What Gets Defined, Gets Measured

A definition and framework for pharmaceutical systems strengthening

Presenter
Helena Walkowiak
Principal Technical Advisor | USAID/SIAPS
Learning Objectives

1. Discuss the rationale for developing metrics to measure pharmaceutical systems strengthening
2. Define *a pharmaceutical system* and *pharmaceutical systems strengthening*
3. Identify a pharmaceutical system’s components, attributes, and outcomes, which are critical for guiding the measurement of progress in improving such systems
4. Discuss the identification and piloting of indicators for pharmaceutical systems strengthening
SIAPS Pharmaceutical Systems Strengthening

Government
MOH, other ministries, regulators, policy makers

Governance

Medical Products

Service Delivery

Human Resources

Financing

Information

Analysis
International health initiatives
Local context
Health status
Health systems

Providers
public/private, NGO, commercial sector, professional associations

Community
patients, consumers, caregivers, civil society

Improved health system performance

Improved coverage & access of evidence-based interventions

Sustainable Health Outcomes and Impact
aligned with:
Country Strategic Plans
and
USG/USAID Health-Specific Results

Monitor and Evaluate Performance

SAIDS
FROM THE AMERICAN PEOPLE
SIAPS
SIAPS Partnership

[Logos and names of partners]

Msh Management Sciences for Health

Accreditation Council for Pharmacy Education

Harvard University
- Pilgrim Institute
- School of Public Health

Logistics Management Institute

University of Washington's Department of Global Health

African Medical and Research Foundation

Ecumenical Pharmaceutical Network

Results for Development

Imperial Health Sciences

VillageReach

William Davidson Institute
No consensus on what constitutes a pharmaceutical system or on an approach to measure its strengthening
Guiding Principles

- Build on existing approaches to health systems strengthening
- Pharmaceutical systems are embedded in and influenced by broader health systems
Methods

- Literature Search and Review
  - 8 definitions
  - 7 frameworks
  - 47 assessment tools

- Consultation with SIAPS Partners

- Targeted Literature Search and Review

Definitions
Identification of Critical System Components and Attributes
Partner Consultation
Relevant Frameworks

Source: Miralles 2010; RPM Plus Program 2005

Source: SIAPS 2013

Source: MSH 2011

Source: Roberts and Reich 2011

Source: WHO health system framework

Source: Bigdeli et al. 2013
Summary of Framework Domains

- Functions/Decision Points
- System Components
- Access/Use Principles/Qualities
- Product Characteristics
- Products Accessed/Used
- Goals
What is a Pharmaceutical System?

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.
What is 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.
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
### System Components

**Pharmaceutical products and services**
Encompasses the functions of selection, procurement, and distribution of pharmaceutical products and related service delivery strategies and interventions that support appropriate and cost-effective use of products.

**Policy, laws, and governance**
Hub of coordination for the system and directly interacts with all other system components. It provides the framework for organizing, financing, and regulating the system and coordinating the activities of the various institutions and actors to achieve the system objectives.

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

**Human resources**
Ensures the availability of adequate numbers of appropriately trained staff for managing the supply and delivery of pharmaceutical products and services.

**Innovation, research and development, manufacturing, and trade**
Includes research and development, domestic manufacturing capacity, and intellectual property protections that shape innovation and trade and affect access to pharmaceutical products.

**Financing**
Management of resources to ensure adequate and sustainable funding for pharmaceutical product purchases and other costs associated with system functioning. It also involves financial risk protection strategies and controlling costs and prices to reduce financial barriers to access.

**Information**
Generation and dissemination of timely, accurate, and reliable information to support decision making. Information is essential to all other components of a pharmaceutical system.
Regulatory Systems: A Closer Look

Regulatory systems ensure the safety, efficacy, and quality of pharmaceutical products and related services.

- Critical Components
- Indicators
Regulatory systems
Focus 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 the appropriateness of product information and issuing, varying, or revoking marketing authorizations.

LICENSING OF ESTABLISHMENTS AND PERSONNEL

INSPECTION AND ENFORCEMENT

QUALITY AND SAFETY SURVEILLANCE

REGULATION AND OVERSIGHT OF CLINICAL TRIALS

CONTROL OF PHARMACEUTICAL MARKETING PRACTICES

Access
Use

Key System Attributes
Performance
Resilience
Regulatory systems

Focus 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 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.

**Key System Attributes**

- **Performance**
- **Resilience**

**Desired Health Outcomes**

- **Access**
- **Use**
Critical System Components

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

- **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 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.

Key System Attributes

**Performance**

**Resilience**

Primary System Outcomes

- **Access**
- **Use**

Desired Health Outcomes
Critical System Components

Regulatory systems
Focus on ensuring the safety, efficacy, and quality of pharmaceutical products and related services.
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PRODUCT ASSESSMENT AND REGISTRATION
LICENSING OF ESTABLISHMENTS AND PERSONNEL
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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 to detect, evaluate, and prevent adverse reactions, medication errors, product-related quality issues, and other problems.

Primary System Outcomes
Access
Use

Desired Health Outcomes

Key System Attributes
Performance
Resilience
Critical System Components

Regulatory systems
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Desired Health Outcomes

- **Access**
- **Use**

Key System Attributes

- **Performance**
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Critical System Components

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- **CONTROL OF PHARMACEUTICAL MARKETING PRACTICES**

Systems for reviewing and monitoring 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.

Key System Attributes

- **Performance**
- **Resilience**

Primary System Outcomes

- **Access**
- **Use**

Desired Health Outcomes
Three Types of Indicators

**Structural**

*Structural indicators* provide information on the system’s capacity to achieve the objectives of each component.

**Process**

*Process indicators* assess the degree to which activities necessary to attain the objectives are carried out.

**Outcome**

*Outcome indicators* measure the results achieved for each component.
Indicators: Product Assessment and Registration

**Structural**
1. Defined structure with clear responsibilities to conduct registration and marketing authorization activities
2. Legal provisions for marketing authorization
3. Updated list of all medical products granted marketing authorization regularly published and publicly available

**Process**
1. Average number of days for decision making on a medicine application for registration

**Outcome**
1. Percentage of medicines on the EML that have at least one registered product available
2. Number of pharmaceutical products registered
Data Collection Pilot

Two in-country data collection methods:

• Existing (or secondary) data from publicly available documents

• Key informant interviews with staff from various government agencies and private-sector companies whose work is related to pharmaceutical management
Publication

Defining pharmaceutical systems strengthening: concepts to enable measurement

Tamara Hafner, Helena Walkowiak, David Lee, Francis Aboagye-Nyame

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Thank you

CO-AUTHORS
Tamara Hafner, David Lee, Francis Aboagye-Nyame.

SIAPS CONSULTATIVE MEETING PARTICIPANTS

Pilot Participants in Bangladesh