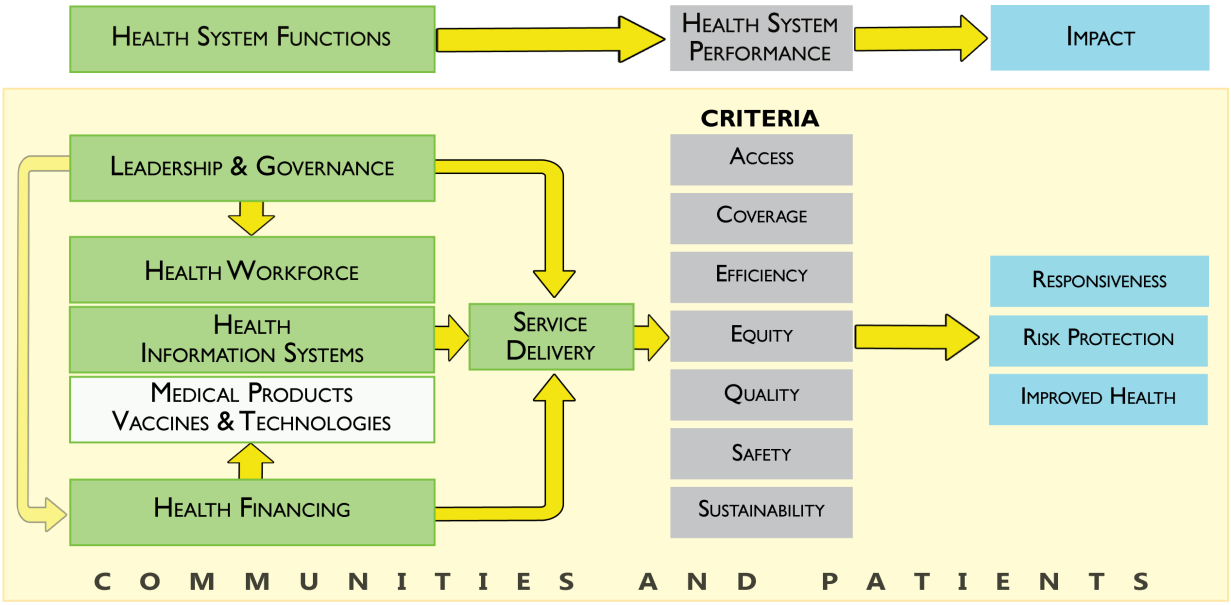
MODULE 6
MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

This module describes the importance of a well-managed procurement and distribution system for medical products, vaccines, and technologies and includes measurable indicators to determine the strengths and weaknesses of an existing system.

FIGURE 3.6.1 IMPACT OF BUILDING BLOCK INTERACTIONS



Introduction

Access to and regular availability of medical products, vaccines, and technologies at affordable prices is central to a functioning health delivery system. The gaps in this system area are critical to the overall performance of the health sector and merit close examination.

A unique feature of this system area is the active role of the private sector. As demand for health services has increased over the past 15 years, so has the quantity of medicines supplied through the private sector. There has been a large increase in the number of private pharmacies and typically, these pharmacies are often the first point of contact in the health system for many consumers, particularly consumers in rural and remote areas. Increasingly, MOHs are exploring ways to leverage private sector expertise and capacity to not only improve the efficiency of the public system, but in some cases, to contract out discrete segments of the public system (e.g., contracting-out of storage and distribution, partnering with private pharmacies in underserved areas). The challenge is to find the right public-private mix that ensures ready access and affordability of quality medicines and technologies to the overall population.

This module presents information that is critical to understanding the importance of how a well-managed system – one that ensures availability and affordability of products and technologies – impacts health service delivery:

- Subsection 6.1 presents and defines the key functions of managing medical products, vaccines, and technologies, and the processes that make up a system for this.
- Subsection 6.2 provides guidelines on preparing a profile of a system for managing medical products, vaccines, and technologies in the country of study.
- Subsection 6.3 presents the indicators to assess the systems and country capabilities to manage medical products, vaccines, and technologies.
- Subsection 6.4 is a guide to summarizing the findings and using them to recommend next steps.
- Subsection 6.5 contains a checklist of topics that the team leader or other writers can use to make sure they have included all recommended content in the chapter.

6.1 What Constitutes Management of Medical Products, Vaccines, and Technologies?

According to WHO, "a well-functioning health system ensures equitable access to essential medical products, vaccines, and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use" (2007). Careful management of pharmaceuticals and technologies 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 medicines and technologies essential to saving lives and improving health will be supplied, managed, and used. These items can be expensive to purchase and many pharmaceuticals are difficult to distribute because of their fragile nature. However, the reverse – lack of good-quality medicines and technologies, or their improper use, has an even higher cost, in terms of resources wasted, illness that could have been prevented or treated, and death.

Because medical supplies, vaccines, and technologies are so important and resources so limited, different methods have been developed to improve the supply of pharmaceuticals while minimizing costs. Managing medical products, vaccines, and technologies 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.

How Does a Management System for Medical Products, Vaccines, and Technologies Work?[1]

Management of medical products, vaccines, and technologies is composed of a set of practices aimed at ensuring equitable access to,[2] timely availability of, and cost-effective and appropriate use of safe, effective medicines, health products, and services in any health care setting. These activities are organized according to the functional components of a framework or system and may take place at various levels of the health system according to the design of the system. The components are the same for all sectors (public, faith-based, private nonprofit, private for-profit) although procedures and activities within each component may differ.

[1] There are many terms used in managing medical products, vaccines, and technologies (please refer to Annex 3.6.A).

[2] According to the Pharmaceutical Management Framework, access is a construct of several dimensions: geographic accessibility, product availability, financial accessibility, and cultural acceptability (Centers for Pharmaceutical Management 2003).

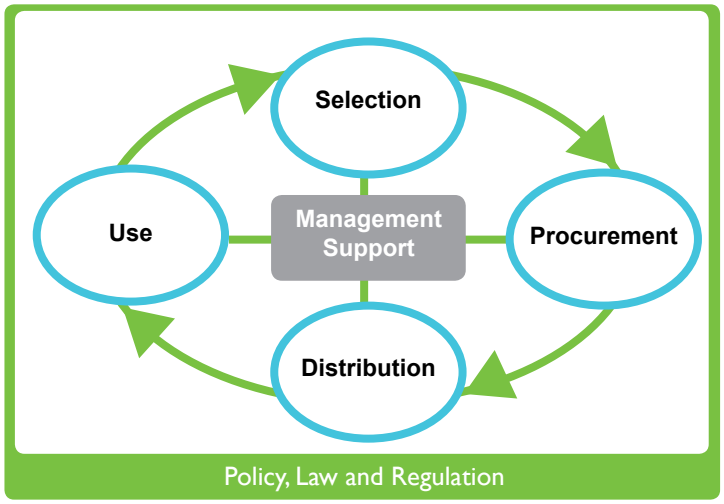
Activities in the management of medical products, vaccines, and technologies system are related to the selection of products that are to circulate in the supply system and to their procurement, distribution, and use (see Figure 3.6.2). Each component of the framework depends on the success of the previous component and contributes to the viability of the next.

The entire framework operates within and is affected by health policies, laws, and regulations that affect both public and private sector actors in the pharmaceutical sector. Health policies, laws, and regulations define priorities that have an impact on:

- Types of products and services that can or should be offered at different types of facilities
- 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

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.

FIGURE 3.6.2 FRAMEWORK FOR MANAGING MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES



Source: Adapted from MSH: http://www.msh.org/projects/sps/SPS-documents/upload/Eng_Pharm_Framework_Letter_rev.pdf

TIP

CONSIDER BOTH THE PUBLIC AND THE PRIVATE SECTOR

At the community level, patients may seek services from public and/or private (commercial or NGO) facilities including CHWs.

- Private facilities may have some level of interaction with the government and may obtain their pharmaceuticals from the public distribution system or parallel systems set up to service facilities individually.
- Private facilities, particularly when left to self-regulate, may obtain their supplies via alternate channels to governments – which can result in higher costs to patients due to low economies of scale and/or facilities obtaining materials through nonreputable sources.
- CHWs obtain their supplies from health facilities and play an important role in providing services and commodities to the community.

It is important to map out the totality of the flow of commodities taking into account all these players to fully understand the system.

