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

MODULE 4: MEDICAL PRODUCTS, VACCINES, AND TECHNOLOGIES

4.1 Introduction

A "well-functioning health system ensures equitable access to [medicines], medical products, vaccines, and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use" (WHO 2007, p. 3).[1] 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 UHC.[2] 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% of total health expenditure and can be as high as 67% (Lu et al. 2011). Medicines account for three of the ten 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).

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 use of these products and technologies. Poor medicine availability—particularly in the public sector where availability of generic medicines is less than 60%—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% of patients in LMICs are treated according to standard treatment guidelines and less than 50% of patients adhere to treatment regimes (Holloway and van Djik 2011).

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

By ensuring access to quality health products, vaccines and technologies, a well-functioning logistics system improves cost-effectiveness and efficiency of the system, ensures quality of care and helps to increase results and impact on the health of the population. Effective supply chains directly contribute to the success or failure of any public or private health care program or service.

[1] Access has four dimensions: availability, affordability, geographical accessibility, and (cultural) acceptability (Penchansky and Thomas 1981; CPM 2003).

[2] In 2014 the World Health Assembly passed Resolution 67.23 stipulating that Health intervention and Technology Assessments (HTA) are necessary globally in order to work towards achievement of Universal Health Coverage (UHC).

Although the public sector is the principle provider of health services and their corresponding medical products, vaccines and medical technology, in many countries the private sector (e.g. commercial, non-profit, community-based or faith-based organizations) play an active role in delivery of services. As demand for health services has increased so has the quantity of medicines and medical technologies supplied through the private sector. 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.

This module presents information that is critical to understanding the importance of how a well-managed system—one that ensures equitable access to medical products, vaccines and technologies and their scientifically sound and cost-effective use—impacts health service delivery. It looks at how the HSA approaches this core health system function, and is organized in the following subsections:

- Subsection 4.1 presents and defines the key functions of managing essential medicines, 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 the this function and a description of each.
- 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 are using the terms medicines, pharmaceuticals and drugs interchangeable. The term “medical products” is inclusive of medicines.

4.2 What Is Supply Chain Management of Medical Products, Vaccines, and Technologies?

A supply chain is a system of organizations, people, activities, information and resources, which are all involved in moving medical products, vaccines and technologies from suppliers to patients. The goal of a health care supply chain is to help ensure that service delivery users are able to obtain and use quality and essential health products when they are needed. The activities of this core health system function are organized according to the functional components of a framework or system and may take place at various levels of the health system according to the design of the system. Managing essential medicines, medical products, vaccines, and technologies represents the whole set of activities aimed at ensuring the timely availability and efficient and appropriate use of safe, effective, quality medicines and related products and services in any health care setting.[3]

Four basic interdependent functions and their activities are involved in supply chain management of medical products, vaccines, and technologies—a) product selection, b) quantification/ procurement, c) storage/ distribution, and d) use. Together these functions make up a continuous supply chain logistics system.

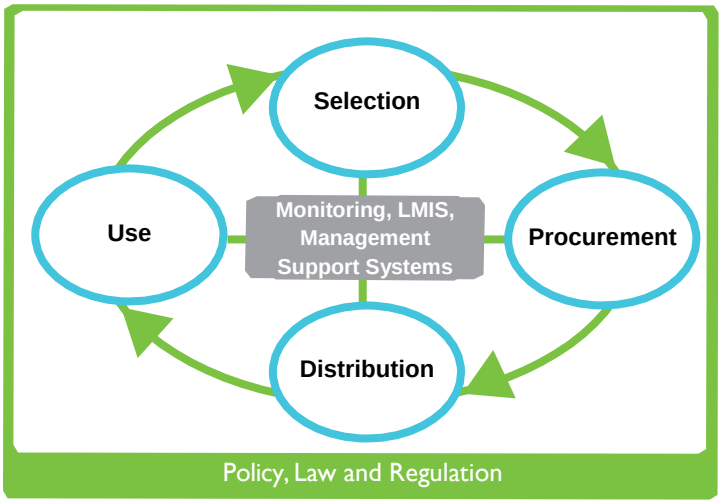
[3] There are many terms used in managing essential medicines, medical products, vaccines, and technologies (please refer to Annex 3.6.A).

Logistics management is the part of supply chain management that plans, implements, and controls the efficient and effective flow and storage of these medicines and products between the origin point and the consumption point in order to meet the needs of patients. As such they are usually depicted as a cycle and build on each other (Figure 3.4.1).

At the center of the cycle is the function of monitoring through a "Management Support System", which encompasses a core set of management support systems including a Logistics Management Information (LMIS) system focused on data collection, compilation, analysis and use. They also include support systems for organization and human resource management, budgeting, and evaluation. The management support systems are enabled (and constrained) by policies, laws, and regulations and supported by good governance principles and practices, which establish and sustain the public commitment to health products supply. These functions are the same regardless of the setting (public or private sectors) and the level of implementation (national, regional, or facility) and are interdependent.

It is important to consider the interconnections between the management functions of a supply chain logistics system and the other core health system functions. Selection, quantification/procurement, and storage/distribution are closely connected to health service delivery, and include the provision of quality care and services that support appropriate use. The management support systems reflect the interconnections with the core health systems functions of leadership and governance, health systems 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. For further information see **The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities**. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiHand.pdf

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



The Medical products, vaccines and technologies module addresses all five health system performance criteria: equity, efficiency, access (including coverage), quality (including safety), and sustainability.

4.3 Developing a Profile of Medical Products, Vaccines, and Technologies

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.

The system of managing medical products, vaccines, and technologies generally reflects the health system in which it operates. Therefore a good starting point for developing an overview of this system is to understand the country landscape, which has significant impacts on the management of the country's medical products, vaccines and technologies.

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. The system of managing medical products, vaccines, and technologies generally reflects the health care system in which it operates. Section 3, Module 1 – Country and Health System Overview provides key information on the organization of the health system, the primary stakeholders and issues affecting the system.

To give the overall HSA team and country stakeholders an overview of the supply chain management systems as part of a greater health system, the HSA team member responsible for this module will develop a profile of the supply chain and its functions across public and private sectors. Future HSA analysis and planning should not be conducted in isolation, but placed in the context of and linked with broader health sector planning, and that is why creating an initial profile is important. Table 3.4.1 provides a set of questions about the health system in order to better understand the country context and develop a profile for this module.

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

Health System Level	Questions
A. Health sector and service delivery	What has been the country's experience with health sector reforms (e.g., decentralization, privatization, reforms related to UHC)?
	What are the different levels of care in the public health care system? What role do private or NGO health providers play at these different levels? • Primary level of care (e.g., health post or clinic) • Secondary level of care (e.g., district hospital) • Tertiary level of care (e.g., specialized hospital)
	At what level of the public health care system is there budget authority for medical products, vaccines and technologies?
	Are the following functions centralized, decentralized or privatized? And if so at what level? • Selection • Quantification • Procurement

Health System Level	Questions
	• Ordering • Warehousing • Distribution • Logistics Information Management
	Is there a LMIS, 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?
	What is the relationship between the private and public supply of medical products, vaccines and technologies medicines? Are products or vaccines donated to private sector for priority programs and interventions? Are private providers required to report health information on products and vaccines used to the public sector and if so how does that work?
	How big is the private pharmaceutical sector? Are there: • Retail pharmacies? • Retail pharmacy chains? • Local Manufacturers? • Large private importers and distributors?
B. National cross-sectoral and international context	Are the following stakeholders present in the country? And if so, what are their roles regarding supply chain management functions (e.g. procurement, distribution, information systems, other)? • NGOs and FBOs • National stakeholders (vertical programs, public or public/private) • Bilateral and multilateral development partners
	What trade issues apply to medical products, vaccines and technologies? • What are the relevant regional, sub-regional and global trade agreements and initiatives? • How do they influence the supply or management of medical products, vaccines and technologies?

Supply Chain Management Functions

The system for managing medical products, vaccines, and technologies can be described by examining the activities associated with the three management functions or cycles namely product selection, quantification/procurement, storage/distribution (and use) along with a fourth cycle to manage and monitor supplies, namely a Logistics Management Information System (LMIS) with management support.

Product Selection is informed by the health needs of the population. It involves estimating the potential benefit of available treatment options and to select the most effective ones. It encompasses developing, updating and publishing Standard Treatment Guidelines (STG) based on scientific evidence and WHO guidance for rational use of essential medicines for priority health problems; selecting products and dosage forms for essential medicines lists, formularies, and insurance reimbursement lists; and deciding which products will be available at each level of the health system. Additionally a National Essential Medicines (NEML) list is developed to enable providers to provide treatment along established STG and serves as a basis for public sector procurement, training of staff and reimbursement. This process ensures that product selections are made using STG and regulatory requirements. It is also used for oversight and guidance of the private sector when services are contracted out. The existence of a formalized system based on review of scientific evidence for regular review of essential medicines lists and

STG for the treatment of priority disease conditions ensures that the health care system uses the most cost-effective and efficacious treatment options available.

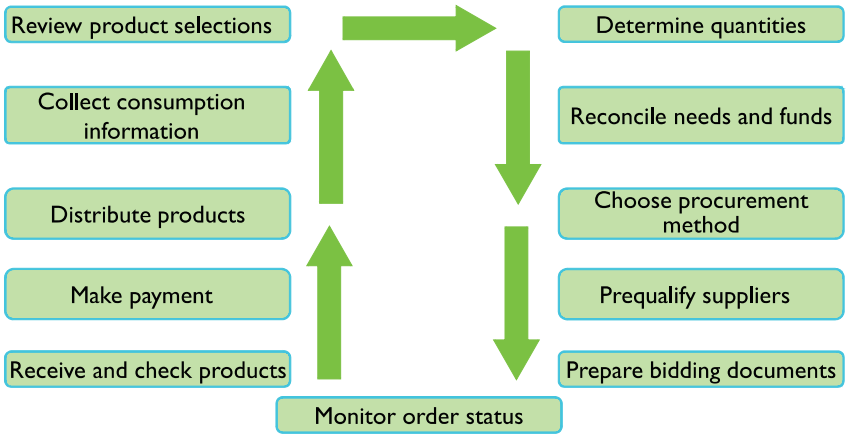
Quantification and Procurement functions include deciding which products to procure based upon the country's EML and quantification for ordering. Quantification, an estimation of quantities and costs of products required for a specific health program (or service) and determining when products should be delivered to ensure uninterrupted supply for the program (or service) is key to uninterrupted services. Effective quantification is dependent upon strong use of data and logistics management information. Accurate forecasting of need is vital to the quantification process and is usually based upon the previous quantities dispensed or services provided.

