

## CHAPTER 10

### PHARMACEUTICAL MANAGEMENT MODULE

#### 10.1 Overview

This chapter presents the pharmaceutical management module of the assessment manual. Section 10.1 defines pharmaceutical management, the key functions of pharmaceutical management, and the various processes that make up a pharmaceutical management system. Section 10.2 provides guidelines on preparing a profile of the pharmaceutical management system in the country of interest. Section 10.3 provides details on pharmaceutical management indicators. Section 10.4 is a brief guide to summarizing the findings and using them to recommend the next steps.

##### 10.1.1 What Is Pharmaceutical Management?

Careful management of pharmaceuticals is directly related to a country's ability to address public health concerns. Even so, many health systems and programs run into difficulty achieving their goals because they have not addressed how the medicines essential to saving lives and improving health will be managed, supplied, and used. Pharmaceuticals can be expensive to purchase and distribute, but shortages of essential medicines, improper use of medicines, and spending on unnecessary or low-quality medicines also have a high cost—wasted resources and preventable illness and death.

Because medicines are so important and resources so limited, ways have been developed to improve the supply and use of medicines while minimizing costs. Pharmaceutical management represents the whole set of activities aimed at ensuring the timely availability and appropriate use of safe, effective quality medicines and related products and services in any health care setting.

The following terms are used in pharmaceutical management.

- **Bid:** A bid is document prepared in response to an expression of procurement needs (also known as a *tender*).
- **Cold chain:** The distribution system used for the storage and transport of pharmaceuticals that require refrigeration (e.g., certain vaccines) is called a *cold chain*. In some countries a formal cold chain is also managed through a vertical program such as an immunization program (e.g., Expanded Programme on Immunization [EPI]).
- **Essential medicines:** The World Health Organization (WHO) defines essential medicines as the limited number of medicines that satisfy the needs of the majority of the population and that should be available at all times. Countries often publish a national essential medicines list (NEML) that identifies the medicines considered to be most important and relevant for the public health needs of that population.
- **Kits:** Kits are standardized packages of essential medicines and supplies that are delivered to the facility. Type and quantities of contents are determined by expected

utilization rates for predefined services. Kits are generally part of a *push* distribution system that does not use requisitions.

- **Lead time:** The time needed to prepare bids, the time required to make an award and place an order, the time required to receive the delivery, and the time between receipt and payment are all defined as *lead time*.
- **Pharmaceuticals:** The term *pharmaceuticals* encompasses medicinal products, vaccines, contraceptives, diagnostics, and medical supplies.
- **Push/pull systems:** Push and pull are two types of distribution systems. In push systems, quantities of supplies and the schedule for their delivery to facilities are determined at a higher (usually central) level with little to no input from lower levels. In pull systems, facilities provide information on actual consumption and needs estimates to higher levels.
- **Rational medicine use:** Rational medicine use occurs when clients/patients are prescribed and dispensed the full amount of the appropriate, quality medicines at the lowest cost to them, to their communities, and to the system, and when clients/patients take the medicines correctly and without interruption.
- **Standard treatment guidelines (STGs):** STGs are disease-oriented guidelines that reflect a consensus on the treatments of choice for common medical conditions. They help practitioners make decisions about appropriate treatments and help to minimize variation in treatments offered by practitioners in the health care system.
- **Tracer products:** Approximately 20 pharmaceuticals or commodities that are selected to evaluate availability of essential products. The items to be selected for a tracer list (see Table 10.1 for a sample) should be relevant for public health priorities and should be expected to be available at all times in the level of facilities of interest (e.g., clinics or hospitals). They are, therefore, likely to be on the NEML.
- **Tender:** Same as *bid*.

For additional definitions and information, see MSH (1995), MSH and WHO (1997), and WHO (2006).

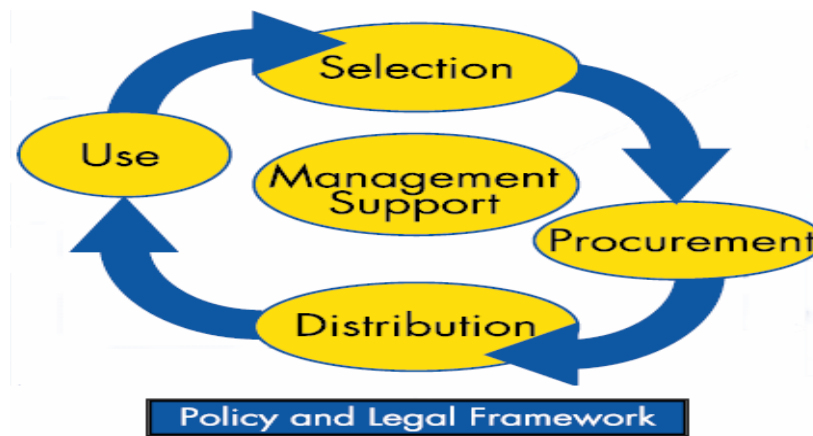
**Table 10.1 Example Trace Product List**

<b>Product</b>	<b>Form, Dosage</b>
Analgesic and antipyretic medicines	
Acetylsalicylic acid (aspirin)	Tablet, 300 mg
Paracetamol	Tablet, 500 mg
Antihelminthic medicines	
Mebendazole	Chewable tablet, 100 mg
Anesthetic medicines	
Ketamine	Vial, 50 mg/ml
Antibacterial medicines	
Amoxicillin	Tablet, 250 mg
Metronidazole	Tablet, 450 mg
Benzympenicillin sodium	Vial, 5 megaunits
Sulfamethoxazole + trimethoprim (co-trimoxazole)	Tablet, 400 mg + 80 mg
Ciprofloxacin	Tablet, 500 mg
Doxycycline	Tablet, 100 mg
Erythromycin	Tablet, 250 mg
Gentamicin	Ampoule, 40 mg/ml
Rifampicin + isoniazid	Tablet, 150 mg/100 mg
Antimalarial medicines	
Sulfadoxine-pyrimethamine	Tablet, 500 mg/25 mg
Quinine dihydrochloride	Ampoule, 300 mg/ml
Cardiovascular medicines	
Propranolol	Tablet, 40 mg
Hydrochlorothiazide	Tablet, 25 mg
Gastrointestinal medicines	
Oral rehydration salts	Sachet
Minerals	
Ferrous sulfate + folic acid	Tablet, 200 mg/0.25 mg
Ophthalmological preparations	
Oxytetracycline eye ointment 1%	Tube, 5 mg
Vaccines	
Polio vaccine	Vial

### **10.1.2 How Does Pharmaceutical Management Work?**

Pharmaceutical management is the set of practices aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines, health products, and services in any health care setting. These activities are organized according to functional components of a cycle or system and may take place at various levels of the health system according to the design of the health system. The components are the same for all sectors although procedures and activities within each component may differ.

Activities in the pharmaceutical management system are related to the selection of products that are to circulate in the supply system and to their procurement, distribution, and use (see Figure 10.1).



Source: *Management Sciences for Health*

**Figure 10.1 Components of the Pharmaceutical Management Cycle**

The pharmaceutical management cycle operates within and is affected by a political, legal, and regulatory framework. This framework defines health priorities that have an impact on the following—

- The types of products and services that can or should be offered at different types of facilities
- The types of personnel needed and required qualifications for carrying out various responsibilities related to the functioning of the cycle
- Quality assurance standards and financial requirements to be met

This cycle applies to the public and private sectors. The capacity to carry out these activities is mediated by the level of management support that is available. Management support includes information systems, human resource capacity, and financial resources.

## 10.2 Developing a Profile of Pharmaceutical Management

### 10.2.1 General Issues

The system of pharmaceutical management generally reflects the health care system in which it operates. The first step to developing a profile of the pharmaceutical management system in a country is to sketch out how the overall health system is organized and how it functions. The following questions should be answered before collecting indicator data.

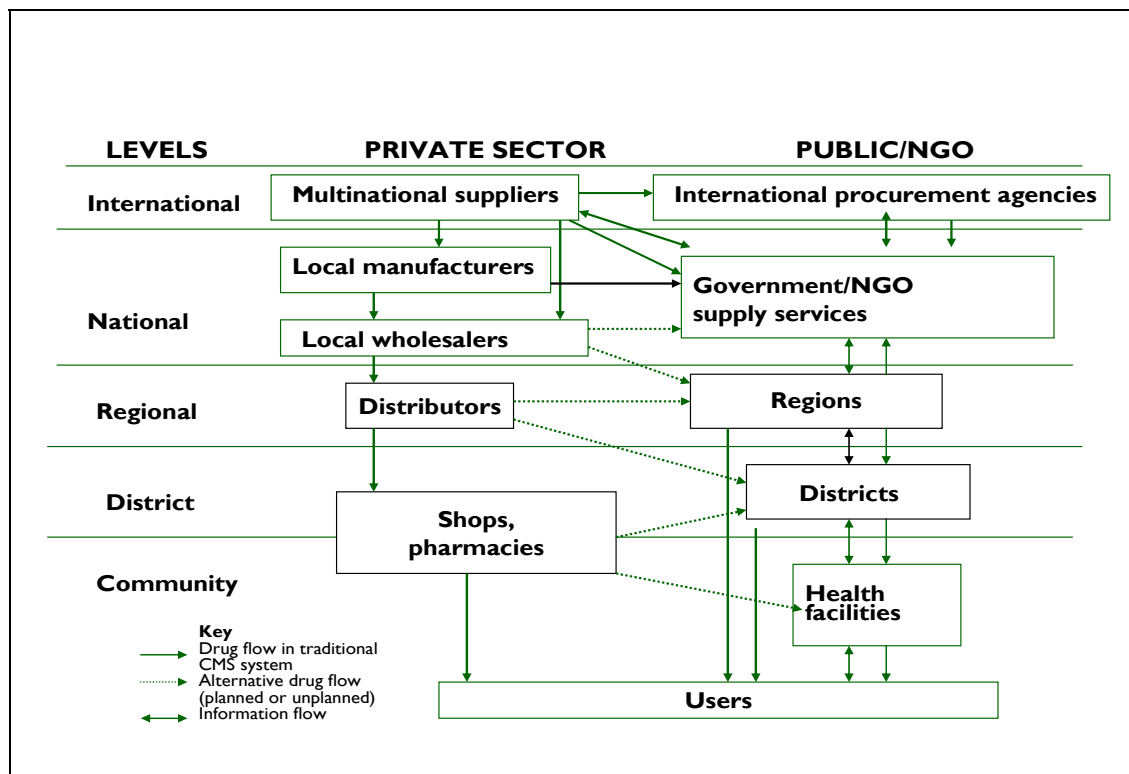
- What is the participation of various levels of care in the public healthcare system? Of the nongovernmental organizations (NGOs) health care delivery system? Of the private health care system?
  - Primary level of care (e.g., health post or clinic)
  - Secondary level of care (e.g., district hospital)
  - Tertiary level of care (e.g., specialized hospital)
- What has been the country's experience with health sector reform (e.g., decentralization, privatization)?
- Are NGOs present in the country? What is their role?
- Are vertical programs present?<sup>1</sup> What is their role?
- What are the prevalence and incidence of major health problems?
- What role do donors play in managing and providing pharmaceuticals?
- What trade issues apply, including the influence of global and regional trade agreements or initiatives (e.g., North American Free Trade Agreement, Central American Free Trade Agreement, Mercosur, Economic Community of West African States, Association of Southeast Asian Nations, World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, Southern African Development Community)?