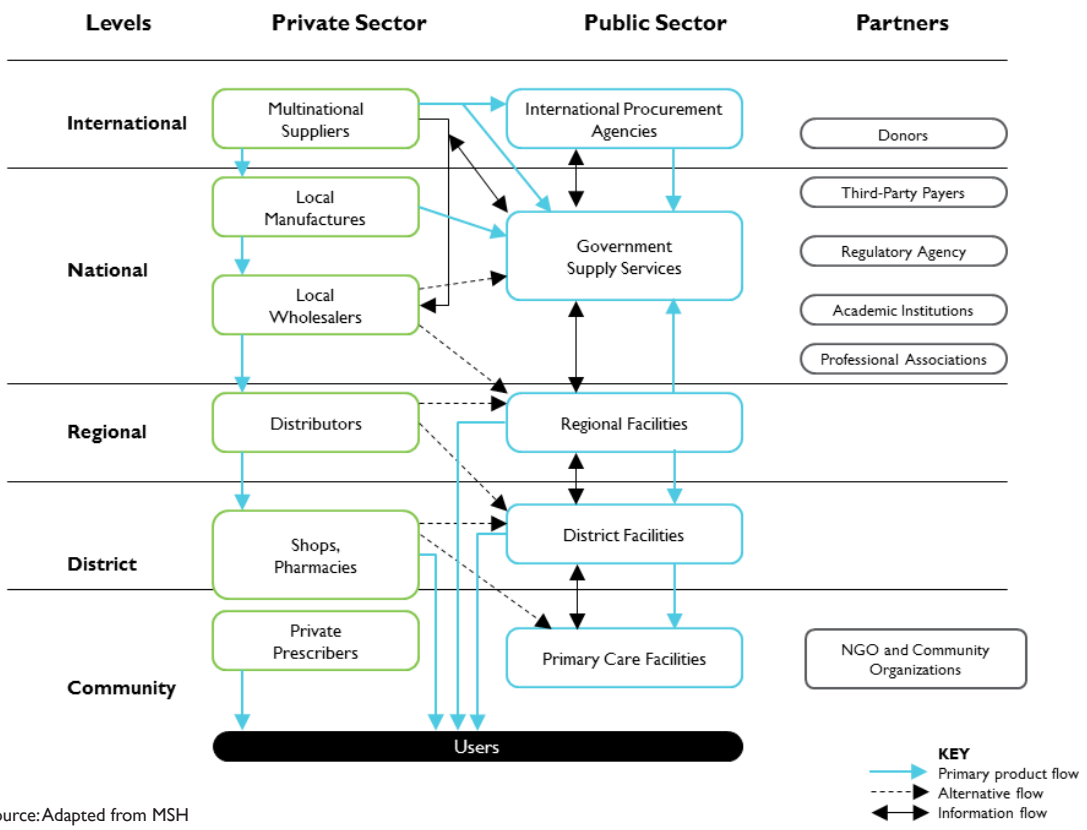
6.2 DEVELOPING A PROFILE OF THE MANAGEMENT SYSTEM FOR MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

OVERVIEW OF THE MANAGEMENT SYSTEM

The medical products, vaccines, and technologies system can be diagrammed in terms of the flow of information, funds, and products. The activities associated with carrying out each component of the system management can also be diagrammed.

The starting point for developing a profile is to diagram the distribution system to show how pharmaceuticals enter and move through the country. Figure 3.6.3 diagrams a typical multilevel distribution system that included private sector participation in the public sector supply system. In this system, medical products, vaccines, and technologies are procured and distributed to a designated level of the distribution chain by the appropriate government unit, NGO,[1] or private sector entity.

FIGURE 3.6.3 TYPICAL COUNTRY DISTRIBUTION SYSTEMS

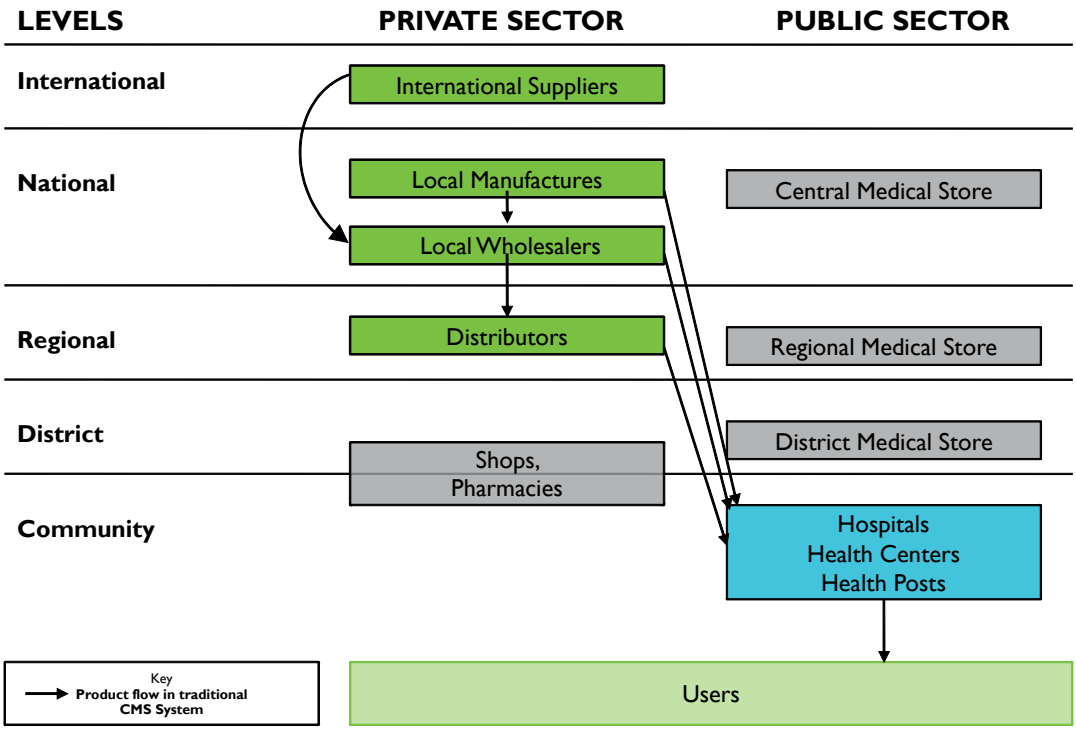


Source: Adapted from MSH

[1] NGOs in some countries have established nonprofit essential drugs supply agencies to provide high-quality medicine products, vaccines, and technologies.

Figure 3.6.4 diagrams an alternative public sector system in which storage and transportation functions are contracted out to private distributors. In this system, medicinal products, vaccines, and technologies are delivered directly to health facilities. Variations to these two models, or a combination of the two, may be implemented in an individual country. Additional flows may be added to demonstrate the channeling of funds, including budget allocations, procurement, payments to suppliers, and payments from clients/patients.

FIGURE 3.6.4 DIRECT DELIVERY MODEL FOR DISTRIBUTION



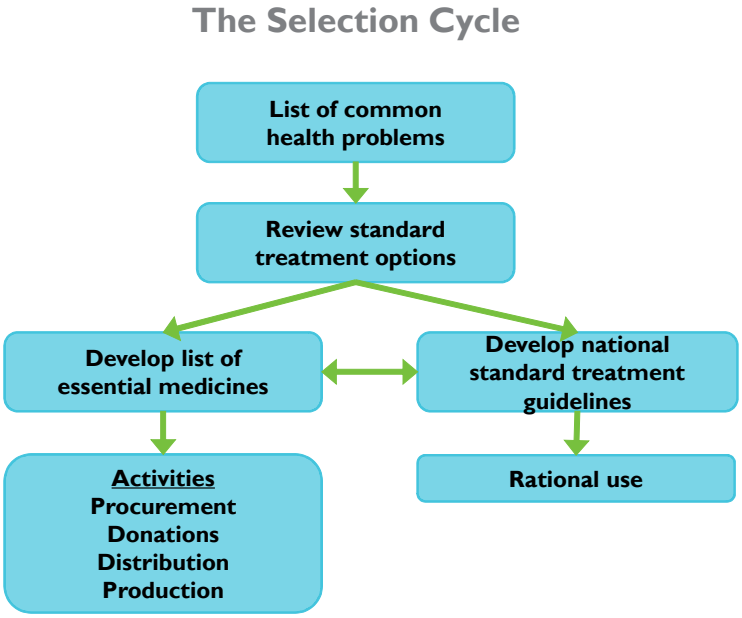
Source: Adapted from MSH
Note: CMS = Central Medical Stores

Technical team members should fully understand all the alternative supply chain flows that may be at play in a country's health system. However, determining the best model for any particular context is beyond the scope of this assessment.

Similar to the system overview, diagrams can be made to illustrate individual aspects of the process of selecting, procuring, and distributing pharmaceuticals. 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. As mentioned above, 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 (NMP). Alternatively, this information can be determined in the course of the in-country assessment.

1. **Selection** involves reviewing the country's priority health problems and identifying treatment options based on national policies and guidelines (see Figure 3.6.5). The existence of a formalized system for regular review of essential medicines lists and standard treatment guidelines (STG) for the treatment of priority disease conditions ensures that the health care system uses the most cost-effective and efficacious treatment options available.