CONSIDER BOTH THE PUBLIC AND THE PRIVATE SECTOR SUPPLY CHAIN

- At the community level, users may seek services from public and/or private (commercial, NGO, FBO) facilities including CHWs.
- Private facilities may have some level of interaction with the government and may obtain medicines and vaccines from the public distribution system or parallel systems set up to service facilities individually.
- Private facilities, and some public ones may also obtain their supplies via alternate channels to governments—which can result in higher costs to patients due to low economies of scale and/or facilities obtaining materials through non-regulated sources that may jeopardize their safety, efficacy and quality
- CHWs obtain their supplies from health facilities and play an important role in providing medical services to the community.
- It is important to map out the totality of the flow of commodities taking into account all these players to fully understand the system.

Procurement regulations must be followed by trained staff with a system of documenting, maintaining, and auditing of records at every level of the procurement function. Several actors may be involved in the country's procurement systems as well as incoming donations to the country. These actors include national procurement centers/departments, national programs, development partners, the World Bank, or a variety of private companies or wholesalers. The procurement system may be centralized, decentralized, or mixed. Technical team members should examine the impact of all stakeholders on the effectiveness of the procurement system. Choosing procurement methods, managing the bidding process, tracking and monitoring procurements, assuring pharmaceutical quality, making price comparisons based on International Reference Pricing (IRP), and monitoring supplier performance stratified by public and private sectors (Figure 3.4.2) are key in the process.

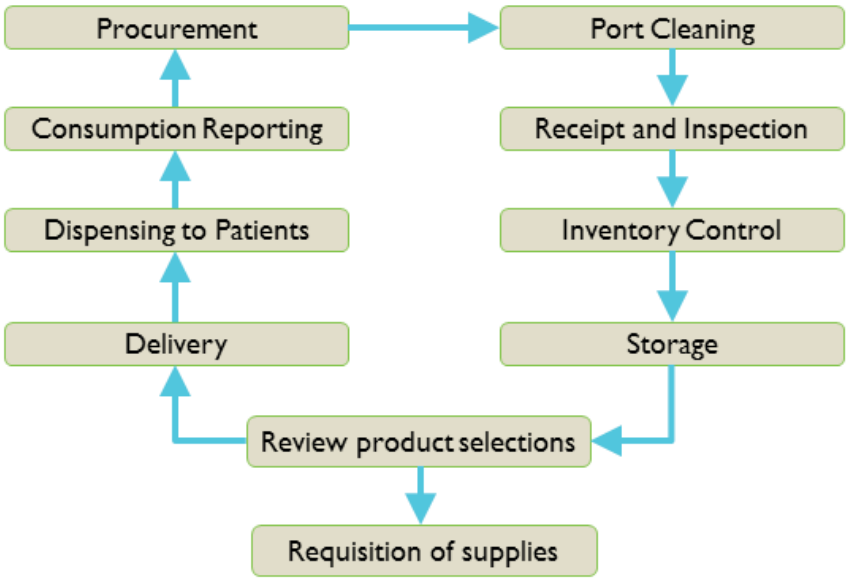
Figure 3.4.2 The Pharmaceutical Quantification and Procurement Cycle



Storage and Distribution include the systems for ensuring that pharmaceuticals are appropriately stored, managed, and transported to their point of use. Distribution involves moving medicines and products down the pipeline from the port facilities, national central warehouse, regional warehouse, district or provincial warehouse, all service delivery points including community-based distribution networks until they are dispensed. Transport management systems are a key factor in successful distribution as are the use of storage guidelines, inventory management systems to ensure there is stock on hand and mechanical and chemical quality, and waste management systems. These systems require visual inspection and physical inventory count, which is where the importance of continuous monitoring and management of supplies through information systems is of vital importance.

Appropriate mechanisms need to be in place to manage inventory, the flow of information, and requisitions. Warehouse infrastructure, including adequacy of storage space, material-handling equipment, transportation equipment and/or contracts, needs to be examined to determine the effectiveness of the logistics systems (Figure 3.4.3).

Figure 3.4.3 The Storage and Distribution Cycle



Mapping the distribution system to show how medical products enter and move through the country can provide a good profile of the system. Essential medicines, medical products, vaccines, and technologies systems can be diagrammed in terms of the flow of information, funds, and products. The activities associated with carrying out each component of the management systems can also be diagrammed. The starting point for developing a profile is to diagram the distribution system to show how pharmaceuticals, medical products and vaccines enter and move through the country. Figure 3.4.4 diagrams an ideal multilevel distribution system that included private sector participation in the public sector supply system. In this system, medical products, vaccines, and technologies are procured and distributed to a designated level of the distribution chain by the appropriate government unit, NGO, or private sector entity.

Figure 3.4.4 Typical Country Distribution System

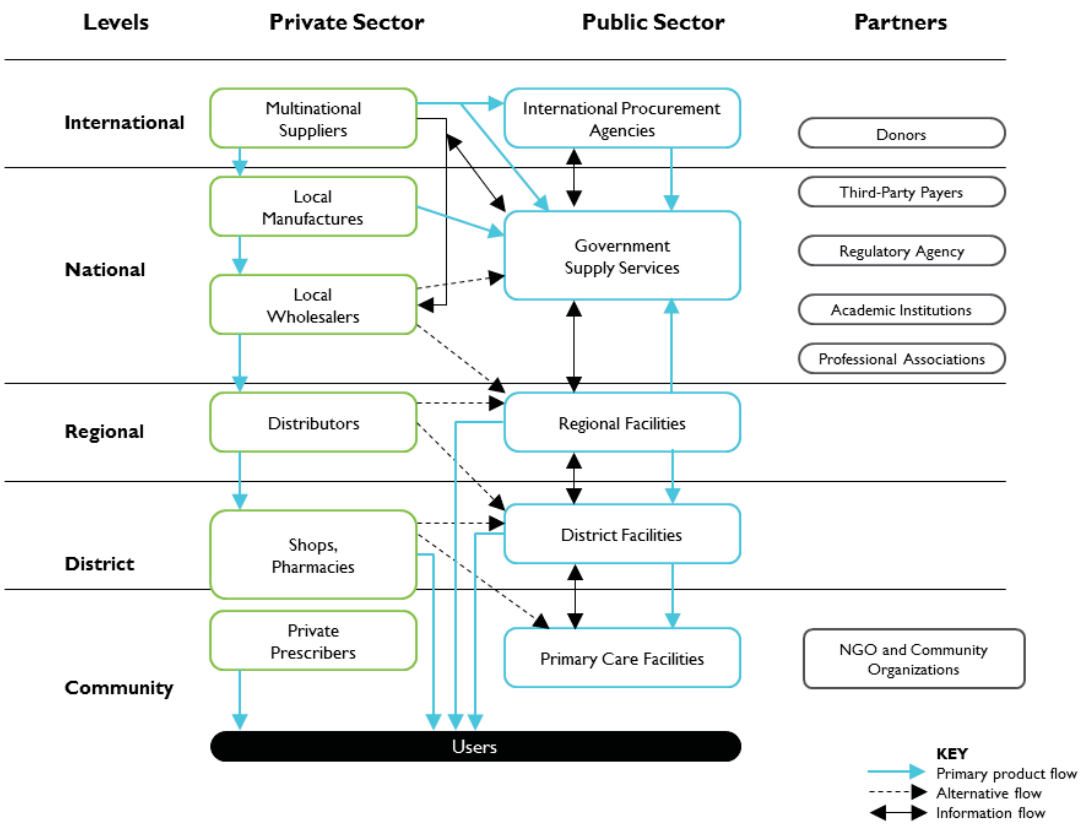
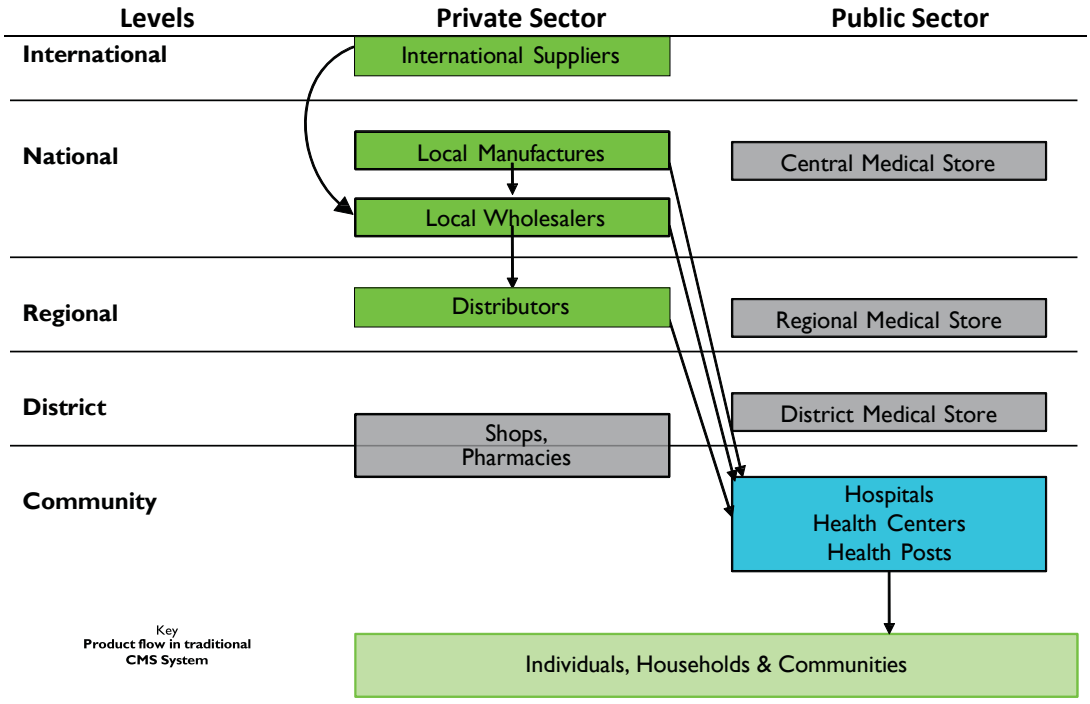


Figure 3.4.5 shows an alternative public sector system in which storage and transportation functions are contracted out to private distributors. In this system, medical products, vaccines, and technologies are delivered directly to health facilities. Variations or combinations of these two models may 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).

