USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

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PSS INSIGHT V2.0—A FRAMEWORK AND INDICATORS FOR MEASURING PHARMACEUTICAL SYSTEMS STRENGTHENING

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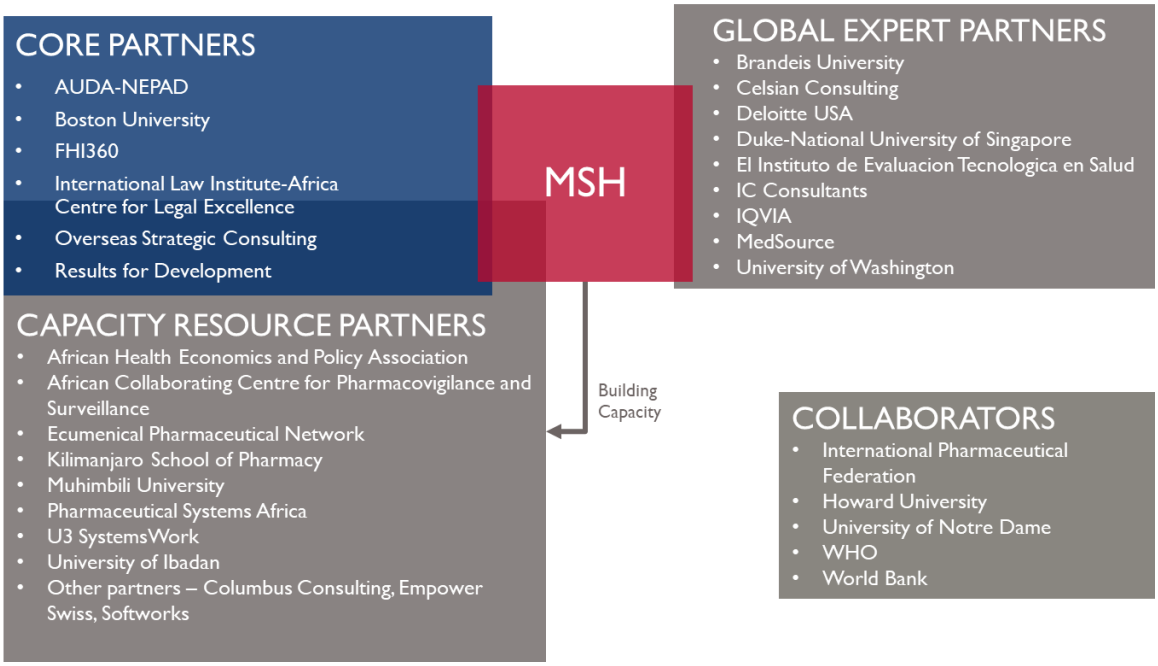
About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

The MTaPS Consortium



This report is submitted by:

USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
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PROJECT SUMMARY

Program Name:		USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
Activity Start Date and End Date:		September 20, 2018 – September 19, 2023
Name of Prime Implementing Partner:		Management Sciences for Health
Contract Number:		7200AA18C00074
MTaPS Partners	**Core Partners**	Boston University, FHI 360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD
	Global Expert Partners	Brandeis University, Deloitte USA, Duke-National University of Singapore, El Instituto de Evaluacion Technologica en Salud, IC Consultants, Imperial Health Sciences, MedSource, QuintilesIMS, University of Washington
	Capacity Resource Partners	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 Systems Work, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa
	Collaborators	International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank

CONTENTS

ACRONYMS AND ABBREVIATIONS

DDD	defined daily dose
EML	essential medicines list
GBT	Global Benchmarking Tool
GLASS	Global Antimicrobial Surveillance System
INCB	International Narcotics Control Board
MOH	ministry of health
MSH	Management Sciences for Health
MTaPS	Medicines, Technologies, and Pharmaceutical Services
OECD	Organisation for Economic Co-operation and Development
PSTA	Pharmaceutical System Transparency and Accountability
R&D	Research and development
SDG	Sustainable Development Goal
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USAID	US Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program is a five-year (2018–2023) project led by Management Sciences for Health (MSH) to provide pharmaceutical systems strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of assisting low- and middle-income countries in ensuring sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

In 2012, USAID awarded the MTaPS predecessor program, Systems for Improved Access to Pharmaceuticals and Services (SIAPS), to MSH. USAID tasked SIAPS with developing a measurement framework and corresponding indicators for determining whether investments in pharmaceutical systems strengthening were contributing to the development of stronger, more sustainable pharmaceutical systems. At that time, there was no standardized approach for the strength of a pharmaceutical system. SIAPS and its partner, Boston University School of Public Health, developed PSS Insight as an indicator-based monitoring tool to measure pharmaceutical systems strengthening across countries and over time. The tool is organized according to seven identified critical system components for measuring pharmaceutical systems strengthening: *pharmaceutical products and related services*; *policy, laws, and governance*; *regulatory systems*; *innovation, research and development, manufacturing, and trade*; *financing*; *human resources*; and *information*. Measures are aligned with each of these components, with the key system attributes of *performance* and *resilience*, as well as with the primary system outcomes of *access* and *use*. The measurement framework for PSS Insight is illustrated in figure 1.

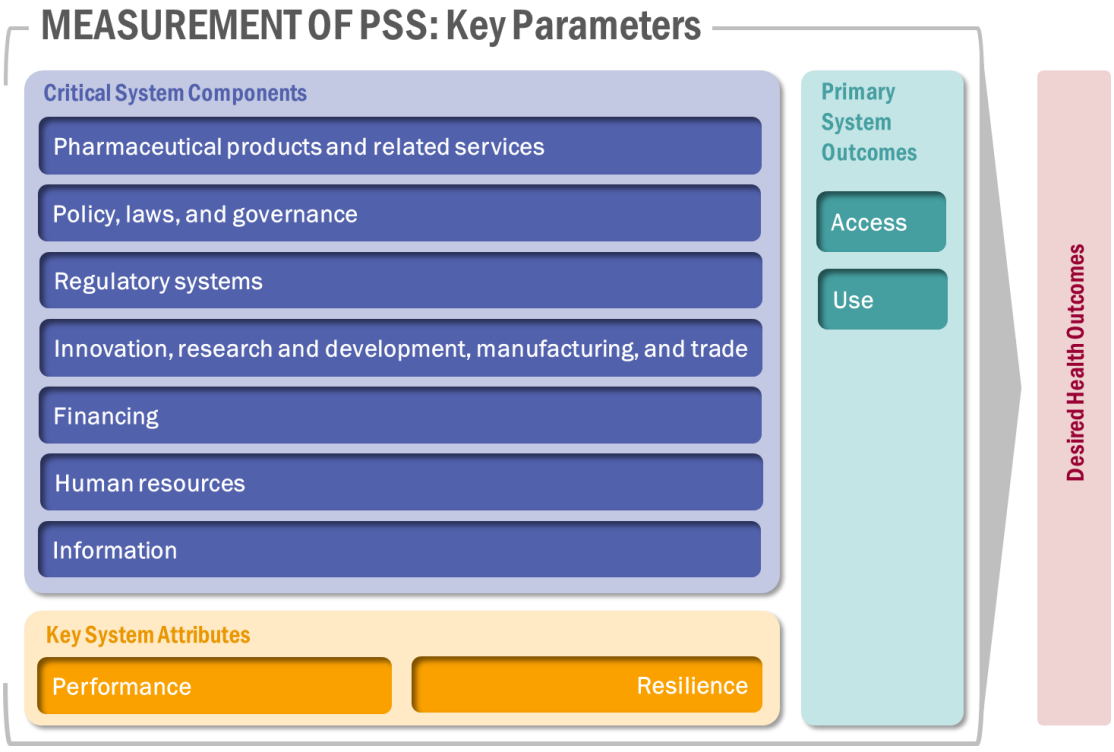

Figure 1. Pharmaceutical systems strengthening measurement framework

Following the inception of the tool under SIAPS, MTaPS recognized the continued need for a tool that measures pharmaceutical systems strengthening holistically, combining indicators across the identified components, and incorporating measures from across domains of pharmaceutical systems – that are normally tracked separately – to provide a more complete picture of the system and its capacity to operate as a whole. Although PSS Insight v1.0, as developed under SIAPS, addresses this need and was the only tool of its kind, following the SIAPS pilots and consultation with the MTaPS Technical Advisory Group and others, MTaPS recognized that a tool with 117 indicators would be overly burdensome for low- and middle-income countries to implement. In 2020, with continued funding from USAID, MTaPS revised the tool, reducing the number of indicators to 38. This version of the tool, PSS Insight v2.0, is an adaptable instrument that is simpler to implement and will continue to help stakeholders in low- and middle-income countries inform their efforts to strengthen national pharmaceutical systems. The indicators included in PSS Insight v2.0 are listed in the following tables.

PSS INSIGHT V2.0 LIST OF INDICATORS FOR SEVEN CRITICAL SYSTEM COMPONENTS

Element	No.	Indicator
Pharmaceutical Products and Related Services		
Selection	PS01	Existence of a national essential medicines list (EML) published within the past five years
	PS02	Existence of a reimbursement list published within the past two years
Procurement	PS03	% of median international price paid for a set of tracer medicines that was part of the last regular ministry of health (MOH) procurement
Distribution	PS04	Mean % availability across a basket of medicines
	PS05	Product losses by value due to expired medicines or damage or theft per value received (%)
Use	PS06	% generic medicines out of total market volume
	PS07	Defined daily dose (DDD) antimicrobial per 1,000 inhabitants
	PS08	% medicines prescribed from a EML or reimbursement list
	PS09	% medicines prescribed as generics
	PS10	% antibiotics prescribed in outpatient settings
	PS11	% population with unmet medicine needs
Policy, Laws, and Governance		
Coordination and Leadership	PLG01	An institutional development plan of the national medicines regulatory authority based on the results of the World Health Organization (WHO) Global Benchmarking Tool (GBT)
	PLG02	A progress report on the institutional development of the national medicines regulatory authority published
	PLG03	Submission of national data to the Global Antimicrobial Surveillance System (GLASS)
	PLG04	Updated national action plan on the containment of antimicrobial resistance

Element	No.	Indicator
Pharmaceutical Laws and Regulations	PLG05	# of annual reports submitted to the International Narcotics Control Board (INCB) in the last five years
Pharmaceutical Policies		No indicators selected—covered in WHO GBT
Ethics, Transparency, and Accountability	PLG06	Pharmaceutical System Transparency and Accountability (PSTA) assessment score
	PLG07	Number of PSTA assessments within the last five years
Regulatory Systems		
Inspection and Enforcement	RS01	% of manufacturing facilities inspected each year
	RS02	% of distribution facilities inspected each year
	RS03	% of dispensing facilities inspected each year
Product Assessment and Registration	RS04	Average number of days for decision making on a medicine application for registration
	RS05	% of medicines on the EML that have at least one registered product available.
Quality and Safety Surveillance	RS06	% of recorded adverse event reports that are assessed for causality
	RS07	% of samples tested that failed quality control testing
Licensing of Establishments and Personnel		No indicators selected—covered in WHO GBT
Regulation and Oversight of Clinical Trials		No indicators selected—covered in WHO GBT
Control of Pharmaceutical Marketing Practices		No indicators selected—covered in WHO GBT
Innovation, Research and Development, Manufacturing, and Trade		
Innovation, Research and Development	IRDT01	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs
Intellectual Property and Trade	IRDT02	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?
	IRDT03	Have any of the following Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities been utilized to date: compulsory licensing provisions, government use, parallel importation provisions, the Bolar exception (10-year time frame)?
Manufacturing Capacity		No indicator selected—lack of validated, cost-effective indicators available

Element	No.	Indicator
Financing		
Resource Coordination, Allocation, Distribution, and Payment	F01	Per capita expenditure on pharmaceuticals
	F02	Share of households with catastrophic medicines-related spending
	F03	Total expenditure on pharmaceuticals (% total expenditure on health)
Costing and Pricing	F04	Median drug price ratio for tracer medicines in the public, private, and mission sectors
Financial Risk Protection	F05	Out-of-pocket expenditure out of total pharmaceutical expenditure
Expenditure Tracking and Monitoring	F06	At least one national health accounts exercise including pharmaceuticals completed in the past five years
Human Resources		
Human Resource Development	HR01	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs
Human Resource Management	HR02	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant
Human Resources Policy and Strategy		No indicators selected—no process or outcome indicators available
Information		
Information Policy and Data Standardization	IM01	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information
Use of Information for Decision Making	IM02	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection
Data Collection, Processing, and Dissemination		No indicators selected—process and outcome indicators were more relevant to information policy and use of information for decision making

PSS INSIGHT V2.0 LIST OF INDICATORS FOR KEY SYSTEM ATTRIBUTES AND PRIMARY SYSTEM OUTCOMES

Dimension	Indicator
Performance	
Efficiency	% of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement (PS03)
	Product losses by value due to expired medicines or damage or theft per value received (%) (PS05)
Quality and Safety	% of samples tested that failed quality control testing (RS07)
	Overall GBT level
Responsiveness	No indicators selected

Dimension	Indicator
Resilience	
Aware	No indicators selected
Diverse	Mean % availability across a basket of medicines (PS04)
Self-Regulating	No indicators selected
Integrated	No indicators selected
Adaptive	No indicators selected
Access	
Affordability	Median (consumer) drug price ratio for tracer medicines in the public, private, and mission sectors (F04)
	MedMon survey outputs on affordability
	Population with household expenditures on health greater than 10% of total household expenditure or income (F02) *or* Sustainable Development Goal (SDG) indicator 3.8.2: Proportion of population with large household expenditures on health as a share of total household expenditure or income
	SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
(Cultural) Acceptability (or Satisfaction)	No indicators selected
(Geographical) Accessibility	Mean % availability across a basket of medicines (PS04)
	MedMon survey outputs on availability
	SDG indicator 3.8.1: Coverage of essential health services
	SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
Availability	Mean % availability across a basket of medicines (PS04)
	MedMon survey outputs on availability
	SDG indicator 3.8.1: Coverage of essential health services
	SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
Use	
Prescribing	% medicines prescribed from EML or reimbursement list (PS08)
	% medicines prescribed as generics (PS09)
	% antibiotics prescribed in outpatient settings (PS10)
Dispensing/Sale or Supply	No indicators selected
Consumption/End-Use	No indicators selected
General Indicator for Use	% population with unmet medicine needs (PS11)

BACKGROUND

MTaPS is a five-year (2018–2023) project led by MSH to provide pharmaceutical systems strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of assisting low- and middle-income countries to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and pharmaceutical services.

In 2012, USAID awarded the MTaPS predecessor program, SIAPS, to MSH. USAID tasked SIAPS with developing a measurement framework and corresponding indicators for determining whether investments in pharmaceutical systems strengthening were contributing to the development of stronger, more sustainable pharmaceutical systems. At that time, there were no widely accepted definitions for a pharmaceutical system or pharmaceutical systems strengthening.

***A pharmaceutical system**: Consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.*

***Pharmaceutical systems strengthening:** The process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to make it more responsive and resilient and to enhance its performance for achieving better health outcomes.*[1]

There was no standardized approach for measuring progress toward stronger, more sustainable systems. SIAPS and its partner, Boston University School of Public Health, developed PSS Insight as an indicator-based monitoring tool to measure pharmaceutical systems strengthening across countries and over time. The tool is organized according to seven identified critical system components for measuring pharmaceutical systems strengthening: *pharmaceutical products and related services*; *policy, laws, and governance*; *regulatory systems*; *innovation, research and development, manufacturing, and trade*; *financing*; *human resources*; and *information*. Each component is further divided into elements, which break down the components into distinct sub-units for measurement.

Following the inception of the tool under SIAPS, the World Health Organization (WHO) initiated efforts to assess progress toward medicine and health-related aspects of the United Nations' 2030 Sustainable Development Goals (SDGs),[2,3] adopted in 2015. WHO also released the global

[1] Hafner T, Walkowiak H. 2014. Defining and Measuring Pharmaceutical Systems Strengthening: Report of the SIAPS Partners' Consultative Meeting. September 11-12, 2014. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

[2] Monitoring the components and predictors of access to medicines. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.

[3] World Health Organization. WHO MedMon App – Measuring price and availability of health products. World Health Organization. Available at: https://www.who.int/medicines/areas/policy/monitoring/empmedmon/en/. 2016.

benchmarking tool (GBT) to evaluate national regulatory systems.[4] The Lancet Commission on Essential Medicines Policies identified a core set of 24 indicators to evaluate essential medicines policies and their impact on access to medicines.[5] MTaPS recognized the continued need for a tool that measures pharmaceutical systems strengthening holistically to complement these efforts. Therefore, PSS Insight v2.0 combines indicators across the identified components and incorporates measures from across domains of pharmaceutical systems that are normally tracked separately to provide a more complete picture of the system and its capacity to operate as a whole. A comparison of the indicators across these initiatives is located in Annex 1. Although PSS Insight v1.0 addresses this need, following the SIAPS pilots and consultation with the MTaPS Technical Advisory Group and others, we recognized that the tool with 117 indicators would be burdensome for countries to implement. The program therefore revised the tool as PSS Insight v2.0, which is an adaptable instrument that is simpler for governments to implement and helps inform their efforts to strengthen their national pharmaceutical system.

PHARMACEUTICAL SYSTEMS STRENGTHENING MEASUREMENT FRAMEWORK

In 2014, SIAPS conducted a series of literature reviews and held a consultative meeting with SIAPS partners and experts in the field to propose definitions for a pharmaceutical system and pharmaceutical systems strengthening as a first step toward developing a PSS measurement framework.[1,6] As part of the consultative process, SIAPS also sought to identify the critical system components, primary system outcomes, and key system attributes that are essential to measure progress in pharmaceutical systems strengthening over time and across countries. SIAPS used the identified parameters to develop the PSS measurement framework (figure 2).

[4] World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. World Health Organization. Available at: http://www.who.int/medicines/regulation/benchmarking_tool/en/. Published. 2017.
[5] Wirtz, Hogerzeil, and Gray. Essential Medicines for Universal Health Coverage. The Lancet 2017; 389 (10067): 403–476
[6] Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. Defining pharmaceutical systems strengthening: concepts to enable measurement, Health Policy and Planning, Volume 32, Issue 4, 1 May 2017, Pages 572–584

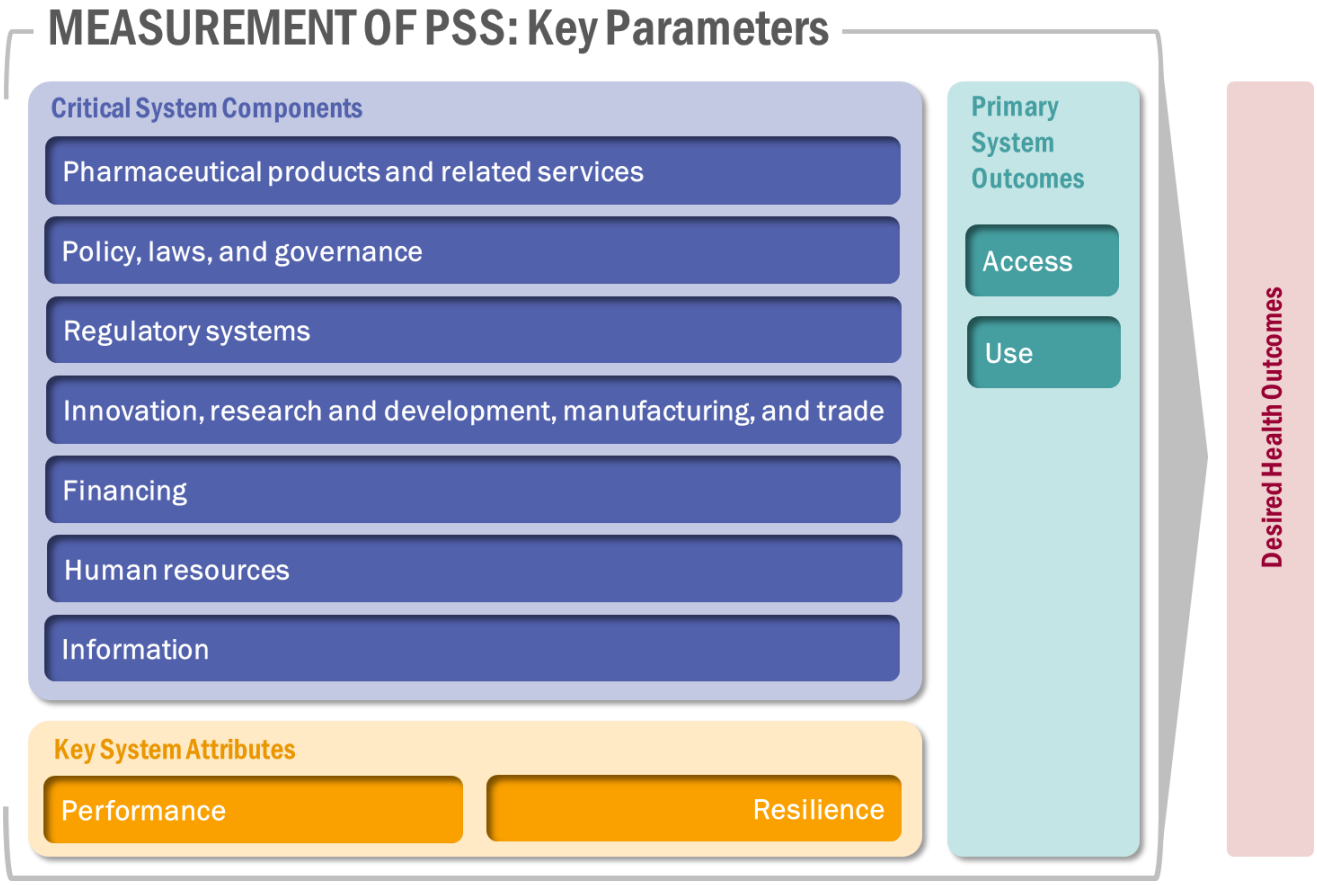

Figure 2. Pharmaceutical systems strengthening measurement framework

The measurement framework consists of seven critical system components and the two key system attributes of *performance* and *resilience*.[7] The critical components and the system's ability to function, as measured by the key system attributes, contribute to the primary system outcomes of *access* and *use*. For each of these key parameters for measurement, the framework identifies elements or dimensions (figure 3).

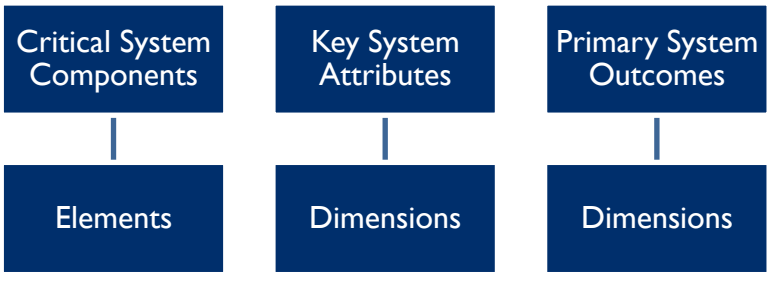

Figure 3. Relationship between measurement framework domains

The components, attributes, and outcomes are subdivided according to the elements and dimensions presented in table 1. Annex 2 provides more information about

[7] At the time the framework was being developed, resilience had been used extensively in other fields but was a fairly new concept being applied to health systems. Resilience concepts in the framework are adapted from: Kruk, ME, Myers M, Varpilah ST, Dahn BT. 2015. What is a resilient health system? Lessons from Ebola. *The Lancet*, 385(9980), 1910–1912.

the measurement framework, as well as the definitions of each parameter for measurement and their corresponding elements or dimensions.

TABLE 1. CRITICAL SYSTEM COMPONENTS AND ELEMENTS

System Components	Elements
Pharmaceutical Products and Related Services	Selection Procurement Distribution Use
Policy, Laws, and Governance	Pharmaceutical Policies Pharmaceutical Laws and Regulations Coordination and Leadership Ethics, Transparency, and Accountability
Regulatory Systems	Product Assessment and Registration Licensing of Establishments and Personnel Inspection and Enforcement Quality and Safety Surveillance Regulation and Oversight of Clinical Trials Control of Pharmaceutical Marketing Practices
Innovation, Research and Development, Manufacturing, and Trade	Innovation, Research, and Development Manufacturing Capacity Intellectual Property and Trade
Financing	Resource Coordination, Allocation, Distribution, and Payment Financial Risk Protection Revenue and Expenditure Tracking and Management Costing and Pricing
Human Resources	Human Resources Policy and Strategy Human Resources Management Human Resources Development
Information	Information Policy and Data Standardization Data Collection, Processing, and Dissemination Use of Information for Decision Making

TABLE 2. KEY SYSTEM ATTRIBUTES AND DIMENSIONS

Key System Attributes	Dimensions
Performance	Efficiency Quality and Safety (relating to pharmaceutical products and pharmaceutical services) Responsiveness[8]
Resilience[7]	Aware Diverse Self-Regulating Integrated Adaptive

TABLE 3. PRIMARY SYSTEM OUTCOMES AND DIMENSIONS

Primary System Outcomes	Dimensions
Access	Affordability (Cultural) Acceptability (or Satisfaction) (Geographical) Accessibility Availability Equity in Access (relating to affordability, accessibility, availability)
Use	Prescribing Dispensing/Sale or Supply Consumption/End Use

PSS INSIGHT TOOL DEVELOPMENT

SIAPS used the PSS measurement framework as the basis for the PSS Insight tool. The development team, comprising SIAPS staff and SIAPS partner Boston University School of Public Health, conducted a literature review to identify and categorize existing indicators according to the components, elements, and dimensions of the framework.[9] This process focused on the element or dimension level, with the explicit goal of selecting three indicators—one structural, one process, and one outcome—for each element or dimension included in the framework. The criteria for indicator selection were validity, reliability, repeatability, attributable, availability, policy relevance, and feasibility of data collection. The tool design allowed for indicators, where scoring or benchmarking was possible and appropriate, to be

[8] Note: System responsiveness overlaps with the primary system outcome of cultural acceptability or satisfaction.
[9] Soucy Brown M, Walkowiak H, Musila R, Aboagye-Nyame F. 2018. *PSS Insight: A Tool for Measuring Progress in Pharmaceutical Systems Strengthening.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

combined to form composite[10] scores for each element/dimension and subsequently each component of the framework. This enabled monitoring and reporting of progress within countries over time, as well as some comparison among countries at the component level. Many indicators were not included in composite scoring because no benchmarks or targets were established in the literature. Using the *pharmaceutical products and related services* component as an example, there are four elements: *selection*, *procurement*, *distribution*, and *use,* and each element is assessed using three indicators, giving a total of 12 indicators associated with the component. These 12 indicators are used to generate five scores—one for each of the four elements and one overall component score for *pharmaceutical products and related services*. Following this logic, based on the number of components (7), attributes (2), and system outcomes (2), as well as their associated elements (27) and dimensions (16), and accounting for overlap between different parts of the framework (where indicators were used more than once to assess different areas of the framework), the target number of indicators was set at 81.

Once the lists of existing indicators were compared to the definitions of the parameters, elements, and dimensions, it became clear that some of the elements would require additional indicators beyond the three initially planned to fully evaluate the concepts included in the definitions. In other areas of the framework, defined concepts were either novel (e.g., pharmaceutical system *resilience)* or had not been well defined or previously measured in the pharmaceutical systems space (e.g., *use of information for decision making)*. Established or validated indicators did not exist or were uncommon in the literature. In these cases, fewer than three indicators were selected, or new indicators were developed to fill the gaps for piloting.

Due to uncertainties regarding feasibility of data collection and availability of data in low- and middle-income country settings, we selected 182 indicators for in-country piloting. SIAPS piloted the tool in Namibia and Bangladesh in 2017. The pilots assessed data availability, quality, and feasibility of collection and led to an indicator reduction exercise, where each indicator was scrutinized according to feasibility of data collection and the validity of the indicator according to its alignment with the PSS measurement framework. Following this process, the PSS Insight development team under SIAPS published PSS Insight v1.0 with 117 indicators.[9]

PSS INSIGHT TOOL REVISION (V2.0)

The original intent of PSS Insight was to develop a tool that was comprehensive enough to measure the most critical components of a pharmaceutical system and its strengthening. However, with the development of comprehensive benchmarking tools for some components (*regulatory systems*, *supply chains*) and the lack of existing data/routinely reported indicators that increased the burden of data collection for countries, there was a need to simplify PSS Insight while still providing an overall picture of pharmaceutical systems strengthening. This prompted MTaPS to systematically reexamine the indicators with the aim of reducing the tool to no more than 50 indicators. The goal was to produce a practical, feasible tool fully oriented to central governments as the end users, while acknowledging parallel initiatives to measure aspects of pharmaceutical systems strengthening. MTaPS also determined that the

[10] Composite indicators combine multiple indicators into a single indicator. A composite score is a single score that encompasses multiple indicators.

most appropriate and feasible way forward would be to refocus the tool toward process and outcome indicators and approach measurement of pharmaceutical systems strengthening at the component level, rather than at the element level.

