Global Health eLearning Center

Good Governance in the Management of Medicines

Introduction

This session explains key terms, describes why pharmaceutical systems are particularly vulnerable to corruption, and discusses the potential impact of poor governance on health systems and patients.

What is Governance?

Governance is defined in different ways. Some definitions focus solely on governments and how they function and exercise authority. Others address protection of the public interest, stakeholder involvement, use of public resources, leadership or direction and oversight of organizations, collective action or decision making, and accountability.

For the purpose of this course, we use the following definition from United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP):

Governance is the process of decision making and the process by which decisions are implemented (or not implemented).

This definition is particularly relevant to pharmaceutical management as important decisions are made and actions taken throughout the process of managing medicines and other pharmaceutical products.

Governance is relevant at all levels in the pharmaceutical system and to all pharmaceutical management functions, including the selection, procurement, distribution, and use of pharmaceutical products. It is not solely the concern of central government or governing bodies, as decisions are made at all levels of the pharmaceutical system—national, sub-national, district, and facility.

How these decisions are made and how they are implemented affects whether patients have access to the medicines they need and whether these medicines are prescribed, dispensed, and used safely and appropriately.

Check out the **GHeL Governance and Health Certificate Program** for more courses on improving governance in health systems.

Sources: Gisselquist 2012; Barbazza and Tello 2014; World Bank 2012; UNDP 1997; OECD 2015; Canadian Institute on Governance 2015; MSH 2013; UNESCAP 2009; SPS 2011

Glossary Term:

accountability
governance
pharmaceutical management
selection
procurement
Distribution
use (of medicines)
pharmaceutical system
Health system
pharmaceutical sector
transparency

Health Systems Strengthening

1. USAID recently launched its Vision for Health Systems Strengthening 2030, which emphasizes a health system strengthening strategy based on three intermediate outcomes: **Equity** – An equitable health system affords every individual a fair opportunity to attain their highest level of health regardless of social or demographic factors, with particular emphasis on underserved, socially excluded, and vulnerable populations
2. **Quality** – A quality health system is responsive to patient and population needs and utilizes data-informed, continuous process improvement to consistently provide safe, effective, trusted, and equitable health care and medical products to improve and maintain health outcomes for all people
3. **Resource Optimization** – Resource optimization ensures that partner-country health systems adopt sustainable approaches to mobilize and use their various resources efficiently, effectively, and transparently to meet population health needs, where efficiency is determined both by the product derived from a given set of resources and the benefit obtained from their allocation.

Source: USAID 2021

What is Good Governance?

There are numerous schools of thought of what constitutes good governance. View a chart that maps the dimensions (also called principles, components, elements, or attributes) cited in the literature to describe or characterize the quality of governance. There is no single definition that captures all these dimensions or that is universally accepted.

The United Nations Development Programme (UNDP) identifies nine interdependent principles that are widely used to characterize good governance. This course uses these principles—strategic vision, participation, transparency, consensus-orientation, rule of law, equity, efficiency and effectiveness, responsiveness, and accountability—to describe good governance in pharmaceutical systems.

These principles of good governance should be applied when making decisions and taking actions in the management of pharmaceutical products and the provision of related services.

Sources: Gisselquist 2012; Barbazza and Tello 2014; UNDP 1997

Glossary Term:

accountability
consensus-orientation
effectiveness and efficiency
Equity
participation
responsiveness
rule of law
strategic vision
transparency
corruption

Highlight

WHO's **Good Governance for Medicines Programme** uses the term “good governance” to refer to “the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient, and ethical management of pharmaceutical systems, in particular medicine regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption” (WHO 2014a).

Governance and Access to Pharmaceuticals

The WHO estimates that at least one-third of the world’s population does not have regular access to essential medicines.

Poor governance in pharmaceutical systems is one of the factors that contributes to gaps in access and inappropriate use of medicines, vaccines, and other health products.

Surveys conducted between 2007 and 2011 in low- and lower-middle-income countries found that the average availability of essential medicines was only 50 percent in the public sector and 67 percent in the private sector. Even where medicines are available in the private sector, they are often unaffordable for the poor.

Health systems depend on the continuous availability of safe, effective, and affordable essential medicines and other health products of assured quality.

Pharmaceutical Products include the following:

- Medicines for the prevention, treatment, and management of diseases and health conditions
- Vaccines

Health products include the following:

- Diagnostic test kits
- Laboratory reagents and supplies
- Medical devices
- Other health commodities, such as condoms

In this course, the term “pharmaceutical products” is used more broadly to encompass medicines, vaccines, and health products.

“**Pharmaceutical management**” refers to the set of functions and activities for managing medicines, vaccines, and health products.

Sources: UN 2012; Hogerzeil and Mirza 2011

Glossary Term:

essential medicines
Private health sector
pharmaceutical management

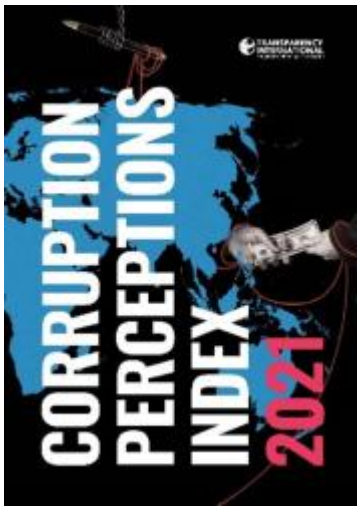
Poor Governance and Corruption

Poor governance allows opportunities for corruption to flourish and enables mismanagement to go undetected.

Corruption is defined by Transparency International as “the abuse of entrusted power for private gain.”

Corruption is a potential consequence of poor governance, as is the problem of mismanagement. The term "mismanagement” is used in this course to refer to management that is incompetent, careless, or inefficient.

The Corruption Perceptions Index published annually by Transparency International measures the perceived levels of public sector corruption in countries.



Sources: Transparency International 2015; Transparency International 2014; Lewis 2007

Why Pharmaceutical Systems are Vulnerable to Corruption

A 2012 study conducted by the US National Institutes of Health found that in both Southeast Asia and sub-Saharan Africa, 35 percent of the antimalarial medicines sampled were substandard.

Additionally, in Southeast Asia, 36 percent of the samples were classified as falsified. In sub-Saharan Africa, the amount was 20 percent.

Poor governance leaves pharmaceutical systems vulnerable to corruption and mismanagement. Pharmaceutical systems are recognized as being particularly vulnerable to fraud and corruption for several reasons:

- The **high market value** of medicines makes them a target for theft.
- The **supply chain is complex** and involves many different partners. This complexity, especially in countries where institutional controls, information systems, and enforcement of regulations are weak, can allow substandard or falsified medicines to enter the supply chain.
- **Large public pharmaceutical budgets** can present a temptation for kickbacks and bribes.
- In many countries, processes such as product registration are based on **discretionary decision making** and lack adequate checks and balances, making them especially susceptible to unethical practices and corruption.
- Patients often do not have **the necessary information to make informed choices** about the medicines they need. As a result, perverse incentives can lead providers to unnecessarily or inappropriately prescribe and sell pharmaceuticals to increase their revenues.

Sources: Nayyar et al. 2012; Cohen, Mrazek, and Hawkins 2007; SPS 2011

Glossary Term:

bribes
fraud
kickbacks
substandard medicines
falsified (medicine, batch)

medicines (or product) registration

Impact and Consequences of Poor Governance

Poor governance can be costly for governments, institutions, and individuals. When it leads to diminished access or the consumption of unsafe, ineffective, or inappropriate medicines, it can also harm patients.

Spending on pharmaceuticals is one of the largest components of total spending on health. On average, pharmaceutical expenditures account for about 25 percent of total health expenditures in low- and middle-income countries. Low-income countries spend on average 30 percent—some as much as 68 percent—of their total health expenditures on medicines and other pharmaceutical products.

Furthermore, donor agencies allocate substantial portions of their funding to procure essential medicines and commodities. Over 40 percent of the Global Fund total expenditures are for medicines, health products, and equipment.

The impact of corruption and mismanagement that can result from poor governance can be substantial:

Wastage or misuse of scarce resources

Corrupt and mismanagement can contribute to high expenditures on medicines, inflated medicine prices, wastage of resources and loss of donor funding. This can have significant cost implications for governments and can decrease medicine availability. The costs for patients and their families can also be substantial—and in some cases catastrophic, when they must pay inflated prices for medicines they need, or purchase unnecessary or ineffective products.

Diminished access to and inappropriate use of medicines

Factors that contribute to gaps in access to essential medicines include insufficient funding; high prices; weak supply systems; and weak regulatory systems that cannot ensure the quality, safety, and efficacy of products and related services. Weaknesses in governance interfere with competition, allow inefficiencies and poor management to go unnoticed, and encourage corrupt practices to thrive.

Consumption of adulterated, substandard, or falsified medicines

Bothsubstandard and falsified medicines may contain too much, too little, or none of the active pharmaceutical ingredients. The consumption or use of substandard and falsified medical products can harm patients and contribute to the spread of antimicrobial resistance. Adulterated or falsified medicines may contain contaminants that can cause harm to patients.

Decreased demand for health service

Medicines promote trust and participation in health services. Stock-outs of medicines and poor quality products can decrease demand for services, increase staff attrition, and ultimately compromise program effectiveness.

Sources: WHO 2009; WHO 2013a; Kohler and Baghdadi-Sabeti 2011; Lu et al. 2011; The Global Fund 2015; SPS 2011

Glossary Term:

adulterated (medicine)
substandard medicines
falsified (medicine, batch)
active pharmaceutical ingredient

Adulterated Medicines Can Kill

Teething medicine contaminated with diethylene glycol, an industrial solvent used in antifreeze, caused 84 deaths of children in Nigeria in 2008-9. An unlicensed chemical dealer sold the solvent in place of glycerin, a common ingredient in medicines, to the manufacturer of the medicine.

Source: Polgreen 2009

Case Reports

Procurement of poor-quality, over-priced condoms

Lack of adherence to procurement rules and procedures resulted in a country procuring 128 million condoms that did not meet quality standards. A investigation by the Global Fund's Office of the Inspector General found the tender process to be non-competitive, as it was advertised only in local newspapers for a short period and also discovered that the winning bid proposal did not address key requirements specified in the tender.

No documentation was found to support the 35 percent price increase (approved one month after the award of what was a fixed-price contract) that increased the tender value by nearly USD 1 million. Moreover, the supplier provided forged documents attesting that the condom manufacturer was WHO-certified and no quality control tests were performed when the first batches arrived in the country.

The problem came to light after the local media reported complaints from users detailing instances where condoms were found to be inadequately lubricated. In some cases, condoms burst during use, putting users at risk of exposure to HIV and other sexually transmitted infections. Poor storage conditions in the medical stores, resulting in temperatures way above the recommended range, was a further concern.

Source: WHO 2015

Recent Safety Issues

- In 2019, the World Health Organization (WHO) issued alerts to national regulatory authorities about serious problems related to the safety of three medicinal products.
- In Cameroon, patients experienced hypoglycemia after taking falsified hydrochlorothiazide tablets, an antihypertensive, which was found to contain the antidiabetic medicine glibenclamide instead.
- In Europe and the Americas, falsified batches of Ponatinib (an antileukemia drug) were discovered to have none of the correct active pharmaceutical ingredient—they contained paracetamol (acetaminophen) instead.

- In Niger, falsified batches of Mencevax ACWY, a meningitis vaccine, were found to be circulating during the vaccination campaign in children against meningitis A.

In each case, WHO strongly urged increased vigilance for affected batches throughout supply chains in these countries and regions and advised that products should only be obtained from authentic and reliable sources. Sources: WHO 2019a, WHO 2019b, WHO 2019c

Glossary Term:

active pharmaceutical ingredient
falsified (medicine, batch)
quality control
National regulatory authority
Safety (of a medicinal product)

More Case Reports

Stockouts and shortages

Surveys of medicine availability at more than 70 health facilities in one region of a country revealed that in the previous four months over 50 percent of the facilities surveyed had experienced stockouts of antiretroviral (ARV) medicines and medicines used to treat TB. In a quarter of the facilities, respondents reported that patients had left the clinic without the ARV medicines they needed because none were available.

These facilities all received their supplies from the same government medical store. Problems with the availability of medicine were reported to be longstanding and were thought to originate from poor management of medicines supply, finances, and human resources, coupled with a lack of mechanisms to hold managers and staff accountable.

Ghost workers and ghost facilities

A special investigation unit uncovered 200 ghost health workers on a country's government payroll. In many cases, the health workers had retired, absconded from duty, or been transferred, yet continued to receive a salary. In one district, the unit found three ghost health centers that had been receiving medicines through the public supply system for over four years after they had been closed.

Improper medicines promotion

In recent years, pharmaceutical companies have made settlements to resolve allegations of fraudulent marketing practices that included improperly promoting medicines for indications not approved by the country's regulatory authority. In addition to promoting medicines for off-label uses, the alleged violations included making false or misleading statements about the safety of medicines, failing to report safety data, and providing free samples to encourage doctors to use products.

