (full amount or co-pay)
c. Free treatment
d. Borrowed
e. Other

22) Did you or family member have to take any medicines for this episode?

Yes_____
No_____,
Do not know____If No or do not know, got to Question 28

23) If yes, what type of medicines? List them all (Please include the specific name of the medicines; the medicines can then be coded to reflect whether they are a specific brand name or generic by the survey coder).

a. _____
b. _____
c. _____
d. _____

24) Where did you buy or procure the medicines from? Check all relevant responses.

a. Pharmacy based in a public health facility/hospital
b. Mission or NGO facility
c. Pharmacy based in a private health facility/hospital
d. Private (stand-alone)pharmacy
e. Traditional healer
f. Drug seller
g. Friend or neighbor

25) Why did you choose to buy or procure the medicines from this particular (see response from Q.24) outlet? Check all relevant responses.

a. Distance to the pharmacy
b. Perceived quality of medicines
c. Availability of medicines
d. Free
e. Stipulated by insurance network
f. Store credit with the particular pharmacy
g. Relationship with the pharmacist

26) How did you pay for the medicines? Check all relevant responses.

a. Health insurance
b. Out of pocket (full amount or co-pay)
c. Free treatment
d. Borrowed
e. Other

27) If answer to Question 18 was No, then follow up with the following question. Possible reasons for not seeking medical care.

a. Did not perceive the illness to be serious enough
b. Nearest medical facility too far
c. No time
d. No transportation means
e. No money

28) If the answer to Question 22 was No, then follow up with the following question. Possible reasons for not taking medicines.

a. Symptoms got better
b. Someone in the household decided medicines were not necessary
c. Allergic reaction to the prescribed medicines
d. Side effects caused to discontinue the medicines.
e. Medicines were not available at public health care facility
f. Medicines were not available at the nearest outlet (pharmacy, drug seller)
g. Could not afford to buy medicines
h. No time to obtain medicines
i. Other

ANNEX E: POTENTIAL DATA SOURCES FOR MATRICES 1-4

National Financing of Pharmaceutical Supply

a. All budget line items associated with pharmaceuticals and medical commodities from audited expenditure accounts at Ministry of Finance/Treasury at national or/and sub-national level.
b. Central Medical Stores and/MOH executed procurement plans at national or/and sub-national level
c. Purchasing or stock records
d. Vertical program executed procurement plans – HIV, TB, Malaria, Vaccines etc.
e. Public/autonomous government hospitals or mission hospitals
f. Medicines Regulatory Agency
g. Ministry of Trade for tracking exports and imports of pharmaceuticals
h. National Bureau of Statistics
i. National or Social Health Insurance Agency
j. Non-Governmental Organizations
k. Private Health Insurers
l. Professional Organizations: physicians, pharmacists, nurses
m. WHO Level I survey (where available, not in all countries) Standardized key informant questionnaires assess the structures and processes related to medicines in a country legislation and regulations; quality control of medicines; essential medicines lists; supply systems; financing; production; rational use; and protection of intellectual property rights.
n. Primary data collection through surveys of private sector corporations to assess their extent of expenditures on pharmaceuticals and medical commodities.

International Financing of Pharmaceutical Supply

a. Donor surveys to estimate their annual contribution to pharmaceutical expenditures. Typically getting donor expenditures on health in general is not an easy task, so primary data collection is the best approach.
b. WHO Statistical Information System (WHOSIS) http://www.who.int/whosis/en/index.html
c. WHO Global InfoBase http://www.who.int/infobase/report.aspx
d. World Bank Development Report http://siteresources.worldbank.org/INTWDR2009/Resources/4231006-1225840759068/WDR09_22_SWDIweb.pdf
e. National Macroeconomics and Health Report http://www.who.int/macrohealth/en/
f. WHO National Health Accounts http://www.who.int/nha/en/
g. WHO Global Burden of Disease and Risk Factors database http://www.who.int/healthinfo/bod/en/index.html
h. Demographic and Health Surveys (DHS): http://www.measuredhs.com/aboutsurveys/start.cfm
i. World Bank Health and Nutrition Data Base (HNPStats)

http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTHEALTHNUTRITIONANDPOPULATION/EXTDATASTATISTICSHNP/EXTHNPSTATS/0,,menuPK:3237172~pagePK:64168427~piPK:64168435~theSitePK:3237118,00.html

j. WHO Level I Pharmaceutical Assessment http://www.who.int/medicines/areas/technical_cooperation/supply_management/AssessMonit/en/index.html
k. WHO Multi-Country Study on Effective Drug Regulation http://www.who.int/medicinedocs/en/d/Js2300e/#Js2300e.17.
l. WHO Ethical Infrastructure for Good Governance http://www.who.int/medicines/areas/policy/goodgovernance/Ethical_Infrastructure.pdf
m. IMS Pharmaceutical Market Assessment Data: http://www.imshealth.com/portal/site/imshealth
n. WHO World Medicines Situation (WMS) http://www.who.int/medicines/areas/policy/world_medicines_situation/en/
o. World Trade Organization: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm
p. International Federation of Pharmaceutical Manufacturers & Associations: https://www.ifpma.org/who-we-are/ifpma-in-brief/
q. Pharmaceutical Security Institute: http://www.psi-inc.org/index.cfm
r. WHO/Health Action International Medicine Price Surveys: http://www.haiweb.org/medicineprices/
s. Reports for the pricing surveys conducted in African countries can be found at: http://www.haiweb.org/medicineprices/
t. In addition to price surveys, WHO/HAI provides information about promotion of medicines at: http://www.haiafrica.org/index.php?option=com_sectionex&view=category&id=24&Itemid=60
u. INRUD: The International Network for Rational Use of Drugs (INRUD) http://apps.who.int/medicinedocs/en/d/Js21188en/
v. WHO World Health Survey (WHS): http://www.who.int/healthinfo/survey/en/
w. International Household Survey Network (IHSN): http://surveynetwork.org/home/
x. Uppsala WHO Collaborating Centre: http://www.who-umc.org

Data from procurement agents

a. Primary data collection through a survey of all procurement agents
b. Forecasting plans from the Central Medical Store and other vertical programs may also help triangulate gaps in information.

Data from providers

a. Household surveys to ascertain out of pocket payments
b. Facility/provider records
c. Insurer records to ascertain out of pocket payments in the form of co-payments or deductibles