FIGURE 3.6.5 COMPONENTS OF THE PUBLIC SELECTION PROCESS SYSTEM



Source: Adapted from MSH

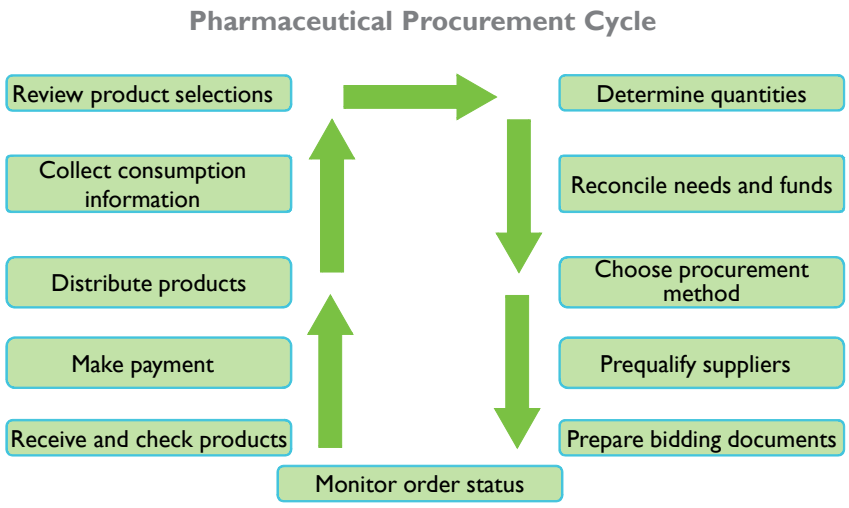
The assessment should examine:

- Is there a system for review of essential medicines lists?
- How often is this undertaken?
- By whom?
- What process do they use?
- How long does it take?
- How are guidelines updated and communicated?

This information will help inform procurement, donation, and other supply chain management decisions.

2. Efficient **procurement management** is composed of elements that collectively ensure that a public health care system is able to obtain the right products at the right prices in a timely manner (see Figure 3.6.6). An efficient procurement policy will also ensure that actors outside the public health care system access and/or import materials that are effectively regulated and consistent with national health care standards of quality. Several actors may be involved in the country's procurement systems including development partners, the World Bank, or a variety of private companies or wholesalers. The procurement system may be centralized, decentralized, or mixed and technical team members should examine the impact of all players on the effectiveness of the procurement system.

FIGURE 3.6.6 THE PROCUREMENT CYCLE



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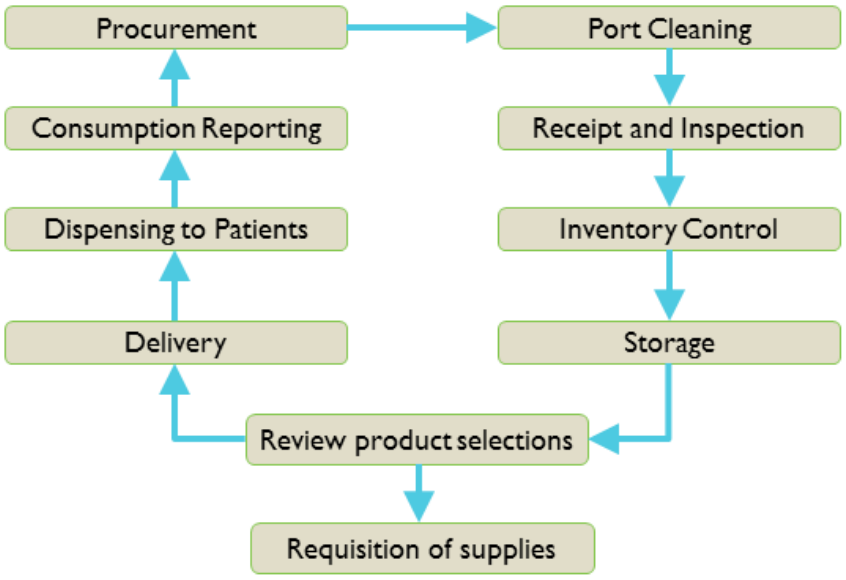
3. An efficient **distribution system** is required to ensure that pharmaceuticals are appropriately stored, managed, and transported to their point of use (see Figure 3.6.7). The various components of the distribution cycle are impacted by the type of supply chain architecture that exists in the country. The various logistics systems in the country may be based on a push or pull system and appropriate mechanisms need to be in place to manage inventory, the flow of information, and requisitions. Warehouse infrastructure, including adequacy of storage space, material-handling equipment, transportation equipment and/or contracts, needs to be examined to determine the effectiveness of the logistics systems.

Note that a country can have a mix of logistics systems. For example, the essential medicines program might be a pull system integrated with other programs such as for HIV/AIDS or family planning, while the EPI might maintain a vertical push system for managing its commodities. It is important to recognize all the different systems in place and examine how they have an impact on each other, where synergies could be built into them, or what recommendations for integration might be appropriate.

FIGURE 3.6.7 THE DISTRIBUTION CYCLE



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DECENTRALIZATION

Government decentralization can have significant impacts on the management of a country's medical products, vaccines, and technologies. Understanding the degree of decentralization will provide context for assessing the management. (See Module 3.1: Country and Health System Overview and Annex 3.1.A: Template for Organizing Information Regarding the Level of Decentralization of a Government.) Assessment questions should be tailored to reflect the level of decentralization, to ensure the questions are relevant to interviewees.

It is now generally understood that some functions of the health system are more appropriately centralized as opposed to decentralized, for example, normative/ stewardship and some procurement functions. Critical issues to consider include where important decision makers are based and their control over the medicines budget, as well as their supervisory and monitoring responsibilities. Critical governance issues include how well decentralized medical product budgets are executed in terms of both technical efficiency (selection of appropriate products and their use), allocative efficiencies (the amount spent on medicines versus something else), and transparency and accountability to the central system.

GENERAL ISSUES

The system of managing medical products, vaccines, and technologies generally reflects the health care system in which it operates. The first step in developing a profile of the system for managing medical products, vaccines, and technologies therefore is to map out how the overall health system, including public and private sector entities, is organized and how it

Country Story: Sub-Saharan African Country

Site visits combined with probing discussions with local staff often reveal undocumented situations that adversely affect the delivery of health care. Site visits to select health facilities at all levels of care during an 2010 HSA in one sub-Saharan African country found stock cards showing the facilities had recently received high-tech and modern equipment, and a supply of essential drugs. However, what the HSA team observed was completely different – the facilities had only antiquated equipment (microscopes, sterilizers, etc.), and there were stock-outs of many drugs. Interviews with facility staff revealed that most of the equipment had been sold to neighboring countries in order to pay staff salaries, which had not been paid for over six months due to political and economic turmoil. A visit to the MOH office showed that power outlets, doorknobs, sinks, and other equipment was missing or just being replaced.

functions. In addition to diagraming the management system, the following questions will help the technical team member to understand the country landscape and context for the management system.

- What is the participation of various levels of care in the public health care system? Of the private health care system? Of the NGO health care delivery 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?
- How big is the private pharmaceutical sector? Particularly retail pharmacies? Are there retail pharmacy chains? Large private importers and distributor? What is the relation of the private supply of medicines with public supply?
- Are vertical programs present?[2] 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)?

[2] Vertical programs, such as TB, Integrated Management of Childhood Illness, or malaria programs, may operate with program-specific essential medicine lists, STGs, procurement processes, and distribution systems. Where vertical programs function separately 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 program 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.

TIP

CONDUCTING THE ASSESSMENT

- Select only indicators that apply to the specific country situation.
- Conduct a thorough desk review of all available secondary data sources before arriving in country.
- Stakeholder interviews should focus on filling information gaps and clarifying issues.
- Coordinate stakeholder interviews with team members so all six modules are covered and avoid interviewing the same stakeholder twice.
- Look at all health actors – public, for-profit and not-for-profit, involved in delivering health services.
- Tailor assessment questions to reflect the level of decentralization so the questions are relevant to the interviewee.
- Schedule team discussions in country to discuss cross-cutting issues and interactions.
- Finalize an outline for the assessment report early on so sections can be written in country.

6.3 ASSESSMENT INDICATORS

This section discusses the indicators related to managing medical products, vaccines, and technologies – it shows the topical areas into which the indicators are grouped, lists data sources to inform the indicators, discusses how to deal with indicators that overlap with other building block modules, defines the indicators, and, in the "Interpretation" and "Issues to Explore" subsections, shows how to work with them. Finally, the section identifies key indicators to which the HSA technical team member can limit their work, if time precludes their measuring all indicators.

TOPICAL AREAS

The indicators for this module are grouped into eight topical areas (see Table 3.6.1), which cut across the many facets of managing medical products, vaccines, and technologies that were illustrated in Figure 3.6.2.

