

## GOVERNANCE IN PHARMACEUTICAL SYSTEMS

### TOPICS

Managing Access to Essential Medicines
Governing Challenges in Pharmaceutical Systems
Governing Bodies and the Pharmaceutical System
Interventions to Improve Governance in Pharmaceutical Systems

As medicines are so important in the performance of health systems, this section provides insights into the unique governance challenges of managing the supply of essential medicines in low- and middle-income countries and discusses practical ways to promote good governance in pharmaceutical systems.

### THE CHALLENGE

*To improve transparency and evidence-based decision-making in the selection of products for inclusion in the formulary list of approved medicines for your hospital, you have been asked to help establish a Pharmacy and Therapeutics Committee (PTC). What recommendations would you make to the Chief Executive Officer regarding the process for setting up this committee to ensure the safe and cost-effective prescribing and use of medicines in your hospital and selecting members for the PTC? What could you do to establish the legitimacy of the new committee to encourage medical staff to adhere to formulary recommendations?*

To achieve the goal of effective health service delivery that supports better health outcomes, health systems and organizations require a reliable supply of safe and affordable essential medicines, vaccines, and other medical supplies of assured quality. However, surveys conducted between 2007 and 2011 in low- and lower-middle income countries found that essential medicines were available

on average in only half of public sector and two-thirds of private sector health facilities.<sup>1</sup> Whether you are a health leader or policy maker at the national level or serving on a district health council or hospital board, you and your governing body members will be concerned about preventing stock-outs of essential medicines, vaccines, and supplies, which can compromise the performance of your health system or organization. Also, given the high value of medicines, encouraging their rational and cost-effective prescribing and use and minimizing avoidable wastage and losses in the supply chain will be other important concerns. Poor governance and corruption in pharmaceutical systems are increasingly acknowledged as important factors that contribute to gaps in access and inappropriate use of medicines, vaccines, medical devices, and other health products worldwide.

## MANAGING ACCESS TO ESSENTIAL MEDICINES

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Managing pharmaceutical products in both public and private sector organizations and at any level of the health care system follows a well-recognized framework (Figure 29.1). A functioning pharmaceutical system efficiently and effectively carries out the interdependent processes of **selection, procurement, distribution**, and activities that support the safe and appropriate **use** of medicines. These processes are enabled and supported by a strong **management support system** (organizational, financial, information and human resources management) and rely on a foundation of appropriate **policies, laws, and regulations**.