Figure 3.4.5 Direct Delivery Model for Distribution



Note: CMS = Central Medical Stores

Note that a country may have a mix of logistics distribution systems. For example, the essential medicines program might be a pull system (ordering based upon inventory levels) integrated with other programs such as for HIV/AIDS or family planning, while the EPI might maintain a vertical push (ordering based upon demand) system for managing its products. It is important to recognize all the different systems in place and examine how they have an impact on each other, where synergies could be built into them, or where integration may be appropriate. Similar to the system overview, diagrams can be made to illustrate individual aspects of the process of selecting, procuring, and distributing pharmaceuticals. The specific agency or entity responsible for carrying out these activities, and therefore the source of key indicator data may differ from country to country.

Monitoring, LMIS, Management Support Systems include gathering and analyzing information for decision-making. For example information about consumption and inventory levels is essential to knowing how much product needs to be ordered or procured. This information is also vital to inventory management. Public ordering strategies will differ from county to country. Some countries may base their ordering decisions on an allocation or “push” system where procurement begins based on demand (either forecasted or actual demand), while others may use a requisition or “pull” system where procurement orders begin upon inventory reaching a certain level. In a “push” system the higher-level health facilities decide what commodities to move down the chain and when to do so while in a “pull” system the lover-level facilities order products as they need them in effect pulling supplies through the supply chain. The difference between these two systems is which level of the health system makes the decision about resupply, not what data are used as ideally data should be the same across levels. Some country decisions may be based on a hybrid push—pull system which demands more accurate forecasting of need and adjusts inventory levels based upon actual utilization. The goal is always to stabilize the supply chain in order to avoid shortages (or surpluses).

Personnel need to be well-trained in logistics management and staff assigned to supervise their work; there needs to be sufficient resources budgeted for procurement, storage space and maintenance, transportation and vehicle maintenance; and ongoing monitoring of supply chain management needs to take place.

4.4 Assessment Indicators

This section outlines core medical products, vaccines, and technologies indicators that can be used in the assessment. 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. For additional indicators to measure the logistics supply chain see **Measuring Supply Chain performance: A Guide to Key Performance Indicators for Public Health Managers.** http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf.

CONDUCTING THE ASSESSMENT

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

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. Topic A and B reflect macro country context; C, D and E pertain to supply chain logistics cycle activities, F and G focus on access and appropriate use, and H pertains to Monitoring, Logistics Management Information Systems (LMIS) and Management Support Systems. These indicators are illustrated in Table 3.4.2 below.

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

Topics	Indicator Numbers
A. Policies, laws, regulations and governance	XX
B. Financing	XX
C. Product Selection	XX
D. Quantification and Procurement	XX
E. Storage and Distribution	XX
F. Geographic Access	XX
G. Appropriate use	XX
H. Monitoring, LMIS, Management Support Systems	XX

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 publically available databases.

    - The World Medicines Situation (WHO 2011) (http://www.who.int/medicines/areas/policy/world_medicines_situation/en/) 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.
    - Pharmaceutical Sector Country Profiles (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html)
    - WHO Essential Medicines and Health Products Portal (http://apps.who.int/medicinedocs/en) is a repository of grey literature and useful source to refer to. It contains a collection of National Medicines and Pharmaceutical Policies (NMP) 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 drug law and national health and medicines/pharmaceutical policy
    - National drug regulatory authority (NDRA) reports/website
    - Documents supporting the public procurement process such as national procurement guidelines; standard bidding documents; standard operating procedures (SOPs) for MOH/public procurement[4]; procurement records and reports
    - Key performance indicators from national procurement centers
    - National procurement plans
    - Quality control laboratory reports and quantification exercises
    - MOF audit reports
    - Service Provision Assessment and physical inventory reports
    - Logistics management information system (LMIS); transport department records
    - Existing health facility surveys or monitoring reports, supervision reports
    - EPI 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.

    - Head of the MOH pharmacy department and the NEMP
    - NDRA

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

- National drug and therapeutics/ selection committee chair
- Drug quality control laboratory
- National drug inspectorate
- MOH pharmacy department
- MOH procurement unit/center or office
- Pharmacy council/board
- Pharmacy and other (e.g., manufacturing, distributors) professional associations and unions
- Private distributors
- Health facilities
- Sub-national health ministry officials
- Private retail pharmacy managers/owners and medical store managers
- Procurement managers at retail pharmacies
- Public and private health facilities managers
- Representatives of agencies throughout the supply chain (both public and private)
- MOF
- Site visit to public warehouse or central medical stores/public sector warehouses/national procurement centers, to examine inventory management systems, public storage, public pharmacies at government facilities, and vertical program managers (EPI, HIV/AIDS, malaria, TB, UN organizations, external development partners)
- 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 drug dispensaries, inventory management and tracking systems, storage conditions
- Department of health services or health services research (university or MOH)
- MOH office of health statistics
- National Regulatory Agency (NRA) responsible for importation regulations

The 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 health financing indicators may not be readily available.

4.5 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.

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 medical products, vaccines and technologies. This area lays out the groundwork or foundation under which logistics and supply chain management systems operate so that high quality essential medicines, medical products and vaccines are available 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 Supplies, Vaccines and Technologies Core Function.

Table 3.4.3 Policies, Laws, Regulations and Governance

Indicator	Definition and Interpretation
Existence of a National Medicine Policy (NMP) that sets objectives and strategies for the pharmaceutical sector based on priority health problems	Yes/No Answer with explanation. An NMP is a guide to action for the pharmaceutical sector. Existence of an NMP indicates commitment to improving the management of medical products, vaccines, and technologies in public and private sectors. If the NMP has been updated in the past ten years, this indicates that the policy is kept up to date. If the country has a National Essential Medicines Program, it is likely that the program has received support or guidance from WHO and that the WHO guidelines on how to develop an NMP (WHO 2001) were followed or used as a template to develop the policy.
Existence of a pharmaceutical sector strategic plan that based on NMP that operationalizes activities, responsibilities, budget and timeline	Yes/No Answer with explanation. A Pharmaceutical sector strategic plan contains near- to long-term sector strengthening goals and linked actions. In many countries, based on the NPP the strategic plan will be an implementation plan which will define roles, responsibilities, key interventions, indicators, planning and budget

Existence of a comprehensive pharmaceutical law	Yes/No Answer with explanation.
	The existence of a comprehensive law demonstrates commitment to improving the management of pharmaceuticals, medical products, vaccines, and technologies in the public and private sectors.
	
	Specific questions to ask the interviewee include:
	• When was the national pharmaceutical law last updated? A law that is more than five years old may be outdated and require revisions to reflect changes in overall health or national development policies and priorities.
	• How does the regulatory framework differ between public and private sectors?
	• Does the law include provisions covering:
	  ○ medicine promotion and advertising?
	  ○ inspection of pharmaceutical establishments?
	  ○ licensing of the following: Manufacturers, Wholesalers or Distributors, Importers or exporters of medicines, Dispensers
	  ○ the control of narcotics, psychotropic substances and precursors?”
	  ○ post-marketing surveillance and safety monitoring
	• Are there legal provisions requiring:
	  ○ the marketing authorization holder to mandatorily report all serious ADRs to the national drug regulatory authority?
	  ○ the regulation of clinical trials?
	• Is there a law permitting generic substitution by pharmacists?
	• Can a copy of the law or guidelines be found either at the regional or district health office or health facility?

Existence of pharmacy licensing requirements and SOPs, and evidence that there is regular monitoring of public and private pharmacies.	Yes/No Answer with explanation. The existence of licensing guidelines and actual monitoring of whether pharmacies are meeting those standards is important indicator of the regulatory oversight function. 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. Specific questions to ask the interviewee include: • Can a copy of the pharmacy licensing requirement and SOPs be found? • When was licensing guideline and SOPs updated? • How is the guideline updated, and by whom (determine whether there is a committee which works on this comprised of quality assurance officials)? • What systems are in place to monitor pharmacy compliance? • Are health authorities at central and at decentralized levels who are tasked with oversight of pharmacies and health care providers able to access and accessing these systems? • Is there a separate entity that performs monitoring function, and if so how often? • What sanctions are placed upon pharmacies for lack of compliance? Are there a computerized registration system that facilitates retrieval of information on: • Registered products? • Licensed providers? • Licensed premises? • Clinical Trials?
Existence of a functioning National Drug Regulatory Authority (NDRA) responsible for the promulgation and enforcement of regulations	Yes/No Answer with explanation. NDRA is a governing regulatory body responsible for oversight of pharmaceutical laws. An effective NDRA indicates commitment to implementing and enforcing pharmaceutical laws and requires proper financing to fulfill its mandate. Follow-up questions include: • What are the specific responsibilities of the NDRA? • What is the relationship of the NDRA to other governmental agencies? • Is it autonomous? • How is it financed? If there is not a clear separation of functions, the NDRA is vulnerable to corruption. • Is the NDRA self-financed? • The institution retains what percentage of the revenues generated by the NDRA? Ask whether the NRA has been assessed by WHO, and if so when? See WHO assessment tool for NRA. (http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/) Another marker of ongoing enforcement and surveillance of product quality includes the existence of a post-marketing quality surveillance system. A post-marketing quality assurance system enables continuous assessment of the product quality determines if the public sector collects data regarding the effectiveness, quality, and safety of marketed products.