METHODOLOGY

A key starting point to reduce the number of PSS Insight indicators was to review the elements in the PSS measurement framework to determine whether any could be combined or eliminated. For the development of v2.0, we used the same indicator selection criteria as for v1.0; however, we prioritized the feasibility of data collection, policy relevance, and user friendliness of PSS Insight v2.0. This also meant that we gave preference to existing validated indicators. Given the focus on strengthening pharmaceutical systems (e.g., how they function and how well they achieve their goals), we also prioritized outcome and process indicators over structural indicators. A comparison of the indicators included in PSS Insight v1.0 and v2.0 is included in Annex 3.

We sought to define benchmarks for each indicator based on existing global benchmarks and targets (included in the indicator reference sheets in Annex 4). Where possible, we also proposed a composite scoring methodology for each component based on existing scoring methodologies (e.g., the WHO GBT for assessing national regulatory systems[11] and the Pharmaceutical System Transparency and Accountability [PSTA] assessment tool[12]). Some indicators lack established targets or benchmarks but are useful for comparison and monitoring trends over time—for example "average number of days for decision making on a medicine application for registration." There is no target established in the literature, but this is a measure of the efficiency of the product registration process and is useful to monitor over time and compare across regulatory systems. Composite scoring will require piloting and further discussion with a wider group of experts and stakeholders to be finalized.

It is important to note that PSS Insight v2.0 focuses on medicines and does not explicitly include diagnostic and other medical devices. Indicators for medical technologies or devices may be added in the future. It is intended to be used in conjunction with the WHO GBT,[4] SDG indicators,[13] and WHO MedMon.[3]

RESULTS

The results of the indicator reduction exercise are structured according to the seven critical system components for measurement and the primary system outcomes of *access* and *use*. For each component,

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[11] WHO. Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. Available at: https://www.who.int/medicines/regulation/benchmarking_tool/en/

[12] WHO. Pharmaceutical System Transparency and Accountability Assessment Tool. Available at: https://www.who.int/medicines/areas/policy/goodgovernance/ggm_sdg-era/en/

[13] United Nations. Sustainable Development Goals – SDG Indicators, metadata repository. Goal 3: Ensure healthy lives and promote well-being for all at all ages. Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. Available at: https://unstats.un.org/sdgs/metadata/?Text=&Goal=3&Target=3.8

we present an overview of the selected indicators, a justification for selection, and any tradeoffs. Refer to Annex 3 for the complete lists of indicators included in PSS Insight v1.0 and v2.0.

PHARMACEUTICAL PRODUCTS AND RELATED SERVICES

***Pharmaceutical Products and Related Services**: "At the center of the pharmaceutical system and encompasses the functions of selection, procurement, and distribution of pharmaceutical products. It also includes systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, retail practices, and correct use by end-users. This component impacts all dimensions of access and use."*[14]

The *pharmaceutical products and services* component comprises four elements: *selection*, *procurement*, *distribution*, and *use*. The list of chosen indicators is shown in table 4.

TABLE 4. PHARMACEUTICAL PRODUCTS AND RELATED SERVICES

	Element	No.	Indicator
Pharmaceutical Products and Related Services	Selection	PS01	Existence of a national essential medicines list (EML) published within the past five years
		PS02	Existence of a reimbursement list published within the past two years
	Procurement	PS03	% of median international price paid for a set of tracer medicines that was part of the last regular ministry of health (MOH) procurement
	Distribution	PS04	Mean % availability across a basket of medicines
		PS05	Product losses by value due to expired medicines or damage or theft per value received (%)
	Use	PS06	% generic medicines out of total market volume
		PS07	Defined daily dose (DDD) antimicrobial per 1,000 inhabitants
		PS08	% medicines prescribed from EML or reimbursement list
		PS09	% medicines prescribed as generics
		PS10	% antibiotics prescribed in outpatient settings
		PS11	% population with unmet medicine needs

[14] The source of this and all of the subsequent definitions is: Hafner T, Walkowiak H. 2014. Defining and Measuring Pharmaceutical Systems Strengthening: Report of the SIAPS Partners' Consultative Meeting. September 11-12, 2014. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

SELECTION

Selection: *"Developing, updating, and publishing standard treatment guidelines for priority health problems, selecting products and dosage forms for essential pharmaceutical product lists, formularies, and insurance reimbursement lists, and deciding which products will be available at each level of the health system."*

These indicators measure the selection process outcomes, which are lists of essential medicines and medicines for reimbursement. The process aspect of list development is captured through the stipulation that lists be updated at specified intervals. Having two indicators separates the essential medicines list (EML) from the reimbursement list. If there is no reimbursement list for the public sector in the country, the indicator pertaining to the EML should be used. The existence of a reimbursement list depends on the maturity and history of a particular country's health system. As countries move toward universal health coverage, ministries of health will need to be explicit in the medicines benefits packages offered under public insurance schemes. That will require a reimbursement list or multiple lists, depending on the number of insurance schemes in the country, updated a minimum of every two years. While it is not expected that a country will have both an EML and a reimbursement list, it is possible, depending on the configuration of the health system. If a country has both lists, both indicators PS01 and PS02 should be collected. If a country has multiple insurance schemes, the reimbursement list of the insurance scheme that serves the largest number of people at or below the national poverty line should be used for computing this indicator.

PROCUREMENT

Procurement*: "Systems for deciding which products to procure, quantifying pharmaceutical product needs, choosing procurement methods, managing procurements (including local purchasing) and donations, assuring pharmaceutical quality, tracking prices, and monitoring supplier performance."*

Public procurement of medicines is a core strategy to increase efficiency in the pharmaceutical system. The indicator "% of median international price (or lower) paid for a set of tracer medicines that was part of the last regular MOH procurement" is well-established and has been widely used as an outcome indicator to assess the procurement performance.[15] For commonly used generic medicines, MSH provides the International Medical Product Price Guide as a reference.[16] Other sources that track the affordability of medicines and report on the median international price paid include WHO's MedMon assessment tool[3] and the World Bank Data Bank indicators on health equity and financial protection.[17] If a country has more than one public procurement institution, the one that serves the poorest people according to the national poverty line should be chosen to assess using this indicator. If procurement is

[15] USAID. Drug management for childhood illness manual. Available at: http://pdf.usaid.gov/pdf_docs/PNACM451.pdf
[16] Management Sciences for Health. Available at: http://mshpriceguide.org/en/home/
[17] World Bank Data Bank – Health Equity and Financial Protection Indicators. Available at: https://databank.worldbank.org/source/health-equity-and-financial-protection-indicators-(hefpi)

decentralized, the average procurement price should be used. For example, if the ministry of health (MOH) is providing services to the poorest patients, the MOH procurement should be assessed.

It is important that countries identify their baseline and measure trends over time. Ideally, the median price ratio is below or equal to 100%; however, it is unrealistic to expect that the country can achieve a median international price or lower for all tracer medicines. Cameron et al. found that the median price ratio depends on the income level of the country, where lower-income countries generally paid less than higher-income countries as compared to the median international reference price.[18]

DISTRIBUTION

***Distribution**: "Systems for importation, managing, storage and monitoring, consumption, stock and quality and security of the inventory, and delivering products to their point of use."*

A well-established outcome indicator for distribution is the "mean % availability of a basket of tracer medicines." This indicator should be reported separately for the public and private sectors. It is noteworthy that in some regions of the world, the public sector does not stock and provide medicines; rather, retail pharmacies dispense medicines (e.g., USA, northern and western European countries). In such cases, tracer medicine availability in the private sector should be used to compute the indicator rather than availability in both the public and private sectors.

The suggested target is >80% according to WHO Non-communicable Disease Action Plan[19] that also includes affordability (Section 3.8.). This indicator is related to SDG indicator 3.b.3: "proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis."[20] While this indicator is the gold standard for reporting on medicines availability and affordability, we determined that the availability of a basket of tracer medicines is a more tailored measure for the *distribution* element and that SDG 3.b.3 is a measure that combines several aspects of *availability* and *affordability*. SDG 3.b.3 is included as a *primary system outcome* indicator later in the results section.

A second indicator for distribution assesses the efficiency of the distribution process: "product losses by value due to expired medicines or damage or theft per value received (%)." This indicator is commonly used in supply chain assessment tools—notably, the USAID National Supply Chain Assessment Tool—to

[18] Cameron et al. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. The Lancet 2009. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61762-6/fulltext
[19] World Health Organization. Non-communicable disease action plan. Available at: https://www.who.int/nmh/events/ncd_action_plan/en/
[20] United Nations. Sustainable Development Goals – SDG Indicators, metadata repository. Goal 3: Ensure healthy lives and promote well-being for all at all ages. Indicator 3.b.3. Available at: https://unstats.un.org/sdgs/metadata/files/Metadata-03-0B-03.pdf

evaluate whether pharmaceutical products are being wasted due to expiry or improper storage (poor inventory management practices) or if they are being diverted by theft.[21]

These two indicators taken together are intended to evaluate whether products are arriving where they are needed and the quality of the distribution process, including inventory management and storage conditions.

USE

***Use**: "Systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, and retail practices within culturally acceptable, integrated service delivery that supports appropriate (including initial and long-term) use by the end user."*

Efficient use of medicines is measured in many regions and globally with the indicators "% of generic medicines out of the total number of medicines prescribed"; "the % of medicines prescribed that are included in the country-relevant benefit package" (e.g., reimbursement list or EML); and "% of patients receiving antibiotics."[22,23,24,25] Data for these indicators are based on a sample of primary care clinic prescriptions as described in the WHO methodology on investigating medicines use.[26] The targets for the three indicators are 80%, 80%, and below 30%, respectively, based on prior validation.[26] We separated a composite prescribing indicator that was included in PSS Insight v1.0 into these three indicators so that they can be tracked and reported separately. They assess different aspects of prescribing practices and their relationship with different aspects of the pharmaceutical policy environment.

The "% of medicines prescribed as generics" indicator examines whether prescribers are adhering to best practice with respect to issuing prescriptions by international nonproprietary name. This can have implications for medicine affordability if patients are prescribed and then dispensed branded products in lieu of an available generic. This indicator in turn is related to the indicator "% of generic medicines out of total market volume," which measures the relative amount (as a percentage) of generic medicines actually dispensed in the country. These two indicators taken together assess both prescribing behavior regarding generic medicines and how many generics are actually available and dispensed in the country.

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[21] USAID. National Supply Chain Assessment Toolkit. 2018. Available at: https://www.ghsupplychain.org/key-initiatives/national-supply-chain-assessment-nsca-toolkit
[22] Dong L, Yan H, Wang D. Drug prescribing indicators in village health clinics across 10 provinces of Western China. Family practice. 2011 Feb 1;28(1):63–7.
[23] Joncheere KD. Implementation of rational pharmacotherapy, Perspectives and Achievements with Rational Pharmacotherapy, 2002. Copenhagen, Denmark: WHO/EURO
[24] Melander A. Variation in drug utilisation in the EU: causes and consequences as illustrated by antibiotics, Perspectives and Achievements with Rational Pharmacotherapy, 2002. Copenhagen, Denmark: WHO/EURO
[25] Santos V, Nitrini SM. Prescription and patient-care indicators in healthcare services, Rev Saude Publica, 2004, vol. 38 (pg. 819–26)
[26] World Health Organization. How to investigate drug use in health facilities. Available at: http://apps.who.int/medicinedocs/en/d/Js2289e/

Similarly, the indicators "% of antibiotics prescribed in outpatient settings" and "defined daily dose (DDD) antimicrobial per 1,000 inhabitants" examine the behavior and prescribing practices of prescribers regarding antimicrobials and the relative amount of antimicrobials prescribed at a population level, respectively.

It is important to note that for some countries, market analysis for population-level indicators is feasible because of the collection of sales data at the national level. In many low- and middle-income countries, these data are not available. Hence, the study of prescriptions in a sample of health facilities is more relevant and meaningful for studying pharmaceutical use in these contexts.

The "% of medicines prescribed from an EML or reimbursement list" indicator connects to the *selection* component and evaluates how the outcome of the selection process relates to the medicines prescribed at the health facility level and the medicines used by people in the country.

The "% of the population with unmet medicine need" indicator measures aspects of product and service *availability* and *geographical accessibility*, *affordability*, and *cultural acceptability* (this indicator is also included in the *primary system outcomes* section in table 11 at the end of the results section). It will be difficult to collect data for this indicator without routine household surveys such as the Demographic Health Survey conducted by USAID in conjunction with country governments. If the current national household surveys related to health do not include this indicator, it should be included in future surveys. Local and regional surveys can fill the gap while the national survey is revised. This difficulty is balanced by the importance of the indicator in evaluating how the pharmaceutical system is serving patients and whether patients feel that their medicine needs are being met, which is the ultimate goal of any pharmaceutical system.

The *use* element of the *pharmaceutical products and related services* component is particularly difficult to measure, especially in systems that do not have electronic prescribing, dispensing, and medical records or well-established reimbursement schemes for pharmaceutical products and services. Indicators for assessing dispensing practices and actual consumption of products by patients or administration by caregivers, including patient knowledge of and compliance with prescriptions, are lacking in the established data collection instruments that were reviewed to develop PSS Insight. Some new indicators to assess these aspects of use were piloted for PSS Insight v1.0 but were too resource intensive to collect. This area requires further research to develop suitable indicators or advance pharmaceutical management information systems to enable extraction of needed information from existing data sets.

POLICY, LAWS, AND GOVERNANCE

Policy, laws, and governance: *"The hub of coordination for the entire system, providing the framework, structures, and systems for organizing, financing, and regulating the system; and coordinating the activities of the various institutions and stakeholders to achieve the system objectives. It takes account of systems for facilitating participation, transparency, and accountability, and the promotion of ethical practices. This component affects all dimensions of access and use."*

In selecting indicators for this component, we considered current global health threats and priorities for pharmaceutical systems, including containment of antimicrobial resistance, appropriate access to and use of controlled substances, and improvement and strengthening of national regulatory capacity for

pharmaceutical products.[27,28] PSS Insight v2.0 includes some indicators not previously included in v1.0 that were selected from recently released/updated WHO tools and reporting mechanisms, including GLASS[29], the PSTA,[12] and the GBT for assessing national regulatory systems.[11]

The *policy, law, and governance* component comprises four elements: *coordination and leadership*; *pharmaceutical laws and regulations*; *pharmaceutical policies*; and *ethics, transparency, and accountability*. Indicators were selected for all elements except *pharmaceutical policies* (table 5), which was eliminated because the only indicator therein, "existence of a national medicines policy", was a structural indicator. We determined that the processes and outcomes aspects of the national medicines policy framework were assessed through the remaining indicators in the *policy, laws, and governance* section, as well as through the WHO GBT (table 5).

TABLE 5. POLICY, LAWS, AND GOVERNANCE

	Element	No.	Indicator
Policy, Laws, and Governance	Coordination and Leadership	PLG01	An institutional development plan of the national medicines regulatory authority based on the results of the GBT
		PLG02	A progress report on the institutional development of the national medicines regulatory authority published
		PLG03	Submission of national data to the Global Antimicrobial Surveillance System (GLASS)
		PLG04	Updated national action plan on the containment of antimicrobial resistance
	Pharmaceutical Laws and Regulations	PLG05	# of annual reports submitted to the International Narcotics Control Board (INCB) in the last five years
	Pharmaceutical Policies		No indicators selected–covered in WHO GBT
	Ethics, Transparency, and Accountability	PLG06	PSTA assessment score
		PLG07	Number of PSTA assessments within the last five years

[27] World Health Organization. Ten Threats to Global Health. 2019. Available at: https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019
[28] World Health Organization. Medicines and Vaccines. WHA 72, 2019. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf?ua=1
[29] World Health Organization. Global Antimicrobial Surveillance System. Available at: https://www.who.int/glass/en/

COORDINATION AND LEADERSHIP

Coordination and leadership: *"Systems for providing direction and engaging, coordinating and aligning expectations, interests and activities among state and non-state institutions and stakeholders and maximizing the use of resources."*

All but one of the indicators—"updated national action plan on the containment of antimicrobial resistance"—are new to PSS Insight v2.0. When selecting indicators for assessing coordination and leadership, we determined that measures would need to align with specific processes, goals, or stakeholder bodies in pharmaceutical systems. Due to the aforementioned pharmaceutical system goals to combat and contain antimicrobial resistance and develop the capacities of medicines regulatory authorities, indicators were selected that assessed planning in these areas and the implementation of these plans, including reporting on progress and compliance. This seemed feasible because the indicators are simple (presence or absence of planning and reporting documents), and the data are publicly available, allowing for easy and objective reporting.

PHARMACEUTICAL LAWS AND REGULATIONS

Pharmaceutical laws and regulations*: "Formulating, implementing, and enforcing comprehensive legislation to regulate activities (including controlled substance scheduling, importation, storage, prescribing, dispensing, and reporting) and pharmaceutical workforce management."*

The only remaining indicator in this element from PSS Insight v1.0 relates to compliance with International Narcotics Control Board (INCB) reporting requirements. This contributes to aligning PSS Insight with existing international tools and mechanisms and adhering to best practices around access to and control of narcotics.[30] Many of the indicators that were previously aligned with this framework were considered redundant with other elements in the *regulatory systems* component as well as with the WHO GBT.

ETHICS, TRANSPARENCY, AND ACCOUNTABILITY

Ethics, transparency, and accountability: *"Stipulation of key principles to guide ethics and the integrity of professional behavior; ethical practices; maintenance of professional competence; and compliance with regulations and accepted standards. Formal processes to consult with and inform key stakeholders, including civil society about major decisions and actions in the pharmaceutical system; and to hold entities and decision makers accountable for their decisions and actions."*

The previous version of PSS Insight used indicators related to specific bodies and processes to assess *ethics, transparency, and accountability*. PSS Insight v1.0 included indicators assessing aspects of *ethics,*

[30] International Narcotics Control Board. Monitoring and supporting governments' compliance with the international drug control treaties – Annual Reports. Available at: https://www.incb.org/incb/en/publications/annual-reports/annual-report.html

transparency, and accountability of selection, procurement, supply management, and regulatory bodies, but this was a resource-intensive approach for getting a general picture of system governance. The WHO PSTA[12] published in 2018 renders the v1.0 indicators unnecessary (PLG15–PLG26 in Annex 3) and provides validated indicators for measuring system governance.

Both of the indicators for this element, "PSTA assessment score" and "number of assessments of the PSTA within the last five years", relate to the execution of this WHO tool—the assessment score measures the outcome aspect of this element, and the frequency of the assessment's completion measures the process aspect. We hope that the tool will be used routinely to assess this critical element of pharmaceutical system governance in a holistic way. We recommend selection of the PSTA functional areas most relevant to the national context, considering that some sections may not apply to every context and therefore can be omitted.

REGULATORY SYSTEMS

***Regulatory systems**: "Focus on ensuring the safety, efficacy, and quality of pharmaceutical products and related services. This component impacts both access and use."*

Significant progress has been made in the assessment of *regulatory systems* since the development of PSS Insight v1.0; for example, the GBT is now widely used to evaluate the structure and processes of national medicines regulatory authorities.[31,32] The GBT provides an aggregated score across all assessment domains and a sub-score for individual domains. WHO encourages countries to develop institutional development plans for their national regulatory authorities according to the results of the GBT assessment. GBT assessment scores are not always published or publicly available, so PSS Insight v2.0's focus is on using these assessments to develop institutional plans and report on progress.

Rather than duplicating the GBT structure and process indicators, PSS Insight v2.0 aims to measure the progress countries have made in finalizing and publishing their institutional development plans as well as regulatory system outcomes. Most of the GBT indicators that assess national regulatory systems are focused on structures and processes with binary yes/no responses. With the goal to have PSS Insight v2.0 indicators complement the GBT, we have chosen quantitative indicators that are currently not included in the GBT.

The *regulatory systems* component of the PSS measurement framework includes six elements: *product assessment and registration*, *licensing of establishments and personnel*, *inspection and enforcement*, *quality and safety surveillance*, *regulation and oversight of clinical trials*, and *control of pharmaceutical marketing practices*. However, to avoid duplication with the WHO GBT, PSS Insight v2.0 includes only three of these:

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[31] Khadem Broojerdi A, Baran Sillo H, Ostad Ali Dehaghi R, Ward M, Refaat M, Parry J. 2020. The World Health Organization Global Benchmarking Tool: an instrument to strengthen medical products regulation and promote universal health coverage. Frontiers in Medicine, 7, 457.
[32] Guzman J, O'Connell E, Kikule K, Hafner T. 2020. The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity. BMJ Global Health, 5(8), e003181.

inspection and enforcement, *product assessment and registration*, and *quality and safety surveillance*, and focuses on outcome indicators only. Table 6 includes the indicators aligned with these elements.

TABLE 6. REGULATORY SYSTEMS

	Element	No.	Indicator
Regulatory Systems	Inspection and Enforcement	RS01	% of manufacturing facilities inspected each year
		RS02	% of distribution facilities inspected each year
		RS03	% of dispensing facilities inspected each year
	Product Assessment and Registration	RS04	Average number of days for decision making on a medicine application for registration
		RS05	% of medicines on the EML that have at least one registered product available
	Quality and Safety Surveillance	RS06	% of recorded adverse event reports that are assessed for causality
		RS07	% of samples tested that failed quality control testing
	Licensing of Establishments and Personnel		No indicators selected—covered in WHO GBT
	Regulation and Oversight of Clinical Trials		No indicators selected—covered in WHO GBT
	Control of Pharmaceutical Marketing Practices		No indicators selected—covered in WHO GBT

INSPECTION AND ENFORCEMENT

Inspection and enforcement: *"Systems for verifying and taking appropriate action to ensure that pharmaceutical establishments and personnel perform pharmaceutical operations in accordance with approved norms, standards, guidelines, and regulations. This applies to manufacturing, import control, supply chain management, and dispensing."*

While the GBT measures the existence of structures and the supporting environment for regulatory *inspection and enforcement* functions, it does not collect data on the number of inspections actually conducted. Reporting inspection functions in relation to the number of relevant facilities in each country provides information on both the size of the pharmaceutical sector within the country and the scope of inspection functions. This indicator does not have established benchmarks or targets but can provide helpful comparisons across countries with similar scale national pharmaceutical operations and can also be monitored over time for changes.

Enforcement is a difficult aspect of *regulatory systems* to assess quantitatively. PSS Insight v1.0 used "number of administrative sanctions in response to regulatory violations" to evaluate this function (Annex 3). In the absence of established benchmarks or methods for comparison, this measure is not particularly useful. The GBT includes the legal framework for enforcing regulations and addressing violations found in the course of pharmaceutical regulatory activities. We concluded that this sufficiently

captures the enforcement aspect of this element and that quantifying the outcomes of enforcement activities is not necessary.

PRODUCT ASSESSMENT AND REGISTRATION

***Product assessment and registration**: "Systems for evaluating the safety, efficacy and quality of pharmaceutical products and appropriateness of product information and issuing, varying, or revoking marketing authorizations."*

The structures and enabling environment for this pharmaceutical regulatory system function are well covered in the GBT. In addition to these structures, it is beneficial to assess the efficiency of the system using "number of days for review and approval of a registration application",[33] and the outcome of the system in terms of how well it aligns with the pharmaceutical selection function, as measured by "% of medicines on the EML with at least one registered product available." Both are important to gauge how the *product assessment and registration* element contributes to the availability of safe, effective pharmaceutical products.

Ideally, 100% of the medicines included in the EML should have at least one registered product available, and this number should either remain at 100% or increase over time if it is below this target. There is no widely accepted benchmark for "average number of days for decision making on a medicine application for registration", but this number can provide helpful comparisons between regulatory systems at similar levels of maturity and should decrease over time as assessment and registration processes become more efficient.

QUALITY AND SAFETY SURVEILLANCE

***Quality and safety surveillance**: "Systems for monitoring and taking action to ensure that pharmaceutical products in the distribution system meet specified quality standards; and detecting, evaluating, and preventing adverse reactions, medication errors, product-related quality problems and others."*

Again, the GBT comprehensively assesses the structures and processes that support the *quality and safety surveillance* element. We concluded that two additional indicators are needed to assess how well this aspect of the regulatory system is functioning—"% of adverse events that were actually assessed for causality" and "% of samples tested that failed quality control testing".

The target for causality assessment should be 100%; in a well-functioning surveillance system, every reported adverse event should be investigated for its relation to a particular pharmaceutical product so that further action can be taken if needed. The "% of samples tested that fail quality control testing" indictor does not have an established benchmark. The number should be low if the product assessment and distribution functions work properly, but it will rarely be zero because there will always be some

[33] WHO. 2007. WHO data collection tool for the review of drug regulatory systems. Practical guidance for conducting a review. Geneva: World Health Organization. Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/

level of poor-quality products circulating in the system, and the surveillance function must be sensitive enough to detect them. This indicator is most relevant when compared across countries and monitored over time.

INNOVATION, RESEARCH AND DEVELOPMENT, MANUFACTURING, AND TRADE

***Innovation, research and development, manufacturing, and trade**: "The entry point for pharmaceutical products into the system. Includes research and development of products; domestic manufacturing capacity; and intellectual property protections in national legislation and international trade agreements that shape innovation and trade and affect access to pharmaceutical products. This component primarily affects access."*

Innovation, research, and development; *manufacturing capacity*; and *intellectual property and trade* are the three elements comprising this component. It is perhaps the most complex of the seven critical system components because some of the elements are affected by factors such as international trade agreements, which are independent of the national pharmaceutical system. Further, some elements are understudied; validated indicators are not available; and data may be confidential or unavailable, particularly in low- and middle-income country contexts.

Many indicators included for this component in v1.0 of the tool were highly relevant but infeasible because of data collection challenges (e.g., list of updated domestic manufacturers is often difficult to access, see Annex 3). As such, for v.2.0 we selected three indicators that are feasible to measure objectively and that have been shown to affect access to medicines.

TABLE 7. INNOVATION, RESEARCH AND DEVELOPMENT (R&D), MANUFACTURING, AND TRADE

	Element	No.	Indicator
Innovation, R&D, Manufacturing, Trade	Innovation, Research, and Development	IRDT01	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs
	Intellectual Property and Trade	IRDT02	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?
		IRDT03	Have any of the following Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities been utilized to date: compulsory licensing provisions, government use, parallel importation provisions, the Bolar exception (10-year time frame)?
	Manufacturing Capacity		No indicator selected—lack of validated, cost-effective indicators available

INNOVATION, RESEARCH, AND DEVELOPMENT

***Innovation, research, and development**: "Priority setting, investment, and building country capacity in research and development and technological innovation to develop pharmaceutical products based on unmet/inadequately addressed public health needs."*

The indicator selected for this element concerns whether pharmaceutical innovation goals are developed and documented to address unmet public health needs. This attempts to explicitly tie

domestic research and innovation to domestic needs so that pharmaceutical development serves the country's population.

INTELLECTUAL PROPERTY AND TRADE

***Intellectual property and trade**: "Incorporating measures consistent with TRIPS into national legislation and using these provisions to promote innovation and safeguard access to affordable essential pharmaceutical products; regulating duties, tariffs for importation of pharmaceutical active ingredients, products and packaging, and non-tariff import controls."*

The trade aspect of this element is assessed through the application of import tariffs to medicines. The WHO Guidelines on Medicines Pricing[34] recommends eliminating tariffs on medicines. The target is for no tariffs to be applied because there is broad agreement that medicines tariffs are inequitable.

The impact of intellectual property laws on the availability of pharmaceuticals is largely dependent on bilateral and multinational trade agreements. The selected indicator assesses whether flexibilities stipulated in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement have been used in the country for pharmaceutical products in the last 10 years. In countries where these flexibilities are reduced or nullified by bilateral or multinational trade agreements, their use will be reduced or become non-existent, which could impact availability and/or price of medical products in the country.[35]

MANUFACTURING CAPACITY

In PSS Insight v1.0, indicators to assess *manufacturing capacity* were developed to characterize the relative sizes of domestic pharmaceutical manufacturing industries and attempt to characterize the level of sophistication of domestic manufacturing. Since established benchmarks are not available for a target volume or share of pharmaceuticals that should be produced domestically, and in many cases policies that favor the domestic market can lead to inefficiencies and inflated prices, we concluded that these measures were not useful to include. Categorizing manufacturers by their varying capabilities was resource-intensive in the pilots and involved site visits to several domestic manufacturers. The information required to compute this indicator is also considered sensitive and privately held and therefore difficult to access in most cases. Furthermore, this information is difficult to interpret, as the relationship between local manufacturing and access to medicines has not been established, and there

[34] World Health Organization. Guideline on Country Pharmaceutical Pricing Policies. Geneva, 2015: World Health Organization. Available at: https://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf

[35] Note that in some cases, the TRIPS flexibilities may not need to be used to reduce prices or otherwise influence trade, as the discussion of their use may be enough to have the intended or desired effect. This is an indicator developed for PSS Insight v1.0 and requires further research to validate. Proposed scoring and benchmarking are included in the indicator reference sheet in Annex 4.

are no standards for determining appropriate levels of domestic manufacturing of pharmaceutical products.

The indicators that have been selected for PSS Insight v2.0 do not measure *manufacturing capacity*. This is an area requiring further research to develop cost-effective and more easily accessible, validated indicators to assess. This area is expected to become more developed in the wake of COVID-19, because domestic manufacturing of certain medical products is increasingly viewed as an issue of national security.