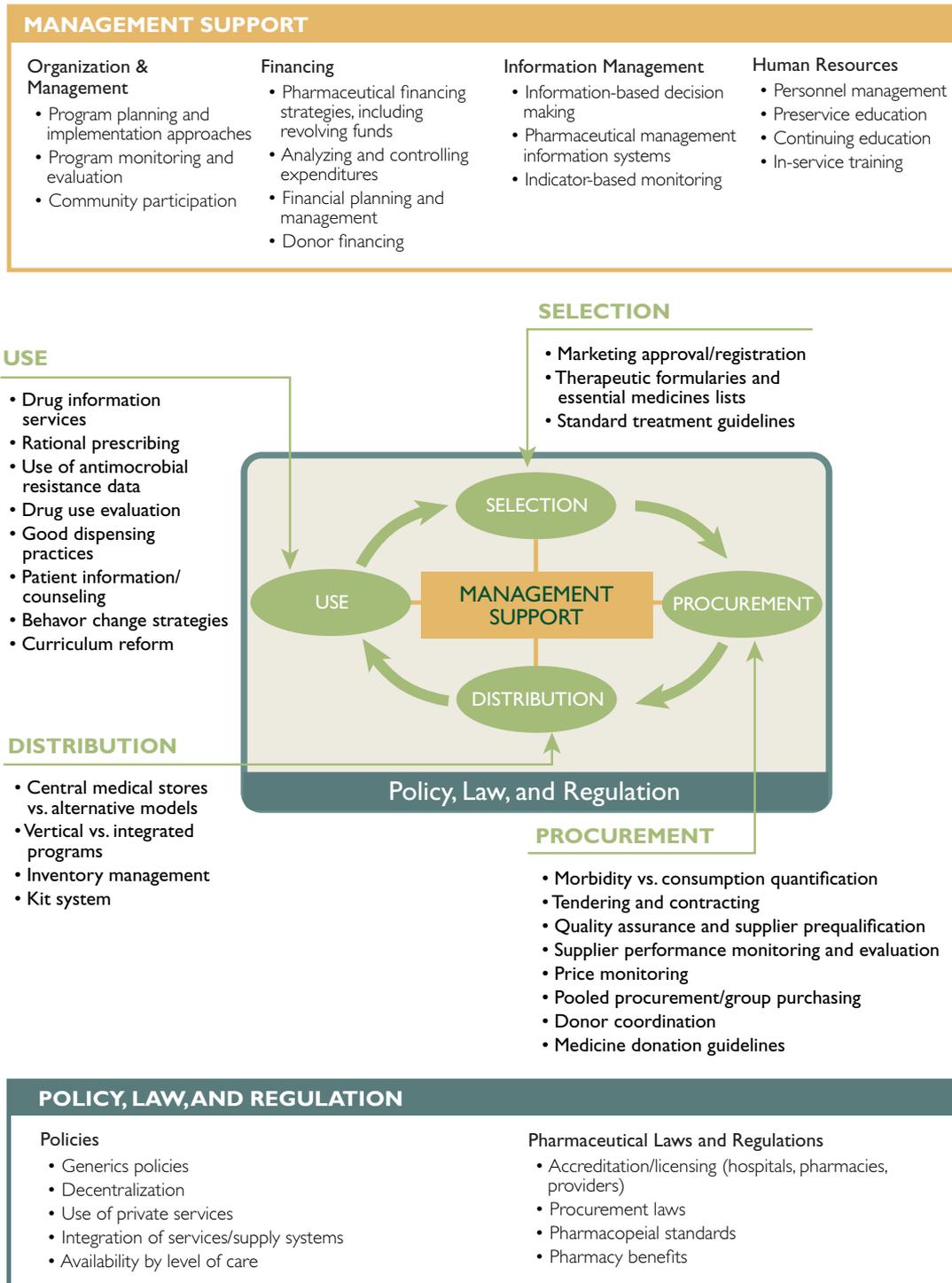
Important decisions have to be made by governing bodies, regulatory authorities, committees and health providers in the performance and oversight of the key functions and activities shown in Figure 29.1 that determine whether patients have access to medicines they need and the pharmaceutical services that support the safe and appropriate use of these products. In addition, decisions made by government, health governing bodies, and management boards about key issues relating to policy and legislation and resource allocation also influence the efficiency and effectiveness of the pharmaceutical system.

Some examples of important decisions in pharmaceutical systems include

- **Clinical trials:** deciding whether to give approval for a clinical trial to be done in a hospital
- **Registration (market authorization):** determining which products to register and release for marketing in a country
- **Control of promotion:** deciding whether to permit advertising of medicines directly to consumers
- **Licensing:** setting criteria for licensing manufacturers, importers, distributors or outlets where medicines may be sold
- **Selection:** deciding which products should be included in a national, regional or hospital essential medicines list or formulary
- **Procurement:** determining specifications to include in a tender for procurement of medicines and other pharmaceutical products

1. United Nations (UN), *Millennium Development Goal 8: The Global Partnership for Development: Making Rhetoric a Reality: MDG Gap Task Force Report 2012* (New York, UN, 2012).

FIGURE 29.1 Pharmaceutical management framework



Source: Pharmaceuticals & Health Technologies Group, MSH. n.d.

- **Distribution:** choosing transporters to distribute medicines to health facilities
- **Prescribing:** deciding whether to prescribe a generic or branded medicine for a patient
- **Dispensing/Supply:** advising on the purchase of a medicine or informing a client if a medicine is not needed
- **Financing:** making decisions about the budget allocation for the purchase of medicines for a country or a health facility
- **Human Resources:** deciding which candidate to appoint as the manager of a warehouse that handles high-value pharmaceuticals
- **Policy and Legislation:** determining import duties and tariffs which influence the price of imported medicines

These and other pharmaceutical management activities can be vulnerable to corruption and unethical practices, especially when procedures are not transparent and checks and balances are inadequate. The different committees, boards, and healthcare providers responsible for these activities must ensure they adhere to principles of good governance including transparency, participation, and accountability when making decisions and performing their statutory, governing, management, or oversight duties.