TABLE 3.6.1 INDICATOR MAP–MANAGING MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

Topical Area	Indicator Numbers
A. Standard indicators	1–4
B. Pharmaceutical policy, laws, and regulations	5–11
C. Selection of pharmaceuticals	12–14
D. Procurement	15–21
E. Storage and distribution	22–24
F. Availability and access to quality products	25–27
G. Appropriate use	28–31
H. Financing pharmaceuticals	32–34

DATA SOURCES

There are many sources to help the team members assess and analyze medical products, vaccines, and technologies. The sources are organized into three main categories:

1. **Standard indicators:** Data are drawn mainly from existing and publicly available international databases.
   - **Data on indicators** 1–4 are available through the Health Systems Database (http://healthsystems2020.healthsystemsdatabase.org/)
   - The *World Medicines Situation* (WHO 2004) (http://apps.who.int/medicinedocs/en/d/Js6160e/) is also an excellent resource. This document, which draws from studies in a wide range of countries and regions, provides an overview of key issues in managing medical products, vaccines, and technologies. Its annexes contain extensive data and information. More recent data may be available from the MOH and/or from project documents.

2. **Secondary sources:** Information for topical areas B through H should be gathered to the extent possible through desk review of reports, forms, and other documents.
   - Existing country studies
   - National drug law and national health and medicines policy
   - National drug regulatory authority (NDRA) reports
   - Documents supporting the public procurement process such as national procurement guidelines; standard bidding documents; standard operating procedures (SOPs) for MOH procurement[1]; procurement records and reports
   - Existing country studies
   - Quality control laboratory reports and quantification exercises
   - MOF audit reports
   - Service Provision Assessment and physical inventory reports
   - Logistics management information system (LMIS); transport department records
   - Existing health facility surveys or monitoring reports
   - EPI reports

3. **Stakeholder interviews:** The document reviews should be complemented, and any information gaps completed, during discussions and interviews with key informants and local stakeholders.
   - Head of the MOH pharmacy department
   - National essential medicines program
   - NDRA
   - National drug and therapeutics committee chair
   - Drug quality control laboratory
   - National drug inspectorate
   - MOH pharmacy department
   - MOH procurement unit or office
   - Pharmacy council/board
   - Pharmacy and other (e.g., manufacturing, distributors) professional associations
   - Private distributors

TIP

PRIORITIZING INDICATORS

If you are able to complete only part of this module because of limited time or resources, do the following:

- First, assess indicators 1–4, because data for them are readily available from the Health Systems Database (http://healthsystems2020.healthsystemsdatabase.org).
- Second, assess indicators 25, 26, 29, and 34.
- Third, if possible, assess all remaining indicators to get a more comprehensive picture of health system financing in the country.

[1] If an independent audit has been conducted, most information will be found there. World Bank project appraisal documents will exist if the country gets funding from the International Bank for Reconstruction and Development.

- Private retail pharmacy managers/owners and medical store managers
- Procurement managers at retail pharmacies
- Public and private health facilities managers
- Representatives of agencies throughout the supply chain (both public and private)
- MOF
- Site visit to public warehouse or central medical stores, to examine public storage, public pharmacies at government facilities, and vertical program managers (EPI, donors)
- Site visits to private pharmacies in urban and rural areas
- Department of health services or health services research (university or MOH)
- MOH office of health statistics
- Agency responsible for importation regulations

Data sources for these indicators may not be readily available. The assessment team member in charge of this module is responsible for organizing and developing a process for the review of documents and key informants' and stakeholders' interview responses to obtain information necessary to make judgments on the indicators listed.

TOPICAL AREA A: STANDARD INDICATORS

Overview

The data for the indicators in topical area A (indicators 1–4) are readily available at the The *World Medicines Situation* (http://apps.who.int/medicinedocs/en/d/Js6160e/) and the Health Systems Database (http://healthsystems2020.healthsystemsdatabase.org/).

STANDARD INDICATORS

Indicator	Definition and Interpretation
1. Total expenditure on pharmaceuticals (% total expenditure on health)	Enables measurement of significance of pharmaceutical spending relative to other spending on health; indicates financial and institutional sustainability of current pharmaceutical purchases. Data estimates in health system database are all in USD at average exchange rate values for the year 2000 Compare country to selected regional or income-level peer group.
2. Total expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita expenditure at average exchange rate in USD. Data estimates from the health system database for this indicator are all in USD at average exchange rate values for the year 2000. Measures magnitude of pharmaceutical spending and indicates financial and institutional sustainability. This measure should be compared to peer groups.

STANDARD INDICATORS CONT...

Indicator	Definition and Interpretation
3. Government expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita spending government spending on pharmaceuticals at average exchange rate in USD. Data estimates from the health system database for this indicator are all in USD at average exchange rate values for the year 2000. Measures magnitude of government spending on pharmaceuticals; indicates financial and institutional sustainability. Compare to selected peer group.
4. Private expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita at average exchange rate in USD. Data estimates from the health system database for this indicator are all in USD at average exchange rate values for the year 2000. Measures magnitude of government spending on pharmaceuticals; indicates financial and institutional sustainability. Compare to selected peer group

TOPICAL AREA B: PHARMACEUTICAL POLICY, LAWS, AND REGULATIONS

Overview

A country's NMP specifies the government's goals for the pharmaceutical sector, the priority of each goal, and the main strategies the government intends to use to attain the goals. 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.

PHARMACEUTICAL POLICY, LAWS, AND REGULATIONS

Indicator	Definition and Interpretation
5. Existence of an NMP or other government document that sets objectives and strategies for the pharmaceutical sector based on priority health problems	An NMP is a guide to action for the pharmaceutical sector. Existence of an NMP indicates commitment to improving the management of medical products, vaccines, and technologies in public and private sectors. If the NMP has been updated in the past five years, this indicates that the policy is kept up to date. If the country has a National Essential Medicines Program, it is likely that the program has received 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.

PHARMACEUTICAL POLICY, LAWS, AND REGULATIONS CONT...

Indicator	Definition and Interpretation
6. Existence of a comprehensive pharmaceutical law	A comprehensive pharmaceutical law includes all of the following components: • A regulatory framework • Principles for selecting medicines, including donations • Strategies for supply and procurement • Promotion of rational use of pharmaceuticals • Economic and financing mechanisms • Control of premises for distribution • Role of health professionals • Monitoring and evaluation mechanisms The existence of a comprehensive law demonstrates commitment to improving the management of medical products, vaccines, and technologies in public and private sectors. Specific questions to ask the interviewee include: • When was the national pharmaceutical law last updated? A law 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. • How does the regulatory framework differ between public and private sectors?
7. Existence of a NDRA responsible for the promulgation and enforcement of regulations	A governing regulatory body responsible for oversight of pharmaceutical laws. An effective NDRA indicates commitment to implementing and enforcing pharmaceutical laws. • 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? If there is not a clear separation of functions, the NDRA is vulnerable to corruption.
8. Existence of a system for pharmaceutical registration	A system for registration of pharmaceuticals in the market allows surveillance of drug quality and adverse events. • Is periodic renewal required, and are pharmacological standards applied? • Is registration based on an assessment of product efficacy, safety, quality, and truth in packaging information? If so, then pharmaceutical registration is part of a comprehensive quality assurance program. • Is the system kept up to date? • What are the 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 application backlog of several months would indicate a problem with the registration process; examining the pharmaceutical registration files will confirm if such a problem exists. Conversely, a very short turnaround time might mean that application information is not being reviewed seriously. If either problem exists, the registration system may simply be for generating revenue. • What are interviewee concerns regarding an underground market and/or unregistered products circulating in the market? The registration process may be considered too cumbersome (e.g., fees too high, delays too long), or the country may have no way to enforce registration requirements. • Some systems accept registration in "reference countries" (neighboring countries or countries with more stringent regulatory systems). This option may make sense for countries where human resource and infrastructure limitations prevent proper application review.

PHARMACEUTICAL POLICY, LAWS, AND REGULATIONS CONT...