	Existence of a system to monitor pharmaceutical product quality is a critical first step, but does not address how well post-marketing surveillance is conducted. To learn more about post-marketing surveillance is conducted, ask the following questions: • Are data available? • Are there PMS strategies/guidelines/plans in place? • Are decisions taken as result of the system adequately enforced? • What is the capacity of the NRA to undertake PMS activities? • Are there parallel PMS activities in the country? • How PMS is organized/structured (Are QC activities centralized or decentralized?) • How information on PMS findings is communicated • Does the country have a system by which providers and consumers can report quality problems? If so, is it a passive, self-reporting system and/or a mandatory reporting system? If it is the latter, a key component of quality assurance is in place. Post-marketing surveillance systems may focus on some priority pharmaceutical therapeutic categories, products known to be particularly prone to problems or sources known to be problematic.
Existence of a National Quality Control Laboratory (NQCL)	Yes/No Answer with explanation. 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 pre- and post-market quality control of pharmaceuticals • Is the National Quality Control Laboratory (NQCL) part of the NDR? 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 non-governmental entities? • Is the NQCL financially independent? • Is the NQCL compliance with international standards? If not, is the NQCL working towards compliance? • Does the NQCL test other products besides pharmaceuticals (food, water, cosmetics...)? • Does the NQCL perform research and training? • Are there backlogs in quality control requests? • Does the personnel turnover affect NQCL performance? • In order to determine level of support from partners, ask if the NQCL prequalified by WHO or ISO certified. Would be important to also know if they receive support from partners to reach international requirements.
Existence of a functioning system for pharmaceutical registration and monitoring	Yes/No Answer with Explanation. A system for registration of pharmaceuticals in the market ensures that the information has been provided to allow proper surveillance of drug quality and adverse events. 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? • 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? • 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? • Is the National Quality Control Laboratory (NQCL) part of the NRDA? • Is medicine's quality assessed during registration? • 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 there a backlog in the evolution of applications received? • What are the concerns about the ability of the registration system 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. If either problem exists, the registration system may simply be for generating revenue. • 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. • Some systems accept 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. • What percentage of EML items that have registered products? See indicator under Topics Quantification and Procurement: Percentage of Procured Products Registered in Country.
Existence of a pharmaco-vigilance system, and actions taken based on findings of system.	Yes/No Answer with explanation. A pharmacovigilance system is a mechanism to monitor adverse medication reactions and events. Ideally pharmacovigilance data should be reported to and aggregated at the national level. A pharmacovigilance system is the first step for monitoring patient safety, but this indicator does not address how well it is performing. If any of the following are present, it indicates an attempt by the country to institute mechanisms to ensure patient safety: • How many adverse drug events are reported annually? • Is there a functional national pharmacovigilance center or mechanism to collate and analyze reports and take action to prevent adverse events? • Is there a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the last year • Is the country a member of the WHO Programme for International Drug Monitoring, and if so has the country been contributing to the program? • Does the country have a system by which providers and consumers can report adverse events? • Is reporting by providers mandatory?

	• Does the country participate in the pharmacovigilance system reporting to the global database, and if so how many notifications to Upsalla Center have been reported? • Are there any active surveillance activities, in the past or planned? • Is there a national medicine safety advisory committee or a subcommittee with similar functions that has met at least once in the last year The indicator does not measure whether actions are taken based on the results/findings reported by pharmacovigilance systems.

Functioning mechanisms exist for licensing and inspection of premises	Yes/No Answer with explanation.
	Functioning mechanisms are in place for licensing, inspection, and control of pharmaceuticals.
	Mechanisms are in place for licensing and inspection of pharmaceuticals manufacturing, storing, and dispensing facilities.
	
	Existence of these mechanisms means a key component of quality assurance is in place, but it does not ensure that licensing, inspection, or other regulatory control activities are fully functional. The following indicators can be used as a follow-up to assess whether these mechanisms are in place and functioning:
	
	• Does the NRAMRA have a unit responsible for issuing pharmaceutical establishment licenses?
	• Is there an up-to-date list of all licensed pharmaceutical establishments available in the country?
	• Are there written guidelines for assessing applications for a license?"
	• What is the number of applications received for a new premise in the reference year?
	• 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):
	  ○ Manufacturing plant
	  ○ Importers
	  ○ Wholesalers
	  ○ Dispensing/selling outlets
	• What is the number of licensed or registered drug retail outlets per government drug inspector?
	• Are there written standard operating procedures (SOPs) for inspectors on how to conduct inspections?
	• Does the MRA carry out regular (at least every two years) post-licensing inspection of all licensed pharmaceutical establishments?
	• What percentage of manufacturers, distributors, and retail outlets are inspected during a one-year period?
	• Is a report of inspections and enforcement results generated regularly?
	• What systems are in place to minimize corruption of inspection staff? (MOH staff are often enticed and bribed by the private sector to ignore poor quality products. Inspection staff corruption is a major and constant concern).

Existence of a code of conduct and Conflict of Interest guidelines that apply to public officials and staff involved in pharmaceutical related activities or posts, and evidence that it is being applied.	Yes/No Answer with explanation. Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts, such as persons working in pharmaceutical services, medicines regulation, licensing, procurement and supply of medicines and other pharmaceutical divisions of the health ministry? Are there guidelines on Conflicts of Interest (COI)? The code of conduct is an officially adopted/promoted document aimed at ensuring accountability and appropriate conduct, including transparency and good governance, that applies to public/government officials and staff involved in pharmaceutical related activities or posts. Are there written guidelines on conflicts of interest (COI) with regard to: • Procurement • Selection • Promotion • Inspection • Registration • Clinical trials This indicator determines if the government is trying to mitigate COI and measures a government's commitment to penalizing public officials for not complying with the required procedure. Written guidelines on COI and a COI declaration form should exist and include, as a minimum the following: • Definition of what a COI is • Rules on the acceptance of gifts • Rules on reporting COI • Mechanism protecting informers of COI • Actions to be taken in case of failure to comply with policy Evidence of enforcement of these regulations (evidence that COI forms are systematically completed by the members of the selection committee and public officials involved in the selection process)

Topic B: Financing

Overview

Because medical products, vaccines and technologies save lives and improve health, financing systems must help ensure access to essential medicines for all segments of the population. Most countries rely on a diverse set of financing mechanisms for these items. Sources of funding may include public financing based on national budgets, 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 Supplies, Vaccines and Technologies Core Function.

Table 3.4.4 Financing of the Medical Supplies, Vaccines and Technologies Core Function

Indicator	Definition and Interpretation
Total expenditure on pharmaceuticals (% total expenditure on health)	Enables measurement of significance of pharmaceutical spending relative to other spending on health; indicates financial and institutional sustainability of current pharmaceutical purchases. Compare country to selected regional or income-level peer group.
Total expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita expenditure at average exchange rate in USD. Measures magnitude of pharmaceutical spending and indicates financial and institutional sustainability. Compare this measure to peer groups.
Government expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita spending government spending on pharmaceuticals at average exchange rate in USD. Measures magnitude of government spending on pharmaceuticals; indicates financial and institutional sustainability. Compare to selected peer group. **Module Link**: Section 3, Module 6—Health Financing, Indicators 4 (government expenditures as percentage of total health expenditure) and 5 (External resources for health as a percentage of total health spending)
Private expenditure on pharmaceuticals (per capita at average exchange rate) in US$	Per capita private spending on pharmaceuticals at average exchange rate in USD. Includes out-of-pocket spending, finances related to private insurance, nongovernmental organizations, and corporations (excluding social security).
Proportion Percentage of annual national expenditure on medicines financed by different stakeholders	Total amount spent on medicines disaggregated by source of funds: • Government • External development partner agencies • Charities • Out-of-pocket payments 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 (NHA) 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. External development partners' commitments are not generally considered to be sustainable. But if they are present examine: • How many development partners are involved? What types of medicines do they support? • Be sure to include contributions by reimbursement mechanisms (public and private sectors) and various sub- national budgets.

	Module link*:* Section 3, Module 6—Health Financing Module, Indicator 4 (Government spending on health as a percentage of total health expenditure) and Indicator 5 (external resources for health as a percentage of total health spending) X and X (government health budget allocation by cost category) and X (local-level spending authority)
Out-of-pocket expenditure for health on medicines	Percentage of out-of-pocket spending on medicine out of total out-of-pocket spending on health. There are various scenarios in which patients may spend out-of-pocket resources to acquire medicines. Although cost recover 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 during stock-outs at public facilities due to ineffective or dysfunctional public procurement systems. In other cases, because the cost of medicines and medicinal treatments can represent a significant percentage of all of the health system costs, governments seek some form of cost sharing, by having patients pay a portion of the cost of medicines. There is also the belief that if patients pay for their medicines, they will use them more wisely. Health insurance programs may include co-payments for medicines, whereas other schemes will only cover the cost of the treatment. Some systems will include the cost of medicines in the overall treatment. The ability to determine when out-of-pocket expenditures for medicines result in an unnecessary barrier to care is a constant concern. This indicator should be considered within the context of the overall health system financing scheme, as well as assessed in relation to where/why patients choose to seek pharmaceuticals at particular locations. **Module Link**: Section 3, Module 2—Service Delivery, Indicator 8 and 9 (financial access).
Financial Access to Medicines	**Definition:** % of respondents who or whose household member was not able to take medicines because household cannot afford medicines" In addition to availability of essential medicines in the facility (geographic), it is important to measure financial access to medicines, particularly for those with chronic conditions. **Numerator** Number of respondents who or whose household member was not able to take medicines because household cannot afford medicines" **Denominator** Total number of respondents **Disaggregation/additional dimension: by disease categories** (at least acute vs chronic), household income, expenditure or wealth, place of residence and gender **Preferred data sources** Household Health Utilization and Expenditure Surveys **Other possible data sources** Other household surveys **Further information and related links**[i]**:** http://www.who.int/medicines/areas/coordination/household_manual_february_2008.pdf **Module Link**: Section 3, Module 2—Service Delivery. Indicator 8 is the same and 9 can be used alternatively; Module 6: Health Financing contains similar indicators.

Topic C: Product Selection

Overview

A National Essential Medicines List (NEML) contains the medicines that best satisfy the priority health care needs of a country and are approved for use. Oftentimes countries develop EMLs for different levels of care in the system based on disease patterns at each level. They are intended to result in more rational prescribing, lower treatment costs, and a more reliable supply of medicines. NEMLs should reflect evidence-based standard treatments for priority public health conditions. The selection of medicines for NEMLs has a considerable impact on the quality of care and efficiency of the health

system. Similarly, evidence-based medicine and product selection, updating and use of Standard Treatment Guidelines (STG), rational use of medicines and generic substitutions are directly related to service delivery and financial coverage.

See Table 3.4.5 for Indicators to assess selection of products under the Medical Supplies, Vaccines and Technologies Core Function.

Table 3.4.5 Indicators to Assess Product Selection for the Medical Supplies, Vaccines and Technologies Core Function

Indicator	Definition and Interpretation
Existence of a NEML published within the past five years, and evidence that it is updated on a regular basis.	Yes/No Answer with explanation. A NEML 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 the national STGs? • Does it identify medicines by level of care? • Has the NEML been updated within the last five years? Does the country review the WHO Model List of Essential Medicines which is updated every two years by the Expert Committee on Selection and Rational Use?. • Is the NEML meant to guide cost control issues (procurement) as well as therapeutic issues (quality of care)? • Are generic names or International Nonproprietary Names (INNs) used consistently throughout the system (prescriptions, LMIS, inventory cards, etc.)? Countries are encouraged to use the INN as it is the non-proprietary 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. Evidence of NEML Updates: Is there an organized group of experts that meets regularly and is responsible for managing, maintaining and updating a 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 sector? • Does the committee have terms of reference (TORs) or SOPs, and are they publically available? The existence of TORs or SOPs indicates that a formalized process is in place and that there are mechanisms to address transparency issues. • 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 NEML for treatment and procurement purposes?