FINANCING

***Financing**: "The management of resources to ensure the adequate and sustainable financing of the pharmaceutical product purchase, related services, and other costs associated with system functioning. Includes financial risk protection strategies and monitoring and controlling costs and prices to reduce financial barriers to accessing pharmaceutical products and related services. This component impacts access and use, but especially the availability, accessibility, and affordability dimensions."*

Measuring the degree of financial protection is key to assessing progress on universal health coverage as one of its goals is to ensure that individuals and households do not suffer financial hardship through health-related expenditures. The *financing* indicators selected for inclusion in PSS Insight v2.0 are listed in table 8.

RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION, AND PAYMENT

***Resource coordination, allocation, distribution, and payment**: "Coordinating country and donor inputs, allocating resources, and distributing adequate and sustainable funding for the purchase, contracting, and payment for pharmaceutical products, human resources, services, infrastructure, and other costs associated with system functioning."*

There is general consensus on core indicators to measure this element's resource allocation aspect, such as "% of pharmaceutical expenditure of total health expenditure"[36,37] and "proportion of out-of-pocket expenditure out of total annual pharmaceutical expenditure",[38] which are two relative measures. An absolute measure of expenditure is "per capita spending on pharmaceuticals". If the absolute expenditure is under a certain threshold, a country would not be able to cover its most basic needs to provide access to medicines.[5] What is contested, however, are the acceptable targets for many of the

[36] OECD Data. Health expenditure and financing: Health expenditure indicators. Available at: https://data.oecd.org/healthres/pharmaceutical-spending.htm
[37] Health Systems 20/20. 2012. The Health System Assessment Approach: A How-To Manual. Version 2.0. Module 6. Available at: https://www.hfgproject.org/wp-content/uploads/2015/02/HSAA_Manual_Version_2_Sept_20121.pdf
[38] USAID. Health Systems 2020. The health system assessment approach: a how-to manual. V2.0. Available at: https://www.hfgproject.org/wp-content/uploads/2015/02/HSAA_Manual_Version_2_Sept_20121.pdf

other indicators. It seems relevant for countries to set their specific targets while keeping the benchmark of countries with a well-functioning coverage scheme in mind.

PSS Insight v2.0 does not include indicators for the resource coordination, distribution, and payment aspects of this element. Validated indicators specific to these financial processes as they relate to pharmaceutical systems did not exist, and the proposed indicators included in PSS Insight v1.0 were difficult to collect. In many instances, national health accounts were not organized with the level of detail required to respond to them (Annex 3). Table 8 lists the indicators for *financing*.

TABLE 8. FINANCING INDICATORS

	Element	No.	Indicator
Financing	Resource Coordination, Allocation, Distribution, and Payment	F01	Per capita expenditure on pharmaceuticals
		F02	Share of households with catastrophic medicines-related spending
		F03	Total expenditure on pharmaceuticals (% total expenditure on health)
	Costing and Pricing	F04	Median drug price ratio for tracer medicines in the public, private, and mission sectors
	Financial Risk Protection	F05	Out-of-pocket expenditure out of total pharmaceutical expenditure
	Expenditure Tracking and Monitoring	F06	At least one national health accounts exercise including pharmaceuticals completed in the past five years

COSTING AND PRICING

***Costing and pricing**: "Systems for analyzing, monitoring, and controlling costs and prices for pharmaceutical products and services."*

This element is measured by one indicator in PSS Insight v2.0: "median (consumer) drug price ratio for tracer medicines" in various sectors. This indicator is well validated and included in routinely used tools. Consumer price information is difficult to collect because it varies by location and must be assessed at the dispensing outlet. WHO MedMon is now rolled out in many countries to promote the routine measurement of medicine prices in the public and private sectors.[3] This indicator should be computed using secondary data sources, such as MedMon. Price components for retail prices, data collection methods, and reporting will vary by country and will not allow for meaningful international comparison. Comparisons may be made across a country's sectors to show how characteristics of the dispensing outlets impact consumer prices, and trends over time should be followed with the end goal of lowering out-of-pocket expenditures on medicines.

***Financial risk protection**: "Establishment and management of systems for pooling resources and providing financial risk protection that include coverage for pharmaceutical products and related services."*

This aspect of *financing* is an essential determinant of access to pharmaceutical products and is measured by the amount of "out-of-pocket spending on pharmaceutical products out of total pharmaceutical

expenditure". It is generally agreed that health financing, including medicines, through out-of-pocket expenditure is inequitable and that public prepaid or tax-funded insurance schemes should be developed to finance them.[39,40,41] A benchmark to consider is the Organisation for Economic Co-operation and Development's (OECD) average percentage of out-of-pocket spending out of total pharmaceutical expenditure, which is 40%.[42] Measurement of out-of-pocket spending over time is an important indication of country performance on financial risk protection.

EXPENDITURE TRACKING AND MONITORING

***Expenditure tracking and monitoring**: "Systems for tracking and oversight of pharmaceutical revenue and expenditures and analyzing and using information to address inequities in access, control expenditures, and reduce inefficiencies and wastage."*

This element is measured through routine implementation of the WHO national health accounts exercise[43] and should include pharmaceutical expenditures. The system of health accounts manual and its accompanying tools comprise a framework for monitoring, analyzing, and reporting health expenditures that is used in many low- and middle-income countries. It should include pharmaceutical products,[44] which typically account for a large proportion of health expenditure.[45]

HUMAN RESOURCES

***Human resources**: "Ensures the availability of adequate numbers of appropriately trained staff for managing the supply and delivery of pharmaceutical products and related services. This component contributes to all dimensions of access and use."*

This component comprises three elements: *human resources policy and strategy*, *human resources development*, and *human resources management*. When selecting indicators for PSS Insight v2.0, we excluded indicators for *human resources policy and strategy* because they pertained more to the

[39] WHO. Health financing – out-of-pocket payments, user fees, and catastrophic expenditures. Available at: https://www.who.int/health_financing/topics/financial-protection/out-of-pocket-payments/en/
[40] World Bank Group – Development Economics. Out-of-pocket expenditures on health – a global stocktake. April 2019. Available at: http://documents1.worldbank.org/curated/en/404051554751713745/pdf/Out-of-Pocket-Expenditures-on-Health-A-Global-Stocktake.pdf
[41] WHO and World Bank. Global Monitoring Report on Financial Protection in Health 2019. Available at: https://www.who.int/healthinfo/universal_health_coverage/report/fp_gmr_2019.pdf?ua=1
[42] OECD. Health at Glance 2015. Available at: https://www.oecd-ilibrary.org/docserver/health_glance-2017-68-en.pdf?expires=1578252636&id=id&accname=guest&checksum=D579793EF012FC0F51CBE79BDB8D8BD2
[43] World Health Organization. Manual – System of Health Accounts. 2011. Available at: https://apps.who.int/nha/database/DocumentationCentre/GetFile/55060821/en
[44] WHO. National health accounts: concepts, data sources and methodology. 2002. Available at: https://www.who.int/health-accounts/documentation/en/NHA_concepts_datasources_methodology.pdf
[45] Xu K, Soucat A, Kutzin J, et al. Public Spending on Health: A Closer Look at Global Trends. Geneva: World Health Organization; 2018 (WHO/HIS/HGF/HFWorkingPaper/18.3). Licence: CC BY-NC-SA 3.0 IGO.

governance aspects of the pharmaceutical system and were structural in nature (Annex 3). The selected indicators for the *human resources* component are listed in table 9.

Neither of the selected indicators captures aspects of the pharmaceutical workforce outside of pharmaceutical service providers, such as pharmacists or pharmacy technicians. There are several ongoing efforts to professionalize and measure the effectiveness of other categories of workers within the pharmaceutical systems (i.e., those that work in pharmaceutical supply chains[46] or within the regulatory system).[4] We rejected indicators that could be disaggregated by worker types across pharmaceutical systems (e.g., "staff turnover rate", which could be applied to multiple segments of the pharmaceutical system) as they did not meet our selection criteria. We determined that other components of the tool captured the effective functioning of those agencies and aspects of pharmaceutical systems, and therefore, focusing on pharmaceutical service providers in this component was most essential. Future iterations of this tool and other efforts to assess pharmaceutical systems should carefully consider the explicit inclusion of human resources across pharmaceutical systems where appropriate indicators are available.

TABLE 9. HUMAN RESOURCES

	Element	No.	Indicator
Human Resources	Human Resource Development	HR01	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs
	Human Resource Management	HR02	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant
	Human Resources Policy and Strategy		No indicators selected—no process or outcome indicators available

HUMAN RESOURCE DEVELOPMENT

***Human resource development**: "Development and maintenance of a skilled pharmaceutical workforce of multiple levels including basic, post-basic and continuous education; systems for authorizing and monitoring educational facilities and training programs to ensure that education is provided in accordance with approved norms, standards, guidelines, and regulations."*

The indicator selected to measure this element pertains to the quality of the country's pre- and in-service pharmacy training programs, namely that governing bodies are tasked with accrediting these programs. We considered indicators to assess the number and types of programs, number of graduates, and use of in-service training by pharmaceutical personnel; however, they were not well defined, difficult

[46] People That Deliver. Building Human Resources for Supply Chain Management – Theory of Change. Available at: https://peoplethatdeliver.org/ptd/sites/default/files/about_us_files/PtD%20Theory%20of%20Change%20Narrative%20Report%20A4%200219_web.pdf

to collect, or redundant when considered alongside the indicator selected for *human resource management*.

HUMAN RESOURCE MANAGEMENT

***Human resource management**: "Systems for registration/counting, recruiting, hiring, deploying, evaluating, supporting, and retaining the pharmacy workforce through the integrated use of data, policy, and practice."*

In general, health systems only report on physicians and nurses per population and not on other human resources for health. However, experts agree that the number of trained human resources is a feasible and meaningful measure to assess the structural capacity of health and pharmaceutical systems.

The number of pharmacy professionals varies by country. For high-income countries, WHO has reported a ratio of at least 1 pharmacist per 1,000 inhabitants.[47] The International Federation of Pharmacists reports an average of 7 pharmacists per 10,000 inhabitants in a sample of 75 countries for which data are available. Rather than targets, these figures provide a sense of how countries fall across a spectrum of income levels and system configurations. Countries should look to their peers to develop their own goals and monitor trends to determine whether to adjust country-specific policies to better develop or distribute pharmaceutical human resources.

INFORMATION

***Information**: "The generation and dissemination of timely and reliable information, which is the foundation for decision making, policy development and implementation, governance and regulation, and planning and allocation of financial, infrastructure, and human resources in the pharmaceutical system. This component impacts both access and use."*

Traditionally, administrative health information systems have not routinely collected information on medicines, which has caused uneven quality of the information available on medicines availability, price, and use. New electronic administrative and clinical information systems may be able to fill this gap if medicine information is incorporated and quality is assured through regular auditing.

The information component comprises three elements: *information policy and data standardization*; *data collection, processing, and dissemination*; and *use of information for decision making*. In PSS Insight v2.0, indicators for *data collection, processing, and dissemination* have been omitted. These indicators were specific to particular sub-systems, functions, and processes and were difficult to generalize to the entire pharmaceutical system or across pharmaceutical systems globally (Annex 3). Instead, we prioritized a set of more generalizable indicators, including how data are used to inform decision making processes. Table 10 lists the selected indicators.

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[47] World Health Organization. Pharmaceutical workforce density. Available at: https://www.who.int/gho/health_workforce/pharmaceutical_density_text/en/

TABLE 10. INFORMATION INDICATORS

	Element	No.	Indicator
Information	Information Policy and Data Standardization	IM01	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information
	Use of Information for Decision Making	IM02	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection
	Data Collection, Processing, and Dissemination		No indicators selected—process and outcome indicators were more relevant to *information policy* and *use of information for decision making*

INFORMATION POLICY AND DATA STANDARDIZATION

***Information policy and data standardization**: "Policy, legislation, regulation, and guidelines for secure information collection, transmission, management, and storage; coordinating stakeholder roles and inputs; data confidentiality and security; selection of core indicators; and use of standards for data."*

"Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information" measures this element and has an assessment question that specifies reporting of core pharmaceutical system indicators (included in the indicator reference sheet in Annex 4). This indicator is general enough to account for variability between pharmaceutical systems but requires that data systems collect and report pharmaceutical-specific indicators and that countries set forth standards to administer and maintain this reporting system. High-income countries have more sophisticated data monitoring and reporting systems because they are electronic. The OECD is a leader in collecting and disseminating pharmaceutical system information.[36] The WHO Southeast Asian Regional Office has demonstrated that it is possible to present relevant pharmaceutical-sector information with far fewer resources and less experience,[48] although we acknowledge that this is more difficult with less-advanced systems for collecting, analyzing, and reporting data.

USE OF INFORMATION FOR DECISION MAKING

***Use of information for decision making**: "Routine and extraordinary use of information for policy and decision making, governance, regulation, monitoring system performance, and resource planning and allocation to support system functioning and promote transparency."*

When we considered the measurement framework and its goals of *access* and *use*, we determined that the most important process to assess through this element is medicine selection. Selection criteria for medicines are often elaborated in publicly available documents, such as terms of reference for selection committees or in the registration application documents for marketing authorization.

[48] World Health Organization Southeast Asian Regional Office. Access to medical products in the South-East Asia Region 2019: Review of progress. Available at: https://apps.who.int/iris/handle/10665/326829

KEY SYSTEM ATTRIBUTES AND PRIMARY SYSTEM OUTCOMES

These concepts are nascent measurement efforts for pharmaceutical systems specifically and health systems more generally. In PSS Insight v1.0, we intended to use indicators from the seven critical system components to measure key system attributes and primary system outcomes. By repurposing and recombining data from across different components of the tool, we hoped to assess the *performance* and *resilience* of pharmaceutical systems and provide a more complete picture of the system outcomes of *access* and *use* by bridging data from multiple components. We found that the component indicators were insufficient to fully assess these concepts, and we developed seven unique indicators to round out the data used to measure system attributes and outcomes. These indicators are included at the end of the indicator table in Annex 3, labelled OA 1–OA 7.

These new indicators proved challenging to collect and apply in our piloting activities, and as a result, they remain unvalidated and require refinement. For these reasons, we did not select these indicators to include in PSS Insight v2.0. We selected the remaining outcome and attribute indicators from the seven critical system component indicators for PSS Insight v2.0, and supplemented them with data collected through other mechanisms, such as the WHO GBT,[4] WHO MedMon,[3] and SDG indicators for assessing progress toward SDG 3.8.[13,20]

PERFORMANCE

Performance consists of three dimensions: *efficiency*, *quality and safety*, and *responsiveness*. Table 11 includes definitions and associated measures for these dimensions.

We pulled the indicators for *efficiency* exclusively from the *pharmaceutical products and related services* component. They examine the efficiency of pharmaceutical procurement (in terms of prices paid, PS03) and pharmaceutical distribution (in terms of product losses, PS05). We considered measures for efficiency relating to *regulation of pharmaceutical products* and *human resource management* as well but did not find relevant indicators for these components. As these concepts are developed through further research, it is important to consider system efficiency as a whole, not just from the perspective of the supply chain.

The dimension of *quality and safety* is assessed through the "number of samples tested that failed quality control testing" (RS07). While this indicator is not associated with a specific target or benchmark, comparisons among countries and monitoring of trends can give countries a sense of their own performance and help them set their own goals and targets. In addition to this indicator from the *regulatory systems* component, assessors should use the overall level of the system according to the latest GBT assessment to gauge how the system regulates the quality and safety of pharmaceutical products and services. We propose that countries aim to obtain a level 4 and include specific goals and interventions to progress toward this target in their institutional development plans following the completion of the GBT assessment.

RESILIENCE

The concept of *resilience* in pharmaceutical systems is quite nascent in research. No validated indicators were found in the literature that were specific to pharmaceutical system resilience at the time PSS Insight v1.0 was developed, and subsequent searches have not yielded additional indicators. We

developed measures for piloting that were mapped to the defined dimensions of system *resilience*, but due to the lack of available data and the fact that these indicators have not been formally validated, we selected only one indicator for *resilience* in PSS Insight v2.0. PS04, "mean % availability across a basket of medicines", may be used to assess the *diverse* dimension of *resilience* if the basket of medicines includes a variety of medicines for a variety of conditions that serve a variety of patient groups. This application of the concept of *diversity* is quite vague, since PSS Insight does not explicitly set parameters for countries' tracer medicines, and there is no established threshold for what constitutes variety or diversity in the construction of a tracer list. Nonetheless, countries should keep diversity in mind when developing their tracer lists for routine monitoring to ensure that they are promoting the availability of an array of pharmaceutical products that serve their populations as a whole. Further research in this area is needed to develop valid, reliable indicators.

TABLE 11. KEY SYSTEM ATTRIBUTES

	Dimension	Definition	Indicator(s)
Performance	**Efficiency**	The capacity to produce the maximum output for a given input. Allocative efficiency refers to using the optimal mix of resources to maximize benefits to society. Technical efficiency refers to using the least amount of resources to produce a given mix of goods and services.[49]	% of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement (PS03)
			Product losses by value due to expired medicines or damage or theft per value received (%) (PS05)
	Quality and Safety	An essential component of access cutting across all dimensions that specifically applies to products in terms of their safety, efficacy, and cost-effectiveness.[50]	% of samples tested that failed quality control testing (RS07)
			Overall GBT maturity level
	Responsiveness	Nonclinical aspects related to the way individuals are treated and the environment in which they are treated.[51] Domains of responsiveness include respect for autonomy, choice of care provider, respect for confidentiality, communication, respect for dignity, access to prompt attention, quality of basic amenities, and access to family and community support.	No indicators selected

[49] WHO Terminology Information System [online glossary] Available at: https://www.who.int/healthsystems/hss_glossary/en/

[50] Management Sciences for Health. 2012. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health

[51] Valentine NB, de Silva A, Kawabata K, Darby C, Murray CJL, Evans DB. 2003. Health system responsiveness: concepts, domains and measurement. In Murray CJL, Evans DB (Eds). Health systems performance assessment: debates, methods and empiricism. Geneva: World Health Organization. Available at: http://www.who.int/responsiveness/papers/MCSS_Analytical_Guidelines.pdf

	Dimension	Definition	Indicator(s)
Resilience	**Aware**	Resilient health systems are aware of the potential health threats and risks to the population and knowledge of the current human, physical, and information assets that highlight areas of strength and vulnerability. This requires effective health information systems and epidemiological surveillance networks.[52]	No indicators selected
	Diverse	Has the capacity to address a broad range of health challenges rather than a select few.[52]	Mean % availability across a basket of medicines (PS04)
	Self-Regulating	Can contain and isolate health threats while delivering core health services and avoiding cascading disruptions throughout the system.[52]	No indicators selected
	Integrated	Brings together diverse stakeholders and ideas to formulate solutions and initiate actions, with clear channels for communication and coordination.[52]	No indicators selected
	Adaptive	Has the ability to transform in ways that improve function in times of crises and adapt to epidemiological and demographic changes in normal times.[52]	No indicators selected

ACCESS

Access to pharmaceutical products has been well-studied and measured.[2,3,21,37] The dimensions of *access* are *affordability, acceptability, accessibility,* and *availability* (table 12).

Affordability may be assessed using indicators F04 and F02 and supplemented by WHO's MedMon tool. This tool assesses both *availability* and *affordability* and is useful for assessing both of these dimensions of *access*. SDG indicator 3.8.2 may be used where data are not available to compute indicator F02. SDG indicator 3.b.3, "proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis",[20] appears throughout the *access* measures and is relevant to assess medicine *availability*, *accessibility*, and *affordability*. This indicator represents the gold standard for reporting on these dimensions of *access*. Where this indicator is not available, we have recommended alternative indicators to assess each dimension individually.

Cultural acceptability or satisfaction is quite important to consider when assessing access to medicines but very difficult to measure. Patient satisfaction indicators from the literature pertain to health services more generally, rather than to pharmaceuticals specifically, or are no longer routinely collected in

[52] Kruk ME, Myers M, Varpilah ST, Dahn BT. 2015. What is a resilient health system? Lessons from Ebola. The Lancet, 385(9980), 1910–1912.

existing data collection instruments.[53,54] These data should be added to national household surveys where possible, but based on the lack of a validated indicator specific to satisfaction with pharmaceutical products or services, we did not select an indicator for this dimension.

Geographical accessibility and *availability* were indistinct when selecting indicators. For definitional purposes, they are discrete concepts. However, when we examined available measures, we determined that the same indicators should apply for both dimensions. Because it is measured at the health facility level or dispensing point, PS04, "mean % availability across a basket of medicines", assesses both the *availability* at the point of service and the *geographical accessibility* when facility characteristics are taken into consideration (e.g., local population density, availability by geographic region). As stated above, WHO's MedMon tool assesses both product *availability* and *affordability* in a standardized way. Relevant indicators from this tool and reports should be used to assess *availability* of medicines according to the procedures established for that tool. SDG indicator 3.8.1, "coverage of essential health services", is not specific to pharmaceutical services but is monitored globally and gives a general picture of health system coverage. Because pharmaceutical products and services are accessed through the health system writ large, lack of coverage for essential health services indicates lack of access to pharmaceutical services as well.

Equity is an important consideration when assessing these dimensions of *access*, though we were unable to find validated indicators that met our selection criteria. We propose assessing *equity* through the disaggregation of relevant patient- or population-level indicators (e.g., "% population with unmet medicine needs", "out of pocket expenditure on medicines out of total medicines expenditure"); patient characteristics (e.g., gender, race/ethnicity, language, wealth quintile, education level); facility-level indicators (e.g., "population per licensed pharmacist, pharmacy technician, or pharmacy assistant"); or facility characteristics (e.g., region/district, urban/rural/peri-urban, funding source, facility level) as appropriate.

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[53] MSH, Center for Pharmaceutical Management. 2003. Access to Essential Medicines: Tanzania, 2001. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health.
[54] MSH, Center for Pharmaceutical Management. Uganda Inspection, Monitoring, and Supervision Model. Prepared for the East African Drug Seller Initiative Project. Management Sciences for Health and the Bill & Melinda Gates Foundation.

TABLE 12. PRIMARY SYSTEM OUTCOMES

	Dimension	Definition	Sub-Dimension and Definition	Indicator(s)
Access	**Affordability**	The relationship between the prices of the products and services and the user's ability to pay for them.[50] Accounts for the financial risk protection goals of the health system.	**Equity in Access (Affordability)** The extent to which a system deals fairly with all concerned.[55]	Median (consumer) drug price ratio for tracer medicines in the public, private, and mission sectors (F04)
				MedMon survey outputs on affordability
				Population with household expenditures on health greater than 10% of total household expenditure or income (F02) or SDG indicator 3.8.2: Proportion of population with large household expenditures on health as a share of total household expenditure or income
				SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
	(Cultural) Acceptability (or Satisfaction)	The relationship between the user's attitudes and expectations about the products and services and the actual characteristics of the products and services.[50]		No indicators selected
	(Geographical) Accessibility	The relationship between the location of the product or service and the location of the eventual user of the product or service.[50]	**Equity in Access (Geographical Accessibility)** The extent to which a system deals fairly with all concerned.[55]	Mean % availability across a basket of medicines (PS04)
				MedMon survey outputs on availability
				SDG indicator 3.8.1: Coverage of essential health services
				SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis

[55] Kelley E, Hurst J. 2006. Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing. http://dx.doi.org/10.1787/440134737301

	Dimension	Definition	Sub-Dimension and Definition	Indicator(s)
	Availability	The relationship between the type and quantity of product or service needed and the type and quantity of product or service provided.[50]	**Equity in Access (Availability)** The extent to which a system deals fairly with all concerned.[55]	Mean % availability across a basket of medicines (PS04)
				MedMon survey outputs on availability
				SDG indicator 3.8.1: Coverage of essential health services
				SDG indicator 3.b.3: Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
Use	**Prescribing**	% medicines prescribed from EML or reimbursement list (PS08)		
		% medicines prescribed as generics (PS09)		
		% antibiotics prescribed in outpatient settings (PS10)		
	Dispensing/Sale or Supply	No indicators selected		
	Consumption/End-Use	No indicators selected		
	General Indicator for Use	% population with unmet medicine needs (PS11)		

USE

Appropriate use of pharmaceutical products and services is a fundamental aim of properly functioning pharmaceutical systems.[56] Even where *access* to pharmaceutical products is unobstructed, *use* may remain a challenge. Getting the correct pharmaceutical product to the correct patient at the correct time and ensuring that the patient consumes the product correctly requires multiple functioning structures and processes to ensure this outcome. As defined, *use* consists of three dimensions: *prescribing, dispensing,* and *consumption/end-use.* Selecting indicators for *use* as a system outcome carries the same challenges as selecting indicators for the *use* element of the *pharmaceutical products and related services* component—namely, that validated, feasible indicators for assessing dispensing and consumption practices are not available. These areas are essential to fully measure appropriate use of pharmaceuticals but require further research to develop measures that may be practically implemented consistently.

To assess *use*, we selected the *prescribing* indicators, PS08–PS10. No indicators were selected for *dispensing* or *consumption/end-use.* The overall indicator "% population with unmet medicine needs" (PS11) was selected to assess *use* more broadly. The challenges in collecting the data required to compute this indicator are discussed in the *pharmaceutical products and related services* sub-section of the results section. While we acknowledge these issues and challenges, we maintain that this indicator is foundational to assessing the primary system outcomes of the pharmaceutical system. Countries should aspire to collect these data through routine household surveys to identify failures in meeting system goals to provide access to and promote appropriate use of pharmaceutical products and services nationally.

DISCUSSION

Characterizing and measuring pharmaceutical systems and their strengthening is a complex and challenging undertaking. Many aspects of pharmaceutical systems have not been previously defined or measured. When selecting indicators to align with the measurement framework, we sought to be as objective as possible while balancing practical concerns (data availability, resource intensity of data collection) with the need to capture enough information to adequately measure the concepts laid out in the framework and to guide pharmaceutical system interventions. We encountered limitations in the availability of validated, relevant indicators that are routinely collected over time and publicly available, particularly in the areas of *human resources*, *financing*, *information*, and *use* of pharmaceutical products. It is essential that pharmaceutical systems data be incorporated into routine data collection instruments to reduce some of the data collection burden and adequately measure pharmaceutical systems and their role within health systems. We have highlighted these gaps throughout the report and recognize the need for further research to clarify these areas and develop appropriate measures. Further, with a smaller tool, we acknowledge limitations in its ability to capture interactions among various components. This was a challenge even with a much larger set of indicators, as a conceptual framework

[56] WHO. The pursuit of responsible use of medicines: sharing and learning from country experiences. 2012. Available at: https://www.who.int/activities/promoting-rational-use-of-medicines/

for combining measures across tools meaningfully does not exist. With a reduced number of indicators, it is even more difficult to assess cross-cutting areas.

The key system attributes and primary system outcomes are also challenging to assess holistically. Nascent concepts of *performance* and *resilience* require further research to develop or adapt appropriate measures to the pharmaceutical system context. Measurement of *use* remains challenging due to the effort required to assess patient-level phenomena, such as consumption, and many aspects such as satisfaction, equity, and accessibility require complex mapping of household characteristics against available pharmaceutical products and services at health facilities. These challenges can only be overcome by developing simpler proxy measures or using sophisticated information systems that are capable of collecting and reporting this level of data routinely.

In PSS Insight v2.0, we have moved away from composite indicators and scoring for each component and have instead proposed targets or benchmarks (where they are supported by the literature) for individual indicators. For some indicators, we suggest comparing across countries and monitoring trends over time, so that countries may set their own goals and targets for improvement. We determined that this was the most appropriate way to analyze and report results, given the reduced number of indicators and the lack of a validated framework for combining measures across elements.

CONCLUSION

Describing and defining pharmaceutical systems and pharmaceutical systems strengthening is increasingly relevant as countries work toward universal health coverage. Global targets and benchmarks such as the United Nations SDGs continually reframe goals and how we assess progress toward them. PSS Insight v2.0 aims to provide a holistic framework for measuring pharmaceutical systems strengthening within this shifting context, across pharmaceutical system functions, and considering a substantial body of work that has sought to measure aspects of pharmaceutical systems for the last several decades. This undertaking has highlighted several areas where more work is needed to develop indicators and to set targets or benchmarks to evaluate progress and allow for meaningful comparisons across countries and over time. Although PSS Insight is intended as a high-level tool that is practical to implement at the country level, including in low- and middle-income country settings, we acknowledge that numerous indicators are aspirational for many contexts. The PSS Insight initiative is iterative—as these indicators are used and countries improve their data collection efforts, we expect to develop the tool further to capture this progress. Our hope is that as pharmaceutical system data are captured regularly and these indicators are included in monitoring systems that the tool will become increasingly practical to use routinely, enabling consistent reporting across countries.

ANNEX 1 – INDICATOR COMPARISON ACROSS INITIATIVES

This Annex includes a comparison of indicators included in PSS Insight v1.0 and v2.0 alongside indicators from the WHO Access Dashboard[57] and the Lancet Commission on Essential Medicines Policies[58]

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Selection	PS 1	Existence of an active national committee responsible for managing the process of maintaining a national essential medicines list				
Pharmaceutical Products & Services	Selection	PS 2	Are there clearly written guidelines for the selection process for including or deleting medicines from the national EML?				
Pharmaceutical Products & Services	Selection	PS 3	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection				

[57] Monitoring the components and predictors of access to medicines. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO.
[58] Wirtz, Hogerzeil & Gray. Essential Medicines for Universal Health Coverage. The Lancet 2017; 389 (10067): 403–476.