## GOVERNING CHALLENGES IN PHARMACEUTICAL SYSTEMS

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Poor governance in health systems increases opportunities for corruption to occur and for mismanagement to go undetected. Pharmaceutical systems are recognized as being particularly vulnerable to fraud and corrupt practices for a number of reasons:<sup>2</sup>

- Medicines and products such as medical devices and laboratory diagnostics have a high market value which makes them a target for theft.
- Large public pharmaceutical budgets can incite offers or requests for kickbacks and bribes.
- The complexity of the supply chain and the involvement of many separate players can allow substandard or falsified medicines to enter the market, particularly in countries where institutional controls and enforcement of regulations is weak.
- In many low- and middle income countries, decision making for functions such as medicines registration and selection are discretionary and can be especially susceptible to corruption and unethical practices.
- Patients often do not have the necessary information to make informed choices about the medicines they need. As a result, health providers can unnecessarily or inappropriately prescribe or sell medicines for personal gain.

2. See: Cohen, J. C., M. F. Mrazek, and L. Hawkins, "Corruption and Pharmaceuticals," in *The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level*, edited by J. E. Campos and S. Pradhan, (Washington, DC: World Bank, 2007).

The impact of poor governance in the pharmaceutical system can be substantial.<sup>3</sup> Corruption and inefficiencies can lead to significant financial losses for a health system or institution and diminish medicines availability. Donors may halt funding to health systems and institutions that they perceive to be corrupt or mismanaged and may be reluctant to provide future funding. Household expenditures can also be significantly impacted when patients and their families have to pay inflated prices for medicines or purchase unnecessary or ineffective products. Medicines can promote trust and participation in health services, but poor availability of medicines due to insufficient funding, weak supply systems or corrupt practices can reduce demand for services, increase staff attrition and ultimately compromise service delivery. Furthermore, poor access to essential medicines, their inappropriate use, and the use of unsafe or poor-quality medicines can harm patients. A more detailed review of the potential governance-related problems that can occur in the performance of key pharmaceutical management functions and some possible consequences for the health system are shown in Table 29.1 on the next page.

## GOVERNING BODIES AND THE PHARMACEUTICAL SYSTEM

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Earlier in this section we discussed the various types of decisions that have to be made about how medicines will be managed, i.e., financed, registered, selected, procured, distributed and prescribed, dispensed, or used in a health system or a health institution. In low- and middle-income countries, what kinds of bodies are responsible for making these decisions and providing oversight to ensure that good governance principles and practices are adhered to during the decision making and implementation processes? The roles and responsibilities may vary from country to country and within a country between different health institutions and the public and the private sectors. Some examples are listed below.

- statutory bodies such as national regulatory authorities responsible for registering and controlling medicines and councils or boards responsible for licensing pharmacies and pharmacy personnel
- governing boards of institutions such as national procurement agencies
- advisory councils, boards and committees that make important decisions in pharmaceutical systems. Some examples include pharmacy and therapeutics committees at national, local or institutional levels that advise on the selection of medicines for essential medicines lists and formularies and procurement tender committees that evaluate bids and award tenders
- health governing bodies such as district health councils, hospital boards, and clinic committees that provide oversight of health service delivery including the provision of pharmaceutical services
- governing bodies outside the health system that make decisions that affect the pharmaceutical system, for example, about import duties and tariffs which can influence the price of imported medicines and thereby decisions on local production

3. World Health Organization (WHO), *Good Governance in the Pharmaceutical Sector*, (Geneva, 2013). Available at: [http://www.who.int/medicines/areas/governance/EMP\\_brochure.pdf](http://www.who.int/medicines/areas/governance/EMP_brochure.pdf)

TABLE 29.1 Potential problems relating to poor governance in pharmaceutical systems