Indicator	Definition and Interpretation
9. Existence of a post-marketing surveillance system	Yes or no with a qualitative description of the post-marketing system that determines if the MOH collects data regarding the effectiveness, quality, and safety of marketed products. Existence of a system to monitor pharmaceutical product quality is a critical first step, but does not address how well post-marketing surveillance is conducted. To learn more about post-marketing surveillance is conducted, ask the following questions: • How long has a post-marketing system been in place? • How extensively is it actually used for detecting and taking action on substandard pharmaceutical products? • Are data available? • What standards are used? • Are decisions taken as result of the system adequately enforced? • Does the country have a system by which providers and consumers can report product problems? If so, is it a passive, self-reporting system and/or a mandatory reporting system? If it is the latter, a key component of quality assurance is in place. Post-marketing surveillance systems may focus on some priority pharmaceutical therapeutic categories, products known to be particularly prone to problems or sources known to be problematic.
10. Existence of a pharmaco-vigilance system	A pharmacovigilance system is a mechanism to monitor adverse medication reactions and events. Ideally pharmacovigilance data should be reported to and aggregated at the national level. A pharmacovigilance system is the first step for monitoring patient safety, but this indicator does not address how well it is performing. If any of the following are present, it indicates an attempt by the country to institute mechanisms to ensure patient safety: • How long has the pharmacovigilance system been in place? • Is the country a member of the WHO Programme for International Drug Monitoring? If so, has the country been contributing to the program? • Is there a national center or mechanism to collate and analyze reports and take action to prevent adverse events? • Does the country have a system by which providers and consumers can report adverse events? If so, is it a passive, self-reporting system or a mandatory reporting system? • Are there any active surveillance activities, in the past or planned? The indicator does not measure whether actions are taken based on the results/findings reported by pharmacovigilance systems.
11. Mechanisms exist for licensing, inspection, and control	Yes or no, the mechanisms are in place for licencing, inspection, and control of pharmaceuticals. Existence of these mechanisms means a key component of quality assurance is in place, but it does not ensure that licensing, inspection, or other regulatory control activities are fully functional. As a result, dig deeper and ask the following questions of both public and private providers in the pharmaceutical sector: • How rigorous is the enforcement of licensing requirements? • Is a report of inspections and enforcement results generated regularly? • Does the country have sufficient qualified staff to conduct all inspection activities? • 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? Review a report. • What systems are in place to minimize corruption of inspection staff? (MOH staff are often enticed and bribed by the private sector to ignore poor quality products. Inspection staff corruption is a major and constant concern).

TOPICAL AREA C: SELECTION OF PHARMACEUTICALS

Overview

A National Essential Medicines List (NEML) is intended to result in more rational prescribing, lower treatment costs, and a more reliable supply of medicines. NEMLs should reflect evidence-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 although the NEML has implications for the private sector (noted below).

COUNTRY STORY: VIETNAM

Facility visits provide important opportunities for observing the local health system context.

While visiting two commune-level health centers in Vietnam, a technical team member noticed that the facilities had beautiful gardens. When asked about the gardens, a nurse explained that the facilities in Vietnam grow many medicinal herbs. The facilities use both Western and Eastern treatment methods. Alternative/traditional medicines may not be on the essential medicines list, but they may be used as a substitute for, or supplement to, medicines found on the list.

SELECTION OF PHARMACEUTICALS

Indicator	Definition and Interpretation
12. Existence of an National Essential Medicines List	A NEML is a list of drugs that satisfy the health care needs of the majority of the population; the drugs should be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford. A current NEML demonstrates a country's commitment to improved prescribing, improved supply management, rational resource allocation, and containing pharmaceutical costs. • Is the NEML based on national STGs? • Does it identify medicines by level of care? • Has the NEML been updated within the last five years? If so, it is likely to contain information most pertinent to current public health concerns and new advances in medicines. • Is the NEML meant to guide cost control issues (procurement) as well as therapeutic issues (quality of care)? • Are generic names or international nonproprietary names (INNs) used consistently throughout the system (prescriptions, logistics management information system (LMIS), inventory cards, etc.)? • Is there evidence of preference for branded products? Why? • Is this stated preference for brands also true in the private sector? • What are consumers' responses to generics? • From which countries? • Do consumers go to private sector in order to purchase brand names not available in the public facilities? For a very small number of products, "bioequivalence" (the generic or therapeutic equivalent may not be biologically equivalent, with clinical implications) may be an issue. Such cases are generally well documented. The definition of purpose and use of the NEML may be stipulated in the NMP.

SELECTION OF PHARMACEUTICALS CONT...

Indicator	Definition and Interpretation
13. Evidence of an active national committee responsible for managing the process of maintaining a NEML	An organized group of experts responsible for managing and maintaining a NEML. An active committee shows awareness of need for up-to-date pharmaceutical information and existence of a system to provide it. If the NEML is updated periodically (see Indicator 12) and an active committee is in place, then the list is updated through a consensus process and not by an individual. • What is the composition of the committee? • Does the committee include the private sector representing different aspects of pharmaceutical sector? • Does this committee have terms of reference (TORs) or 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 committee has SOPs, do they require review of 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 and practitioners? Does the country have a system to monitor compliance to the NEML for treatment and procurement purposes? As some countries develop their systems for managing medical products, vaccines, and technologies, they may rely on a generic NEML developed by WHO, or the NEML of a neighboring country that has a similar epidemiological profile.
14. What is the total number of pharmaceuticals on the NEML? (dosage forms and strengths)	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. 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: • First-level care facilities: 40–50 pharmaceutical products • Secondary care facilities: 150–200 pharmaceutical products • Tertiary care facilities: 300–400 pharmaceutical products How stable has the NEML been over time? Are more items added than eliminated? 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

Topical Area D: Procurement

Overview

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

- **Centralized system:** Procurement is conducted 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 decentralized health systems, pharmaceutical procurement is still done at the central level to maintain an economy of scale. Tendering may be done at the central level, with purchases from centrally approved vendors conducted at the lower levels.

Because procurement involves many steps and agencies, the technical team member 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.

The focus here is on procurement for the public sector. However, because a growing number of developing-country consumers rely on private provision of drugs, the assessment includes questions on procurement of medicines in the private sector. Taking the time to meet with procurement officers of large retail drug stores and private importers and distributors indicates if the private sector is complying with regulations, and therefore helping ensure that quality drugs are available through private channels.

PROCUREMENT

Indicator	Definition and Interpretation
15. Existence of formal SOPs for conducting procurement of pharmaceuticals	Formalized SOPs include detailed descriptions of the roles and responsibilities of all offices and agencies involved in the procurement of pharmaceuticals. SOPs promote accountability and transparency. Are there any formal mechanisms in place to bring together the many stakeholder groups that help to create or use SOPs? • Has an independent audit of the public sector procurement been conducted within the last three years? • Were the SOPs developed specifically for health sector goods and pharmaceuticals, or are they general SOPs? The general procurement guidelines are inadequate for pharmaceuticals. The procurement of pharmaceuticals requires unique considerations, including specifications and sourcing issues. Use this indicator in centralized and decentralized systems.
16. Use of generic or international nonproprietary names (INNs) for MOH procurement	Yes or no. This indicator measures a country's commitment to rational resource allocation and the containment of pharmaceutical costs. Generic names refer to the chemical names defining the medicines. In most cases, the generic is the same as the INN. Note: Generic names are to be differentiated from generic branded products. Use of generic or INN names facilitates competition among suppliers and manufacturers on the basis of the chemical entity of interest. Do health professionals feel pressure to procure brand name products due to detailing by medical representatives? Use this indicator in centralized and decentralized systems.
17. Percentage of procurements or purchases according to plan	The indicator reflects the reliability of a central procurement system. • More than two central pharmaceutical procurements (defined here as tenders, not orders against contracts) per year suggests system inefficiencies and a high level of activity. Several procurements or unplanned procurements may be related to poor quantification, supply planning, or to problems with the availability of financing at the time procurement is needed. How many unprogrammed (emergency) procurements occurred in the last two years? This number indicates the effectiveness of procurement planning and regular procurements. Frequent emergency procurements may indicate problems with planning and programming of regular procurement needs, barring force majeure. • What was the value of 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. • 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. What percentage of items listed for procurement in the last three tenders were actually purchased? A high percentage would indicate successful tenders and good quantification. It would imply lesser need for emergency purchases and a possible willingness among suppliers to bid and participate in the procurement system. 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.

PROCUREMENT CONT...

Indicator	Definition and Interpretation
18. Percentage (by value) of MOH pharmaceuticals is procured through competitive bids	The MOH has a competitive bidding process in place to procure pharmaceuticals. 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. • Why is procurement not conducted through competitive bid? • What reasons are cited? Not all items are best procured through competitive tenders. For example, because the reliable suppliers for vaccines are so few, these products are usually procured through direct purchase. • 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 can be due to a number of factors but may indicate that the procurement process is not very competitive. Use this indicator in centralized and decentralized systems. For decentralized systems, revise the question to cover the relevant procurement entity and not the MOH. A well-organized procurement unit should have this information readily available. An estimate of the value would be acceptable in most cases if the question is also asked about the percentage of suppliers that are international versus national or local.
19. Existence of a procurement pre- or post-qualification process for suppliers and products	This indicator demonstrates quality assurance within the procurement system and whether the process is based on review of objective information about product safety, efficacy, quality, and manufacturer/supply capacity. If quality assurance is present, it can limit participation of suppliers and products of dubious quality in the procurement process. • What is the procurement pre/post- qualification process for suppliers and products? • Is the process transparent? • Are the criteria for qualification clear? • Does the country participate in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce? Use this indicator in centralized and decentralized systems
20. Pharmaceuticals procured based on reliable estimates	"Past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate." (WHO 1999). Measures efficiency and appropriate use of resources. The more reliable needs estimates are, the lower the risk of overstock and stock-outs. • 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 these 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? "In many countries consumption data are incomplete or do not reflect real demand because the supply pipeline has not always been full and drug use has not always been rational. In such cases the morbidity-based and extrapolated consumption techniques may be used to estimate procurement requirements." (WHO 1999). Use this indicator in centralized and decentralized systems.
21. Private sector procurement processes	The private sector plays a big role in procuring pharmaceuticals. In many cases, importation of drugs distributed and sold in the private sector is unregulated. As a result, it is important to interview private sector importers (wholesalers) and distributors along with procurement officers for private pharmacies to assess whether they are following guidelines or international best practices (e.g., purchasing known brands and generics from reputable manufacturers).