Product selection based upon NEML	Number of products selected for procurement that are listed on the NEML / Total number of products procured X 100 This indicator determines whether the NEML is being used for product selection and whether product selection is limited to the NEML. For each product that a program selects for procurement, this indicator measures the percentage of those products that are listed on a NEML. Typically, governments regularly update their NEMLs to reflect health priorities. An NEML identifies medicines or commodities that are a priority in providing the basic health care requirements for a country. If a product is not on the NEML, it may receive lower priority and funding, or it may require a special waiver for procurement. The World Health Organization (WHO) provides a model EML at— http://www.who.int/medicines/publications/essentialmedicines/en/index.html The indicator can establish whether products that are regularly procured are essential products. Also, in many instances, products on the NEML are exempt from value added tax (VAT) and customs fees; also, the registration process for products on the NEML may be less cumbersome. Note: Related indicators may include: Is procurement restricted to products on the EML, or are there barriers to procuring products outside the list? Are there policies regarding generic versus branded product selection and brand (product) proliferation? Current national procurement policies and guidelines may contain restrictions or provide guidance on selecting generic products, or they may limit the number of brands of a specific product that enter the country. Procuring generic products can be more cost efficient than procuring branded products. However, policies should be in place to monitor the proliferation of brands but still allow for private sector competition. Derived from: http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf
Percentage of average (International Reference Price) IRP Paid	(Average unit cost of item / average international cost of item) X 100 This indicator measures the unit cost per item charged by an external supplier as a percentage of the average international unit price. It can be calculated for any supplier that supplies products to a requesting facility. It can be measured over any time period, but one year is standard. This indicator measures the cost of items procured relative to the average international price paid. The lower the percentage of the average international price paid, the more the cost savings. Conversely, if the indicator is greater than 100 percent, the country is paying a premium on the average international prices. Management Science for Health's (MSH's) International Drug Price Indicator Guide lists the most current average international prices for pharmaceuticals. This indicator can be used to measure the costs of items within a specific procurement or across multiple procurements. If more than one procurement is being analyzed, the average unit cost of each item across the procurements should be used. Determine a select set of tracer drugs to assess based on the list found in Annex XX. Related indicator may be used: Percentage of IRP paid including Freight and Insurance or Total Freight Charges (by supplier or by product) http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf

Topic D: Quantification and Procurement

Overview

The primary purpose of quantification and procurement is to provide regular delivery of adequate quantities of good quality supplies at the lowest possible cost. In order to achieve this medicine and medical product quantification is vital. Quantification—the process of estimating quantities and costs of products and determining when they should be delivered to ensure adequate supply links information on services and products from the facility level with program policies, plans and STG at the national level —is a continuous process that requires ongoing monitoring and routine updates. Forecasting uses the data collected on medicines and medical supplies to estimate the quantity of each product that will be dispensed during the exercise year. Once forecasting takes place, estimate the total product requirements and costs for the program or facility. These steps are prerequisites to procurement.

National procurement decisions take place within a country's policy and legal framework; they may be made at the central level or be decentralized down to the facility level. Some steps of the procurement process may be centralized while others take place at the local level. Knowing where each step takes place is critical. It will contribute to identifying the appropriate stakeholders to interview. For example:

- Centralized system: Procurement is conducted by a national procurement unit/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, procurement takes 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, because a growing number of developing-country consumers rely on private provision of medicines and health products, the assessment includes questions on procurement of medicines and medical products in the private sector as well. Taking the time to meet with procurement officers of large retail drug stores and private importers and distributors indicates if the private sector is complying with regulations, and therefore helping ensure that quality assured medicines and supplies are available through private channels.

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

Table 3.4.6 Indicators to Assess Quantification and Procurement under the Medical Supplies, Vaccines and Technologies core function

Indicator	Definition and Interpretation
Forecast accuracy	(Forecast consumption—actual consumption / actual consumption) X 100 Measures efficiency and appropriate use of resources. The more reliable needs estimates are, the lower the risk of overstock and stock-outs. For all products that the program has committed to supplying, this indicator measures the percentage of difference between forecasts previously made for a year and the actual consumption or issues data for that year. The team should calculate the indicator for a selection of medicines (3-5 medicines/ vaccines) each product for which a forecast is made. Accurate forecasting (and quantification) helps countries and organizations improve financial management and procure adequate quantities of each product, thereby reducing the likelihood of wastage or shortage, and increasing the likelihood of meeting customer needs with available products. Forecasts are an estimate of future demand. Other than a make-to-order replenishment system, forecasts are typically incorrect. But, certain methods that can aid in reducing the forecast error, e.g., analyzing historical consumption data and estimating future trends. Documenting the reasons for particularly wide discrepancies (including assumptions used in preparing the forecast) helps put the results into perspective and may lead to insights for improving future forecasts. Data obtained through visits to health facilities to review forecasting and consumption/distribution records, and by analyzing a) List of products that the program has committed to supplying b) Forecasts, by product, for the year c) Actual consumption or issues data, by product, for the year. Measures efficiency and appropriate use of resources. The more reliable needs estimates are, the lower the risk of overstock and stock-outs. • How and at what levels is quantification conducted? • What data are used (historical consumption data, morbidity data, a combination of these two, or other)? A combination of data is the most reliable. Some systems have access only to historical consumption data from facilities. • What is the quality of these data? • When was the last time a national quantification was conducted? • To what extent do needs exceed the available budget for procurement? • How are discrepancies resolved? Note: For use at the level where long-term procurement decisions are made—most commonly the central level—but it can also be applied to other levels of the system if forecasting has been decentralized and if facilities determine their own order quantities. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf

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. • Are there any formal mechanisms in place to bring together the many stakeholder groups that help to create or use SOPs? • Has an independent audit of the public sector procurement been conducted within the last three years? • Were the SOPs developed specifically for health sector goods and pharmaceuticals, or are they general SOPs? Note: General procurement guidelines are inadequate for pharmaceuticals. Procurement of pharmaceuticals requires unique considerations, including specifications and sourcing issues.
Use of generic or international nonproprietary Names (INNs) 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 names facilitates competition among suppliers and manufacturers on the basis of the chemical entity of interest. Do health professionals feel pressure to procure brand name products? Note: Generic names are to be differentiated from generic branded products.
Is public sector procurement limited to medicines and supplies on the EML? If yes, are there provisions for purchasing medicines not on the EML?	A Yes/No Answer with explanation. Document what medicines or supplies not found on the EML, if any, are procured by public sector and under what circumstances. Use this indicator in centralized and decentralized systems.
Percentage of actual types and quantities of procured products according to planned for the same period.	(Quantity of procured products received during a defined period divided / total quantity planned for the same period) X 100. This indicator measures 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, e.g. the planned quantities were not accurate, the budget for ordering the planned quantities was not available, needs have changed since the previous forecasting exercise, or un-programmed emergency requests. The indicator reflects the reliability of a central procurement system. • More than two central pharmaceutical procurements (defined here as tenders, not orders against contracts) per year 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. How many un-programmed (emergency) procurements occurred in the last two

	years? This number indicates the effectiveness of procurement planning and regular procurements. Frequent emergency procurements may indicate problems with planning and programming of regular procurement needs, barring force majeure. • What was the value of emergency procurements (as a percentage of the pharmaceutical budget over those two years)? This value adds further insight on effectiveness of the procurement program. Most funds should be spent on regular procurements. Emergency procurements should not represent a significant portion of the pharmaceutical procurement budget. • What is the average lead-time for procurement? Shorter lead times are preferred but must be appropriate for • the specific context. An unpredictable lead-time contributes to stock-outs. What percentage of items listed for procurement in the last three tenders were actually purchased? A high percentage would indicate successful tenders and good quantification. It would imply lesser need for emergency purchases and a possible willingness among suppliers to bid and participate in the procurement system. Use this indicator in centralized and decentralized systems. National procurements may be negatively affected by local purchases made by health facilities unless agile information systems are in place to ensure that purchase information is communicated to the central level. This indicator assesses the performance of forecasting and supply planning. A poorly planned supply chain results in large quantities of emergency or unplanned orders, which are more costly than planned orders. Further, these emergency orders may not enter the supply chain in time to avoid stock-outs, which can limit product availability. 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, PO lead times; review of the accuracy of LMIS data, forecasts, and procurement plans; review of timeliness of reporting; review and possible adjustment of the time span of the procurement cycle. These indicators can help to identify opportunities for improvements in planning. Related indicators include: • Percentage of purchase orders/ contracts issued as emergency orders. (Number of emergency orders / Total number of orders placed) X 100. This indicator measures the percentage of POs or contracts that are issued as emergency orders, (with a lead time of one month or less), out of all POs or contracts placed during a defined period of time. • Ratio of Unit prices Paid through Emergency Procurement vs. Competitive Bidding Process. Unit price of item under emergency procurement / Unit price of the same item under International Competitive Bidding (ICB) procurement. This indicator measures the ration of the unit price in an emergency procurement versus through a proper procurement planning process with sufficient led time to avoid emergency procurements.