---

<sup>1</sup> Vertical programs, such as tuberculosis, Integrated Management of Childhood Illness, or malaria programs, may operate with program-specific essential medicine lists, STGs, procurement processes, and distribution systems. In cases where vertical programs conduct separate functions from the general public system, the basic components of the pharmaceutical management cycle apply. For a general evaluation of the performance of the pharmaceutical management system, however, determining the effectiveness of their contribution to the access of pharmaceuticals is generally sufficient. For example, tracer lists that are used to assess the availability of key products may include products that are sourced through vertical programs. Problems with availability may then lead to further inquiry to determine why availability is poor.

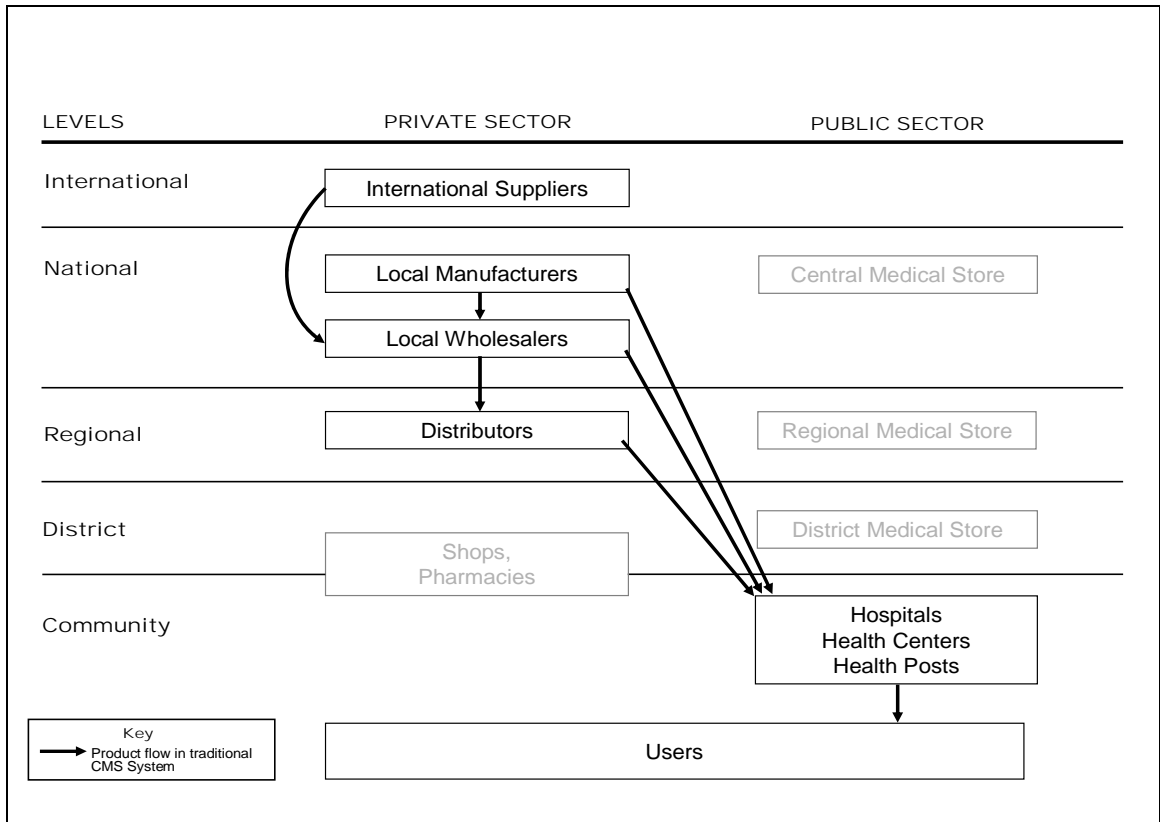
### 10.2.2 Pharmaceutical Management Flows

The pharmaceutical management system can be diagrammed in terms of the flow of information, funds, and products. The activities involved with carrying out each component of the pharmaceutical management system can be diagrammed. Perhaps the easiest place to start in developing a profile is by diagramming the distribution system to show how pharmaceuticals enter and move through the country. Figure 10.2 diagrams a typical multilevel distribution system, including the participation of the private sector in the public sector supply system. Figure 10.3 diagrams an alternative public sector system in which storage and transportation functions are contracted out to the private sector distributors. Additional flows may be added to demonstrate the flow of funds, including the budget allocation, procurement, payments to suppliers, and payments from clients/patients. Similarly, diagrams can be made to illustrate the process of selecting and quantifying pharmaceuticals. These models allow for numerous potential variations. Determining the best model for any particular context is beyond the scope of this assessment.



Note: CMS = Central Medical Stores  
 Source: Management Sciences for Health

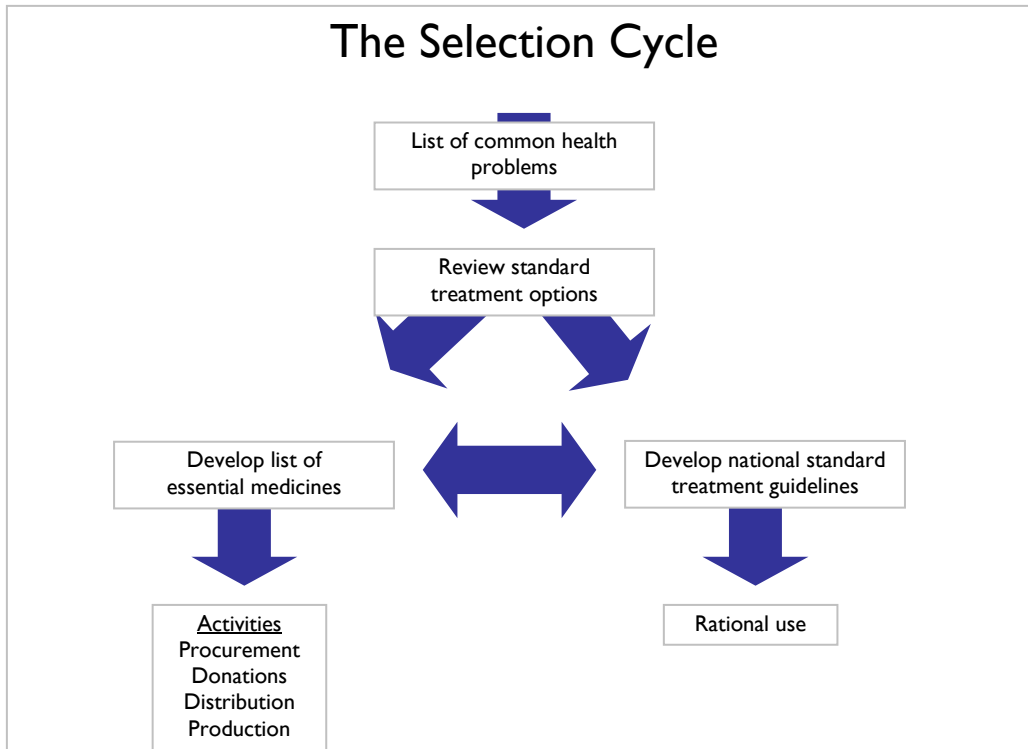
Figure 10.2 Typical Country Distribution System



Note: CMS = Central Medical Stores  
 Source: Management Sciences for Health

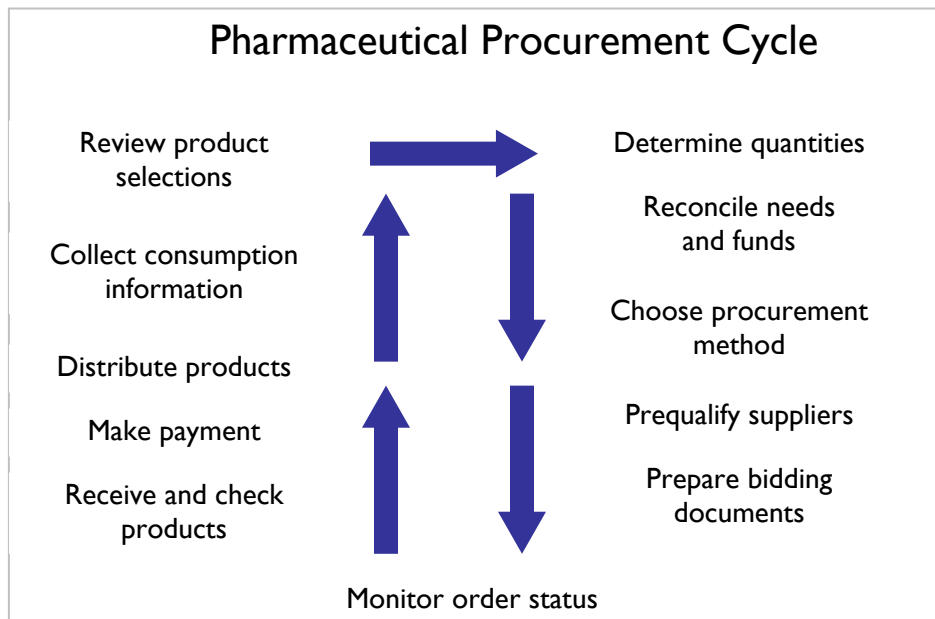
**Figure 10.3 Direct Delivery Model for Distribution**

The following diagrams (Figures 10.4, 10.5, and 10.6) highlight critical steps in the system’s selection, procurement, and distribution components. The specific agency or entity responsible for carrying out these activities, and therefore the source of key indicator data, can differ from country to country. Some functions, such as procurement, may be contracted out by the public sector to private agencies. One source for this information is the national medicines policy. Alternatively, this information can be determined in the course of the in-country assessment.