TOPICAL AREA E: STORAGE AND DISTRIBUTION

Overview

The storage and distribution area includes all activities related to managing inventory: ordering, receiving, storing, and issuing supplies. These activities may take place at various levels of the system. The goals of distribution 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.

STORAGE AND DISTRIBUTION

Indicator	Definition and Interpretation
22. Value of inventory loss over 12 months	This indicator measures wastage or inefficiencies in the inventory management system and identifies opportunities for minimizing costs. Inventory loss is a holding cost. Inventory loss should be looked at for each level of the distribution chain. Current standards for commercial firms put inventory loss at a range of 20–30 percent of holding costs. Standards can vary by country or region, thus for comparison purposes, a few local private sector suppliers can be queried about their norms. This is the percentage of average inventory value Compare the value of inventory loss and other holding costs in public entities with commercial firms in the country, by level of the health system or distribution chain. Large disparities in the figures suggest opportunities for improvement. For example, where costs are lower in the commercial sector, options may include contracting out for selected services. Types of inventory loss that can be examined in detail include: • Expiry: Indicates that stock is not moving fast enough, that products purchased are not used, or that products have too short a shelf life. • Damage: Indicates storage or transport problems. • Obsolescence: Indicates that products purchased do not meet needs. • Theft: Indicates that enhanced security measures are needed. If available, list the inventory losses 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 an unusual event or instead to ongoing storage problems, such as storage facilities that are dilapidated or of inadequate size or construction. Other costs in the distribution system that can be explored include transportation costs (e.g., fuel, vehicle depreciation, personnel, and maintenance) and storage costs (e.g., personnel, rent, machinery, and utilities). Transportation and storage costs should be minimized and ideally should be compared to the commercial sector in country. 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
23. Percentage of deliveries or pick-ups according to plan	This indicator measures the level of performance of the order processing system. Medical store systems typically set a schedule for pick-up or delivery of orders for lower-level facilities. Multiple deliveries or pick-ups outside the planned schedule indicate problems with either the orders placed by requisitioning sites or that the medical store is not able to meet the demands of the regular order. Other problems that can contribute to this may include poor route planning and unavailability of transportation or financial resources. The ability of lower-level facility personnel to adequately determine their needs may also impact on the efficiency of the order processing system.

Storage and Distribution

Indicator	Definition and Interpretation
24. Existence of refrigeration units with functional temperature controls at each level of the distribution system	Public and/or private distribution systems include a cold chain. Interruptions in the cold chain (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 some systems, the cold chain is best managed as a separate vertical program. Provide a qualitative description of units (refrigerators or coolers) at different levels of the distribution system (central, regional, district, facility) • Are the thermostats checked regularly? • Are facilities equipped with a backup power supply? Are temperature logs/charts kept? Are there temperature controlled vehicles or cool boxes used to transport temperature sensitive commodities routinely? • Are private sector facilities required to maintain a cold chain? 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

Topical Area F: Availability and Access to Quality Products

Overview

This topical area examines availability of medicines, vaccines, and technologies as well as their appropriate use. Physical availability is 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. If possible, physical availability should be measured repeatedly over a period sufficient to cover at least one procurement cycle, and preferably three cycles. 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. (A sample tracer list is presented in Annex 3.6.B.)

Country Story: St Kitts and Nevis

Many MOHs do not consider themselves to be in partnership with the private health sector, but health system and private sector assessments reveal, a wealth of informal and ad hoc partnerships between the sectors. In St. Kitts and Nevis, the MOH experiences frequent stock-outs in medicines and laboratory reagents. MOH staff, through informal working relationships with private pharmacies and labs, refer patients to private pharmacies that "lend" medicines so the public sector patient does not have to pay. MOH labs "borrow" reagents from private ones and/or use private lab equipment for free when MOH equipment requires repair. The MOH re-supplies the private pharmacies and labs once the drugs and reagents arrive.

AVAILABILITY AND ACCESS

Indicator	Definition and Interpretation
25 Percentage of a set of unexpired tracer items is available	This indicator measures the physical availability of a set of essential or key medicines where they are expected to be in both public and private facilities. This is presented as a percentage at time of study and over a period of time in a sample of public and private facilities. Ideal levels would be at or nearly 100 percent unexpired tracers available. 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. Is availability more of a problem for some products than for others? Why? When? • What is the average frequency of stock-outs for tracer items at different levels of the health system (e.g., central medical stores, regional medical stores, health facilities) over a 12-month period? Compare this information across public and private facilities. The 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. • If stock-outs occur, what is the average duration of stock-outs for tracer items at different levels of the health system (central medical stores, regional medical stores, health facilities)? This information may be available from existing studies. • Review questions posed in the stock status table of the Logistics Indicators Assessment Tool (LIAT) (USAID, Deliver Project, Task 1 2008). http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LIAT.doc for a subset of products. • What happens when there are stock-outs in the public sector? Do consumers go to the private sector? 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.
26. Percentage of households more than 5/10/20 km from health facility/pharmacy to dispense essential medicines	This indicator measures geographic access to and availability of public and private facilities with dispensary services. This is presented as a percentage of households measured against (1) public and (2) private facilities. 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. • Are there concerns about the existence of unlicensed facilities? • Are unlicensed facilities more widely distributed geographically than licensed outlets? • The private pharmaceutical sector is the primary source of medicines consumed in many countries. One of the primary reasons is easy access to a private pharmacy compared to a public health facility. 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. • Does the country have different categories of medicine outlets? • What is the basis for differentiation? • Are they all licensed? Do they stock quality medicines? Module link: Module 3. 4, Health Service Delivery, Indicator 8 (people living within X km of health facility)
27. Existence of licensing provisions or incentives for private wholesalers and retailers	This legislation determines who is allowed to practice pharmacy and the conditions under which a pharmacy may operate, and it sets out rules for prescription and sales of drugs. (Lowe and RF, Montagu D. 2009) The presence of licensing provisions or incentives (e.g., certificate of need, tax incentives, and access to subsidized products) 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. 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? 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 assigning 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.

TOPICAL AREA G: APPROPRIATE USE

Overview

The aim of any system for managing medical products, vaccines, and technologies 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 28–31, which relate to the appropriate use of pharmaceuticals, should be explored for both the public and private sectors.

APPROPRIATE USE

Indicator	Definition and Interpretation
28. SOPs for dispensing and counseling available	Standard procedures and consistent training assist dispensers to provide quality services to patients in the public and private sectors. There should be evidence that the strategic plan is being implemented. A high percentage of dispensers who are trained will indicate a commitment to promoting good dispensing practices. Good dispensing practices go beyond counting and handing over medicines. They include providing counseling and information on how to take the drug, how to dispose of it, and how to recognize and respond to adverse events; in most countries, this is considered an essential dispensing function. Determine if private providers have also received this training and apply it.
29. Existence of functioning mechanisms to improve the prescribing and dispensing practices	The commitment to ensure the appropriate use of medicines is generally described in a NMP. 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 Drugs and Therapeutic Committees (DTCs). These committees exist primarily at the hospital level, but they may support review of prescribing at the lower-level facilities. 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. However, the following questions may be helpful for probing into the local situation: • Are regular reviews of prescribing practices conducted at the public facility level? In private facilities? • How regular are the reviews of public facilities? Private facilities? • Who is responsible for conducting these reviews? • Are decisions/actions taken as a result of the finding of reviews and are these decisions enforced? • 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? • 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)?

APPROPRIATE USE CONT...