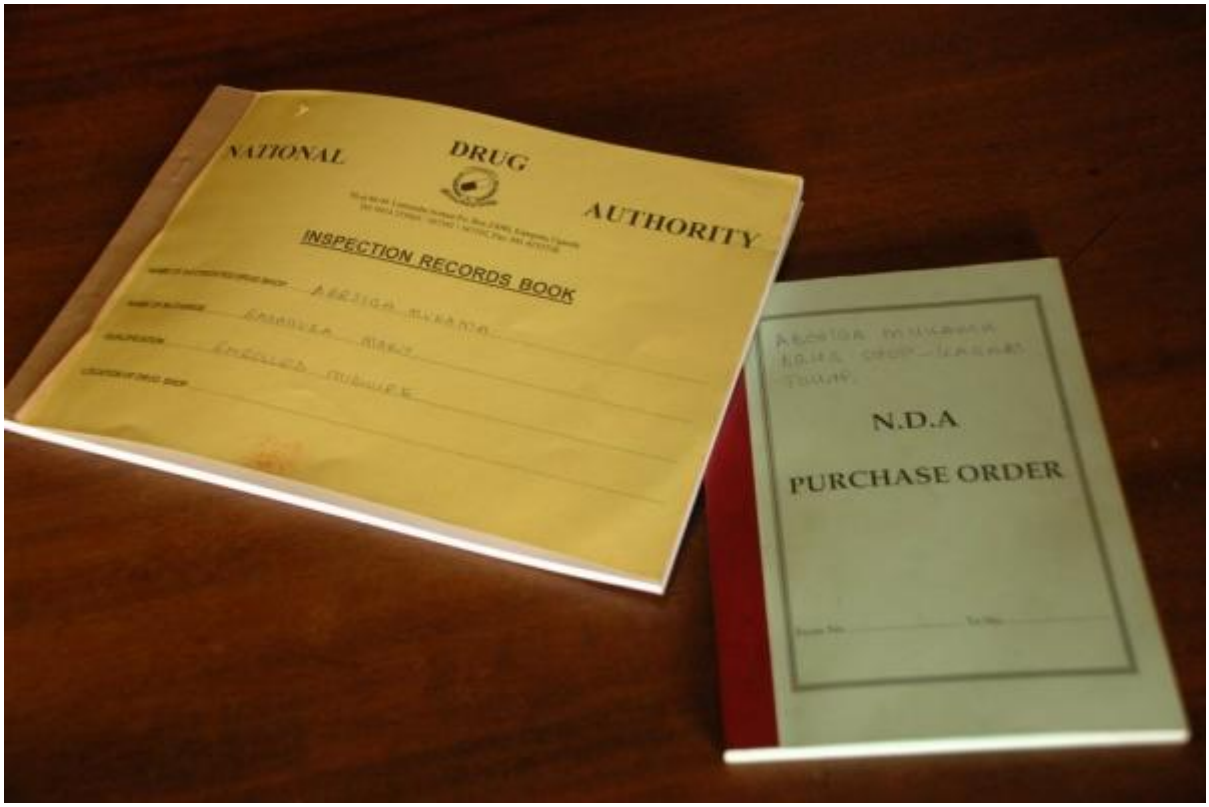
Poor governance leaves health systems vulnerable to corruption and mismanagement. When these problems occur in pharmaceutical systems, the ramifications can be costly for governments, institutions, and individuals. As these cases developed from recent WHO, Global Fund and media reports illustrate, corruption and poor management can also diminish access to medicines and lead to the consumption of adulterated, ineffective, or inappropriate products that harm patients. Good governance in pharmaceutical management is an important concern for governments, citizens, development partners, and other stakeholders.

Glossary Term:

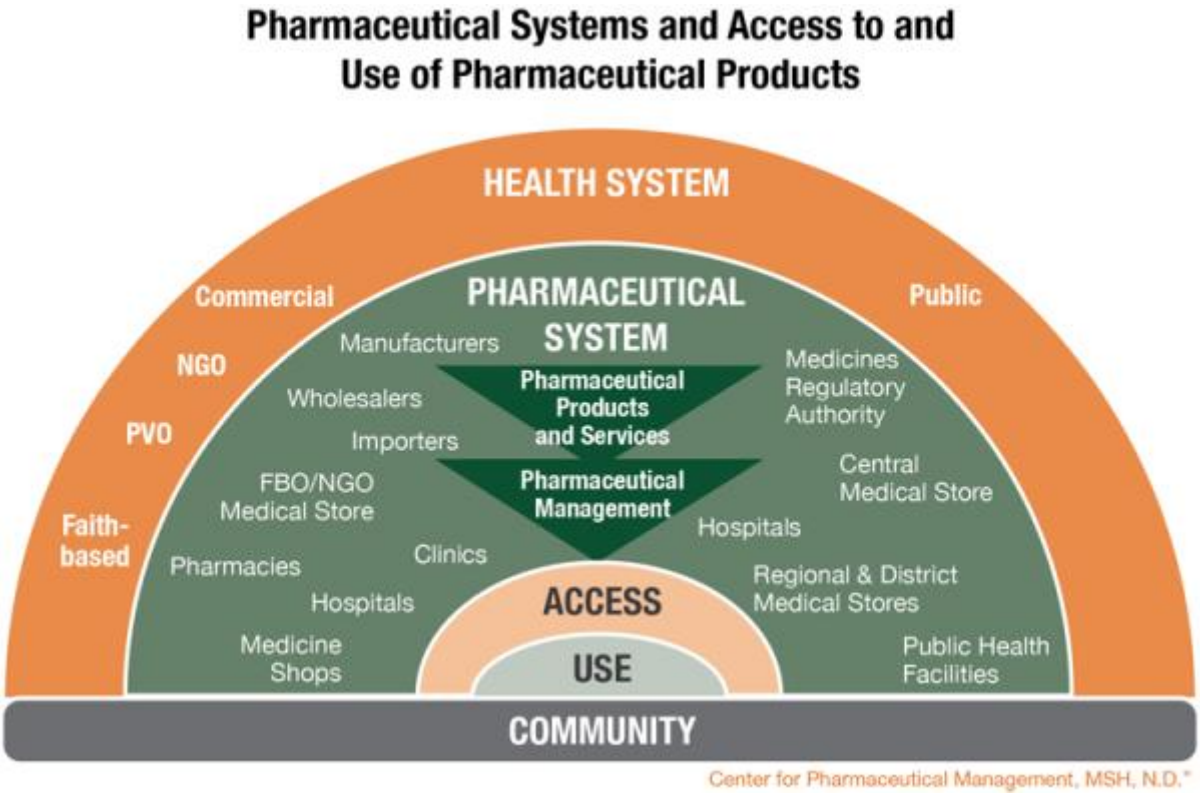
antiretroviral (ARV)

Good Governance in Pharmaceutical Systems

This session describes core pharmaceutical management functions and activities and gives examples of problems that can occur when governance is weak. It also introduces a framework for strengthening governance in pharmaceutical systems.



What is a Pharmaceutical System?



The WHO defines a health system as encompassing “all organizations, people, and actions whose primary intent is to promote, restore, or maintain health.” A health system includes structures, institutions, and individuals in both the public and private sectors that take actions that affect health at all levels—national, regional, facility, community, and household.

A pharmaceutical system is a sub-system of a health system. Its objective is to ensure timely and equitable access to and appropriate use of safe, effective, quality pharmaceutical products and related services in any given healthcare setting through a set of functions and activities called pharmaceutical management. **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 enhance responsive and resilient system performance for achieving better health outcomes. The critical components of a pharmaceutical system are its core functions and structures, the supporting health system resources, and enabling policy, legal, and governance frameworks.

Access has four components:

- **Availability**: Essential medicines and other health products needed by health programs and patients are continuously available
- **Accessibility**: Patients are able to access pharmaceutical products and services at a place they can reach and at a time that is convenient for them
- **Affordability**: Patients are able to pay the price asked
- **Acceptability**: The products and services are provided with the patient's or caregiver’s cultural and personal preferences in mind

To help achieve desired health outcomes, access to pharmaceuticals needs to be combined with the provision of quality care and services that support appropriate use (prescribing, dispensing, and consumption or use by the patient). This includes activities such as providing medication-related information and counseling, supporting self-care, and monitoring medicine use.

Sources: CPM, MSH n.d.; WHO 2007; Hafner and Walkowiak 2014; MSH 2012

Glossary Term:

pharmaceutical sector
pharmaceutical system
health program
pharmaceutical systems strengthening

Pharmaceutical sector

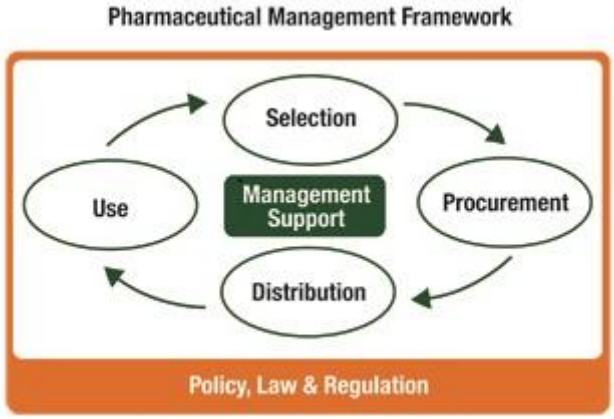
The terms “**pharmaceutical system**” and “**pharmaceutical sector**” are often used interchangeably. In this course, the term “pharmaceutical sector” is used to refer to the actors—government, private for-profit, and not-for-profit organizations—that are involved in the actions that culminate in patients having access to pharmaceuticals and related services.

Pharmaceutical Systems Strengthening

USAID’s Vision for Health Systems Strengthening 2030 defines the following priorities for strengthening pharmaceutical systems as part of its strategy of cross-cutting health system strengthening:
“USAID examines the full system required for the delivery of safe and effective pharmaceuticals to patients who need them, including by ensuring a seamless process from the selection of medicines to their use. PSS requires regulatory regimes that include the registration of products through streamlined registration processes while safeguarding public health by inspections and surveillance to ensure product quality, safety, and efficacy; supply chain management including public- and private-sectors; accreditation and other pharmacy-practice reforms to promote the rational use of products and combat antimicrobial resistance; pharmacovigilance/prescribing/dispensing policies; post-marketing surveillance of the quality of products; the

inclusion or prioritization of medicines in health benefit packages; health technology assessments; the tracking of pharmaceutical expenditures; supply chain management including the cold chain; and the manufacturing of quality products."
Source: USAID 2021

What is Pharmaceutical Management?



Pharmaceutical management is the set of functions and activities carried out in any health system to ensure access to and appropriate use of safe, effective, and quality pharmaceuticals.

Regardless of the setting (public or private sector) and the level of implementation (national, district, or facility), these activities can be organized around four basic interdependent functions depicted as a cycle in the pharmaceutical management framework:

- **Selection** involves the careful choice of medicines, vaccines, and health products based on the needs of the population that is to be served
- **Procurement** includes quantifying requirements and selecting efficient and effective procurement methods to obtain competitive prices for products of acceptable quality from reliable suppliers
- **Distribution** includes stock control, inventory management, and delivery of pharmaceuticals to health facilities where and when they are needed, while minimizing losses due to expiry, damage, and theft
- **Use** (of medicines) includes the appropriate prescribing, dispensing, and use of medicines by patients to achieve desired health outcomes

The four core functions are interdependent and so are depicted as a cycle**.** For example, decisions about what to procure are based on decisions about the selection of products needed to treat health conditions.

These functions build on each other. If activities are not well coordinated, problems such as medicine shortages and increased costs can arise. A breakdown in any step in the cycle can cause the whole pharmaceutical management process to fail.

Sources: MSH 2012
Glossary Term:
inventory management
procurement methods
quantification

Management Support

At the center of the pharmaceutical management framework is management support, which includes the systems, processes, and resources that enable and support the core functions and associated activities. Without functioning organizational structures, adequate financing, reliable information management, and motivated and trained staff, the four core functions cannot be performed effectively.