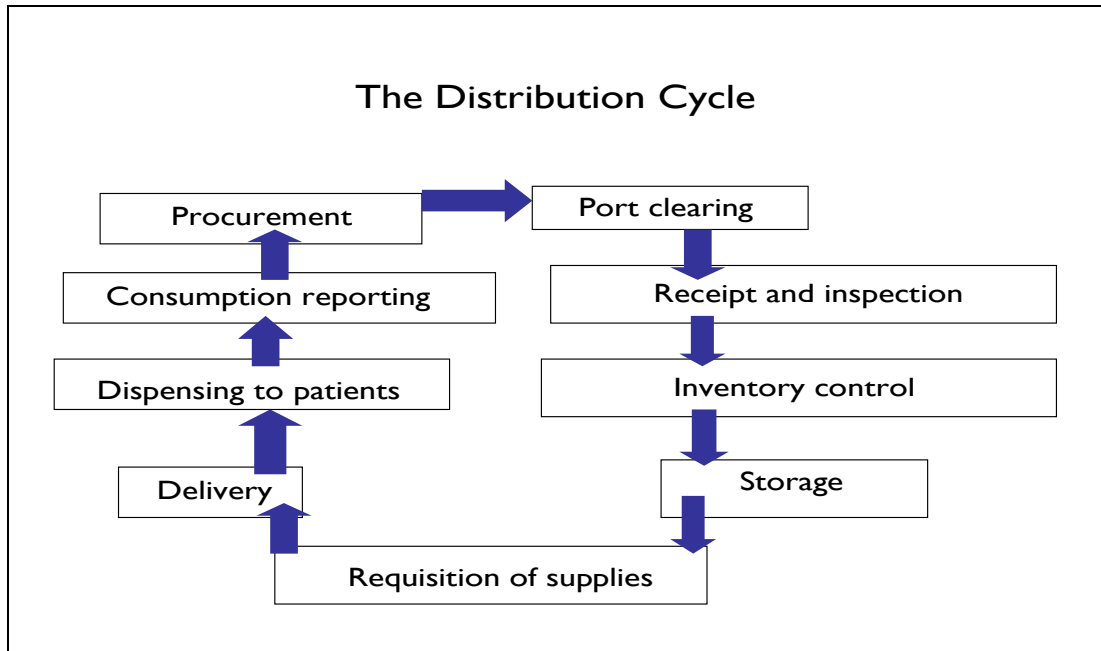
Source: Management Sciences for Health

**Figure 10.4 Components of the Selection Process for a Public Health System**



Source: Management Sciences for Health

**Figure 10.5 Steps in the Procurement Cycle**



Source: Management Sciences for Health

Figure 10.6 The Distribution Cycle

### 10.3 Indicator-based Assessment

#### 10.3.1 Topical Areas

The pharmaceutical management module is divided into Components 1 and 2 as described in Chapter 2 of this manual. The indicators in Component 2 are grouped by topical areas relevant to pharmaceutical management, summarized as follows—

- A. Pharmaceutical Policy, Laws, and Regulations
- B. Selection of Pharmaceuticals
- C. Procurement.
- D. Storage and Distribution
- E. Appropriate Use
- F. Availability
- G. Access to Quality Products and Services
- H. Financing Pharmaceuticals

#### 10.3.2 Detailed Descriptions of Pharmaceutical Management Indicators

Table 10.2 groups the indicators in this module by topic.

**Table 10.2 Indicator Map—Pharmaceutical Management**

<b>Component</b>	<b>Topical Area</b>	<b>Indicator Numbers</b>
Component 1	Not applicable	1–4
Component 2	Pharmaceutical Policy, Laws, and Regulations	5–11
	Selection of Pharmaceuticals	12–15
	Procurement	16–22
	Storage and Distribution	23–26
	Appropriate Use	27–29
	Availability	30
	Access to Quality Products and Services	31–36
	Financing Pharmaceuticals	37–39

### 10.3.2.1 Component 1

The pharmaceutical module includes four indicators in Component 1. The source of all four indicators is *The World Medicines Situation* (WHO 2004). This document draws from recent studies in a wide range of countries and regions that may be considered for a health system performance assessment. It also provides an overview of key issues in pharmaceutical management. The annexes of *The World Medicines Situation* include extensive data and information. The following four indicators were selected as key performance indicators that would be available for most countries.

<b>1. Total expenditure on pharmaceuticals (% total expenditure on health)</b>	
<b>Definition, rationale, and interpretation</b>	Measures relative significance of pharmaceutical spending relative to other spending on health; indicates financial and institutional sustainability Compare to selected peer group
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> .
<b>2. Total expenditure on pharmaceuticals (per capita average exchange rate)</b>	
<b>Definition, rationale, and interpretation</b>	Measures magnitude of pharmaceutical spending; indicates financial and institutional sustainability Compare to selected peer group.
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> .
<b>3. Government expenditure on pharmaceuticals (per capita average exchange rate)</b>	
<b>Definition, rationale, and interpretation</b>	Measures magnitude of government spending on pharmaceuticals; indicates financial and institutional sustainability Compare to selected peer group
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> .
<b>4. Private expenditure on pharmaceuticals (per capita average exchange rate)</b>	
<b>Definition, rationale, and interpretation</b>	Measures magnitude of private sector spending on pharmaceuticals; indicates financial and institutional sustainability Compare to selected peer group
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> .

### 10.3.2.2 Component 2

The Component 2 indicators are organized by topical area. In total, 35 Component 2 indicators are included in this chapter. In addition, suggested issues to explore are noted for some indicators.

#### **A. Pharmaceutical Policy, Laws, and Regulations**

A country's national medicines policy specifies the government's goals for the pharmaceutical sector, their relative importance, and the main strategies used to attain them. An NMP provides a framework for developing pharmaceutical laws and regulations, which are important because of the complexity and risk inherent in the pharmaceutical sector.

Indicators 5–11 relate to pharmaceutical laws and policies.

<b>5. Is there a National Essential Medicines Policy (NMP) or other government document that sets objectives and strategies for the pharmaceutical sector based on priority health problems?</b>	
--	--

<b>Definition, rationale, and interpretation</b>	An NMP is a guide to action for the pharmaceutical sector. Existence of an NMP indicates commitment to improving pharmaceutical management in public and private sectors.
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> . WHO database; existing country studies
<b>Stakeholders to interview</b>	Head of the Ministry of Health (MOH) pharmacy department, National Essential Medicines Program
<b>Issues to explore</b>	Has it been updated in the past 10 years? A response of “yes” indicates that the policy is kept up to date.
<b>Notes and caveats</b>	If the country has a National Essential Medicines Program, most likely that program has received some support or guidance from WHO and that the WHO guidelines on how to develop an NMP (WHO 2001) were followed or used as a template to develop the policy.

**6. Is there a comprehensive pharmaceutical law?**

<b>Definition, rationale, and interpretation</b>	Assesses existence or absence of a comprehensive national pharmaceutical law  The existence of a comprehensive law demonstrates commitment to improving pharmaceutical management in public and private sectors. A comprehensive law will include all of the following components— <ul style="list-style-type: none"> <li>• A regulatory framework</li> <li>• Principles for selecting medicines, including donations</li> <li>• Strategies for supply and procurement</li> <li>• Promotion of rational use of pharmaceuticals</li> <li>• Economic and financing mechanisms</li> <li>• Role of health professionals</li> <li>• Monitoring and evaluation mechanisms</li> </ul>
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> . WHO database; existing country studies
<b>Stakeholders to interview</b>	Head of the MOH pharmacy department National Essential Medicines Program
<b>Issues to explore</b>	When was the national pharmaceutical law last updated? A policy that is more than five years old may be outdated and require revisions to reflect changes in overall health or national development policies and priorities.
<b>Notes and caveats</b>	Some countries will combine the national medicines law with the national medicines policy.

**7. Is there a National Drug Regulatory Authority (NDRA) responsible for the promulgation of regulations and for enforcement?**

<b>Definition, rationale, and interpretation</b>	Indicates commitment to implementing and enforcing pharmaceutical laws
<b>Suggested data source</b>	National health and medicines policy; existing country studies
<b>Stakeholders to interview</b>	Head of the MOH pharmacy department National Essential Medicines Program, NDRA
<b>Issues to explore</b>	What are the specific responsibilities of the NDRA? What is the relationship of the NDRA to other governmental agencies? Is it autonomous? How is it financed?
<b>Notes and caveats</b>	If there is not a clear separation of functions, the NDRA is vulnerable to corruption.

**8. Is there a system for pharmaceutical registration?**

<b>Definition, rationale, and interpretation</b>	Indicates existence of a system to authorize circulation of pharmaceuticals on the market
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> . National drug law; existing country studies; NDRA reports
<b>Stakeholders to interview</b>	Head of the MOH pharmacy department National Essential Medicines Program NDRA director
<b>Issues to explore</b>	<p>Is periodic renewal required, and are pharmacological standards applied? Is registration based on an assessment of product efficacy, safety, quality, and truth of packaging information? If so, then pharmaceutical registration is part of a comprehensive quality assurance program.</p> <p>Is the system kept up to date? Do you have any concerns about the ability of the registration system to keep up with applications? What is the average turnaround time for pharmaceutical registration applications? Although there is no gold standard or optimal turnaround time, an indicator of problems would be having a backlog of several months, which may be confirmed by an examination of dossiers. A very short turnaround time may indicate that the process is not seriously examining the information provided.</p> <p>In the absence of the system characteristics listed above, the registration system may simply be a revenue generating system.</p> <p>Do you have concerns about a black market, products that are circulating in the market and are not registered? The process of registration may be considered too cumbersome (e.g., fees too high, delays too long), or the country may have no way to enforce registration requirements.</p>
<b>Notes and caveats</b>	Some systems may accept registration in reference countries (often neighboring countries or countries with similar systems). This option may be rational for countries that have several types of human resource limitations.

**9. Does the pharmaceutical registration system generate revenue for the MOH?**

<b>Definition, rationale, and interpretation</b>	Measures the potential for financial sustainability of the registration system for the MOH
<b>Suggested data source</b>	NDRA reports
<b>Stakeholders to interview</b>	NDRA director

**9. Does the pharmaceutical registration system generate revenue for the MOH?**

**Issues to explore** If yes, are revenue targets consistently met? If targets are met, sustainability of the registration system may be achieved.

**Notes and caveats** You may not be able to obtain information about revenues and expenditures of the NDRA. Again, this issue relates more to transparency than performance per se.

**10. Is there a system for the collection of data regarding the efficacy, quality, and safety of marketed products (postmarketing surveillance)?**

**Definition, rationale, and interpretation** Indicates existence of system to monitor pharmaceutical product quality problems; does not address how well postmarketing surveillance is conducted

**Suggested data source** NDRA reports

**Stakeholders to interview** NDRA, director of pharmacy department, Drug Quality Control Laboratory, National Drug Inspectorate

**Issues to explore** How long has the system been in place? How extensively is it actually used for tracking action on substandard pharmaceutical products? Are data available? What standards are used?

Does the country have a system by which providers and consumers can report product problems? If so, is it a passive, self-reporting system or a mandatory reporting system? If it is the latter, a key component of quality assurance is in place. This indicator does not address how well follow-up on reports is conducted.

**Notes and caveats** Postmarketing surveillance systems may focus on some priority pharmaceutical therapeutic categories or products known to be particularly prone to problems.

**11. Do mechanisms exist for the licensing, inspection and control of (1) pharmaceutical personnel, (2) manufacturers, (3) distributors/importers, and (4) pharmacies/drug retail stores?**

**Definition, rationale, and interpretation** Indicates existence of mechanisms to enforce regulations and ensure quality of pharmaceuticals on the market

If these mechanisms are used, a key component of quality assurance is in place. This indicator does not address whether licensing, inspection, or control activities are fully functional.

