



# PSS— —INSIGHT

A Tool for Measuring Progress in  
Pharmaceutical System Strengthening



*Presenter*

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# Introduction

- **PSS Insight** consists of a set of metrics, housed in an online data management tool, to measure pharmaceutical system strengthening across countries and over time.
- SIAPS developed the tool to enable countries and their partners to identify priority areas within pharmaceutical systems for additional scrutiny and strengthening and to measure changes in system performance over time.



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# Framework & Areas for Measurement

## 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



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# From Conceptual Framework to Measurement Tool

- Reviewed thousands of indicators from existing assessment tools
- Consultation with BUSPH to develop indicator selection criteria
- Piloted 182 indicators in Namibia and Bangladesh
- Concurrent desktop review to determine data availability from other sources
- Post-pilot indicator review, refinement for inclusion in the web-based tool.



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# Building the Survey

## PSS Survey Builder

### STEP 2 of 4: SELECT COMPONENTS & INTERVIEW ENTITIES

COMPONENTS
<input checked="" type="checkbox"/> FINANCING
<input type="checkbox"/> HUMAN RESOURCES
<input type="checkbox"/> INFORMATION
<input type="checkbox"/> INNOVATION, RESEARCH AND DEVELOPMENT, MANUFACTURING, AND TRADE
<input type="checkbox"/> OUTCOMES & ATTRIBUTES
<input type="checkbox"/> PHARMACEUTICAL PRODUCTS AND SERVICES
<input checked="" type="checkbox"/> POLICY, LAWS, AND GOVERNANCE
<input type="checkbox"/> REGULATORY SYSTEMS

ENTITY NAME IN PSS	ENTITY NAME IN SURVEY
Clinical Trials Oversight	<input type="text" value="Clinical Trials Oversight"/>
CMS & Warehouses	<input type="text" value="CMS &amp; Warehouses"/>
Distributors	<input type="text" value="Distributors"/>
Document Review	<input type="text" value="Document Review"/>
Health Facilities	<input type="text" value="Health Facilities"/>
MOH Budget-Finance Division	<input type="text" value="MOH Budget-Finance Division"/>
MOH HR Division	<input type="text" value="MOH HR Division"/>
MOH Pharma Body	<input type="text" value="MOH Pharma Body"/>
PV Center	<input type="text" value="PV Center"/>

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# Interviews

## Interview Questionnaire



### COMPONENT

POLICY, LAWS, AND GOVERNANCE

### ELEMENT

PHARMACEUTICAL LAWS AND REGULATIONS

### INDICATOR

**PLG 14** # of annual reports submitted to the International Narcotics Control Board (INCB) in last 5 years

### INDICATOR TYPE

Process

### ATTRIBUTE/OUTCOME

### DIMENSION

HR 10a    PLG 1a    PLG 14g    PLG 17e

SAVE DRAFT

### ASSESSMENT QUESTION

HR 10a PRIVATE SECTOR

### RESPONSE

Yes

### NOTES & COMMENTS

This is a private company

NEXT >

### 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 ... [Read More](#)



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# Data Analysis & Results



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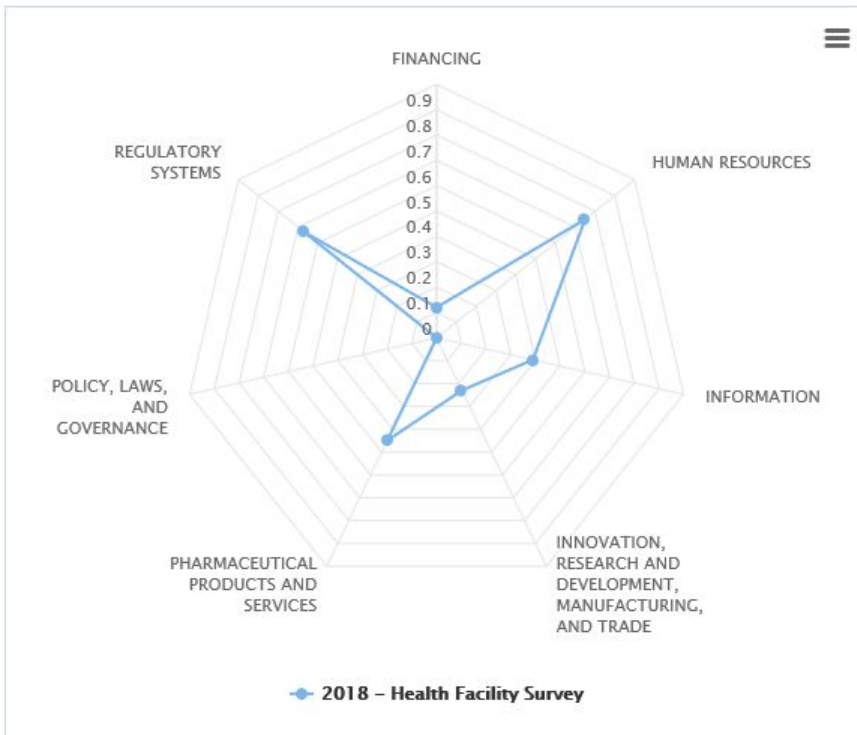
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# Component Scores

Selected Countries: 1

2018 - Health Facility Survey



Component	2018 - Health Facility Survey
FINANCING	0.12000
HUMAN RESOURCES	0.75000
INFORMATION	0.39000
INNOVATION, RESEARCH AND DEVELOPMENT, MANUFACTURING, AND TRADE	0.23000
PHARMACEUTICAL PRODUCTS AND SERVICES	0.45000
POLICY, LAWS, AND GOVERNANCE	0.00000
REGULATORY SYSTEMS	0.67000