Pharmaceutical management functions	Potential problems	Possible consequences
Policies and Legislation	<ul style="list-style-type: none"> <li>Lack of or weak/outdated policies and legislation</li> <li>Weak enforcement of policies and legislation</li> <li>Corruption in licensing processes</li> <li>Inadequacies in medicine regulatory system</li> </ul>	<ul style="list-style-type: none"> <li>Facilities do not meet standards for delivery of quality services</li> <li>Practitioners lack competencies or skills</li> <li>Products available that do not meet safety, efficacy, and/or quality standards</li> </ul>
Selection	<ul style="list-style-type: none"> <li>Failure to use criteria to select products</li> <li>Corrupt practices in selection process (e.g., bribery, power pressure)</li> </ul>	<ul style="list-style-type: none"> <li>Less effective or more expensive products selected</li> <li>Rational prescribing and use compromised</li> </ul>
Procurement	<ul style="list-style-type: none"> <li>Product specifications in tenders favor certain supplier(s)</li> <li>Awarding contracts to suppliers that do not meet criteria</li> <li>Lack of consequences for poor supplier performance</li> </ul>	<ul style="list-style-type: none"> <li>Unreliable supplier service</li> <li>Purchase of inappropriate, poor quality, falsified, or highly priced products</li> <li>Stock-outs and wastage of medicines and supplies</li> </ul>
Storage/distribution	<ul style="list-style-type: none"> <li>Lack of or failure to use criteria to select distributors</li> <li>Poor enforcement of auditing procedures at storage areas</li> </ul>	<ul style="list-style-type: none"> <li>Unreliable distributor service</li> <li>Over expenditure</li> <li>Stock-outs of medicines and supplies</li> </ul>
Use	<ul style="list-style-type: none"> <li>Unethical practices resulting in inappropriate prescribing or sale/supply of medicine</li> <li>Inappropriate charges (informal payments, substitution of cheaper brand at higher price, patients who have to supply own medicines while in institutions)</li> </ul>	<ul style="list-style-type: none"> <li>Compromised patient care</li> <li>Higher out-of-pocket expenses for patients</li> </ul>
Financing	<ul style="list-style-type: none"> <li>Inadequate, misappropriated, or mismanaged funds</li> <li>Non-compliance with or weak enforcement of reporting and auditing (medicines and assets)</li> <li>Late payments to suppliers</li> </ul>	<ul style="list-style-type: none"> <li>Decreased funding to procure medicines and deliver services</li> <li>Stock-outs, inefficiencies</li> </ul>
Organizational management	<ul style="list-style-type: none"> <li>Oversight bodies do not exist or do not function</li> <li>Inappropriate appointments to or political interference with consultative or oversight bodies</li> <li>Conflict of interest</li> </ul>	<ul style="list-style-type: none"> <li>Inadequate oversight of key processes (e.g., tendering, financial management)</li> <li>Loss of trust among staff and patients</li> </ul>
Human resource management	<ul style="list-style-type: none"> <li>Promotion/benefits not based on merit (nepotism, bribery)</li> <li>Inadequate accountability</li> <li>Absenteeism, kickbacks, demand for informal fees, ghost workers</li> </ul>	<ul style="list-style-type: none"> <li>Poor performance of duties</li> <li>Attrition</li> <li>Unethical behavior</li> <li>Abuse of resources</li> </ul>
Information management	<ul style="list-style-type: none"> <li>Information not available, not trusted, or not used for decision making due to lack of reliability or timeliness</li> <li>Information not publicly available, resulting in lack of transparency and accountability</li> </ul>	<ul style="list-style-type: none"> <li>Lack of information makes governance and management difficult, including identifying and controlling theft or fraud</li> </ul>

Source: Strengthening Pharmaceutical Systems (SPS), *Pharmaceuticals and the Public Interest: The Importance of Good Governance* [submitted to the US Agency for International Development by the SPS Program], (Arlington, VA: Management Sciences for Health, 2011); p. 6

## INTERVENTIONS TO IMPROVE GOVERNANCE IN PHARMACEUTICAL SYSTEMS

Governing bodies at the national, provincial and facility levels are increasingly involved in designing and implementing interventions to strengthen governance at all steps of the pharmaceutical management process. The design and implementation of these interventions should be guided by a clear conceptual model embracing key governance principles. Work by the USAID-supported Strengthening Pharmaceutical Systems (SPS) Program<sup>4</sup> defines several actions within the framework of Figure 29.2 below.