**Suggested data source** Country reports

*Module link:* Governance, indicator 40c (pharmaceutical regulation processes)

**11. Do mechanisms exist for the licensing, inspection and control of (1) pharmaceutical personnel, (2) manufacturers, (3) distributors/importers, and (4) pharmacies/drug retail stores?**

<b>Stakeholders to interview</b>	NDRA, Head of Pharmacy Inspection
<b>Issues to explore</b>	<p>How rigorous is the enforcement of licensing requirements? Is a report of inspections and enforcement results generated regularly?</p> <p>Does the country have sufficient qualified staff to conduct all inspection activities?</p> <p>Are statistics available about compliance and enforcement of pharmaceutical laws and regulations? Available statistics are evidence of a functioning system for follow-up. How often are the statistics produced? Ask to see a report.</p>
<b>Notes and caveats</b>	MOH staff are often wooed and recruited by the private sector. Inspection staff recruitment is often a major and constant concern.

**B. Selection of Pharmaceuticals**

The rationale for using an NEML is that it leads to more rational prescribing, lower treatment costs, and more reliable supply of medicines. NEMLS are based on consensus-based standard treatments for priority public health conditions. The selection of medicines for NEMLS has a considerable impact on the quality of care. Indicators 12–15 relate to pharmaceutical selection that is meant to guide treatment in the public sector.

**12. Is there a national essential medicines list (NEML)?**

<b>Definition, rationale, and interpretation</b>	Measures a country's commitment to rational resource allocation and containing pharmaceutical costs
<b>Suggested data source</b>	<p>WHO (2004). <i>The World Medicines Situation</i>.</p> <p>National Essential Medicines Program; WHO reports</p>
<b>Stakeholders to interview</b>	National Essential Medicines Program, MOH pharmacy department
<b>Issues to explore</b>	<p>Is the NEML based on national STGs? Does it identify medicines by level of care?</p> <p>Was the NEML updated within the last three years? If so, it likely to contain information most pertinent to current public health concerns and new advances in medicines.</p> <p>Is the NEML meant to guide cost control issues (procurement) as well as therapeutic issues (quality of care)?</p>

**12. Is there a national essential medicines list (NEML)?**

**Notes and caveats** The definition of purpose and use of the NEML may be stipulated in the national medicines policy.

**13. Is there an active national committee responsible for managing the process of maintaining a national medicines list?**

**Definition, rationale, and interpretation** Measures awareness of need for up-to-date pharmaceutical information and existence of a system to provide it  
 If the NEML is being updated (see Indicator 12 above) and an active committee is in place, then the medicines list is being updated by a committee and not by an individual.

**Suggested data source** National Essential Medicines Program

**Stakeholders to interview** MOH pharmacy department, National Essential Medicines Program, National Drug and Therapeutics Committee (DTC) Chair

**Issues to explore** Does this committee have terms of reference (TORs) or standard operating procedures (SOPs)? The existence of TORs or SOPs indicates that a formalized process is in place and that issues of transparency are being addressed.  
 If the country has SOPs, do they require review or up-to-date, unbiased scientific data? Does the committee have access to such data?  
 Does the country have a system for distributing the NEML to facilities?

**Notes and caveats** As some countries develop their pharmaceutical management systems, they may rely on a generic EML developed by WHO, or the NEML of a neighboring country that shares a similar epidemiological profile.

**14. What is the total number of pharmaceuticals (in dosage forms and strengths) on the NEML?**

**Definition, rationale, and interpretation** On average, NEMLs normally contain 300–400 individual pharmaceutical products. The country’s morbidity and mortality situation should be the guide for the number of products on the NEML, and lower mortality and morbidity ratios should be consistent with a shorter list of NEML products. Consideration should be given to what is appropriate by level of care.

**Suggested data source** National Essential Medicines Program, existing country studies, NEML documents and policy

**14. What is the total number of pharmaceuticals (in dosage forms and strengths) on the NEML?**

<b>Stakeholders to interview</b>	This information would be available in the NEML and would require an actual count. Copies of the NEML may be obtained from the pharmacy department, National Essential Medicines Program, and the MOH procurement office.
<b>Issues to explore</b>	<p>The number of pharmaceutical products for any one level of care should not exceed the total number of items on the NEML. On average, the spread of items by type of facility is likely to be as follows—</p> <ul style="list-style-type: none"> <li>• First-level care facilities: 40–50 pharmaceutical products</li> <li>• Secondary care facilities: 150–200 pharmaceutical products</li> <li>• Tertiary care facilities: 300–400 pharmaceutical products</li> </ul> <p>How stable has the NEML been over time? Are more items added than eliminated?</p>
<b>Notes and caveats</b>	Increases in the number of medicines over time may indicate that items are not reviewed for obsolescence or lack of need. New items are often added to the list to replace items already on the list.

**15. Are international nonproprietary names (INN) or generic names used for products on the list?**

<b>Definition, rationale, and interpretation</b>	Helps to ensure that the NEML contains no duplications of medicines; facilitates reviews of therapeutic equivalence and cost-efficacy (studies typically refer to the chemical entities rather than branded products)
<b>Suggested data source</b>	WHO (2004). <i>The World Medicines Situation</i> . Review of the NEML
<b>Stakeholders to interview</b>	This information may be determined by a visual review of the list.
<b>Issues to explore</b>	<p>Are generic names used throughout the pharmaceutical management information system management system (inventory cards)?</p> <p>Is the list used for procurement purposes?</p> <p>Is any preference given for brand name products? Why? For some products (very few), bioequivalence may be an issue (the generic or therapeutic equivalent may not be bioequivalent and may have clinical implications). Such cases are generally well documented.</p>
<b>Notes and caveats</b>	None.

### C. Procurement

The primary purpose of procurement is to provide regular delivery of adequate quantities of high-quality supplies at the lowest cost. National procurement decisions take place within a country's policy and legal framework and may take place at the central level or be decentralized down to the facility level. Some steps of the procurement process may be centralized whereas others take place at the local level. Understanding the where the various steps of procurement take place is critical. It will contribute to identifying the appropriate stakeholders to interview. For example—

- *Centralized system:* Procurement is conducted at central level by a national procurement unit (which may be a parastatal enterprise).
- *Decentralized system:* Procurement is conducted by subnational entities, including regional or provincial authorities and facilities.
- *Mixed systems:* In some systems that have decentralized as a result of health sector reform, pharmaceutical systems have been redesigned to maintain economies of scale at the central level, so prices may be tendered or negotiated at the central level and actual purchases from approved suppliers at approved prices are made at the local level by budgetary units.

For the purposes of this assessment, the focus will be on procurement for the public sector. Indicators 16–22 relate to the procurement of pharmaceuticals. Because procurement involves many steps and agencies, you should, during the document review and interviews, develop and refine a step-by-step description of how procurement takes place and who the responsible authorities and agents are.

#### 16. Are there formal standard operational procedures (SOPs) for conducting procurement of pharmaceuticals in the public sector?

<b>Definition, rationale, and interpretation</b>	Formalized SOPs include detailed descriptions of the roles and responsibilities of all offices and agencies involved in the procurement process. They promote accountability and transparency.
<b>Suggested data source</b>	National procurement guidelines, standard bidding documents
<b>Stakeholders to interview</b>	Procurement unit or office, relevant agency
<b>Issues to explore</b>	<p>Has an independent audit of the public sector procurement been conducted within the last three years?</p> <p>Were the SOPs developed specifically for health sector goods and pharmaceuticals, or are they general SOPs? The procurement of pharmaceuticals requires unique considerations, including specifications and sourcing issues. General procurement guidelines are inadequate for pharmaceuticals.</p>
<b>Notes and caveats</b>	Use this indicator in centralized and decentralized systems.

**17. Are generic or INN used for MOH procurement of pharmaceuticals? (Generic names are to be differentiated from generic branded products.)**

<b>Definition, rationale, and interpretation</b>	<p>Measures a country's commitment to rational resource allocation and containing pharmaceutical costs</p> <p>Generic names refer to the chemical names defining the medicines. In most cases, the generic is the same as the INN. Use of generic or INN names facilitates competition among suppliers and manufacturers on the basis of the chemical entity of interest.</p>
<b>Suggested data source</b>	<p>SOPs for MOH procurement</p> <p>If an independent audit has been conducted, most information will be found there.</p> <p>Procurement guidelines; actual procurement lists</p>
<b>Stakeholders to interview</b>	<p>MOH procurement office (or responsible authority)</p>
<b>Issues to explore</b>	<p>Do health professionals feel pressure to procure brand name products that are used by visiting practitioners from other countries?</p> <p>Does the country have an NEML? Is procurement limited to the list?</p>
<b>Notes and caveats</b>	<p>Use this indicator in centralized and decentralized systems.</p>

**18. On average, how many procurements are conducted per year?**

<b>Definition, rationale, and interpretation</b>	<p>Demonstrates level of activity of the central procurement system</p> <p>More than two central pharmaceutical procurements per year suggest system inefficiencies and a high level of activity. Inefficiencies may be related to poor quantification or to problems with the availability of financing at the time procurement is needed.</p>
<b>Suggested data source</b>	<p>Procurement guidelines and actual procurement lists, existing country studies</p>
<b>Stakeholders to interview</b>	<p>Procurement office</p>
<b>Issues to explore</b>	<ol style="list-style-type: none"> <li>a. How many unprogrammed (emergency) procurements occurred in the last two years? This number indicates the effectiveness of regular procurements. Any emergency procurements may indicate problems with planning and programming of regular procurement needs, barring force majeure.</li> <li>b. What was the value of those emergency procurements (as a percentage of the pharmaceutical budget over those two years)? This value adds further insight on effectiveness of the procurement program. Most funds should be spent on regular procurements. Emergency procurements should not represent a significant portion of the pharmaceutical procurement budget.</li> </ol>

**18. On average, how many procurements are conducted per year?**

- c. What is the average lead time for procurement? Shorter lead times are preferred but must be appropriate for the specific context. An unpredictable lead time contributes to stock-outs.
- d. What percentage of items listed for procurement in the last three tenders were actually purchased? A high percentage would indicate successful tenders. It would imply lesser need for emergency purchases and a possible willingness among suppliers to bid and participate in the procurement system

**Notes and caveats**

Use this indicator in centralized and decentralized systems. National procurements may be negatively affected by local purchases made by health facilities unless agile information systems are in place to ensure that purchase information is communicated to the central level.

**19. On average, what percentage (by value) of MOH pharmaceuticals is procured through competitive bid?**

**Definition, rationale, and interpretation**

Measures the degree of potential cost minimization afforded through competitive procurement

Competitive tenders are among the best ways to lower the cost of pharmaceutical purchases. Competitive bidding may be open to both international and national bidders or only to national bidders. The choice of method used depends largely on the market (availability of qualified suppliers) and national economic development policies. A high percentage of procurement through competitive processes suggests that the purchaser is obtaining reasonable prices.