Management support includes the following:

- Organization and management
- Financing
- Information management
- Human resources management

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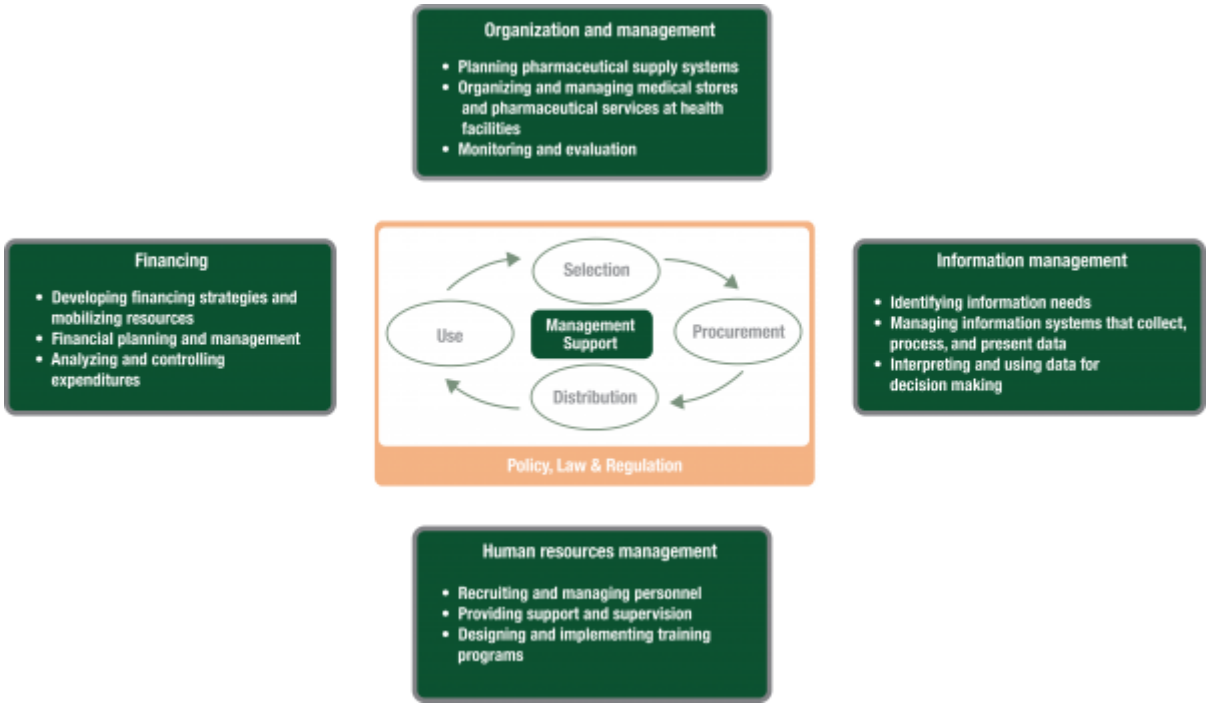
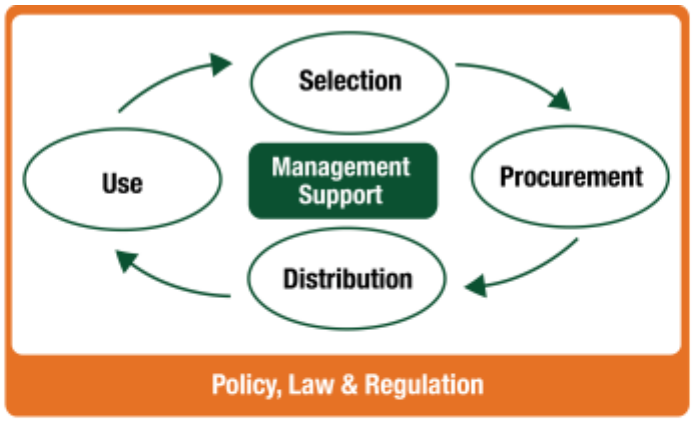


Source: MSH 2012

Policies, Laws, and Regulations

The core pharmaceutical management functions rely on a foundation of appropriate policies, laws, and regulations, which, when supported by good governance, support and sustain a reliable supply of essential pharmaceuticals and their appropriate use.



Policies

Includes formulating and implementing policies for:

- The selection, procurement, distribution, and use of pharmaceuticals
- Provision of pharmaceutical services, including decentralization
- Use of generic pharmaceuticals
- Promotion of pharmaceuticals
- Use of the private sector to provide services

Laws & Regulations

Includes formulating and enforcing laws and regulations for:

- Licensing of manufacturers, importers, distributors or outlets where pharmaceuticals may be sold
- Quality assurance, including inspection and enforcement
- Control of pharmaceuticals
- Registration and licensing of health care professionals
- Curbing corruption

Source: MSH 2012

Glossary Term:

licensing (of premises where medicines can be sold)
medicines (or product) registration

Examples of Decision-Making in Pharmaceutical Systems

Important decisions are made and actions taken throughout the pharmaceutical system, including when developing policies and legislation, allocating resources, and managing pharmaceuticals and providing related services.

Here are some examples:

- **Selection**: Deciding which antibiotics should be included in an essential medicines list or formulary
- **Procurement**: Determining condom specifications to include in a tender for procurement of family planning commodities, evaluating bids, and awarding tenders
- **Distribution**: Choosing transporters to deliver vaccines to health facilities
- **Use**: Advising mothers on the purchase of appropriate medicines for their children and informing them if a medicine is not needed
- **Management Support**: Selecting a candidate to appoint as the manager of a warehouse that handles high-value pharmaceuticals
- **Policy, Law, and Regulation**: Setting criteria for licensing pharmacies and retail outlets where medicines may be sold in order to uphold quality while safeguarding access to products and services, especially in rural areas where there are few pharmacists

Pharmaceutical management activities can be vulnerable to corruption and unethical practices, especially when procedures are not transparent and adequate checks and balances are lacking. The different committees, boards, and healthcare providers must ensure they apply the principles of good governance when making decisions and performing their statutory, management, or oversight obligations.

Governance is about how decisions are made and implemented. Management is concerned with communicating expectations and planning and using resources efficiently to produce the intended results. Governance issues can affect all the key pharmaceutical management functions, as well as the supporting management systems, and policy and legislative decision making to a greater or lesser degree. When strengthening any part of the pharmaceutical system, it is important to ensure that governance issues are considered.

Sources: WHO 2009; Cohen, Mrazek, and Hawkins 2007; SPS 2011; MSH 2010

Glossary Term:

competitive bid
statutory
specifications
essential medicines list
management support
licensing (of premises where medicines can be sold)

Potential Problems and Consequences of Poor Governance

Governance issues can impact all of the key pharmaceutical management functions as well as the supporting management systems and the development and implementation of policies, laws, and regulations.

Here are some examples of problems related to weak or poor governance that can occur in the performance of key activities and some possible consequences for health systems and patients.

Potential Problems and possible Consequences of Poor Governance

Pharmaceuticals Management Function	Potential Problems	Possible Consequences
Policies and legislation	Lack of, or weak/outdated policies and legislation	Products available that do not meet safety, efficacy, and/or quality standards
Selection	Corrupt practices (e.g. bribery) in process of selecting medicines for Essential Medicine List	Less effective or more expensive products selected
Procurement	Product specifications in tenders favor a certain supplier(s)	Purchase of inappropriate, poor quality, falsified, or highly-priced products
Storage/ Distribution	Poor enforcement of auditing procedures at storage areas	Stock-outs of medicines and supplies
Use	Inappropriate charges (e.g. informal payments)	Higher out-of-pocket expenses for patients
Organizational management	Inappropriate appointments to or political interference with consultative or oversight bodies	Inadequate oversight of key processes (e.g.tendering, financial management)
Financing	Inadequate, misappropriated, or mismanaged funds	Decreased funding to procure medicines and deliver services
Information management	Information not available, not trusted, or not used for decision making due to lack of reliability or timeliness	Lack of information creates governance and management challenges (e.g. identifying and controlling theft or fraud)
Human resources management	Promotion/benefits based on nepotism or bribery, and not on merit	Poor performance of duties

Further examples and an expanded version of the table above are available in Pharmaceuticals and the Public Interest: The Importance of Good Governance.

Sources: Cohen, Mrazek & Hawkins 2007; Nordberg & Vian 2008; SPS 2011

Glossary Term:

bribes

specifications

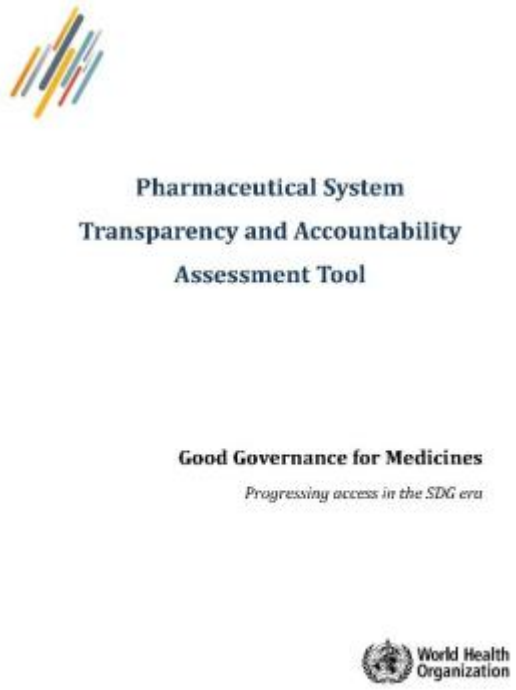
Assessment of Vulnerability to Corruption

Since 2004, 37 countries have conducted transparency assessments of their national public pharmaceutical systems using the WHO standardized tool Measuring Transparency in the Public Pharmaceutical Sector: Assessment Instrument. The Good Governance for Medicines program evaluation report summarizes findings of assessments conducted between 2004 and 2012.

Assessment reports are available on the WHO website for Benin, Cameroon, Jordan, Kenya, Lebanon, Malawi, Oman, the Syrian Arab Republic, and Zambia. A four-country assessment report compares findings from the Lao People's Democratic Republic, Malaysia, the Philippines, and Thailand. A five-country assessment report is also available for Bolivia, Cambodia, Indonesia, Mongolia, and Papua New Guinea.

Source: WHO 2013a

In 2018, the World Health Organization published a new tool to assess transparency and accountability in pharmaceutical systems: the Pharmaceutical Systems Transparency and Accountability Assessment Tool.
The following cross-cutting areas and eight core functional areas of the pharmaceutical system are included in the assessment:



Cross-cutting areas

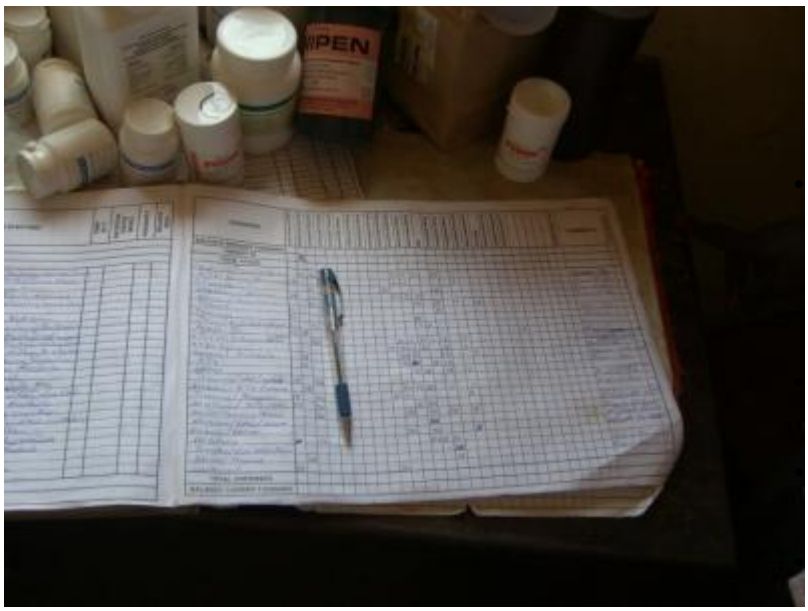
- Access to information
- Public participation
- Medicines policy
- Code of conduct and anti-corruption measures
- Managing conflict of interest

Functional areas

1. Registration and marketing authorization of pharmaceutical products
2. Licensing premises of manufacturers, wholesalers and retailers
3. Regulatory inspections of manufacturers, wholesalers, retailers and CROs
4. Pharmaceutical promotion and independent information
5. Clinical trial oversight
6. Medicine selection and reimbursement lists
7. Public procurement
8. Distribution

Learn more about the tool here

Common Governance Weaknesses



Weaknesses in governance that commonly occur in the key pharmaceutical management functions and related activities can be broadly clustered into the following groups:

Absence of, weak, or outdated policies, legislation, and guidelines that provide the foundation for good governance in pharmaceutical management or their ineffective or inequitable enforcement

Absence or inadequate functioning of decision making and oversight bodies

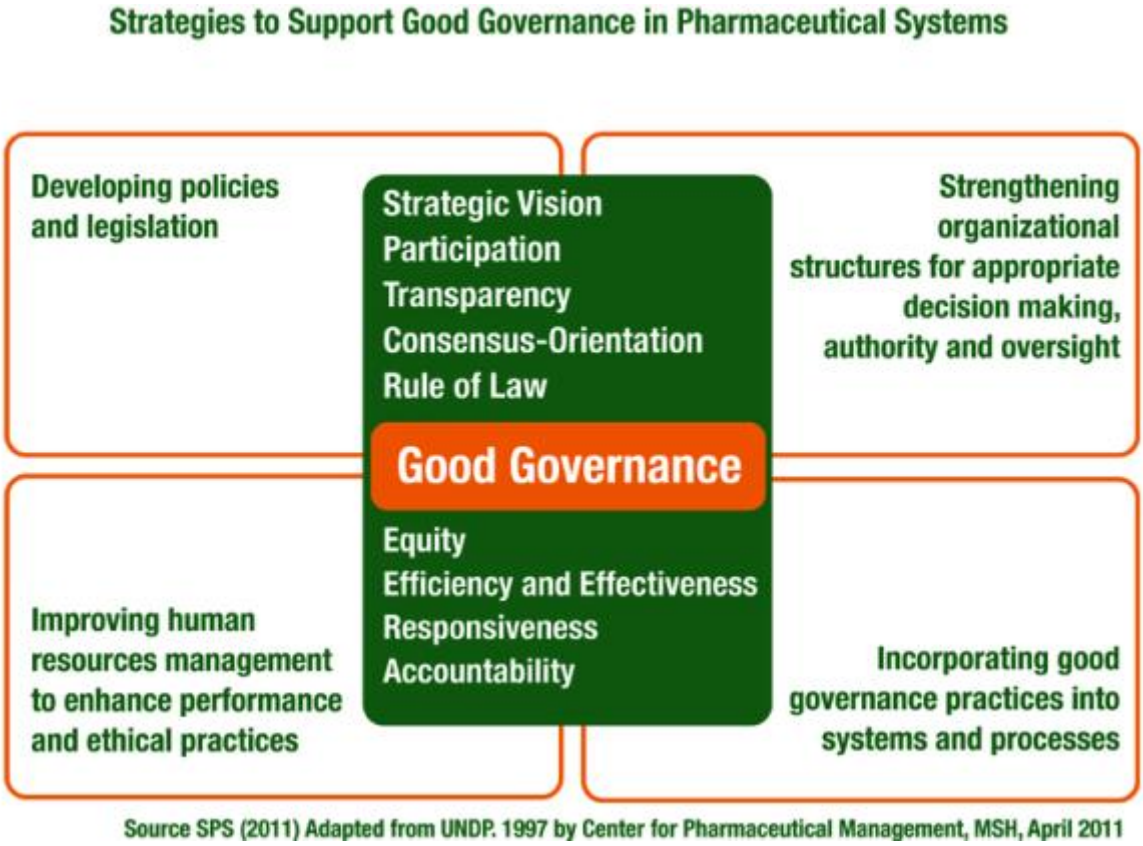
Pharmaceutical processes not conducted in accordance with good governance principles

Weak human resource management systems and procedures that fail to correct poor performance and limit unethical practices

Source: SPS 2011

A Framework for Strengthening Governance

The framework below represents a systems approach to strengthening governance in pharmaceutical systems. This approach focuses on supporting adherence to the principles of good governance.