FIGURE 29.2 Framework for strengthening governance in pharmaceutical systems



Source: Strengthening Pharmaceutical Systems (SPS), *Pharmaceuticals and the Public Interest: The Importance of Good Governance* [submitted to the US Agency for International Development by the SPS Program], (Arlington, VA: Management Sciences for Health, 2011); p. 7.

This approach focuses on interventions in these four areas:

- **Policies and legislation** supported by rule of law
- **Organizational structures** able to exercise appropriate decision making, authority, and oversight
- **Systems and processes** that are transparent, ethical, accountable, and grounded in well-formed policies and legislation
- **Human resource management systems** that promote effective performance and ethical practices

4. The SPS Program (2007-2011) and its successor program, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program (2011-2016) are implemented by MSH with partners.

## Developing Policies and Legislation

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Medicines must be carefully regulated because they are widely bought and sold, and because products that are unsafe or incorrectly used are potentially dangerous. Pharmaceutical policies and legislation provide the framework for how medicines and other pharmaceutical products will be regulated in a country. To reduce piecemeal approaches to policy making which can lead to confusion in putting policy into practice and conflicting policy guidance, WHO recommends that countries prepare a national medicines policy (NMP) which sets out a guide for action for providing safe and effective medicines of assured quality that are affordable, accessible, and rationally used. The NMP provides the basis for pharmaceutical legislation and a guide for coordinating activities among pharmaceutical sector stakeholders. Sound legislation and fairness, equity, and impartiality in its enforcement is critical to control the availability, promotion, prescribing, and dispensing of medicines; the provision of product information; and the licensing and oversight of pharmaceutical establishments and professional staff. Legislation must be supported by policies, guidelines, and standard operating procedures that define norms and standards of practice, provide guidance for decision making, and incorporate checks and balances for pharmaceutical management activities at all levels.

## Strengthening Organizational Structures

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Given that strong lobbies may try to influence decision making and processes in pharmaceutical systems, it is important to ensure that members of the governing bodies and decision-making structures described earlier in this section are chosen on the basis of documented, objective criteria that relate to their knowledge or skills to mitigate political interference, nepotism, and corruption in their appointment. To increase transparency and accountability, members may represent different sectors and constituencies, including civil society. In low- and middle-income countries, experts such as clinical pharmacologists are rare and may sit on the boards of several organizations as well as consult for the pharmaceutical industry. Conflicts of interest can arise from these relationships, for example, with pharmaceutical manufacturers who have strong interests in getting their products registered, included on essential medicines lists, and prescribed. These relationships need to be declared, documented, and managed.

## Incorporating Good Governance Practices into Systems and Processes

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To minimize bias, undue influence and inconsistency, decision-making in pharmaceutical systems, for example for awarding tenders for procurement of medicine, should be guided by clearly-defined criteria. Where appropriate, an appeals process should be available to appeal against decisions made. To serve the public interest, meeting reports that include decisions reached (for example, contracts awarded and prices paid in public procurements) should be easily available for public scrutiny. Written procedures that set out standards for performing pharmaceutical management activities such as inventory management should be available and adhered to, to promote efficiency and effectiveness and reduce opportu-

nities for fraud, theft, and other corrupt practices. Because pharmaceutical systems and processes are particularly susceptible to corruption, systems for oversight and audit are essential and must have adequate capacity, autonomy, and funding to function effectively.