**Suggested data source**

WHO (2004). *The World Medicines Situation*.

Existing country studies; procurement records, and reports

**Stakeholders to interview**

Procurement officer

**Issues to explore**

Why is procurement not conducted through competitive bid? What reasons are cited?

What was the percentage of average international price paid for the last regular procurement (for tracer products)? This information may be available from existing studies. A study may compare prices to neighbors in the region or to statistics for the country over time. If procurement prices compare favorably to average international prices, it is a rough measure of the effectiveness of the procurement system. Results higher than the average international price may indicate that the procurement might have been able to result in lower prices.



**21. Are samples requested and tested as part of the procurement process?**

**Issues to explore** Is the capacity to conduct testing sufficient?

**Notes and caveats** Use this indicator in centralized and decentralized systems.

---

**22. Are quantities of pharmaceuticals to be procured based on reliable estimates?**

**Definition, rationale, and interpretation** Measures efficiency and appropriate use of resources  
If reliable needs estimates are used, then the risk of overstock and stock-outs are reduced.

**Suggested data source** Procurement SOPs, reports from quantification exercises; interviews

**Stakeholders to interview** Pharmacy department, medical stores manager, procurement unit, health facilities managers

**Issues to explore** How and at what levels is quantification conducted? What data are used (historical consumption data, morbidity data, a combination of these two, or other)? A combination of data is the most reliable.  
Some systems have access only to historical consumption data from facilities. What is the quality of this data?  
When was the last time a national quantification was conducted?  
To what extent do needs exceed the available budget for procurement? How are discrepancies resolved?

**Notes and caveats** Use this indicator in centralized and decentralized systems.

---

**D. Storage and Distribution**

The storage and distribution topical area includes all activities related to managing an inventory: ordering, receiving, storing, issuing, and reordering supplies. These activities may take place at various levels of the system. The goals of inventory management are to protect stored items from loss, damage, theft, or wastage, and to manage the reliable movement of supplies from source to user in the least expensive way. Indicators 23–26 relate to the storage and distribution of pharmaceuticals.

**23. Is distribution of (some or all) pharmaceuticals managed through a push or pull system?**

<b>Definition, rationale, and interpretation</b>	<p>Indicates the type of information system and storage requirements that should be in place</p> <p>Pull, or requisition-based, systems require staff at facilities to be able to predict requirements in a timely fashion and for suppliers to provide needs. This procedure requires an understanding of consumption patterns.</p> <p>In a push system, supplies are sent to facilities in the absence of a specific request. This procedure may result in overstocks of unused items or supplies may not arrive when needed. Push systems tend to be logistically easier to manage.</p> <p>Kits are often used in push systems but may also be used in a pull system. Some health systems may use a combination of push and pull, depending on the type of product and the presence of vertical programs.</p>
<b>Suggested data source</b>	Country distribution plan
<b>Stakeholders to interview</b>	Medical stores department, pharmacy department, private sector distributors
<b>Issues to explore</b>	<p>Systems that are very fragile with extreme human capacity limitations may be best supported initially by a kit-based push system.</p> <p>Storage and distribution functions may be conducted by different agencies and sectors. Who is involved in distributing medicines? MOH medical stores and vehicles? NGO-owned stores and vehicles? Or are storage and transportation services contracted out?</p> <p>How is information about receipt and use of supplies communicated to the central level?</p>
<b>Notes and caveats</b>	<p>Kit-based push systems are often donor supported.</p> <p>If storage and distribution functions are contracted out, do potential contractors compete on the basis of tenders? How are they selected? Which agency is responsible for monitoring contract performance?</p>

**24. Are there independent supply systems for vertical programs (such as tuberculosis, malaria, HIV/AIDS)? For what programs?**

<b>Definition, rationale, and interpretation</b>	To give them greater control over the supplies they need, vertical programs are often defined by their own supply systems. This kind of definition often occurs when the MOH system is considered to be weak.
<b>Suggested data source</b>	<p>MOH reports</p> <p><i>Module link:</i> Health Service Delivery, indicator 21 (number of vertical programs)</p>

**24. Are there independent supply systems for vertical programs (such as tuberculosis, malaria, HIV/AIDS)? For what programs?**

<b>Stakeholders to interview</b>	Pharmacy department, medical stores department, donors
<b>Issues to explore</b>	Are these programs coordinated for distribution? How involved is the MOH in the planning for these vertical programs? What is the impact of donor control on vertical or parallel systems?
<b>Notes and caveats</b>	None

**25. Value of inventory loss (as % of average inventory value) over 12 months**

<b>Definition, rationale, and interpretation</b>	Inventory loss is a holding cost. This indicator measures waste or efficiency of the inventory management system and identifies opportunities for minimizing costs. Current standards for commercial firms dictate a maximum 20–30 percent of costs due to holding costs, one part of which are inventory loss costs. Current standards for commercial firms dictate a maximum 5 percent of expenses due to inventory loss. A total value of inventory loss of 5 percent may be cause for concern about the management of products.
<b>Suggested data source</b>	MOH reports, existing country studies, Ministry of Finance (MOF) reports
<b>Stakeholders to interview</b>	Medical store department, MOF
<b>Issues to explore</b>	<p>Compare the value of inventory loss among public entities and commercial firms in the country. Large disparities in the figures would suggest opportunities for improved efficiencies. For example, where costs are lower in the commercial sector, options may include contracting out for commercial services.</p> <p>Types of inventory loss that can be examined in detail include—</p> <ul style="list-style-type: none"> <li>• <i>Expiry</i>: Loss due to expiry indicates that stock is not moving fast enough, that unused products are purchased, or that products have too short a shelf life.</li> <li>• <i>Damage</i>: Loss due to damage indicates storage or transport problems.</li> <li>• <i>Obsolescence</i>: Loss due to obsolescence indicates that products purchased do not meet needs.</li> <li>• <i>Theft</i>: Loss due to theft indicates that enhanced security measures are needed.</li> </ul> <p>If available, list the inventory loss experienced by each of the participants in the distribution system (e.g., public, private, donor). Note if any of the losses might have been due to any particular unusual event or basic storage conditions, such as storage facilities that are dilapidated or of inadequate size or construction.</p>

**25. Value of inventory loss (as % of average inventory value) over 12 months**

Other costs in the distribution system that can be explored include transportation costs (e.g., fuel, vehicle depreciation, maintenance) and other storage costs (e.g., personnel, rent, machinery, utilities). Transportation and storage costs should be minimized and ideally should be compared to the commercial sector in country.

**Notes and caveats**

The information should cover at least 12 months or one procurement cycle. If possible, obtain this information for the last three years. If large values have been lost, especially due to theft or unexplained reasons, it may not be prudent to probe. You may note whether losses occur regularly or appear to be sporadic.

**26. At each level of the distribution system (central, regional, district, facility), are there refrigeration units (such as refrigerators or coolers) with functional temperature control?**

**Definition, rationale, and interpretation**

Distribution systems include a cold chain of some sort. Interruptions in the cold chain due to inadequate or insufficient cold storage for sensitive products, such as vaccines, can result in damage and loss of important commodities. Each level of the distribution system should have functioning units to provide cold storage of temperature-sensitive commodities. In weaker systems, the cold chain is best managed as a separate vertical program.

**Suggested data source**

Existing health facility surveys or monitoring reports, EPI reports

**Stakeholders to interview**

Pharmacy department,; medical stores department, vertical program managers (EPI, donors)

**Issues to explore**

Are the thermostats checked regularly? Are facilities equipped with a backup power supply?  
  
Are private sector facilities required to maintain a cold chain?

**Notes and caveats**

In some countries, a separate cold chain is managed by vertical programs. EPI, for example, is typically managed separately. The main supply system should still maintain some system for other products that require temperature control. This system may include electric- or gas-operated refrigerators as well as simple cold boxes.

**E. Appropriate Use**

The aim of any pharmaceutical management system is to deliver the correct product to the client/patient who needs it, and the steps of selection, procurement, and distribution are necessary precursors to the rational use of medicines. The rational use of medicines means that client/patients are prescribed and dispensed the full amount of the appropriate, high-quality medicine when needed, at the lowest cost to them, to their communities, and to the system, and that clients/patients take the medicines correctly and without interruption. Indicators 27–29 relate to the appropriate use of pharmaceuticals and should be explored for both the public and private sectors.

**27. Are there any functioning mechanisms/tools in place to improve the use of medicines in hospitals and health facilities?**

<b>Definition, rationale, and interpretation</b>	The commitment to ensuring the appropriate use of medicines is generally described in a national medicines policy. The procedures and corresponding tools may also be specified. Tools that help improve the use of medicines include STGs, prescription controls such as limited formularies, dispensing controls, and pre- and in-service training in rational medicines use. Supervision and regular reviews of prescribing and dispensing practices should support the use of such tools. Prescribing reviews may be conducted by formalized DTCs. These committees may exist at the hospital level primarily, but they may support review of prescribing at the lower level facilities.
<b>Suggested data source</b>	NMP, existing country reports and special studies
<b>Stakeholders to interview</b>	MOH pharmacy department, National Essential Medicines Program, National Pharmacy and Therapeutics Committee Chair
<b>Issues to explore</b>	<p>Are regular reviews of prescribing practices conducted at the public facility level? How regular are the reviews? Who is responsible for conducting these reviews?</p> <p>Does the country have any active DTCs? How long have the DTCs been active? Is there a national network of DTCs? Are DTCs active in both public and private hospitals?</p> <p>Do public facilities have any managerial controls of prescribing (e.g., limited formularies, prescribing by generic name only, limiting the number of medicines prescribed per client/patient)?</p> <p>Are regular reviews of prescribing practices conducted at the public facility level? How regular are the reviews? Who is responsible for conducting these reviews?</p>
<b>Notes and caveats</b>	There is no gold standard for the number of medicines per prescription. Types of prescribing problems often identified include prescribing multiple antibiotics in a single prescription or other irrational combinations, and prescribing inappropriate medicines or amounts for a given indication. Understanding the reasons for poor prescribing and dispensing, and hence the most appropriate interventions, requires in-depth research that is beyond the scope of this assessment.

