

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components

Pharmaceutical products and related services

Policy, laws, and governance

Regulatory systems

Innovation, research and development, manufacturing, and trade

Financing

Human resources

Information

## Key System Attributes

Performance

Resilience

## Primary System Outcomes

Access

Use

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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 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



DISTRIBUTION



USE



ELEMENTS

## Primary System Outcomes

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ELEMENTS

SELECTION

PROCUREMENT

DISTRIBUTION

USE

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.



## Primary System Outcomes

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ELEMENTS

SELECTION

PROCUREMENT

DISTRIBUTION

USE

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



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Access

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ELEMENTS

SELECTION

PROCUREMENT

DISTRIBUTION

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.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

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Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

PHARMACEUTICAL POLICIES

PHARMACEUTICAL LAWS AND REGULATIONS

COORDINATION AND LEADERSHIP

ETHICS, TRANSPARENCY AND ACCOUNTABILITY

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.



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Access

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ELEMENTS

PHARMACEUTICAL POLICIES

PHARMACEUTICAL LAWS AND REGULATIONS

COORDINATION AND LEADERSHIP

ETHICS, TRANSPARENCY AND ACCOUNTABILITY

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



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ELEMENTS

PHARMACEUTICAL POLICIES

PHARMACEUTICAL LAWS AND REGULATIONS

COORDINATION AND LEADERSHIP

ETHICS, TRANSPARENCY AND ACCOUNTABILITY

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.



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Access

Use

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ELEMENTS

PHARMACEUTICAL POLICIES

PHARMACEUTICAL LAWS AND REGULATIONS

COORDINATION AND LEADERSHIP

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.



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# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Regulatory systems

Focuses on ensuring the safety, efficacy, and quality of pharmaceutical products and related services.



This component affects both access and use.



ELEMENTS

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

Systems for evaluating the safety, efficacy and quality of pharmaceutical products and appropriateness of product information and issuing, varying or revoking marketing authorizations.

## Primary System Outcomes

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INSPECTION AND ENFORCEMENT

QUALITY AND SAFETY SURVEILLANCE

REGULATION AND OVERSIGHT OF CLINICAL TRIALS

CONTROL OF PHARMACEUTICAL MARKETING PRACTICES

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.

## Primary System Outcomes

Access

Use

## Key System Attributes

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INSPECTION AND ENFORCEMENT

QUALITY AND SAFETY SURVEILLANCE

REGULATION AND OVERSIGHT OF CLINICAL TRIALS

CONTROL OF PHARMACEUTICAL MARKETING PRACTICES

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.

## Primary System Outcomes

Access

Use

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INSPECTION AND ENFORCEMENT

QUALITY AND SAFETY SURVEILLANCE

REGULATION AND OVERSIGHT OF CLINICAL TRIALS

CONTROL OF PHARMACEUTICAL MARKETING PRACTICES

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.

## Primary System Outcomes

Access

Use

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Performance

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Desired Health Outcomes

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## Critical System Components



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ELEMENTS

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

Systems for authorizing clinical trials and verifying that they are conducted in accordance with approved norms, standards, guidelines and regulations.

## Primary System Outcomes

Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Regulatory systems

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ELEMENTS

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

Systems for reviewing and monitoring the marketing practices including advertising of pharmaceutical products (including prescription and over-the-counter) to prevent the dissemination of inaccurate and misleading information; and taking action in case of violations.

## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

INNOVATION, RESEARCH AND DEVELOPMENT

MANUFACTURING CAPACITY

INTELLECTUAL PROPERTY AND TRADE

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.



## Primary System Outcomes

Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience



# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Innovation, research and development, manufacturing, and trade

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This component primarily affects access.



ELEMENTS

INNOVATION, RESEARCH AND DEVELOPMENT

MANUFACTURING CAPACITY

INTELLECTUAL PROPERTY AND TRADE

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.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

INNOVATION, RESEARCH AND DEVELOPMENT

MANUFACTURING CAPACITY

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.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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

REVENUE AND EXPENDITURE TRACKING AND MANAGEMENT

COSTING AND PRICING

ELEMENTS



## Primary System Outcomes

Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Financing

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This component affects access and use, but especially the availability, accessibility, and affordability dimensions.



ELEMENTS

RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION AND PAYMENT

FINANCIAL RISK PROTECTION STRATEGIES

REVENUE AND EXPENDITURE TRACKING AND MANAGEMENT

COSTING AND PRICING

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



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Financing

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This component affects access and use, but especially the availability, accessibility, and affordability dimensions.



RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION AND PAYMENT

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.

FINANCIAL RISK PROTECTION STRATEGIES

REVENUE AND EXPENDITURE TRACKING AND MANAGEMENT

COSTING AND PRICING

ELEMENTS



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Financing

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ELEMENTS

RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION AND PAYMENT

FINANCIAL RISK PROTECTION STRATEGIES

REVENUE AND EXPENDITURE TRACKING AND MANAGEMENT

COSTING AND PRICING

Systems for analyzing, monitoring and controlling costs and prices for pharmaceutical products and services.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

HUMAN RESOURCES POLICY AND STRATEGY

HUMAN RESOURCES MANAGEMENT

HUMAN RESOURCES DEVELOPMENT

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.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Human resources

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This component contributes to all dimensions of access and use.



ELEMENTS

HUMAN RESOURCES POLICY AND STRATEGY

HUMAN RESOURCES MANAGEMENT

HUMAN RESOURCES DEVELOPMENT

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

## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes



# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

HUMAN RESOURCES POLICY AND STRATEGY

HUMAN RESOURCES MANAGEMENT

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.

## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

INFORMATION POLICY AND DATA  
STANDARDIZATION

DATA COLLECTION, PROCESSING, AND  
DISSEMINATION

USE OF INFORMATION FOR DECISION MAKING

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.



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Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### Information

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ELEMENTS

INFORMATION POLICY AND DATA  
STANDARDIZATION

DATA COLLECTION, PROCESSING, AND  
DISSEMINATION

USE OF INFORMATION FOR DECISION MAKING

Systems, technologies, and infrastructure for the collection, verification, and processing of data and dissemination of timely, accurate, and relevant information.



## Primary System Outcomes

Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components



### 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.



ELEMENTS

INFORMATION POLICY AND DATA  
STANDARDIZATION

DATA COLLECTION, PROCESSING, AND  
DISSEMINATION

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.



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Access

Use

## Key System Attributes

Performance

Resilience

Desired Health Outcomes

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## Critical System Components

Pharmaceutical products and related services

Policy, laws, and governance

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Innovation, research and development, manufacturing, and trade

Financing

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Information

## Key System Attributes

Performance

Resilience

## Primary System Outcomes

Access

Use

DIMENSIONS

AFFORDABILITY

The relationship between the prices of the products and services and the user's ability to pay for them.\* Accounts for the financial risk protection goals of the health system.

ACCEPTABILITY (OR SATISFACTION)

ACCESSIBILITY

AVAILABILITY

EQUITY IN AFFORDABILITY

The extent to which a system deals fairly with all concerned.\*\*

Desired Health Outcomes

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

\*\*Kelley, E., & Hurst, J. (2006). Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing.

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## Key System Attributes

Performance

Resilience

## Primary System Outcomes

Access

Use

DIMENSIONS

AFFORDABILITY

ACCEPTABILITY  
(OR SATISFACTION)

ACCESSIBILITY

AVAILABILITY

The relationship between the user's attitudes and expectations about the products and services and the actual characteristics of the products and services.\*

Desired Health Outcomes

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## Critical System Components

Pharmaceutical products and related services

Policy, laws, and governance

Regulatory systems

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Financing

Human resources

Information

## Key System Attributes

Performance

Resilience

## Primary System Outcomes

Access

Use

DIMENSIONS

AFFORDABILITY

ACCEPTABILITY  
(OR SATISFACTION)

ACCESSIBILITY

AVAILABILITY

The relationship between the location of the product or service and the location of the eventual user of the product or service.\*

EQUITY IN  
GEOGRAPHICAL ACCESSIBILITY

The extent to which a system deals fairly with all concerned.\*\*

Desired Health Outcomes

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

\*\*Kelley, E., & Hurst, J. (2006). Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing.

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## Primary System Outcomes

Access

Use

DIMENSIONS

AFFORDABILITY

ACCEPTABILITY  
(OR SATISFACTION)

ACCESSIBILITY

AVAILABILITY

The relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided.\*

EQUITY IN AVAILABILITY

The extent to which a system deals fairly with all concerned.\*\*

Desired Health Outcomes

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

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Access

Use

DIMENSIONS

PRESCRIBING

DISPENSING /  
SALE OR SUPPLY

CONSUMPTION /  
END-USE

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.

Desired Health Outcomes

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Access

Use

DIMENSIONS

PRESCRIBING

DISPENSING /  
SALE OR SUPPLY

CONSUMPTION /  
END-USE

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.

Desired Health Outcomes

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components

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Access

Use

DIMENSIONS

PRESCRIBING

DISPENSING /  
SALE OR SUPPLY

CONSUMPTION /  
END-USE

Intake or application of a pharmaceutical product by the consumer or administration by the caregiver or end user. Includes adherence which is the extent to which a person takes or administers medication as prescribed by their health care provider.

Desired Health Outcomes

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Performance

Resilience

DIMENSIONS

EFFICIENCY

QUALITY AND SAFETY

RESPONSIVENESS

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.

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Financing

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## Key System Attributes

Performance

Resilience

DIMENSIONS

EFFICIENCY

QUALITY AND SAFETY

RESPONSIVENESS

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\*

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Innovation, research and development, manufacturing, and trade

Financing

Human resources

Information

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Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience

DIMENSIONS

EFFICIENCY

QUALITY AND SAFETY

RESPONSIVENESS

Non clinical aspects related to the way individuals are treated and the environment in which they are treated.\* 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.

\*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.

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Pharmaceutical products and related services

Policy, laws, and governance

Regulatory systems

Innovation, research and development, manufacturing, and trade

Financing

Human resources

Information

## Primary System Outcomes

Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience

DIMENSIONS

AWARE

DIVERSE

SELF-REGULATING

INTEGRATED

ADAPTIVE

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.\*

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components

Pharmaceutical products and related services

Policy, laws, and governance

Regulatory systems

Innovation, research and development, manufacturing, and trade

Financing

Human resources

Information

## Primary System Outcomes

Access

Use

Desired Health Outcomes

## Key System Attributes

Performance

Resilience

DIMENSIONS

AWARE

DIVERSE

SELF-REGULATING

INTEGRATED

ADAPTIVE

Has the capacity to address a broad range of health challenges rather than a select few.\*



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Can contain and isolate health threats while delivering core health services and avoiding cascading disruptions throughout the system.\*

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## Critical System Components

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ADAPTIVE

Brings together diverse stakeholders and ideas to formulate solutions and initiate actions, with clear channels for communication and coordination.\*

# MEASUREMENT OF PSS: Key Parameters

## Critical System Components

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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.\*