Existence and application of a procurement pre- or post-qualification process for products	A Yes/No answer with explanation. This indicator demonstrates quality assurance within the procurement system and whether the process is based on review of objective information about product safety, efficacy, quality, and manufacturer/supply capacity. If quality assurance is present, it can limit participation of suppliers and products of dubious quality in the procurement process. • What is the procurement pre/post- qualification process for suppliers and products? • Is the process transparent? • Are the criteria for qualification clear? The Model Quality Assurance System for Procurement Agencies (MQAS) is used for prequalification of sources by procurement agencies. WHO Technical report Series http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/
Percentage of Procured Products Registered in-Country	(Number of products procured that are registered in-country / Total number of products procured) X 100 Typically products are registered to ensure that they meet specific quality standards and to prevent products from being procured from substandard manufacturers. This indicator can also reflect the ease of registering both branded and generic products in a country, indicating the flexibility to bring in the most cost-effective products. A low percentage of registered products could imply that there are other problems within the system such as a lack of capacity to register products quickly enough, a lack of government oversight. This indicator should be examined with data over a one-year period.
Percentage of products that meet Stringent Regulatory Authority (SRA) or WHO standards.	(Number of products procured that meet SRA or WHO standards / Total number of products procured) X 100 This indicator measures the percentage of products procured that meet SRA or WHO standards. This could measure the percentage within a class of product, such as contraceptives, ARVs, essential medicines, etc.; or, as a whole, for all products procured during a specific period of time. To ensure that only high-quality products are being procured, countries should aim to have 100% of products procured meet these standards. See Measuring Supply Chain performance: A Guide to Key Performance Indicators for Public Health Managers for a more in-depth look at a variety of indicators which could be used to measure a country's performance. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf
Public Sector and Private sector procurement processes	For public sector procurement processes, look for transparency, checks and balances in financial management, the bidding and selection processes, funding, expenditure tracking and cost controls. Note where financial decisions are made for procurement and what funding streams are used. Explanation. In many cases, importation of drugs distributed and sold in the private sector is unregulated. As a result, it is important to interview private sector importers (wholesalers) and distributors along with procurement officers for private pharmacies to assess whether they are following guidelines or international best practices (e.g., purchasing known brands and generics from reputable manufacturers).

Average lead time for contract/ purchase (PO) order issue	(Sum of number of days between when each decision to order was made and when each contract or PO was issued / total number of contracts or POs issued during a specified period of time) The average time it takes from when a decision to order is made to when the procurement unit issues the contract or PO. For planning it is important to know the amount of expected lead time required to develop contracts/POs. This indicator measures the efficiency with which requests are processed and POs prepared. Long lead times will extend the procurement cycle and will delay the time in issuing a PO with 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. Other related indicators for procurement may include lead-time for contract award.

Topic E: Storage and Distribution

Overview

The storage and distribution function includes all activities related to warehousing, transportation, and distribution and maintaining the quality of the product. Activities include: ordering, receiving, transporting, storing, issuing supplies, and managing waste. These activities take place at various levels of the system. The goals of this area are to protect procured items from loss, damage, and theft. This is done through 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 MQAS.

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

Table 3.4.7 Indicators to Assess Storage and Distribution of medical products, vaccines and technologies

Indicator	Definition and Interpretation
On-Time Arrivals	(Number of shipments arriving within agreed time window / Total number of shipments) X 100 This indicator measures percentage of shipments arriving on time for a set delivery date during a defined period of time. Late deliveries can cause stock-outs, not only at the receiving facility, but throughout the in-country network. It can indicate transportation problems in the system, such as condition of vehicles, difficult terrain, indicating the need to adjust schedules accordingly, or it can indicator driver performance issues. This can be applied to a specific product, route, or a health facility. Related Indicator: Average Delivery Time. Sum of total number of hours/days from dispatch to receipt at destination for all shipments / Number of shipments Ask whether this is a transport monitoring system in place. Review vehicle logs and requisition and issue vouchers/receipt vouchers. This indicator reflects the efficiency of the transport and distribution systems. Long transit times should be considered when planning inventory levels and shipment schedules. Monitoring average transit times for a specific region, route, or facility

	can help managers improve response time and efficiency and reduce wastage. This indicator measures the average transit time (hours or days) from when a shipment leaves a facility until it arrives at its destination, for a specified warehouse, distribution point, region or district, vehicle or route during a defined period of time, usually one year. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf
Percentage of public/MOH storage units and health facilities with up-to-date refrigerator temperature monitoring records and functional controls at each level of the distribution system	(Number of public/MOH storage and health facilities with up-to-date refrigerator temperature monitoring records / Total number of MOH storage and health facilities visited) X 100. Indicates 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 quality stock. Public and/or private distribution systems include a cold chain. Interruptions in the cold chain (inadequate or insufficient cold storage for sensitive products, such as vaccines) can result in damage and loss of important commodities. Each level of the distribution system should have functioning units to provide cold storage of temperature-sensitive commodities. In some systems, the cold chain is best managed as a separate vertical program. Provide a qualitative description of units (refrigerators or coolers) at different levels of the distribution system (central, regional, district, facility) • Are the thermostats checked regularly? • Are facilities equipped with a backup power supply? Are temperature logs/charts kept? Are there temperature • controlled vehicles or cool boxes used to transport temperature sensitive commodities routinely? • Are private sector facilities required to maintain a cold chain? In some countries a separate cold chain is managed by vertical programs. EPI, for example, is typically managed separately. The main supply system should still maintain some system for other products that require temperature control. This system may include electric- or gas-operated refrigerators as well as simple cold boxes. Module link: Section 3, Module Service Delivery has a similar indicator.

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 costs. Inventory loss is a holding cost. This is the percentage of average inventory value. Inventory loss should be looked at for each level of the distribution chain. Current standards for commercial firms put inventory loss at a range of 20-30 percent of holding costs. Standards can vary by country or region, thus for comparison purposes, a few local private sector suppliers can be queried about their norms. Compare the value of inventory loss and other holding costs in public entities with commercial firms in the country, by level of the health system or distribution chain. Large disparities in the figures suggest opportunities for improvement. For example, where costs are lower in the commercial sector, options may include contracting out for selected services. Types of inventory loss that can be examined in detail include: • Expiry: Indicates that stock is not moving fast enough, that products purchased are not used, or that products • have too short a shelf life. • Damage: Indicates storage or transport problems. • Obsolescence: Indicates that products purchased do not meet needs. • Theft: Indicates that enhanced security measures are needed. If available, list the inventory losses experienced by each of the participants in the distribution system (e.g., public, private, donor). Note if any of the losses might have been due to an unusual event or instead to ongoing storage problems, such as storage facilities that are dilapidated or of inadequate size or construction. Other costs in the distribution system that can be explored include transportation costs (e.g., fuel, vehicle depreciation, personnel, and maintenance) and storage costs (e.g., personnel, rent, machinery, and utilities). Transportation and storage costs should be minimized and ideally should be compared to the commercial sector in country. The information should cover at least 12 months or one procurement cycle. If possible, obtain this information for the last three years. If large values have been lost, especially due to theft or unexplained reasons, it may not be prudent to probe. Note whether losses occur regularly or appear to be sporadic.
Existence of appropriate procedures for disposal of expired and/or spoiled medicines at medical stores/health facilities	Yes/no indicator. 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, good quality medicines could be diverted, after being reported as spoiled or expired. If there is no appropriate disposal system, disposed medicines can become an environmental hazard. There should be a written standard procedure for disposal of unwanted medicines including as a minimum: • A mechanism for safe disposal • A mechanism to notify MRA 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.

Percentage of storage facilities meeting acceptable storage conditions	(Number of facilities meeting each acceptable storage conditions / Total number of facilities visited) X 100. This indicator measures the risk of medicines quality being compromised and the extent of proper management. In order to determine whether proper conditions are being met, look at recommended storage practices listing conditions required to protect the integrity of products at all levels of the distribution system and corresponding SOPs and compare this to actual practices. Check and see what supervision and inspection processes take place on a regular basis and document those processes. Recommended storage conditions may include: • Products are stored and organized in a manner accessible for First-Expiry/First- Out (FEFO) counting and general management. • The facility makes it a practice to separate damaged and/or expired products from good products and remove them from inventory. • Products are protected from direct sunlight at all times of the day and during all seasons. • Cartons and products are protected from water and humidity during all seasons. • Storage area is secured with a lock and key, but accessible during normal working hours, with access limited to authorized personnel. • Products are stored at the appropriate temperature during all seasons according to product temperature specifications. • Storeroom is maintained in good condition (e.g., cleaned, all trash removed, shelves are strong, boxes are organized, pest free). • The current space is sufficient for existing products and reasonable expansion (i.e., receipt of expected product deliveries for the foreseeable future). • Products that are ready for distribution are arranged so that identification labels and expiry dates and/or manufacturing dates are visible. • Products are stacked at least 10 cm (4 inches) off the floor. • Products are stacked at least 30 cm (1 foot) away from the walls and other stacks. • Products are stored separately from insecticides and chemicals. • Products are stacked no more than 2.5 meters (8 feet) high. • Fire safety equipment is available and accessible.
Average Transportation Cost per km/volume/ weight	Sum of all transportation costs / Total number of km or m3 / kg of product shipped. The average transportation cost per kilometer (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/weight can help managers monitor these costs, over time, to follow trends and to make budgetary and operational decisions about delivery schedules (e.g., frequency), use of vehicles, routing, outsourcing, etc.

Topic F: Geographic Access

Overview

Geographic assess to medical supplies and vaccines in particular is measured through one key indicator. Unless people are able to get to where products are offered, they won't be able to fully have 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 indicator to assess geographic access to medical products and vaccines.

Table 3.4.8 Indicator to Assess Geographic Access to Medical Products and Vaccines

Indicator	Definition and Interpretation
Percentage of households more than 5/10/20 km from health facility/pharmacy to dispense essential medicines	This indicator measures geographic access to and availability of public and private facilities with dispensary services. This is presented as a percentage of households measured against (1) public and (2) private facilities. A high percentage of households more than 5, 10, or 20 km from a health facility or pharmacy indicates that services may not be located in places where people need them. • Are there concerns about the existence of unlicensed facilities? • Are unlicensed facilities more widely distributed geographically than licensed outlets? • The private pharmaceutical sector is the primary source of medicines consumed in many countries. One of the primary reasons is easy access to a private pharmacy compared to a public health facility. A high ratio of • population per medicine retail outlet in the private sector indicates a potential need to identify opportunities to improve private sector pharmaceutical service coverage. • Does the country have different categories of medicine outlets? • What is the basis for differentiation? • Are they all licensed? Do they stock quality medicines? Note: The Stock Out Rate indicator also measure of access found in this module in Topic H: Monitoring/LMIS/Management Support Systems. Module link: Section 2, Module 2, Service Delivery, Indicator 8 (people living within X km of health facility)

Topic G: Appropriate Use

Overview

The appropriate use of medicines means that patients are prescribed and dispensed the full amount of the appropriate, quality assured medicine when needed, at the lowest cost to them, to their communities, and to the system, and that patients adhere to the treatment regimen. Indicators XX–XX, 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 and vaccines.