**28. Are there national therapeutic guides with standardized treatments for common health problems?**

<b>Definition, rationale, and interpretation</b>	<p>Indicates potential capacity to provide consistent treatment for common health problems</p> <p>If guidelines and STGs exist, evidence-based best practices for treatments of common conditions are reviewed and codified.</p>
<b>Suggested data source</b>	<p>Existing country reports</p> <p><i>Module link:</i> Health Service Delivery, indicator 25 (existence of clinical standards)</p>
<b>Stakeholders to interview</b>	<p>Pharmacy department, National Essential Medicines Program, National Pharmacy and Therapeutics Committee Chair</p>
<b>Issues to explore</b>	<p>Are the guidelines used to develop the NEML? Are they used to guide procurement activities?</p> <p>When were the guideline last updated? Does the system that ensures that the guidelines are updated rely on use of unbiased pharmaceutical information? If so, treatments and medicines are consistent with changing evidence-based best practices and changing country disease patterns.</p> <p>Are these guidelines distributed to and used in the private sector?</p>
<b>Notes and caveats</b>	<p>Guidelines may be developed by national health insurance agencies, NGOs, and international health agencies such as WHO. These guidelines may not be consistent with each other.</p>

**29. Are the treatment guidelines used for basic and in-service training of health personnel?**

<b>Definition, rationale, and interpretation</b>	<p>Indicates dissemination of treatment guidelines to health personnel and greater potential for guidelines to be implemented by health care professionals in the public and private sectors</p>
<b>Suggested data source</b>	<p>Curricula; existing country studies</p> <p><i>Module link:</i> Health Service Delivery, indicator 28 (quality assurance processes)</p>
<b>Stakeholders to interview</b>	<p>Pharmacy department; medical, pharmacy, and nursing schools</p>
<b>Issues to explore</b>	<p>Are treatment guidelines used for supervision and monitoring activities in public-sector health facilities? If so, supervision and monitoring practices incorporate oversight of quality and appropriateness of treatment.</p>

**29. Are the treatment guidelines used for basic and in-service training of health personnel?**

What percentage of prescriptions in the public-sector health facilities complies with the treatment guidelines for a tracer condition? Ideally, 100 percent of prescriptions are consistent with guidelines. This level of consistency is rarely the case, however. If monitoring is in place (see above) and data are available, an improvement trend for this indicator would indicate improved appropriateness of prescribing practices for that tracer condition.

Other information that may be available includes the average number of pharmaceuticals prescribed for a given condition and the average number of antibiotics per prescription. Both may demonstrate over- or underprescribing depending on the treatment guidelines for the health condition studied.

**Notes and caveats**

Evaluating medical records to determine appropriate diagnosis and prescribing is a labor intensive effort, and needed information may not be recorded. Few systems capture this information in a computerized fashion.

**F. Availability**

Physical availability is defined by the relationship between the location, time, type, and quantity of product or service needed and the location, time, type, and quantity of the product or service provided. Indicator 30 is perhaps the single most important outcome indicator of the functioning of a pharmaceutical management system. It should be measured repeatedly over a period sufficient to cover at least one procurement cycle, preferably three. It should be measured at all relevant points in the distribution system (central, regional, and municipal medical stores; health facilities; and pharmacies) and in all relevant sectors (public, private, and NGO). To simplify this measure and to keep focused on priority issues, a sample list of tracer products should be used for this measure. A sample tracer list is presented in Table 10.1.

**30. What percentage of a set of unexpired tracer items is available (at time of study and over a period of time) in a sample of facilities?**

**Definition, rationale, and interpretation**

Measures the physical availability of a set of essential or key medicines where they are expected to be

Ideal levels would approximate 100 percent. Low levels of availability indicate potential problems with procurement, including poor quantification, distribution, and inventory management. Shortages can lead to failure to treat clients/patients and may lead to high-cost emergency purchases. Note that only unexpired products are considered.

**Suggested data source**

These data are not collected as part of this assessment. Ideally data would be available from a computerized pharmaceutical management information system or reports from supervisory or inspection visits.

**30. What percentage of a set of unexpired tracer items is available (at time of study and over a period of time) in a sample of facilities?**

<b>Stakeholders to interview</b>	Pharmacy department; National Essential Medicines Program, medical stores managers, pharmacy managers.
<b>Issues to explore</b>	<p>Is availability more of a problem for some products than for others? Why? When?</p> <p>What is the average frequency of stock-outs for tracer items at different levels of the health system (e.g., CMSs, regional medical stores, health facilities) over a 12-month period? This information may be available from existing studies that look at a specific set of tracer items. Ideal levels would approximate zero percent, or no stock-outs, over a prolonged period of time.</p> <p>If stock-outs occur, what is the average duration of stock-outs for tracer items at different levels of the health system (CMSs, regional medical stores, health facilities)? This information may be available from existing studies.</p>
<b>Notes and caveats</b>	You must consider the impact of the procurement cycle at the time of the study. Note which types of tracer items were used in the study, and determine if the study authors checked if the products were expired.

**G. Access to Quality Products and Services**

Access to quality pharmaceutical products and services involves physical access to those products and services and the quality of the products and services that are provided. Indicators 31–36 relate to access to quality pharmaceutical products and services.

**31. What percent of the population has access to a public or private health facility/pharmacy that dispenses pharmaceuticals?**

<b>Definition, rationale, and interpretation</b>	<p>Measures geographic access to pharmaceutical services</p> <p>A high percentage indicates a high level of access to health facilities that offer quality pharmaceutical services.</p>
<b>Suggested data source</b>	<p>National health services statistics</p> <p><i>Module link:</i> Health Service Delivery, indicator 14 (people living within X km of a health facility)</p>
<b>Stakeholders to interview</b>	Department of health services or health services research (university or MOH), office of health statistics
<b>Issues to explore</b>	<p>What categories of facilities are licensed to dispense pharmaceuticals? Are any sources of pharmaceuticals not licensed but nonetheless popular among clients/patients because they are easily accessible?</p> <p>Are private sector facilities and pharmacies more accessible than public sector facilities?</p>

**31. What percent of the population has access to a public or private health facility/pharmacy that dispenses pharmaceuticals?**

**Notes and caveats**

This indicator needs to be adapted to the system being assessed. For example, in some systems, public health facilities do not dispense medicines so availability cannot be assessed for these facilities. If clients/patients must fill their prescriptions at a private sector retail pharmacy, the indicator must be applied to the pharmacy.

If information is available, differentiate between licensed and unlicensed facilities.

---

**32. Are there any licensing provisions or incentives in place to increase geographic access by consumers/patients to quality products and services through private wholesalers and retailers?**

**Definition, rationale, and interpretation**

Measures the potential role of the private sector in improving access to medicines

The presence of licensing provisions or incentives for the private sector indicates a commitment to and potential for a private sector role in providing medicines to the market. It does not measure the level of involvement of the private sector in the market.

---

**Suggested data source**

National health or medicines policy, pharmacy laws and regulations

---

**Stakeholders to interview**

Department of health services or health services research (university or MOH), office of health statistics, private sector representatives

---

**Issues to explore**

What is the capacity to implement these policies? What has actually taken place?

What are the barriers for the private sector to participate in public health initiatives to improve access to medicines?

---

**Notes and caveats**

In some countries, the sale of all medicines is limited to designated outlets with a responsible, licensed professional. An example of increasing access to essential medicines is the assignation of over-the-counter status to medicines so that they can be sold in a larger variety of commercial outlets. Similarly, the definition of outlets permitted to sell medicines may be broadened to include a wider variety of shops. Shops may be offered a tax incentive if they are established in remote or otherwise underserved areas.

---

**33. Population per licensed pharmacist or pharmacy technician**

<b>Definition, rationale, and interpretation</b>	<p>Measures coverage of pharmaceutical services; indicates access to and availability of skilled pharmacy personnel in the country</p> <p>A high ratio of population per pharmacist or pharmacy technician indicates a potential need to improve pharmaceutical service delivery and should include in their human resource management plan the recruitment, training, and development of this resource.</p>
<b>Suggested data source</b>	<p>National health services study</p> <p><i>Module link:</i> Core Module, section 5.3.4 (organization of government and private health sector); Health Service Delivery, indicator 13 (ratio of health care professionals to population)</p>
<b>Stakeholders to interview</b>	<p>Department of health services or health services research (university or MOH), office of health statistics</p>
<b>Issues to explore</b>	<p>If data are available, compare population per licensed pharmacist or pharmacy technician in the private and public sectors. The private pharmaceutical sector is the primary source of medicines consumed in many countries. A high ratio of population per pharmacist or pharmacy technician in the private sector indicates a potential need to identify opportunities to improve private sector pharmaceutical service coverage.</p>
<b>Notes and caveats</b>	<p>None</p>

**34. Population per authorized prescriber**

<b>Definition, rationale, and interpretation</b>	<p>Measures access to and availability of prescribers</p> <p>Adequate numbers of technically qualified staff who are authorized to prescribe medicines are essential to a sound health care system.</p>
<b>Suggested data source</b>	<p>National health services study</p> <p><i>Module link:</i> Health Service Delivery, indicator 13 (ratio of health care professionals to population)</p>
<b>Stakeholders to interview</b>	<p>Department of health services or health services research (university or MOH), office of health statistics</p>
<b>Issues to explore</b>	<p>If available, compare population per authorized prescriber in the private and public sectors. A high ratio of population to prescriber in the private or public sector (or both) may indicate a need to improve the coverage of prescribers in the population.</p> <p>Where are most prescribers trained? Would the majority be exposed to the national STGs?</p>
<b>Notes and caveats</b>	<p>None</p>

**35. Population per drug retail outlet in the private sector**

<b>Definition, rationale, and interpretation</b>	Measures coverage of pharmaceutical services in the private sector The private pharmaceutical sector is the primary source of medicines consumed in many countries. A high ratio of population per medicine retail outlet in the private sector indicates a potential need to identify opportunities to improve private sector pharmaceutical service coverage.
<b>Suggested data source</b>	National health services study
<b>Stakeholders to interview</b>	Department of health services or health services research (university or MOH), office of health statistics
<b>Issues to explore</b>	Does the country have different categories of medicine outlets? What is the basis for differentiation? Are they all licensed?
<b>Notes and caveats</b>	None

**36. Percent of households more than 5/10/20 km from a health facility/pharmacy that is expected to dispense a set of tracer items in stock**

<b>Definition, rationale, and interpretation</b>	Measures geographic access to and availability of facilities with dispensary services A high percentage of households more than 5, 10, or 20 km from a health facility or pharmacy indicates that services may not be located in places where people need them.
<b>Suggested data source</b>	National health services study; other special studies <i>Module link:</i> Health Service Delivery, indicator 14 (people living within X km of health facility)
<b>Stakeholders to interview</b>	Department of health services or health services research (university or MOH), office of health statistics
<b>Issues to explore</b>	Are there concerns about the existence of unlicensed facilities? Are unlicensed facilities more widely distributed geographically than licensed outlets?
<b>Notes and caveats</b>	None

**H. Financing Pharmaceuticals**

Because pharmaceuticals save lives and improve health, financing systems must help ensure access to essential medicines for all segments of the population. Most countries rely on a diverse set of financing mechanisms for pharmaceuticals. Sources of funding may include public

financing based on national budgets, donor contributions, and direct private spending or indirect spending through insurance programs. Indicators 37–40 address these issues.