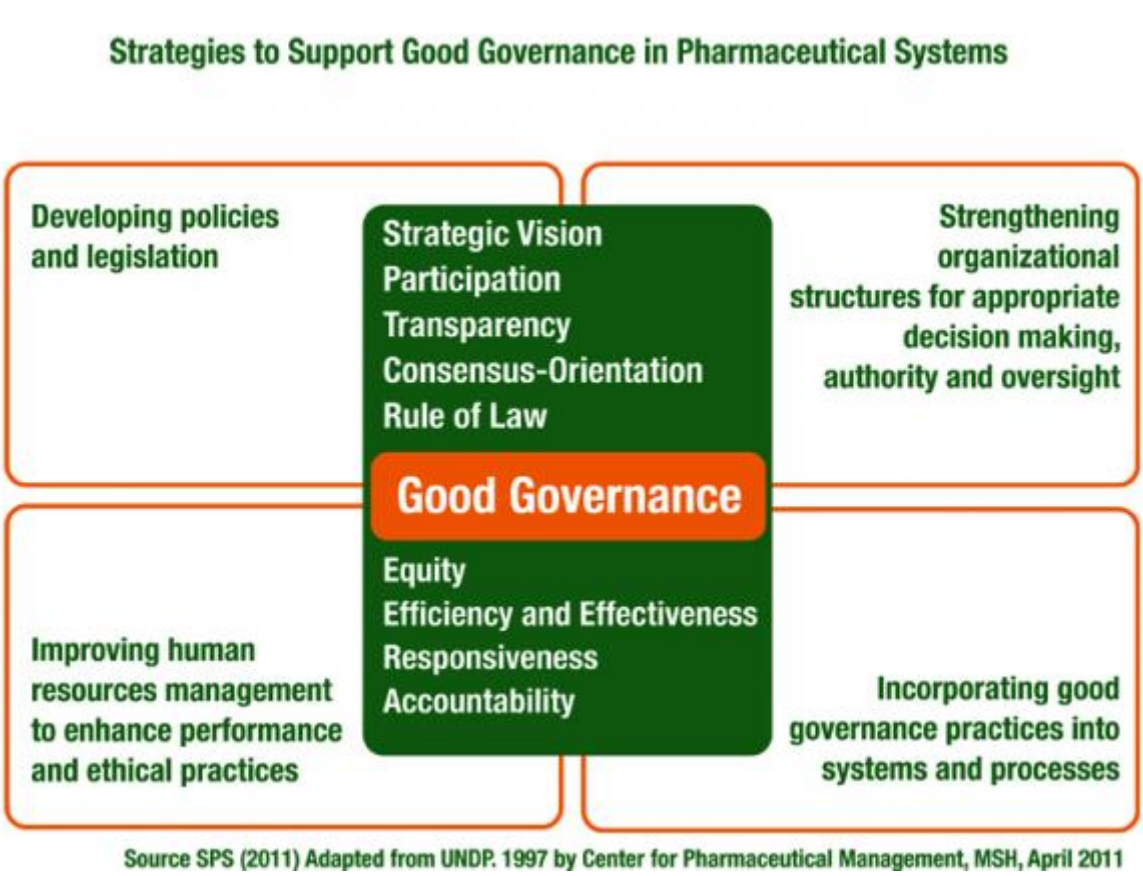
As noted earlier, a pharmaceutical system consists of all the structures, resources, processes, and people that aim to ensure equitable and timely access to and appropriate, cost-effective use of safe, effective, and quality pharmaceuticals and related services. In this framework, potential interventions are organized into those that target critical governance weaknesses related to organizational structures, processes and resources, and people in pharmaceutical systems. Because the pharmaceutical system must be carefully regulated, the framework also includes a set of interventions that address vulnerabilities related to policies and legislation.

The selection of strategies and priorities for implementation will depend on the country and local context. Governments and stakeholders will need to determine which interventions are most relevant, appropriate, and feasible based on priorities and available funding.

Source: SPS 2011

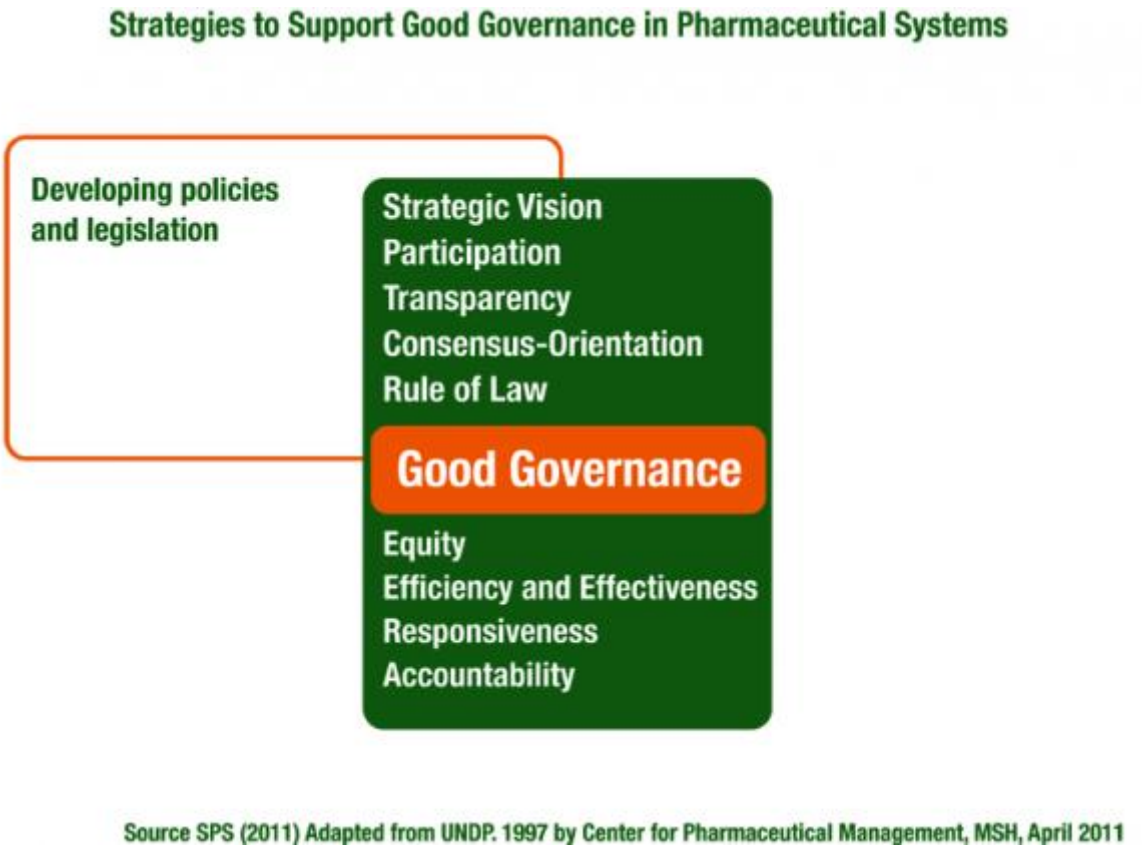
Policies and Legislation

This session is the first of four sessions that discuss interventions that can strengthen governance in pharmaceutical systems using the governance framework introduced in the last session.



Developing Policies and Legislation

This session describes interventions that focus on the formulation, implementation, and enforcement of policies, legislation, and norms and standards.



Glossary Term:
norms and standards

Importance of Robust Policies and Legislation

Pharmaceuticals must be carefully regulated because they are widely bought and sold, and because products that are unsafe or incorrectly used are potentially dangerous. Regulation that is too restrictive can constrain access to medicines and services that support their appropriate use. Policies and legislation provide the framework for how pharmaceuticals will be regulated in a country.

The national pharmaceutical policy (also called the national medicines or drug policy) sets out the government's political commitments and goals for the pharmaceutical system and provides the basis for pharmaceutical legislation. This policy should be aligned with the country's strategic vision for health services. Here is the guidance provided by WHO on developing and implementing a national drug policy.

National pharmaceutical legislation, which may include laws, regulations and rules, typically contain provisions that do the following:

- **Define the types of pharmaceutical products to be regulated**; for example, medicines, medical devices, and herbal medicines
- **Establish a national regulatory agency** responsible for assuring that only products that meet acceptable standards of safety, quality, and efficacy are registered and available
- **Regulate the licensing of facilities** where medicines are manufactured or stored and outlets where they are sold
- **Control the prescribing, dispensing, and promotion of pharmaceuticals**
- **Regulate clinical trials and establish mechanisms for post-marketing surveillance** to monitor the safety of pharmaceuticals
- **Set out procedures** for enforcing legislation and sanctions for non-compliance

Legislation must be supported by policies, guidelines, and standard operating procedures that define norms and standards of practice for selection, procurement, distribution, and use of pharmaceuticals.

Sources: MSH 2012, WHO 2009, SPS 2011

Glossary Term:

national pharmaceutical policy
norms and standards
post marketing surveillance
standard operating procedures

Strengthening Governance: Policies and Legislation

To strengthen governance, countries should establish and enforce robust policies and legislation:

- Formulate and oversee the implementation of robust, enforceable policies and legislation that support the country's priorities

- Enforce legislation by setting up oversight mechanisms, including inspection of facilities
- Legislate for statutory bodies to control the registration of medicines, licensing of premises, and registration of persons handling medicines
- Establish Good Practice Guidelines that set out norms and standards for performing pharmaceutical functions, based on international guidance and best practices
- Introduce requirements for pharmaceutical companies to comply with codes of practice on medicines promotion
- Establish post-marketing surveillance programs to monitor the safety of medicines

Additionally, they should promote good governance in development and enforcement processes:

- Promote transparency by making details of policies, legislation, and regulations publicly available
- Build the capacity of stakeholders such as patient rights groups to enable them to participate effectively in the formulation of policies and legislation
- Ensure that processes for enforcement of legislation promote fairness, equity, and impartiality in accordance with rule of law and hold those responsible for enforcement accountable

Sources: Kohler and Baghdad-Sabeti 2011; Cohen, Mrazek, and Hawkins 2007; SPS 2011; WHO 2009

Glossary Term:

statutory

post marketing surveillance

Did You Know?

Assessments of transparency and vulnerability to corruption in 25 countries revealed that although most have laws that define standards for marketing, rarely are all aspects of **medicines promotion** addressed, such as procedures for submitting complaints.

For the most part, the public and health workers do not know that any provisions to control promotion exist and enforcement of sanctions for violations is weak.

Source: Kohler and Baghdadi-Sabeti 2011

The Challenge: Policies & Legislation in Mallevus

Pharmaceutical policies and legislation in Mallevus are confusing and outdated. Watch the video below to learn more.

What should the Director of Pharmaceutical Services and partners do to address these issues?

Disclaimer: This scenario is fictional and does not represent any one country, region, or situation.

Possible Recommendations

As a first step, partners could help the Directorate of Pharmaceutical Services advocate for Ministry of Health commitment in revising the legislation to address the poor control of medicines in Mallevus. The advocacy messages should explain why the current situation has the potential to cause serious harm to its citizens.

The Ministry of Health may need technical assistance with developing a plan for updating the laws in Mallevus. Activities may involve helping country counterparts identify and use international guidance and best practices to map out the process, including steps to promote stakeholder participation and transparency.

Partners could also assist counterparts and stakeholders to review the existing legislation and compare it with international guidance to identify gaps and inconsistencies and helping to draft legislation that includes provisions to do several things:

- Establish a national regulatory authority responsible for assuring the safety, quality, and efficacy of medicines available in Mallevus
- Regulate licensing of facilities where medicines are sold and persons who may sell them to control the sale of medicines while safeguarding access to products and services, especially in remote regions of the country
- Control medicines promotion to prevent inaccurate or misleading advertising to the public

To promote transparency, the Ministry may need assistance to identify key stakeholders to involve in the legislative reform process and to consult with on the draft legislation. Activities may also include developing and publishing articles in the media to keep the public informed on the process and progress made.