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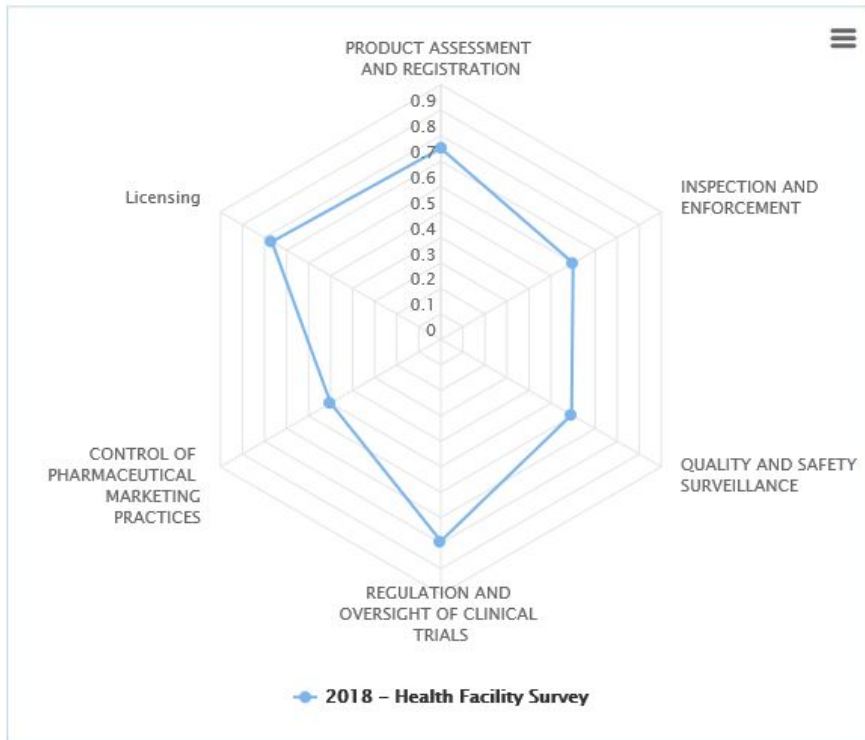


# Element Scores

Selected Countries: 1

2018 - Health Facility Survey

REGULATORY SYSTEMS



Element	2018 - Health Facility Survey
CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	0.50000
INSPECTION AND ENFORCEMENT	0.60000
Licensing	0.76667
PRODUCT ASSESSMENT AND REGISTRATION	0.75000
QUALITY AND SAFETY SURVEILLANCE	0.59300
REGULATION AND OVERSIGHT OF CLINICAL TRIALS	0.79167



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# Indicator Level Score Report

Indicator Score Report

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Selected Countries: 1

2018 - Health Facility Survey

REGULATORY SYSTEMS

All Element

Component	Element	Indicator	2018 - Health Facility Survey
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Are there controls on medicine promotion based on regulations?	1.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Existence of a formal complaints procedure to report unethical promotional practices	0.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Is there an entity or committee responsible for monitoring and enforcing the provisions on medicine promotion?	1.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Percentage of identified advertisement violations for which sanctions were implemented	55.0000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Percentage of monitored advertisements/promotions found to be in violation of regulations	79.0000
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Are there legal provisions to collect samples?	



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# Interview Report

## Interview Response Details Report

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Mali	2018 - Health Facility Survey	All Entity
REGULATORY SYSTEMS	All Element	All Indicator

Show 10 entries

Search:

Assessment Question	Response	Notes & Comments
<b>Component:</b> REGULATORY SYSTEMS		
<b>Element:</b> CONTROL OF PHARMACEUTICAL MARKETING PRACTICES		
<b>Indicator:</b> RS 1 - Are there controls on medicine promotion based on regulations?		
RS 1a - Are there controls on medicine promotion based on regulations?	Yes	
RS 1b - Do regulations require pre-approval for advertisements and/or promotional materials?	Yes	
<b>Indicator:</b> RS 3 - Percentage of identified advertisement violations for which sanctions were implemented		
RS 3b - In the reference year, what is the total number of violations found by the monitoring committee or service?	150	
RS 3c - In the reference year, what is the total number of sanctions implemented for promotional materials found to be in violation of specified regulations?	120	
<b>Indicator:</b> RS 7 - Percentage of manufacturing, distribution, and dispensing facilities inspected each year		
RS 7c - 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)?	50	
RS 7f - In the reference year, what is the total number of registered distributors that were inspected?	25	
RS 7b - In the reference year, what is the total number of licensed pharmaceutical manufacturers registered in the country?	200	



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# Tool Features and Benefits

**Modular &  
Customizable**

**Online & Offline  
Data Entry  
Capability**

**Global &  
Regional Tool**

**Open Data  
Repository**

**Holistic System  
Strengthening &  
Measurement**

**Comparisons &  
Trends**

**Custom &  
Exportable  
Reports**

**Novel Areas for  
Measurement**

**Targeted  
Intervention &  
Investment**



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# Lessons Learned and Challenges

- Poor secondary data availability from existing/validated indicator-based assessments
- Several emerging areas identified that require further indicator development
  - Resilience
  - Patient satisfaction/acceptability
  - Innovation, R&D, manufacturing, and trade
- Varying pharmaceutical and health system structures across countries make tool design and generalization complex
  - e.g., Decentralization, levels of care
- Scoring and weighting



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**(SIAPS)**



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# Thank you



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