**37. What proportion of the annual national expenditure on medicines is by the government budget, donors, charities, and private patients?**

<b>Definition, rationale, and interpretation</b>	Measures personal or individual burden of pharmaceutical spending and the sustainability of financing
<b>Suggested data source</b>	WHO national accounts database, World Bank country reports; existing country studies  <i>Module link:</i> Health Financing, indicators 13 (government health budget allocation by cost category) and 14 (local level spending authority)
<b>Stakeholders to interview</b>	Health services financing department; health services research department (MOH or university), local World Bank representative, donors
<b>Issues to explore</b>	What is the spending by income level? By urban-rural split? By condition? These breakdowns measure the equity of personal or individual burden of pharmaceutical spending. If disparity exists in out-of-pocket expenditures among income groups, then equity and financial access are issues.  Donor commitments are not generally considered to be sustainable. How many donors are involved? What types of medicines do they support?
<b>Notes and caveats</b>	Be sure to include contributions by reimbursement mechanisms (public and private sectors) and various subnational budgets.

**38. Is there a system to recover the cost of pharmaceuticals dispensed in MOH facilities?**

<b>Definition, rationale, and interpretation</b>	In most countries, the funds available through government budgets and donors are not sufficient to meet rising demands for medicines. Existence of a cost recovery system, which is defined as any system that supports medicine costs by charging clients/patients, indicates that mechanisms are in place to supplement the pharmaceutical budget.
<b>Suggested data source</b>	National Medicines or Health Policy states if cost recovery is a policy, MOH or MOF reports for performance of cost recovery programs  <i>Module link:</i> Health Financing, indicators 15 and 16 (user fees)
<b>Stakeholders to interview</b>	Pharmacy department, health services financing department
<b>Issues to explore</b>	What is the value of pharmaceutical cost recovery funds received as a percentage of the total acquisition cost of pharmaceuticals? This figure provides an indication of whether cost recovery systems exist in practice or on paper only and how much is recovered. A high percentage indicates that cost recovery provides a significant source of funds to the pharmaceutical procurement system.

**38. Is there a system to recover the cost of pharmaceuticals dispensed in MOH facilities?**

What portion of recovered costs is used for purposes other than to replenish stock? Did you find evidence that cost recovery schemes are not meeting targets (e.g., are revolving drug funds [RDFs] decapitalizing)?

When was the system instituted? Why? Are there any political concerns or management issues regarding the system?

**Notes and caveats**

RDFs are a common type of cost recovery mechanism. RDFs may be at a national level, “cash and carry” type of medical store and can also be at the facility level although at that level, data on the performance may not be available.

Pharmaceutical cost recovery may be achieved through fees for medicines dispensed or may be incorporated into an overall fee for visit.

**39. Is there a price control mechanism for pharmaceuticals in the private sector?**

**Definition, rationale, and interpretation**

Records whether policies and regulations control the prices of pharmaceuticals in the private sector

Governments often attempt to influence the price of medicines and their affordability by controlling the level of profit the private sector can obtain from pharmaceutical sales. This indicator demonstrates the existence of price controls but does not indicate the type or performance of control and enforcement.

**Suggested data source**

WHO (2004). *The World Medicines Situation*.

Nation medicines and health policy

**Stakeholders to interview**

Pharmacy department, Ministry of Commerce, wholesalers and retailers of pharmaceuticals

**Issues to explore**

When was the policy adopted? How is it enforced?

How often is the policy reviewed?

Are data available on the performance of the cost control measures to address affordability to clients/patients?

Are all medicines covered by price controls? How are the medicines selected for price controls?

**Notes and caveats**

Price controls are often ceilings placed on prices that may be charged to clients/patients. Retail outlets may compete on the basis of discounts on this ceiling.

### **10.3.3 Summary of Issues to Address in Stakeholder Interviews**

This section includes a summary listing of the types of stakeholders to interview in assessing the indicators from Component 2 and the issues to address with each stakeholder. This information will help the assessors in planning the topics to discuss in stakeholder interviews. Table 10.3 provides a summary.

**Table 10.3 Summary of Issues to Address in Stakeholder Interviews**

<b>Profile of Stakeholder to Interview</b>	<b>Issues to Discuss with Stakeholder</b>
Head or director of the pharmacy department, others at the pharmacy department, Department of Medical Services	<ul style="list-style-type: none"> <li>• Existence of a national medicines policy and pharmaceutical law</li> <li>• Role of the NDRA</li> <li>• Existence of a pharmaceutical registration system</li> <li>• Composition of the NEML</li> <li>• Structure of the distribution system</li> <li>• Existence of DTCs</li> <li>• Existence of STGs</li> <li>• Costs of pharmaceuticals</li> </ul>
National Essential Medicines Program	<ul style="list-style-type: none"> <li>• Existence of a national medicines policy and pharmaceutical law</li> <li>• Role of the NDRA</li> <li>• Existence of a pharmaceutical registration system</li> <li>• Composition of the NEML</li> <li>• Existence of DTCs</li> <li>• Existence of STGs</li> </ul>
NDRA or director of the NDRA	<ul style="list-style-type: none"> <li>• Role of the NDRA</li> <li>• Existence of a pharmaceutical registration system</li> <li>• Practices for postmarketing surveillance of pharmaceuticals</li> <li>• Practices for licensing, inspection, and control of pharmacies, pharmacy personnel, manufacturers, importers, and other entities</li> </ul>
Drug Quality Control Laboratory	<ul style="list-style-type: none"> <li>• Practices for postmarketing surveillance of pharmaceuticals</li> </ul>
National Drug Inspectorate, Head of Pharmacy Inspection	<ul style="list-style-type: none"> <li>• Practices for postmarketing surveillance of pharmaceuticals</li> <li>• Practices for licensing, inspection, and control of pharmacies, pharmacy personnel, manufacturers, importers, and other entities</li> </ul>
Procurement office, MOH	<ul style="list-style-type: none"> <li>• Processes for procurement</li> <li>• Results of procurement (number and values of</li> </ul>

Profile of Stakeholder to Interview	Issues to Discuss with Stakeholder
	procurements, number and types of suppliers, supplier performance issues)
Medical stores department	<ul style="list-style-type: none"> <li>• Structure of the distribution (storage and transportation) system in both the public and private sectors</li> <li>• Availability of pharmaceuticals</li> </ul>
Donors	<ul style="list-style-type: none"> <li>• Existence of health programs, including information, education, and communication</li> <li>• Type of procurements</li> <li>• Structure of the distribution system</li> <li>• Provisions for human resource capacity building and training</li> <li>• Development of the infrastructure</li> </ul>
MOF	<ul style="list-style-type: none"> <li>• Composition of budgets, amounts of expenditures</li> <li>• Costs of the distribution system</li> <li>• Costs of pharmaceuticals</li> <li>• Sales of pharmaceuticals</li> </ul>
Vertical program managers (e.g., EPI)	<ul style="list-style-type: none"> <li>• Structure of the distribution system</li> </ul>
National DTC Chair	<ul style="list-style-type: none"> <li>• Composition of the NEML</li> <li>• Role of the DTCs</li> <li>• Existence of STGs</li> </ul>
Medical, pharmacy, and nursing schools	<ul style="list-style-type: none"> <li>• Existence of STGs</li> </ul>
Department of Health Services or Health Services Research (university or MOH)	<ul style="list-style-type: none"> <li>• Access to health facilities or pharmacies, pharmacy personnel, and prescribers</li> <li>• Costs of pharmaceuticals</li> </ul>
Office of Health Statistics	<ul style="list-style-type: none"> <li>• Access to health facilities or pharmacies (public and private), pharmacy personnel, and prescribers</li> <li>• Handling of priority health problems</li> </ul>
Health Services Financing Department	<ul style="list-style-type: none"> <li>• Prices of pharmaceuticals</li> <li>• Costs of pharmaceutical benefits programs</li> </ul>
Local World Bank representative	<ul style="list-style-type: none"> <li>• Prices of pharmaceuticals</li> <li>• Sales of pharmaceutical</li> </ul>
Local pharmaceutical industry, wholesale and retail and associations	<ul style="list-style-type: none"> <li>• Prices of pharmaceuticals</li> <li>• Sales of pharmaceutical, control of costs</li> <li>• Capacity for storage and distribution</li> <li>• Extent of the geographic reach</li> <li>• Opinion of MOH as a purchaser of pharmaceuticals</li> </ul>
National public insurance institution (procurement unit)	<ul style="list-style-type: none"> <li>• Prices of pharmaceuticals</li> <li>• Expenditures for pharmaceuticals</li> </ul>

## 10.4 Summarizing Findings and Developing Recommendations

Chapter 4 describes the process that the team will use to synthesize and integrate findings and prioritize recommendations across modules. To prepare for this team effort, each team member must analyze the data collected for his or her module(s) to distill findings and propose potential interventions. Each module assessor should be able to present findings and conclusions for his or her module(s), first to other members of the team and eventually at a stakeholder workshop and in the assessment report (see Chapter 3, Annex 3J for a proposed outline for the report). This process is an iterative one; findings and conclusions from other modules will contribute to sharpening and prioritizing overall findings and recommendations. Below are some generic methods for summarizing findings and developing potential interventions for this module.

### 10.4.1 Summarizing Findings

Using a table that is organized by the topic areas of your module (see Table 10.4) may be the easiest way to summarize and group your findings. (This process is Phase 1 for summarizing findings as described in Chapter 4.) Note that additional rows can be added to the table if you need to include other topic areas based on your specific country context. Examples of summarized findings for system impacts on performance criteria are provided in Annex 4A of Chapter 4. In anticipation of working with other team members to put findings in the SWOT framework (strengths, weaknesses, opportunities, and threats), you can label each finding as either an S, W, O, or T (please refer to Chapter 4 for additional explanation on the SWOT framework). The “Comments” column can be used to highlight links to other modules and possible impact on health system performance in terms of equity, access, quality, efficiency, and sustainability.

**Table 10.4 Summary of Findings—Pharmaceutical Management Module**

<b>Indicator or Topical Area</b>	<b>Findings</b> (Designate as S=strength, W=weakness, O=opportunity, T=threat.)	<b>Source(s)</b> (List specific documents, interviews, and other materials.)	<b>Comments<sup>a</sup></b>

<sup>a</sup>List impact with respect to the five health systems performance criteria (equity, access, quality, efficiency, and sustainability) and list any links to other modules.

Table 10.5 is an example of how the table might be completed.