Other important activities may involve advocating for adoption of the new legislation by the National Parliament of Mallevus.

Glossary Term:

National regulatory authority

Swaziland: Improving the Control of Medicines

The Ministry of Health in Swaziland has embarked on updating legislation to regulate the control of medicines and the pharmacy profession. The existing legislation no longer serves as an effective legal framework for the pharmaceutical sector.

As a first step, Swaziland developed a comprehensive National Pharmaceutical Policy with the support of WHO, which provided the strategic vision and basis for the legislative reform. The USAID-funded Strengthening Pharmaceutical Systems (SPS) Program then helped the Ministry review the existing legislation to align it with the National Pharmaceutical Policy and facilitate a series of consultative workshops to enable stakeholders to comment on the proposed legislative provisions.

Two bills were drafted as a result of these efforts:

- **The Medicines and Related Substances Control Bill** (provides for the establishment of a Medicines Regulatory Authority in Swaziland)
- **The Pharmacy Bill** (regulates the profession and practice of pharmacy)

To promote transparency, the draft bills were presented to government and private-sector stakeholders for comment. The media reported on proceedings of the consultations.

Systems for Improved Access to Pharmaceuticals and Services (SIAPS), the USAID-funded follow-on program to SPS, assisted the Ministry of Health to advocate for enactment of the bills and to conduct seminars to educate newly elected legislators on the need for new legislation and the content of the draft

bills. The updated legislation is now being debated by the Parliamentary commitees, and once approved can be enacted into law. To expedite the implementation of the Medicines and Related Substances Control Bill, once passed, SIAPS has also helped the Ministry of Health to draft the set of accompanying regulations.

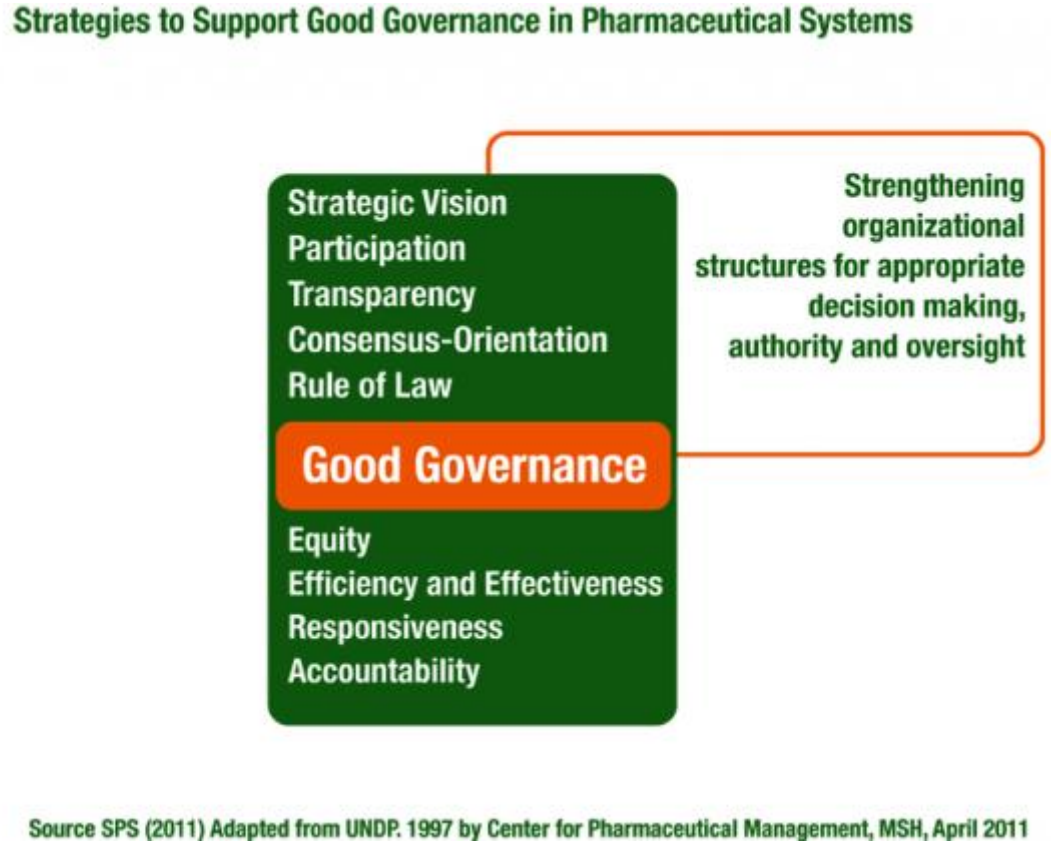
Read more about SIAPS' work in Swaziland.

Source: SIAPS 2014a

Glossary Term:
national pharmaceutical policy

Organizational Structures

This session discusses strategies for increasing transparency and accountability of committees, boards, and other bodies that make important decisions in pharmaceutical systems.



Importance of Well-Functioning Structures

Well-functioning organizational structures that can initiate and sustain improvements in pharmaceutical systems are a key component of country ownership. Oversight bodies with adequate capacity and funding are essential to ensure accountability.

Increasing transparency and accountability of health system committees and boards that make important decisions related to pharmaceutical management is central to improving governance.

Some examples of committees and boards include the following:

- National regulatory authorities responsible for registering medicines and for post-marketing surveillance
- National or regional structures responsible for licensing pharmaceutical entities such as manufacturers, importers, distributors, and retail pharmacies

- Pharmacy and therapeutics committees at national, regional and institutional levels that advise on the selection of medicines for essential medicines lists and formularies
- Committees or boards that manage or oversee the tender process for procurement, including advertising tenders, evaluating bids, awarding tenders, and managing contracts
- Audit committees that oversee audit functions, internal controls, and financial reporting processes

Whether these committees and boards operate independently or within the Ministry of Health or other government department, they must be independent and impartial to minimize undue influence in decision making.

Sources: SPS 2011, WHO 2009

Glossary Term:

pharmacy and therapeutics committees
National regulatory authority
post marketing surveillance
essential medicines list

Selecting Committee and Board Members

Committee and board members should be appointed or hired on the basis of documented, objective criteria that relate to their technical expertise, knowledge or skills to mitigate political interference, nepotism, and corruption in the appointment of members.

Members may represent different constituencies or sectors, including civil society, to promote transparency and accountability. Users of health services should also have a voice; for example, through organizations that represent their interests.

Conflicts of Interest

All members must declare and document conflicts of interest that may influence decision making. Such conflicts may arise when a committee or board member has competing personal or professional interests that make it difficult to carry out his or her duties impartially.

Conflicts of interest can arise from relationships with manufacturers who have strong interests in getting their products registered, included on essential medicines lists, procured, prescribed, dispensed, or sold.

In low- and middle-income countries, experts in fields such as pharmacoepidemiology are rare and may sit on the boards of several organizations as well as consult for the pharmaceutical industry. For example, a potential conflict of interest would arise if an expert had received honoraria from a pharmaceutical

company to lecture at promotional events, then participated in selection decisions concerning the inclusion of products manufactured by that company in the national essential medicines list.

Participating in the evaluation and award of a pharmaceutical tender that includes a bid from a supplier where a family member is a director, employee, or shareholder is another example of a potential conflict of interest. These relationships should be declared and documented.

Sources: SPS 2011; WHO 2009

Glossary Term:

civil society
pharmacoepidemiology
voice
conflict of interest

Strengthening Governance: Organizational Structures

Governance can be strengthened by establishing and fostering effective and transparent committees and boards. Any strong organizational structure should include the following:

- **Objective criteria and procedures** for the selection of members
- Sufficient **autonomy** to help mitigate undue influence in member selection and decision making
- Membership that promotes **transparent and appropriate** stakeholder and civil society **participation**.
- **Publicly available terms of reference** that clearly define membership, authority, roles and responsibilities, and lines of authority
- **Written procedures or codes of conduct** for avoiding, declaring, and managing conflict of interest. A code of conduct sets out principles, values, standards, and rules of behavior that guide the decisions and procedures of an organization and its members.

- **Legitimacy,** which is fostered by making members' names, credentials, and selection criteria publicly available
- **Adequate capacity** with members who are well-informed, prepared, and equipped with resources and expertise to enable appropriate decision making, authority, and oversight

Sources: Kohler and Baghdadi-Sabeti 2011; Cohen, Mrazek and Hawkins 2007; SPS 2011; WHO 2009

Glossary Term:

codes of conduct
terms of reference
conflict of interest

Did You Know?

Only seven of 25 countries that conducted transparency assessments had official criteria for selecting members of their **national medicine selection committees** (Kohler and Baghdadi-Sabeti 2011).

The Challenge: Essential Medicines Committee in Etria

The Essential Medicines Commitee does not include all stakeholders and some members might have a conflict of interest. Watch the video below to learn more.

What recommendations could the Director of Pharmacy propose?

Disclaimer: This scenario is fictional and does not represent any one country, region, or situation.

Glossary Term:

essential medicines list

Possible Recommendations

The Director of Pharmacy should begin by identifying international guidance and best practices in the region for establishing Essential Medicines Committees. The next step would be to share these with the Minister of Health and agree on which critical recommendations and practices should be adopted in Etria.

Other recommendations include the following:

- Identify key stakeholders with an interest in the revision of the Essential Medicines List and draw up terms of reference for the committee. This can help promote transparency and participation.
- Maintain objective criteria for selection of members to ensure valid representation of key stakeholders, including disease programs and civil society.

- Develop a procedure for appointing members and a code of conduct for members on declaring and avoiding conflicts of interest.
- Solicit feedback on proposed terms of reference, committee membership and appointment procedures, criteria for selection, and conflict of interest guidance.
- Set up an oversight process to ensure that members are appointed in line with the selection criteria and that all members complete a conflict of interest declaration.
- Promote transparency and legitimacy of the committee by posting the final terms of reference, as well as members' names, credentials, and selection criteria, on the Ministry of Health website.

Benin: Revising the Legal Framework for the Central Medical Stores

Created in 1989, Benin's Central Medical Stores—the Centrale d'Achat des Médicaments Essentiels et des Consommables Médicaux (CAME)—is responsible for procuring and distributing essential pharmaceuticals and medical supplies to public health facilities and private health centers throughout the country.

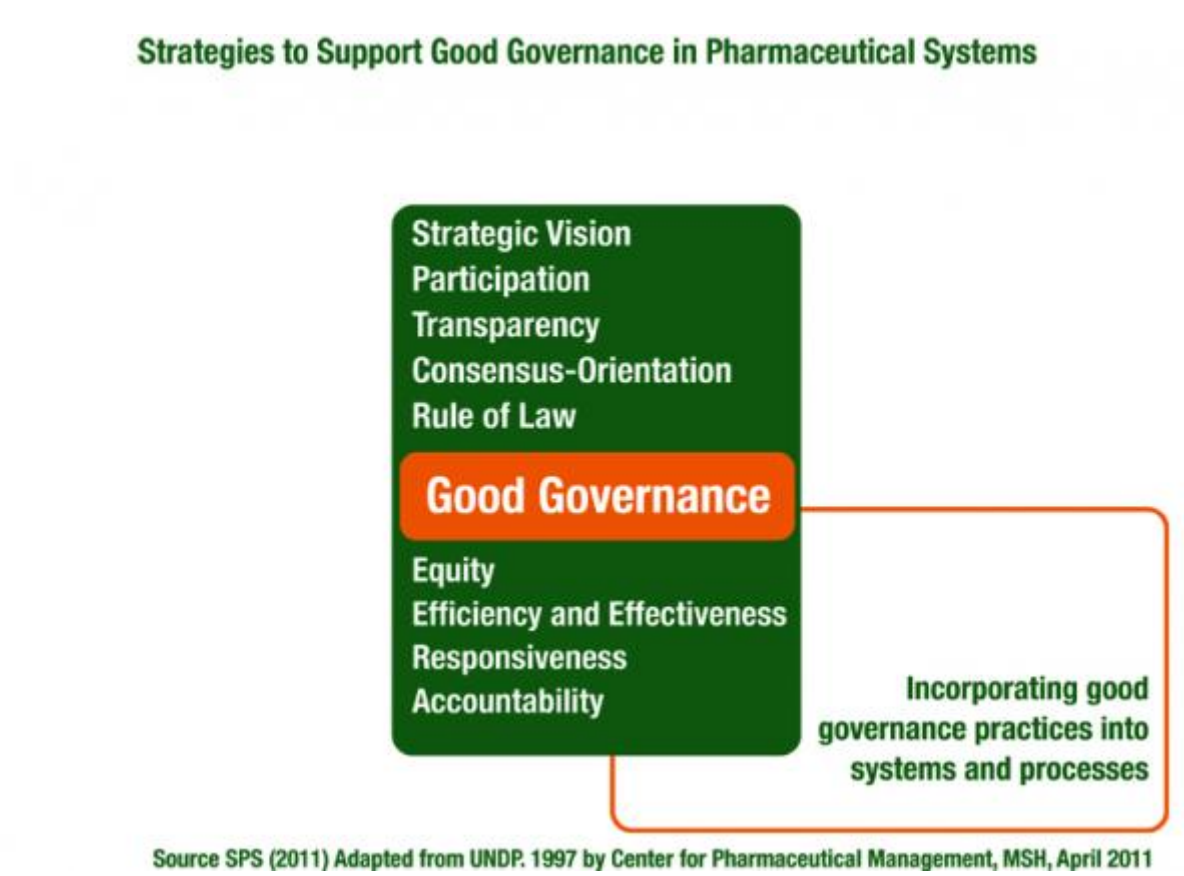
In 2010, the Government of Benin, with assistance from the US President's Malaria Initiative (PMI), developed a new legal framework for CAME to resolve ambiguities in its legal standing and create conditions for improved efficiency, governance, and management in the organization.

The revised legal framework, which was developed through a consensus-based process involving key stakeholders from the health sector, clarifies CAME's legal status as an autonomous institution with a public function. The criteria for membership of its General Assembly (CAME's management committee) and Board of Directors, and the procedure for the appointment of members, are also addressed in the revised statutes. The list of organizations that should be represented on these governance bodies has been expanded to better reflect the stakeholders in Benin's pharmaceutical sector.

Sources: PMI 2011; SPS 2011

Systems and Processes

This session discusses interventions that promote good governance in decision making and pharmaceutical management processes and activities. It also outlines strategies for improving oversight in pharmaceutical systems.



The Importance of Good Governance in Decision Making and Activities

Decision making is susceptible to bias and inconsistency when processes are not transparent and decision-makers are not held accountable. To minimize these problems,decision making in the pharmaceutical systemmust meet the following criteria:

- Guided by **robust criteria** that are based on best practices and international standards
- Based on **independent, sound, and unbiased evidence** rather than personal experience, and unaffected by the special interests of decision makers
- **Transparent** with, decisions being well documented and made available for scrutiny by stakeholders (including the public)

Mismanagement, corruption, and unethical practices in pharmaceutical management functions and activities (selection, procurement, distribution, and use) **and financial management may also be significant concerns.** To maximize efficiency and effectiveness and reduce vulnerability to corruption, activities such as inventory management of pharmaceuticals and inspections of manufacturing facilities should be conducted in accordance with standards and procedures that are grounded in best practices and international guidance.

The WHO has developed a number of good practice guidelines for pharmaceutical management:

- Good Manufacturing Practices
- Good Practices for National Pharmaceutical Control Laboratories
- Operational Principles for Good Pharmaceutical Procurement
- Good Distribution Practices
- Good Storage Practices
- Good Prescribing Practices
- Good Dispensing Practices

Sources: SPS 2011; WHO 2009

Strengthening Governance: Decision Making and Activities

Governance can be strengthened by creating standards and guidance for decision making and for performing pharmaceutical management functions and activities.

In terms of decision making, it is important to have the following:

- **Clearly defined criteria** for decision making based on best practices and international guidance, where appropriate
- Decisions that are **evidence-based** and made in accordance with the agreed criteria
- **Written procedures** that document the decision-making process and set out rules for declaring and avoiding conflicts of interest
- **Published reports** of meetings and decisions, including (as much as possible) the reasons that informed a particular decision
- An **appeals process**, where appropriate

TENDERS

Parliament flouts bidding laws

For pharmaceutical management functions and activities, consider the following:

- Establish **clearly defined standards** for pharmaceutical management functions and activities based on best practices and international guidance, such as the WHO good practice guidelines presented on the previous page
- Develop and monitor adherence to **standard operating procedures** based on these standards
- Strengthen **record keeping and procedures** to track and control pharmaceuticals that flow through supply chains
- Set up formal procedures for **whistle blowing** and **submitting complaints**

Sources: Cohen, Mrazek, and Hawkins 2007; SPS 2011; WHO 2009

Glossary Term:
whistle blowing

Highlight: Evidence-Based Decision Making

The WHO guidelines for the use of antiretroviral medicines for treating or preventing HIV infection is an example of international guidance that can be used to inform the development of national standard treatment guidelines in low- and middle-income countries.

For each clinical recommendation, the guidelines indicate the strength of the recommendation (strong or conditional) and the quality of the evidence (high, moderate, low, or very low).

Good Governance and Oversight

In addition to standards for pharmaceutical management functions and activities, **oversight mechanisms are needed to ensure compliance with the standards set and to detect mismanagement and corruption.**

Examples of oversight mechanisms include the following:

- Systems for overseeing pharmaceutical management functions (such as procurement and distribution)
- Evaluating stock management to identify theft or mismanagement
- Auditing financial management processes

To promote transparency, information on key performance indicators, such as prices paid for pharmaceuticals, **should be made widely available and compared with international reference prices** (see box for sources).

Entities that carry out audit and oversight functions may be internal or external to the government agency or organization. These entities must have adequate capacity, autonomy, and funding to function effectively.

Civil society groups increasingly play a role in monitoring the performance of health systems. For example, through its Treatment Access Watch program, Positive-Generation, a local civil society organization in Cameroon reports weekly on the availability of antiretroviral medicines and HIV rapid test kits at 74 health facilities across all 10 of Cameroon's regions, as well as notable incidents, such as when health workers demand inappropriate or elevated fees.

Sources: SPS 2011, WHO 2009; Positive-Generation 2015

Glossary Term:
reference prices

Did You Know?

Countries can use international reference prices to check whether they are paying fair prices for pharmaceuticals. Some sources are listed here.

MSH International Drug Price Indicator Guide

WHO Global Price Reporting Mechanism (GPRM): antiretroviral medicines

Médecins Sans Frontières' (MSF) Untangling the Web

Strengthening Governance: Improving Oversight

Below are factors that contribute to improved oversight and thereby stronger governance.

- **Autonomy and adequate powers for entities** responsible for auditing, inspection, enforcement, and applying sanctions
- Governing bodies and senior management have the **capacity to provide effective oversight**
- **Strong monitoring and evaluation** of the pharmaceutical system (for example, monitoring of pharmaceutical expenditures, prescribing, and dispensing in order to identify unusual patterns)
- **Information system technologies** that produce reliable information and effectively monitor processes and outcomes (discussed further in Session on Working with Countries to Strengthen Governance)
- **Publicly available performance monitoring findings** (for example, prices paid, stockouts reported, results of audits and inspections performed
- **Involvement of civil society groups and the public** in monitoring the performance of health systems (for example, checking the availability of medicines at health facilities)

Sources: Cohen Mrazek, and Hawkins 2007; SPS 2011; WHO 2009

Ideas in Action: Stop Stockouts

In South Africa, local civil society groups in partnership with international health organizations have launched the Stop Stock Outs project, which asks both patients and health care workers to report on stockouts and shortages of essential medicines at government health facilities. Reports can be submitted online or by email, phone, and SMS.

Check out the second annual report and stockout map at the stockouts.org.

Source: Stop Stock Outs 2015

The Challenge: Central Medical Stores in Nadev

Nadev is experiencing governance weaknesses in the procurement processess for its Central Medical Stores (CMS). Watch the video below to learn more.

What technical assistance activities could the USAID Mission support in response to the request from the Ministry of Health?

Disclaimer: This scenario is fictional and does not represent any one country, region, or situation.

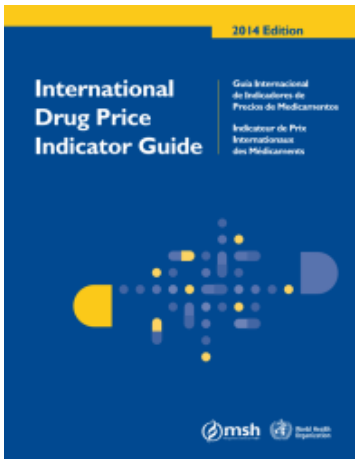
https://youtu.be/dqmxEGuaM6I
Glossary Term:
competitive bid

Possible Technical Assistance

Depending on the role of other partners and available funding, USAID could offer to support the Ministry of Health and the CMS to address priority governance concerns in three areas:

1. **Improve procurement processes and procedures:**
    - Revising processes and procedures for tendering to address gaps and inconsistencies, taking into account best practices and international guidance
    - Introducing clearly defined criteria for awarding tenders
    - Establishing or bolstering mechanisms for monitoring adherence to procedures

2. **Bolster oversight and accountability:**
    - Strengthening auditing functions (develop tools and standard operating procedures for monitoring and auditing functions at the CMS; provide training and mentoring for audit staff; and prepare a budget to support audits and monitoring activities)
    - Instituting performance monitoring and setting performance targets for the CMS core functions
    - Collecting and analyzing data and developing a dashboard to display pertinent information to facilitate performance monitoring
    - Periodically conducting a survey to compare prices paid with international reference prices



3. **Enhance procurement transparency:**
    - Developing the Ministry of Health website to enable tendering procedures to be posted together with bids and prices paid
    - Helping counterparts review options for making the results of audits and performance monitoring publicly available

Sources: Cohen, Mrazek, and Hawkins 2007; SPS 2011; Vian 2006; WHO 2009

South Africa: Improving Efficiency and Governance in the Supply Chain

PEPFAR and the USAID-funded projects SIAPS and Supply Chain Management System (SCMS) assisted staff from the KwaZulu-Natal Provincial Pharmaceutical Supply Depot (PPSD) to apply a quality improvement approach to addressing inefficiencies and improving accountability in the supply chain. The initiative started in 2013 to address long order processing times at the depot, which were leading to stockouts and staff dissatisfaction at the over 550 facilities that the depot serves. It also resulted in more emergency orders, which further disrupted routine processes.

With assistance from SIAPS and SCMS, the depot staff instituted the following changes:

- Analyzed ordering processes, staff roles, and workloads to identify key bottlenecks and opportunities for reorganizing processes to improve efficiency and effectiveness
- Reviewed and clarified roles and responsibilities of personnel to improve accountability
- Introduced a tool to track the time taken to complete each key step in the order filling process
- Established a Quality Management System (QMS) to bolster control, consistency and accountability and build quality into warehouse distribution processes
- Segregated key functions in line with best practices to improve governance
- Introduced quality initiatives to improve compliance with regulatory requirements relating to financial control and good distribution practices

As a result of these initiatives, the depot staff has reduced the average time taken to process an order from 27 days in 2013 to 10 days as of 2015. The QMS Committee continues to meet every two weeks to conduct internal audits and plan and review quality initiatives to address deficiencies, including those identified by external regulatory authorities.

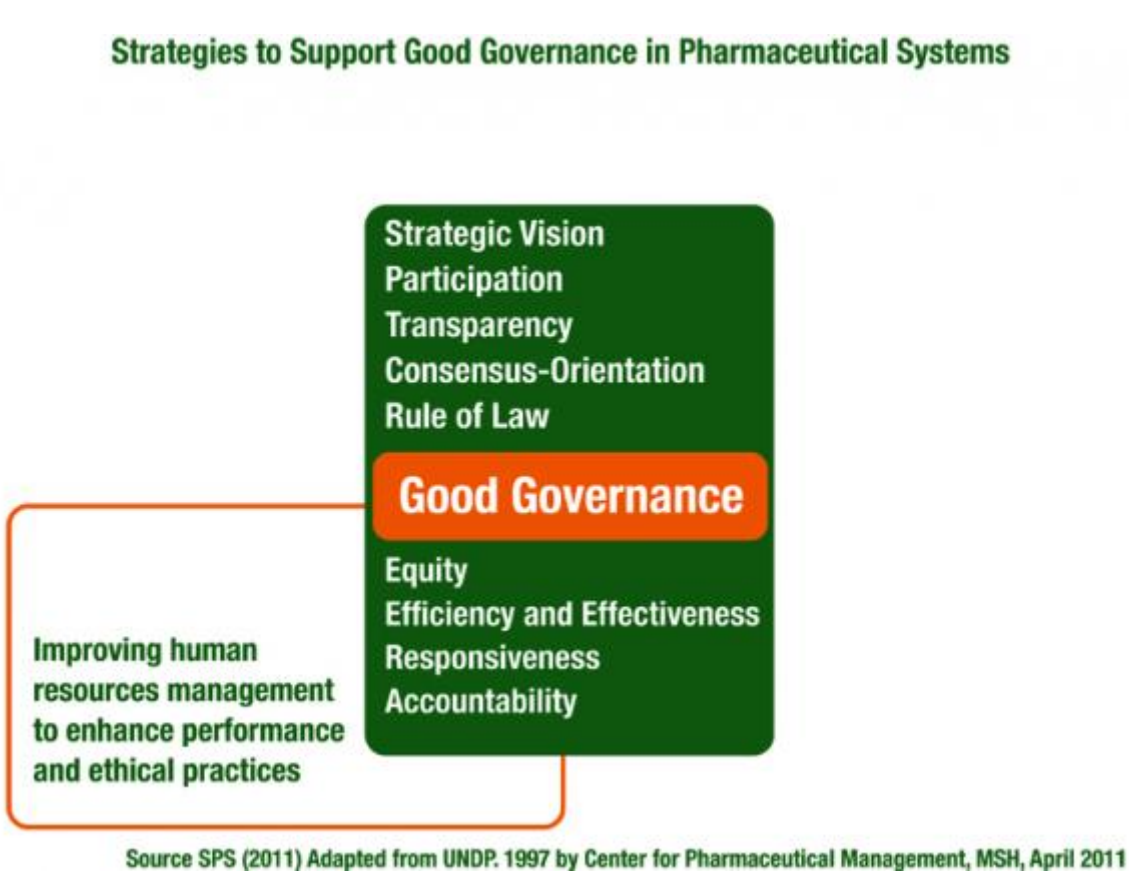
Source: SIAPS 2015

Highlight: PMI Diversion of Medicines

Read the U.S. President's Malaria Initiative (PMI) Approach and Steps to Counter Theft and Diversion of Medicines.