Indicator	Definition and Interpretation
30. Existence of national therapeutic guides with standardized treatments for common health problems	Up-to-date guidelines and STGs indicate that evidence-based best practices for treatment of common conditions are reviewed and codified. • Are the guidelines used to develop the NEML? • When were the guidelines last updated? • Does the system that ensures that the guidelines are updated rely on unbiased clinical and pharmaceutical information? If so, treatments are consistent with changing evidence-based best practices and changing country disease patterns. • Are these guidelines distributed to and used in all levels of the health care system and to the private sector? 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. Also see Service Delivery Module, Indicator 24 (existence of clinical standards).
31. Existence of treatment guidelines used for pre- and in-service training of health personnel in both public and private sector	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. If treatment guidelines exist, ask the following questions: • Are treatment guidelines used for supervision and monitoring activities in public-sector health facilities? In private facilities? If so, supervision and monitoring practices incorporate oversight of quality and appropriateness of treatment. • 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. Compare supervision of public facilities to private facilities. • 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. 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 except possibly in the private sector. Module Link: Service Delivery Module, Indicators 23 and 27 (quality assurance processes), Module 3.5, Human Resources for Health, Indicators 12 and 18 (Production of new health care workers is responsive to the needs of the health care system)

TOPICAL AREA H: FINANCING OF MEDICAL PRODUCTS, VACCINES AND TECHNOLOGIES

Overview

Because medical products, vaccines and technologies 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 these items. Sources of funding may include public financing based on national budgets, donor contributions, and direct private spending or indirect spending through insurance programs.

FINANCING OF MEDICAL PRODUCTS, VACCINES AND TECHNOLOGIES

Indicator	Definition and Interpretation
32. Proportion of annual national expenditure on medicines financed by government budget, donors, charities, and private patients (last through out-of-pocket payments)	Total amount spent on medicines distributed by source of funds. To better understand this indicator disaggregate in terms of: • Spending by income level • Ratio of urban-rural expenditures • Expenditures 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. But if they are present examine: • How many donors are involved? What types of medicines do they support? • Be sure to include contributions by reimbursement mechanisms (public and private sectors) and various sub-national budgets. *Module link:* Health Financing Module, Indicators 9 and 12 (government health budget allocation by cost category) and 13 (local-level spending authority)
33. Existence of a system to recover the cost of pharmaceuticals dispensed in MOH facilities	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. If a system of cost-recovery exists, follow up with the following questions: • 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. • What portion of recovered costs is used for purposes other than to replenish stock? Is there evidence that cost-recovery schemes are not meeting targets (e.g., are revolving drug funds being depleted?) • When was the system instituted? Why? • Are there any political concerns or management issues regarding the system? Revolving drug funds are a common type of cost recovery mechanism. The funds may be at a national-level "cash and carry" type of medical store. They 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. *Module link*: Health Financing Module, Indicators 20–22 (user fees)

FINANCING OF MEDICAL PRODUCTS, VACCINES AND TECHNOLOGIES CONT...

Indicator	Definition and Interpretation
34. Out-of-pocket expenditure for health on medicines	Percentage of out-of-pocket spending on medicine out of total out-of-pocket spending on health. There are various scenarios in which patients may spend out-of-pocket resources to acquire medicines. Although medicines are in principle 'free of charge' in many public systems, patients may choose to access private pharmacies due to perceptions of higher quality and/or during stock-outs at public facilities due to ineffective or dysfunctional public procurement systems. In other cases, because the cost of medicines and medicinal treatments can represent a significant percentage of all of the health system costs, governments seek some form of cost sharing, by having patients pay a portion of the cost of medicines. There is also the belief that if patients pay for their medicines, they will use them more wisely. Health insurance programs may include co-payments for medicines, whereas other schemes will only cover the cost of the treatment. Some systems will include the cost of medicines in the overall treatment. The ability to determine when out-of-pocket expenditures for medicines result in an unnecessary barrier to care is a constant concern. This indicator should be considered within the context of the overall health system financing scheme, as well as assessed in relation to where/why patients choose to seek pharmaceuticals at particular locations

KEY INDICATORS TABLE

Table 3.6.2 identifies four indicators from the medical product, vaccines, and technologies indicator list that are particularly useful to: (1) monitor and track medical products, vaccines, and technologies management progress over time; and (2) guide the technical team with severe time constraints to focus on the most important measures of medical products, vaccines, and technologies. Depending on the scope and time and resources available for the country assessment, this list should be modified.

TABLE 3.6.2 KEY INDICATORS

No.	Indicator
25.	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?
26.	Percentage of households more than 5/10/20 km from a public or private health facility/ pharmacy that is expected to dispense essential medicines
29.	Are there any functioning mechanisms/tools in place to improve the prescribing and dispensing practices in hospitals and health facilities?
34.	Percentage of out-of pocket expenditure for health on medicines

6.4 SUMMARIZING FINDINGS AND DEVELOPING RECOMMENDATIONS

Section 2, Module 4, describes the process that the HSA 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 in the assessment report (see Annex 2.1.C for a suggested outline for the report). This process is iteractive; 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.

ANALYZING DATA AND SUMMARIZING FINDINGS

Using a table that is organized by the module topic areas (see Tables 3.6.3 for a template and Table 3.6.4 for an example) is a methodical way to summarize and group findings as data are collected. Note that additional rows can be added to the table if additional topic areas are included based on the specific country context. In anticipation of putting findings in the SWOT framework, each finding should be labeled as S, W, O, or T (please refer to Module 2.4 for additional explanation on the SWOT framework). The "Comments" column can be used to highlight links to other modules and possible impacts on health system performance in terms of equity, efficiency, access, quality, and sustainability. Additional guidance on which indicators address each of the WHO performance criteria is included in Table 3.6.5.

TABLE 3.6.3 TEMPLATE: SUMMARY OF FINDINGS–MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES MODULE

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

[a] List impact with respect to the five health systems performance criteria: equity, efficiency, access, quality, and sustainability. Also list any links to other chapters.

Table 3.6.4 is an example of the completed table.

TABLE 3.6.4 SUMMARY OF FINDINGS – MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES MODULE

Indicator or Topical Area	Findings (Designate as S=strength, W=weakness, O=opportunity, T=threat.)	Source(s) (List specific documents, interviews, and other materials.)	Comments*
Availability	Poor availability in health facilities (W); better availability in private sector but not well controlled (O)	Observations in public and private 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 National Medicines Policy (NMP), interviews with the pharmacy department staff	Link with Governance module
Selection	National Essential Medicines List used as basis for kit system in public sector (S)	Draft NMP	Link with quality of care
Procurement	Ministry of Finance (MOF) conducts international competitive bids on behalf of the Ministry of Health (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); private sector able to procure reliable drugs at all different price points (O)	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); but private sector has further reach (O)	Interviews with the director of the pharmacy department and the medical stores manager ; private wholesalers and distributers	Link with equity and access
Use	Standard treatment guidelines 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); private retail and chain pharmacies have state of the art IT systems; willing to share info with MOH (O)	Observations in health facilities, interview with staff in the pharmacy department; private pharmacy owners	Link with Health Service Delivery module
Financing	Dependency on donors for kits (W), facilities make local purchases (W); but private sector can procure some needed drugs at affordable prices (O)	Interview with MOH; MOF audit report; procurement officers of private importers and retail pharmacies	Link with sustainability, and with Health Service Delivery and Health Financing modules

* List impact with respect to the five health systems performance criteria: equity, efficiency, access, quality, and sustainability. Also list any links to other chapters.

TABLE 3.6.5 LIST OF SUGGESTED MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES INDICATORS ADDRESSING THE KEY HEALTH SYSTEM PERFORMANCE CRITERIA

Performance Criteria	Suggested Indicator from HRH Module
Equity	34. Percentage of out-of pocket expenditure for health on medicines
Efficiency	17. Percentage of procurements/purchase according to plan
Access (including coverage)	26. Percentage of households more than 5/10/20 km from (1) public and (2) private health facility/ pharmacy that is expected to dispense essential medicines
Quality (including safety)	9. Is there a system for the collection of data regarding the efficacy, quality, and safety of marketed products (post-marketing surveillance)?
Sustainability	33. Is there a system to recover the cost of pharmaceuticals dispensed in MOH facilities?
	22. Active stakeholder participation in HRH policy and processes

Each indicator includes specific suggestions for interpretation. When examining medical products, vaccines, and technologies though, it is important to consider each topical area as a whole and not look simply at the area's individual indicators – small problems may be symptoms of larger, systemic issues.

As discussed in Section 1, Module 1, WHO's health system performance criteria can also be used to examine the strengths and weaknesses of the health system. Table 3.6.5 summarizes the medical products, vaccines, and technologies indicators that address each of the five key performance criteria highlighted by WHO: equity, efficiency, access, quality, and sustainability (WHO 2000).