**Table 10.5 Summary of Findings—Pharmaceutical Management Module (Example)**

<b>Indicator or Topical Area</b>	<b>Findings</b> (Designate as S=strength, W=weakness, O=opportunity, T=threat.)	<b>Source(s)</b> (List specific documents, interviews, and other materials.)	<b>Comments<sup>a</sup></b>
Availability	Poor availability in health facilities (W); better availability in private sector but not well controlled (O)	Observations in facilities, interviews with donors	Link with quality of care
Policy, laws, and regulations	There is a national drug policy draft (S); several relevant laws exist (S); poor enforcement capacity (T)	Draft NMP, interviews with the pharmacy department staff	Link with Governance module
Selection	NEML used as basis for kit system in public sector (S)	Draft NMP	Link with quality of care
Procurement	MOF conducts international competitive bids on behalf of the MOH for a limited number and quantity of essential medicines, but the process is not transparent (W); donors do not feel confident about current capacity (T)	Audit report; interview with the director of procurement, MOF	Link with efficiency and sustainability
Distribution	Kit system for essential medicines, with distribution, facilitated by donor and NGOs depending on province (O); many areas with limited to no access by road (W)	Interviews with the director of the pharmacy department and the medical stores manager	Link with equity and access
Use	STGs for some, not all, conditions endorsed by MOH (W); no data on quality of medicine prescribing or use (W)	Interview with the director of the pharmacy department, university department of clinical therapeutics	Link with quality
Information Systems	Inventory management information is systematically collected at central and facility levels (W,T)	Observations in health facilities, interview with staff in the pharmacy department	Link with Health Service Delivery Module
Financing	Dependency on donors for kits (W), facilities make local purchases (W)	Interview with MOH; MOF audit report	Link with sustainability, and with Health Service Delivery and Health Financing Modules

<sup>a</sup>List impact with respect to the five health systems performance criteria (equity, access, quality, efficiency, and sustainability) and list any links to other modules.

### 10.4.2 Developing Recommendations

After you have summarized findings for your module (as in Section 10.4.1 above), it is time to synthesize findings across modules and develop recommendations for health systems interventions. Phase 2 of Chapter 4 suggests an approach for doing this with your team. Below is a list of common issues and interventions seen in the area of pharmaceutical management; you may find it helpful to consider these points in developing your recommendations.

- **Availability**

- *Finding:* Facilities have low availability of key essential medicines.
- *Possible interventions or activities:* Low availability of essential medicines in the public sector may be affected by several elements of the pharmaceutical and public health system, for example, poor quantification practices, poor storage management practices, or inefficient distribution. Additional study is required to identify the root causes and possible appropriate interventions. Low availability of essential medicines in the private sector, when several other products are available in the market, reflects a low demand for those products. Irrational prescribing may be creating problems in both sectors.

- **Pharmaceutical policy, laws, and regulations**

- *Finding:* Up-to-date policies and laws regulating the pharmaceutical sector, including a national medicines policy are lacking. Registration system does not address product quality.
- *Possible interventions or activities:* Consider updating the NMP. Work with the NDRA to develop or update policies and procedures for the pharmaceutical registration system. Develop SOPs, and provide training to improve inspection capacity.

- **Selection**

- *Finding:* NEML does not exist, is out-of-date, or does not include medicines for key health conditions.
- *Possible interventions or activities:* Formulate a committee or process to review and revise the NEML based on morbidity patterns and standard treatment guidelines. Establish drug information centers or an alternative mechanism to increase access to unbiased information about medicines.

- **Appropriate use**

- *Finding:* Prescribing does not follow STGs, national STGs do not exist or are out-of-date, or STGs do not include guidelines for key public health conditions.
- *Possible interventions or activities:* Formulate a committee or process to review and revise STGs based on morbidity patterns and evidence-based best practices. Make copies of STGs available to facilities and providers. Provide training on the guidelines to practitioners. Establish DTCs and provide training to DTCs; provide pre- and in-service training on appropriate prescribing; develop managerial interventions to restrict prescribing.

- **Procurement**

- *Finding:* At the national level, purchasing prices are high compared to international prices.
- *Possible interventions or activities:* Review and update procurement procedures according to international best practices (e.g., competitive bidding, appropriate specifications, and delivery and payment terms). Provide training on procurement procedures and practices.

- **Storage and distribution**

- *Finding:* Holding costs (storage costs and inventory loss) are high relative to inventory value.
- *Possible interventions or activities:* Improve inventory management practices through training on inventory management functions and monitoring of key indicators. Explore lower cost alternatives with private sector (e.g., contract with prime distributor).

- **Access to products and services**

- *Finding:* Geographic access to public health centers that provide pharmaceuticals and pharmaceutical services is limited; a relatively greater number and wider distribution of private sector outlets exist, albeit offering varied quality services.
- *Possible interventions or activities:* If availability of essential products is not a problem in the private sector, study opportunities to partner with distributors and retailers to fill the gaps in the delivery system. Identify opportunities for strengthening human resource capacity to manage pharmaceuticals (public and private sectors). Develop accreditation system to increase the number of outlets in the quality services in the private sector and thus to complement the public sector.

- **Financing**

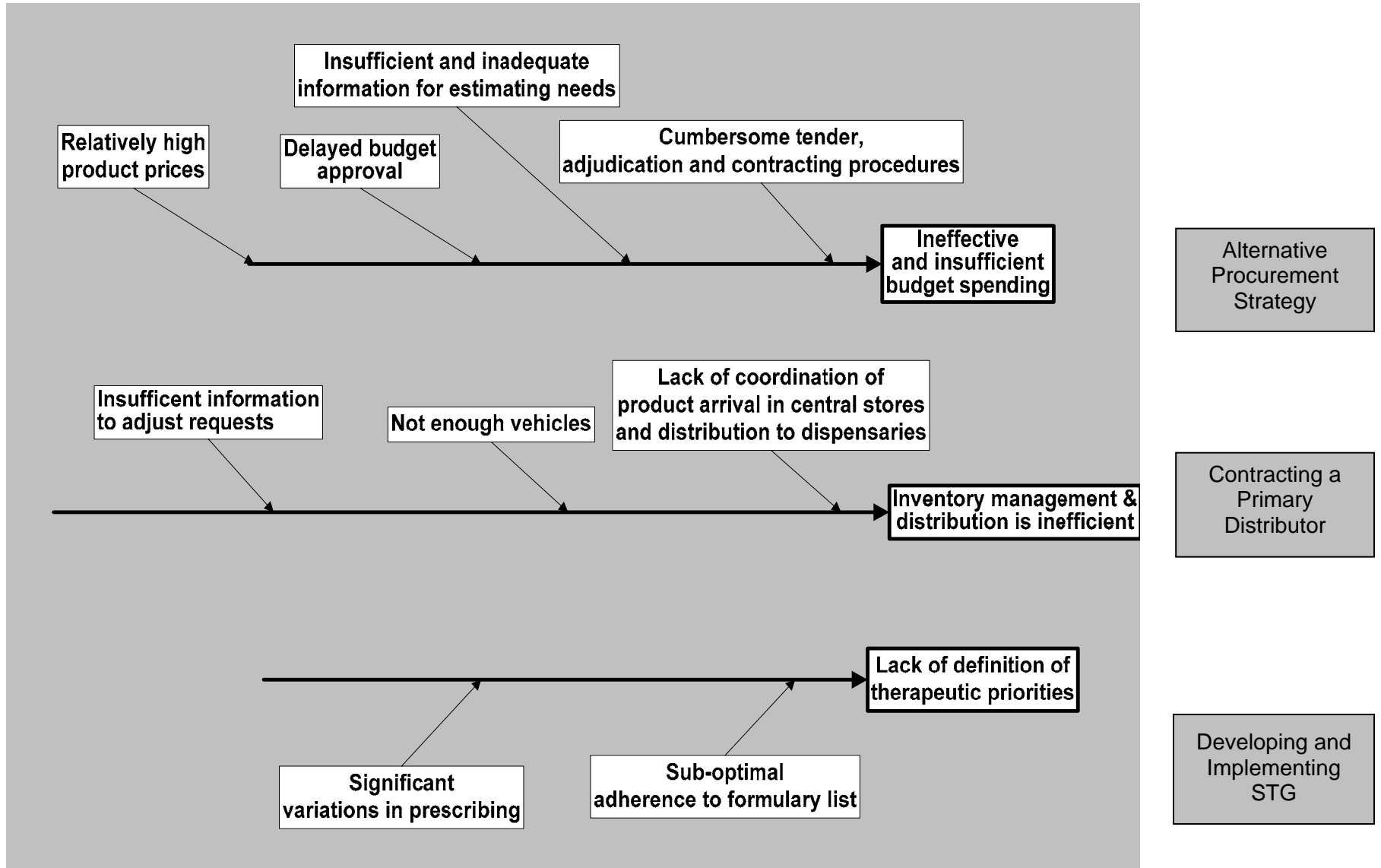
- *Finding:* The level of public financing of pharmaceutical expenses is low.
- *Possible interventions or activities:*
  - National level (and subnational level in decentralized systems): Study cost recovery or other cost-sharing options (e.g., RDFs and insurance). Improve efficiencies elsewhere in the system to reduce costs. Study alternatives for reallocation of funds (review medicine selection to focus more on priority medicines).
  - Facility level: Explore options for cost recovery or other cost sharing (e.g., RDFs and community-based insurance).

Figure 10.7 demonstrates how observed performance problems can be linked to appropriate interventions. Note that some issues and observed problems may actually be only the symptoms of larger systemic problems. Careful consideration must be given to historical, economic, sociocultural, and political factors that may have contributed to or exacerbated current performance problems. Keep in mind the U.S Agency for International Development (USAID) Mission’s priorities,<sup>2</sup> their competitive advantages compared to that of other donors, and the gaps in current donor programming, as well as opportunities for consistent, coordinated donor focus.<sup>3</sup> In addition, consult the Mission’s “Strategic Objectives and Intermediate Results” document for the health sector for potential linkages to pharmaceutical management issues.

---

<sup>2</sup> If this assessment is being done with the MOH as the primary audience, prioritization of problem areas and recommendations will need to focus on a broader range, because the MOH is responsible for addressing all health systems issues. Prioritization can be done based on criteria such as urgency, government priorities, and funding possibilities.

<sup>3</sup> For example, other donors may participate in a sector-wide approach while USAID leads with technical assistance, or other donors may focus on the public sector while USAID focuses on the private sector.



Source: Management Sciences for Health

Figure 10.7 Sample Fishbone Diagram of Pharmaceutical Management Issues and Potential Interventions

## References

MSH (Management Sciences for Health). 1995. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach*. Arlington, VA: MSH.  
<<http://erc.msh.org/newpages/english/toolkit/rpma.pdf>> (accessed Sept. 29, 2006).

MSH and WHO (Management Sciences for Health and World Health Organization). 1997. *Managing Drug Supply*. 2nd ed. West Hartford, CT: Kumarian Press.

WHO (World Health Organization). 2001. *How to Develop and Implement a National Drug Policy*. 2nd ed. Malta: WHO.

———. 2004. *The World Medicines Situation*. Geneva: WHO.  
<[http://w3.who.sea.org/LinkFiles/Reports\\_World\\_Medicines\\_Situation.pdf](http://w3.who.sea.org/LinkFiles/Reports_World_Medicines_Situation.pdf)> (accessed Sept. 29, 2006).

———. 2006. “Medicines Policy and Standards, Technical Cooperation for Essential Drugs and Traditional Medicine.” <<http://www.who.int/medicines/>> (accessed Sept. 29, 2006).