## Enhancing Performance and Ethical Practices

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To prevent interference or nepotism in the appointment or promotion of staff that handle high-value medicines or participate in activities that are vulnerable to corruption, job vacancies that specify required experience and qualifications together with criteria for selection or promotion of personnel must be publicly available and adhered to. Sufficient staff need be made available to enable important principles such as separation of key responsibilities (e.g., requisitioning and receiving medicines) and oversight (inspections, audits, supervision) to be properly implemented. Formal systems for whistle-blowing and enabling patients to submit complaints should be set up and publicized. Also important in the pharmaceutical sector are codes of conduct, such as those that control the advertising of medicines by the pharmaceutical industry and the acceptance of gifts and payments by health care providers. To be effective, these must be monitored and enforced with meaningful sanctions.

## Good Governing Practices in Pharmaceutical Systems

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By applying the five governing practices described earlier in this book, health leaders and governing body members can help to improve the performance of pharmaceutical systems and reduce the wastage and loss of valuable medicines and financial resources.

**Cultivating Accountability:** To improve governance in pharmaceutical systems and reduce opportunities for corruption, governing and oversight bodies play an essential role in ensuring that their institution or organization is accountable to stakeholders (patients, communities, elected politicians, and public and private purchasers and providers of health services). There must be clear accountability for:

- the development, implementation, and enforcement of relevant policies, laws, and standards;
- establishment of effective organizational structures and oversight bodies;
- ensuring that decision making and oversight processes are transparent, ethical, and conducted in accordance with best practices;
- monitoring and introducing measures to ensure effective performance and ethical behavior of the workforce and players such as the pharmaceutical industry.

**Engaging Stakeholders:** Many of the committees and boards that make decisions in pharmaceutical systems include members that represent different constituencies or sectors, including civil society, to promote participation, transparency, and accountability. In addition, civil society organizations increasingly play a role in checking medicines avail-

ability in public health facilities in low- and middle-income countries and use this information to pressure officials to take action to address stock-outs.<sup>5</sup> Engaging stakeholders in coordination committees that bring together donors and other supply chain partners to enable information sharing, procurement planning, and resource mobilization can help to increase efficiency and minimize stock-outs of medicine. To improve the prospect that newly-developed or revised pharmaceutical policies, legislation, and strategic plans will be implemented successfully, governing bodies should ensure that stakeholders and civil society groups have opportunities to participate in the development process.

**Setting Strategic Direction:** Governments articulate their political commitments and medium- to long-term goals for the country's pharmaceutical sector in the NMP. They may also express broader objectives aimed at furthering the concepts of essential medicines, universal health coverage, and access to medicines as a human right. The successful implementation of an NMP depends heavily on political commitment by the government and support from all stakeholders in the pharmaceutical sector. A well-informed national pharmaceutical sector strategic plan should be developed to provide the road map for achieving NMP priorities and objectives, funding requirements, timelines, and methods for measuring progress. Health institutions in the public, private, and nongovernmental sector should ensure that their strategic plans incorporate clear goals and a plan for mobilizing adequate resources to secure the supply of essential medicines and provide for their safe and responsible use.

**Stewarding Resources:** In many low- and middle-income countries, insufficient financing and inadequate human, financial, and technological resources for managing medicines efficiently and minimizing waste and corruption are common causes of poor access to medicines. Governing bodies play a critical role in mobilizing and deploying resources for the purchase of medicines and pharmaceutical management activities, and in ensuring that sufficient human resources are allocated to provide for separation of key responsibilities and the provision of oversight. In addition, robust record-keeping and monitoring systems are important to track and control medicines as they move through supply chains. Pharmaceutical expenditure, stock-outs, and prescribing and dispensing patterns should be routinely monitored to identify unusual patterns and anomalies. Ongoing supervision and oversight checks such as regular and unannounced audits of warehouses and pharmacies, all play a part in reducing problems such as theft and wastage. Technologies that allow real-time monitoring of procurement and distribution, biometric scanners that control access to warehouses, and bar coding of products are increasingly being used in low- and middle-income countries to improve transparency and reduce corruption. [Page 14.8](#) describes some suggestions for reducing corruption in the pharmaceutical sector.

**Continuously Improving Governance:** Members who serve on governing bodies and other committees responsible for decision making and oversight often come from outside the pharmaceutical sector. Given the complexities of the pharmaceutical system, it is critical to develop the capacities of these members and empower them with the tools, skills, and information needed to make effective contributions.

