SECTION 3: GUIDANCE ON ASSESSMENT OF THE HEALTH SYSTEM AND ITS CORE FUNCTIONS

MODULE 4: MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

This module describes the importance of a management system for medical products, vaccines, and technologies and includes measurable indicators to determine the strengths and weaknesses of an existing system.
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**ACRONYMS**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTC</td>
<td>Drugs and Therapeutic Committees</td>
</tr>
<tr>
<td>EML</td>
<td>Essential Medicines List</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded program on immunization</td>
</tr>
<tr>
<td>INN</td>
<td>International Nonproprietary Names</td>
</tr>
<tr>
<td>IRP</td>
<td>International Reference Pricing</td>
</tr>
<tr>
<td>LMIS</td>
<td>Logistics Management Information System</td>
</tr>
<tr>
<td>KM</td>
<td>Kilometers</td>
</tr>
<tr>
<td>MOF</td>
<td>Ministry of Finance</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
</tr>
<tr>
<td>NMRA</td>
<td>National Medicines Regulatory Authority</td>
</tr>
<tr>
<td>NEML</td>
<td>National Essential Medicines List</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicine Policy</td>
</tr>
<tr>
<td>NQCL</td>
<td>National Quality Control Laboratory</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>STGs</td>
<td>Standard Treatment Guidelines</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>UHC</td>
<td>Universal Health Coverage</td>
</tr>
</tbody>
</table>
I. INTRODUCTION

A “well-functioning health system ensures equitable access to medical products, vaccines, and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use” (WHO 2007a). Shortcomings in this system function merit close examination because they can undermine the overall performance of health systems and their ability to achieve the goals of universal health coverage (UHC). Medicines are critical for achieving the health and risk protection goals of UHC, but can also be a major source of health system inefficiencies. In low- and middle-income countries, medicines on average account for 25 percent of total health expenditure and can be as high as 67 percent (Lu et al. 2011). Medicines account for 3 of the 10 leading sources of inefficiencies in health systems. These inefficiencies result from, among other factors, the underuse of generics, higher than necessary medicine prices, falsified and substandard products, and inappropriate and ineffective use (WHO 2010). Careful management of medical products, vaccines and technologies is therefore critical to mitigate the waste of scarce health system resources.

Ensuring equitable access to medical products, vaccines, and technologies—and their appropriate use—is a core function of the health system. However, health systems struggle to ensure access to and the appropriate and cost-effective use of these products and technologies. Access refers to affordability, (cultural) acceptability, (geographical) accessibility and availability (Penchansky and Thomas 1981; CPM 2003). Poor medicine availability—particularly in the public sector, where availability of generic medicines is less than 60 percent—is a major barrier to access (Cameron et al. 2011). Availability is generally higher in the private sector, but prices are usually much higher. Out-of-pocket expenditure on medicines can place undue financial burden on households (Wagner et al. 2011), and high medicine expenditures may threaten the sustainability of health systems (Bigdeli et al. 2014). With respect to appropriate use, only 30-40 percent of patients in low- and middle-income countries are treated according to standard treatment guidelines (STGs), and less than 50 percent of patients adhere to treatment regimens (Holloway and van Dijk 2011).

By ensuring equitable and timely access to safe, effective, quality medical products, vaccines, and technologies, and their appropriate and cost-effective use, a well-functioning pharmaceutical system improves cost effectiveness and efficiency of the system, promotes quality of care, and helps to achieve better health outcomes.

Although the public sector is the principal provider of health services and pharmaceutical products, in many countries the private sector (e.g., commercial, not-for-profit, community-based or faith-based organizations) plays an active role in the delivery of pharmaceutical products and services. As demand for health services has increased, so has the quantity of medicines and other pharmaceutical products supplied through the private sector. The private sector is often a first point of contact in the health system for many consumers. In a few countries, health ministries are trying to leverage private sector expertise and capacity to improve the efficiency of the public system, and in some cases contract out discrete segments of the public system (e.g., contracting out of storage and distribution, partnering with private pharmacies in underserved areas). One challenge is finding the right public-private mix that ensures equitable and timely access to medicines.
This module presents information that is critical to understanding the importance of how a well-managed pharmaceutical system impacts health service delivery. It looks at how the HSA team assesses this core health system function. The module is organized in the following subsections:

- Subsection 4.1 presents and defines the health system function of managing medical products, vaccines, and technologies and the processes that make up a system for this.
- Subsection 4.2 provides guidelines on preparing a profile of a system for managing medical products, vaccines, and technologies in the country of study.
- Subsection 4.3 presents the indicators organized into eight topics used to assess this function and a description of each topic.
- Subsection 4.4 is a guide to summarizing the findings and recommending next steps.
- Subsection 4.5 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.

Throughout this manual, we interchangeably use the terms medicines and pharmaceuticals. The terms “pharmaceutical products” and “medical products” are inclusive of medicines.

2. WHAT CONSTITUTES MANAGEMENT OF MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES?

The part of the health system that is concerned with the core function of ensuring access to and the appropriate use of essential medicines, vaccines and technologies, is called the pharmaceutical system. A pharmaceutical system consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes (Hafner et al. 2016). The management of medical products, vaccines, and technologies (often called pharmaceutical management) represents the set of activities aimed at achieving these goals in any health care setting. It involves four basic functions—selection, procurement, distribution, and use. These functions are the same regardless of the setting (public or private sectors) and the level of implementation (national, regional, or facility). Supply chain or logistics management encompasses procurement and distribution activities involved in moving medical products from suppliers to service delivery points.

Selection, procurement, distribution, and use are typically depicted as a cycle because they are interdependent and build on each other (Figure 3.4.1). The capacity to perform these functions is mediated by a core of management support systems including: organization, financing and sustainability, information management, and human resources management. The management functions and support systems are enabled (and constrained) by policies, laws, and regulations and supported by good governance principles and practices that establish and sustain the public commitment to essential medicine supply.

It is important to consider the interconnections between the four pharmaceutical management functions and the other core health system functions. Selection, procurement, and distribution are closely connected to health service delivery. Use includes the provision of quality care and services that support appropriate prescribing, dispensing or sale, and end-use of products. Moreover, the management support systems reflect the interconnections with the core health systems functions of leadership and governance, health system financing, health information systems, and health workforce. Policies, laws, and regulations provide the framework and systems for organizing, financing, and
regulating medical products, vaccines, and technologies and ensuring their safety, quality, and efficacy. The medical products, vaccines, and technologies module addresses all five health system performance criteria: equity, efficiency, access (including coverage), quality (including safety), and sustainability.

**Figure 3.4.1 Framework for Managing Medical Products, Vaccines, and Technologies**

![Diagram of the framework for managing medical products, vaccines, and technologies]

Source: Management Sciences for Health, 2012

### TIP BOX
**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 the interview questions to each level of decentralization so they 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.

### 3. DEVELOPING A PROFILE OF THE SYSTEM FOR MANAGING MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

The pharmaceutical system generally reflects the health system in which it operates. Therefore, a good starting point for developing an overview of the system for managing medical products, vaccines and technologies is to understand the health system context and country landscape.

A first step is to map out how the overall health system—including public and private sector entities—is organized and how the service delivery system is structured. Section 3, Module 1—Country and Health System Overview, provides key information on the organization of the health system, the primary stakeholders, and the issues affecting the system.

Table 3.4.1 provides a set of questions to help the HSA team understand the country and health system context and develop a profile for this module. Annex 3.1.A provides a template to report the level of decentralization of the health system with respect to the medical products, vaccines, and technologies function. Future HSA analysis and planning should not be conducted in isolation, but placed in the
A context of and linked with broader health sector planning, and that is why creating an initial profile is important.

Table 3.4.1. Questions to Help Describe and Assess Medical Products, Vaccines, and Technologies Within the Country Context

<table>
<thead>
<tr>
<th>Health System Level</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Health sector and service delivery</strong></td>
<td>What has been the country’s experience with health-sector reforms (e.g., decentralization, privatization, reforms related to UHC)?</td>
</tr>
<tr>
<td></td>
<td>What are the different levels of care in the public health care system? What role do private or non-governmental (NGO) health providers play at these different levels?</td>
</tr>
<tr>
<td></td>
<td>• Primary level of care (e.g., health post or clinic)</td>
</tr>
<tr>
<td></td>
<td>• Secondary level of care (e.g., district hospital)</td>
</tr>
<tr>
<td></td>
<td>• Tertiary level of care (e.g., specialized hospital)</td>
</tr>
<tr>
<td></td>
<td>At what level of the public health care system is there budget authority for medical products, vaccines, and technologies?</td>
</tr>
<tr>
<td></td>
<td>Are the following functions centralized, decentralized, or privatized? And if so, who are the responsible authorities/agents and at what level?</td>
</tr>
<tr>
<td></td>
<td>• Selection</td>
</tr>
<tr>
<td></td>
<td>• Quantification</td>
</tr>
<tr>
<td></td>
<td>• Procurement</td>
</tr>
<tr>
<td></td>
<td>• Distribution (warehousing and transportation)</td>
</tr>
<tr>
<td></td>
<td>Is there a Pharmaceutical Management Information System that includes the following components, and if so, how does it work? How does information flow between levels of the health system and agencies within it? How is information used in decision-making?</td>
</tr>
<tr>
<td></td>
<td>• Logistics Management Information System (LMIS)</td>
</tr>
<tr>
<td></td>
<td>• Patient-specific information (e.g. adherence)</td>
</tr>
<tr>
<td></td>
<td>• Quality and safety surveillance information (product quality problems, adverse drug reactions)</td>
</tr>
<tr>
<td></td>
<td>• Financial information</td>
</tr>
<tr>
<td></td>
<td>• Operations information (e.g. distribution of human resources and facilities)</td>
</tr>
<tr>
<td></td>
<td>What is the relationship between the private and public supply of medical products, vaccines, and technologies medicines? Are products or vaccines supplied to the private sector free of charge for priority programs and interventions? Are private providers required to report health information on products and vaccines supplied to the public sector and if so, how does that work?</td>
</tr>
<tr>
<td></td>
<td>How big is the private pharmaceutical sector? Are there:</td>
</tr>
<tr>
<td></td>
<td>• Retail pharmacies?</td>
</tr>
<tr>
<td></td>
<td>• Retail pharmacy chains?</td>
</tr>
<tr>
<td></td>
<td>• Local manufacturers?</td>
</tr>
<tr>
<td></td>
<td>• Large private importers and distributors?</td>
</tr>
</tbody>
</table>
Health System Level | Questions
--- | ---
B. National cross-sectoral and international context | Are the following stakeholders or programs present in the country? And if so, what are their roles regarding management functions (e.g. procurement, warehousing, distribution, other)?
- NGOs including faith-based organization(s)
- Vertical programs (e.g. HIV, tuberculosis (TB), malaria)
- Bilateral and multilateral development partners

| | What trade issues apply to medical products, vaccines, and technologies?
- What are the relevant regional, subregional and global trade agreements and initiatives?
- How do they influence the supply or management of medical products, vaccines, and technologies?