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Selection	PS 4	Existence of a national essential medicines list and a national list of medicines for reimbursement published within the past five years	PS01	Existence of a national essential medicines list published within the past five years		
Pharmaceutical Products & Services	Selection			PS02	Existence of a reimbursement list published within the past two years		
Pharmaceutical Products & Services	Selection	PS 5	What is the total number of pharmaceuticals on the national EML?				
Pharmaceutical Products & Services	Procurement	PS 6	Existence of a procurement pre- or post- qualification process for suppliers and products				
Pharmaceutical Products & Services	Procurement	PS 7	Formal written procurement policy in place				
Pharmaceutical Products & Services	Procurement	PS 8	Existence of formal SOPs for conducting procurement of pharmaceuticals				
Pharmaceutical Products & Services	Procurement	PS 9	Value of medicines purchased through competitive tender, out of value of medicines purchased.				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Procurement	PS 10	Percentage of purchase orders/contracts issued as emergency orders				
Pharmaceutical Products & Services	Procurement	PS 11	Is procurement based on a formal quantification of medicines needs?				
Pharmaceutical Products & Services	Procurement	PS 12	Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement	PS03	% of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement	Ratio of median price of products procured and the international median reference price	Median public sector procurement or reimbursement price of essential medicines as a percentage of international reference price
Pharmaceutical Products & Services	Procurement	PS 13	Order fill rate (correct quantities and products delivered in good condition) – Central Level			% of orders received on time in full (OTIF)	
						% of invoices paid on-time	
						% of procurement based on EML (core)	
Pharmaceutical Products & Services	Distribution	PS 14	Percentage of storage facilities meeting acceptable storage conditions				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Distribution	PS 15	Percentage of storage facilities employing proper inventory management practices				
Pharmaceutical Products & Services	Distribution	PS 16	Is there a system in place to track the movement of pharmaceuticals from a warehouse to a service delivery point?				
Pharmaceutical Products & Services	Distribution	PS 17	Average percentage of stock records that corresponds with physical counts for a set of tracer medicines in storage and health facilities				
Pharmaceutical Products & Services	Distribution	PS 18	Mean % availability across a basket of medicines	PS04	Mean % availability across a basket of medicines		Median availability of a basket of essential medicines in the public and private sectors (%)
						Average stockout duration (in nr of days)	
Pharmaceutical Products & Services	Distribution	PS 19	Product losses by value due to expired medicines or damage or theft per value received (percentage)	PS05	Product losses by value due to expired medicines or damage or theft per value received (%)		
Pharmaceutical Products & Services	Distribution	PS 20	Order Lead Time				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Use	PS 21	Existence of legal provisions to allow/encourage generic substitution in all sectors				
Pharmaceutical Products & Services	Use	PS 22	Existence of national STGs and mechanisms for regular updating of STGs				
Pharmaceutical Products & Services	Coordination and Leadership	PS 23	Multidisciplinary national taskforce or working group for Antimicrobial Resistance (AMR) containment exists				
Pharmaceutical Products & Services	Coordination and Leadership	PS 24	Existence of a national Antimicrobial Resistance strategy				
Pharmaceutical Products & Services	Use	PS 25	Medicines use reviews and 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.	PS06	% generic medicines out of total market volume		Market share of multi-source medicines (branded and unbranded generic products) by volume and value in public and private sector
Pharmaceutical Products & Services	Use			PS07	Defined daily dose (DDD) for antimicrobials (per 1000 population)		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Pharmaceutical Products & Services	Use	PS 26	Percentage of encounters at health facilities at which health care staff members explained the dose and frequency of the prescribed medicines to the patient or caregiver				
Pharmaceutical Products & Services	Use	PS 27	Optimal level of medicines prescribing indicators (includes medicines prescribed from reimbursement list/EML, polypharmacy, injections, antibiotics, prescription by generic name)	PS08	% Medicines prescribed from an EML or reimbursement list	% of prescriptions based on EML	
Pharmaceutical Products & Services	Use			PS09	% Medicines prescribed as generics		
Pharmaceutical Products & Services	Use			PS10	% Antibiotics prescribed in outpatient settings		
							Quality of prescribing in public and private sector
Pharmaceutical Products & Services	Use			PS11	% population with unmet medicine needs		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
						% of medicines dispensed based on EML	
Pharmaceutical Products & Services	Use	PS 28	Percentage of patients surveyed that know correct information about their medications				
							Existence of an independent national programme or institute promoting scientifically sound and cost-effective use of medicines (yes/no)
							Stakeholder representation including civil society and patient representatives in the independent programme or institute is specifically provided for (yes/no)
							Adherence to national standard treatment guidelines for common conditions in public and private sectors
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 1	Existence of a published national medicines policy				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 2	Is there a National Medicines Policy (NMP) implementation plan [or pharmaceutical sector strategic plan] that sets activities, responsibilities, budget and timeline?				
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 3	Regular evaluation of policy impacts as part of a policy process				
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 4	Is the NMP integrated into or included in the published/official national health policy/plan?				
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 5	Has there been an evaluation of the national medicines policy in the last 5 years?				
Policy, Laws, and Governance	Coordination and Leadership	PLG 6	Platform or strategy exists for the coordination of pharmacovigilance activities at the national level				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Coordination and Leadership			PLG01	An institutional development plan of the national medicines regulatory authority based on the results of the GBT exists		
Policy, Laws, and Governance	Coordination and Leadership			PLG02	A progress report on the institutional development of the national medicines regulatory authority published		
Policy, Laws, and Governance	Coordination and Leadership	PLG 7	Multidisciplinary national taskforce or working group for Antimicrobial Resistance (AMR) containment established with a documented Terms of Reference (TOR) that met at least once in past year				
Policy, Laws, and Governance	Coordination and Leadership			PLG03	Submission of national data to the Global Antimicrobial Surveillance System (GLASS)		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Coordination and Leadership	PLG 8	There is organized stakeholder engagement throughout the entire policy/strategic planning process				
Policy, Laws, and Governance	Coordination and Leadership	PLG 9	Existence of an intersectoral committee for pharmaceutical sector policy and planning				
Policy, Laws, and Governance	Coordination and Leadership	PLG 10	Existence of a national Antimicrobial Resistance strategy	PLG04	Updated National Action Plan on the containment of antimicrobial resistance		
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 11	Existence of a comprehensive pharmaceutical law [or legislative framework]				
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 12	Is your country a signatory to the international conventions on the control of narcotics, psychotropic substances and precursors?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 13	# of annual reports submitted to the International Narcotics Control Board (INCB) in the last 5 years	PLG05	# of annual reports submitted to the INCB in the last five years		
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 14	Existence of a National Drug or Medicines Regulatory Authority responsible for the promulgation and enforcement of regulations				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 15	Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 15	Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 16	Are there legal provisions requiring transparency and accountability in administrative decision making for public pharmaceutical sector agencies				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 17	Are there written guidelines or a policy on conflicts of interest with regard to the following functions:				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 18	Is there a formal appeals [and review] system for applicants who have their medicine applications rejected [for licensing, selection, registration, procurement]?				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 19	Percentage of pharmaceutical related commissions and bodies with stakeholder representation				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 20	Number of procurement audits conducted (complete and published) in the last 5 years				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 21	Does the government use transparent and explicit procedures for procurement of pharmaceutical products?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 22	Publication of proceedings or minutes by pharmaceutical commissions and committees.				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 23	Number of COI statements submitted annually and at each meeting of any pharmaceutical commission or committee, and included in the record of the meeting				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 24	Number of complaints received and responded to within specified timeline				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 25	Reports of audits are published and publicly available (as requested)				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 26	Percentage of regulatory reviews and appeals completed within timeframe				
Policy, Laws, and Governance	Ethics, Transparency, and Accountability			PLG06	PSTA assessment score		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Policy, Laws, and Governance	Ethics, Transparency, and Accountability			PLG07	Number of PSTA assessments within the last five years		
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 1	Are there controls on medicine promotion based on regulations?				
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 2	Is there an entity or committee responsible for monitoring and enforcing the provisions on medicine promotion?				A legally enforceable code of marketing practice is in place and implemented (yes/no)
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 3	Percentage of identified advertisement violations for which sanctions were implemented				
Regulatory Systems	Inspection and Enforcement	RS 4	Are there legal provisions to inspect premises and collect samples?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Regulatory Systems	Inspection and Enforcement	RS 5	Documented procedures are available and implemented for different inspection activities, as for inspection preparation, conduction and/or reporting.				
Regulatory Systems	Inspection and Enforcement	RS 6	Number of licensed or registered medicines retail outlets per government medicines inspector				
Regulatory Systems	Inspection and Enforcement	RS 7	Percentage of manufacturing, distribution, and dispensing facilities inspected each year	RS01	% of manufacturing facilities inspected each year		
Regulatory Systems	Inspection and Enforcement			RS02	% of distribution facilities inspected each year		
Regulatory Systems	Inspection and Enforcement			RS03	% of dispensing facilities inspected each year		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Regulatory Systems	Inspection and Enforcement	RS 8	Percentage of inspection violations at retail or dispensing outlets that have been addressed with administrative measures or sanctions			% inspection finding violations for which regulatory and legal action were taken	
						% of products inspected with valid market authorization	
Regulatory Systems	Licensing	RS 9	There are legal provisions for licensing of pharmaceutical facilities throughout the pharmaceutical system and based on Good Practices (GXP) compliance.			% licensed establishments compliant with GXP	
Regulatory Systems	Licensing	RS 10	The updated list/database of all licensed facilities is regularly published and publicly available			% licensed premises that have valid licences within the relevant local legislation timeframes	
Regulatory Systems	Licensing	RS 11	Percentage of license applications for new retail and dispensing outlets that are reviewed within the specified period of time				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Regulatory Systems	Product Assessment and Registration	RS 12	There is a defined structure with clear responsibilities to conduct registration and marketing authorization activities.				
Regulatory Systems	Product Assessment and Registration	RS 13	Are there legal provisions for marketing authorization? (that are publicly available)				
Regulatory Systems	Product Assessment and Registration	RS 14	Annually Updated list of all medical products granted marketing authorization is regularly published and publicly available.				
Regulatory Systems	Product Assessment and Registration	RS 15	Average number of days for decision making on a medicine application for registration	RS04	Average number of days for decision making on a medicine application for registration	Average days for review and granting MA for generic medicines	
Regulatory Systems	Product Assessment and Registration	RS 16	Percentage of medicines on the EML that have at least one registered product available.	RS05	% of medicines on the EML that have at least one registered product available.	% of EML with at least 3 registered products	

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
							Number of national approvals of new chemical entities and generic products based on a Common Technical Document without any additional national requirements for quality, efficacy, and safety, as a percentage of total new chemical entities and generic approvals
							Current and accumulated total number of medicines included in the WHO/UN Prequalification Programme (disaggregated by unique strength or dosage and pharmaceutical classes)
Regulatory Systems	Product Assessment and Registration	RS 17	Number of medicines registered				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
							Number of core National Medicine Regulatory Agency performance indicators (listed in panel 12) that are independently assessed and publicly reported
Regulatory Systems	Quality and Safety Surveillance	RS 18	Are there any laws, regulations, policies, programmes or procedures for detecting and combating substandard or falsified medicines?				
Regulatory Systems	Quality and Safety Surveillance	RS 19	Existence of a pharmacovigilance system with monitoring and reporting mechanisms				
Regulatory Systems	Quality and Safety Surveillance	RS 20	Percentage of recorded adverse event reports that are assessed for causality	RS06	% of recorded adverse event reports that are assessed for causality		
						No. adverse events following immunization per million population	

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Regulatory Systems	Quality and Safety Surveillance	RS 21	Percentage of total samples collected (planned or otherwise) that were tested				
Regulatory Systems	Quality and Safety Surveillance	RS 22	Number of decisions taken based on product testing results out of total number of samples tested in the reference year				
							Number of pharmacovigilance reports for medicines submitted to the Uppsala Monitoring Centre per million population per year
							Results of quality testing are publicly available
Regulatory Systems	Quality and Safety Surveillance	RS 23	Percentage of samples tested that failed quality control testing	RS07	% of samples tested that failed quality control testing	Ratio of drugs that failed quality testing against the number that were sampled	Number of failed quality control samples of essential medicines procured as a % of total number of samples of procured products tested per year (per procurement agency)

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 24	Legal provisions and/or regulations for clinical trials (CT) oversight exist.				
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 25	Existence of national guidelines on Good Clinical Practice				
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 26	How many inspections of clinical trials were conducted in the last calendar year?				
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 27	Number of decisions taken (approvals, refusals, suspensions) on clinical trials applications in the reference year				
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 1	Existence of a national science and technology or innovation policy				
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 2	Existence of a national or regional health research policy				
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 3	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs	IRDT01	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
							Share of the research pipeline reflecting new molecules for diseases within the scope of the ATM Index461 (per company)
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 4	Number of pharmaceutical manufacturing companies located in country				
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 5	Percentage of pharmaceutical manufacturing sites with GMP certification				
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 6	Medicines production capability in the country				
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 7	Percentage of products on EML that are currently manufactured or co-manufactured within the country				
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 8	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?	IRDT02	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 9	Which of the following TRIPS flexibilities have been incorporated into the intellectual property framework as applied to pharmaceutical products: Compulsory licensing provisions, Government use, Parallel importing provisions, the Bolar exception?				
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 10	Have any of the following TRIPS flexibilities been utilized to date: Compulsory licensing provisions, Government use, Parallel importation provisions, the Bolar exception (10-year time frame)?	IRDT03	Have any of the following TRIPS flexibilities been utilized to date: Compulsory licensing provisions, Government use, Parallel importation provisions, the Bolar exception (10-year time frame)?		National laws, including patent and medicines regulation laws, contain effective provisions for the application of all Trade-Related Aspects of Intellectual Property Rights -compatible flexibilities (yes/no)
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 11	How many compulsory licenses have been issued in the past two years?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
							Number of licence agreements concerning essential medicines concluded through patent pooling, stratified by in-licence and out-licence
							Number of products produced under an Essential Medicines Patent Pool licence that are authorised by at least one of the following: International Council for Harmonisation or Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme member, or WHO/UN Prequalification Programme
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 1	Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 2	Which of the following pharmaceutical financing sources exist to cover the cost of pharmaceuticals dispensed: Government, Donor, Insurances, OOP, Employers				
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 3	Does the national health accounts system capture pharmaceutical expenditures?				
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 4	Existence of a joint annual review and planning process for pharmaceutical financing, where financial needs are reviewed; commitments are made, involving all major stakeholders and partners				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 6	Proportion of annual pharmaceutical expenditure on medicines financed by: Public, OOP, private health insurance, private employers			% government expenditure out of total expenditure on pharmaceuticals	Public sector expenditure on pharmaceuticals as a percentage of total pharmaceutical expenditure
Financing	Resource Coordination, Allocation, Distribution, & Payment			F01	Per capita expenditure on pharmaceuticals	Per capita expenditure on pharmaceuticals	Per capita total pharmaceutical expenditure
Financing	Resource Coordination, Allocation, Distribution, & Payment			F02	Population with household expenditures on health greater than 10% of total household expenditure or income	% of household income on medicines ± assistive technologies	Household expenditure on pharmaceuticals as a percentage of total household expenditure
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 7	Total expenditure on pharmaceuticals (% total expenditure on health)	F03	Total expenditure on pharmaceuticals (% total expenditure on health)	% pharmaceutical expenditure out of total health expenditure	Total pharmaceutical expenditure as a percentage of total health expenditure
						% of the reimbursement volume spent on essential medicines	

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Costing & Pricing	F 8	Is a national medicine prices monitoring system for retail/patient prices in place?				
Financing	Costing & Pricing	F 9	Is there a policy covering medicine prices that applies to the public sector, the private sector, or non-governmental organizations? If yes, which of the following policies covering medicine prices apply: Maximum wholesale mark-up, Maximum retail mark-up				
Financing	Costing & Pricing	F 10	Availability of price information for different stages of the pharmaceutical value chain				
Financing	Costing & Pricing	F 11	% of facilities/dispensaries that post prices for pharmaceuticals and pharmaceutical services				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Costing & Pricing	F 12	% of products for which retail/consumer prices have been surveyed in last year				
Financing	Costing & Pricing	F 13	Median drug price ratio for tracer medicines in the public, private, and mission sectors	F04	Median (consumer) drug price ratio for tracer medicines in the public, private, and mission sectors		Median consumer price ratio of a basket of essential medicines in the public and private sectors
						ABC analysis (top medicines by expenditure/volume)	
Financing	Financial Risk Protection	F 14	Is there a national policy to subsidize or provide at least some medicines free of charge for certain conditions				
Financing	Financial Risk Protection	F 15	Country has established a national or social insurance program				
Financing	Financial Risk Protection	F 16	Are health insurances, by law or regulation, required to cover medicines costs, either partial or in total				
Financing	Financial Risk Protection	F 17	Insurance coverage (% covered by public or private health insurance)			% of population covered by health insurance that includes pharmaceutical benefits	

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Financial Risk Protection	F 18	Which of the following types of patients receive medicines for free or subsidized: Patients who cannot afford them, Children under 5 years, Older children, Pregnant women, Elderly patients				
Financing	Financial Risk Protection	F 19	National or social health insurance copayments				
Financing	Financial Risk Protection	F 20	Average # of days worked by lowest paid government employee to pay for treatment of specified tracer conditions				
Financing	Financial Risk Protection	F 21	Percentage of patients who pay a charge for medicines they receive in MOH health facilities				
Financing	Financial Risk Protection	F 22	Out-of-pocket expenditure out of total pharmaceutical expenditure	F05	Out-of-pocket expenditure out of total pharmaceutical expenditure		Out-of-pocket expenditure on pharmaceuticals as a percentage of total pharmaceutical expenditure

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Financing	Expenditure Tracking & Monitoring	F 23	Responsibility for National Health Accounts (including pharmaceutical accounts) has been delegated to a specific body and provided with a budget for implementation.				
Financing	Expenditure Tracking & Monitoring	F 24	% of facilities/dispensaries that record pharmaceutical dispensing and payments				
Financing	Expenditure Tracking & Monitoring	F 25	At least one national health accounts exercise including pharmaceuticals completed in the past five years.	F06	At least one national health accounts exercise including pharmaceuticals completed in the past five years.		
Human Resources	Human Resource Development	HR 1	Four prescribing issues are part of the basic curricula in most health training institutions for: doctors, nurses, pharmacists, and pharmacy assistants/ technicians				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Human Resources	Human Resource Development	HR 2	Are there obligatory, non- commercially funded continuing education programs that include use of medicines for: doctors, nurses, pharmacists, pharmacy assistants/ technicians				
Human Resources	Human Resource Development	HR 3	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs	HR01	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs		
Human Resources	Human Resource Development	HR 4	Number of pharmaceutical management training programs accredited by a relevant governing body				
Human Resources	Human Resource Development	HR 5	Number of pharmaceutical personnel who have attended at least one training session in the last year, out of total number of pharmaceutical personnel surveyed				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Human Resources	Human Resource Development	HR 6	Annual number of graduates of health professions educational institutions per 100 000 population – by occupation				
Human Resources	Human Resource Management	HR 7	Existence of a list of cadres providing pharmaceutical services in the country and number of years of training required and associated job descriptions				
Human Resources	Human Resource Management	HR 8	Proportion of pharmaceutical health workers that undergo annual performance review				
Human Resources	Human Resource Management	HR 9	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant	HR02	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant		
Human Resources	Human Resource Management	HR 10	Distribution of pharmaceutical human resources by occupation by cadre, public/private, and place of work				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Human Resources	Human Resource Management	HR 11	Pharmaceutical Staff Turnover Rate				
Human Resources	Human Resource Management	HR 12	Proportion of pharmaceutical positions that are vacant				
Human Resources	Human Resource Management	HR 13	Proportion of foreign trained and foreign workforce of the total pharmaceutical human resources by cadre				
Human Resources	Human Resource Policy and Strategy	HR 14	Costed, prioritized pharmaceutical sector human resources management/ development plan exists				
Human Resources	Human Resource Policy and Strategy	HR 15	There is a national human resources database that tracks the number of health professionals in pharmaceutical cadres by major professional category working in the public and/or the private sector				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Human Resources	Human Resource Policy and Strategy	HR 16	Proportion of facilities with non-pharmaceutical cadres providing pharmaceutical services				
Information	Data Collection, Processing, and Dissemination	IM 1	Established functioning system for requesting, receiving, processing, and disseminating pharmaceutical sector information				
Information	Data Collection, Processing, and Dissemination	IM 2	Percentage of LMIS reports submitted on-time and complete to the central level				
Information	Data Collection, Processing, and Dissemination	IM 3	Annual data are produced on the availability of tracer medicines and commodities in public and private facilities				
Information	Information Policy and Data Standardization	IM 4	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information	IM01	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Information	Information Policy and Data Standardization	IM 5	Existence of a national set of pharmaceutical indicators with targets and regular reporting				
Information	Use of Information for Decision Making	IM 6	Percentage of facilities that received feedback on previously submitted reports				
Information	Use of Information for Decision Making	IM 7	Pharmaceutical procurement and logistics reviews are conducted regularly and findings are used for interventions at relevant levels				
Information	Use of Information for Decision Making	IM 8	Medicines use reviews and evaluations are conducted regularly and findings are used for interventions at relevant levels				
Information	Use of Information for Decision Making	9	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection	IM02	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection		
Information	Use of Information for Decision Making	10	Is procurement based on a reliable quantification of medicine needs?				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Information	Use of Information for Decision Making	11	Percentage of adverse event reports received for which decisions were issued				
Outcomes and Attributes	Access, Acceptability	OA 1	Satisfaction with the results of the last visit to a public health facility				
Outcomes and Attributes	Geographical Accessibility	OA 2	Percentage of households more than 20 kilometers away from a dispensing facility or pharmacy				
Outcomes and Attributes	Access, Geographical Accessibility, Equity	OA 3	Population per facility that dispenses or sells pharmaceutical products (public and private, urban and rural)				
Outcomes and Attributes	Performance, Responsiveness	OA 5	Existence of mechanisms, such as surveys, for obtaining client input on appropriate, timely, and effective access to health services				

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator	v2.0 ID#	PSS Insight 2.0 Indicator	WHO Access Dashboard Indicators	Lancet Commission Indicators
Outcomes and Attributes	Resilience, Self-Regulating	OA 6	Average time lag between identification of a safety signal of a serious adverse drug event or significant medicine safety issue and communication to health care workers and the public				
Outcomes and Attributes	Resilience, Adaptive	OA 7	Emergency Pharmaceutical Preparedness Plan in place				
Outcomes and Attributes	Use, Consumption/ End-Use	OA 4	Percentage of patients with 100% on time pill pickup during a defined period for HIV, TB, or other chronic diseases				

ANNEX 2 – PHARMACEUTICAL SYSTEMS STRENGTHENING: DEFINITIONS AND MEASUREMENT FRAMEWORK

DEFINITIONS

Efforts to measure progress in strengthening pharmaceutical systems (PSS) have been hampered by the lack of clear definitions and widely accepted reliable measures. In 2016, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program proposed the following definitions, which emerged from a comprehensive literature search and an expert consultation based on an analysis of existing definitions and frameworks.[59]

A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.

Pharmaceutical systems strengthening is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to make it more responsive and resilient and to enhance its performance for achieving better health outcomes.

MEASUREMENT FRAMEWORK FOR PHARMACEUTICAL SYSTEMS STRENGTHENING

The above definitions underscore that a pharmaceutical system should be regarded as a subsystem of a health system and that the outcomes of a pharmaceutical system—and the goals of pharmaceutical systems strengthening (PSS)—contribute to achieving better health outcomes and other health system goals. The pharmaceutical system definition provides the foundation for measuring the system's performance. The PSS definition identifies resilience as a key characteristic of a well-functioning pharmaceutical system and underlines the need to measure it as a system attribute along with dimensions of system performance, including responsiveness. These definitions form the basis for the PSS measurement framework presented in Figure 4 which SIAPS has used to guide the development of a tool for measuring progress in systems strengthening.

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[59] Hafner, Tamara, Helena Walkowiak, David Lee, and Francis Aboagye-Nyame. "Defining pharmaceutical systems strengthening: concepts to enable measurement." *Health Policy and Planning*, 2016. doi:10.1093/heapol/czw153

Critical System Components

Underperformance within a critical component can disrupt the overall performance of the pharmaceutical system. Identifying areas of underperformance and neglect in a system is therefore a prerequisite for strengthening. *Seven system components* were identified in the expert consultation as essential for measuring progress in PSS. Table 13 presents the rationale for selecting the components shown in Figure 4.

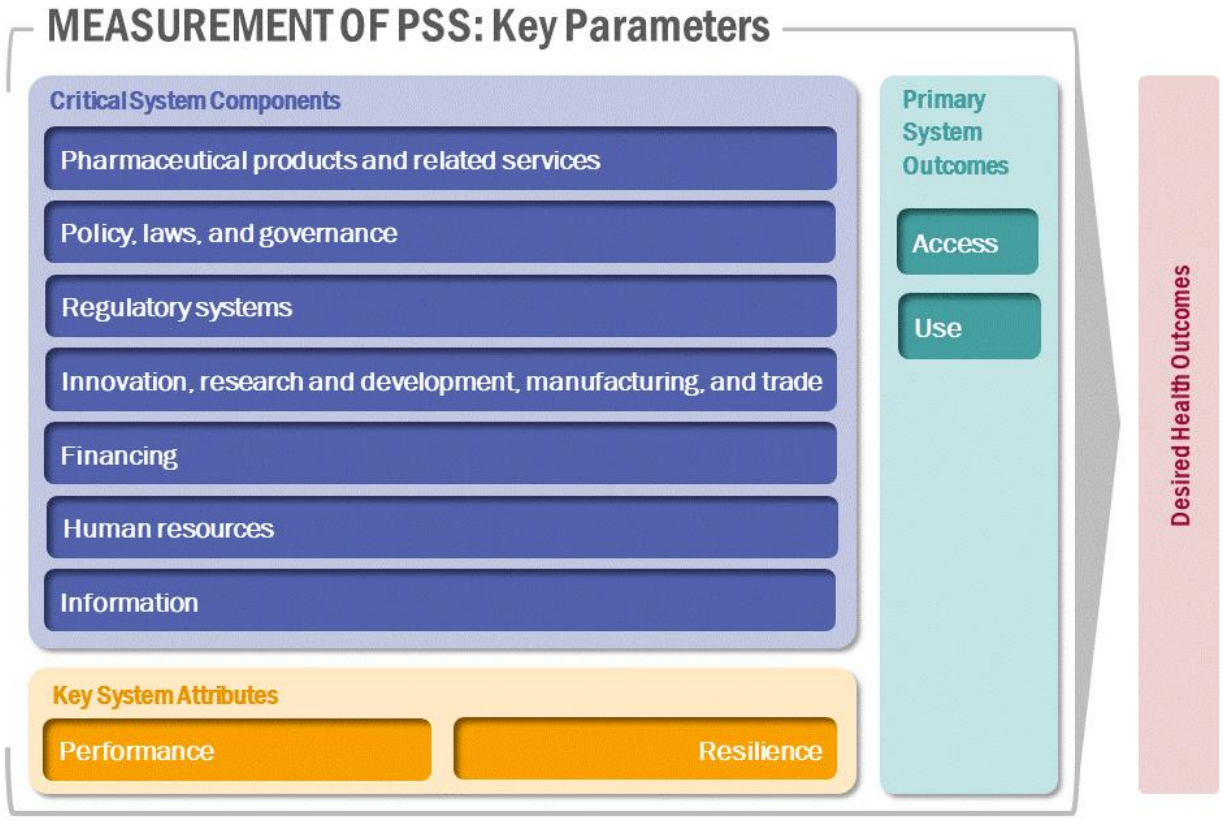

Figure 4: PSS Measurement Framework: Critical Components, Key Attributes, and Primary Outcomes

These seven components are not intended as an exhaustive list of what constitutes a pharmaceutical system. Rather, they are meant to guide the measurement of PSS and provide a high-level picture of the functioning of the pharmaceutical system as a complete entity. The connections of the pharmaceutical system with the broader health system are reflected in components such as *Policy, Laws and Governance; Financing; Human Resources;* and *Information*. However, a seven-component system cannot and is not intended to capture the full complexity of these and other interrelationships.

The seven critical system components are not intended to be an exhaustive list of what constitutes a pharmaceutical system. Rather, they are meant to guide the measurement of PSS and provide a high-level picture of the functioning of the pharmaceutical system as a complete entity.

For each of the critical components, the most important *elements* that reflect performance and are associated with resilience and sustainability were identified. The key elements associated with each component are listed and described in Table 13. These elements provide the foundation for the selection of three types of indicators—structural, process, and outcome. *Structural indicators* provide information on the system's capacity to achieve the objectives of each component. *Process indicators* assess the degree to which activities necessary to attain the objectives are carried out. *Outcome indicators* measure the results achieved for each component. The selection of indicators was guided by the following criteria: validity, availability, reliability, policy-relevance, repeatability, and attributability.