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5. Stop Stock Outs Project, 2015. Available at: <http://stockouts.org/about-us.html>

Whether your governing body works at the national level overseeing the pharmaceutical system for your country, or you serve on a district health council or a hospital board, you should become more familiar with pharmaceutical management activities that culminate in the supply and appropriate use of safe, quality-assured, cost effective medicines. Some key governance actions for your discussion and decision-making at selected types of governing bodies are shown below.

### National Medicines Regulatory Authority

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- Develop a mission statement and strategic plan that identifies goals for the agency including safeguarding its autonomy.
- Revise policies and legislation to address inconsistencies, gaps and weaknesses using transparent processes (consult stakeholders, inform the public).
- Develop terms of reference that define roles and responsibilities of advisory committees and use objective criteria for member selection.
- Maintain best practices and transparency in decision making based on clear criteria.
- Make rules for declaring and managing conflicts of interest and for meeting with applicants for registration of products, and establishing an appeals mechanism.
- Maintain transparency, equity, and impartiality in the inspection process by rotating inspectors, auditing inspection reports, and establishing a complaints and appeals process.

### Supply Chain Oversight Committee

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- Make the committee's scope, lines of authority, mandate, and membership publicly available to promote transparency.
- Develop capacity, skills and knowledge to enable committee members to fulfil their role effectively and assure appropriate orientation for new members.
- Provide oversight to ensure that procedures for core supply chain functions (procurement, warehousing, distribution, service liaison) are in line with best practices and international guidelines that promote transparency and that systems are in place to monitor strict adherence to them.
- Verify that criteria for awarding contracts are explicit, followed, and made publicly available together with the bids awarded and prices paid.
- Check that tender committee members submit declarations of interest and declared conflicts are appropriately managed.
- Ensure that oversight bodies exist and supply chain auditors have adequate competency, resources, and autonomy to function effectively, and require them to report regularly.

- Require that warehouses have information systems, technologies and security systems that can adequately track products and funding; monitor supply chain processes and stock-outs; and identify and reduce opportunities for theft and fraud.
- Verify that supplier performance is monitored and reports used effectively to improve performance and to inform future tenders.

### Hospital Pharmacy and Therapeutics Committee (PTC)

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- Make PTC committee membership and terms of reference (selection of medicines for inclusion in the hospital formulary, monitoring and promoting rational use) publicly available.
- Adhere to evidence-based medicines selection processes (procedures based on international guidance, explicit criteria for decision making, informed by WHO essential medicines list and other objective information).
- Maintain transparency in selection procedures and decisions (circulate agenda and application forms, invite observers, report on products added or deleted and justifications, members present, declared conflicts of interest, and process for appealing decisions).
- Involve key stakeholders and opinion leaders early on to foster political buy in and support.
- Advise the hospital management team on the development of policies to control promotion by pharmaceutical industry representatives (sponsored trainings, medicine samples, gifts and payments) on hospital premises.

Among these actions, which two or three are the most important in your situation and why?

For these two or three actions, what factors are most likely to frustrate their successful accomplishment?

What can be done to improve the prospects that the interventions will be successfully implemented?

## APPENDIX 29.1

Resources for Further Study

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Strengthening Pharmaceutical Systems (SPS), *Pharmaceuticals and the Public Interest: The Importance of Good Governance* [submitted to the US Agency for International Development by the SPS Program], (Arlington, VA: Management Sciences for Health, 2011). Available at: [http://projects.msh.org/projects/sps/SPS-Documents/upload/sps\\_governance\\_pub\\_final\\_2011.pdf](http://projects.msh.org/projects/sps/SPS-Documents/upload/sps_governance_pub_final_2011.pdf)

World Health Organization (WHO), *Good Governance in the Pharmaceutical Sector* (Geneva, 2013). Available at: [http://www.who.int/medicines/areas/governance/EMP\\_brochure.pdf](http://www.who.int/medicines/areas/governance/EMP_brochure.pdf)

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Management Sciences for Health (MSH), *MDS-3: Managing Access to Medicines and Health Technologies*, (Arlington, VA: Management Sciences for Health, 2012). Available at: <http://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies>