Pharmaceuticals and the Public Interest

The Importance of Good Governance

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SPS Strengthening Pharmaceutical Systems

About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Recommended Citation

Strengthening Pharmaceutical Systems (SPS). *Pharmaceuticals and the Public Interest: The Importance of Good Governance*. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.

APRIL 2011

Introduction

HEALTH SYSTEMS rely on the continuous availability of safe, affordable pharmaceuticals (medicines, vaccines, diagnostics, and other medical supplies) of assured quality. However, surveys conducted between 2001 and 2007 in 27 developing countries found that the availability of essential medicines averaged only 35 percent in the public sector and 63 percent in the private sector (UN 2008). The World Health Organization (WHO) estimates that almost two billion people lack regular access to essential medicines and that addressing this gap could save up to 10 million lives every year (WHO 2004). Poor access—including lack of availability—and irrational use of pharmaceuticals influence the performance of health systems and ultimately affect health outcomes.

Factors that contribute to gaps in access and inappropriate use of pharmaceuticals include weaknesses in governance in pharmaceutical systems. These systems encompass a set of interdependent, multi-step activities often involving numerous partners. This complexity, coupled with the large amounts of money generally involved, makes pharmaceutical systems susceptible to mismanagement and corrupt practices. Estimates suggest that corruption siphons off 10 to 25 percent of global public spending on medicines (WHO/GGM 2008a), which can diminish medicine availability, often for the most vulnerable populations. Poor governance in the pharmaceutical sector can be costly for governments, and when it leads to the consumption of contaminated or counterfeit products, harmful for citizens. According to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), many countries in Africa have areas where more than 30 percent of the medicines on sale may be counterfeit, that is, deliberately mislabeled with respect to identity or source (WHO/IMPACT 2008).

Initiatives, such as the President's Emergency Plan for AIDS Relief, the President's Malaria Initiative, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, allocate a significant proportion of funding to procure essential medicines and commodities. Of the USD 15.5 billion approved in grants by the Global Fund, almost half have been allocated for medicines and supplies (Global Fund 2009).

This report is made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number GHN-A-00-07-00002-00. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

These increases in donor funding have come with requirements for greater transparency and accountability in how funds for pharmaceuticals are used. As a result of this increased scrutiny, critical weaknesses related to governance and management practices within health systems have come to light. With donor resources diminishing because of the global economic slowdown, calls for using existing resources more efficiently and reducing losses are increasing (Nishtar et al. 2009). Furthermore, unless attention is given to strengthening governance in health systems, any improvements made in health service delivery are unlikely to be sustainable (WHO Maximizing Positive Synergies Collaborative Group 2009).

WHO emphasizes the importance of governance by identifying it (together with leadership) as perhaps the most critical of its six health system building blocks (WHO 2007a). Stronger governance is associated with more effective relations between stakeholders, including donors and counterparts, suppliers and clients, and providers and patients. Moreover, strengthening governance improves health system performance and can ultimately improve health outcomes. For example, Gupta, Davoodi, and Tiongson (2000) showed that levels of corruption are clearly related to child mortality and other health outcomes.

The Strengthening Pharmaceutical Systems (SPS) Program has developed this paper to provide US Agency for International Development (USAID) health program managers, country counterparts (including policy makers and health care managers and workers), and other stakeholders with an understanding of how governance issues permeate pharmaceutical management and influence the effectiveness of health programs. The paper also describes examples of interventions related to governance that can strengthen pharmaceutical systems in resource-constrained settings. With this understanding, USAID and country counterparts should be better able to determine ways to improve governance in the pharmaceutical sector, identify opportunities for collaborating with others, and target improvement interventions.

What is Good Governance?

Governance is defined in different ways. In some cases, the focus is solely on governments and how they function and exercise authority. Other definitions address protection of the public interest, stakeholder involvement, use of public resources, leadership or direction of organizations, decision making, and accountability. As a result, the scope of governance and the distinction between governance and management is not always clear. In the context of pharmaceutical management, the SPS Program uses the United Nations Economic and Social Commission for Asia and the Pacific definition of governance as "the process of decision making and the process by which decisions are implemented (or not implemented)" (UNESCAP 2009). Governance is therefore about relationships between individuals or institutions and the way in which decisions are made and implemented at all levels of the pharmaceutical system.

The term *good governance* is used with a great deal of flexibility—there is no single definition or delineation of scope that is universally accepted. The United Nations Development Programme (UNDP) identifies nine interdependent principles that are widely used to characterize good governance (UNDP 1997). SPS applies these principles, shown in Figure 1 and defined in Box 1, to describe good governance in pharmaceutical management.

Adapted from UNDP. 1997. Governance for sustainable human development. http://mirror.undp.org/magnet/policy/

FIGURE 1.
UNDP Characteristics of Good Governance

BOX 1. UNDP CHARACTERISTICS OF GOOD GOVERNANCE: DEFINITIONS

Strategic vision: Leaders and the public have a broad and long-term perspective on good governance and human development, along with a sense of what is needed for such development (UNDP 1997).

Participation: All men and women should have a voice in decision making, either directly or through legitimate intermediate institutions that represent their interests. Effective participation occurs when group members have an adequate and equal opportunity to place questions on the agenda and to express their preferences about the final outcome during decision making (UNDP 1997).

Transparency: Sharing information and acting in an open manner. Processes, institutions, and information are directly accessible to those concerned with them, and enough information is provided to understand and monitor them. Transparency allows stakeholders to gather information that may be critical to uncovering abuses and defending their interests. Transparent systems have clear procedures for public decision making and open channels of communication between stakeholders and officials, and make a wide range of information accessible (UNDP 1997).

Consensus-orientation: Good governance requires mediation of the different interests in society to reach a broad consensus on what is in the best interest of the whole community and how this can be achieved (UNESCAP 2009).

Rule of law: The rule of law reigns over government, protecting citizens against arbitrary state action, and over society generally, governing relations among private interests. The rule of law is an essential precondition for accountability and predictability in both the public and private sectors (UNDP 1997).

Equity: Impartial or just treatment, requiring that similar cases be treated in similar ways (UNDP 1997).

Effectiveness and efficiency: Processes and institutions produce results that meet needs while making the best use of resources at their disposal (UNDP 1997).

Responsiveness: Institutions and processes try to serve all stakeholders within a reasonable timeframe (UNESCAP 2009).

Accountability: The requirement that officials answer to stakeholders on the disposal of their powers and duties, act on criticisms or requirements made of them, and accept (some) responsibility for failure, incompetence, or deceit. Accountability requires freedom of information, stakeholders who are able to organize, and the rule of law (UNDP 1997).

The word *governance* is also used in other contexts that have relevance in health systems. Box 2 lists some of its uses that can be of importance to the pharmaceutical sector.

In recent years, much attention has been given to strengthening governance in the health sector with a particular focus on improving transparency and reducing corruption. Clarifying the distinctions between weak or poor governance, corruption, and lack of transparency is important. Transparency International defines corruption as "the abuse of entrusted power for private gain" (Transparency International 2009). Corruption is a potential consequence of poor governance, as are other problems, such as mismanagement. Indeed, targeting ineptitudes and inefficiencies that result from mismanagement can be a politically acceptable starting point for governance interventions. The terms *governance* and *transparency* are sometimes used interchangeably. Transparency is, however, one of the principles of good governance, albeit an important one. Lack of transparency can allow inefficient or corrupt practices to thrive.

The Importance of Good Governance in Pharmaceutical Systems

Managing pharmaceuticals in any setting (public or private) and at any level of the health care system follows a well-recognized framework (Figure 2). A functioning pharmaceutical system encompasses the interdependent processes of *selection*, *procurement*, *distribution,* and *use* of medicines together with the *pharmaceutical services* that support patient care and treatment. These activities and services are enabled by a strong *management support system* that includes financial, organizational, human resource, and information management.

BOX 2. CONTEXTUAL USES OF GOVERNANCE RELEVANT TO THE PHARMACEUTICAL SECTOR

Clinical governance: First described in the United Kingdom's National Health Service (NHS) and defined as "a framework through which [NHS] organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (Scally et al. 1998). Clinical governance encompasses the following elements: education and training, clinical audit, clinical effectiveness, research and development, openness, and risk management (Starey 2001). In the pharmaceutical sector, clinical governance underpins efforts to improve and maintain the quality and safety of clinical patient care services and includes pharmaceutical care activities.

Corporate governance: Set of processes, customs, policies, laws, and institutions affecting the way a corporation is directed, administered, or controlled. Corporate governance also includes the relationships among the many stakeholders involved (www.en.wikipedia.org). Corporate governance has relevance to the operations of both private and parastatal companies operating in the pharmaceutical sector, including manufacturers, distributors, and procurement agencies.

Global health governance: Loosely defined as the structures, systems, rules, and processes at the global level for (1) making decisions about health policy and priority setting; (2) financing and implementing global health initiatives, programs, and plans; and (3) ensuring appropriate and effective systems of accountability (McCoy 2009). The illicit trade in counterfeit medicines, often across national borders, is one example of an issue related to governance that is being addressed at the global level.

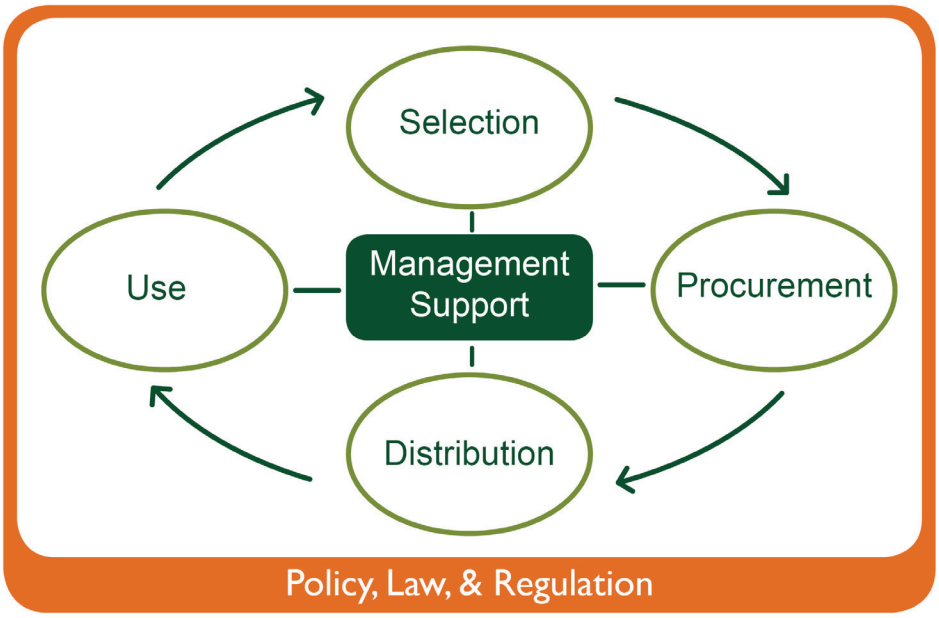

FIGURE 2.
Pharmaceutical Management Framework

Pharmaceutical services include activities relating to the sale or supply of medicines (whether or not by prescription), the provision of medicine information and counseling to ensure their appropriate use, and the monitoring of medicine use to achieve desired health outcomes. Other important components are the dissemination of information to promote public health, the formulation and implementation of policies and practices to improve pharmaceutical care, and the training of health care workers. The framework relies on *policies, laws,* and *regulations*, which when supported by good governance, sustain the commitment to pharmaceutical supply.

The various decisions and actions taken in the process of managing pharmaceuticals and providing pharmaceutical services are exercises in assuring that good governance principles are followed at each step. Table 1 outlines some examples of potential problems related to poor governance that can occur in the performance of key activities and shows some possible consequences for the health system.

The pharmaceutical sector is recognized as being particularly vulnerable to abuses of power and position for a number of reasons (Cohen et al. 2007)—

- The high market value of medicines makes them a target for theft.
- The supply chain is complex and involves many separate partners.
- Public pharmaceutical budgets can be sizeable, presenting a temptation for kickbacks and bribes.
- Processes, such as product registration, can be especially susceptible to corruption and unethical practices when they are based on discretionary decision making and lack adequate checks and balances.
- Patients often do not have the necessary information to make informed choices about the medicines they need, and perverse incentives can lead providers to unnecessarily or inappropriately prescribe or sell pharmaceuticals.

TABLE 1.

Pharmaceutical Management Framework

Pharmaceutical management functions	Potential problems	Possible consequences
Policies and legislation	Lack of or weak/outdated policies and legislation Weak enforcement of policies and legislation Corruption in licensing processes Inadequacies in medicine regulatory system	Facilities do not meet standards for delivery of quality services Practitioners lack competencies or skills Products available that do not meet safety, efficacy, and/or quality standards
Selection	Failure to use criteria to select products Corrupt practices in selection process (e.g., bribery, power pressure)	Less effective or more expensive products selected Rational prescribing and use compromised
Procurement	Product specifications in tenders favor certain supplier(s) Awarding contracts to suppliers that do not meet criteria Lack of consequences for poor supplier performance	Unreliable supplier service Purchase of inappropriate, poor quality, counterfeit, or highly priced products Stock-outs and wastage of medicines and supplies
Storage/ distribution	Lack of or failure to use criteria to select distributors Poor enforcement of auditing procedures at storage areas	Unreliable distributor service Over expenditure Stock-outs of medicines and supplies
Use	Unethical practices resulting in inappropriate prescribing or sale/supply of medicine Inappropriate charges (informal payments, substitution of cheaper brand at higher price, patients have to supply own medicines while in institutions)	Compromised patient care Higher out-of-pocket expenses for patients
Financing	Inadequate, misappropriated, or mismanaged funds Non-compliance with or weak enforcement of reporting and auditing (medicines and assets) Late payments to suppliers	Decreased funding to procure medicines and deliver services Stock-outs, inefficiencies
Organizational management	Oversight bodies do not exist or do not function Inappropriate appointments to or political interference with consultative or oversight bodies Conflict of interest	Inadequate oversight of key processes (e.g., tendering, financial management) Loss of trust among staff and patients
Human resource management	Promotion/benefits not based on merit (nepotism, bribery) Inadequate accountability Absenteeism, kickbacks, demand for informal fees, ghost workers	Poor performance of duties Attrition Unethical behavior Abuse of resources
Information management	Information not available, not trusted, or not used for decision making due to lack of reliability or timeliness Information not publicly available, resulting in lack of transparency and accountability	Lack of information makes governance and management difficult, including identifying and controlling theft or fraud

The impact of corrupt practices and mismanagement in the pharmaceutical sector can be substantial. Not only are valuable health sector resources lost, but future donor funding can be compromised by the loss of credibility. Medicines promote trust and participation in health services, and poor availability can increase staff attrition, decrease demand for services, and ultimately reduce program effectiveness. Moreover, lack of access to essential medicines, their irrational use, and the use of unsafe or poor-quality medicines can harm patients.

What Can be Done to Strengthen Governance in Pharmaceutical Systems?

Clearly, governance is an important concern for countries and their development partners who work to strengthen pharmaceutical systems. Addressing critical system weaknesses maximizes investments and sustains outcomes in the long term. In this section, we set out options for strengthening governance in pharmaceutical systems and outline some potential technical assistance activities to support countries, institutions, and stakeholders in their efforts. We use a systems-orientated approach to organize interventions that support adherence to one or more principles of good governance (Figure 3).

Adapted from UNDP. 1997. Governance for sustainable human development. http://mirror.undp.org/magnet/policy/

FIGURE 3.

Strategies to Support the Implementation of Good Governance Principles in Pharmaceutical Systems

This approach focuses on establishing—

- **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

Because governance is about the way decisions are made and implemented, it follows that good governance is not solely the responsibility of the central government or governing bodies. At each level of the health care system, various organizations and individuals make decisions and take actions while managing pharmaceuticals and providing pharmaceutical services. The challenge is to make them realize that they all have a role to play in adhering to the principles of good governance in the performance of their duties.

In this document, we focus on interventions that strengthen governance. However, reducing opportunities for corruption and addressing mismanagement in pharmaceutical systems typically requires a combination of interventions that target both poor governance and weak management practices. In reality, activities to improve governance and medicines management are often implemented concurrently.

Development of Policies and Legislation

Because pharmaceuticals are ubiquitous commodities that are readily bought and sold and because unsafe products and their incorrect use are potentially dangerous, pharmaceuticals must be carefully regulated. Policies and legislation provide the framework for *how* pharmaceuticals will be regulated in a country. National legislation, which includes laws and regulations, typically includes measures to control the availability, prescribing, and dispensing of medicines as well as the provision of product information. Generally, legislation also includes provisions for the licensing and oversight of pharmaceutical establishments and professional staff. It provides for the establishment of statutory bodies, such as the national regulatory agency responsible for assuring that only products that meet acceptable standards of safety, quality, and efficacy are registered and available in a country. Legislation is also needed to regulate clinical trials and to establish mechanisms of post-marketing surveillance to monitor medicine safety. The development of national pharmaceutical legislation usually begins with the preparation of a national pharmaceutical policy, which should be grounded in the country's strategic vision for pharmaceutical services. To meet the criteria for good governance, the pharmaceutical policy-making process should be participatory and transparent.

Laws and regulations and their administration should reflect the characteristics of good governance. The rule of law must be applied when enforcing legislation to ensure fairness, equity, and impartiality. Mechanisms need to be in place to enable stakeholders and civil society to participate in the formulation of legislation, and those responsible for enforcement must be held accountable. To be effective, laws and regulations should be grounded in best practices, kept updated, and be enforceable. They should specify standards to apply, define criteria for performing functions, and set out legal sanctions and procedures for appealing decisions. In addition to laws and regulations, countries need to establish pharmaceutical policies and guidelines that define norms, such as standards of practice. Opportunities for

abuse increase when policies are not coherent, roles and responsibilities are not clear, and when conflicting interests are not addressed. Setting norms and standards and applying them to pharmaceutical services are a shared responsibility among health care professionals (endorsed by their professional or trade associations), consumers and patients, and public health authorities.

Technical assistance typically includes helping governments develop well-informed, enforceable medicine policies and legislation that support the country's priorities and promote good governance in the pharmaceutical sector. Activities may also include assisting countries to assess compliance with applicable legislation. Technical assistance needs often depend on a country's level of development; for example, countries that are emerging from conflict may need new policies and legislation, whereas, in more developed countries, the focus may be on updating and strengthening what exists. National governments may need help to identify best practices that inform the development of norms and standards for performing key functions. Other important activities may include facilitating participation in the policy and legislative development process, for example, through empowering civil society groups with tools, skills, and information. SPS's support to the Ministry of Health in Swaziland to update legislation using a participatory and transparent process is a good example of this approach (Box 3).

Box 3. Updating legislation to improve the control of medicine in Swaziland

The Ministry of Health in Swaziland embarked on a process of updating the country's legislation governing the control of medicines and the pharmacy profession. The existing legislation, including Swaziland's Pharmacy Act of 1929, is outdated, and the weak regulatory system led to concerns about the quality, safety, and efficacy of medicines used in the country. Other issues included the availability of many unregistered products, a mushrooming of unlicensed medicine vendors, and opportunities for counterfeit products to penetrate the market. Poor control of medicines has the potential to cause serious harm to the people of Swaziland.

In 2007, the Directorate of Pharmaceutical Services asked SPS for technical assistance to revise the existing medicine and pharmacy legislation. As a first step, Swaziland, with the support of WHO, developed a comprehensive National Pharmaceutical Policy, which provided a strategic vision and a basis for legislative reform. SPS participated in the policy development process and then helped the Ministry review existing legislative provisions. A series of consultative workshops facilitated by SPS enabled stakeholders in government and nongovernmental organizations to participate at the development phase and comment on the proposed legislative framework. This feedback was considered in the drafting of two new laws, the Pharmacy Bill and the Medicines and Related Substances Bill. The draft legislation provides for the establishment of the first ever Medicines Regulatory Authority in Swaziland as well as for a Pharmacy Council to regulate the pharmacy profession.

To ensure transparency, the draft medicine and pharmacy bills were presented to inter-ministerial representatives and nongovernment and private sector stakeholders for comment. Feedback received during these consultations has been positive. The Minister of Health updated elected officials in Parliament on the status of the draft bills, and the media reported his comments and the proceedings of the consultation workshop held with private sector stakeholders. The next step is to present the draft bills to Parliament.

Strengthening Organizational Structures for Appropriate Decision Making, Authority, and Oversight

Certain bodies, such as those that provide oversight, are essential to ensure good governance in pharmaceutical systems. In addition, increasing transparency and participation in organizational structures of health systems or institutions is central to improving governance. These structures can include committees or boards responsible for developing and implementing policies and legislation, making decisions related to pharmaceutical management, and providing oversight.

Examples of organizational structures include—

- Medicine regulatory authorities responsible for registering and controlling medicines and for pharmacovigilance
- National or regional structures responsible for licensing pharmaceutical entities such as manufacturers, importers, distributors, and retail establishments
- Pharmacy and therapeutics committees at national, local, or institutional levels that advise on the selection of medicines for essential medicines lists and formularies
- Boards or committees that manage the tender process, including issuing tenders, evaluating bids, and awarding tenders or contracts
- Audit committees that oversee audit functions, internal controls, and financial reporting processes

These structures may be independent statutory bodies or they may fall under the auspices of the Ministry of Health or other government departments. Good governance requires committees not only to be independent and impartial, but also to be perceived as such. For instance, regulatory bodies should be autonomous to minimize undue influence in decision making. Factors such as political interference, nepotism, or corruption should not influence the appointment of members. Members should be appointed or hired on the basis of documented, objective criteria. Such criteria may relate to technical expertise, knowledge and skills, or representation of a particular group or constituency. Ideally, members should have complementary skills and expertise that enable the group to address challenges effectively. In some cases, members may represent different constituencies and sectors, including civil society, to promote transparency and accountability. Users of health services must also have a voice, either directly or through organizations that represent their interests. Membership and leadership positions may be rotated to avoid individual members having undue influence over decision making.

Declaration of conflict of interest is an important step to establish a committee or a board's legitimacy. For example, conflicts of interest can arise from relationships with manufacturers who have strong interests in getting their products registered; included on essential medicines lists; and prescribed, dispensed, or sold. Similarly,

interactions with pharmaceutical establishments and training institutes whose viability can depend on their licensing, certification, or accreditation may be perceived as inappropriate. In developing countries, experts in fields such as pharmacoepidemiology are rare. Consequently, certain specialists may sit on the boards of several organizations and also routinely consult for the pharmaceutical industry. Such relationships must be declared and documented. A committee or board should have clearly defined terms of reference that describe membership, authority, and roles and responsibilities. These terms of reference should be publicly available, together with members' names and credentials and the criteria for selecting them, as well as any declared conflicts of interest.

Potential technical assistance activities include building advocacy for and highlighting the benefits of effective and transparent structures with broad stakeholder participation. Helping governments and institutions evaluate existing structures and identify those that are missing or gaps in governance are also important activities (Box 4). SPS has helped partners in several countries design or review committee membership and develop clearly defined criteria for member selection, terms of reference, and roles and responsibilities.

Incorporating Good Governance Practices into Systems and Processes

As discussed earlier, strong lobbies may try to influence decision making and processes in the pharmaceutical sector. The different committees and boards must ensure that they apply the principles of good governance when making decisions and performing their statutory, management, and oversight obligations. Mismanagement, corruption, and unethical practices in routine pharmaceutical operations and financial management are also significant concerns. In addition to establishing standards for these operations, systems must incorporate mechanisms to ensure compliance with the standards set.

Decision Making. Important decisions have to be made at various steps of the pharmaceutical management cycle. Examples of such decisions include determining which medicines to register or place on an essential medicines list, which criteria to include in a pharmaceutical tender, or which service provider to choose to distribute medicine. To minimize bias, undue influence, and inconsistency, decision making must be guided by clearly defined criteria based on best practices and, where appropriate, international standards. Furthermore, committee or board members should base their decisions on sound and unbiased evidence rather than on personal opinion and, as far as possible, use a consensus process. To promote effective participation, all members should be encouraged to contribute to the agenda and to the final decisions. Procedures should allow for formal consultation with stakeholders, where appropriate.

BOX 4. REVISION TO BENIN'S CENTRAL MEDICAL STORES LEGAL FRAMEWORK DOCUMENTS USHERS IN INCREASED TRANSPARENCY AND ACCOUNTABILITY

Created in 1989, Benin's Central Medical Stores, known as the Centrale d'Achat des Médicaments Essentiels et des Consommables Médicaux (CAME), procures and distributes pharmaceuticals and medical supplies to public health facilities and private nonprofit and for-profit health centers. In 2008, USAID asked SPS to evaluate CAME's governance and transparency. Among the governance-related elements examined in the course of the evaluation were CAME's legal status and the structure and functioning of its governance bodies.

Since its inception, CAME's legal status had been that of a project under the authority of the Ministry of Health (MoH). The 1996 articles of CAME's incorporation did not clearly define the type of legal entity CAME constituted (parastatal or autonomous) and was silent or ambiguous on key elements related to CAME's internal functioning and its relationship with MoH. In addition, the legal agreement between CAME and the government that authorized CAME's operations lapsed in 2007. As a result of CAME's ambiguous legal standing and its outdated legal agreement, MoH had no legal basis on which to seek redress if CAME did not achieve its public health objectives or if it were found to be misusing funds. This ambiguity also legally prevented CAME from entering into contracts for financial relationships with donors, regulatory relationships with MoH, and client/service relationships with health facilities. Other governance-related problems included the lack of terms of reference describing membership criteria, authority, and roles and responsibilities for CAME's governance bodies, its General Assembly, and the Board of Directors.

With assistance from SPS, CAME's articles of incorporation were revised and the legal agreement between CAME and the Government updated through a consensus-based process that involved key stakeholders from the health sector. Two workshops facilitated by SPS consultants enabled stakeholders to consider options for a revised legal framework for the CAME and contribute to identifying the key elements requiring revision. Based on these agreements, SPS prepared and submitted the revised draft articles of incorporation and legal agreement to Benin's Council of Ministers through the USAID/Benin Mission in August 2009. Following discussions between MoH and the Ministry of Economic Development, the Council of Ministers adopted them in January 2010.

In addition to clarifying CAME's legal status as an autonomous institution with a public function, the revised articles of incorporation also address procedures for modifying the articles and criteria for membership of the General Assembly and Board of Directors, as well as the procedure for the appointment of members. The articles expand the list of organizations that should be represented on these governance bodies to better reflect the stakeholders in the pharmaceutical sector. They also strengthen accountability by specifying the performance indicators that CAME must report on annually to the Board of Directors. In August 2010, as part of USAID's ongoing support to CAME, SPS trained CAME's Board of Directors in good governance and central medical stores management.

In the interests of transparency, reports of meetings and decisions reached, such as pharmaceutical products registered and contracts awarded in public sector procurements, should be widely available for public scrutiny. As far as possible, the reasons that informed a particular decision should also be made known. Committees should develop and publicize guidelines describing standards, the information required, and the application process. In addition, they should publish written procedures that document the decision-making process and set out rules for declaring and avoiding conflicts of interest including guidance on communicating with applicants and interested parties. Where appropriate, an appeals process should allow officials and institutions to be held accountable for their decisions.

Technical assistance activities typically include helping countries develop criteria and procedures for decision making that are in line with best practices and international standards.

Operational Processes. Various operational processes culminate in patients having access to essential pharmaceuticals. To maximize effectiveness and efficiency, these processes should adhere to clearly defined standards based on best practices and international guidance. Examples of such international guidelines include Good Manufacturing Practices (WHO 2007b), Good Procurement Practices (WHO 1999), and Good Storage Practices (WHO 2007c). Because large amounts of money flow through pharmaceutical systems, it is crucial that financial management takes place in accordance with financial policies and applicable legislation relating to financial control.

Technical assistance commonly involves helping countries and institutions identify and address inadequacies in existing standards or develop missing standards. Complementary interventions that focus on management include developing standard operating procedures based on these revised standards. Improving the timely availability of accurate data so that processes, such as quantification, can be performed objectively is also important.

Oversight. Good governance requires the existence of systems and procedures to provide oversight and hold entities and staff accountable for their performance. Moreover, these oversight mechanisms must have adequate capacity and funding to function effectively. Examples include systems for overseeing the procurement process, including prices paid, and auditing warehouse operations to identify theft or mismanagement. Entities that fulfill audit or oversight functions may be internal or external to the government agency or organization. The Global Fund oversees its operations and projects through the Office of the Inspector General, an independent unit that reports directly to Global Fund Board. The Inspector General receives resources from the Board to conduct any audit, inspection, investigation, or other oversight work it deems appropriate, including pharmaceutical procurements using Global Fund grants (Global Fund 2010). Civil society groups increasingly play a role in monitoring the performance of health systems and holding governments and officials accountable. For example, Health Action International (HAI) Africa is a regional network of nongovernmental organizations that has partnered with Oxfam and local civil society groups to check the availability of essential medicines at government health facilities in Kenya, Malawi, Uganda, and Zambia. They use this information to pressure governments to take action to address gaps as part of the "Stop Stock-outs" campaign (Stop Stock-outs 2009).

SPS has assisted a number of countries strengthen systems for oversight, particularly for procurement activities. Box 5 describes SPS's help in addressing oversight weaknesses in Kenya's public sector procurement system.

Information Systems. The importance of information systems in improving transparency and thereby accountability in pharmaceutical management cannot be underestimated. Good governance also includes using information to solve problems and unblock bottlenecks. Entities tasked with providing oversight may be paralyzed if they do not have the necessary data, if they have no confidence in the data available,

or if they are unable to interpret it. Governments and organizations need to publish and disseminate information in ways that allow stakeholders and civil society groups to understand it and use it to monitor processes and outcomes that concern them. In addition to reporting on performance to the relevant authority, information should be disseminated to pertinent stakeholders to promote transparency. Reports must

BOX 5. SUPPORTING THE MINISTRY OF HEALTH TO IMPROVE GOVERNANCE IN KENYA'S PUBLIC PHARMACEUTICAL PROCUREMENT SYSTEM

In 2005, a Kenya Anti-Corruption Authority review of pharmaceutical procurement and logistics revealed major inefficiencies and governance gaps, including weak oversight bodies and non-transparent procurement practices. In response, the Government of Kenya, with assistance from development partners, began implementing initiatives to make public procurement more transparent, reduce leakage and wastage, and increase accountability through the Public Financial Management Strategy.

In April 2007, the Governments of Kenya and the United States signed an agreement under the Millennium Challenge Account Threshold Program (MCA-TP) that supported governance initiatives. The agreement focused on reducing corruption by overhauling the public procurement system with a specific focus on health care. Recognizing weaknesses in the procurement system, USAID asked SPS to provide technical assistance to strengthen Kenya Medical Supplies Agency (KEMSA) systems with MCA-TP funding. In 2008, SPS and partners from the Logistics Management Institute and the Ecumenical Pharmaceutical Network conducted a comprehensive assessment of KEMSA to validate planned MCA-TP interventions, identify areas of weakness, and make recommendations for closing gaps.

Ongoing SPS technical assistance has focused on—

- Strengthening KEMSA's procurement capacity and accountability
- Improving supply chain management of medicines and supplies
- Building Ministry of Health capacity to monitor and assess KEMSA's procurement functions
- Strengthening the tracking of medical supplies and improving availability and use in rural health facilities

To address critical weaknesses in governance, SPS has provided technical support for the following activities—

- Establishment of the Supply Chain Oversight Committee (SCOC) by the Ministry of Health through the development of a charter. Committee members are appointed by and report to the Permanent Secretary in the Ministry of Health; names of new members will be published in the gazette to promote transparency. The SCOC Charter describes the Committee's lines of authority, scope, mandate, and membership. Its role is one of proactive oversight and results-oriented performance monitoring.
- Development of audit tools, training, and mentoring of SCOC's supply chain auditors through an audit of KEMSA's procurement and distribution processes. In addition, SPS supported the preparation of training materials for capacitating future auditors.
- Provision of training on corporate governance to KEMSA's Board of Directors and senior management.
- Development and update of standard operating procedures for most of KEMSA's core functions (procurement, warehousing, distribution, and service liaison) in line with best practices and international standards.
- Posting of procurement tender prices on KEMSA's updated website to promote transparency. In August 2009, a survey comparing KEMSA's procurement prices with major manufacturers, suppliers, other public procurement bodies, and the *International Drug Price Indicator Guide* found that KEMSA offered value for money.

Next steps include institutionalizing the SCOC in the Department of Pharmacy structure and providing for it in a budget line.

be accurate and up to date with significant and relevant information presented in a balanced, objective, and understandable manner. Performance targets should be presented with results achieved. The SPS Program is working extensively with governments and institutions to strengthen their pharmaceutical management information systems to generate the reliable data needed for evidence-based decision making, operations, and oversight and also to build their capacity to take appropriate actions based on the information reported (Box 6).

Improving Human Resources Management to Enhance Performance and Ethical Practices

Staff working in the pharmaceutical sector frequently handle high-value pharmaceuticals or participate in activities that are vulnerable to collusion and other corrupt practices. Therefore, preventing political interference or nepotism is critical in the appointment of personnel. Explicit criteria for employee recruitment, selection, or promotion and job descriptions that specify required qualifications and experience encourage fairness and equity. Making job vacancies, criteria, and rules for selection or promotion publicly available promotes transparency.

In many resource-limited countries, the ability to exercise good governance in the pharmaceutical sector is hindered by a lack of human resources. Important principles, such as separation of key responsibilities (e.g., ordering and receiving pharmaceuticals), and oversight activities, such as audits, are not routinely implemented because of staff shortages. Low salaries, inadequate staffing, and poor

BOX 6. STRENGTHENING INFORMATION SYSTEMS TO SUPPORT DECISION MAKING AND OVERSIGHT IN THE DOMINICAN REPUBLIC'S TB PROGRAM

In 2003, the Dominican Republic had one of the highest rates of tuberculosis (TB) in Latin America. However, the national TB program lacked the necessary information to make important decisions and to promptly address the TB medicine stock crisis of 2003–04. With USAID resources, the Rational Pharmaceutical Management (RPM) Plus Program, the predecessor to SPS, helped design and implement a TB pharmaceutical management information system to support evidence-based decision making, oversight, and accountability. Preliminary data showed a depletion of safety stock in some health facilities and an oversupply of some medicines in others. Furthermore, because of devaluation of the local currency, resources to procure TB medicines were insufficient to meet demand. By using data generated by the system, RPM Plus showed that the cost of a course of treatment for a new patient had increased from USD 32 in 2004 to USD 155 in 2005.

The first action was to redistribute extra stock of medicines from some facilities to ease shortages in others. Next, RPM Plus and USAID presented the price analysis to Ministry of Health and TB program authorities and recommended they procure lower-priced, quality medicines through international agencies. As a result, a Ministerial Decree was promulgated that required TB medicines to be procured through the Global Drug Facility. The annual savings were estimated at about USD 775,000. As of 2010, the information system continues to routinely generate data on stock levels at facilities. In addition to enabling program managers to respond to the stock crisis, the price information allowed the national TB program to make important decisions about procurement that maximized the efficient and effective use of public resources.

work conditions can contribute to weak performance and tempt staff to engage in theft and other corrupt practices. Clear performance standards, job descriptions, and ongoing supervision all play a part in addressing deficient performance and managing problems, such as absenteeism. Adequate incentives for good performance and defined disciplinary actions for transgressions are also needed. Formal systems for submitting complaints allow patients and customers to report poor staff performance and unethical behavior, such as unofficial charges (Box 7). Also important in the pharmaceutical sector are codes of ethics and codes of conduct supported by monitoring and enforcement, including sanctions for misconduct. Educational activities help to raise awareness of the importance of good governance and ethics in pharmacy practice and promote adherence to codes and standards of practice.

Technical assistance activities may include assisting governments and institutions to identify human resource management gaps that compromise the exercise of good governance and to build advocacy and implement approaches for addressing those gaps.

BOX 7. SPS SUPPORTS KENYA'S DEPARTMENT OF PHARMACY TO IMPROVE PERFORMANCE AND ETHICAL PRACTICES IN PHARMACEUTICAL SERVICES IN THE PUBLIC SECTOR

The Kenya Civil Service Reform Program has introduced results-based performance appraisals and target setting to improve efficiency and productivity in the civil service. Target setting is implemented through performance contracts that define responsibilities and expectations between parties to achieve mutually agreed results. Performance contracts promote accountability by measuring the extent to which public officers achieve targets. Chief Officers in all government ministries have signed performance contracts, which have cascaded down to all departments, divisions, sections/units, and individual public officers in the Ministries of Health. At the individual officer's level, the development of an annual individual work plan commits each person to contribute to the Ministerial Performance Contract.

Citizen's Service Delivery Charters inform citizens and clients of government services about public officers' commitments in both performance contracts and individual work plans. Each charter outlines what the institution does, services provided, the standard of service that the user can expect, responsibility of the service users, and details of how users may seek redress if dissatisfied with the service received.

SPS helped the Department of Pharmacy develop the Health Facility Level Citizen's Service Delivery Charter for pharmaceutical services in English and Kiswahili. To support the charter's implementation, a simple handbook has been developed for pharmacy staff that converts the charter's commitments into service delivery expectations for clients. The charter for pharmaceutical service describes the responsibilities of the facility's pharmacy department and clients' rights and responsibilities and seeks feedback on pharmacy service delivery.

SPS, the Department of Pharmacy, and other stakeholders have also identified and developed priority standard operating procedures for pharmaceutical services as tools to support implementation of the Citizen's Service Delivery Charter. The charter, handbook, and standard operating procedures form a package to promote effective performance, ethical practices, and the delivery of safe and quality pharmaceutical services and care. These documents have been reviewed by stakeholders and finalized. The next steps will include printing, an official launch, structured regional dissemination, and distribution to facilities.

The SPS Operational Approach

In many settings, governance issues affect all of the key pharmaceutical management functions to a greater or lesser degree; for example, problems are rarely restricted to pharmaceutical procurement alone. Although requests for governance-related technical assistance typically focus on one area, such as procurement or selection of medicines, the SPS Program aims to work with USAID Missions and local partners to take a system-wide, comprehensive approach where possible. As described previously, in many countries, the ability to exercise good governance in the pharmaceutical sector is frequently constrained by the relevant entities' lack of capacity to lead, manage, and provide appropriate oversight. As a result, an important aspect of the SPS approach includes working with countries to build the capacity of government agencies and institutions to support good governance.

The SPS operational approach for providing technical assistance at the national and institutional level comprises the following steps—

- **Assess the existing situation.** SPS works with partners to identify strengths and weaknesses in governance by using an indicator-based methodology, such as the WHO Assessment Instrument for Measuring Transparency in the Public Pharmaceutical Sector (WHO 2009). Assessments typically form the baseline for measuring improvements. Engaging stakeholders that represent a broad range of constituencies in the assessment phase helps to build ownership of the improvement process. SPS also endeavors to ensure that broader assessments to identify and address inefficiencies or poor performance in the pharmaceutical sector assess governance issues as appropriate (Box 8).

- **Develop a customized system improvement model.** SPS uses the assessment findings to review options with in-country stakeholders and identify relevant, feasible, and sustainable approaches to improve governance. A thorough analysis of the options is critical because governance activities that are effective in one country, health program, or institution may not work in others. As mentioned earlier, a country's level of development will influence the type of assistance that it needs. Corrupt and unethical practices can flourish in countries for two reasons. First, countries may lack policies and legislation, oversight bodies, and the capacity to implement good governance practices; second, the pieces may all be in place and in line with international standards, but are not implemented or respected. Although interventions in these situations will differ, the key issue is to motivate counterparts to commit to and invest in addressing critical weaknesses. As part of the options analysis, SPS helps USAID program managers and local partners distinguish problems and solutions that are appropriate to tackle from those that are best led by other initiatives or in-country entities. A strategy is developed that allows for phased implementation on the basis of local priorities and realities. Important considerations include opportunities, political will and readiness for change,

funding availability, and likely opposition to and support for potential interventions. Combining discipline-based strategies, such as establishing legislation with adequate sanctions, with values-based strategies, such as promoting professional codes of conduct, can be a useful approach (WHO GGM 2008b).

- **Provide technical assistance for implementation.** SPS works with other initiatives and stakeholders to support partners to implement interventions, develop local capacity, and build advocacy for change. A helpful early step

BOX 8. STRENGTHENING THE MEDICINES REGULATORY SYSTEM IN NAMIBIA

The Medicines and Related Substances Control Act 13 of 2003 established the Namibia Medicines Regulatory Council (NMRC) as the statutory body responsible for regulating medicines to ensure quality, safety, and efficacy. Regulations to the Act came into effect in 2008. NMRC has wide-ranging responsibilities that include registering medicines; licensing importers, exporters, and dispensers other than pharmacists; and monitoring pharmaceutical advertising and promotion. The NMRC secretariat was, however, not well equipped to support its complex mandate.

SPS has been working with Namibia's Ministry of Health and Social Services since 2004 to help strengthen the medicines regulatory system. In 2008, the Ministry asked SPS to help build the NMRC secretariat's ability to meet its myriad responsibilities. In November 2008, SPS used the WHO assessment tool (WHO 2002) to assess the NMRC's regulatory capacity and drafted recommendations to address identified limitations in the regulatory structures and processes. Subsequently, SPS reviewed the new regulations to identify inconsistencies, gaps, and weaknesses.

Key assessment results and activities related to governance are described below.

Strategic vision: The NMRC did not have a strategic framework, vision, or mission statement. SPS worked with the agency to develop these organizational components, including goals for a five-year strategic plan.

Medicine legislation and policy: Namibia has relevant policies and legislation to assure the quality, safety, and efficacy of the country's medicine supply. Issues that required attention included a lack of regulation of medical devices, complementary and alternative medicines, and medicine promotion. SPS helped draft guidelines for the ethical promotion of health products and is developing guiding principles to regulate complementary and alternative medicines.

Regulatory structures: To promote good governance in how NMRC operates, SPS drafted terms of reference for the Council's committees that defined roles, responsibilities, and committee functions. SPS also drafted a conflict of interest form to be completed by members of the Council, committees, and the secretariat to help enforce transparency. NMRC adopted the terms of reference and the conflict of interest guidance in 2010. In addition, the Council will publish members' names, conflict of interest declarations, and voting records on the NMRC website. This new website, developed with SPS assistance, also increases transparency of Namibia's medicine-regulatory activities. Options have also been presented for transforming the NMRC into an autonomous organization.

Product registration: To help clear the backlog of product registration dossiers awaiting review, SPS made recommendations to streamline the process. To help increase overall registration efficiency, SPS developed and introduced a registration software package called PharmaDex to help increase registration efficiency. Next steps include linking PharmaDex to the NMRC website and establishing a process to submit applications electronically.

Licensing and inspection: The licensing and inspection unit has no database to document its activities, such as inspection reports. SPS is augmenting PharmaDex into an integrated regulatory solution to strengthen data collection, analysis, and reporting on licensing and inspection activities. This enhanced software will also make it easier to monitor the NMRC's performance and create management reports, which will be available to stakeholders.

is explaining to stakeholders the benefits of strengthening governance as an important part of the institutional capacity-building process.

- **Monitor and evaluate activities.** A primary component of our operational approach is helping in-country partners establish indicator-based monitoring to objectively measure improvements in governance. Ongoing monitoring also makes it possible to identify needed revisions to strategies that were put in place to reduce corruption. Results from monitoring should be publicly available. Technical assistance will usually include strengthening pharmaceutical management information systems to generate reliable data needed for producing governance indicators at each level. In addition, SPS works with partners to document and share successful approaches and lessons learned.

Governance issues are rarely specific to one system or one ministry, or only to the public or the private sector. In the pharmaceutical system alone, governance issues may relate to the ministries of health, commerce, and finance, among others. Other stakeholders include research-based industry, manufacturers, wholesalers, distributors, professional associations, drug sellers, educational institutions, media, health care providers and consumers, regulators, and enforcers. Addressing problems, such as counterfeit medicines, may require joint action by these various groups and the establishment of mechanisms for collaboration. SPS can help facilitate constructive dialogue among different stakeholders to achieve mutual understanding and reach agreement on best next steps.

Improving governance may require changing cultural traditions, long-standing processes, and deeply entrenched power relationships that pervade the entire government and society. Sometimes, what is considered appropriate in one cultural context may be considered a form of corruption or unethical behavior in another. Challenging such matters in the name of anticorruption can be considered impolite and even threatening. SPS endeavors to deal with vested interests and value systems in a sensitive way; however, sensitivities and potential conflicts of interest can stall important activities or decisions and the risks of retaliation are real. For this reason, being aware of other initiatives that target some of these aspects can be helpful. The annex includes a brief description of some of the global initiatives working to address governance and corruption related to pharmaceuticals and provides links for more information. Some global initiatives also work at the local level, and various local organizations and agencies make natural partners and allies for USAID-funded initiatives in the pharmaceutical sector. Identifying in-country opportunities for leveraging is key to avoiding duplicative or fragmented approaches.

To conclude, improving governance in pharmaceutical management systems can help reduce inefficiencies and limited effectiveness that result from mismanagement and corrupt practices. Addressing critical weaknesses through a systems-oriented approach that promotes good governance in the process of providing pharmaceuticals and services at each level of the health care system can maximize country and donor investments and ultimately promote sustainability.

Annex. Global Initiatives Working to Address Governance and Corruption Issues

Medicines Transparency Alliance (MeTA)
http://www.medicinestransparency.org/

Launched in 2008, MeTA is a multi-partner alliance working to improve access to medicines by increasing transparency and accountability in the health care marketplace. During its pilot phase, which ran until mid-2010, MeTA focused on making information about medicines publicly available in seven countries—Ghana, Jordan, Kyrgyzstan, Peru, the Philippines, Uganda, and Zambia. The initiative is working to strengthen national capacity to collect, analyze, disseminate, and use data on the quality, availability, price, promotion, and use of medicines. In the pilot, the MeTA International Secretariat, together with WHO and the World Bank, provided technical support to countries in medicines supply and policy, communication, civil society strengthening, private sector engagement, and multi-stakeholder processes. The United Kingdom Department for International Development provided funding for the pilot phase. MeTA is now exploring options for funding future work.

The three-step approach developed by the program includes—

- National assessment of the level of transparency and vulnerability to corruption of key functions in medicines regulation and supply management systems in the public sector using a standardized instrument.
- 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.
- Implementation and promotion of the national program on GGM

USAID Health Systems 20/20 Program
http://www.healthsystems2020.org/

Health Systems 20/20, a five-year (2006–2011) USAID-funded cooperative agreement, offers USAID-supported countries help in solving problems in health governance, finance, operations, and capacity building. The two-pronged governance-improvement approach focuses on working with citizens and oversight entities inside and outside of government to enhance capacity to exercise voice and accountability (demand side) and to strengthen the Ministry of Health and other health sector entities (supply side).

Health Action International
www.haiweb.org/

Health Action International (HAI) is implementing two initiatives in cooperation with WHO.

- **HAI Global Regulation of Pharmaceutical Promotion Initiative**
  http://www.haiweb.org/03_other.htm

  This initiative will be carried out in selected countries and conducted as two complementary projects in partnership with WHO—

  - Measuring the Impact of Pharmaceutical Promotion Regulation. The goal of this project is to develop indicators that will measure the effectiveness of national regulations on pharmaceutical promotion.
  - Practical Implementation of the WHO Ethical Criteria. The goal is to offer practical proposals to countries on how to incorporate the principles of the WHO Ethical Criteria into national legislation and regulation.

  Also in collaboration with WHO, HAI has developed the WHO/HAI Pilot Manual to help medical and pharmacy students understand and respond to pharmaceutical promotion.

- **Medicine Price Surveys**
  http://www.haiweb.org/medicineprices/

  In May 2008, HAI and WHO published the second edition of a manual on how to collect and analyze medicine prices (including prices to patients and government procurement prices) across sectors and regions in a country, as well as medicine availability. The results of over 50 surveys are currently available in the database.

World Bank: Governance Group of the World Bank Institute
http://www.worldbank.org/wbi/governance

The World Bank Governance Group has many ongoing governance and anti-corruption initiatives that focus on increasing internal organizational integrity, minimizing corruption on World Bank-funded projects, and helping countries improve governance and control corruption. The World Bank Institute approach is based on participatory action-oriented learning, capacity-building tools, and diagnostic surveys. The Governance Group supports several datasets including the Worldwide Governance Indicators available at http://info.worldbank.org/governance/wgi/index.asp.

WHO Good Governance for Medicines (GGM) Programme
http://www.who.int/medicines/ggm/en/index.html

Initiated in 2004, the goal of the Good Governance for Medicines Programme is to curb corruption in pharmaceutical systems by applying transparent and accountable administrative procedures and promoting ethical practices among health professionals. As of November 2010, the program was operating in 26 countries across six WHO regions.

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Acknowledgements

SPS would like to acknowledge with gratitude the contributions of the following individuals and organizations in writing and reviewing this document. In addition to those listed below, we appreciate the comments received from other SPS and Center for Pharmaceutical Management staff members.

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