### 3.1 Pharmaceutical Management Functions

The system for managing medical products, vaccines, and technologies can be described by examining the activities associated with the four management functions—selection, procurement, distribution and use. Management support systems, including information management systems for logistics and other functions, are discussed in Topic H.

**Selection** is informed by the health needs of the population. It encompasses developing, updating, and publishing STGs for priority health problems based on scientific evidence and WHO guidance; selecting products and dosage forms for essential medicines and other medical products lists, formularies, and insurance reimbursement lists; and deciding which products will be available at each level of the health system (Figure 3.4.2). Additionally, a national essential medicines list (NEML) is developed to encourage providers to make selection decisions in line with established STGs and regulatory requirements and serves as a basis for public sector procurement, donation programs, training of staff, and reimbursement decisions. It is also used for oversight and guidance of the private sector when services are contracted out. STGs together with essential medicines lists and formularies can help to standardize and optimize patient care and promote appropriate medicines use. Additionally, they lead to better supply and lower costs. The existence of a formalized system based on review of scientific evidence for regular review of essential medicines lists and STGs for the treatment of priority disease conditions ensures that the health care system uses the most cost-effective and efficacious treatment options available.
Quantification—an estimation of quantities and costs of products required for a specific health program (or service) and determining when products should be delivered to ensure continuous supply for the program (or service)—is key to maintaining uninterrupted service delivery. Effective quantification is dependent on a well-functioning logistics management information system and robust analysis and use of data. Procurement functions include deciding which products to obtain based on the country’s NEML and quantifying requirements to order. Choosing procurement methods, managing the bidding process, tracking and monitoring procurements, assuring pharmaceutical quality, tracking prices and making comparisons based on International Reference Pricing (IRP), and monitoring supplier performance stratified by public and private sectors are key steps in the process (Figure 3.4.3). Staff must be trained on procurement regulations and standard operating procedures (SOPs), and oversight mechanisms are needed to ensure adherence, together with a system of documenting, maintaining, and auditing of records at every step of the procurement process. Several actors may be involved with a country’s procurement system and incoming donations. These actors may include national procurement centers/departments, national programs, development partners, the World Bank, and a variety of private companies or wholesalers. The procurement system may be centralized, decentralized, or mixed. HSA technical team members should examine the impact of all stakeholders on the effectiveness of the procurement system.
Figure 3.4.3. The Pharmaceutical Procurement Cycle

![Diagram of the Pharmaceutical Procurement Cycle]

Source: Adapted from Management Sciences for Health, 2012

**Distribution** includes the systems for ensuring that pharmaceuticals are appropriately stored, managed, and transported to their point of use in the most cost-effective way. Figure 3.4.4 shows the various components of the distribution cycle. Distribution involves moving medical products, vaccines and technologies down the pipeline from the port facilities, through the national (central), regional, provincial and/or district warehouse to all service delivery points—including community-based distribution networks—where they are dispensed, sold or used by the provider. Successful distribution relies on effective transport management systems, availability of and adherence to good storage procedures and practices, and well-functioning inventory management systems to ensure stock is available at service delivery points. Systems to maintain product quality throughout the distribution system and waste management systems to safely dispose of expired or damaged products are also important. An effective LMIS that enables continuous monitoring and effective management of supplies, as well as reporting of information on consumption and inventory levels, is of vital importance.

Appropriate mechanisms need to be in place to manage inventory, the flow of information, and the requisition of supplies. Warehouse infrastructure—including adequacy of storage space, material-handling equipment, transportation vehicles and/or contracts—needs to be examined to determine the effectiveness of the logistics systems.
Mapping the distribution system to show how medical products enter and move through the country and the actors involved provides a useful profile of the system. Such mapping depicts the flow of information, funds, and products in the system. Figure 3.4.5 diagrams a typical multi-level distribution system that includes private sector participation in a 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, or private sector entity.
Figure 3.4.6 shows an alternative public sector system in which storage and transportation functions are contracted out to private distributors. In this system, medical products, vaccines, and technologies are delivered directly to health facilities. Variations or combinations of these two models may be implemented in a given country. Additional flows may be added to these diagrams to demonstrate the flow of information or funds (e.g., budget allocations, procurement, payments to suppliers, and payments from clients/patients).
Note that a country may have a mix of distribution systems for different types of products or funding sources. For example, the country may use a pull system (where the facility determines its needs independently e.g. when the inventory reaches a certain level) for essential medicines. This system may be integrated with other programs such as HIV or family planning, while the national expanded program on immunization (EPI) might maintain a vertical push system (where an entity higher up in the distribution system decides which products to move down the chain and when to do so) for managing its vaccines. Some country decisions may be based on a hybrid push–pull system which requires more accurate forecasting of need and adjusts inventory levels based upon actual utilization. It is important that the HSA team identifies all the different systems in place and examine how they affect each other, where synergies could be built in, or where integration may be appropriate. 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 specific aspects of the procurement and distribution processes. The specific agency or entity responsible for carrying out these activities—and therefore the source of key indicator data—may differ from country to country.

**Use** involves appropriate prescribing, dispensing or sale, and correct use of medicines and other medical products by patients or service providers. When prescribing, dispensing or selling a medicine, service providers should provide adequate information to the patients about the medicine and ensure that they...
understand what dose to take and the duration of therapy. Inappropriate medicines use may involve overuse, underuse, or incorrect use. Inappropriate use also includes cases where an ineffective or unsafe medicine is prescribed, dispensed or purchased. Strategies recommended by WHO to improve the use of medicines include interventions such as the establishment of drugs and therapeutics committees (DTC), development and use of STGs, and regular evaluations of medicine use (WHO 2004). DTCs, also called pharmacy and therapeutics committees, are an important mechanism for improving prescribing and dispensing practices at district or facility under its jurisdiction. Their responsibilities typically include the development of local or institutional formularies, agreeing on appropriate treatment protocols (based on national STGs) and conducting medicines use evaluations. An important method for improving medicines use in health facilities involves assessing how medicines are prescribed, dispensed, and consumed, and using the findings to identify interventions and monitor their impact.

4. ASSESSMENT INDICATORS

This section outlines core indicators that can be used to assess the management of medical products, vaccines, and technologies. It shows the topics into which the indicators are grouped, defines the indicators, lists data sources to inform the indicators, and identifies and discusses indicators that overlap with other modules. Finally, the section identifies key priority indicators to which the HSA technical team members can limit their work—if time precludes measuring all indicators.

4.1 Topics

The indicators are grouped into eight topics (Table 3.4.2), which cut across the many facets of managing medical products, vaccines, and technologies. Topics A and B reflect macro country context; C, D, and E pertain to pharmaceutical management activities; F and G focus on access and appropriate use; and H pertains to management support systems.

Table 3.4.2. Indicator Map—Managing Medical Products, Vaccines, and Technologies

<table>
<thead>
<tr>
<th>Topics</th>
<th>Indicator Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Policies, laws, regulations, and governance</td>
<td>1-11</td>
</tr>
<tr>
<td>B. Financing</td>
<td>12-17</td>
</tr>
<tr>
<td>C. Selection</td>
<td>18-20</td>
</tr>
<tr>
<td>D. Procurement</td>
<td>21-31</td>
</tr>
<tr>
<td>E. Distribution</td>
<td>32-39</td>
</tr>
<tr>
<td>F. Access</td>
<td>40-42</td>
</tr>
<tr>
<td>G. Appropriate use</td>
<td>43-47</td>
</tr>
<tr>
<td>H. Management support systems</td>
<td>48-52</td>
</tr>
</tbody>
</table>
4.2 Data Sources

There are many data sources to help the team members assess the medical products, vaccines, and technologies core function. They are organized into three main categories:

1. **Databases**: Data are drawn mainly from existing and publicly available databases.
   - *The World Medicines Situation 2011* (WHO 2011) provides analyses and an overview of key issues in managing medical products, vaccines, and technologies. Its annexes contain pharmaceutical expenditure data from a wide range of countries and regions. More recent data may be available from ministries of health and/or from project documents.
   - *Essential Medicines and Health Products Information Portal* (WHO n.d.-b) is a repository of grey literature and useful reference sources. It contains a collection of National Medicine Policies (NMPs) and NEMLs.

2. **Secondary sources**: Information for topics A through G should be gathered to the extent possible through desk review of reports, forms, and other documents.
   - Existing country studies/surveys and assessments performed by international partners
   - National pharmaceutical law and national health and medicines/pharmaceutical policy
   - National Medicines Regulatory Authority (NMRA) reports/website
   - Documents supporting the public procurement process such as national procurement guidelines; standard bidding documents; standard operating procedures (SOPs) for MOH/public procurement; procurement records and reports
   - Key performance indicators from national procurement centers
   - National procurement plans
   - Quality control laboratory reports and quantification exercises
   - Ministry of Finance (MOF) audit reports
   - LMIS; transport department records
   - Existing health facility surveys or monitoring reports, supervision reports
   - EPI reports
   - Service provision assessment and physical inventory reports

3. **Stakeholder interviews and site visits**: The document reviews should be complemented—and any information gaps completed—during discussions and interviews with key informants and local stakeholders.
   - Drug quality control laboratory
   - National regulatory agency responsible for importation regulations
   - National drug inspectorate
   - NMRA
   - National drug and therapeutics/selection committee chair
   - MOH procurement unit/center or office
   - Head of the MOH pharmacy department
   - Subnational health ministry officials
   - MOF
   - MOH office of health statistics
• Private retail pharmacy managers/owners and medical store managers
• Procurement managers at retail pharmacies
• Private distributors
• Public and private health facilities managers
• Pharmacy council/board
• Pharmacy and other (e.g., manufacturing, distributors) professional associations and unions
• Representatives of agencies throughout the supply chain (both public and private)
• Department of health services or health services research (university or MOH)
• Site visits to private pharmacies in urban and rural areas
• Site visits to public—and if time permits private—health facilities in urban and rural areas to examine medicine dispensaries, inventory management and tracking systems, storage conditions.
• Site visit to public warehouse or central medical stores/public sector warehouses/national procurement centers, to examine inventory management systems, public storage, public pharmacies at government facilities, and vertical program managers (EPI, HIV, malaria, TB, United Nations organizations, external development partners)

The HSA technical team member will be responsible for organizing and developing a process for the review of records, documents, and key informants’ and stakeholders’ interview responses to obtain information necessary to make judgments on the indicators listed. While the medical products, vaccines, and technologies module has many indicators, it is not essential to measure all of them; some may not be as relevant in the assessment country. In addition, data sources for all the indicators may not be readily available.

4.3 Detailed Indicator Descriptions

This section provides an overview of each topic area and then a table that gives a definition and interpretation of each indicator.

4.4 Topic A: Policies, Laws, Regulations, and Governance

Overview

This topic area assesses the policies, laws, and regulatory framework and structures that exist for organizing, financing, and regulating the management of medical products, vaccines, and technologies; coordinating the activities of the various institutions and stakeholders involved; and ensuring the safety, efficacy, and quality of products. This area lays out the foundation on which pharmaceutical systems operate so that safe, effective, quality medical products, vaccines and technologies are available, affordable, and accessible to clients when they need them.

See Table 3.4.3 for a list of indicators to assess policies, laws, regulations, and governance for the medical products, vaccines, and technologies core function.
Table 3.4.3. Indicators to Assess Policies, Laws, Regulations and Governance for the Medical Products, Vaccines, and Technologies Core Function

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
</table>
| 1. Existence of a national medicine policy (NMP) | Yes/no answer with explanation.  
An NMP (also called a national pharmaceutical or drug policy) is a guide to action for the pharmaceutical sector. It is an official government statement that sets out the government’s objectives and priorities for the pharmaceutical sector based on priority health problems, and strategies for attaining them.  
Existence of an NMP indicates commitment to improving the management of medical products, vaccines, and technologies in the public and private sectors. An official NMP is one that has been endorsed or officially adopted by the government. A published document is accessible to the public or appropriate stakeholders. If the NMP has been updated in the past 5 years, this indicates that the policy is kept up to date. The NMP should be developed through a systematic process of consultation with all interested parties. If the country has received support or guidance from WHO to develop or update the NMP, it is likely that the WHO guidelines on how to develop an NMP (WHO 2001) were followed or used as a template to develop the policy.  
Specific questions to ask the interviewee include:  
• Does a NMP exist?  
• What is the year of publication of the most recent version of the NMP?  
• Has the document been officially adopted or endorsed by the government?  
• Is it publicly available? |
| 2. Existence of a pharmaceutical-sector strategic plan | Yes/no answer with explanation.  
A pharmaceutical sector strategic plan contains near- to long-term sector strengthening goals and linked actions. In many countries, the strategic plan is based on the NMP, (and called a NMP implementation plan) and identifies activities, roles, responsibilities, budget requirements and timelines for each component of the NMP.  
Specific questions to ask the interviewee include:  
• Does a pharmaceutical sector strategic plan (or NMP implementation plan) exist?  
• If yes, when was it last updated?  
• Does the government develop annual action plans based on the strategy? If yes, do the plans include indicators to monitor implementation? |
### 3. Existence of a comprehensive pharmaceutical law

<table>
<thead>
<tr>
<th>Yes/no answer with explanation.</th>
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</thead>
<tbody>
<tr>
<td>The existence of a comprehensive pharmaceutical law or legislative framework demonstrates commitment to improving the management of medical products, vaccines, and technologies in the public and private sectors. The legislation should also provide for the establishment and operation of an NMRA to ensure that the manufacture, trade, and use of medicines are regulated appropriately.</td>
</tr>
<tr>
<td>Specific questions to ask the interviewee include:</td>
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<tr>
<td>- When was the national pharmaceutical law last updated? A law that is more than 5 years old may be outdated and require revisions to reflect changes in overall health or national development policies and priorities.</td>
</tr>
<tr>
<td>- Have regulations [or equivalent subordinate instruments] been issued based on the pharmaceutical legislation?</td>
</tr>
<tr>
<td>- Does the law or legislative framework include provisions for:</td>
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<tr>
<td>- Establishment of an NMRA?</td>
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<tr>
<td>- Importation and exportation of medicines?</td>
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<tr>
<td>- Market authorizations?</td>
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<tr>
<td>- Medicine promotion and advertising?</td>
</tr>
<tr>
<td>- Licensing of the following: manufacturers, wholesalers or distributors, importers or exporters of medicines, prescribers and dispensers?</td>
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<tr>
<td>- Inspection of pharmaceutical establishments?</td>
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<tr>
<td>- Regulation of clinical trials?</td>
</tr>
<tr>
<td>- Postmarketing surveillance and safety monitoring?</td>
</tr>
<tr>
<td>- The marketing authorization holder to mandatorily report all serious adverse drug reactions to the NMRA?</td>
</tr>
<tr>
<td>- Is there a law permitting generic substitution by pharmacists?</td>
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</tbody>
</table>

### 4. Existence of a functioning NMRA responsible for the promulgation and enforcement of regulations

<table>
<thead>
<tr>
<th>Yes/no answer with explanation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMRA (also called a national drug regulatory authority) is a governing regulatory body responsible for conducting relevant regulatory functions. An effective NMRA indicates commitment to implementing and enforcing pharmaceutical laws and ensuring that clients receive safe, effective and quality medical products. The NMRA requires adequate capacity and resources to fulfill its mandate.</td>
</tr>
<tr>
<td>Follow-up questions to ask the interviewee include:</td>
</tr>
<tr>
<td>- What are the specific responsibilities of the NMRA?</td>
</tr>
<tr>
<td>- What is the relationship of the NMRA to other governmental agencies?</td>
</tr>
<tr>
<td>- Is it autonomous?</td>
</tr>
<tr>
<td>- How is it financed? If there is not a clear separation of functions, the NMRA is vulnerable to corruption.</td>
</tr>
<tr>
<td>- Is the NMRA self-financed?</td>
</tr>
<tr>
<td>- What percentage of the revenues generated by the NMRA is retained by the institution?</td>
</tr>
<tr>
<td>- Are medicines regulatory functions (e.g. licensing) performed on an ad-hoc basis by an office, group, or department that performs other pharmaceutical functions, such as procurement or supply management?</td>
</tr>
</tbody>
</table>

### 5. Existence of a National Quality

<table>
<thead>
<tr>
<th>Yes/no answer with explanation.</th>
</tr>
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</table>
**Control Laboratory (NQCL)**

NQCL is a national institution with the mandate to perform quality control of pharmaceuticals for regulatory purposes. The existence of NQCL indicates there is a system in place to conduct premarket and postmarket quality control of pharmaceuticals.

Follow-up questions to ask the interviewee include:
- Is the NQCL part of the NMRA? If not, how are they organizationally related?
- Are there other quality control laboratories associated with the NQCL that support its regulatory function?
- Does the NQCL provide services to nongovernmental entities?
- Is the NQCL financially independent?
- Is the NQCL in compliance with international standards? If not, is the NQCL working toward compliance?
- Does the NQCL test products other than pharmaceuticals (food, water, cosmetics, etc.)?
- Does the NQCL perform research and training?
- Are there backlogs in quality control requests?
- Does the personnel turnover affect NQCL performance?
- Is the NQCL prequalified by WHO or certified by the International Organization for Standardization (ISO certified)? Does the NQCL receive support from partners to reach international requirements?

---

**6. Existence of a functioning system for pharmaceutical registration**

Yes/no answer with explanation.

A system for registration of pharmaceuticals in the market (issuing market authorizations) that is impartial and ensures that applications submitted for registration are assessed for efficacy, safety, quality, accuracy, and completeness of product information. The body or agency responsible for evaluating applications may be a committee, a unit of the NMRA, or some other body that is charged with the completion of these activities.

Specific follow-up questions include:
- Is periodic renewal required and are pharmacological standards applied?
- Is there a functioning formal committee involved in the assessment of the applications for registration of pharmaceutical products? If yes, does the body meet regularly (at least once in the last six months)?
- Is there an up-to-date list of all registered pharmaceutical products available in the country? What is the number of products registered?
- What is the fee to register a product? How frequently are fees re-assessed?
- Does the dossier submitted for registration include information on product efficacy, safety, quality, and packaging information?
- Is there a quality assurance process in place to review the information included in the dossier?
- Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?
- What is the average turnaround time for pharmaceutical registration applications?
- What is the average number of days for decision making on a new drug?
- Is there an accelerated registration process for specific pharmaceutical products?
- Is registration in “reference countries” (neighboring countries or countries with more stringent regulatory systems) accepted? This option may make sense for countries where human resource and infrastructure limitations prevent proper application review.
- Is there a backlog in the evaluation of applications received?
- Are there concerns about the registration system’s ability to keep up with 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.

- What are the concerns of interviewees 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.
- What percentage of EML items have at least one registered product?

See Indicator under Topic H: Management Support Systems: Existence of a computerized registration system that facilitates retrieval of information on registered products, licensed providers and premises and clinical trials

<table>
<thead>
<tr>
<th>7. Existence of a pharmacovigilance system</th>
<th>Yes/no answer with explanation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated mechanisms and processes for monitoring the safety and effectiveness of medicines and medical devices are an essential component of a well-functioning pharmaceutical system. A pharmacovigilance system that has functioning mechanisms in place for monitoring and reporting adverse drug reactions and events is a first step for safeguarding public health. Ideally, pharmacovigilance data should be reported to and aggregated at the national level.</td>
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<tr>
<td>This indicator does not address how well the system is performing and if actions are being taken to prevent adverse events based on the reports and findings generated by pharmacovigilance monitoring and reporting systems. The presence of any of the following indicates efforts by the country to institute mechanisms to improve medicines safety:</td>
<td></td>
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<tr>
<td>- How many adverse drug events are reported annually?</td>
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<tr>
<td>- Is there a functional national pharmacovigilance center or mechanism to collate and analyze reports and take action to prevent adverse events?</td>
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<tr>
<td>- Is there a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the last year?</td>
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<tr>
<td>- Does the country have a system by which providers and consumers can report adverse events?</td>
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<tr>
<td>- Is reporting of all serious adverse drug events by the marketing authorization holder to NMRA mandatory?</td>
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<tr>
<td>- Are there any active surveillance activities ongoing? Have there been any activities in the past or are any planned?</td>
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<tr>
<td>- Is the country a member of the WHO Programme for International Drug Monitoring, and if so has the country been contributing to the program? How many notifications have been submitted in the last year?</td>
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<tr>
<td>Note: The indicator does not measure whether actions are taken based on the results/findings reported by pharmacovigilance systems.</td>
<td></td>
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</tbody>
</table>
| 8. Existence of a post-marketing quality surveillance system | Yes/no answer with explanation.  
A post-marketing quality assurance system enables continuous assessment of the quality 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 the system, ask the following questions:  
- Are data available? If so, how many product quality issues were reported in the previous year?  
- How is information on quality surveillance findings communicated?  
- Are decisions taken as a result of the system reports/findings and are they adequately enforced?  
- How is the system organized/structured? Are quality control activities centralized or decentralized? Are there parallel quality surveillance activities in the country?  
- Are there guidelines in place for post-marketing quality surveillance?  
- What is the capacity of the NMRA to undertake quality surveillance activities?  
- Does the country have a system by which providers and consumers can report quality problems?  

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. |
|---|---|
| 9. Mechanisms exist for licensing and inspection of pharmaceutical establishments | Yes/no answer with explanation.  
Mechanisms are in place for licensing of pharmaceutical establishments and inspection/monitoring to ensure that individuals who manufacture, import, distribute, or dispense or sell medical products are properly qualified, approved, and registered and that premises and practices meet established standards.  

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 and oversight activities are fully functional. The following questions can be used to assess whether licensing mechanisms are in place and functioning:  
- Does the NMRA have a unit responsible for issuing pharmaceutical establishment licenses for each of the following?  
  - Manufacturers  
  - Importers and exporters  
  - Wholesalers and distributors  
  - Pharmacy dispensing/retail outlets  
- Are there written guidelines for assessing applications for a license for each type of pharmaceutical establishment?  
- What is the number of applications received for a new premise in the last year for each type of pharmaceutical establishment?  
- Is there an up-to-date list of all licensed pharmaceutical establishments available in the country?  
- What is the percentage of licensed premises (of the total number of each type of premises in the country) for each of the following (indicate the year)?  
  - Manufacturers  
  - Importers and exporters  
  - Wholesalers and distributors |
Follow-up questions to ask the interviewee to explore whether monitoring and inspection mechanisms are in place and functioning include:

- What entity is responsible for inspection/monitoring of manufacturers, wholesalers and distributors, and pharmacy dispensing/retail outlets?
- What is the number of licensed or registered drug retail outlets per government drug inspector?
- Does the NMRA carry out regular (at least every 2 years) post-licensing inspection of all licensed pharmaceutical establishments?
- What percentage of manufacturers, wholesalers and distributors, and pharmacy dispensing/retail outlets are inspected during a one-year period?
- Are there written SOPs for inspectors on how to conduct inspections?
- How rigorous is the enforcement of licensing requirements?
- Is a report of inspections and enforcement results generated regularly?
- What systems are in place to minimize corruption of inspection staff? (The offering of bribes to inspectors by private establishments to ignore poor quality products or compliance with standards is a major and constant concern.)
- What sanctions are placed on establishments for lack of compliance?

See Indicator under Topic H: Management Support Systems: Existence of a computerized registration system that facilitates retrieval of information on registered products, licensed providers and premises and clinical trials.
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
</table>
| 10. Existence of a code of conduct that applies to public officials and staff involved in pharmaceutical-related activities or posts, and evidence that it is being applied | Yes/no answer with explanation.  
The code of conduct is an officially adopted/promoted document that specifies standards of performance in order to hold public officials and staff involved in pharmaceutical-related activities or posts accountable for their behaviors and actions pertaining to their official capacities. There may be a code of conduct that applies to all public employees including MOH employees or separate codes for employees involved in specific activities.  
Specific questions to ask the interviewee include:  
- Is there a code of conduct that applies to all public employees and staff involved in pharmaceutical-related activities or posts?  
- Is there a specific code that applies to public officials and employees involved in:  
  - Medicines regulation and other staff working at the NMRA?  
  - Licensing of pharmaceutical premises and personnel?  
  - Inspectors?  
  - Pharmaceutical procurement?  
  - Supply chain management? |
| 11. Existence of conflict of interest guidelines that apply to public officials and staff involved in pharmaceutical-related activities | Yes/no answer with explanation.  
The existence of conflict of interest guidelines indicates that the government recognizes the importance of identifying and managing real or perceived conflicts of interest that have the potential to influence decisions made by employees, committee members and consultants/expert advisors involved in regulatory, medicines selection, procurement and other pharmaceutical-related activities.  
Written guidelines on conflicts of interest and a declaration form should exist and include, at a minimum, the following:  
- Definition of what a conflict of interest is  
- Rules on the acceptance of gifts  
- Rules on reporting conflicts of interest  
- Mechanism protecting informers of conflicts of interest  
- Actions to be taken in case of failure to comply with policy  
Specific questions to ask the interviewee include:  
- Are there written guidelines on conflicts of interest for individuals engaged in the following functions:  
  - Medicines registration?  
  - Inspection?  
  - Regulation of clinical trials?  
  - Control of medicines promotion?  
  - Selection?  
  - Procurement?  
- Are conflict of interest forms systematically completed by public officials and staff involved in these activities? |
4.5 Topic B: 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 products 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, external development partner contributions, and direct private spending or indirect spending through insurance programs.

See Table 3.4.4 for a list of indicators to assess financing of the medical products, vaccines, and technologies core function.

Table 3.4.4. Indicators to Assess Financing of the Medical Products, Vaccines, and Technologies Core Function

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Total expenditure on pharmaceuticals (percentage total expenditure on health)</td>
<td>Total expenditure on pharmaceuticals as a percentage of total expenditure on health. Enables measurement of the significance of pharmaceutical spending relative to other spending on health; indicates financial and institutional sustainability of current pharmaceutical purchases. Compare the country to selected regional or income-level peer group. Module link: Module 2—Service Delivery Indicators (financial access to health services), (financial access to medicines), and (out-of-pocket expenditure as percentage of total health expenditure).</td>
</tr>
<tr>
<td>13. Total expenditure on pharmaceuticals (per capita at average exchange rate) in U.S. dollars</td>
<td>Per capita expenditure on pharmaceuticals at average exchange rate in U.S. dollars. Measures magnitude of pharmaceutical spending and indicates financial and institutional sustainability. Compare this measure to peer groups. Module link: Module 2—Service Delivery Indicators (financial access to health services), (financial access to medicines), and (out-of-pocket expenditure as percentage of total health expenditure).</td>
</tr>
<tr>
<td>14. Government expenditure on pharmaceuticals (per capita at average exchange rate) in U.S. dollars</td>
<td>Per capita government spending on pharmaceuticals at average exchange rate in U.S. dollars. Includes government allotment, health ministry expenditure, donor contributions provided in the country, etc. Measures magnitude of government spending on pharmaceuticals; indicates financial and institutional sustainability. Compare to selected peer group. Module link: Module 6—Health Financing Indicator (government expenditure on health as percentage of total health expenditure)</td>
</tr>
</tbody>
</table>
15. Proportion of annual national expenditure on pharmaceuticals financed by different stakeholders

The proportion of annual total amount spent on pharmaceuticals is disaggregated by source of funds: Government, External development partner agencies, Charities, Out-of-pocket payments, Private health insurance, Private employers (e.g., mining companies). Disaggregating pharmaceutical expenditure by source of funding allows assessment of sustainability of funding and provides a measure of diversity. This information can also be used to assess the financial burden of out of pocket payments on health consumers relative to pharmaceutical expenditure overall.

External development partners’ commitments are not generally considered sustainable. But if they are present, examine:
- How many development partners are involved, and
- What types of medicines they support

**Module link:** Module 6—Health Financing Indicators (government spending on health as a percentage of total health expenditure), (external resources for health as a percentage of total health spending), (general government expenditure on health as a percentage of total health expenditure), (external resources for health as a percentage of total health spending), (prioritization and the process of government health budget formulation/government health budget allocation by cost category), and (local-level spending authority and institutional capacity).

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16. Percentage of out-of-pocket expenditure for health spent on medicines

The percentage of out-of-pocket spending on medicines is measured 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 cost-recovery mechanisms may be the basis for funding in some countries, in others, medicines are provided free of charge. However, patients may choose to access private pharmacies due to perceptions of higher quality and/or when medicines are out of stock at public facilities. Health insurance programs may require copayments for medicines and some schemes may only cover the cost of services. 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.

To better understand this indicator, disaggregate in terms of:
- Income level
- Geographical area (rural/urban or subnational divisions)
- Disease type

If available, look at national health accounts data. 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.

**Module links:**
Module 2—Service Delivery Indicator (financial access to health services and financial access to medicines)
17. Percentage of respondents who indicate that they forego medicines due to cost

Percent of respondents who say that prescribed medicines were not taken by themselves or a household member “because household cannot afford medicines.”

In addition to availability and geographical accessibility, it is important to measure financial access to medicines (affordability), particularly for household members that require medicines for chronic conditions.

This indicator may be collected through household health utilization and expenditure surveys or other household surveys. Enquire if the country has conducted a household survey using *Manual for the Household Survey to Measure Access and Use of Medicines* (WHO 2008) or a similar tool.

**Module links:**
- Module 2—Service Delivery Indicator (identical indicator—financial access to medicines)
- Module 6—Health Financing Indicators (out-of-pocket expenditure as a percentage of total expenditure on health) and (fragmentation and sustainability of financial protection mechanisms).

### 4.6 Topic C: Selection

**Overview**

An NEML contains the medicines considered as optimal treatment choices to satisfy the priority health care needs of a country. Countries may specify which products will be available for use at each level of the health system in the NEML or alternatively develop essential medicines lists (EMLs) for different system levels based on local disease patterns. EMLs are intended to result in more appropriate and cost-effective 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 and efficiency of the health system. Similarly, evidence-based medicine and product selection, updating and use of STGs, and the promotion of generic substitution all positively influence service delivery and the financial coverage goals of UHC.

See Table 3.4.5 for indicators to assess selection of products under the medical products, vaccines, and technologies core function. Indicators that pertain to the use of the NEML for guiding procurement are included in Topic D: Procurement.
### Table 3.4.5. Indicators to Assess Product Selection for the Medical Products, Vaccines, and Technologies Core Function

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
</table>
| 18. Existence of an NEML published within the past 5 years | Yes/no answer with explanation.  
An NEML is a list of medicines that satisfy the health care needs of the majority of the population; the medicines should be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.  
An NEML that is updated regularly (at least once every 5 years) is likely to contain information most pertinent to current public health concerns and new advances in medicines. A current NEML demonstrates a country’s commitment to improved prescribing, improved supply management, rational resource allocation, and containing pharmaceutical costs.  
Additional follow-up questions include:  
- Are there explicit criteria for selecting medicines on the NEML?  
- Is the NEML based on evidence and in line with national STGs?  
- Does the NEML identify medicines by level of care?  
- Has the NEML been updated within the last 5 years? As part of the NEML revision process, does the country review the *WHO Model List of Essential Medicines* (WHO 2015), which is updated every 2 years by the Expert Committee on Selection and Rational Use?  
- Is the NEML meant to be used as a guide for procurement as well as for therapeutic issues (quality of care)?  
- Are generic names or international nonproprietary names (INN) used consistently throughout the system (prescriptions, LMIS, inventory cards, etc.)? Countries are encouraged to use the INN, as it is the nonproprietary name given to pharmaceutical substances or active pharmaceutical ingredients. All branded products also carry the INN name.  
- 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.)  
See Indicator under Topic D: Procurement: Product selection for procurement based on NEML. |
| 19. Evidence of an active national committee responsible for managing the process of maintaining an NEML | Yes/no answer with explanation.  
Is there an organized group of experts that meets regularly and is responsible for managing, maintaining, and updating an NEML? If the NEML is updated periodically and an active committee is in place, then the list is more likely to be updated through a consensus process and scientific evidence rather than by an individual.  
Additional follow-up questions include:  
- What is the composition of the committee?  
- Does the committee membership include the private sector representing different stakeholders from the appropriate areas of the pharmaceutical and medical sectors?  
- Does the committee have terms of reference or SOPs, and are they publically available? The existence of terms of reference or SOPs indicates that a formalized process is in place and when made publically available, a commitment to promoting transparency on how decisions are made.  
- If SOPs exist, do they require review of up-to-date, unbiased scientific data? Does the committee have access to such data?  
- Does the country have a dissemination strategy and a system for distributing the NEML to facilities and practitioners? Does the country have a system to monitor compliance to the |
20. Total number of pharmaceuticals on the NEML?

On average, NEMLs normally contain 300–400 individual pharmaceutical products. The country’s epidemiological profile 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.

The number of pharmaceutical products for any one level of care should not exceed the total number of items on the NEML. Consideration should be given to what is appropriate by level of care. 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

4.7 Topic D: Procurement

Overview

The primary purpose of procurement is to provide regular delivery of adequate quantities of good quality supplies at the lowest possible cost. Deciding which products to procure and quantifying pharmaceutical product needs is the first step in procurement and a prerequisite for meeting procurement goals. Quantification—the process of estimating quantities and costs of products and determining when they should be delivered to maintain uninterrupted supply—may be centralized or decentralized down to lower levels in the health system. Regardless of how quantification is organized, inaccuracies in the forecasting of future demand will always occur because consumption can fluctuate. Many countries have established mechanisms such as multi-stakeholder committees to validate data and assumptions, and instituted continuous processes for monitoring and routine updates of quantification estimates.

Similarly, other 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 and will contribute to identifying the appropriate stakeholders to interview. For example:

- Centralized system: Procurement is conducted by a national procurement unit/department/center (which may be a parastatal enterprise or an NGO with a public health mission confirmed through a convention).
- Decentralized system: Procurement is conducted by subnational entities, including regional or provincial authorities and facilities such as big hospitals.
- Mixed systems: In some decentralized health systems, some procurement processes take place 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 lower levels.

See Section 3, Module 1—Country and Health System Overview, for further explanation on types of decentralization with a health system.
Because procurement involves many steps and agencies, the team should, during the document review and interviews, develop and refine a step-by-step description of how quantification and procurement take place, who the responsible authorities and agencies are, and what type of ordering system is in place.

Although the focus here is on procurement for the public sector, the assessment also includes questions on procurement of medicines and medical products in the private sector because a growing number of developing country consumers rely on private provision of medicines and health products. Taking the time to meet with procurement officers of large retail drug stores and private importers and distributors can provide information on whether the private sector is complying with procurement regulations—therefore helping ensure that quality-assured medicines and supplies are available through private channels.

See Table 3.4.6 for Indicators to assess procurement under the medical products, vaccines, and technologies core function.

Table 3.4.6. Indicators to Assess Procurement under the Medical Products, Vaccines, and Technologies Core Function

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. Product selection for procurement based on NEmL</td>
<td>( \frac{\text{Value of medicines from the NEmL procured in the public sector}}{\text{total value of medicines procured in the public sector}} \times 100 )</td>
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<tr>
<td></td>
<td>This indicator determines whether the NEmL is being used to guide product selection for procurement and the extent to which product selection is limited to the NEmL. The indicator is calculated for one year. If the value of medicines from the NEmL is not known or too difficult to calculate, the following indicator can be used instead: Percentage of products selected for procurement that are listed on the NEmL.</td>
</tr>
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<td></td>
<td>The indicator can establish whether products that are regularly procured are essential products. If a product is not on the NEmL, it may receive lower priority and funding or it may require a special waiver for procurement. This indicator can be used in centralized and decentralized systems.</td>
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<td>Related questions may include:</td>
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<td>- Is procurement restricted to products on the EML?</td>
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<td></td>
<td>- Are there provisions for purchasing medicines not on the EML?</td>
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<tr>
<td></td>
<td>See Indicator under Topic C: Selection: Existence of an NEmL published within the past 5 years</td>
</tr>
<tr>
<td>23. Pharmaceuticals procured based on reliable estimates</td>
<td>Yes/no answer with explanation.</td>
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<td></td>
<td>This indicator measures efficiency and appropriate use of resources. The more accurate and reliable estimates are the lower the risk of wastage or shortage.</td>
</tr>
<tr>
<td></td>
<td>Additional follow-up questions can assess whether pharmaceuticals are quantified on the basis of reliable estimates:</td>
</tr>
<tr>
<td></td>
<td>- How and at what levels is quantification conducted?</td>
</tr>
<tr>
<td></td>
<td>- Is the process for conducting quantification documented?</td>
</tr>
<tr>
<td></td>
<td>- 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.</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>What is the quality of these data?</td>
<td>This indicator can be used in both centralized and decentralized systems.</td>
</tr>
<tr>
<td>When was the last time a national quantification was conducted?</td>
<td></td>
</tr>
<tr>
<td>To what extent do needs exceed the available budget for procurement?</td>
<td></td>
</tr>
<tr>
<td>How are discrepancies resolved?</td>
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</tr>
</tbody>
</table>

**Module link:**
Module 6—Health Financing Indicator (local level spending authority and institutional capacity)

---

### 24. Existence of a formal written procurement policy

Yes/no answer with explanation.

A formal written procurement policy includes a detailed description of the roles and responsibilities of all offices and agencies involved in the procurement process. The policy should also cover procurement methodology to be utilized and mechanism for ensuring accountability, competition and transparency.

A written policy provides the standards and rules by which procurement need to be conducted and for holding all agent involved to account.

Follow-up question to ask:
- Was the policy developed specifically for health-sector goods and pharmaceuticals or is it a general policy? If a general policy, is there a section that specifically addresses health-sector goods and pharmaceuticals?
- Does it include a timeline and guidelines for the tendering process, including mechanisms for handling disputes?
- When was the policy developed/last updated? Were international best practice guidelines reviewed as part of the development process (e.g. WHO Operational Principles for Good Pharmaceutical Procurement [WHO 1999])?

### 25. Existence of formal SOPs for conducting procurement of pharmaceuticals

Yes/no answer with explanation.

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.

Follow-up question to ask:
- Were the SOPs developed specifically for health-sector goods and pharmaceuticals or are they general SOPs?
- When updating the SOPs, is there a formal mechanism to consult the stakeholders that use SOPs?
- Has an independent audit of the public sector procurement been conducted within the last 3 years?

**Note:** General procurement SOPs are inadequate for pharmaceuticals. Procurement of pharmaceuticals requires unique considerations, including specifications and sourcing issues.

### 26. Use of generic or INN for public procurement

Yes/no answer with explanation.

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. Use of generic or INN facilitates competition among suppliers and manufacturers on the basis of the chemical entity of interest.
Follow-up question to ask:
- Do procurement personnel feel pressured to procure brand-name products?

Note: Generic names are to be differentiated from generic-branded products. Generic names are the international non-proprietary (chemical) name of the product, while the generic-brand name is the manufacturer-specific name used for marketing purposes.

27. Percentage (by value) of MOH pharmaceuticals procured through competitive bids

(\text{Value of MOH pharmaceuticals procured through competitive bids} / \text{Value of total MOH pharmaceutical procurement}) \times 100

A high percentage of procurement through competitive processes suggests that the purchaser is obtaining reasonable prices. 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. It is important to understand why (if not) procurement is not conducted through competitive bids and document the reasons 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.

A related indicator is the “Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement” (see indicator #31 below). 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.

28. Existence and application of a procurement prequalification or postqualification process for suppliers and products

Yes/no answer with explanation.

This indicator demonstrates quality assurance within the procurement system and whether the process is based on a review of objective information about product safety, efficacy, quality, and manufacturer/supply capacity.

Quality assurance can limit the participation of suppliers and products of dubious quality in the procurement process.

Follow-up questions to ask include:
- What is the procurement prequalification and postqualification process for suppliers and products?
- Is the process transparent?
- Are the criteria for qualification clear?

The Model Quality Assurance System for Procurement Agencies is used for prequalification of sources by procurement agencies. See WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO 2014).

29. Average lead time for contract/purchase order issue

The average time it takes from when a decision to order is made to when the procurement unit issues the contract or purchase order. It is calculated as follows:

(\text{Sum of number of days from when each decision to order was made to when each contract or purchase order was issued} / \text{total number of contracts or purchase order issued during a}
specified period of time).

For planning, it is important to know the expected lead time required to develop contracts/purchase orders. This indicator measures the efficiency with which requests are processed and purchase orders are prepared. Long lead times will extend the procurement cycle and will delay the time in issuing a purchase order to the supplier or manufacturer. This, in turn, will lead to delays in orders being placed and delays in shipments, potentially leading to shortages and stock outs. Improving the contract issue lead time will improve response times to in-country facilities that need the products. A related indicator for procurement may include lead time for contract award.

<table>
<thead>
<tr>
<th>30. Percentage of products procured according to plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Quantity of procured products received during a defined period/total quantity planned for the same period) X 100.</td>
</tr>
</tbody>
</table>

The indicator reflects the reliability of a central procurement system, measuring how closely the quantities of medicines received matched the expected quantities in a given period. The target is for the total quantities received to be as close as possible to those planned for procurement. Any variation should be explained—for example, the planned quantities were not accurate, insufficient budget for ordering the planned quantities, needs changed since the previous forecasting exercise, or emergencies occurred that altered needs.

Other points to consider when interpreting this indicator include:

- More than two central pharmaceutical procurements (defined here as tenders, not orders against contracts) per year suggest 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.
- What was the value of emergency procurements (as a percentage of the pharmaceutical budget over the last 2 years)? This value adds further insight on effectiveness of the procurement program. Emergency procurements should not represent a significant portion of the pharmaceutical procurement budget. A high percentage of emergency orders can indicate the failure of a number of processes including, among other factors: the adjustment of maximum/minimum levels; purchase order lead times; review of the accuracy of LMIS data, forecasts, and procurement plans; review of timeliness of reporting; and review and possible adjustment of the time span of the procurement cycle.
- What was the ratio of unit prices paid through emergency procurement versus competitive bidding process?
- 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.

The indicator can help to identify opportunities for improvements in planning.

<table>
<thead>
<tr>
<th>31. Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>This indicator measures the median price paid for a set of tracer medicines that was part of the last MOH procurement as a percentage of the median international price. The computation involves two steps:</td>
</tr>
<tr>
<td>• First, the percentages are calculated for each of the tracer medicines by dividing the purchase cost of the comparison unit (e.g., tablet, milliliter, etc.) at the last regular MOH procurement by the median international price of that unit and multiplying the result by 100.</td>
</tr>
</tbody>
</table>

32
MOH procurement

% of Median = (Comparison Unit Price/Median International Unit Price) X 100

- Second, the average percentage for all tracer medicines is calculated by summing their percentages and dividing by the total number on the list.

Average % of All = Sum of percentages of all tracer medicines /total number of tracer medicines

This indicator measures the cost of items procured relative to the median international price paid. It will help determine the potential savings to the MOH that could be achieved if procurement practices are improved. The higher the percentage, the greater the potential cost savings.

The median international reference prices for the essential medicines (as price per tablet or therapeutic unit) are available through Management Sciences for Health’s *International Medical Products Price Guide*. The international reference prices have been selected for comparison as they are widely available, updated frequently, and relatively stable over time.

This indicator can also be used to examine access in terms of affordability of medicines

**Note:** When focusing on the private sector, NGO and community-based facilities providing medicines can also be included in the calculation.

### 4.8 Topic E: Distribution

**Overview**

The distribution function includes all activities related to warehousing, managing inventory, and transportation. Activities include: ordering, transporting, receiving, storing, issuing supplies, and managing waste. These activities take place at various levels of the system. An important goal of this system function is to protect procured items from loss, damage, theft, and wastage. This is achieved by managing the reliable movement of supplies from source to user in the least expensive way while guaranteeing the quality of products along the supply chain. Note: For quality assurance indicators, refer to the corresponding modules of the Model Quality Assurance System for Procurement Agencies.

See Table 3.4.7 for indicators to assess distribution of medical products, vaccines, and technologies.

**Table 3.4.7. Indicators to Assess Distribution for the Medical Products, Vaccines, and Technologies**

<table>
<thead>
<tr>
<th>Core Function</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator</td>
<td></td>
</tr>
<tr>
<td>32. Existence of SOPs for each level of the distribution system</td>
<td>Yes/no answer with evidence and explanation.</td>
</tr>
<tr>
<td></td>
<td>SOPs include detailed descriptions of the specific roles and responsibilities of staff involved in all distribution activities. SOPs provide specific guidance to staff on how to properly manage supplies of medicines, vaccines, and other medical products. They also promote transparency and accountability and form the basis for supervision and audits. When SOPs do not exist or are not effectively implemented, stock-outs and expiries of products may occur and theft or diversion may go undetected.</td>
</tr>
<tr>
<td></td>
<td>Specific follow-up questions include:</td>
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<tr>
<td></td>
<td>• Do written SOPs exist for each level of the system, and are they readily accessible? If so, where can they be found?</td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>
| Does the private sector also follow these SOPs?  
Are staff using the SOPs across all levels of the system?  
Has there been training in the use of the SOPs? If so, by whom, when, and is there regular refresher training offered? Does the private sector participate in these trainings?  |
| 33. Order fill rate  
(Number of order lines, stock-keeping units (SKUs) or cases shipped and received in initial shipment/total quantity ordered) X 100.  
This indicator measures a supplier's ability to fill orders completely in terms of items and quantity as defined in the contract/purchase order during a definite period of time.  
Deliveries may be divided into multiple shipments through an agreement, but they still must be received in full by a specified date. Shipments should always be checked against the shipping notice and the purchase order. What was shipped may not be what was ordered. Even though a distributor may supply products only a few times a year, in most cases the supplier should be expected to fill orders completely, or almost completely, unless alternate agreements have been made, in which case it should be noted. For suppliers that are routinely noncompliant, it may be necessary to identify which items are causing the most problems and find another mechanism for obtaining those items.  |
| 34. Inventory average accuracy rate  
(Number of items where stock record count equals physical stock count/total number of items counted) X 100.  
The indicator calculates the average percentage of inventory records (e.g. stock ledger, bin card, or automated system), where the balance on the record corresponds exactly with the physical stock count for a set of indicator products. Inventory records are official inventory forms and registers used to document medicine receipts, issues, balances, and other related information.  
This indicator measures the accuracy of data on product stock levels at a facility and provides information on how accurately the facilities are tracking their inventories. Physical stock, stock record, and LMIS report counts refer to the amount of each product that is shown as undamaged, unexpired, and available for use in a service delivery facility or warehouse. Having accurate stock-on-hand values is essential for forecasting and procurement exercises as well as for proper picking and distribution. These are generally calculated during physical inventories, which can be done on a fixed schedule (e.g., all items are counted annually), or they can be done with higher frequency such that each item is counted according to its own schedule (e.g., aspirin is counted quarterly; Norplant is counted annually). Annual physical inventories are likely to reveal more items in error than more frequent checks.  
Some facilities update records periodically rather than on an ongoing basis. The technical team should consider this possibility when reviewing the accuracy of the record-keeping system. If records are not updated on an ongoing basis, steps should be taken to account for recent issues/receipts of medicines and to add/subtract these accounts from the most recent record balance available.  
Team members can report each measure of discrepancy (or agreement) by facility or in the aggregate and should report for each product of interest. It may also be useful to use these measures to calculate the percent of facilities that keep accurate stock records and produce accurate reports (defined as reports showing that discrepancies for all products fall within a margin of error agreed to by the program).  
Possible reasons for poor record accuracy include the following: (1) incorrect recording of amounts received and issued (by picker if manual system, by data entry person if automated system).  |
<table>
<thead>
<tr>
<th>35. Percentage of storage facilities meeting acceptable storage conditions</th>
<th>(Number of facilities meeting each acceptable storage conditions/total number of facilities visited) X 100.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>This indicator measures the risk of the quality of medicines being compromised. A checklist based on recommended storage practices can be used to determine whether proper conditions are being met and to compare recommended and actual practices. Enquire about the supervision and inspection processes that take place on a regular basis; reports of these activities may be a source of data.</strong></td>
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<tr>
<td><strong>Recommended storage conditions may include:</strong></td>
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<tr>
<td>• Products are stored and organized in a manner accessible for first-expiry/first-out counting and general management.</td>
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<tr>
<td>• The facility makes it a practice to separate damaged and/or expired products from good quality products and remove damaged/expired products from the inventory.</td>
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<tr>
<td>• Products are protected from direct sunlight at all times of the day and during all seasons.</td>
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</tr>
<tr>
<td>• Cartons and products are protected from water and humidity during all seasons.</td>
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<tr>
<td>• Storage area is secured with a lock and key, but remains accessible during normal working hours—with access limited to authorized personnel.</td>
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<tr>
<td>• Products are stored at the appropriate temperature during all seasons according to product temperature specifications.</td>
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</tr>
<tr>
<td>• Storeroom is maintained in good condition (e.g., cleaned, all trash removed, shelves are strong, boxes are organized, pest free).</td>
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<tr>
<td>• The current space is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for the foreseeable future).</td>
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</tr>
<tr>
<td>• Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible.</td>
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</tr>
<tr>
<td>• Products are stacked at least 10 centimeters (4 inches) off the floor.</td>
<td></td>
</tr>
<tr>
<td>• Products are stacked at least 30 centimeters (1 foot) away from the walls and other stacks.</td>
<td></td>
</tr>
<tr>
<td>• Products are stored separately from insecticides and chemicals.</td>
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</tr>
<tr>
<td>• Products are stacked no more than 2.5 meters (8 feet) high.</td>
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</tr>
<tr>
<td>• Fire safety equipment is available and accessible.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>36. Percentage of public/MOH storage units and health facilities with up-to-date refrigerator temperature monitoring records at each level of the distribution system</th>
<th>(Number of public or MOH storage and health facilities with up-to-date refrigerator temperature monitoring records/total number of MOH storage and health facilities visited) X 100.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>This indicator measures whether personnel are adhering to recommended procedures. Theoretically, all (100%) facilities should have a working refrigerator and regularly updated refrigerator temperature monitoring records. Low percentages highlight possible problems in monitoring storage and/or maintaining stock quality.</strong></td>
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</tr>
<tr>
<td>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. This system may include electric- or gas-operated refrigerators as well as simple cold boxes.</td>
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<tr>
<td>Provide a qualitative description of units (refrigerators or coolers) at different levels of the distribution system (central, regional, district, facility). Specific questions include:</td>
<td></td>
</tr>
<tr>
<td>• Are the thermostats checked regularly?</td>
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</tbody>
</table>
| 37. Existence of appropriate procedures for disposal of expired and/or spoiled medicines at medical stores/health facilities | Yes/no answer with evidence and explanation. Is there evidence of a guideline for disposal of expired/spoiled medicines? | Medicines can sometimes expire or become spoiled at the medical stores and health facilities’ store level. If there is no appropriate monitoring system, such medicines could be relabeled, repacked, and sold on the market. Also, the theft of good quality medicines that are reported as spoiled or expired can go undetected. If there is no appropriate disposal system, discarded medicines can become an environmental hazard. There should be a written SOP for disposal of unwanted medicines including, at a minimum:  
- A mechanism for safe disposal  
- A mechanism to notify NMRA or appropriate oversight body about expired or spoiled medicines  
- A committee responsible for the supervision of disposal of medicines  
- Minutes taken on the disposal and signed by the members of the committee  
- A list of disposed medicines |
| --- | --- | --- |
| 38. Average transportation cost per km/volume/weight | Sum of all transportation costs/total number of kilometer (km) or per cubic meter or per kilogram of product shipped. | The average transportation cost per km or volume or weight (as relevant/appropriate) related to a specific driver, route, or facility, or carrier (if outsourced) during a defined period of time—including inbound and outbound transport, fuel, tires, maintenance, acquiring and staffing a fleet, or, if outsourced, freight bills.  
Calculating average transportation cost per km, volume or weight can help managers monitor these costs over time, follow trends, and make budgetary and operational decisions about delivery schedules (e.g., frequency), use of vehicles, routing, outsourcing, etc. |
| 39. Value of inventory loss | (Total value of damaged products/value of shipped products) X 100. | This indicator measures wastage or inefficiencies in the inventory management system and identifies opportunities for minimizing losses. Inventory loss is a holding cost, which is calculated as a percentage of average inventory value. Inventory loss should be monitored at 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.  
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, external development partners). Note if any of the losses might have been due to an unusual event or instead to ongoing storage problems, such as 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; see indicator #38 above) 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 3 years. If large values have been lost—especially due to theft or unexplained reasons—it may not be prudent to probe. Note whether losses occur regularly or appear to be sporadic.

4.9 Topic F: Access

Overview

Access refers to affordability, (cultural) acceptability, (geographical) accessibility and availability of medical products, vaccines, and technologies. Affordability (financial accessibility) is measured under Topic B of this module. Availability is the relationship between the type, and quantity of product or service needed and the type, and quantity of the product or service provided. Unless the product is accessible and people are able to get to where products are offered, they will not be able to have full access to health services. This measure is tied directly to measurement of geographic access in the Service Delivery module.

See Table 3.4.8 for the indicators to assess access to medical products, vaccines and technologies.

Table 3.4.8. Indicators to Assess Access to Medical Products, Vaccines and Technologies
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
</table>
| 40. Percentage of households more than 5/10/20 km from health facility/pharmacy that is expected to dispense essential medicines | (Number of households living more than 5, 10 or 20 km from a health facility or pharmacy that is expected to dispense essential medicines/total number of households) X 100. This indicator measures geographical access to and availability of public and private facilities with dispensing services and is presented as a percentage of households measured against (1) public facilities 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. 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 or retail outlet 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. Probing questions include:  
- Does the country have different categories of medicine outlets?  
- What is the basis for differentiation?  
- Are they all licensed? Do they stock quality medicines?  
- Are there concerns about the existence of unlicensed facilities?  
- Are unlicensed facilities more widely distributed geographically than licensed outlets?  
**Module link:** Module 2—Service Delivery Indicator (number of primary care facilities per 10,000 population) and (geographic access to health services). |
| 41. Percentage of a set of unexpired tracer items available | (Number of tracer items available/total set of tracer items) X 100. This indicator measures the physical availability of a predetermined set of unexpired essential or key medicines expected to be in both public and private facilities. It is reported either as the percentage availability at the time of visit, or the mean percentage availability for a specified period of time (e.g. 1 year) for a sample of public and private facilities. Determine a select set of tracer drugs to assess based on the list found in Annex 3.4.A. Ideal levels would be at or nearly 100 percent unexpired tracer items available. Low levels of availability indicate potential problems with procurement (including poor quantification), distribution, or inventory management. Shortages can lead to failure to treat clients/patients and may lead to high-cost emergency purchases. Additional probing questions include:  
- 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. For a form and instructions for assessing stock status see Logistics Indicators Assessment Tool (USAID DELIVER project 2008) |
• 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.

<table>
<thead>
<tr>
<th>42. Median consumer price ratio of 14 selected essential medicines in public and private health facilities</th>
</tr>
</thead>
</table>

(Median unit price paid by consumers for a specific medicine during previous year/median international reference price for same medicine during previous year)

This indicator measures the affordability of medicines to consumers. It can be used to examine access in terms of affordability of essential medicines at the time of survey and to compare trends over time.

The consumer price ratios for essential medicines are calculated as the ratio between median unit prices and the median international reference prices for that same product for the year preceding the survey. The median international reference prices for the essential medicines (as price per tablet or therapeutic unit) are available through Management Sciences for Health’s *International Medical Products Price Guide*. The international reference prices have been selected for comparison as they are widely available, updated frequently, and are relatively stable over time. Determine a select set of tracer drugs to assess based on the list found in Annex 3.4.A.

Note: When focusing on the private sector, NGO and community-based facilities providing medicines can also be included in the calculation.

**Topic G: Appropriate Use**

**Overview**

Selection, procurement, and distribution are necessary precursors to the appropriate use of medicines. The appropriate use of medicines means that patients are prescribed and dispensed (or sold) the full amount of the appropriate, quality-assured medicine when needed and at the lowest cost to them, to their communities, and to the system. Further, appropriate use requires that service providers adequately inform patients about the medicines being prescribed or dispensed and that patients adhere to the treatment regimen. Indicators 43-47, which relate to the appropriate use of pharmaceuticals, should be assessed for both the public and private sectors.

See Table 3.4.9 for indicators to assess appropriate use of medical products, vaccines and technologies.

**Table 3.4.9. Indicators to Assess Appropriate Use of Medical Products, Vaccines and Technologies**
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
</table>
| 43. Existence of functioning drugs and therapeutic committees (DTC) or other mechanisms to improve prescribing and dispensing practices | Yes/no answer with explanation.  
The commitment to ensure the appropriate use of medicines is generally described in the NMP. The procedures and corresponding tools may also be specified. Tools that help improve the use of medicines include STGs and 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. In countries having national health insurance systems and electronic claims systems, an analysis of those claims should be done. Prescribing reviews may be conducted by formalized DTC (also called Pharmacy and Therapeutics Committees) or other organized mechanisms. 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 DTC been active? Is there a national network of DTC?  
- 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)? |
| 44. Existence of national therapeutic guidelines with standardized treatments for common conditions | Yes/no answer with explanation.  
Up-to-date national therapeutic guidelines and STGs indicate that evidence-based best practices for treatment of common conditions are reviewed and codified.  
Probing questions include:  
- When were the guidelines last updated?  
- Are the guidelines used to develop the NEML?  
- 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. |

Module link:  
Module 2—Service Delivery Indicators under Topic D: Quality of Health Services
| 45. STGs used for pre- and in-service training of health personnel in both public and private sector | Yes/no answer with explanation.  
Indicates that STGs are available, disseminated to and used to train health personnel and a greater potential for guidelines to be implemented by health care professionals in the public and private sectors.  
If STGs exist, ask the following questions:  
- Are STGs part of the basic curricula in most health training institutions for doctors, nurses, pharmacists, pharmacy assistants, and paramedical staff?  
- Are in-service trainings provided on STGs for doctors, nurses, pharmacists, pharmacy assistants, and paramedical staff? Are these trainings provided to staff in both the public and the private sectors?  
Follow-up questions include:  
- Are STGs used for supervision and monitoring activities in public sector health facilities? In private facilities? If so, do supervision and monitoring practices incorporate oversight of quality and appropriateness of treatment?  
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 and through insurance programs with automated systems.  
**Module links:**  
Module 2—Service Delivery Indicators under Topic D: Quality of Health Services  
Module 3—Human Resources for Health Indicators under Topic B: HRH education |

| 46. Percentage of medicines prescribed based on national STG, an essential medicines list or formulary. | (Number of products prescribed which are listed on the STG or essential medicines list or local formulary /total number of products prescribed) X 100.  
Note that the denominator will be greater than the number of prescriptions checked because patients may receive multiple medications; each individual product must be counted separately toward the numerator and/or denominator.  
This indicator measures the degree to which prescribing practices conform to existing local standards of pharmaceutical treatment for important health conditions. It assesses the extent to which prescribing complies with treatment guidelines for one or more tracer conditions. Ideally, 100 percent of prescriptions are consistent with guidelines. However, this level of consistency is rarely the case. If monitoring is in place 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 under-prescribing depending on the treatment guidelines for the health condition studied. |
47. SOPs for dispensing and medication counseling available

<table>
<thead>
<tr>
<th>Yes/no answer with explanation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard procedures and consistent training enable dispensers to provide quality services to patients in the public and private sectors. If SOPs are available and a high percentage of dispensers have been trained on them, this indicates a commitment to promoting good dispensing practices. Good dispensing practices include providing medication counseling and information on how to take the medicines and recognize and respond to adverse events.</td>
</tr>
<tr>
<td>Determine whether private facilities have access and training to SOPs, as well as whether they are applying it.</td>
</tr>
</tbody>
</table>

### 4.10 Topic H: Management Support Systems

**Overview**

The pharmaceutical system depends on financing, information management and human resources—three essential management support systems—for the resources and support to effectively and efficiently perform selection, procurement, distribution, and use functions. Indicators specific to the financing of medical products, vaccines, and technologies are presented earlier in this module in Topic B. Module 6 covers financing to support health (and pharmaceutical) system activities.

Timely and reliable information is critical for pharmaceutical policy development and implementation; governance and regulation; monitoring and evaluating system performance; and planning and allocation of financial, infrastructure, and human resources. All four pharmaceutical management functions depend on the systematic collection and use of information. A well-functioning pharmaceutical management information system is needed to enable policy makers, program managers, and health care providers to monitor patient safety, post-market intelligence, product registration, product quality, and finances. In addition, a robust and effective LMIS that collects, organizes, and presents accurate and timely logistics information across all levels of the health system is critical to the success of supply chain activities. This information is used for decision-making vital to ensuring that there is always a sufficient supply of medicines and medical products on hand for use at service delivery points.

Adequate numbers of appropriately trained staff are needed to perform key functions. This includes supervisors, inspectors, and auditors to provide oversight. The indicators in this topical area are specific to the management of information and human resources for the medical products, vaccines, and health technologies function and complement indicators in Modules 7—HMIS and Module 3—Human Resources for Health.

See Table 3.4. 10 for the indicators to assess the information and human resource management support systems for the medical products, vaccines, and technologies core function.

**Table 3.4.10. Indicators to Assess the Management Support Systems for the Medical Products, Vaccines, and Technologies Core Function**
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition and Interpretation</th>
</tr>
</thead>
</table>
| 48. Percentage of health facilities that completed and submitted an LMIS report for the most recent reporting period | (Health facilities that submitted an LMIS form within the specified time period / total number of health facilities) X 100  
Logistics systems rely on regular and accurate reporting by health facilities to make decisions on resupply or redistribution of stock and to inform quantification and procurement functions. At a minimum, facilities should submit regular reports on the stock on hand, amount dispensed to clients or used, and any losses and adjustments. LMIS reports are necessary to monitor and evaluate performance, correct for underperformance if necessary, and to increase accountability. |
| 49. Existence of a computerized registration system that facilitates retrieval of information on registered products, licensed providers and premises and clinical trials | Yes/no answer with explanation. Is there a computerized registration system that facilitates retrieval of information on:  
1) Registered products?  
2) Licensed providers?  
3) Licensed premises?  
4) Clinical trials?"  
A computerized registration system makes the information on registered products, providers, premises and clinical trials more readily accessible and more easily updated and monitored by the responsible authorities  
Module links:  
Module 7—HMIS Indicators  
Also see Indicators under Topic A: Policies, Laws, Regulations and Governance: Existence of a functioning system for pharmaceutical registration and Mechanisms exist for licensing and inspection of pharmaceutical establishments. |
| 50. Number of licensed pharmacist and pharmacy technician per 100,000 population | (Total number of licensed pharmacist and pharmacy technician/ total population) X 100,000  
For purposes of this indicator, pharmacist is defined as a person holding a university degree in pharmacy, and pharmacy technician is defined as a person who has completed formal course work leading to a certificate or diploma in pharmacy technology. Only these personnel who work full or part-time in the health care system (includes both the public and private sectors) should be counted.  
This indicator provides information on the level of coverage of pharmaceutical staff. It should be adapted to align with the different types of cadres of pharmacy personnel in the country and can be disaggregated by regions to highlight where disparities exist.  
Module link:  
Module 3—Human Resources for Health Indicator (geographical distribution: health worker density per 1000 population per cadre, subnational districts) |
| 51. Percentage of facilities with staff trained in stock management | (The number of facilities with staff trained in stock management/ total number of facilities) X 100.  
If staff members are not trained in stock management, this increases the likelihood of poor stock management at facilities, which may cause stock outs, excess of stocks, expiration of the medicines, or simply theft and diversion. Staff should be knowledgeable of the SOP for stock management and understand their specific roles and responsibilities with regard to stock management. |
52. Percentage of facilities that received monitoring visits for pharmaceutical management during the previous 6 months

(\text{The number of facilities that received at least one pharmaceutical management monitoring visit in the last 6 months/the total number of facilities}) \times 100.

Regular monitoring visits and supportive supervision is critical to ensure that pharmacy personnel have access to, understand, and adhere to standards set out in SOPs and other pharmaceutical guidelines. It is also important to check that storage and dispensing areas meet required standards and to get feedback from staff on problems faced.

Supervision includes reviewing order forms, examining stock cards/ledger books, reviewing storage and dispensing conditions, conducting a physical inventory, reviewing the dispensing register, and observing dispensing practices and medication counseling in a sample of patient encounters.

4.11 Key Indicators Table

Table 3.4.11 identifies six indicators from the medical product, vaccines, and technologies indicator list that are particularly useful to: (1) monitor and track progress over time and (2) guide the technical team with severe time constraints to focus on the most important measures for this module. Depending on the scope, time, and resources available for the country assessment, this list should be modified to add additional indicators.

Table 3.4.11. Key Indicators for Medical Products, Vaccines, and Technologies

<table>
<thead>
<tr>
<th>No.</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>41.</td>
<td>Percentage of a set of unexpired tracer items available (at time of study and over a period of time) in a sample of facilities</td>
</tr>
<tr>
<td>40.</td>
<td>Percentage of households more than 5/10/20 km from health facility/ pharmacy that is expected to dispense essential medicines</td>
</tr>
<tr>
<td>16.</td>
<td>Percentage of out-of-pocket expenditure for health spent on medicines</td>
</tr>
<tr>
<td>31.</td>
<td>Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement</td>
</tr>
<tr>
<td>39.</td>
<td>Value of inventory loss</td>
</tr>
<tr>
<td>46.</td>
<td>Percentage of medicines prescribed based on national STG, an essential medicines list or formulary</td>
</tr>
</tbody>
</table>
5. **SUMMARIZING FINDINGS AND DEVELOPING RECOMMENDATIONS**

Each team member must analyze the data collected for his or her module(s) to distill findings and propose potential interventions. Once this is done, the module team member 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.B for a suggested outline for the report). This process is iterative; findings and conclusions from other modules will contribute to sharpening and prioritizing overall findings and recommendations. While Section 2, Module 4—Steps of the HSA Approach: Conducting the Assessment, describes in detail the process that the HSA team will use to synthesize and integrate findings and prioritize recommendations across modules, a brief explanation with generic methods for summarizing findings and developing potential interventions for this module is found below.

5.1 **Analyzing Data and Summarizing Findings**

Using a table that is organized by the module topics (see Table 3.4.12 for a template and Table 3.4.13 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 topics are included based on the specific country context. In anticipation of putting findings in the Strengths, Weaknesses, Opportunities, and Threats (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 3.4.14.

**Table 3.4.12. Template: Summary of Findings—Medical Products, Vaccines, and Technologies Module**

<table>
<thead>
<tr>
<th>Indicator or topic</th>
<th>Findings (Designate as S=strength, W=weakness, O=opportunity, T=threat)</th>
<th>Source(s) (List specific documents, interviews, and other materials)</th>
<th>Comments*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

* List impact with respect to the five health systems performance criteria: equity, efficiency, access, quality, and sustainability. Also, list any links to other modules.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Findings (Designate as S=strength, W=weakness, O=opportunity, T=threat.)</th>
<th>Source(s) (List specific documents, interviews, and other materials.)</th>
<th>Comments*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy, laws, regulations, and governance</td>
<td>There is a national pharmaceutical law in effect and a medicine policy draft is under development (S); several relevant laws exist (S); poor enforcement capacity (T).</td>
<td>Draft NMP, interviews with the pharmacy department staff</td>
<td>Module link: Governance Module</td>
</tr>
<tr>
<td>Financing</td>
<td>Dependency on external development partners for kits (W), private expenditure on pharmaceuticals increasing from year to year (W); facilities make local purchases (S); but private sector can procure some needed medicines at affordable prices (O).</td>
<td>Interview with MOH; MOF audit report; procurement officers of private importers and retail pharmacies</td>
<td>Module link: Service Delivery; Financing, Sustainability</td>
</tr>
<tr>
<td>Selection</td>
<td>NEML is used as basis for kit system in public sector (S).</td>
<td>NEML updated in the last 5 years, interviews with national drug and therapeutics/selection committee chair and/or members</td>
<td>Module link: Service Delivery, Quality of Care; Health Financing</td>
</tr>
<tr>
<td>Procurement</td>
<td>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, nor is it based on systematic quantification process (W); external development partners do not feel confident about current capacity (T); products procured not on list of pre-approved suppliers (T); private sector able to procure reliable medicines at all different price points (O).</td>
<td>Audit report; interview with the director of procurement, interviews with private providers, manufacturers, MOF</td>
<td>Link with measures of efficiency and sustainability. Module link: Health Information Systems, Health Finance</td>
</tr>
<tr>
<td>Distribution</td>
<td>There is a pharmaceutical ration kit system for medicines and medical supplies, with distribution, facilitated by external development partners and NGOs depending on province (S); many areas with limited-to-no access by road (W); but private sector has further reach (O).</td>
<td>Interviews with the director of the pharmacy department and the medical stores manager; private wholesalers and retail distributors</td>
<td>Module link: Service Delivery, Measures of Equity and Access</td>
</tr>
</tbody>
</table>
As discussed in Section 1, WHO’s health system performance criteria and Annex 2.4.A can also be used to examine the strengths and weaknesses of the health system. Table 3.4.14 summarizes the medical products, vaccines, and technologies indicators that address each of the five key health system performance criteria highlighted by WHO: equity, efficiency, access, quality, and sustainability.

**Table 3.4.14. List of Suggested Medical Products, Vaccines, and Technologies Indicators Addressing the Key Health System Performance Criteria**

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>Suggested Indicator from the Medical Products, Vaccines, and Technologies Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity</td>
<td>16. Percentage of out-of-pocket expenditure for health spent on medicines disaggregated into different subgroups (e.g., geographic location, age group, gender, race and ethnicity, socioeconomic status)</td>
</tr>
<tr>
<td>Efficiency</td>
<td>31. Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement</td>
</tr>
</tbody>
</table>
| Access (including coverage) | 40. Percentage of households more than 5/10/20 km from health facility/pharmacy that is expected to dispense essential medicines  
                                        41. Percentage of a set of unexpired tracer items available  
                                        17. Percentage of respondents who indicate that they forego medicines due to cost |
| Quality (including safety) | 6. Existence of a functioning system for pharmaceutical registration |
| Sustainability       | 15. Proportion of annual national expenditures on pharmaceuticals financed by different stakeholders |
Each indicator includes specific suggestions for interpretation. However, when examining medical products, vaccines, and technologies, it is important to consider each topic as a whole and not look simply at the topic’s individual indicators—small problems may be symptoms of larger systemic issues. And of course, many of the pharmaceutical system functions are influenced by the other health system functions, so these also need to be cross referenced.

It may be helpful to organize the description of the module profile and key findings according to topics. 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 topics and include:

- Current situation
- Policy, legal, and regulatory environment
- Financing
- Selection
- Procurement
- Distribution
- Access
- Appropriate use
- Management support systems

## 5.2 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 3.4.7 demonstrates how observed performance problems can be linked to appropriate interventions. 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 priorities and competitive advantages of various external development partners—and the gaps in current external development partner programming—as well as opportunities for consistent, coordinated external development partner 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. This information can then help to identify appropriate alternative interventions.
Section 2, Module 4—Analyze Findings and Develop Recommendations, suggests an approach for synthesizing findings across modules with your team and for crafting recommendations. Table 3.4.15 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>
<thead>
<tr>
<th>Health Systems Gap</th>
<th>Possible Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmaceutical policies, laws, regulations, and governance</strong></td>
<td></td>
</tr>
</tbody>
</table>
| No up-to-date policies and laws regulating the pharmaceutical sector, including an 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 NMRA 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 the private sector into public sector regulatory framework. Involve professional associations as mechanism to distribute new policies, guidelines, and to offer in-service training. |
| **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 medicines 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 medicines funds and community-based insurance). |
| **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 and mortality patterns and STG.  
  • Establish drug information centers or an alternative mechanism to increase access to unbiased information about medicines. |
| **Procurement** | |
| At the national level, purchasing prices are high compared to international reference 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 the private sector to determine where and how to purchase at lower prices, if applicable. |
| **Distribution** | |
| Holding costs (storage costs and inventory loss) are high relative to inventory value. |  
  • Improve available warehousing options.  
  • Develop SOPs and institute standards for warehouse management, train warehouse managers, and develop and operationalize a checklist to be reviewed daily by managers.  
  • Strengthen 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). |
### Access

<table>
<thead>
<tr>
<th>Public facilities experience stock outs of key essential medicines:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Insufficient public funds to purchase essential medicines</td>
<td>• Strengthen public sector capacity to forecast and purchase essential medicines.</td>
</tr>
<tr>
<td>• Inefficient government procurement and distribution systems</td>
<td>• Strengthen inventory management practices through optimizing flows, development of SOP, training on inventory management functions, and monitoring of key indicators.</td>
</tr>
<tr>
<td></td>
<td>• Create an inventory management system with alerts when products run low.</td>
</tr>
<tr>
<td></td>
<td>• Explore opportunities to partner with private sector distributors to get essential medicine to rural areas more regularly.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Explore alternative methods to increase public funds to purchase essential medicines (e.g., user fees for drugs).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Geographic access to public health centers that provide pharmaceutical services is limited:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Greater number and wider distribution of private sector outlets exist</td>
<td>• 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.</td>
</tr>
<tr>
<td>• Varied quality of private services</td>
<td>• Open external development partner-sponsored training to include private providers for improved therapeutic practices in underserved areas.</td>
</tr>
<tr>
<td></td>
<td>• Develop accreditation system to license the number of private sector outlets in underserved areas, ensuring quality and thus complementing the public sector.</td>
</tr>
<tr>
<td></td>
<td>• Explore ways to reduce the cost of the essential medicines delivered by private pharmacists (e.g., donated), ensuring affordability.</td>
</tr>
</tbody>
</table>

### Appropriate Use

<table>
<thead>
<tr>
<th>Prescribing does not follow STG, national STGs do not exist or are out-of-date, or STGs do not include guidelines for key public health conditions.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Formulate a committee or process, including the private sector, to review and revise STGs based on morbidity patterns and evidence-based best practices.</td>
</tr>
<tr>
<td></td>
<td>• Make copies of STGs available to all facilities and all providers, public and private alike. Provide training on the guidelines to practitioners, including the private sector, through professional associations or by opening up public sector training.</td>
</tr>
<tr>
<td></td>
<td>• Establish DTCs and provide training; provide pre- and in-service training on appropriate prescribing to all providers.</td>
</tr>
<tr>
<td></td>
<td>• Develop managerial interventions to restrict prescribing that can be applied in both public and private sectors.</td>
</tr>
</tbody>
</table>
6. **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, which should include:
    - a. Selection
    - b. Procurement
    - c. Distribution
    - d. Health system organization (decentralization)
    - e. End user, community

- **Medical Products, Vaccines, and Technologies Assessment Indicators**
  - A. Pharmaceutical policies, laws, regulations, and governance
  - B. Financing
  - C. Selection
  - D. Procurement
  - E. Distribution
  - F. Access
  - G. Appropriate use
  - H. Management support systems

- **Summary of Findings and Recommendations**
  - A. Presentation of findings
  - B. Recommendations
7. BIBLIOGRAPHY


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1 In 2014 the World Health Assembly passed Resolution 67.23, stipulating that health intervention and technology assessments are necessary globally in order to work toward achievement of UHC.