Human Resources Management

This session outlines interventions that aim to enhance the performance and ethical practices of health workers who manage medicines and provide related services.



Importance of Effective Human Resources Management

Staff working in pharmaceutical systems frequently handle high-value pharmaceuticals or participate in activities that are vulnerable to corruption. Human resources management procedures that promote equity, fairness, and transparency in staff recruitment and promotion are critical to prevent interference or nepotism in the appointment or promotion of personnel.

Good governance in pharmaceutical systems relies on effective human resources planning and management to ensure that adequate numbers of appropriately trained and competent personnel are available to enable staff to adhere to best practice guidelines and procedures.

Clear performance standards, job descriptions, and structured supervision all play a part in addressing poor performance and problems, such as absenteeism. Formal systems for submitting complaints enable patients and customers to report poor staff performance and unethical behavior.

To promote good governance, it is important to have the following:

- **Policies and procedures** for staff recruitment, development, and promotion that promote fairness, equity, and transparency.
- Clearly defined **criteria for employee recruitment, selection, and promotion** and ensure that they are applied. Job vacancies, job descriptions, and rules for selection or promotion should be publicly available.
- **Adequate resources** to ensure that best practices, including separation of key responsibilities(for example, ordering and receipt of pharmaceuticals), can be properly implemented and adequate supervision and oversight provided.
- **Clear performance standards and ongoing supervision**. Provide incentives to encourage good performance and apply sanctions for criminal and unethical behavior.

- **Information for patients and customers** on service delivery expectations and fees. Set up and publicize formal **systems for submitting complaints** and whistle-blowing.

Source: Cohen, Mrazek, and Hawkins 2007; SPS 2011; WHO 2009

Improving Ethical Practices

Also important in pharmaceutical systems are codes of conduct and codes of ethics supported by monitoring and enforcement to promote ethical behavior. In many countries, professional associations play a role in developing codes of ethics and encouraging their members to adhere to them.

To enhance ethical practices, consider the following:

- Develop **codes of conduct**, provide training on ethical practices, and monitor compliance to them.
- Encourage **professional associations** to develop and promote codes of ethics and provide educational activities to raise awareness. Explore opportunities for engaging the associations in monitoring and enforcement.
- Require doctors to report **gifts and payments** from the pharmaceutical industry and establish policies to reduce perverse incentives (for example, by separating prescribing and dispensing roles).

Sources: Cohen, Mrazek, and Hawkins 2007; SPS 2011; WHO 2009

Glossary Term:

professional associations
code of ethics
codes of conduct

Ideas in Action: Code of Ethics

Kenya's Pharmacy and Poisons Board has developed a code of ethics that sets out principles with which all registered pharmacists are expected to comply.

Source: Pharmacy and Poisons Board, Kenya/Pharmaceutical Society of Kenya 2015

The Challenge: Ethical Personnel Practices in Ossarano

The new Chief Pharmacist in the Province of Ossarano has been called upon to address several issues with pharmacy services and pharmaceutical personnel in the central hospital and in six district hospitals. Watch the video below to learn more, and consider possible actions to address these problems.

What could the Chief Pharmacist do to address these issues?

Disclaimer: This scenario is fictional and does not represent any one country, region, or situation.

Possible Activities

The Chief Pharmacist could work with managers and staff to **tackle performance issues** in the following ways**:**

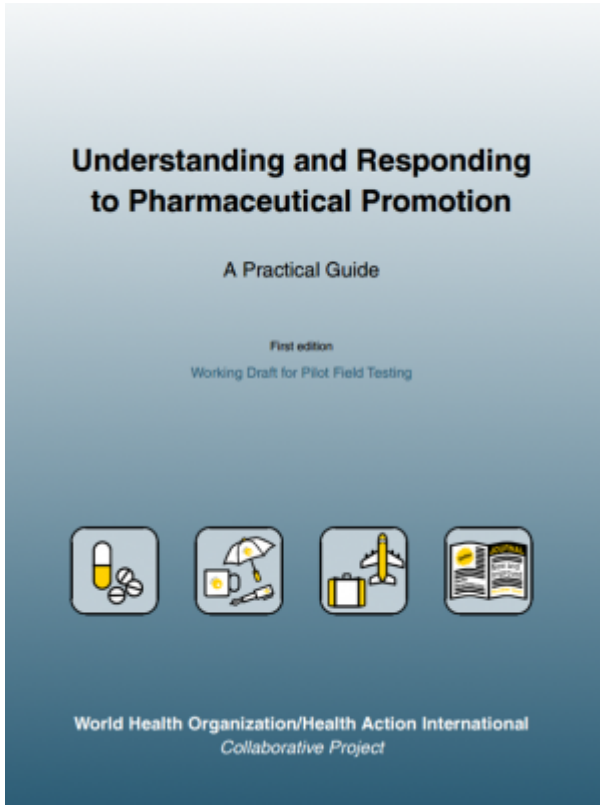
- Reviewing the job descriptions for the pharmacy staff with human resources managers to ensure that their responsibilities are clearly defined.
- Meeting with pharmacy staff and their managers to set clear performance standards for pharmacies that specify opening hours and targets for waiting times.
- Establishing systems for regular supervision of pharmacies to check adherence to agreed performance standards (for example, working hours) and take disciplinary action as appropriate.

She can also **address the problem of inappropriate charges** (and ethical considerations) by doing several things:

- Developing a poster that sets out fees to be paid for medicines as well as details of which patients are exempt from the payment of fees.
- Working with hospital managers to ensure that the poster is displayed outside pharmacies and that details are provided on how patients can provide feedback on the service and submit complaints.
- Holding a workshop with pharmacy staff to review and adopt the national pharmacy assocation code of ethics, or develop one for the province if a national code does not exist.

Finally, she can **improve management at the Provincial Medical Stores** by working with the provincial human resources manager to ensure that the job description for the post specifies the required qualifications and experience and that clearly defined criteria for recruitment are developed. Her follow-on actions would involve ensuring that the job vacancy is advertised widely and checking that recruitment criteria are adhered to.

Educating About the Promotion of Pharmaceuticals



The WHO has long been concerned about the effect of improper pharmaceutical promotion on prescribing and dispensing practices. Studies have shown that **doctors who depend more on promotional information from the pharmaceutical industry tend to prescribe less appropriately**, prescribe more often, and adopt new medicines more quickly (Norris et al. 2005).

WHO's Ethical Criteria for Medicinal Drug Promotion , adopted by the World Health Assembly in 1988, provide **general principles for ethical standards in drug promotion** that countries, manufacturers, distributors and advertisers, and consumer groups can use to develop their own codes and guidelines. The criteria address the content of advertisements and information for prescribers and patients, provision of free samples, sponsorship of symposia and scientific meetings, and the activities of medical representatives.

More recently, recognizing that **medical and pharmacy students need to be educated early on how pharmaceutical promotion can influence prescribing and dispensing behaviors**, Health Action International and the WHO have published a manual that summarizes medicine marketing and promotion issues . The manual is designed to be used by medical and pharmacy schools to educate students on how to critically analyze promotional material and how to access unbiased and independent information about medicines.

Source: Norris et al. 2005; WHO 1988; WHO/HAI 2011

Working with Countries to Strengthen Governance

This session briefly outlines the operational approach and some of the key considerations when working with countries and partners to strengthen governance in pharmaceutical systems.

Assessment and Advocacy

The operational approach for providing technical assistance to strengthen governance in pharmaceutical systems at both the national and institutional levels typically follows the steps outlined on this and the next page.

Step 1: Assess the existing situation

The first step involves **an assessment to identify strengths and weaknesses as well as factors that will inform the selection of improvement options.** An indicator-based measurement of system performance using a tool such as the WHO's *Measuring Transparency in the Public Pharmaceutical Sector* provides a baseline against which improvements can be measured.

Because governance can affect all pharmaceutical management functions, it is essential to ensure that governance issues are considered when working to strengthen any component of the pharmaceutical system.

It is important to engage stakeholders that represent a broad range of constituencies during the assessment. Addressing governance-related problems in pharmaceutical systems—for example, falsified medicines—may require joint action by multiple ministries, collaboration with diverse stakeholders, and mechanisms for coordinated action.

This phase may be preceded by or include advocacy for reform and efforts to highlight the benefits of improving governance (for example, more patients can be treated if wastage and theft of medicines are reduced).

Sources: SPS 2011; Cohen, Mrazek, and Hawkins 2007; WHO 2009

Implementing Improvement Strategies

Step 2: Develop a customized system improvement model

The assessment findings should then be used to review intervention options with in-country ministries and stakeholders to identify relevant, feasible, and sustainable approaches to improve governance. This step (called options analysis) is important because governance activities that are effective in one country, health program, or institution may not succeed in another.

The type of assistance that a country needs depends on its level of development. Also, corrupt and unethical practices can occur for two reasons requiring different types of interventions:

- Countries may lack policies, legislation, oversight bodies, and the capacity to implement good governance practices
- The above may all exist, but are not implemented or adhered to

Combining discipline-based strategies (for example, developing legislation with adequate sanctions) and values-based strategies (for example, promoting codes of ethics) can be a useful approach. It is important to motivate ministries and stakeholders to commit and invest in the strategies selected to address critical gaps. The opportunities, political will, and readiness for change are also key considerations.

Step 3: Provide technical assistance for implementation

Technical assistance providers work with other initiatives and stakeholders to support countries to build advocacy for change, implement interventions, and develop local capacity, including for managing change.

Step 4: Monitor and evaluate activities

Helping in-country partners establish indicator-based monitoring to objectively measure improvements in governance is a key component of the operational approach. Ongoing monitoring also helps local institutions and partners identify needed changes to strategies put in place to reduce corruption. Also important is strengthening pharmaceutical management information systems to generate reliable data needed for producing governance indicators at each level.

Sources: SPS 2011; Cohen, Mrazek, and Hawkins 2007; WHO 2009; WHO 2014a

Coordinating Efforts

Strengthening governance in pharmaceutical systems may require changing cultural traditions and long-standing processes. Therefore, it is important to consider sensitivities and potential risks.

- Sometimes what is considered to be a form of corruption or unethical behavior in one cultural context may be considered appropriate in another.
- Deeply rooted power relationships may spread throughout the government and society.
- Challenging traditions and established processes can be considered impolite and even threatening.
- In some situations, focusing on reducing inefficiencies that result from mismanagement in pharmaceutical systems can be a more acceptable starting point for strengthening governance than tackling corruption.

An important step of the options analysis process is distinguishing which problems and interventions to address and which are best led by other initiatives or in-country partners. It can be helpful to be aware of and coordinate with other initiatives that are working to address poor governance and corruption to avoid duplication and fragmented approaches.

Some global initiatives also work at the local level, and various local organizations and agencies are natural partners for USAID-funded initiatives in pharmaceutical systems.

At the end of this course, we briefly describe some of the USAID-funded projects that provide technical assistance to strengthen governance and also some global initiatives that focus on governance and corruption in pharmaceutical systems.

Sources: USAID Center for Democracy and Governance 1999; SPS 2011

Investing in Information Systems

Information systems are fundamental to improving transparency and thereby accountability in pharmaceutical systems. Timely, accurate, up-to-date information is essential for oversight and to ensure that functions such as quantification can be performed objectively.

Oversight and decision making bodies may come to a standstill if they do not have the necessary data, have no confidence in the data available, or cannot interpret it. **To promote transparency, information should be disseminated to stakeholders in ways that allow them to understand and use it to monitor processes and outcomes that concern them.**

Investments to strengthen information systems are critical to supporting and sustaining good governance in pharmaceutical systems. Support to countries may include assisting partners to do the following:

- Identify key information needs for decision making, performing functions and activities, and oversight (for example, for managing the TB medicines supply chain)
- Improve timely collection, processing, and presentation of quality data (for example, supply chain managers will need reliable data on quantities of TB medicines that are used, in stock, wasted, and due to expire at health facilities)
- Build capacity for interpreting and using data to monitor processes and outcomes, and for decision making (for example, for developing estimates of future needs of TB medicines based on usage and estimated cases to be treated)
- Generate reliable data needed to produce key governance indicators (for example, managers can track the median percentage of time out of stock of TB medicines to check how well the supply chain system

is working)

Source: SPS 2011
Glossary Term:
quantification

Harnessing Technology

Information technology long used in high-income countries is increasingly being used to improve transparency and accountability in low- and middle-income country pharmaceutical systems:

- **Electronic Tendering Systems** promote transparency by publishing tenders relating to key pharmaceutical functions on the internet, along with the contracts awarded
- **Procurement and Supply Chain Monitoring Portals** allow real-time data monitoring of procurement and distribution processes through interactive dashboards
- **Packaging technologies** such as bar coding and scanning, holograms, radio identification (RFID) tags, and electronic product codes are used to track and prevent pilferage of pharmaceuticals
- **Vehicle tracking systems** utilize satellite tracking to trace the progress of a vehicle and compare it to the planned route
- **Biometric scanners** are used to control access to warehouses and time-reporting

Sources: Vian 2006; MSH 2012; Chêne 2009
Glossary Term:
biometric scanners
radio identification (RFID) tag

Using Technology: Case Study of Bangladesh

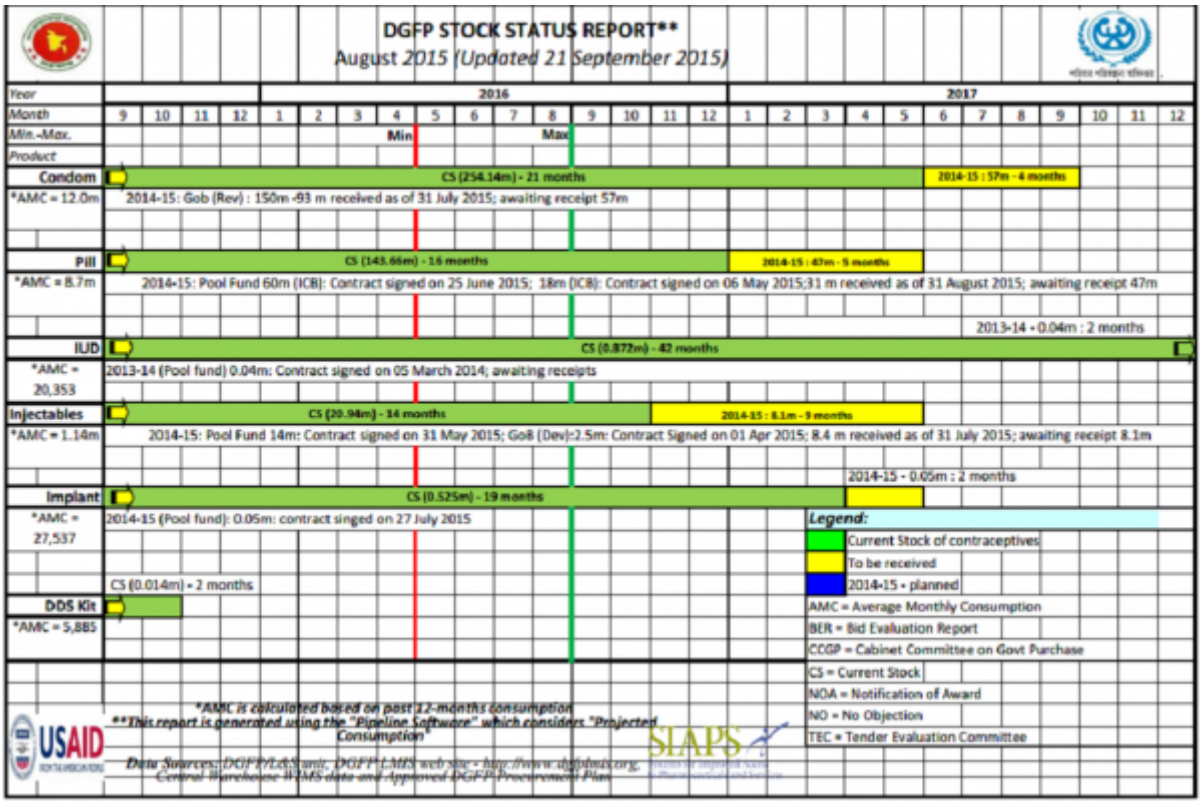
In Bangladesh, the USAID-funded SIAPS program worked with the Ministry of Health and Family Welfare (MOHFW), its directorates, the Directorate General of Family Planning (DGFP), the Directorate General of Health Services (DGHS), and collaborating partners to develop the Supply Chain Management Portal, an online procurement tracking system for family planning and health commodities. The portal enables managers to monitor procurement processes through an interactive dashboard.

In addition to providing information on procurement delays, the portal sends SMS and email notifications of delays to managers so that they can take timely and appropriate action to mitigate potential shortages and overstock.

By providing information on current DGFP and DGHS procurement opportunities and tender results, the system has helped to foster transparency and accountability. It also enables donors to review procurement plans, thus accelerating the clearance process.

The Supply Chain Management Portal has enabled the MOHFW improve procurement efficiency—for example, between 2010 and 2014, the portal helped to reduce the average procurement lead time for family planning commodities from 78 weeks to 33 weeks.

Read more about this activity.



Source: SIAPS 2014b

Initiatives to Improve Governance

This session outlines the USAID-funded programs that provide technical assistance to help countries strengthen governance in health and pharmaceutical systems. It also presents key global initiatives that are working to address governance and corruption issues that affect access to and appropriate use of pharmaceuticals.

USAID-Funded Programs

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

Funded by USAID and led by Management Sciences for Health and its consortium of partners, the goal of the five-year Medicines, Technologies, and Pharmaceutical Services (MTaPS) program (2018–2023) is to help low- and middle- income countries strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medical products and pharmaceutical services by:SIAPS' approach to improving governance in pharmaceutical systems focused on helping countries to establish the following:

- Strengthening pharmaceutical-sector governance
- Increasing institutional and human resource capacity for pharmaceutical management and services, including regulation of medical products
- Increasing the availability and use of pharmaceutical information for decision making and advancing the global learning agenda
- Optimizing pharmaceutical-sector financing, including resource allocation and use
- Improving pharmaceutical services, including product availability and patient-centered care, to achieve health outcomes

The MTaPS program assists countries in strengthening pharmaceutical-sector governance, which is key to achieving the global sustainable development goal SDG 3.8 of improving access to "safe, effective, quality and affordable essential medicines and vaccines for all." MTaPS achieves this through:

- Increasing transparency and accountability throughout the pharmaceutical system

- Improving and enforcing evidence-based medicines policies, laws, regulations, guidelines, norms, and standards
- Increasing stakeholder engagement and empowerment, including civil society and consumers
- Working with country stakeholders to identify areas in need of reform in the pharmaceutical sector

Learn more about the MTaPS program's governance work here

USAID Health Finance and Governance (HFG) Project

The HFG Project ended in 2018 and focused on improving health finance and governance systems leading to expanded access to health care and improved health outcomes. The project has a number of governance and leadership resources available.

USAID Leadership, Management, and Governance (LMG) Project

The mission of the LMG project was to improve leadership, management, and governance practices to strengthen health systems and improve health for all. The project developed a variety of governance capacity-building resources.

USAID Health Policy Project

The Health Policy Project worked to strengthen national and subnational policy, advocacy, governance, and financing to support strategic, equitable and sustainable health programming in developing countries. The project developed a number of governance-related resources. Work continues under the Health Policy Plus project.

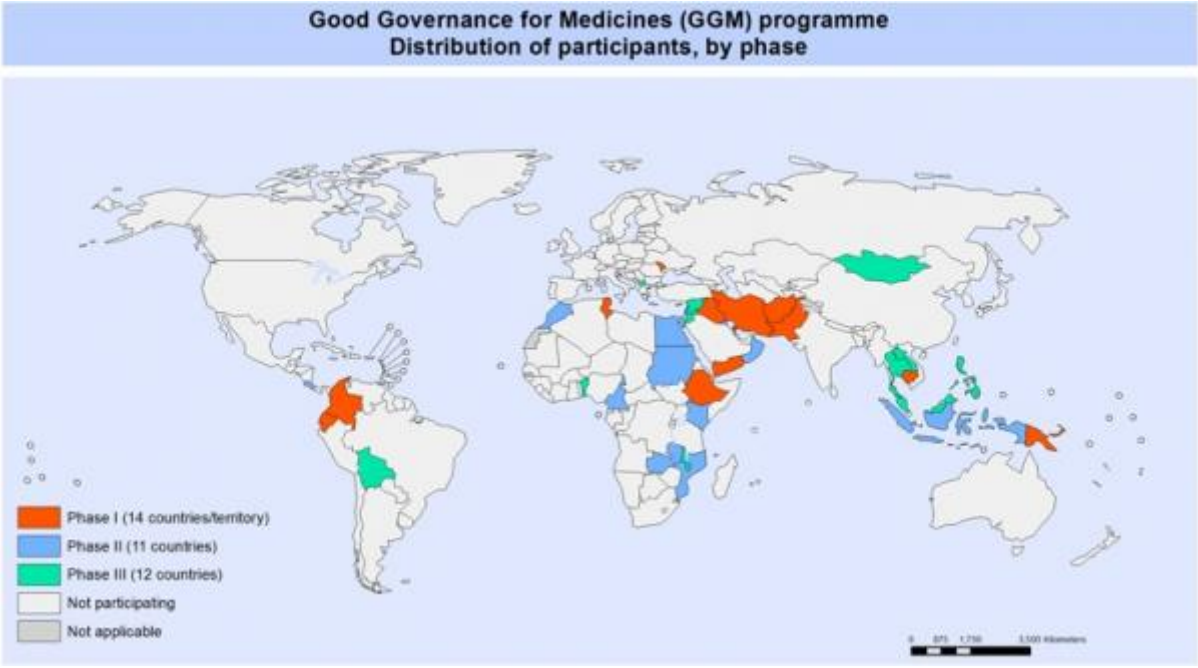
WHO Good Governance for Medicines (GGM) Program

The WHO Good Governance for Medicines (GGM) program was launched in 2004 with the goal of contributing to health systems strengthening and preventing corruption by promoting good governance in the pharmaceutical sector. The program worked in 38 participating countries/territories, concluding in 2015 with work in Zimbabwe.

The GGM program supports policy-makers and national officials to understand where the strengths and weaknesses lie in national pharmaceutical systems and assists in developing appropriate interventions that can be implemented and applied. The approach developed by the program includes the following:

- **Phase I**: National assessment of the levels of transparency and vulnerability to corruption of key functions in medicines regulation and supply management systems in the public sector using a standardized instrument.
- **Phase II**: Development of a national program on GGM through a nationwide consultation process with key stakeholders. These components can include an ethical framework and code of conduct, regulations and administrative procedures, collaboration with other initiatives, whistle-blowing mechanisms, sanctions, and a GGM implementing task force.
- **Phase III**: Implementation and promotion of the national program on GGM

As of 2014, 14 countries/territories were in Phase I, 11 countries were in Phase II, and 12 countries were in Phase III.



More Resources

- Read the evaluation of the work of the GGM program from 2004 to 2012
- Read the compilation of country case studies and best practices in the World Health Report 2010 Background Paper, No 25: WHO Good Governance for Medicines programme: an innovative approach to prevent corruption in the pharmaceutical sector
- Download WHO standardized tool Measuring Transparency in the Public Pharmaceutical Sector: Assessment Instrument
- Find assessment reports for Benin, Cameroon, Jordan, Kenya, Lebanon, Malawi, Oman, Syrian Arab Republic, and Zambia. A four-country assessment report compares findings from Lao People's Democratic Republic, Malaysia, the Philippines, and Thailand. A five-country assessment report is also available for Bolivia, Cambodia, Indonesia, Mongolia, and Papua New Guinea.
- Review the Good Governance for Medicines Model Framework Updated Version 2014
- Additional information about WHO's governance work in health systems can be found here

Sources: WHO 2014a; WHO 2014b; WHO 2013b

Other Global Initiatives

Health Systems Governance Collaborative
Launched in 2016, the Health Systems Governance Collaborative is a group of practitioners, policy makers, academics, civil society representatives, agencies, decision-makers and other committed citizens seeking to connect and engage about important health systems governance issues.
The Collaborative fosters creative and safe spaces to address the health systems governance challenges (such as corruption, power inequities, lack of capacities, gross mismanagement, poor distribution of knowledge and resources and unequal access to health) and promote real impact on the ground.

Medicines Transparency Alliance (MeTA)

Launched in 2008, the MeTA initiative aimed to improve access, availability, and affordability of medicines by increasing transparency and accountability in the healthcare marketplace through multi-stakeholder collaboration. Seven countries participated in the initiative: Ghana, Jordan, Kyrgyzstan, Peru, the Philippines, Uganda, and Zambia.

In its second phase and guided by the WHO and Health Action International (HAI), MeTA continued to work to strengthen national capacity to collect, analyze, and share data on the selection, procurement, quality, availability, pricing, promotion and use of medicines. In Phase 2, MeTA placed more emphasis on increasing the use of data to inform discussions on policy and make recommendations for actions to improve access to medicines through its multi-stakeholder engagement approach.

Resources

- Learn what countries did in MeTA Phase 2
- Explore the MeTA toolbox

Health Action International

Health Action International (HAI) is a non-government organization (NGO) that works to increase access to essential medicines and improve the rational use of medicines in collaboration with over 200 members including consumer groups, public interest NGOs, healthcare providers, academics, media, and individuals in more than 70 countries.

HAI is implementing the Project on Medicine Prices and Availability in collaboration with WHO. In 2008, HAI and the WHO published the second edition of a manual that provides guidance on collecting and analyzing medicine prices (including prices for patients and government procurement prices) and medicine availability across sectors and regions in a country. The results of over 100 surveys are now available in the database.

WHO MedMon

The methodology to assess medicine availability and affordability developed by HAI and WHO has been adapted to collect and report data to respond to SDG3.b.3 using a WHO-developed mobile app called MedMon. As of 2019, MedMon had been piloted or implemented in over 20 capital cities and 5 countries to assess medicine pricing, availability, and affordability. More information on MedMon is available here.

Transparency International UK

In 2014, Transparency International UK set up the Pharmaceutical & Healthcare Programme, which aims to engage pharmaceutical and healthcare companies, civil society, regulatory bodies, and international organizations to reduce corruption and promote transparency, integrity, and accountability in the pharmaceutical and healthcare sectors. The HealthWorks portal is a repository of recent work by Transparency International in this area.