Table 3.4.9 Indicators to Assess Appropriate Use of Medical Products and Vaccines

Indicator	Definition and Interpretation
Existence of functioning Drugs and Therapeutic Committees (DTCs) 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 a National Medicine Prescription (NMP) guideline. The procedures and corresponding tools may also be specified. Tools that help improve the use of medicines include STGs, prescription controls such as limited formularies, dispensing controls, and pre- and in-service training in rational medicines use. Supervision and regular reviews of prescribing and dispensing practices should support the use of such tools. 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 DTCs 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 DTCs been active? Is there a national network of DTCs? • Are DTCs active in both public and private hospitals? • Do public facilities have any managerial controls of prescribing (e.g., limited formularies, prescribing by generic name only, limiting the number of medicines prescribed per client/patient)?
Existence of National Therapeutic Guidelines (NTG) in accordance with STG common conditions	A Yes/No Answer with explanation. Up-to-date NTG and STGs indicate that evidence-based best practices for treatment of common conditions are reviewed and codified. • Are the guidelines used to develop the NEM U • When were the guidelines last updated? • Does the system that ensures that the guidelines are updated rely on unbiased clinical and pharmaceutical information? If so, treatments are consistent with changing evidence-based best practices and changing country disease patterns. • Are these guidelines distributed to and used in all levels of the health care system and to the private sector? Guidelines may be developed by national health insurance agencies, NGOs, and international health agencies such as WHO. These guidelines may not be consistent with each other. Module link:

Existence and use of Standard Treatment Guidelines (STG) for prescribing and dispensing of medications for pre- and in-service training of health personnel in both public and private sector.	A Yes/No Answer with explanation. Indicates dissemination of treatment guidelines to health personnel and greater potential for guidelines to be implemented by health care professionals in the public and private sectors. If treatment guidelines exist, ask the following questions: • Are treatment guidelines used for supervision and monitoring activities in public-sector health facilities? In private facilities? If so, supervision and monitoring practices incorporate oversight of quality and appropriateness of treatment. • 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. 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 link: Service Delivery Module, Indicators 23 and 27 (quality assurance processes), Module 3.5, Human Resources for Health, Indicators 12 and 18 (Production of new health care workers is responsive to the needs of the health care system)

Topic H: Monitoring, LMIS, Management Support Systems

Overview

Management support systems in pharmaceutical and medical supply logistics systems revolve around systematic collection and use of information and the trained personnel and supervision required for this activity. They also require adequate staff to perform these functions and supervisors to oversee them. Sufficient budget must be available to ensure adequate stock. It is important that the supply chain system be continuously monitored and evaluated on a periodic basis.

Accurate and timely information is critical for the success of the supply chain system. It is important to note that data for managing a Logistics Information Management System (LMIS) is separate and distinct from data about patients and health services, which is what a Health Management Information System (HMIS) collects. A LMIS is the system, which collects, organizes and presents logistics data across all levels of the health system. This information is used for decision-making vital to ensuring that there is always sufficient supply of medicines and medical products on hand for use at service delivery points. An HMIS, covered in Module 7 focuses on morbidity, mortality and service utilization data, and data are collected and recorded daily and compiled and reported monthly or quarterly. These data are analyzed monthly and quarterly to determine disease patterns and may be used annually to track these patterns and service utilization. A LMIS collects data about medicines and medical products including quantities issued, dispensed, consumed, ordered, received, lost or damaged. LMIS data is collected and recorded daily and generally compiled and reported monthly or quarterly. Logistics information is looked at daily to assess stock status and monthly or quarterly to determine resupply, while quantification exercises (covered under the Quantification and Procurement Topic) takes place on an annual basis. To measure

availability of stock, a sample list of tracer products should be used. A sample tracer list is presented in Annex 3.6.B.

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

Table 3.4.10 Indicators to Assess the LMIS and Management Support Systems for the medical products, vaccines and technologies core function.

Indicator	Definition and Interpretation
Existence of inventory management guidelines for each level of the storage and distribution system.	A yes/no indicator with evidence and explanation. Is there an inventory management guideline and is it readily accessible? Are staff using the guideline across levels of the system? Has there been training in the use of the inventory management guideline, and if so whom, when, and is there regular refresher training offered? SOPs guide the staff working in the distribution chain and help them properly manage the stock. If SOPs do not exist or are not effectively implemented, there could be stock-outs, excess of stocks, expiration of the medicines or simply theft and diversion. There should be a document specifying the SOPs for stock management, which detail the specific roles and responsibilities of staff with regard to stock management.
Percentage of facilities with staff trained in stock management	(The number of facilities with staff trained in stock management, divided by the total number of facilities) multiplied by 100. If staffs 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 SOPs for stock management and understand their specific roles and responsibilities with regard to stock management.
Percentage of facilities receiving supervision for logistics/inventory management during the previous six months	(FILL IN) Supervision includes reviewing order forms, examining stock cards/ledger books, reviewing storage conditions, conducting physical inventory and reviewing the dispensing register.
Order fill rate	(Number of order lines/SKUs/cases shipped and received in initial shipment / Total quantity ordered) X 100 The orders that were filled as requested and shipped (transported) to country, warehouse or service delivery point. This indicator measures a supplier's ability to fill orders completely in terms of items and quantity as defined in the contract / PO during a definite period of time. Shipments may be divided into multiple shipments through an agreement, but still must be received in full by a specified date. This indicator measures the ability of the supplier to fill POs correctly. Shipments should always be checked against the shipping notice and the PO. What was shipped may not be what was ordered. Even though a supplier 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, as noted above. 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 http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf

Stock out rates	(Number of facilities that experienced stock out of a specific product / Total number of facilities that are expected to offer the product) X 100 This indicator measures the percentage of facilities (e.g., service delivery points [SDP], warehouses) that experienced a stock out of a specific product that the site is expected to provide, at any point, within a defined period of time (e.g., the past six or 12 months). Stock out rates can be calculated for a single product across facilities or aggregated for all products carried by a certain type of facility, or with a certain region. It can be measured over any time period of time but one year is typical. For this assessment it is recommended that the team look at a set of tracer drugs. This indicator measures product **availability**—or absence—over a period of time; it represents the overall ability of a facility or program to meet client's needs with a full range of products and services. Of course, if this indicator is used, stock records must be available and maintained regularly. It should also be used in conjunction with other indicators, such as the *stocked according to plan* indicator, because, to avoid stock outs, facilities can ration supplies. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf **Module link**: Section 3, Module 2—Service Delivery contains similar indicators on availability.
Inventory Average Accuracy rate	(Number of items where stock record county equals physical stock count / Total number of items counted) X 100 The indicator reflects the average percentage of in-stock indicator drug inventory records, which corresponds exactly with physical stock count for a set of indicator drugs. This indicator measures the quality of the stock record-keeping system, and whether balances recorded on a stock ledger, bin card, or automated system are similar to the actual inventory on hand. It 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. This is generally calculated during a physical inventory. Physical inventories 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 are counts done with higher frequency. Stock records are official inventory forms and registers used to document medicine receipts, issues, balances, and other related information. Some facilities update records periodically rather than on an ongoing basis. The technique 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). The following are possible reasons for poor record accuracy: Incorrect recording of amounts received and issued (by picker if manual system, by data entry person if automated system), Incorrect items or amounts picked by the picker, Incorrect counting of amounts received, Mathematical errors (by data entry person)
Routine analysis and dissemination of defined parameters for pharmaceutical management and rational use.	Yes/no indicator with explanation. Is there routine analysis and dissemination of defined parameters for pharmaceutical management and rational use?
Pharmaceutical management reviews or evaluations are conducted regularly, and findings are used for interventions at relevant levels (e.g., hospital, polyclinic, clinic) and in public and private sectors as appropriate	Yes/no indicator. Provide evidence. National Pharmaceutical Policies generally include indicators to measure appropriate use, and should be regularly monitored. Are pharmaceutical management reviews and evaluations conducted regularly? Are the findings used for interventions at the relevant levels (e.g., hospital, polyclinic, clinic) in public and private sectors as appropriate? Are their defined parameters for pharmaceutical management and rational use, and are they being followed? Periodic assessment of pharmaceutical utilization data should be used to inform policy. It would be important to know if the public sector/MoH has identified key utilization indicators, and if they have the capacity to analyze them. Institutions that regularly (monthly, quarterly, annually) conduct reviews are better prepared to address critical management functions, including clinical quality of care and financial cost control issues. Assessor should determine relevant levels in advance. Consider private sector as it relates to public sector policies, such as contracting for services and accreditation.

Key Indicators Table

Table 3.4.11 identifies six indicators from the medical product, vaccines, and technologies indicator list that are particularly useful to: (I) 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

No.	Indicator
	Stock outs of select tracer drugs.
	Inventory Average Accuracy Rate
	On Time Arrivals
	Percentage of households more than 5/I0/20 km from a public or private health facility/ pharmacy that is expected to dispense essential medicines
	Product Selection based upon NEML
	Percentage of IRP Paid

4.6 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.C 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.

Analyzing Data and Summarizing Findings

Using a table that is organized by the module topics (see Tables 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 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

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

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

Table 3.4.13 is an example of the completed table.

Table 3.4.13 Summary of Findings—Medical Products, Vaccines, and Technologies Module

Indicator or Topic	Findings (Designate as S=strength, W=weakness, O=opportunity, T=threat.)	Source(s) (List specific documents, interviews, and other materials.)	Comments*
LMIS / Inventory Management/ Availability	Poor availability in health facilities Inventory management information is not systematically collected at central and facility levels (W, T); better availability in private sector but not well controlled, some private retail and chain pharmacies have state of the art IT systems and are willing to share info with MOH (O)	Observations in health facilities at sample sites across levels of the system, interview with staff in the pharmacy department; private pharmacy owners, external development partners	Module Link: Service Delivery, quality of care
Policy, laws, regulations and governance	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)	Draft National Medicines Policy (NMP), interviews with the pharmacy department staff	Module Link: Governance Module
Selection	NEML used as basis for kit system in public sector (S)	Draft NMP	Module Link: Service Delivery, quality of care; Health Financing
Quantification and Procurement	Ministry of Finance (MOF) conducts international competitive bids on behalf of the Ministry of Health (MOH) for a limited number and quantity of essential medicines, but the process is not transparent nor is it based upon 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 drugs at all different price points (O)	Audit report; interview with the director of procurement, interviews with private providers, manufacturers, MOF	Link with measures of efficiency and sustainability
Storage and Distribution	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)	Interviews with the director of the pharmacy department and the medical stores manager; private wholesalers and retail distributers	Module Link: Service Delivery, measures of equity and access

Indicator or Topic	Findings (Designate as S=strength, W=weakness, O=opportunity, T=threat.)	Source(s) (List specific documents, interviews, and other materials.)	Comments*
Appropriate Use	Standard treatment guidelines for some, not all, conditions endorsed by MOH (W); no data on quality of medicine prescribing nor use (W)	Interview with the director of the pharmacy department, university department of clinical therapeutics, site visits to health facilities at various levels of the system	Module Link: Service Delivery, quality
Financing	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 drugs at affordable prices (O)	Interview with MOH; MOF audit report; procurement officers of private importers and retail pharmacies	Module Link: Service Delivery; Financing, sustainability

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

As discussed in Section 1, WHO's health system performance criteria 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

Performance Criteria	Suggested Indicator from the Medical Products, Vaccines and Technologies Module
Equity	Percentage of out-of-pocket expenditure for health on medicines disaggregated into different subgroups (e.g. geographic location, age group, gender, race and ethnicity, socioeconomic status)
Efficiency	Percentage of International Reference Prices Paid.
Access (including coverage)	Percentage of households more than 5/l0/20 km from health facility/pharmacy to dispense essential medicines Stock outs of select tracer drugs. Percentage of respondent who or whose household member was not able to take medicines because the household cannot afford them. (see Module 6—Health Financing)
Quality (including safety)	Existence of a functioning system for pharmaceutical registration and monitoring.
Sustainability	Proportion percentage of annual national expenditures on medicines financed by different stakeholders

Each indicator includes specific suggestions for interpretation. When examining medical products, vaccines, and technologies though, 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 supply chain 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

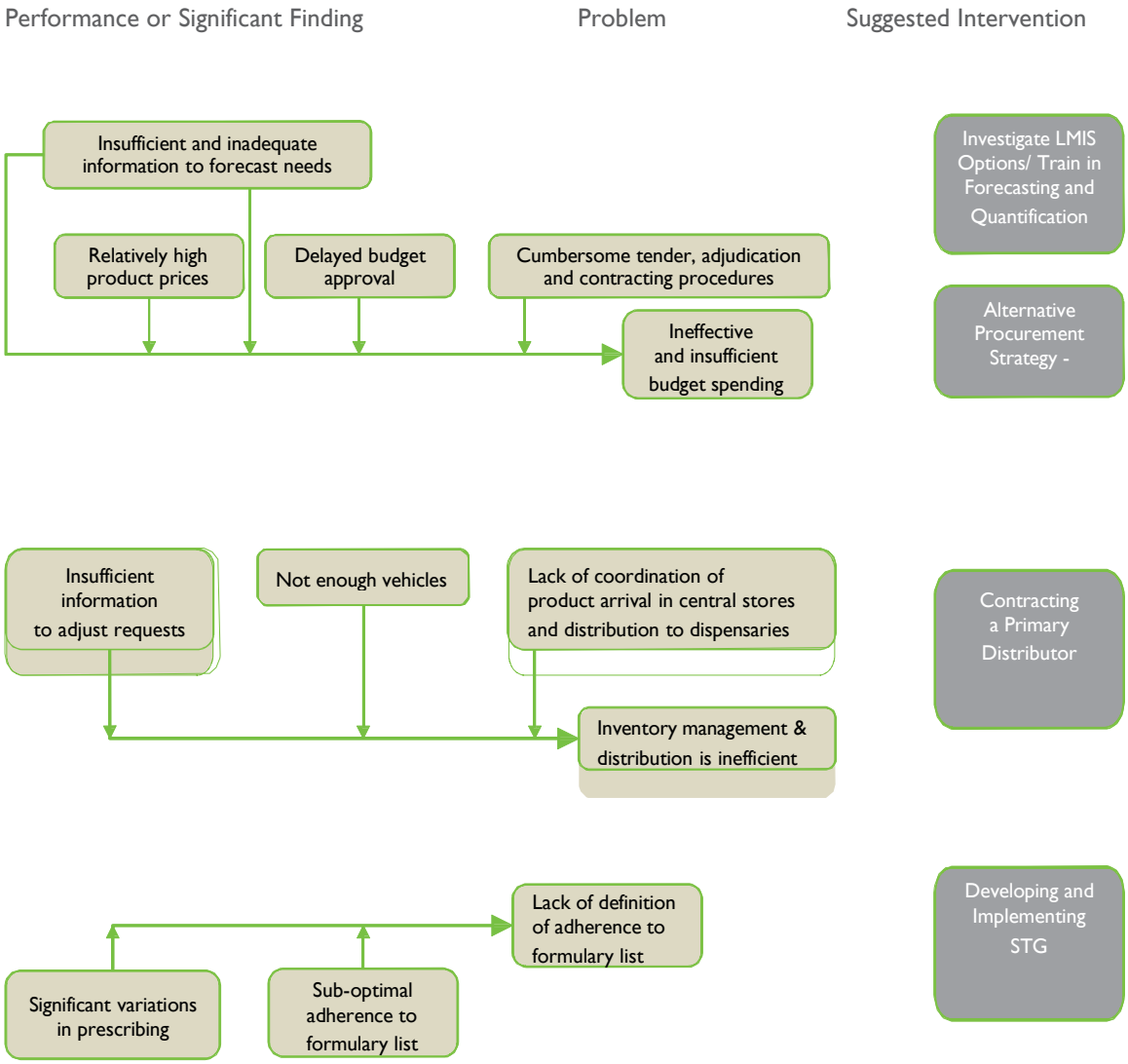
gap?), some of the subheadings can be combined and/or eliminated. The headings correspond to the topics and include:

- Current situation (see Annex 3.6.C for examples on how to present the data)
- Policy, Legal and Regulatory environment
- Financing
- Selection
- Quantification and Procurement
- Storage and Distribution
- Geographic Access
- Appropriate use
- Logistics Management Information Systems and other management support

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 3.4.6 demonstrates how observed performance problems can be linked to appropriate interventions. Careful consideration must be given to historical, economic, socio-cultural, and political factors that may have contributed to or exacerbated current performance problems. Keep in mind the priorities and competitive advantages of various external development partners, and the gaps in current donor programming, as well as opportunities for consistent, coordinated donor focus. To use the fishbone diagram, start by identifying a problem statement. In the diagram, one problem statement is “inventory management and distribution is inefficient.” Use information collected from the assessment to determine all the factors that ‘cause’ the problem. Using this information can then help to identify appropriate alternative interventions.

Figure 3.4.6 Sample Fishbone Diagram of Managing Medical Products, Vaccines, and Technologies Issues and Potential 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 3.4.15 Illustrative Recommendations for Medical Products, Vaccines, and Technologies Issues

Health Systems Gap	Possible Interventions
LMIS, Inventory Management, Quantification, Access	
Public facilities experience stock- outs of key essential medicines • Insufficient public funds to purchase essential medicines • Inefficient govt procurement and distribution systems	• Strengthen public sector capacity to forecast and purchase essential medicines. • Strengthen inventory management practices through optimizing flows, development of SOPs, training on inventory management functions and monitoring of key indicators. • Create an inventory management system with alerts when products run low. • Explore opportunities to partner with private sector distributors to get essential medicine out to rural areas more regularly. • 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. • Explore alternative methods to increase public funds to purchase essential medicines (e.g., user fees for drugs).
Geographic access to public health centers that provide pharmaceutical services is limited • Greater number and wider distribution of private sector outlets exist • Varied quality of private services	• If availability of essential products is not a problem in the private sector, study opportunities to partner with distributors and retailers to fill the gaps in the delivery system. • Open up external development partner-sponsored training to include private providers for improved therapeutic practices in underserved areas. • Develop accreditation system to license the number of private sector outlets in underserved areas ensuring quality and thus complementing the public sector. • Explore ways to reduce the cost of the essential medicines delivered by private pharmacists (e.g., donated) ensuring affordability.
Pharmaceutical policies, laws, regulations and governance	
No up-to-date policies and laws regulating the pharmaceutical sector, including a NMP • Private sector self-regulating • Registration system does not address product quality.	• Update the NMP with participation of public and private stakeholder groups. • Using same participatory process, work with the NDRA to develop or update policies and procedures for the pharmaceutical registration system. • Include private sector leaders in pharmaceuticals sector in policy and planning as one of many strategies to bring private sector into public sector regulatory framework. Involve professional associations as mechanism to distribute new policies, guidelines and to offer in-service training.
Product 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 STGs. • Establish drug information centers or an alternative mechanism to increase access to unbiased information about medicines.

Appropriate Use	
• Prescribing does not follow STGs, • National STGs do not exist or are out-of-date, or • STGs do not include guidelines for key public health conditions	• Formulate a committee or process including the private sector to review and revise STGs based on morbidity patterns and evidence-based best practices. • Make copies of STGs available to all facilities and all providers (public and private alike. Provide training on the guidelines to practitioners including private sector through professional associations or by opening up public sector training. • Establish DTCs and provide training to DTCs; provide pre- and in-service training on appropriate prescribing to all providers. • Develop managerial interventions to restrict prescribing that can be applied in both public and private sectors.
Quantification and 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 private sector to determine where and how able to purchase at lower prices, if applicable.
Storage and Distribution	
Holding costs (storage costs and inventory loss) are high relative to inventory value	• Improve 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).
Financing	
The level of public financing of pharmaceutical expenses is low	• National level (and subnational level in decentralized systems): Study cost recovery or other cost-sharing options (e.g., revolving drug funds and insurance). • Improve efficiencies elsewhere in the system to reduce costs. • Study alternatives for reallocation of funds (review medicine selection to focus more on priority medicines). Facility level: Explore options for cost recovery or other cost sharing (e.g., revolving drug funds and community-based insurance).

4.7 Assessment Report Checklist: Medical Products, Vaccines, and Technologies

☐ Profile of Country Medical Products, Vaccines, and Technologies

A. Overview of Medical Products, Vaccines, and Technologies

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

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

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

a. Product Selection

b. Quantification and Procurement

c. Storage and 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. Product Selection

C. Quantification and Procurement

D. Storage and Distribution

E. Geographic Access

F. Appropriate use

G. Financing

H. LMIS, Inventory Management, Management Support Systems

☐ Summary of Findings and Recommendations

A. Presentation of findings

B. Recommendations

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[i] World Health Organization. (2008). *Manual for the Household Survey to Measure Access and Use of Medicines* (draft). Retrieved from http://www.who.int/medicines/areas/coordination/household_manual_february_2008.pdf