Outcome indicators that demonstrate underperformance can point to areas for more in-depth assessment to identify structural and process-related weaknesses and failures that threaten system sustainability. Monitoring the system and identifying underperformance using a comprehensive set of indicators allows for the selection of strategies that address the specific areas where a pharmaceutical system can be strengthened. Full interpretation of these indicators will have to consider the various relationships and interactions that exist among the system components. In addition to providing a snapshot of the system, regular monitoring over time can demonstrate change and track the effects of interventions across system components that are interconnected.

Primary System Outcomes

PSS measurement tools also need to include indicators that track the extent to which a pharmaceutical system is achieving its purpose in ensuring access to pharmaceutical products and related services, and positively influencing use. Equitable and timely access to, and appropriate and cost-effective use of, safe, effective and quality pharmaceutical products ultimately contribute to the achievement of desired health outcomes and other health system goals.

All seven components contribute in varying degrees to *access and use*, the primary system outcomes. Access refers to *affordability, acceptability (or satisfaction), geographical accessibility,* and *availability*.[60] Access indicators also need to account for *equity* to measure the extent to which the system deals fairly with different population subgroups defined socially, economically, demographically or geographically within countries. Use refers to *prescribing*, *dispensing (or sale or supply to the user)* and *consumption (or end-use)*.

[60] Management Sciences for Health. 2012. MDS-3: *Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

The key dimensions associated with each primary system outcome are described in Table 14. Poor system function will be reflected in these measures and should lead to further probing of relationships and interactions among system components to identify possible causes.

Key System Attributes

Performance and *resilience* are two system attributes that are important for measuring pharmaceutical systems strengthening. Three dimensions of performance were selected for inclusion in the PSS measurement framework; the *efficiency* with which the system allocates products and services among the population and at what cost; the *quality and safety* of pharmaceutical products and related services; and the *responsiveness* of the pharmaceutical system to the health needs of the population. Metrics associated with these three dimensions of performance can be useful in identifying underperformance in pharmaceutical systems and the effects—intended or not—of interventions in these systems.

While a pharmaceutical system may function adequately now, it will need to adapt to future challenges which brings in concepts related to sustainability and resilience. Resilience is the capacity of the system to prepare for and effectively respond to crises thereby maintaining core functions, adapting to changing circumstances as needed and, transforming when social and economic conditions make the existing system no longer viable.[61]

The key dimensions associated with these attributes are described in Table 15.

Contribution to Health System Outcomes

Pharmaceutical systems do not operate in a vacuum; they are embedded in health systems. Pharmaceutical system outcomes aim to contribute to the wider health system goals. Here we explain how the primary system outcomes and key attributes identified in the PSS measurement framework relate to the achievement of desired health outcomes and other health system goals.

Existing health system and health system strengthening frameworks, including the World Health Organization (WHO) health systems 'building blocks' framework[62] and framework used by US Agency for International Development (USAID) to guide its work in health systems strengthening[63] commonly identify health improvement, equity, efficiency, responsiveness,

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[61] Adapted from Kruk ME, Myers M, Varpilah ST et al. 2015. What is a resilient health system? Lessons from Ebola. *The Lancet* 385(9980): 1910-1912

[62] World Health Organization. Everybody's business: strengthening health systems to improve outcomes. WHO's framework for action. Geneva: WHO, 2007

[63] USAID's Vision for Health Systems Strengthening (2015-2019) https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf

financial protection, access, coverage, quality and safety as health system goals but sometimes differ in their treatment of these goals as intermediate or ultimate system goals.

The PSS measurement framework identifies equitable access to and use of safe, effective, quality and safe pharmaceutical products and related services as primary system outcomes (Table 14). The affordability dimension of access to pharmaceutical products includes the monitoring of costs at both the user and system level and so accounts for the financial protection goals of the health system. The PSS framework also identifies efficiency, quality and safety, and responsiveness as dimensions of system performance, which together with resilience are the two primary system attributes (Table 15).

The multiple determinants of coverage extend beyond the boundaries of the pharmaceutical system and so it is not included as an explicit parameter in the PSS measurement framework. Further, although the ultimate goal of a pharmaceutical system is to improve health outcomes, the multiple determinants of health make it impossible to solely attribute positive improvements in health to changes within the pharmaceutical system.

TABLE 13: MEASURING PSS: CRITICAL SYSTEM COMPONENTS AND ASSOCIATED ELEMENTS

COMPONENT	ELEMENT	
PHARMACEUTICAL PRODUCTS AND SERVICES At the center of the pharmaceutical system and encompasses the functions of selection, procurement, and distribution of pharmaceutical products. It also includes systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, retail practices, and correct use by end-users. This component affects all dimensions of access and use.	SELECTION	Developing, updating and publishing standard treatment guidelines for priority health problems; selecting products and dosage forms for essential pharmaceutical product lists, formularies, and insurance reimbursement lists; and deciding which products will be available at each level of the health system.
	PROCUREMENT	Systems for deciding which products to procure, quantifying pharmaceutical product needs, choosing procurement methods, managing procurements (including local purchasing) and donations, assuring pharmaceutical quality, tracking prices, and monitoring supplier performance.
	DISTRIBUTION	Systems for importing, managing, storing inventory; monitoring consumption, stock, quality and security, and delivering products to their point of use.
	USE	Systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, and retail practices within culturally acceptable, integrated service delivery that supports appropriate (including initial and long-term) use by the end user.
POLICY, LAWS, AND GOVERNANCE The hub of coordination for the entire system, providing the framework, structures, and systems for organizing, financing, and regulating the system; and coordinating the activities of the various institutions and stakeholders to achieve the system objectives. It takes account of systems for facilitating participation, transparency, and accountability, and the promotion of ethical practices. This component affects all dimensions of access and use.	PHARMACEUTICAL POLICIES	Accessing, analyzing, and using data to formulate a national medicines policy and other pharmaceutical policies and strategies, and developing and implementing evidence-based strategic plans to support the achievement of identified priorities and goals.
	PHARMACEUTICAL LAWS AND REGULATIONS	Formulating, implementing and enforcing comprehensive legislation to regulate activities (including controlled substance scheduling, importation, storage, prescribing, dispensing and reporting) and pharmaceutical workforce management.
	COORDINATION AND LEADERSHIP	Systems for providing direction; engaging, coordinating and aligning expectations, interests and activities among state and non-state institutions and stakeholders; and maximizing the use of resources.
	ETHICS, TRANSPARENCY AND ACCOUNTABILITY	Stipulation of key principles to guide ethics and the integrity of professional behavior; ethical practices; maintenance of professional competence; and compliance with regulations and accepted standards. Formal processes to consult with and inform key stakeholders, including civil society about major decisions and actions in the pharmaceutical system; and to hold entities and decision makers accountable for their decisions and actions.

Component	Element	
Regulatory Systems Focuses on ensuring the safety, efficacy, and quality of pharmaceutical products and related services. This component affects both access and use.	Product Assessment and Registration	Systems for evaluating the safety, efficacy, and quality of pharmaceutical products and appropriateness of product information; and issuing, varying or revoking marketing authorizations.
	Licensing of Establishments and Personnel	Systems for authorizing pharmaceutical establishments and personnel to manufacture, import, export, store, distribute, assess product quality, and sell, supply or dispense pharmaceutical products in accordance with approved and published norms, standards, guidelines, and regulations.
	Inspection and Enforcement	Systems for verifying and taking appropriate action to ensure that pharmaceutical establishments and personnel perform pharmaceutical operations in accordance with approved norms, standards, guidelines, and regulations. This applies to manufacturing, import control, supply chain management, and dispensing.
	Quality and Safety Surveillance	Systems for monitoring and taking action to ensure that pharmaceutical products in the distribution system meet specified quality standards; and detecting, evaluating, and preventing adverse reactions, medication errors, product-related quality problems and others.
	Regulation and Oversight of Clinical Trials	Systems for authorizing clinical trials and verifying that they are conducted in accordance with approved norms, standards, guidelines and regulations.
	Control of Pharmaceutical Marketing Practices	Systems for reviewing and monitoring the marketing practices including advertising of pharmaceutical products (both prescription and non-prescription) to prevent the dissemination of inaccurate and misleading information; and taking action in case of violations.
Innovation, Research and Development, Manufacturing, and Trade The entry point for pharmaceutical products into the system. Includes research and development of products; domestic manufacturing capacity; and intellectual property protections in national legislation and international trade agreements that shape innovation and trade, and affect access to pharmaceutical products. This component primarily affects access.	Innovation, Research and Development	Priority setting, investment, and building country capacity in research and development and technological innovation to develop pharmaceutical products based on unmet/inadequately addressed public health needs.
	Manufacturing Capacity	Human resources, financing, physical infrastructure, and mechanisms to facilitate technology transfer and domestic production of pharmaceutical products of assured quality in compliance with good manufacturing practice (GMP) standards.
	Intellectual Property and Trade	Incorporating measures consistent with TRIPS into national legislation and using these provisions to promote innovation and safeguard access to affordable essential pharmaceutical products; regulating duties, tariffs for importation of pharmaceutical active ingredients, products and packaging, and non-tariff import controls.

Component	Element	
Financing The management of resources to ensure the adequate and sustainable financing of the pharmaceutical product purchase, related services, and other costs associated with system functioning. Includes financial risk protection strategies and monitoring and controlling costs and prices to reduce financial barriers to accessing pharmaceutical products and related services. This component affects access and use, but especially the availability, accessibility, and affordability dimensions.	Resource Coordination, Allocation, Distribution and Payment	Coordinating country and donor inputs, allocating resources, and distributing adequate and sustainable funding for the purchase, contracting, and payment for pharmaceutical products, human resources, services, infrastructure and other costs associated with system functioning.
	Financial Risk Protection Strategies	Establishment and management of systems for pooling resources and providing financial risk protection that include coverage for pharmaceutical products and related services.
	Revenue and Expenditure Tracking and Management	Systems for tracking and oversight of pharmaceutical revenue and expenditures; analyzing and using information to address inequities in access, control expenditures, and reduce inefficiencies and wastage.
	Costing and Pricing	Systems for analyzing, monitoring and controlling costs and prices for pharmaceutical products and services.
Human Resources Ensures the availability of adequate numbers of appropriately trained staff for managing the supply and delivery of pharmaceutical products and related services. This component contributes to all dimensions of access and use.	Human Resources Policy and Strategy	Human resources policy, strategy, and guidelines for scopes of practice, work standards, and workforce planning for recruiting, developing, and deploying the pharmacy workforce to provide the necessary coverage and capacity.
	Human Resources Management	Systems for registration/counting, recruiting, hiring, deploying, evaluating, supporting, and retaining the pharmacy workforce through the integrated use of data, policy, and practice.
	Human Resources Development	Development and maintenance of a skilled pharmaceutical workforce of multiple levels including basic, post-basic and continuous education; systems for authorizing and monitoring educational facilities and training programs to ensure that education is provided in accordance with approved norms, standards, guidelines, and regulations.
Information The generation and dissemination of timely and reliable information, which is the foundation for decision making, policy development and implementation, governance and regulation, and planning and allocation of financial, infrastructure, and human resources in the pharmaceutical system. This component affects both access and use.	Information Policy and Data Standardization	Policy, legislation, regulation, and guidelines for secure information collection, transmission, management and storage; coordinating stakeholder roles and inputs; data confidentiality and security; selection of core indicators; and use of standards for data.
	Data Collection, Processing, and Dissemination	Systems, technologies, and infrastructure for the collection, verification, and processing of data and dissemination of timely, accurate, and relevant information.
	Use of Information for Decision Making	Routine and extraordinary use of information for policy and decision making, governance, regulation, monitoring system performance, and resource planning and allocation to support system functioning and promote transparency.

TABLE 14: MEASURING PSS: PRIMARY SYSTEM OUTCOMES

PRIMARY OUTCOME	DIMENSION		
ACCESS	AFFORDABILITY		The relationship between the prices of the products and services and the user's ability to pay for them.[64] Accounts for the financial risk protection goals of the health system.
		EQUITY IN AFFORDABILITY	The extent to which a system deals fairly with all concerned[65]
	ACCEPTABILITY (OR SATISFACTION)		The relationship between the user's attitudes and expectations about the products and services and the actual characteristics of the products and services.[6]
	GEOGRAPHICAL ACCESSIBILITY		The relationship between the location of the product or service and the location of the eventual user of the product or service[6]
		EQUITY IN GEOGRAPHICAL ACCESSIBILITY	The extent to which a system deals fairly with all concerned[7]
	AVAILABILITY		The relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided[6]
		EQUITY IN AVAILABILITY	The extent to which a system deals fairly with all concerned[7]
USE	PRESCRIBING		Selecting and advising the use of a pharmaceutical product, whether prescription or non-prescription, for the prevention, treatment or management of a medical condition based on safety, efficacy, suitability, and cost. Includes the provision of information and counseling to support appropriate decision making and use by the consumer or end-user.
	DISPENSING / SALE OR SUPPLY		The preparation and sale or supply of a pharmaceutical product, whether or not by prescription. Includes the provision of information and counseling to support appropriate decision making and use by the consumer or end-user.
	CONSUMPTION / END-USE		Intake or application of a pharmaceutical product by the consumer or administration by the caregiver or end use. Includes adherence which is the extent to which a person takes or uses the product as prescribed by a health care provider.

[64] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health
[65] Kelley,E., & Hurst, J. (2006). Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing. http://dx.doi.org/10.1787/440134737301

TABLE 15: MEASURING PSS: KEY SYSTEM ATTRIBUTES

SYSTEM ATTRIBUTE	DIMENSION		
PERFORMANCE	EFFICIENCY		The capacity to produce the maximum output for a given input.[66] Allocative efficiency refers to using the optimal mix of resources to maximize benefits to society. Technical efficiency refers to using the least amount of resources to produce a given mix of goods and services.
	QUALITY AND SAFETY	PHARMACEUTICAL PRODUCTS	An essential component of access cutting across all the dimensions, but which specifically applies to products in terms of their safety, efficacy, and cost-effectiveness[67]
		PHARMACEUTICAL / RELATED SERVICES	
	RESPONSIVENESS		Non clinical aspects related to the way individuals are treated and the environment in which they are treated.[68] Domains of responsiveness include: respect for autonomy, choice of care provider, respect for confidentiality, communication, respect for dignity, access to prompt attention, quality of basic amenities, and access to family and community support.
RESILIENCE	AWARE		Resilient health systems are aware of the potential health threats and risks to the population and knowledge of the current human, physical, and information assets that highlight areas of strength and vulnerability. This requires effective health information systems and epidemiological surveillance networks.[69]
	DIVERSE		Has the capacity to address a broad range of health challenges rather than a select few.69
	SELF-REGULATING		Can contain and isolate health threats while delivering core health services and avoiding cascading disruptions throughout the system.[69]
	INTEGRATED		Brings together diverse stakeholders and ideas to formulate solutions and initiate actions, with clear channels for communication and coordination. [69]

[66] WHO Terminology Information System [online glossary] http://www.who.int/health-systems-performance/docs/glossary.htm
[67] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health
[68] Valentine NB, de Silva A, Kawabata K, Darby C, Murray CJL, Evans DB. (2003.) Health system responsiveness: concepts, domains and measurement. In Murray CJL, Evans DB (Eds). Health systems performance assessment: debates, methods and empiricism. Geneva: World Health Organization.
[69] Kruk, M.E., Myers, M., Varpilah, S. T., & Dahn, B. T. (2015) What is a resilient health system? Lessons from Ebola. *The Lancet,* 385(9980), 1910-1912.

System Attribute	Dimension	
	Adaptive	Has the ability to transform in ways that improve function in times of crises, and adapt to epidemiological and demographic changes in normal times. [69]

ANNEX 3 – INDICATOR REDUCTION FROM V1.0 TO V2.0

This Annex includes a comparison of indicators included in PSS Insight v1.0 and v2.0.

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Pharmaceutical Products & Services	Selection	PS 1	Existence of an active national committee responsible for managing the process of maintaining a national essential medicines list		
Pharmaceutical Products & Services	Selection	PS 2	Are there clearly written guidelines for the selection process for including or deleting medicines from the national EML?		
Pharmaceutical Products & Services	Selection	PS 3	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection		
Pharmaceutical Products & Services	Selection	PS 4	Existence of a national essential medicines list and a national list of medicines for reimbursement published within the past five years	PS01	Existence of a national essential medicines list published within the past five years
Pharmaceutical Products & Services	Selection			PS02	Existence of a reimbursement list published within the past two years
Pharmaceutical Products & Services	Selection	PS 5	What is the total number of pharmaceuticals on the national EML?		
Pharmaceutical Products & Services	Procurement	PS 6	Existence of a procurement pre- or post-qualification process for suppliers and products		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Pharmaceutical Products & Services	Procurement	PS 7	Formal written procurement policy in place		
Pharmaceutical Products & Services	Procurement	PS 8	Existence of formal SOPs for conducting procurement of pharmaceuticals		
Pharmaceutical Products & Services	Procurement	PS 9	Value of medicines purchased through competitive tender, out of value of medicines purchased.		
Pharmaceutical Products & Services	Procurement	PS 10	Percentage of purchase orders/contracts issued as emergency orders		
Pharmaceutical Products & Services	Procurement	PS 11	Is procurement based on a formal quantification of medicines needs?		
Pharmaceutical Products & Services	Procurement	PS 12	Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement	PS03	Percentage of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement*
Pharmaceutical Products & Services	Procurement	PS 13	Order fill rate (correct quantities and products delivered in good condition) – Central Level		
Pharmaceutical Products & Services	Distribution	PS 14	Percentage of storage facilities meeting acceptable storage conditions†		
Pharmaceutical Products & Services	Distribution	PS 15	Percentage of storage facilities employing proper inventory management practices†		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Pharmaceutical Products & Services	Distribution	PS 16	Is there a system in place to track the movement of pharmaceuticals from a warehouse to a service delivery point?		
Pharmaceutical Products & Services	Distribution	PS 17	Average percentage of stock records that corresponds with physical counts for a set of tracer medicines in storage and health facilities		
Pharmaceutical Products & Services	Distribution	PS 18	Mean % availability across a basket of medicines	PS04	Mean % availability across a basket of medicines*
Pharmaceutical Products & Services	Distribution	PS 19	Product losses by value due to expired medicines or damage or theft per value received (percentage)	PS05	Product losses by value due to expired medicines or damage or theft per value received (%)*
Pharmaceutical Products & Services	Distribution	PS 20	Order Lead Time		
Pharmaceutical Products & Services	Use	PS 21	Existence of legal provisions to allow/encourage generic substitution in all sectors		
Pharmaceutical Products & Services	Use	PS 22	Existence of national STGs and mechanisms for regular updating of STGs		
Pharmaceutical Products & Services	Coordination and Leadership	PS 23	Multidisciplinary national taskforce or working group for Antimicrobial Resistance (AMR) containment exists		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Pharmaceutical Products & Services	Coordination and Leadership	PS 24	Existence of a national Antimicrobial Resistance strategy		
Pharmaceutical Products & Services	Use	PS 25	Medicines use reviews and 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.	PS06	% generic medicines out of total market volume
Pharmaceutical Products & Services	Use			PS07	Defined daily dose (DDD) for antimicrobials (per 1000 population)
Pharmaceutical Products & Services	Use	PS 26	Percentage of encounters at health facilities at which health care staff members explained the dose and frequency of the prescribed medicines to the patient or caregiver†		
Pharmaceutical Products & Services	Use	PS 27	Optimal level of medicines prescribing indicators (includes medicines prescribed from reimbursement list/EML, polypharmacy, injections, antibiotics, prescription by generic name)	PS08	% Medicines prescribed from an EML or reimbursement list*
Pharmaceutical Products & Services	Use			PS09	% Medicines prescribed as generics*
Pharmaceutical Products & Services	Use			PS10	% Antibiotics prescribed in outpatient settings*

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Pharmaceutical Products & Services	Use			PS11	% population with unmet medicine needs*
Pharmaceutical Products & Services	Use	PS 28	Percentage of patients surveyed that know correct information about their medications†		
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 1	Existence of a published national medicines policy		
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 2	Is there a National Medicines Policy (NMP) implementation plan [or pharmaceutical sector strategic plan] that sets activities, responsibilities, budget and timeline?		
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 3	Regular evaluation of policy impacts as part of a policy process		
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 4	Is the NMP integrated into or included in the published/official national health policy/plan?		
Policy, Laws, and Governance	Pharmaceutical Policies	PLG 5	Has there been an evaluation of the national medicines policy in the last 5 years?		
Policy, Laws, and Governance	Coordination and Leadership	PLG 6	Platform or strategy exists for the coordination of pharmacovigilance activities at the national level		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Policy, Laws, and Governance	Coordination and Leadership			PLG01	An institutional development plan of the national medicines regulatory authority based on the results of the GBT exists
Policy, Laws, and Governance	Coordination and Leadership			PLG02	A progress report on the institutional development of the national medicines regulatory authority published
Policy, Laws, and Governance	Coordination and Leadership	PLG 7	Multidisciplinary national taskforce or working group for Antimicrobial Resistance (AMR) containment established with a documented Terms of Reference (TOR) that met at least once in past year		
Policy, Laws, and Governance	Coordination and Leadership			PLG03	Submission of national data to the Global Antimicrobial Surveillance System (GLASS)
Policy, Laws, and Governance	Coordination and Leadership	PLG 8	There is organized stakeholder engagement throughout the entire policy/strategic planning process		
Policy, Laws, and Governance	Coordination and Leadership	PLG 9	Existence of an intersectoral committee for pharmaceutical sector policy and planning		
Policy, Laws, and Governance	Coordination and Leadership	PLG 10	Existence of a national Antimicrobial Resistance strategy	PLG04	Updated National Action Plan on the containment of antimicrobial resistance
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 11	Existence of a comprehensive pharmaceutical law [or legislative framework]		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 12	Is your country a signatory to the international conventions on the control of narcotics, psychotropic substances and precursors?		
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 13	# of annual reports submitted to the International Narcotics Control Board (INCB) in the last 5 years	PLG05	# of annual reports submitted to the INCB in the last five years
Policy, Laws, and Governance	Pharmaceutical Laws and Regulations	PLG 14	Existence of a National Drug or Medicines Regulatory Authority responsible for the promulgation and enforcement of regulations		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 15	Is there a code of conduct that applies to public officials and staff involved in pharmaceutical related activities or posts		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 16	Are there legal provisions requiring transparency and accountability in administrative decision making for public pharmaceutical sector agencies		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 17	Are there written guidelines or a policy on conflicts of interest with regard to the following functions: (product registration, product selection, procurement)†		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 18	Is there a formal appeals [and review] system for applicants who have their medicine applications rejected [for licensing, selection, registration, procurement]?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 19	Percentage of pharmaceutical related commissions and bodies with stakeholder representation		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 20	Number of procurement audits conducted (complete and published) in the last 5 years		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 21	Does the government use transparent and explicit procedures for procurement of pharmaceutical products?		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 22	Publication of proceedings or minutes by pharmaceutical commissions and committees.		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 23	Number of COI statements submitted annually and at each meeting of any pharmaceutical commission or committee, and included in the record of the meeting		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 24	Number of complaints received and responded to within specified timeline		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 25	Reports of audits are published and publicly available (as requested)		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Policy, Laws, and Governance	Ethics, Transparency, and Accountability	PLG 26	Percentage of regulatory reviews and appeals completed within timeframe†		
Policy, Laws, and Governance	Ethics, Transparency, and Accountability			PLG06	Pharmaceutical System Transparency and Accountability assessment score
Policy, Laws, and Governance	Ethics, Transparency, and Accountability			PLG07	Number of assessments of the Pharmaceutical System Transparency and Accountability within the last 5 years
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 1	Are there controls on medicine promotion based on regulations?		
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 2	Is there an entity or committee responsible for monitoring and enforcing the provisions on medicine promotion?		
Regulatory Systems	Control of Pharmaceutical Marketing Practices	RS 3	% of identified advertisement violations for which sanctions were implemented		
Regulatory Systems	Inspection and Enforcement	RS 4	Are there legal provisions to inspect premises and collect samples?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Regulatory Systems	Inspection and Enforcement	RS 5	Documented procedures are available and implemented for different inspection activities, as for inspection preparation, conduction and/or reporting.		
Regulatory Systems	Inspection and Enforcement	RS 6	Number of licensed or registered medicines retail outlets per government medicines inspector		
Regulatory Systems	Inspection and Enforcement	RS 7	% of manufacturing, distribution, and dispensing facilities inspected each year	RS01	% of manufacturing facilities inspected each year
Regulatory Systems	Inspection and Enforcement			RS02	% of distribution facilities inspected each year
Regulatory Systems	Inspection and Enforcement			RS03	% of dispensing facilities inspected each year
Regulatory Systems	Inspection and Enforcement	RS 8	% of inspection violations at retail or dispensing outlets that have been addressed with administrative measures or sanctions		
Regulatory Systems	Licensing	RS 9	There are legal provisions for licensing of pharmaceutical facilities throughout the pharmaceutical system and based on Good Practices (GXP) compliance.		
Regulatory Systems	Licensing	RS 10	The updated list/database of all licensed facilities is regularly published and publicly available		
Regulatory Systems	Licensing	RS 11	% of license applications for new retail and dispensing outlets that are reviewed within the specified period of time		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Regulatory Systems	Product Assessment and Registration	RS 12	There is a defined structure with clear responsibilities to conduct registration and marketing authorization activities.		
Regulatory Systems	Product Assessment and Registration	RS 13	Are there legal provisions for marketing authorization? (that are publicly available)		
Regulatory Systems	Product Assessment and Registration	RS 14	Annually Updated list of all medical products granted marketing authorization is regularly published and publicly available.		
Regulatory Systems	Product Assessment and Registration	RS 15	Average number of days for decision making on a medicine application for registration	RS04	Average number of days for decision making on a medicine application for registration
Regulatory Systems	Product Assessment and Registration	RS 16	Percentage of medicines on the EML that have at least one registered product available.	RS05	% of medicines on the EML that have at least one registered product available.
Regulatory Systems	Product Assessment and Registration	RS 17	Number of medicines registered		
Regulatory Systems	Quality and Safety Surveillance	RS 18	Are there any laws, regulations, policies, programmes or procedures for detecting and combating substandard or falsified medicines?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Regulatory Systems	Quality and Safety Surveillance	RS 19	Existence of a pharmacovigilance system with monitoring and reporting mechanisms		
Regulatory Systems	Quality and Safety Surveillance	RS 20	Percentage of recorded adverse event reports that are assessed for causality	RS06	% of recorded adverse event reports that are assessed for causality
Regulatory Systems	Quality and Safety Surveillance	RS 21	Percentage of total samples collected (planned or otherwise) that were tested		
Regulatory Systems	Quality and Safety Surveillance	RS 22	Number of decisions taken based on product testing results out of total number of samples tested in the reference year		
Regulatory Systems	Quality and Safety Surveillance	RS 23	Percentage of samples tested that failed quality control testing	RS07	% of samples tested that failed quality control testing*
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 24	Legal provisions and/or regulations for clinical trials (CT) oversight exist.		
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 25	Existence of national guidelines on Good Clinical Practice		
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 26	How many inspections of clinical trials were conducted in the last calendar year?		
Regulatory Systems	Regulation and Oversight of Clinical Trials	RS 27	Number of decisions taken (approvals, refusals, suspensions) on clinical trials applications in the reference year		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 1	Existence of a national science and technology or innovation policy†		
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 2	Existence of a national or regional health research policy†		
Innovation, R&D, Manufacturing, Trade	Innovation, Research & Development	IRD 3	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs†	IRDT01	Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 4	Number of pharmaceutical manufacturing companies located in country†		
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 5	Percentage of pharmaceutical manufacturing sites with GMP certification†		
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 6	Medicines production capability in the country†		
Innovation, R&D, Manufacturing, Trade	Manufacturing Capacity	IRD 7	Percentage of products on EML that are currently manufactured or co-manufactured within the country†		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 8	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?†	IRDT02	Are medicines subject to import tariffs? If so, what are the tariff amounts applied?
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 9	Which of the following TRIPS flexibilities have been incorporated into the intellectual property framework as applied to pharmaceutical products: Compulsory licensing provisions, Government use, Parallel importing provisions, the Bolar exception?†		
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 10	Have any of the following TRIPS flexibilities been utilized to date: Compulsory licensing provisions, Government use, Parallel importation provisions, the Bolar exception (10 year time frame)?†	IRDT03	Have any of the following TRIPS flexibilities been utilized to date: Compulsory licensing provisions, Government use, Parallel importation provisions, the Bolar exception (10 year time frame)?
Innovation, R&D, Manufacturing, Trade	Intellectual Property & Trade	IRD 11	How many compulsory licenses have been issued in the past two years?†		
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 1	Is revenue from fees or the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 2	Which of the following pharmaceutical financing sources exist to cover the cost of pharmaceuticals dispensed: Government, Donor, Insurances, OOP, Employers		
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 3	Does the national health accounts system capture pharmaceutical expenditures?		
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 4	Existence of a joint annual review and planning process for pharmaceutical financing, where financial needs are reviewed; commitments are made, involving all major stakeholders and partners		
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 6	Proportion of annual pharmaceutical expenditure on medicines financed by: Public, OOP, private health insurance, private employers		
Financing	Resource Coordination, Allocation, Distribution, & Payment			F01	Per capita expenditure on pharmaceuticals

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Financing	Resource Coordination, Allocation, Distribution, & Payment			F02	Population with household expenditures on health greater than 10% of total household expenditure or income*
Financing	Resource Coordination, Allocation, Distribution, & Payment	F 7	Total expenditure on pharmaceuticals (% total expenditure on health)	F03	Total expenditure on pharmaceuticals (% total expenditure on health)
Financing	Costing & Pricing	F 8	Is a national medicine prices monitoring system for retail/patient prices in place?		
Financing	Costing & Pricing	F 9	Is there a policy covering medicine prices that applies to the public sector, the private sector, or non- governmental organizations? If yes, which of the following policies covering medicine prices apply: Maximum wholesale mark-up, Maximum retail mark-up		
Financing	Costing & Pricing	F 10	Availability of price information for different stages of the pharmaceutical value chain		
Financing	Costing & Pricing	F 11	% of facilities/dispensaries that post prices for pharmaceuticals and pharmaceutical services		
Financing	Costing & Pricing	F 12	% of products for which retail/consumer prices have been surveyed in last year		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Financing	Costing & Pricing	F 13	Median drug price ratio for tracer medicines in the public, private, and mission sectors	F04	Median (consumer) drug price ratio for tracer medicines in the public, private, and mission sectors*
Financing	Financial Risk Protection	F 14	Is there a national policy to subsidize or provide at least some medicines free of charge for certain conditions		
Financing	Financial Risk Protection	F 15	Country has established a national or social insurance program		
Financing	Financial Risk Protection	F 16	Are health insurances, by law or regulation, required to cover medicines costs, either partial or in total		
Financing	Financial Risk Protection	F 17	Insurance coverage (% covered by public or private health insurance)		
Financing	Financial Risk Protection	F 18	Which of the following types of patients receive medicines for free or subsidized: Patients who cannot afford them, Children under 5 years, Older children, Pregnant women, Elderly patients†		
Financing	Financial Risk Protection	F 19	National or social health insurance copayments		
Financing	Financial Risk Protection	F 20	Average # of days worked by lowest paid government employee to pay for treatment of specified tracer conditions		
Financing	Financial Risk Protection	F 21	Percentage of patients who pay a charge for medicines they receive in MOH health facilities		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Financing	Financial Risk Protection	F 22	Out-of-pocket expenditure out of total pharmaceutical expenditure	F05	Out-of-pocket expenditure out of total pharmaceutical expenditure
Financing	Expenditure Tracking & Monitoring	F 23	Responsibility for National Health Accounts (including pharmaceutical accounts) has been delegated to a specific body and provided with a budget for implementation.		
Financing	Expenditure Tracking & Monitoring	F 24	% of facilities/dispensaries that record pharmaceutical dispensing and payments		
Financing	Expenditure Tracking & Monitoring	F 25	At least one national health accounts exercise including pharmaceuticals completed in the past five years.	F06	At least one national health accounts exercise including pharmaceuticals completed in the past five years.
Human Resources	Human Resource Development	HR 1	Four prescribing issues are part of the basic curricula in most health training institutions for: doctors, nurses, pharmacists, and pharmacy assistants/ technicians		
Human Resources	Human Resource Development	HR 2	Are there obligatory, non- commercially funded continuing education programs that include use of medicines for: doctors, nurses, pharmacists, pharmacy assistants/ technicians		
Human Resources	Human Resource Development	HR 3	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs	HR01	Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs
Human Resources	Human Resource Development	HR 4	Number of pharmaceutical management training programs accredited by a relevant governing body		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Human Resources	Human Resource Development	HR 5	Number of pharmaceutical personnel who have attended at least one training session in the last year, out of total number of pharmaceutical personnel surveyed		
Human Resources	Human Resource Development	HR 6	Annual number of graduates of health professions educational institutions per 100,000 population – by occupation		
Human Resources	Human Resource Management	HR 7	Existence of a list of cadres providing pharmaceutical services in the country and number of years of training required and associated job descriptions		
Human Resources	Human Resource Management	HR 8	Proportion of pharmaceutical health workers that undergo annual performance review		
Human Resources	Human Resource Management	HR 9	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant	HR02	Population per licensed pharmacist, pharmacy technician, or pharmacy assistant
Human Resources	Human Resource Management	HR 10	Distribution of pharmaceutical human resources by occupation by cadre, public/private, and place of work†		
Human Resources	Human Resource Management	HR 11	Pharmaceutical Staff Turnover Rate		
Human Resources	Human Resource Management	HR 12	Proportion of pharmaceutical positions that are vacant		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Human Resources	Human Resource Management	HR 13	Proportion of foreign trained and foreign workforce of the total pharmaceutical human resources by cadre		
Human Resources	Human Resource Policy and Strategy	HR 14	Costed, prioritized pharmaceutical sector human resources management/ development plan exists		
Human Resources	Human Resource Policy and Strategy	HR 15	There is a national human resources database that tracks the number of health professionals in pharmaceutical cadres by major professional category working in the public and/or the private sector		
Human Resources	Human Resource Policy and Strategy	HR 16	Proportion of facilities with non-pharmaceutical cadres providing pharmaceutical services		
Information	Data Collection, Processing, and Dissemination	IM 1	Established functioning system for requesting, receiving, processing, and disseminating pharmaceutical sector information		
Information	Data Collection, Processing, and Dissemination	IM 2	Percentage of LMIS reports submitted on-time and complete to the central level		
Information	Data Collection, Processing, and Dissemination	IM 3	Annual data are produced on the availability of tracer medicines and commodities in public and private facilities		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Information	Information Policy and Data Standardization	IM 4	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information	IM01	Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information
Information	Information Policy and Data Standardization	IM 5	Existence of a national set of pharmaceutical indicators with targets and regular reporting		
Information	Use of Information for Decision Making	IM 6	Percentage of facilities that received feedback on previously submitted reports		
Information	Use of Information for Decision Making	IM 7	Pharmaceutical procurement and logistics reviews are conducted regularly and findings are used for interventions at relevant levels†		
Information	Use of Information for Decision Making	IM 8	Medicines use reviews and evaluations are conducted regularly and findings are used for interventions at relevant levels		
Information	Use of Information for Decision Making	9	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection	IM02	Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection
Information	Use of Information for Decision Making	10	Is procurement based on a reliable quantification of medicine needs?		

PSS Insight Component	PSS Insight Element	v1.0 ID#	PSS Insight v1.0 Indicator († indicates new indicators developed for v1.0)	v2.0 ID#	PSS Insight 2.0 Indicator (* specifies Key System Attribute or Primary System Outcome indicator)
Information	Use of Information for Decision Making	11	Percentage of adverse event reports received for which decisions were issued		
Outcomes and Attributes	Access, Acceptability	OA 1	Satisfaction with the results of the last visit to a public health facility		
Outcomes and Attributes	Geographical Accessibility	OA 2	Percentage of households more than 20 kilometers away from a dispensing facility or pharmacy		
Outcomes and Attributes	Access, Geographical Accessibility, Equity	OA 3	Population per facility that dispenses or sells pharmaceutical products (public and private, urban and rural)		
Outcomes and Attributes	Performance, Responsiveness	OA 5	Existence of mechanisms, such as surveys, for obtaining client input on appropriate, timely, and effective access to health services†		
Outcomes and Attributes	Resilience, Self-Regulating	OA 6	Average time lag between identification of a safety signal of a serious adverse drug event or significant medicine safety issue and communication to health care workers and the public		
Outcomes and Attributes	Resilience, Adaptive	OA 7	Emergency Pharmaceutical Preparedness Plan in place†		
Outcomes and Attributes	Use, Consumption/ End-Use	OA 4	Percentage of patients with 100% on time pill pickup during a defined period for HIV, TB, or other chronic diseases†		

ANNEX 4 – PERFORMANCE INDICATOR REFERENCE SHEETS

PHARMACEUTICAL PRODUCTS & RELATED SERVICES

SELECTION

Indicator Name:	**Existence of a national essential medicines list published within the past five years**
PSS Insight Indicator #:	PS01
Data Type:	Categorical
Topic:	Selection
Definition:	This indicator monitors existence of an up-to-date Essential Medicines List (EML), it is intended for use with or in place of indicator PS02. If there is no reimbursement list for the public sector in the country, indicator PS01 pertaining to the EML should be used. If the country has both an EML and a separate list for reimbursement of pharmaceutical products, use both PS01 and PS02.
Assessment Questions:	Is there a national list of essential medicines?
	What is the year of publication of the latest version of the national essential medicines list?
Purpose and Issues:	The purpose of this indicator is to verify that a document exists that can provide some measure of the relevance/prioritization of medicines available in country. The existence of an EML demonstrates priority setting to contain expenditure while optimizing health benefits. Essential medicines lists should be updated at least every five years.
Preferred Data Sources:	Published list, Formulary or selection committee
Method of Estimation:	Yes/No
Proposed Scoring or Benchmarking:	Countries should have an EML, with a publication or revision date within the past five years of the data of data collection.
Expected Frequency of Data Dissemination:	Annually
Indicator Reference Number(s):	0012
Indicator Source(s):	Health Systems 20/20. (2012). The Health System Assessment Approach: A How-To Manual. Version 2.0. Module 6. www.healthsystemassessment.org

Indicator Name:	**Existence of a reimbursement list published within the past two years**
PSS Insight Indicator #:	PS02
Data Type:	Categorical
Topic:	Selection
Definition:	This indicator monitors existence of an up-to-date reimbursement list for pharmaceutical products in the public sector. It is intended for use with or in place of indicator PS01. If there is no reimbursement list for the public sector in the country, indicator PS01 pertaining to the EML should be used. If the country has both an EML and a separate list for reimbursement of pharmaceutical products, use both PS01 and PS02.
Assessment Questions:	What is the year of publication of the latest version of the national essential medicines list?
	Is there a national list of medicines for reimbursement? (Note: if the EML is used for this purpose please respond "Yes" and write EML in comments)
	What is the year of publication of the latest version of the reimbursement list? (Note: if the EML is used for this purpose please enter the year of publication of the EML)
Purpose and Issues:	The purpose of this indicator is to verify that a document exists that can provide some measure of the relevance/prioritization of medicines available in country. A reimbursement list demonstrates priority setting to contain expenditure while optimizing health benefits. The existence of a reimbursement list depends on the maturity and history of a particular country's health system. As countries move toward universal health coverage (UHC), ministries of health will need to be explicit in the medicines benefits packages offered under public insurance schemes. Over time, we expect more countries to publish a reimbursement list. A country's target is to have a reimbursement list or multiple lists, depending on the number of insurance schemes in the country, updated a minimum of every two years. If a country has multiple insurance schemes, the reimbursement list of the insurance scheme that serves the largest number of poor people should be used for computing this indicator.
Preferred Data Sources:	Published list, Formulary or selection committee
Method of Estimation:	Yes/No
Proposed Scoring or Benchmarking:	Each country should have 1 or more lists of pharmaceutical products for reimbursement under their public health insurance schemes. If the EML is used for this purpose, specify that the reimbursement list in use is the EML. Reimbursement lists should be updated at least every 2 years – the publication or revision date should be within 2 years of the date of data collection.
Indicator Reference Number(s):	0012
Indicator Source(s):	Health Systems 20/20. (2012). The Health System Assessment Approach: A How-To Manual. Version 2.0. Module 6. www.healthsystemassessment.org

PROCUREMENT

Indicator Name:	**% of median international price paid for a set of tracer medicines that was part of the last regular MOH procurement**
PSS Insight Indicator #:	PS03
Data Type:	Continuous
Topic:	Procurement
Definition:	This indicator tracks the potential overspending/savings on tracer medicines. Median international price is the median free on board (FOB) price from a set of international suppliers, adjusted to reflect estimated cost, insurance, and freight (CIF) prices. One source of price information is the MSH International Drug Price Indicator Guide. The last regular procurement price refers to the CIF price paid during the last regular MOH procurement.
Assessment Questions:	Does the country track the procurement prices of tracer medicines (as determined by the country)?
	If "Yes" please obtain a copy of the pricing information
Purpose and Issues:	Rationale: This indicator will help determine the potential savings to the MOH that could be achieved if procurement practices are improved.
Preferred Data Sources:	MSH Price Guide, MOH- Procurement unit, Central medical stores
Method of Estimation:	The indicator should be presented as the percentages of median international prices for the set of country-defined tracer medicines. If data are collected from different levels of the system, a separate average should be calculated for each level. If a country has more than one public institution, the one that serves the poorest people according to the national poverty level should be chosen to assess using this indicator. If procurement is decentralized, the average procurement price should be used. For instance, if the Ministry of Health institutions are providing services to the poorest patients, the Ministry of Health procurement should be assessed. The computation involves two steps: First, the percentages are calculated for each of the tracer medicines by dividing the purchase cost of the comparison unit (e.g., tablet, milliliter, etc.) at the last regular MOH procurement by the median international price of that unit and multiplying the result by 100%. $\%\ of\ Median\ Price_{individual} = \frac{Country\ comparison\ unit\ price}{Median\ international\ unit\ price} \times 100\%$ Second, the average percentage for all tracer medicines is calculated by summing their percentages and dividing by the total number on the list. $\%\ of\ Median\ Price_{set} = \frac{\sum \%\ of\ Median\ Price_{individual}}{Total\ number\ of\ tracer\ medicines\ in\ set}$

Proposed Scoring or Benchmarking:	The original source of the indicator does not set a specific target value. It is important that countries identify their baseline and measure trends over time. Ideally, the median price ratio is below or equal to 100%, however, it is unrealistic to expect that for all tracer medicines a median international price or lower is achieved. Cameron et al found that the median price ratio depends on the income level of the country where the median price ratio is lower for lower income countries than for higher income countries. Comparison of procurement price indices across countries may be useful to compare and contrast the efficiency of procurement processes in different systems, though context (country size, accessibility to transport, income level, etc.) are important contextual factors when attempting to compare across countries.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Every five years
Cross References:	DRUG MANAGEMENT FOR CHILDHOOD ILLNESS MANUAL (See pages 144-145)
URL:	http://pdf.usaid.gov/pdf_docs/PNACM451.pdf

DISTRIBUTION

Indicator Name:	**Mean % availability across a basket of medicines**
PSS Insight Indicator #:	PS04
Data Type:	Continuous
Topic:	Distribution
Definition:	The mean availability of a basket of medicines is the % of availability of each preselected product that is available at the time of the facility visit divided by the total number of preselected products on the list.
Assessment Questions:	If the country collects this data routinely, please enter the percentage (mean) availability across a nationally defined basket of tracer medicines and obtain a copy of their data. If the country does not routinely collect this information, it should be assessed according to the WHO and HAI methodology referenced below.
Purpose and Issues:	Availability is a condition to guarantee access to medicines at the point of service for the consumer or patient.
Preferred Data Sources:	Results of facility surveys, interview at MOH pharmaceutical division

Method of Estimation:	To compute the mean % availability across a basket of medicines, for each product included in the tracer basket, total the number of facilities where the product is physically present at the time or the survey, divided by the total number of facilities surveyed. Do this for each product in the basket, then sum each fraction and divide the total by the number of tracer products included in the basket. Multiply this by 100% to compute the mean % availability across the tracer basket. $$Mean\ \%\ Availability_{Basket} = \frac{\sum \frac{\#\ facilities\ where\ each\ product\ is\ present}{Total\ number\ of\ facilities\ surveyed}}{Total\ \#\ tracer\ products\ surveyed} \times 100\%$$
Proposed Scoring or Benchmarking:	Countries should aim for 100% product availability across their tracer baskets; however this may not be appropriate for all contexts. It is possible that certain tracer basket medicines should only be available in secondary or tertiary facilities, for example. Countries should define their tracer baskets according to the epidemiological needs of the country and to provide stock availability data across facility types and conditions. Over time, countries should aim to improve stock availability.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annually
URL:	http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf
Indicator Reference Number(s):	0657
Indicator Source(s):	WHO and HAI. (2008). Measuring medicine prices, availability, affordability and price components, 2nd ed. Geneva: World Health Organization and Health Action International. http://www.haiweb.org/medicineprices/manual/documents.html

Indicator Name:	**Product losses by value due to expired medicines or damage or theft per value received (%)**
PSS Insight Indicator #:	PS05
Data Type:	Continuous
Topic:	Distribution
Definition:	During storage and distribution of medicines, products may not reach their destination for different reasons: loss during transport, expiry, theft, etc. This indicator measures the % of products by value that are not available out of the total value of products procured
Assessment Questions:	In the last calendar year (or the latest year for which data are available) what is the total value of product losses due to expiry, damage, and/or theft? Please indicate the appropriate currency.
	In the reference year, what is the value of pharmaceuticals procured? Please indicate the appropriate currency.
	What is the last year for which data are available?

Purpose and Issues:	To increase efficiency, it is important to minimize waste of products. The closer the indicator value to zero the better. This indicator is intended for use in the public sector only and may only be assessed in systems where the public sector procures pharmaceutical products and distributes them or contracts with a third-party distributor who must report product losses by these categories. In some cases, these data are considered sensitive and are either not collected or may be difficult to obtain.
Preferred Data Sources:	Stock availability records, procurement records, audit reports, registers and police reports. Interviews at MOH pharmaceutical division, CMS, warehouses
Method of Estimation:	$\frac{\text{Value of product loss to expiry, damage, theft following receipt}}{\text{Total value of products received}} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should aim to reduce product losses over time. The ideal target is 0%.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annually
Indicator Reference Number(s):	0812
Indicator Source(s):	Wendt, D. (2012). Health system rapid diagnostic tool framework. Operational guide and metrics to measure the strength of priority health system functions. Durham NC: FHI 360. http://www.fhi360.org/sites/default/files/media/documents/Health%20System%20Rapid%20Diagnostic%20Tool.pdf

USE

Indicator Name:	**% Generic medicines out of total market volume**
PSS Insight Indicator #:	PS06
Data Type:	Continuous
Topic:	Use
Definition:	Generic: A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. Total market volume: The total number of units (doses, tablets, cases, boxes) dispensed in the country. This can be restricted to the public sector only, or can be disaggregated by procuring entity – donors, government, non-profit/non-governmental, private sector etc.
Assessment Questions:	How many units of medicines were dispensed in total (by each procuring entity) during the last year for which data are available?
	During this same period, how many of these dispensed units were generic medicines?
	What is the last year for which data are available?
Purpose and Issues:	Generic medicines are generally cheaper to procure and for consumers to purchase than branded or originator products. This represents cost savings to both the procuring entity and the patient. Ideally, this indicator should be computed using unit volumes, rather than values, and should be for volumes dispensed, rather that procured. In systems where dispensing records are readily available, the indicator as defined will give a sense of the relative amount of generic medicines actually dispensed and used in the country, at the patient level. This data may be difficult to obtain in systems without centralized or electronic dispensing records. Where procurement values are available, this may be substituted for volumes instead, but will be less relevant to use and more relevant to the element of selection, as it examines relative volumes procured at central level, rather than volumes in use by patients or dispensed at facility level. Similarly, if volumes are not available, values may be used. Once again, procurement values will shift the meaning of the indicator to be most relevant as a medicine selection indicator. Values of medicines dispensed will still highlight aspects of medicine use, however the relative share of generics to branded products will be obscured, as branded products are generally more expensive. The most useful iteration of this indicator involves computing it twice – once with dispensed volumes and again with dispensed values, to illustrate the relative share of dispensed medicines that are generics (based on volume) and the relative cost of generic medicines compared with branded products at the facility level (based on values).
Preferred Data Sources:	Dispensing records of health facilities

Method of Estimation:	$\frac{Volume\ of\ generic\ medicines\ dispensed}{Total\ volume\ of\ medicines\ dispensed} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should monitor their trends over time and aim to increase the share of generics dispensed in the country. Percentages of generics dispensed should be closer to 100%, but it is impractical to expect 100% of medicines dispensed are generics.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annual
Indicator Source(s):	Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf

Indicator Name:	**Defined daily dose (DDD) for antimicrobials (per 1000 population)**
PSS Insight Indicator #:	PS07
Data Type:	Continuous
Topic:	Use
Definition:	Drug consumption can be expressed in cost, number of units, number of prescriptions or by the physical quantity of drugs. However these variables can vary between regions and countries over time. This limits comparisons of drug consumption at an international level. To address this, a technical unit of measurement, the Defined Daily Dose (DDD) was created. Defined Daily Dose (DDD): The assumed average maintenance dose per day for a drug used for its main indication in adults.[70] Antimicrobials: An antimicrobial is an agent that kills microorganisms or stops their growth. These are included in ATC code group J.
Assessment Questions:	This should be computed according to the methodology in the WHO DDD Toolkit. For more information, refer to the Method of Estimation section.

[70] World Health Organization. DDD Toolkit – Definition and general considerations. Available from: https://www.who.int/tools/atc-ddd-toolkit/about-ddd

Purpose and Issues:	DDDs are only assigned for medicines given an ATC codes. The DDDs are allocated to drugs by the WHO Collaborating Centre in Oslo, working in close association with the WHO International Working Group on Drug Statistics Methodology. Only one DDD is assigned per ATC code and route of administration (e.g. oral formulation). The DDD is sometimes a dose that is rarely or never prescribed because it is an average of two or more commonly used doses. The DDD is a unit of measurement and does not necessarily correspond to the recommended or Prescribed Daily Dose (PDD). Therapeutic doses for individual patients and patient groups will often differ from the DDD as they will be based on individual characteristics such as age, weight, ethnic differences, type and severity of disease, and pharmacokinetic considerations. Drug utilization data presented in DDDs give a rough estimate of consumption and not an exact picture of actual use. DDDs provide a fixed unit of measurement independent of price, currencies, package size and strength enabling the researcher to assess trends in drug utilization and to perform comparisons between population groups. By applying DDD it is possible to: Examine changes in drug utilization over time Make international comparisons Evaluate the effect of an intervention on drug use Document the relative therapy intensity with various groups of drugs Follow the changes in the use of a class of drugs Evaluate regulatory effects and effects of interventions on prescribing patterns.
Preferred Data Sources:	WHO DDD Index for reference or benchmark DDD (Available here: https://www.whocc.no/atc_ddd_index/), dispensing records to compute DDD for selected antimicrobial agents.
Method of Estimation:	Use dispensing, procurement, or consumption data to convert volumes of selected antimicrobials to units of DDD, according to the WHO index. Divide this number by the country's population during the reference year, and multiply by 1000, to compute DDD per 1000 inhabitants during the reference year. Further information on the methodology can be found here: https://www.whocc.no/use_of_atc_ddd/ To select antimicrobials for monitoring and to design an antimicrobial monitoring program, use the WHO methodology for a global programme on surveillance of antimicrobial consumption: https://www.who.int/medicines/areas/rational_use/WHO_AMCsurveillance_1.0.pdf
Proposed Scoring or Benchmarking:	Countries should monitor their trends over time and aim to align their consumption of antimicrobials with the DDD index as determined by the WHO.
Unit of Measure:	Decimal

Expected Frequency of Data Dissemination:	Annual
Indicator Source(s):	World Health Organization Collaborating Centre for Drug Statistics Methodology. Use of ATC/DDD – DDD Indicators. Available from: https://www.whocc.no/use_of_atc_ddd/#indica

Indicator Name:	**% Medicines prescribed from an EML or reimbursement list**
PSS Insight Indicator #:	PS08
Data Type:	Continuous
Topic:	Use
Definition:	This indicator is based on a review of prescriptions within the country. It involves matching the prescription with a product on the essential medicines list or the relevant reimbursement list referenced in indicator PS02
Assessment Questions:	Of the 20 prescriptions reviewed, how many medicines were listed in the essential medicines list or reimbursement list?
Purpose and Issues:	The percentage of medicines prescribed from an EML or reimbursement list connects to the Selection component and evaluates how the outcome of the selection process actually relates to the medicines prescribed at health facility level and used by patients in the country. Ideally, this should be done as a routine monitoring exercise using electronic prescribing records. In low- and middle- income country settings, this can be completed through a manual review of prescriptions at health facilities. We have used 20 prescriptions per facility as an example sample size, but adjustments can be made according to country context. Variations in sampling should be made explicit in any reporting documents. It is important to note that the indicator is based on prescriptions from an EML or reimbursement list, not dispensing records. The indicator is intended to examine prescribing behaviors, and products may be substituted at the dispensing point to align with EML or reimbursement lists, and obscure what is actually being prescribed if dispensing records are used.
Preferred Data Sources:	Prescription data collected at health facility level through observed patient encounters and records reviews, electronic prescribing records.
Method of Estimation:	$\%\ Medicines\ from\ EML = \frac{\#\ Medicines\ listed\ on\ EML\ or\ list}{\#\ Medicines\ reviewed} \times 100\%$

Proposed Scoring or Benchmarking:	Prescribers should be using the EML or reimbursement list to prescribe from whenever possible. In theory, these lists should also align with the national standard treatment guidelines. These documents together serve to standardize prescribing behavior and align prescriptions with medicine selection processes and according to clinical best practice according to the diagnosed condition. Prescribing from the EML or reimbursement list also reduces costs to patients, who would likely pay out of pocket for any medicine that is not included on the EML or reimbursement list that they are subject to. Countries should monitor their trends over time. The target is 80%, based on prior work to validate the indicator,[26] as it is impractical to assume that every prescription should be covered by the EML or reimbursement list, particularly for rare diseases or specialized treatment, such as those for cancer, for example.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	At least every five years
Cross References:	Dong L, Yan H, Wang D. Drug prescribing indicators in village health clinics across 10 provinces of Western China. Fam Pract 2011;28:63
URL:	http://fampra.oxfordjournals.org/content/28/1/63.long
Indicator Reference Number(s):	I6.5.5a, 0300, 0384, 0074, 0382, 0506, 0076, 0385, 0078, 0383
Indicator Source(s):	MSH, Center for Pharmaceutical Management. Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs. Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID February 2013. World Health Organization. (1993). How to investigate drug use in health facilities: selected drug use indicators. EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/ WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/

	WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/

Indicator Name:	**% Medicines prescribed as generics**
PSS Insight Indicator #:	PS09
Data Type:	Continuous
Topic:	Use
Definition:	Generic: A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.[71] This indicator is based on a review of prescriptions within the country. It involves matching the prescription with an international non-proprietary name (INN) or generic product name
Assessment Questions:	Of the 20 prescriptions reviewed, how many medicines were prescribed using generic name or INN?
Purpose and Issues:	The percentage of medicines prescribed as generics examines whether prescribers are adhering to best practice and issuing prescriptions by international nonproprietary name (INN), which can have implications on medicine affordability if patients are prescribed and dispensed branded products in lieu of an available generic. This relates to the indicator "% of generic medicines out of total market volume," which seeks to survey the relative amount of generic medicines actually dispensed in the country. These two indicators taken together assess both prescribing behavior regarding generic medicines and how many generics are actually used and dispensed in the country. It is important to note that the indicator is based on prescriptions, not dispensing records. The indicator is intended to examine prescribing behaviors, and products may be substituted at the dispensing point, and obscure what is actually being prescribed if dispensing records are used.

[71] World Health Organization. International Nonproprietary Names Programme and Classification of Medical Products. Available from: https://www.who.int/teams/health-product-and-policy-standards/inn/#:~:text=International%20Nonproprietary%20Names%20(INN)%20facilitate,known%20as%20a%20generic%20name.

Preferred Data Sources:	Prescription data collected at health facility level through observed patient encounters and records reviews, electronic prescribing records.
Method of Estimation:	$\%\ Medicines\ prescribed\ by\ INN = \frac{\#\ Medicines\ prescribed\ by\ INN}{\#\ Medicines\ reviewed} \times 100\%$
Proposed Scoring or Benchmarking:	Prescribers should be prescribing by INN whenever possible. Very few prescriptions should contain medicines for which a generic product does not exist or an INN has not been assigned. Prescribing by INN potentially reduces costs to patients, as products included on EML or reimbursement lists are listed according to INN, and any discrepancy from the listed products may preclude substitution of a generic at the dispensing point and cause patients to pay out of pocket for a higher priced branded product, when a generic may be available at reduced or no cost to them. This is particularly true in settings where generic substitution by the dispenser is not permitted. Countries should monitor their trends over time. The target is 80%, based on prior work validating the indicator,[26] as it is impractical to assume that every medicine has at least one generic product available in the country.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	At least every five years
Cross References:	Dong L, Yan H, Wang D. Drug prescribing indicators in village health clinics across 10 provinces of Western China. Fam Pract 2011;28:63
URL:	http://fampra.oxfordjournals.org/content/28/1/63.long
Indicator Reference Number(s):	I6.5.5a, 0300, 0384, 0074, 0382, 0506, 0076, 0385, 0078, 0383
Indicator Source(s):	MSH, Center for Pharmaceutical Management. Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs. Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID February 2013. World Health Organization. (1993). How to investigate drug use in health facilities: selected drug use indicators. EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/ WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf

	WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/

Indicator Name:	**% Antibiotics prescribed in outpatient settings**
PSS Insight Indicator #:	PS10
Data Type:	Continuous
Topic:	Use
Definition:	Antimicrobials: An antimicrobial is an agent that kills microorganisms or stops their growth. These are included in ATC code group J. An antibiotic is an antimicrobial agent that helps stop infections caused by bacteria. They do this by killing the bacteria or by keeping them from copying themselves or reproducing. Antibiotics are included in ATC code group J01. An outpatient setting is a health care facility where patients are treated without being admitted to the facility for extended observation, stay, or treatment. This indicator is based on a review of prescriptions within the country. It involves identifying the number of antimicrobials included in each reviewed prescription, compared to the total number of medicines prescribed.
Assessment Questions:	Of the 20 prescriptions reviewed, how many medicines were antibiotics?
Purpose and Issues:	This indicator examines the behavior and practices of prescribers regarding antimicrobials, which are often over-prescribed. This is a major contributing force to antimicrobial resistance, which threatens the viability of key antimicrobial medicines for future use in fighting key global diseases. It is important to note that the indicator is based on prescriptions, not dispensing records. The indicator is intended to examine prescribing behaviors, and products may be substituted at the dispensing point, and obscure what is actually being prescribed if dispensing records are used.
Preferred Data Sources:	Prescription data collected at health facility level through observed patient encounters and records reviews, electronic prescribing records. These should be specific to outpatient contexts.
Method of Estimation:	$\%\ Antiobiotics\ prescribed = \frac{\#\ Antibiotics\ prescribed}{\#\ Medicines\ reviewed} \times 100\%$

Proposed Scoring or Benchmarking:	Countries should monitor their trends over time. The target is 30%, based on prior work to validate this indicator.[26]
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	At least every five years
Cross References:	Dong L, Yan H, Wang D. Drug prescribing indicators in village health clinics across 10 provinces of Western China. Fam Pract 2011;28:63
URL:	http://fampra.oxfordjournals.org/content/28/1/63.long
Indicator Reference Number(s):	I6.5.5a, 0300, 0384, 0074, 0382, 0506, 0076, 0385, 0078, 0383
Indicator Source(s):	MSH, Center for Pharmaceutical Management. Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs. Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID February 2013. World Health Organization. (1993). How to investigate drug use in health facilities: selected drug use indicators. EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/ WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/ WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf WH0. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/

Indicator Name:	**% Population with unmet medicine needs**
PSS Insight Indicator #:	PS11
Data Type:	Continuous
Topic:	Use
Definition:	Unmet medicine need: Self-reported unmet need for pharmaceutical products and services, measured by the "unmet needs of healthcare" concept.[72] This is typically attributed to three factors – distance to treatment, wait times, and cost of treatment.
Assessment Questions:	Was there any time during the last 12 months when, in your opinion, you needed a medical examination or treatment for a health problem but you did not receive it?
	What was the main reason for not obtaining treatment? a) Could not afford to (too expensive); b) Waiting list; c) Could not take time because of work, care for children or for others; d) Too far to travel/no means of transportation; e) Fear of doctor / hospitals / examination / treatment; f) Wanted to wait and see if problem got better on its own; g) Didn't know any good doctor or specialist; h) Other reason
Purpose and Issues:	This indicator should be collected through routine household surveys, so if a data collection instrument of this nature does not exist in the country, we acknowledge that this indicator will be difficult to collect. This difficulty is balanced by the importance of the indicator in evaluating how the pharmaceutical system is serving patients, and whether patients feel that their medicine needs are being met, which is the ultimate goal of any pharmaceutical system.
Preferred Data Sources:	Household surveys
Method of Estimation:	$\frac{\#\ of\ households\ reporting\ unmet\ medicine\ need}{\#\ of\ households\ surveyed} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should monitor their trends over time and aim to decrease the share of their populations that report unmet medicine needs.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	At least every five years
Indicator Source(s):	World Health Organization – Global Health Observatory. Extent of self-reported unmet need for health care services in different sub-groups of population. Available from: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/855

[72] Vreman RA, Heikkinen I, Schuurman A, Sapede C, Garcia JL, Hedberg N, Athanasiou D, Grueger J, Leufkens HG, Goettsch WG. Unmet medical need: an introduction to definitions and stakeholder perceptions. Value in Health. 2019 Nov 1;22(11):1275-82.

POLICY, LAWS, AND GOVERNANCE

COORDINATION & LEADERSHIP

Indicator Name:	**An institutional development plan of the national medicines regulatory authority based on the results of the GBT exists**
PSS Insight Indicator #:	PLG01
Data Type:	Categorical
Topic:	Coordination and leadership
Definition:	The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables WHO and regulatory authorities to:[11] • identify strengths and areas for improvement; • facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps; • prioritize IDP interventions; and • monitor progress and achievements.
Assessment Questions:	Has the country completed at least 1 GBT assessment?
	Has the country developed and published an institutional development plan as a result of the last GBT exercise?
Purpose and Issues:	Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation. Published institutional development plans provide a roadmap for system improvement and are the result of coordination and planning across several pharmaceutical system functions.
Preferred Data Sources:	Published IDP
Proposed Scoring or Benchmarking:	All countries should aim to prepare and publish an IDP within 1 year of completing a GBT assessment
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	At least every five years
Cross References:	World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. World Health Organization.
URL:	http://www. who. int/medicines/regulation/benchmarking_tool/en/. Published. 2017.

Indicator Name:	**A progress report on the institutional development of the national medicines regulatory authority published**
PSS Insight Indicator #:	PLG02
Data Type:	Categorical
Topic:	Coordination and leadership
Definition:	The Global Benchmarking Tool (GBT) represents the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables WHO and regulatory authorities to:[11] • identify strengths and areas for improvement; • facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps; • prioritize IDP interventions; and • monitor progress and achievements. Countries should report progress towards the goals and system improvements documented in the institutional development plan.
Assessment Questions:	Has the country completed at least 1 GBT assessment?
	Has the country developed and published an institutional development plan as a result of the last GBT exercise?
	Has the country published a progress report for the institutional development plan?
Purpose and Issues:	Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation. Published institutional development plans provide a roadmap for system improvement and are the result of coordination and planning across several pharmaceutical system functions. Progress reports toward the goals identified in the institutional development plan hold stakeholders accountable for advancing toward these goals.
Preferred Data Sources:	Published IDP, published IDP progress report
Proposed Scoring or Benchmarking:	All countries should aim to prepare and publish an IDP within 1 year of completing a GBT assessment
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	At least every five years
Cross References:	World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. World Health Organization.
URL:	http://www. who. int/medicines/regulation/benchmarking_tool/en/. Published. 2017.

Indicator Name:	**Submission of national data to the Global Antimicrobial Resistance Surveillance System (GLASS)**
PSS Insight Indicator #:	PLG03
Data Type:	Categorical
Topic:	Coordination and leadership
Definition:	Launched in October 2015, the Global Antimicrobial Resistance Surveillance System (GLASS) is being developed to support the global action plan on antimicrobial resistance. The aim is to support global surveillance and research in order to strengthen the evidence base on antimicrobial resistance (AMR) and help informing decision making and drive national, regional, and global actions.
Assessment Questions:	Has the country submitted data to GLASS within the past 12 months?
Purpose and Issues:	GLASS promotes and supports a standardized approach to the collection, analysis and sharing of AMR data at a global level by encouraging and facilitating the establishment of national AMR surveillance systems that are capable of monitoring AMR trends and producing reliable and comparable data. GLASS objectives: • Foster national surveillance systems and harmonized global standards; • estimate the extent and burden of AMR globally by selected indicators; • analyse and report global data on AMR on a regular basis; • detect emerging resistance and its international spread; • inform implementation of targeted prevention and control programmes; and • assess the impact of interventions. Participation in GLASS promotes coordination and leadership domestically, to collect, analyze, and report national data, as well as globally, to benefit from and contribute to a global coordination mechanism with the aim of combatting antimicrobial resistance.
Preferred Data Sources:	GLASS data submission reports, GLASS annual reports
Proposed Scoring or Benchmarking:	Countries should aim to actively participate in GLASS and submit data according to their reporting requirements
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	Annual
Cross References:	World Health Organization - Global Antimicrobial Resistance Surveillance System (GLASS)
URL:	https://www.who.int/glass/en/

Indicator Name:	**Updated National Action Plan on the containment of antimicrobial resistance**
PSS Insight Indicator #:	PLG04
Data Type:	Categorical
Topic:	Coordination and Leadership
Definition:	In May 2015, the Sixty-eight World Health Assembly adopted the global action plan on antimicrobial resistance. The goal of the global action plan is to ensure, for as long as possible, continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them. The World Health Assembly also urged all Member States to develop and have in place by 2017, national action plans on antimicrobial resistance that are aligned with the objectives of the global action plan.
Assessment Questions:	Has the country developed and published a national action plan on the containment of antimicrobial resistance?
	What is the year of the most recent update or revision of the action plan?
Purpose and Issues:	The prevention and containment of antimicrobial resistance requires an intersectoral national action plan.
Preferred Data Sources:	Published document (dated), interview at Ministry of Health or related governing body pertaining to pharmaceuticals
Method of Estimation:	Yes/No
Proposed Scoring or Benchmarking:	Countries should have developed a national action plan – the WHO stated that its goal was to have all member states publish plans by 2017. Plans should be reviewed and updated at least every five years.
Unit of Measure:	
Expected Frequency of Data Dissemination:	five years
Cross References:	World Health Organization. Antimicrobial resistance – National Action Plans.
URL:	https://www.who.int/antimicrobial-resistance/national-action-plans/en/

PHARMACEUTICAL LAWS & REGULATIONS

Indicator Name:	**# of annual reports submitted to the INCB in last five years**
PSS Insight Indicator #:	PLG05
Data Type:	Discrete – ordinal
Topic:	Pharmaceutical Laws and Regulations

Definition:	The International Narcotics Control Board (INCB) is the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. The drug control conventions established a control regime that would ensure the availability of controlled substances for medical and scientific production while preventing their illicit production, trafficking and abuse. An essential component of this regime is a system under which governments are requested to estimate the quantities of controlled substances required for legitimate purposes and to limit the use of and trade in such substances to within those estimates. The ability of the INCB to monitor the functioning of the drug control mechanisms established by the conventions relies, in part, on governments providing it with estimated quantities of controlled substances required for legitimate purposes in their countries.
Assessment Questions:	If the country is a signatory to the 1961 Convention on Narcotic Drugs:
	for how many of the past five years have annual statistics reports on narcotics (Form C) been submitted to the INCB ? How many annual statistical reports on narcotics (Form C) have been submitted to the INCB in the previous 5 calendar years?
	Have annual estimates for narcotics been submitted to INCB each of the previous five years? How many annual estimates for narcotic drugs have been submitted to the INCB in the previous 5 calendar years?
	How often is the estimate for narcotic drugs revised? (Ex. "Every __ years")
	What is the year of the previous revision to the narcotic drug estimate?
	If the country is a signatory to the 1971 Convention on Psychotropic Substances:
	How many annual statistical reports on psychotropic substances (Form P) have been submitted to the INCB in the previous 5 calendar years?
	How many annual estimates for psychotropic substances have been submitted to the INCB in the previous five calendar years?
	How often is the estimate for psychotropic substances revised? (Ex. "Every __ years")
	What is the year of the previous revision to the psychotropic substances estimate?
Purpose and Issues:	Submitting annual reports to the INCB allows the board to evaluate overall compliance with the provisions of the international drug control treaties. This also ensures that adequate quantities of narcotics and psychotropic substances are available to meet the needs of the country for medical purposes and ensure appropriate access to these products for palliative care.
Preferred Data Sources:	INCB Annual Reports
Method of Estimation:	Number of annual reports
Proposed Scoring or Benchmarking:	Each country should be a signatory to the 1961 and 1971 conventions and should complete their annual reporting requirements every year.
Unit of Measure:	Integer
Expected Frequency of Data Dissemination:	Annually

URL:	https://www.incb.org/ https://www.incb.org/incb/en/treaty-compliance/index.html https://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf

ETHICS, TRANSPARENCY, AND ACCOUNTABILITY

Indicator Name:	**Pharmaceutical System Transparency and Accountability (PSTA) assessment score**
PSS Insight Indicator #:	PLG06
Data Type:	Continuous
Topic:	Ethics, Transparency, and Accountability
Definition:	WHO has developed the PSTA assessment tool to assist countries with the assessment of the public availability of key documentation that facilitates accountability of the pharmaceutical system. This document is intended for policy makers and concerned stakeholders with an interest in improving governance in the pharmaceutical system as well as for those who will carry out an assessment. The assessment results are intended to be used to: • Identify strengths and weaknesses with regards to transparency of pharmaceutical information • Inform priority setting • Develop targeted policy interventions • Periodically to monitor progress The main focus of the assessment is on transparency and accountability in the public sector. Other sectors are included in the assessment when relevant for accountability.
Purpose and Issues:	Transparency and accountability are consistently identified as key to attaining stronger pharmaceutical system governance. Increasing the level of transparency and accountability in the pharmaceutical system decreases vulnerabilities for corruption and unethical practices and improves efficiency, credibility and public trust in government institutions. Opportunities for corrupt practices such as bribery, embezzlement, misappropriation of funds and diversion of medicines that occur throughout the pharmaceutical system can be minimized when standards and clear responsibilities are assigned; decisions and results are documented and made public to show whether standards and commitments have been met; and corrective actions, including sanctions, are enforced if necessary. Note that the tool has been designed according to modules. To use the tool to assess this element, multiple scores are needed to aggregate for a complete system score. This indicator is considered incomplete if only some, and not all, modules of the tool are completed. Modules completed over multiple years may be combined to form a complete assessment score if the modules were completed within 3 years.
Preferred Data Sources:	PSTA assessment
Method of Estimation:	The PSTA assessment generates scores across a number of domains in the tool. These can be reported separately and aggregated together to produce an overall score, which should be reported here.

Proposed Scoring or Benchmarking:	Use the methodology outlined in the tool manual (reference below) to benchmark transparency and accountability as high, moderate, or low according to the benchmarks in the manual.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Every five years
Cross Reference:	PSTA assessment tool. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
URL:	https://apps.who.int/iris/handle/10665/275370

Indicator Name:	**Number of PSTA assessments within the last five years**
PSS Insight Indicator #:	PLG07
Data Type:	Discrete - ordinal
Topic:	Ethics, Transparency, and Accountability
Definition:	WHO has developed the PSTA assessment tool to assist countries with the assessment of the public availability of key documentation that facilitates accountability of the pharmaceutical system. This document is intended for policy makers and concerned stakeholders with an interest in improving governance in the pharmaceutical system as well as for those who will carry out an assessment. The assessment results are intended to be used to: • Identify strengths and weaknesses with regards to transparency of pharmaceutical information • Inform priority setting • Develop targeted policy interventions • Periodically to monitor progress The main focus of the assessment is on transparency and accountability in the public sector. Other sectors are included in the assessment when relevant for accountability.
Purpose and Issues:	Transparency and accountability are consistently identified as key to attaining stronger pharmaceutical system governance. Increasing the level of transparency and accountability in the pharmaceutical system decreases vulnerabilities for corruption and unethical practices and improves efficiency, credibility and public trust in government institutions. Opportunities for corrupt practices such as bribery, embezzlement, misappropriation of funds and diversion of medicines that occur throughout the pharmaceutical system can be minimized when standards and clear responsibilities are assigned; decisions and results are documented and made public to show whether standards and commitments have been met; and corrective actions, including sanctions, are enforced if necessary.
Preferred Data Sources:	PSTA assessment
Method of Estimation:	Enter the number of PSTA assessments completed within the past five years

Proposed Scoring or Benchmarking:	The tool manual does not specify a recommended frequency for applying the assessment. The assessment should have been completed at least once in the preceding 5 year period.
Unit of Measure:	Integer
Expected Frequency of Data Dissemination:	Every five years
Cross Reference:	Pharmaceutical System Transparency and Accountability Assessment Tool. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
URL:	https://apps.who.int/iris/handle/10665/275370

REGULATORY SYSTEMS

INSPECTION & ENFORCEMENT

Indicator Name:	**% of manufacturing facilities inspected each year**
PSS Insight Indicator #:	RS01
Data Type:	Continuous
Topic:	Inspection and Enforcement
Definition:	Manufacturing facilities should be inspected to ensure the safety and quality of pharmaceuticals produced. A manufacturing facility is defined as any facility that is licensed and registered in the country to manufacture pharmaceuticals. The indicator should be calculated for the previous calendar year, or the latest year for which data are available
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total number of licensed pharmaceutical manufacturers registered in the country?
	In the reference year, what is the total number of registered manufacturers that were inspected, either by the NMRA or another authorized entity (stringent regulatory authority, WHO, reciprocated inspection/certification authority?
Purpose and Issues:	This indicator assesses the capacity of inspectors to monitor the safety and quality of manufacturing processes for pharmaceuticals produced domestically in the country. Higher percentages indicate a higher capacity to inspect pharmaceutical establishments for quality and safety control, and compliance with pharmaceutical regulations in the country.
Preferred Data Sources:	Annual inspection reports, NMRA interview
Method of Estimation:	For domestic manufacturers in a given year: $\frac{\#\ Manufacturing\ facilities\ inspected}{\#\ Manufacturing\ facilities\ registered} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should monitor trends over time. Depending on the size of domestic manufacturing in the country, it may not be practical to inspect 100% of these facilities annually.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annually
Cross References:	Indicators for Monitoring National Drug Policies. (See Page 117)
URL:	http://apps.who.int/medicinedocs/en/d/Jwhozip14e/

Indicator Reference Number(s):	I1.8.3
Indicator Source(s):	MSH - CPM, University Research Corporation, PAHO, USAID. Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program. July 1995

Indicator Name:	**% of distribution facilities inspected each year**
PSS Insight Indicator #:	RS02
Data Type:	Continuous
Topic:	Inspection and Enforcement
Definition:	Distribution facilities should be inspected to ensure the safety and quality of pharmaceuticals in the supply chain. Distribution facilities are defined as facilities licensed and registered to distribute pharmaceuticals within the country. This includes both private distributors or wholesalers, and public distributions agencies and warehouses. The indicator should be calculated for the previous calendar year, or the latest year for which data are available
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total number of licensed pharmaceutical distributors registered in the country?
	In the reference year, what is the total number of registered distributors that were inspected?
Purpose and Issues:	This indicator assesses the capacity of inspectors to monitor the safety and quality of distribution processes for pharmaceuticals available for sale or consumption in the country. Higher percentages indicate a higher capacity to inspect pharmaceutical establishments for quality and safety control, and compliance with pharmaceutical regulations in the country.
Preferred Data Sources:	Annual inspection reports, NMRA interview
Method of Estimation:	For distributors in a given year: $\frac{\#\ Distribution\ facilities\ inspected}{\#\ Distribution\ facilities\ registered} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should monitor trends over time. Depending on the size of domestic distribution in the country, it may not be practical to inspect 100% of these facilities annually.
Unit of Measure:	Percentage (%)
Expected Frequency of	Annually

Data Dissemination:	
Cross References:	Indicators for Monitoring National Drug Policies. (See Page 117)
URL:	http://apps.who.int/medicinedocs/en/d/Jwhozip14e/
Indicator Reference Number(s):	I1.8.3
Indicator Source(s):	MSH - CPM, University Research Corporation, PAHO, USAID. Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program. July 1995

Indicator Name:	**% of dispensing facilities inspected each year**
PSS Insight Indicator #:	RS03
Data Type:	Continuous
Topic:	Inspection and Enforcement
Definition:	Dispensing facilities are defined as facilities licensed and registered to dispense pharmaceuticals within the country. The indicator should be calculated for the previous calendar year, or the latest year for which data are available
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total number of licensed pharmaceutical dispensing facilities or retail outlets registered in the country?
	In the reference year, what is the total number of registered dispensing facilities or retail outlets that were inspected)?
Purpose and Issues:	This indicator assesses the capacity of inspectors to monitor the safety and quality of dispensing processes for pharmaceuticals available for sale or consumption in the country. Higher percentages indicate a higher capacity to inspect pharmaceutical establishments for quality and safety control, and compliance with pharmaceutical regulations in the country.
Preferred Data Sources:	Annual inspection reports, NMRA interview
Method of Estimation:	For dispensing facilities in a given year: $\frac{\#\ Dispensing\ facilities\ inspected}{\#\ Dispensing\ facilities\ registered} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should monitor trends over time. It is likely not feasible to inspect 100% of dispensing facilities in the country on an annual basis, but countries should aim to inspect as many facilities as possible.
Unit of Measure:	Percentage (%)

Expected Frequency of Data Dissemination:	Annually
Cross References:	Indicators for Monitoring National Drug Policies. (See Page 117)
URL:	http://apps.who.int/medicinedocs/en/d/Jwhozip14e/
Indicator Reference Number(s):	I1.8.3
Indicator Source(s):	MSH - CPM, University Research Corporation, PAHO, USAID. Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program. July 1995

PRODUCT ASSESSMENT & REGISTRATION

Indicator Name:	**Average number of days for decision making on a medicine application for registration**
PSS Insight Indicator #:	RS04
Data Type:	Continuous
Topic:	Product Assessment and Registration
Definition:	Decision making on an application for registration of a pharmaceutical product can include approvals and rejections. An approval grants market authorization and registration to the entity responsible for the new medicine. A rejection prohibits market authorization and registration. A decision date is the date on which the decision was communicated formally to the applicant. Number of days are defined as the number of working days from the submission of the application until formal notification of decision, unless otherwise specified. National SOPs should specify whether or not holidays are included in the timeframe. Number of days excludes those in which the application is on hold while clarification is sought from the applicant. A new/novel drug or a New Molecular Entity (NME) is an active compound, complex, molecule that previously has not been approved by the regulatory authority in the country. A generic drug is generally defined as a drug product that is equivalent to a reference product in active pharmaceutical ingredient, dosage form, strength, route of administration, quality and performance characteristics and intended use. Many countries have different application processes for “new” and “generic” pharmaceutical products.
Assessment Questions:	For new pharmaceutical products:
	If the country tracks the average number of days taken to review an application for pharmaceutical product registration, please enter the current value here (In the

	Comments box, please note if this is for new pharmaceutical products only, or if this includes all registration applications)
	If the country does not routinely collect this information, enter the total number of business days (excluding days "on hold" pending clarification, and national holidays) taken to review the previous 10 applications for registration of a NEW pharmaceutical product
	For generic pharmaceutical products:
	If the country tracks the average number of days taken to review an application for pharmaceutical product registration, please enter the current value here (In the Comments box, please note if this is for generic pharmaceutical products only, or if this includes all registration applications)
	If the country does not routinely collect this information, enter the total number of business days (excluding days "on hold" pending clarification, and national holidays) taken to review the previous 10 applications for registration of a GENERIC pharmaceutical product
Purpose and Issues:	Decisions should be made within a time period adequate for assessing a new medicine application. Decisions that are made too quickly may allow an unsafe and/or non-efficacious medicine on the market; decisions that take long periods of time may prevent new medicines from reaching the market.
Preferred Data Sources:	Documents of the NMRA specifying receipt of application and date of decision, NMRA interview
Method of Estimation:	Number of days between receipt of application and date of decision (excluding days where application is on hold while clarification is sought from applicant)/# of applications received (if the country tracks this data) or 10
Proposed Scoring or Benchmarking:	Countries should monitor trends over time and aim to expedite approval times to promote access to pharmaceutical products in the country. However, this should not be done at the expense of a thorough quality and safety review process.
Unit of Measure:	Days
Expected Frequency of Data Dissemination:	Yearly
Cross References:	Australian Therapeutic Goods Administration
URL:	https://www.tga.gov.au/publication/half-yearly-performance-report-snapshot-july-december-2015
Indicator Reference Number(s):	0556, 0555
Indicator Source(s):	WHO. (2007). WHO data collection tool for the review of drug regulatory systems. Practical guidance for conducting a review. Geneva: World Health Organization. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/

Indicator Name:	**% of medicines on the EML that have at least one registered product available.**
PSS Insight Indicator #:	RS05
Data Type:	Continuous
Topic:	Product Assessment and Registration
Definition:	Registered products are pharmaceutical products that have been assessed for safety and efficacy, among other criteria, by the National Medicines Regulatory Authority (or equivalent body) and have been granted approval for sale or distribution in the country. Registration should be determined by molecule or INN, dose and form of administration. Products may be registered more than once based on formulation, so it is important to exclude duplicate registered products in both the numerator and denominator. An Essential Medicines List (EML) is a published list of priority medicines that satisfy the priority health care needs of the population.
Assessment Questions:	If the country tracks this information, enter the percentage of EML medicines that have at least one product registered.
	If the country does not track this information, obtain the latest copies of both the national EML and the registered products list to perform the comparison.
Purpose and Issues:	The purpose is to show how closely market authorization follows the priorities set in the national EML.
Preferred Data Sources:	National EML and National Registration list
Method of Estimation:	Calculated as: $$\frac{\#\ Medicines\ on\ EML\ with\ corresponding\ registered\ product}{Total\ \#\ medicines\ on\ EML} \times 100\%$$ Exclude duplicate registered products *see definition above*
Proposed Scoring or Benchmarking:	100% of products on the EML should have at least one registered product available in the country
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Every time the national EML is revised

QUALITY & SAFETY SURVEILLANCE

Indicator Name:	**% of recorded adverse event reports that are assessed for causality**
PSS Insight Indicator #:	RS06
Data Type:	Continuous
Topic:	Quality and Safety Surveillance

Definition:	An adverse event is defined as a medical occurrence temporally associated with the use of a pharmaceutical product, but not necessarily causally related. A causality assessment is meant to determine whether, and to what extent, a pharmaceutical is associated with an adverse event. Causality assessments should be part of pharmacovigilance systems to monitor pharmaceutical safety and quality. Criteria for assessing causality should be determined according to one of the established systems (algorithms) – Ex. the WHO/UMC system or the Naranjo system. The indicator should be calculated for the previous calendar year, or the latest year for which data are available (please specify)
Assessment Questions:	What is the last calendar year for which data are available?
	What is the total number of Adverse Event reports recorded in the previous calendar year (or last year for which data are available)?
	What is the total number of Adverse Event reports assessed for causality in the reference year?
Purpose and Issues:	All received AE reports should be assessed for causality, to determine whether the events are associated with a particular pharmaceutical product.
Preferred Data Sources:	Records and/or reports of adverse events and causality assessments at the pharmacovigilance center
Method of Estimation:	Calculated as: $$\frac{\#\ AE\ reports\ assessed\ for\ causality}{Total\ \#\ AE\ reports\ received} \times 100\%$$
Proposed Scoring or Benchmarking:	100% of AE reports should be assessed for causality
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annually
Cross References:	The use of the WHO-UMC system for standardised case causality assessment
URL:	http://who-umc.org/Graphics/24734.pdf
Indicator Reference Number(s):	0530
Indicator Source(s):	Ratanawijitrasin, S. & Wondemagegnehu, E. (2002). Effective drug regulation. A multicountry study. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf

Indicator Name:	**% of samples tested that failed quality control testing**
PSS Insight Indicator #:	RS07

Data Type:	Continuous
Topic:	Quality and Safety Surveillance
Definition:	The indicator is based on randomly collected samples; if quality control is done only on drugs under suspicion, it should be clearly indicated in the final reports, as the percentage obtained will certainly be higher. The indicator should be calculated for the previous calendar year, or the latest year for which data are available (please specify)
Assessment Questions:	What is the last calendar year for which data are available?
	What is the total number of samples tested in the previous calendar year (or last year for which data are available)?
	What is the total number of samples tested that failed quality control testing in the previous calendar year (or last year for which data are available)?
Purpose and Issues:	If procurement is done in a proper manner — good selection of suppliers, extensive specifications, etc. — the indicator should be close to 0%. Limitations: The indicator is meaningful only if the quality control laboratory functions properly. In addition, if the denominator is too small compared with the total number of drugs procured, the indicator will not give a good picture of the real situation
Preferred Data Sources:	Data are normally available from the procurement unit or from the quality control laboratory.
Method of Estimation:	$\frac{\#\ Medicines\ or\ batches\ failed\ quality\ testing}{Total\ \#\ medicines\ or\ batches\ tested} \times 100\%$
Proposed Scoring or Benchmarking:	The percentage of samples tested that fail quality control testing does not have an established benchmark. The number should be low, as a result of the product assessment and distribution functions working properly, but should not be zero, as there will always be some level of poor quality products circulating in the system, and the surveillance function must be sensitive enough to detect it. This indicator is most helpful when compared across countries and monitored over time.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annually
Cross References:	Indicators for Monitoring National Drug Policies. (See page 143)
URL:	http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf
Indicator Reference Number(s):	0486
Indicator Source(s):	Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf

INNOVATION, RESEARCH & DEVELOPMENT, MANUFACTURING, AND TRADE

INNOVATION, RESEARCH & DEVELOPMENT

Indicator Name:	**Pharmaceutical innovation goals identified and documented to address unmet or inadequately met public health needs**
PSS Insight Indicator #:	IRDMT01
Data Type:	Categorical
Topic:	Innovation, Research & Development
Definition:	In addition to being stated and/or described as pharmaceutical innovation goals, these must genuinely improve consumer welfare by addressing unmet priority public health needs. Pharmaceutical innovation may be product-related, pertain to service delivery, better disseminate information to drive demand, etc.
Assessment Questions:	Is there a document or a discrete list of pharmaceutical innovation goals?
	Do they detail the unmet public health needs that they are working to address?
	Are they publicly available and disseminated regularly across pharmaceutical units and departments?
Purpose and Issues:	The purpose of this indicator is to look at concerted efforts to lay foundation for filling unmet public health needs. Issues: existence of innovation goals does not mean that these are being addressed; rather it just provides a direction for potential investments in pharmaceuticals.
Preferred Data Sources:	National ministry or institute of science and technology, national or regional health innovation body
Method of Estimation:	
Proposed Scoring or Benchmarking:	Countries should document their innovation goals to drive research into public health needs that are relevant to the country. Countries should review and update these at least every five years.
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	Every five years

INTELLECTUAL PROPERTY AND TRADE

Indicator Name:	**Are medicines subject to import tariffs? If so, what are the tariff amounts applied?**
PSS Insight Indicator #:	IRDMT02
Data Type:	Categorical
Topic:	Intellectual Property & Trade

Definition:	Import tariffs consist of customs duties, or other import charges, which are payable on goods of a particular type when they enter the economic territory. For the purpose of this indicator, subject to means that import tariffs are applied to medicines.
Assessment Questions:	Are medicines subject to import tariffs? (If some, but not all medicines are subject, please describe in the Notes box)
Purpose and Issues:	Import tariffs typically cause a foreign goods to be more expensive because the tariff is added to the price. Therefore, the consumer must pay a higher price to purchase an imported medicine.
Preferred Data Sources:	Regulation on import tariffs, WTO database. The public procurement office or procurement department of the MOH may also have this information
Proposed Scoring or Benchmarking:	Countries should not apply tariffs to imported medicines, so that pharmaceutical prices are not raised through tariffs from the country.
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	Annually
Cross References:	Comtrade: UN Comtrade is a repository of official trade statistics, Price Waterhouse Cooper has excellent database on tax summaries for 155 countries worldwide
URL:	http://comtrade.un.org/ http://taxsummaries.pwc.com/

Indicator Name:	**Have any of the following TRIPS flexibilities been utilized to date: compulsory licensing provisions, government use, parallel importation provisions, the Bolar exception (10 year time frame)?**
PSS Insight Indicator #:	IRDMT03
Data Type:	Continuous
Topic:	Intellectual Property & Trade

Definition:	The provisions of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are binding on all WTO Member States. TRIPS sets minimum standards of intellectual property (IP) protection that all WTO Member countries are required to provide. For instance, the TRIPS Agreement states that all patents shall be available for at least 20 years from the filing date, whereas before TRIPS the patent term varied greatly among countries (7, 10, 17 or 20 years). All WTO Members have to incorporate this 20-year patent term in their own patent laws. Least developed countries have until 2031 to become fully TRIPS compliant. Compulsory licensing: A judicial or administrative authority grants a license, without the consent of the rights holder, to a third party, to manufacture a product still under patent. Government use provisions enable an administrative authority to grant a license to a third party, without the consent of the rights holder, to address identified public health needs. Parallel importation is importation, without the consent of the rights -holder, of a patented product marketed in another country either by the patent holder or with the patent-holder's consent. Parallel importation enables promotion of competition for the patented product by allowing importation of equivalent patented products sold at lower prices in other countries. A Bolar exception is an early working provision whereby generic pharmaceutical manufacturers the use of a patented product for the purposes of preparing an application for marketing approval of a follow-on product is considered non-infringing.
Assessment Questions:	Within the last 10 years, have any compulsory licenses been granted for pharmaceutical products?
	Within the last 10 years, have government use provisions been utilized for pharmaceutical products?
	Within the last 10 years, has parallel importation been undertaken for pharmaceutical products?
	Within the last 10 years, has a manufacturer been granted permission in the country to use the Bolar exception or early working provision to expedite production of pharmaceutical products?
Purpose and Issues:	The provisions of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are binding on all WTO Member States. TRIPS sets minimum standards of intellectual property (IP) protection that all WTO Member countries are required to provide. For instance, the TRIPS Agreement states that all patents shall be available for at least 20 years from the filing date, whereas before TRIPS the patent term varied greatly among countries (7, 10, 17 or 20 years). All WTO Members have to incorporate this 20-year patent term in their own patent laws. Least developed countries have until 2031 to become fully TRIPS compliant.
Preferred Data Sources:	Government Patent Office, World Trade Organization register of intent to use any of the listed provisions

Proposed Scoring or Benchmarking:	Countries should have executed at least one of the flexibilities listed within the past 10 years
Unit of Measure:	Yes/No
Expected Frequency of Data Dissemination:	Annually
Cross References:	Operational Package for Monitoring and Assessing Country Pharmaceutical Situations. (See page 65)
URL:	http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf

FINANCING

RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION, AND PAYMENT

Indicator Name:	**Per capita expenditure on pharmaceuticals**
PSS Insight Indicator #:	F01
Data Type:	Continuous
Topic:	Costing & Pricing
Definition:	Pharmaceutical expenditure includes spending on prescription medicines and self-medication, often referred to as over-the-counter products. For some countries, other medical non-durables such as syringes, bandages, etc. may be included in the total. It also includes pharmacists' remuneration when the latter is separate from the price of medicines. Pharmaceuticals consumed in hospitals are excluded (on average they account for around 15% of total pharmaceutical spending). Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to "net" spending, i.e. adjusted for possible rebates payable by manufacturers, wholesalers or pharmacies. This indicator is measured as a share of total health spending, in USD per capita (using economy-wide PPPs) and as a share of GDP. The indicator should be calculated for the previous calendar year, or the latest year for which data are available.
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total amount of public funds (in local currency) spent in the country to purchase pharmaceutical products? (Note: this includes direct government spending through health programs, government-funded insurance programs, and donor expenditure)
	In the reference year, what is the total population of the country?
Purpose and Issues:	Pharmaceuticals account for an important share of all expenditure on health. The amount spent on pharmaceuticals per capita varies considerably and demonstrates health investment priorities in a given country.
Preferred Data Sources:	National Health Accounts
Method of Estimation:	$\frac{Total\ public\ spending\ on\ pharmaceuticals}{Country\ population}$
Proposed Scoring or Benchmarking:	If the absolute expenditure is under a certain threshold a country would not be able to cover the most basic needs in terms of pharmaceutical access. This threshold is not established in the literature, so countries should set their specific targets but keep the benchmark of countries with well-functioning coverage schemes in mind.
Unit of Measure:	Local currency or US$ per capita

Expected Frequency of Data Dissemination:	Annual
Cross References:	Pharmaceutical spending covers expenditure on prescription medicines and self-medication, often referred to as over-the-counter products. In some countries, other medical non-durable goods are also included. Pharmaceutical Expenditure
URL:	OECD (2011), "Pharmaceutical expenditure", in Health at a Glance 2011: OECD Indicators, OECD Publishing. http://dx.doi.org/10.1787/health_glance-2011-63-en
Indicator Reference Number(s):	0001
Indicator Source(s):	Health Systems 20/20. (2012). The Health System Assessment Approach: A How-To Manual. Version 2.0. Module 6. www.healthsystemassessment.org

Indicator Name:	**Population with household expenditures on health greater than 10% of total household expenditure or income**
PSS Insight Indicator #:	F02
Data Type:	Continuous
Topic:	Costing & Pricing
Definition:	The proportion of a country's population that spends over 10% of their household income on health related expenses. Health expenditures are likely to expose households to financial hardship in particular when they exceed a pre-defined threshold of a household's ability to pay. When this happens they are characterized as being catastrophic. Within the SDG monitoring framework (SDG indicator 3.8.2), the proportion of the population facing catastrophic expenditures is measured as the population weighted average of the number of households with "large household expenditures on health" as a share of total household expenditure or income (household's budget). Large is defined as health expenditures exceeding 10% of total household expenditure or income.
Purpose and Issues:	Medicine related expenditures have been found to comprise a large portion of out of pocket health expenditure. It would be preferable to use an indicator that assesses out of pocket expenditure specifically on medicines, compared with household ability to pay, but this indicator is not routinely collected. This indicator has been chosen because countries are required to report it for monitoring the sustainable development goals. This is an imperfect proxy to assess medicine affordability in terms of ability to pay.
Preferred Data Sources:	WHO global health observatory – SDG indicators, National Health Accounts, Household budget surveys, Household income and expenditure surveys, Household socioeconomic and living standards surveys

Method of Estimation:	The global and regional incidence of the proportion of the population with household expenditures on health greater than 10% of total household expenditure or income is estimated as the population weighted average of the country level share of people with such catastrophic health expenditures (SDG 3.8.2, 10% threshold) for a reference year. Incidence at the country level for the reference year is estimated using different methods depending upon the availability of information for that country around or at the reference year (T*). • In countries for which there is an observed incidence rate of the SDG indicator 3.8.2 at the 10% threshold in the reference year T*, this point is used. • When there are at least two observed incidence rates of the SDG indicator 3.8.2 at the 10% threshold around the reference over a 5 year window around the reference year [T*–5; T*+5], linear interpolation is used to project the value of the proportion of "the population with household expenditures on health greater than 10% of total household expenditure or income" in the reference year. • If only one observed incidence rate of the SDG indicator 3.8.2 at the 10% threshold is available either before or after the reference year and within a five year window before or after the reference year (T*+ or T*-5),, a multilevel model of the rate of catastrophic payments (SDG indicator 3.8.2, 10% threshold) is ¬estimated using the aggregate share of out-of-pocket over total consumption expenditure as the explanatory variable • For countries with no observed incidence rate over a 10-year window around the reference year, the multilevel model is used to project the survey point to the reference year using the share of aggregate out-of-pocket over total consumption if that information is available. If such information is not available, the regional median value of the SDG indicator 3.8.2 at the 10% threshold is used instead to impute the incidence rate for those countries in the reference year. The country estimates for the reference year are then aggregated up to the regional and global levels to compute the "Total population with household expenditures on health greater than 10% of total household income or expenditure" in millions. The proportion of the total population at global and regional level is then calculated by expressing these numbers as a share of the relevant population, equivalent to taking a population-weighted average of the relevant country rates.
Proposed Scoring or Benchmarking:	Target is 0% of households spend more than 10% of income on health expenditures
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	2-3 years
Indicator Reference Number(s):	4844 – SDG Indicator 3.8.2
Indicator Source(s):	WHO Global Health Observatory Indicators https://www.who.int/data/gho/data/indicators/indicator-details/GHO/population-with-household-expenditures-on-health-greater-than-10-of-total-household-expenditure-or-income-(sdg-3-8-2)-(-)

Indicator Name:	**Total expenditure on pharmaceuticals (% total expenditure on health)**
PSS Insight Indicator #:	F03
Data Type:	Continuous
Topic:	Costing & Pricing
Definition:	Pharmaceutical expenditure includes spending on prescription medicines and self-medication, often referred to as over-the-counter products. For some countries, other medical non-durables such as syringes, bandages, etc. may be included in the total. It also includes pharmacists' remuneration when the latter is separate from the price of medicines. Pharmaceuticals consumed in hospitals are excluded (on average they account for around 15% of total pharmaceutical spending). Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to "net" spending, i.e. adjusted for possible rebates payable by manufacturers, wholesalers or pharmacies. This indicator is measured as a share of total health spending, in USD per capita (using economy-wide PPPs) and as a share of GDP. The indicator should be calculated for the previous calendar year, or the latest year for which data are available.
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total amount of public funds (in local currency) spent in the country to purchase pharmaceutical products? (Note: this includes direct government spending through health programs, government-funded insurance programs, and donor expenditure)
	In the reference year, what is the total amount of public funds (in local currency) spent in the country on health? (Note: this includes direct government spending through health programs, government-funded insurance programs, and donor expenditure)
Purpose and Issues:	Pharmaceuticals account for an important share of all expenditure on health. The amount spent on pharmaceuticals compared to health expenditure overall varies considerably and demonstrates health investment priorities in a given country.
Preferred Data Sources:	National Health Accounts
Method of Estimation:	$\frac{Total\ pharmaceutical\ expenditure}{Total\ expenditure\ on\ health} \times 100\%$
Proposed Scoring or Benchmarking:	Countries should set specific targets but keep the benchmark of countries with well-functioning coverage schemes in mind
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annual

Cross References:	OECD (2011), "Pharmaceutical expenditure", in Health at a Glance 2011: OECD Indicators, OECD Publishing.
URL:	http://dx.doi.org/10.1787/health_glance-2011-63-en
Indicator Reference Number(s):	0001
Indicator Source(s):	Health Systems 20/20. (2012). The Health System Assessment Approach: A How-To Manual. Version 2.0. Module 6. www.healthsystemassessment.org

COSTING & PRICING

Indicator Name:	**Median (consumer) drug price ratio for tracer medicines in the public, private, and mission sectors**
PSS Insight Indicator #:	F04
Data Type:	Continuous
Topic:	Costing & Pricing
Definition:	Consumer price ratios are calculated as the ratio between median unit prices (e.g. price per tablet or therapeutic unit) and Management Sciences for Health (MSH) median international reference prices for that exact product for the year preceding the survey. The public sector consists of any government program providing pharmaceutical products. This includes any health facilities or programs funded by the Ministry of Health (or subordinate health program) budgets, or programs/agencies receiving funding through national or publicly-funded social insurance schemes, or funding from any level of government – from national to regional to local. For the purpose of this indicator, the private sector consists of any facility dispensing, selling, or providing pharmaceutical products to consumers without government funding. This may include private for-profit businesses, facilities affiliated with private insurance schemes, employer-based health facilities etc. Mission sector: This consists of non-governmental organizations, charities, and/or faith-based agencies. Generic: A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. If the country collects their own data on pricing, please obtain a copy. If the country relies on WHO/HAI pricing surveys for this information, the data are disaggregated using the following categories: Originator brand: Generally the product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety, and quality, according to requirements at the time of authorization: e.g. Valium. The

	originator product always has a brand name; this name may, however, vary between countries. Most sold generic: The generic with the highest volume of sales at the sample site. Lowest price generic: The lowest-priced generic product is the one with the lowest unit price or price per pill, tablet, dose, or ml. If there is only one generically equivalent product that corresponds to each originator brand on the tracer list, it is the lowest-priced generic available at that outlet. This is evaluated at each sample outlet. Public sector procurement prices: Prices paid by the public sector to purchase the pharmaceutical product from the manufacturer or wholesaler. Public sector patient prices: Prices paid by consumers in public sector facilities. This includes the price for the medicine only. Price analysis is not performed if medicines are provided for a fixed fee or if dispensing or appointment fees are applied to the medicine, but the medicine itself is provided free of charge. Private sector patient prices: Prices paid by consumers in private sector facilities. Mission sector patient prices: Prices paid by consumers at mission sector facilities.
Assessment Questions:	Does the country collect this information regularly for a set of tracer medicines?
	If possible, obtain a copy of their pricing data. If the country does not routinely collect this data, it may be obtained through the methodology referenced in the Cross Reference, below.
Purpose and Issues:	Medicines account for 20-60% of health spending in low- and middle-income countries (LMICs). Furthermore, up to 90% of the population in LMICs purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and are a major burden on government budgets. This indicator helps to assess affordability of medicines within the country Limitations: These data are collected by WHO and HAI on an irregular basis. Available price data may be out of date. Sample sizes may be limited due to inconsistent disease burdens in participating countries – not all surveyed countries may purchase all of the selected tracer medicines defined by WHO and HAI for the pricing survey.
Preferred Data Sources:	National surveys of medicine price and availability conducted using a standard methodology developed by WHO and HAI. Data on the price of a specific list of medicines are collected in six geographic or administrative areas in a sample of at least 4 medicine dispensing points per geographic area. These data are included in the WHO country pharmaceutical profiles: http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index1.html And are also available here from HAI: http://www.haiweb.org/MedPriceDatabase/ Countries may also monitor prices on select tracer medicines as part of routine price

	monitoring systems. If these national data are available, please obtain a copy to supplement and/or update data from WHO.
Method of Estimation:	$\frac{\textit{Median unit price paid by consumers for a specific medicine during previous year}}{\textit{Median international reference price for same medicine during previous year}}$
Proposed Scoring or Benchmarking:	There is no threshold established in the literature, so countries should set their specific targets but keep the benchmark of countries with well-functioning coverage schemes in mind and monitor trends over time.
Unit of Measure:	Ratio
Expected Frequency of Data Dissemination:	Every 3-5 years
Cross References:	MONITORING THE BUILDING BLOCKS OF HEALTH SYSTEMS: A HANDBOOK OF INDICATORS AND THEIR MEASUREMENT STRATEGIES. (See page 64)
URL:	http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_full_web.pdf
URL:	http://www.cpc.unc.edu/measure/prh/rh_indicators/crosscutting/hss/ratio-of-median-local-medicine-price-to

FINANCIAL RISK PROTECTION

Indicator Name:	**Out-of-pocket expenditure out of total pharmaceutical expenditure**
PSS Insight Indicator #:	F05
Data Type:	Continuous
Topic:	Financial Risk Protection
Definition:	Total pharmaceutical expenditure includes any money spent in the country (from any source) to finance or purchase pharmaceutical products. Out-of-pocket expenditure includes any payment made by consumers for pharmaceutical products. This includes payments for the direct sale of medicines, copayments under insurance schemes or for partially subsidized medicines, or payments for pharmaceutical related fees, such as dispensing fees. The indicator should be calculated for the previous calendar year, or the latest year for which data are available.
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what is the total amount (in local currency) spent in the country to purchase pharmaceutical products?
	In the reference year, what is the total amount (in local currency) spent out of pocket to purchase pharmaceutical products?
Purpose and Issues:	This indicator provides information on the burden of health care financing on households and the level of financial protection prevailing in the country.
Preferred Data Sources:	National Health Accounts

Method of Estimation:	$\frac{Out\ of\ pocket\ expenditure\ on\ pharmaceuticals}{Total\ expenditure\ on\ pharmaceuticals} \times 100\%$
Proposed Scoring or Benchmarking:	There is no threshold established in the literature, so countries should set their specific targets but keep the benchmark of countries with well-functioning coverage schemes in mind and monitor trends over time.
Unit of Measure:	Percentage (%)
Expected Frequency of Data Dissemination:	Annual
Cross References:	The Health System Assessment Approach: A How-To Manual
URL:	https://www.hfgproject.org/wp-content/uploads/2015/02/HSAA_Manual_Version_2_Sept_20121.pdf

EXPENDITURE TRACKING & MONITORING

Indicator Name:	**At least one national health accounts exercise including pharmaceuticals completed in the past five years.**
PSS Insight Indicator #:	F06
Data Type:	Categorical
Topic:	Expenditure Tracking & Monitoring
Definition:	National Health Accounts (NHA) exercise is an internationally recognized methodology used to track total expenditures in a health system for a specified period of time. Data on medicines expenditures can be obtained from National Health Accounts (NHA), which is a systematic, comprehensive, and consistent monitoring of resource flows in a country's health system for a given period. The NHA is designed to capture the full range of information contained in resource flows and reflects the main functions of health care financing, such as resource mobilization and allocation, pooling and insurance, purchasing of care, and the distribution of benefits.
Assessment Questions:	When was the last National Health Accounts exercise performed (specify year only)?
	Did the previous NHA exercise include pharmaceuticals?
Purpose and Issues:	Monthly, quarterly, or annually for routine administrative records. A validation exercise should be conducted every 3–5 years against a national population-based or facility-based assessment. In practical terms, the cost of collecting and processing nationally representative data on the health workforce will be marginal for exercises that already include questions on occupation, education, and place of work (e.g. population census or labor force survey).
Preferred Data Sources:	National health accounts
Method of Estimation:	Yes/No

Proposed Scoring or Benchmarking:	Countries should complete National Health Accounts exercises at least once every five years, and they should track and monitor pharmaceutical expenditures and revenue explicitly, within their system of health accounts.
Expected Frequency of Data Dissemination:	Every five years
Cross References:	Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies
URL:	WHO. (2010). Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/
Indicator Reference Number(s):	1006
Indicator Source(s):	WHO. (2010). Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/

HUMAN RESOURCES

HUMAN RESOURCE DEVELOPMENT

Indicator Name:	**Existence of governing bodies tasked with accreditation of pre- and in-service pharmacy training programs**
PSS Insight Indicator #:	HR01
Data Type:	Categorical
Topic:	Human Resource Development
Definition:	Accreditation requires a review and subsequent granting of formal recognition after meeting certain agreed criteria by the country's capacity building or learning institution overseeing professional development or education Relevant governing body should be defined by individual countries. May include ministerial CPD desk, higher learning accreditation boards, universities and colleges offering specific health related training courses Pre-service training programs provide instruction to pharmacy and health workers prior to graduation from school, while post-service is defined as training that occurs after graduation.
Assessment Questions:	Are there governing bodies tasked with accreditation of pre-service pharmacy training programs? (Please record the name of the body/ institution)
	Are there governing bodies tasked with accreditation of in-service pharmacy training programs? (Please record the name of the body/ institution)
Purpose and Issues:	Accreditation ensures that educational institutions adhere to defined standards
Preferred Data Sources:	Accreditation board annual report, interviews at National Medicines Regulatory Authority (for in-service programs) and/or Ministry of Education (for pre-service programs)
Method of Estimation:	Yes/No
Proposed Scoring or Benchmarking:	Countries should have a body formally charged with the accreditation of pharmacy service training programs, to ensure their quality and standardize elements of pre- and in-service workforce development.
Expected Frequency of Data Dissemination:	Annually
Cross References:	Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs
URL:	http://siapsprogram.org/publication/continuing-pharmaceutical-education-guide-to-establishing-quality-assured-and-accredited-programs/

HUMAN RESOURCE MANAGEMENT

Indicator Name:	**Population per licensed pharmacist, pharmacy technician, or pharmacy assistant**

PSS Insight Indicator #:	HR02
Data Type:	Continuous
Topic:	Human Resource Management
Definition:	Employment in the public sector means that the facilities of employment and the positions are financed through government funding. Private sector employees are employed by any facilities outside of the public sector. For purposes of this indicator, pharmacist is defined as a person holding a university degree in pharmacy, and pharmacy technician is defined as a person who has completed formal course work leading to a certificate or diploma in pharmacy technology. Only these personnel who work full or part-time in the health care system which is surveyed should be counted.
Assessment Questions:	What is the last calendar year for which data are available?
	In the reference year, what was the total population in the country?
	What is the number of licensed pharmacists employed by the public sector in the country?
	What is the number of licensed pharmacy technicians employed by the public sector in the country?
	What is the number of licensed pharmacy assistants employed by the public sector in the country?
	What is the number of licensed pharmacists employed by the private sector in the country?
	What is the number of licensed pharmacy technicians employed by the private sector in the country?
	What is the number of licensed pharmacy assistants employed by the private sector in the country?
Purpose and Issues:	This indicator provides information on the level of coverage of the different cadres. Data may not be available by cadre or broken down by sector of employment.
Preferred Data Sources:	Register with the licensing body/NMRA
Method of Estimation:	$\frac{Licensed\ pharmaceutical\ personnel}{Country\ population}$
Proposed Scoring or Benchmarking:	There is no threshold established in the literature, so countries should set their specific targets but keep the benchmark of countries with well-functioning coverage schemes in mind and monitor trends over time.
Unit of Measure:	Proportion
Expected Frequency of Data Dissemination:	Every five years
Cross References:	Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. (See page 72)

URL:	MSH - CPM, University Research Corporation, PAHO, USAID. Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program. July 1995
Indicator Reference Number(s):	0838, I1.6.2
Indicator Source(s):	Wendt, D. (2012). Health system rapid diagnostic tool framework. Operational guide and metrics to measure the strength of priority health system functions. Durham NC: FHI 360. http://www.fhi360.org/sites/default/files/media/documents/Health%20System%20Rapid%20Diagnostic%20Tool.pdf MSH - CPM, University Research Corporation, PAHO, USAID. Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program. July 1995

INFORMATION

INFORMATION POLICY AND DATA STANDARDIZATION

Indicator Name:	**Existence of a policy or strategy that sets standards for collection and management of pharmaceutical information**
PSS Insight Indicator #:	IM01
Data Type:	Categorical
Topic:	Information Policy and Data Standardization
Definition:	Existence of national policy or strategy that defines clear standards and guidelines for: 1) data collection, 2) data analysis, and 3) reporting procedures to be performed with pharmaceutical data from different sources. The document also defines indicators for data management. Data management is the identification of data sources, collection of data, data analysis, generation of reports, and dissemination of data. Pharmaceutical system indicators typically collect data on product availability, consumption, quality, and movement through the system. This should be combined with patient and provider data, including information on pharmaceutical personnel, prescribing and dispensing, consumption of pharmaceuticals, and medicine safety. It is possible that the standards and indicators assessed in this indicator may be found in different documents, rather than in one document. For the purpose of this indicator, as long as each component is located within any policy or strategy document, mark “yes” for the appropriate assessment question.
Assessment Questions:	Does a policy or strategy exist to set standards for the pharmaceutical information system?
	Does the policy or strategy set standards for:
	Does the policy or strategy set standards for: Data collection?
	Does the policy or strategy set standards for: Data management?
	Does the policy or strategy set standards for: Reporting procedures?
	Does a national set of indicators for the pharmaceutical system exist?
	Are there specific targets set for each indicator?
	Are data analyzed and reports disseminated at least once per year?
Purpose and Issues:	Clear policies are required for generating reliable pharmaceutical system indicators. Issues: Pharmaceutical indicators may not be separate from health system indicators. In this case, assessors will need to obtain the list of indicators for the health system to determine whether the list contains indicators pertaining to the pharmaceutical system.
Preferred Data Sources:	Annual report
Method of Estimation:	Yes/No

Proposed Scoring or Benchmarking:	Countries should have a specific policy or strategy that specifies which information regarding pharmaceuticals should be collected, and how this data is to be collected, analyzed, reported, and used.
Expected Frequency of Data Dissemination:	Annual

USE OF INFORMATION FOR DECISION MAKING

Indicator Name:	**Data on safety, efficacy, and cost effectiveness of medicines available and used to inform essential medicines selection**
PSS Insight Indicator #:	IM02
Data Type:	Categorical
Topic:	Selection
Definition:	The information on safety and efficacy is critical to make decisions on essential medicines selection. Cost effectiveness should be taken into consideration when choosing between therapeutic alternatives.
Assessment Questions:	Based on the last meeting's minutes or documentation of the last discussion on selecting essential medicines, which of the following data were used to inform the discussion and final decision:
	Safety?
	Efficacy?
	Cost-effectiveness?
Purpose and Issues:	Determining the safety and efficacy of specific pharmaceutical products requires access to relevant, up-to-date, and unbiased information, such as summaries of relevant clinical guidelines, systematic literature reviews, important references, and quality assurance standards. Cost effectiveness should be taken into consideration when choosing between therapeutic alternatives. Personal observations should not be used as justification for selecting a medication, nor should selection be based on sales figures of a medicine's popularity in the market. This indicator should be based on proceedings or minutes of the selection committee, rather than the required information for a dossier submission for marketing authorization. This demonstrates that the data are actually used in the decision making process, rather than requested for the application and then ultimately disregarded during actual medicine selection.
Preferred Data Sources:	Reports and minutes of committee meetings on selection of medicines
Method of Estimation:	Yes/No
Proposed Scoring or Benchmarking:	Countries should use and weigh all of this information when completing medicine selection processes.

Expected Frequency of Data Dissemination:	Annually
URL:	http://apps.who.int/medicinedocs/documents/s19592en/s19592en.pdf (see page 15)
URL:	http://www.merckmanuals.com/home/drugs/overview-of-drugs/drug-effectiveness-and-safety

KEY SYSTEM ATTRIBUTES & PRIMARY SYSTEM OUTCOMES

Most of the indicators in these sections are drawn from the Critical System Components for measurement sections of the tool. A few additional indicators have been selected from external tools to supplement those indicators. The performance indicator reference sheets or metadata required to collect these indicators are cited below. In instances where specific reference sheets are not publicly available, the tool or manual is cited.

Overall GBT maturity level: World Health Organization. WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. World Health Organization. http://www.who.int/medicines/regulation/benchmarking_tool/en/ Published 2017.

WHO MedMon: World Health Organization. WHO MedMon App – Measuring price and availability of health products. World Health Organization. https://www.who.int/medicines/areas/policy/monitoring/empmedmon/en/ 2016.

SDG 3.8.2: United Nations. Sustainable Development Goals – SDG Indicators, metadata repository. Goal 3: Ensure healthy lives and promote well-being for all at all ages. Indicator 3.8.2. Proportion of population with large household expenditure on health as a share of total household expenditure or income. Available from: https://unstats.un.org/sdgs/metadata/files/Metadata-03-08-02.pdf

SDG 3.b.3: United Nations. Sustainable Development Goals – SDG Indicators, metadata repository. Goal 3: Ensure healthy lives and promote well-being for all at all ages. Indicator 3.b.3. Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis. Available from: https://unstats.un.org/sdgs/metadata/files/Metadata-03-0B-03.pdf

SDG 3.8.1: United Nations. Sustainable Development Goals – SDG Indicators, metadata repository. Goal 3: Ensure healthy lives and promote well-being for all at all ages. Indicator 3.8.1. Coverage of essential health services. Available from: https://unstats.un.org/sdgs/metadata/files/Metadata-03-08-01.pdf