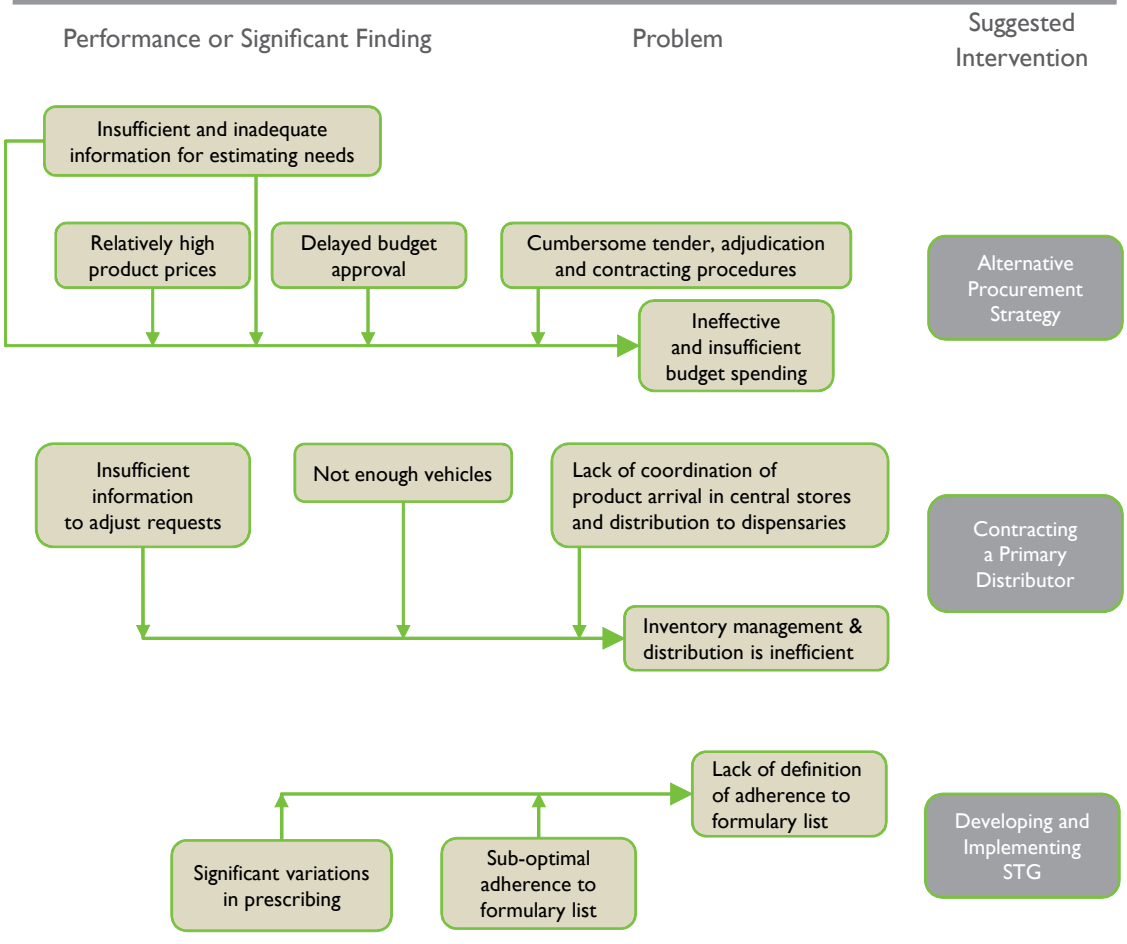
It may be helpful to organize the description of the medicines, vaccines, and technology profile and key findings according to topical areas. Depending on the amount of data collected and their importance (e.g., is it really a critical health system gap?), some of the subheadings can be combined and/or eliminated. The headings correspond to the topical areas and include:

- Current situation (see Annex 3.6.C for examples on how to present the data)
- Policy environment supporting medicines, vaccines, and technologies
- Selection and procurement
- Storage and distribution
- Availability and access to quality products
- Appropriate use
- Financing to purchase medicines, vaccines and technologies

Developing Recommendations

Summary findings will be synthesized across all the modules to identify and prioritize major issues and develop recommendations for health system interventions. Figure 3.6.8 demonstrates how observed performance problems can be linked to appropriate interventions. Careful consideration must be given to historical, economic, socio-cultural, and political factors that may have contributed to or exacerbated current performance problems. Keep in mind the priorities and competitive advantages of various donors, and the gaps in current donor programming, as well as opportunities for consistent, coordinated donor focus. To use the fishbone diagram, start by identifying a problem statement. In the diagram, one problem statement is "inventory management and distribution is inefficient." Use information collected from the assessment to determine all the factors that 'cause' the problem. Using this information can then help to identify appropriate alternative interventions.

Figure 3.6.8 Sample Fishbone Diagram of Managing Medical Products, Vaccines, and Technologies Issues and Potential Interventions



Source: MSH

Section 2, Module 4, Analyze Findings, suggests an approach for synthesizing findings across modules with your team and for crafting recommendations. Table 3.6.6 contains a list of common issues and interventions seen in the area of managing medical products, vaccines, and technologies. These points can be helpful in developing recommendations.

TABLE 3.6.6 ILLUSTRATIVE RECOMMENDATIONS FOR MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES ISSUES

Health Systems Gap	Possible Interventions
Availability and Access	
Public facilities experience stock-outs of key essential medicines • Insufficient public funds to purchase essential medicines • Inefficient govt procurement and distribution systems	• Explore alternative methods to increase public funds to purchase essential medicines (e.g., user fees for drugs). • Strengthen public sector capacity to forecast and purchase essential medicines. • Explore opportunities to partner with private sector distributors to get essential medicine out to rural areas more regularly. • Better coordinate with the private sector during stock-outs, referring patients to private pharmacies and possibly working out affordable prices for medicines for public sector patients.
Geographic access to public health centers that provide pharmaceutical services is limited • Greater number and wider distribution of private sector outlets exist • Varied quality of private services	• 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. • Open up donor-sponsored training to strengthen private sector clinical skills in underserved areas. • Develop accreditation system to license the number of private sector outlets in underserved areas ensuring quality and thus complementing the public sector. • Explore ways to reduce the cost of the essential medicines delivered by private pharmacists (e.g., donated) ensuring affordability.
Pharmaceutical policy, laws, and regulations	
No up-to-date policies and laws regulating the pharmaceutical sector, including a NMP • Private sector self-regulating • Registration system does not address product quality.	• Update the NMP with participation of public and private stakeholder groups. • Using same participatory process, work with the NDRA to develop or update policies and procedures for the pharmaceutical registration system. • Include private sector leaders in pharmaceuticals sector in policy and planning as one of many strategies to bring private sector into public sector regulatory framework. Involve professional associations as mechanism to distribute new policies, guidelines and to offer in-service training.
Selection	
NEML does not exist, is out of date, or does not include medicines for key health conditions	• Formulate a committee or process to review and revise the NEML based on morbidity patterns and STGs. • Establish drug information centers or an alternative mechanism to increase access to unbiased information about medicines.
Appropriate use	
• 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	• Formulate a committee or process including the private sector to review and revise STGs based on morbidity patterns and evidence-based best practices. • Make copies of STGs available to all facilities and all providers (public and private alike. Provide training on the guidelines to practitioners including private sector through professional associations or by opening up public sector training. • Establish DTCs and provide training to DTCs; provide pre- and in-service training on appropriate prescribing to all providers. • Develop managerial interventions to restrict prescribing that can be applied in both public and private sectors.

TABLE 3.6.6: ILLUSTRATIVE RECOMMENDATIONS FOR MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES ISSUES, CONT

Health Systems Gap	Possible Interventions
Procurement	
At the national level, purchasing prices are high compared to international prices	• Review and update procurement procedures according to international best practices (e.g., competitive bidding, transparent processes, appropriate specifications, and delivery and payment terms). • Provide training on procurement procedures and practices. • Compare prices in private sector to determine where and how able to purchase at lower prices, if applicable.
Storage and distribution	
Holding costs (storage costs and inventory loss) are high relative to inventory value	• Improve inventory management practices through optimizing flows, development of SOPs, training on inventory management functions and monitoring of key indicators. • Explore lower-cost alternatives with private sector (e.g., contract with prime distributor).
Financing	
The level of public financing of pharmaceutical expenses is low	• National level (and subnational level in decentralized systems): Study cost recovery or other cost-sharing options (e.g., revolving drug funds 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., revolving drug funds and community-based insurance).

6.5 ASSESSMENT REPORT CHECKLIST: MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

❑ **Profile of Country Medical Products, Vaccines, and Technologies**

A. Overview of Medical Products, Vaccines, and Technologies

a. What constitutes management of medical products, vaccines, and technologies?

b. How does a management system for medical products, vaccines, and technologies work?

B. Create medical products, vaccines, and technologies flowchart (should include):

a. Management

b. Distribution

c. Selection

d. Procurement

e. Decentralization

❑ **Medical Products, Vaccines, and Technologies Assessment Indicators**

A. Standard Indicators

B. Pharmaceutical policy, laws, and regulations

C. Selection of pharmaceuticals

D. Procurement

E. Storage and distribution

F. Availability and access to quality

G. Appropriate use

H. Financing pharmaceuticals

❑ **Summary of Findings and Recommendations**

A. Presentation of findings

B. Recommendations