THE WORLD MEDICINES SITUATION 2011

GOOD GOVERNANCE FOR THE PHARMACEUTICAL SECTOR

Jillian Clare Kohler
University of Toronto, Canada

Guitelle Baghdadi-Sabeti
Department of Essential Medicines and Pharmaceutical Policies, WHO, Geneva

World Health Organization

GENEVA 2011

The World Medicines Situation 2011
3rd Edition

SUMMARY

■ Good governance is increasingly understood as necessary for improving access to medicines and contributing to health systems strengthening. This chapter reviews the findings of studies carried out in 25 countries that have examined governance of key functions of pharmaceutical systems within the framework of WHO's Good Governance for Medicines (GGM) programme.

■ The goal of the GGM programme, an innovative WHO initiative launched in late 2004, is to reduce corruption in pharmaceutical systems through the application of transparent, accountable administrative procedures grounded in laws and regulations, and the promotion of ethical practices.

■ The country studies, which are based on a common methodology, have revealed strengths and several weaknesses in existing pharmaceutical systems and have provided policy-makers with relevant information to help them better understand the nature of the problems facing the sector and where interventions need to take place.

■ Common strengths in the pharmaceutical systems and procedures include the use of standard application forms in the registration process of medicines, use of national essential medicines lists, existence of standard operating procedures for procurement of medicines and well-established tender committees.

■ Common weaknesses include a lack of access to information, poor enforcement and implementation of laws and regulations, absence of conflict of interest policies among members of various committees, and an inability to ensure that the proper incentives are in place to lessen the likelihood of corruption at both the individual and institutional levels.

■ Governments can reduce corruption by promoting transparency and ethical practices, and by introducing simple measures, such as justification for committee membership, terms of reference, conflict of interest policies and descriptions of the purpose of the committees. International organizations, such as WHO, can provide technical support for these efforts.

1.1　　　　　　　　**INTRODUCTION: THE CASE FOR GOOD GOVERNANCE**

Each year, an estimated US$ 5.3 trillion is spent worldwide on providing health services (*1*). It is estimated that 25% of total health expenditure is spent on pharmaceuticals (see the chapter on expenditure). Regrettably, and for a variety of reasons, a significant proportion of these resources are wasted – one example being corruption in the system – resulting in significant losses, in terms of both health and economics Corruption within the pharmaceutical sector is of increasing concern, not simply because of the cost implications but more importantly because it denies many people access to medicines, which, provided they are of good quality and used appropriately, offer a cost-effective solution to many health problems.

It is estimated that anywhere between 10% and 25% of global spending on public procurement is lost to corruption (*2*). Medicine spending is more or less likely to be beset by such problems. In addition, there is evidence to suggest that the circulation of counterfeit and substandard medicines is increasing globally (*3*). Such losses are largely the result of the weak and ineffective medicine regulatory systems and poorly managed medicine supply chains that prevail in many countries. As a means of tackling corruption and unethical practices in the pharmaceutical sector, better governance therefore becomes something of a priority. Better governance matters because corruption, when ignored or viewed benignly, diverts government resources from public health services and jeopardises any health gains made by measures to promote equity in access and rational use of medicines. Good governance also matters because corruption hinders development. The World Bank has identified corruption as the single greatest obstacle to social and economic development (*4*). Furthermore, in 2009 the UN Secretary General stated that corruption represents one of the biggest impediments to the worldwide efforts to achieve the Millennium Development Goals (*5*).

Good governance matters because the potential for corruption exists everywhere.

The potential for corruption exists everywhere, in every country and at any point in the pharmaceutical supply chain. For example, there can be collusion in the procurement process, falsification of efficacy and safety data, price-fixing by cartels, and leakages and diversion in the distribution chain. Although a global phenomenon, affecting both high- and low-income countries, corruption – and its consequences – tend to be more apparent in the pharmaceutical systems of low-income countries, where, due to resource constraints, legislation and regulations are typically enforced less effectively. As a result, in many countries supply and distribution processes are often poorly defined and documented, and institutional checks and balances limited. These systematic deficiencies contribute to an environment that allows corrupt practices to occur unnoticed and without penalty.

Corruption can divert government resources from public health services with negative impacts on the poor.

Corruption in the pharmaceutical sector has a disproportionate impact on the poor who are dependent on public health systems for the medicines they need. A recent World Bank publication notes, "While corruption in the pharmaceutical system can affect a country's entire population, it is typically the poor who are most susceptible to its detrimental effects. When public health-care systems cover pharmaceuticals, it is the poor who are obviously more dependent on the system than the rich and who suffer the consequences of its mismanagement more acutely (*6*)."

Corruption's causes are complex, and its presence not easy to confirm. It is often difficult to identify corruption outright, given that it is not always possible to distinguish corrupt practices from inefficient ones. However, this has not, stopped the international community from working towards improving good governance in the pharmaceutical sector by building up a basic understanding of what contributes to corruption. As Cohen, Mrazek & Hawkins note, "the first step towards stopping corruption in the pharmaceutical sector is to understand its structure, actors and motivations, and to identify the key points where corruption can occur" (*7*).

Acknowledging that corruption can no longer be ignored and guided by WHO's medicines strategy for 2004–2007, WHO initiated the Good Governance for Medicines (GGM) programme in late 2004 (*8*). Its goal is to contribute to strengthening heath systems and reducing corruption in pharmaceutical systems through the application of transparent, accountable administrative procedures and the promotion of ethical practices. By helping policy-makers understand where the strengths and weaknesses lie in the pharmaceutical system, appropriate interventions can be applied. The GGM web site provides the details of the programme.[1]

Since the launch of the GGM programme, the drive to reduce corruption and waste in the pharmaceutical sector has gained momentum among public health officials working in ministries of health and national medicines regulatory authorities around the world. The GGM programme is currently active in 26 countries and is fostering complementary initiatives by other international organizations. For example, the World Bank is increasing its work in the area of governance and anticorruption to reduce poverty and improve economic growth in all sectors, including health and the pharmaceutical system (*1*). Also, the Medicines Transparency Alliance (MeTA) is working to improve transparency in the sector through measures to encourage disclosure of information and multi-stakeholder collaboration (*9*). The GGM programme also builds on the pioneering anti-corruption efforts of Transparency International and international agencies, such as the World Bank, the United Nations Development Programme (UNDP) and the United Nations Office on Drugs and Crime (UNODC) which made corruption an accepted area in development.

1.2 ASSESSING VULNERABILITY TO CORRUPTION IN THE PHARMACEUTICAL SECTOR

1.2.1 The Good Governance for Medicines programme

The GGM programme relies on two core strategies. The first is a "top-down" discipline-based strategy which seeks to help governments establish anti-corruption laws and improve legislation and regulation governing the pharmaceutical sector. The second is a "bottom-up" values-based strategy that aims to help governments build institutional integrity through the promotion of ethical practices.

Implementation occurs through a three-phase model process:

- **Phase I:** national assessment of the level of transparency and potential vulnerability to corruption of the national pharmaceutical system. The results of the assessments conducted to date in 25 countries will be the focus of this chapter.

- **Phase II:** development of a national GGM framework through a consultation process involving key stakeholders. Once officially adopted, the GGM framework document will serve as a policy document and usually includes: an ethical framework and code of conduct, regulations and administrative procedures, collaboration mechanisms with other good governance and anticorruption initiatives, whistle-blowing mechanisms, and sanctions for reprehensible acts.

- **Phase III:** implementation of the national GGM programme. This will require the systematic training of government officials and health professionals, as well as communications and advocacy campaigns, which are essential for enlisting the support of civil servants, for building the momentum to sustain programme implementation, and for ensuring long term positive changes are made that help to improve how the pharmaceutical system functions.

---

[1] http://www.who.int/medicines/ggm

1.2.2   **Assessment methodology**

The Phase 1 national assessment seeks to measure, in a semi-quantitative manner, the pharmaceutical sector's vulnerability to corruption, by examining and scoring national performance in up to eight core regulatory and supply management functions, as follows:

- medicines registration
- licensing of pharmaceutical establishments
- inspection of pharmaceutical establishments
- control of medicines promotion
- control of clinical trials
- selection of medicines
- procurement
- distribution.

The end result is a baseline situation analysis of sector transparency that can be used to monitor the country's progress over time. The goal of the GGM programme is not to measure corruption per se but rather to examine the resistance or vulnerability of the system to unethical practices. The national assessment is intended to serve as an entry point for the development and promotion of a national programme on good governance (phases II and III) and should not be seen as an end in itself. Its primary purpose is to help policy-makers understand where they need to direct their effort and resources in terms of improving the functioning of their pharmaceutical system.

The analysis of vulnerability to corruption in the pharmaceutical sector that will be discussed in subsequent sections draws on the results obtained from national transparency assessments (Phase I) undertaken since the GGM programme started in 2004. All 26 national transparency assessments conducted to date have used WHO's standardized assessment instrument (*10*).[1] National assessments have been conducted at different times and used slightly different versions, as the assessment instrument was regularly revised in the light of experience gained in new countries. Additionally, the number of functions assessed in-country vary between three and eight depending on when the country joined the GGM programme.

The objective and methodology of WHO's assessment instrument are summarized in Box 1.1. The assessment instrument includes quantitative and qualitative sets of indicators as well as questions to obtain the perceptions of key informants (KIs). Government "buy-in" and cooperation is vital in order to obtain good results, and most importantly so that appropriate measures are taken to implement the recommendations and fill in the gaps identified by the assessment.

The process of national assessment puts emphasis on a system's actual structure, focusing on mechanisms designed to prevent undesirable practices, such as administrative procedures that either limit or prevent transparency and accountability. It also provides an opportunity to examine how different stakeholders interpret and make use of or follow the systems and procedures in various areas of the pharmaceutical sector.

---

[1] To date assessment have been conducted in 26 countries, however only 25 had completed their assessments at the time of writing. Likewise several functions were added later therefore not all countries have reported on all functions of the pharmaceutical system.

BOX **1.1**

> ## GGM Phase I – assessment instrument, the process and scoring
>
> ■ The objective is to assess the level of transparency of eight functions of pharmaceutical systems (related to regulatory and supply functions). The main assumption is that the more transparent, the lower the rating in terms of corruption vulnerability.
>
> ■ The goal is not to measure corruption, but to examine how resistant or vulnerable the system is towards corrupt practices.
>
> ■ The assessment is carried out by at least two national assessors (NAs) from well-known and trusted independent organizations who have a good knowledge of the country's pharmaceutical sector.
>
> ■ NAs conduct semi-structured interviews to collect (with predefined questionnaires) qualitative and quantitative information on structural and procedural indicators, and on perceptions.
>
> ■ Four methods are used to determine the level of transparency, however only methods 1 and 2 are used in the final scoring:
>
> — Method 1: questions requiring a binary answer (yes/no)
> — Method 2: questions with sub-questions requiring a binary answer (yes/no)
> — Method 3: subjective questions probing perceptions (Likert Scale)
> — Method 4: open questions for collecting additional information and recommendations.
>
> ■ NAs interview KIs from various stakeholders to ensure different perspective are represented: the ministry of health, medicines regulatory authority, public hospitals, private sector companies, wholesalers and manufacturers, professional associations, civil society organizations and international organizations.
>
> ■ Information is also extracted through a desk review from public government web sites and other relevant sources, to validate the findings.
>
> ■ Responses from methods 1 and 2 are used to score each function and calculate the vulnerability to corruption. Scoring is converted to a simple scale of 0 (maximum) to 10 (minimum) vulnerability to corruption. This scoring gives an indication of the KI's knowledge about the existence of structures and the processes in place, and to what extent these are used and enforced in the management of pharmaceutical affairs.
>
> ■ Responses from methods 3 and 4 are used to provide further richness to the information and to give KIs the opportunity to provide other information relevant to the area of assessment.

1.2.3 Overall country rankings

The quantitative results of the studies (both published and non-published) are shown in Table 1.1 below. The higher the scores are, the more transparent the function is and the less vulnerable to corruption it will be. The black circles show the functions found vulnerable in the majority of countries, and the blue circles the less vulnerable. From a first glance one can see that all countries show some weaknesses, in various degrees and in different functions, that can be overcome by filling the gaps identified.

Results for individual countries (i.e. scores for each country for each of the assessed functional areas) are given in Annex 1.

Of the eight functions of the pharmaceutical system assessed, control of medicines promotion appears to be the one most vulnerable to corruption. Selection of essential medicines and inspection of pharmaceutical manufacturers and distributors also emerged as areas

TABLE **1.1** **Rating national pharmaceutical sectors according to their vulnerability to corruption (on a scale from 0 to 10)**

Rating system (score)	Pharmaceutical functions (number of countries)							
	Registration	Licensing	Inspection	Promotion	Clinical trials	Selection	Procurement	Distribution
Extremely vulnerable (0.0–2.0)	0	0	0	5	0	1	0	0
Very vulnerable (2.1– 4.0)	2	0	3	5	2	4	1	0
Moderately vulnerable (4.1–6.0)	11	3	10	10	1	9	4	1
Marginally vulnerable (6.1–8.0)	11	3	7	1	3	9	16	8
Minimally vulnerable (8.1–10.0)	1	0	1	0	0	2	4	4
Total number of countries	25	6	21	21	6	25	25	13

Source: See reference *10*

with greater vulnerability to corruption (see Table 1.1, results ringed in black). In most of the countries surveyed, systems and procedures governing the procurement and distribution of medicines appear to be fairly robust, and the necessary documentation in place, implying that these functional areas are generally less vulnerable to corruption. (see Table 1.1, results ringed in blue).

Comparison of the national assessments reveals an almost universal lack of public access to information about the pharmaceutical sector (e.g. details of legislation, regulations and written procedures). There is also a widespread lack of formalized selection criteria for membership of national drug selection committees (in 18 out of 25 countries) and at least 19 countries acknowledged that their drug registration committees did not have proper (i.e. documented) operating policies and procedures. In those countries where this type of information did exist, it was not always made available to the public. Conflict of interest policies were identified as another area of weakness; these were either entirely absent, or where they did exist, poorly implemented.

The assessment instrument continues to evolve to capture more information and to better suit country needs. Among the 25 countries with completed assessments, systems governing licensing and clinical trials were only examined in only six countries. (see Table 1.1). These two areas were added at a later date, and so countries who conducted their assessments early on and therefore according to an earlier methodology wouldn't have compiled data on these two areas of the pharmaceutical system.

The details of pharmaceutical areas and functions of countries assessed are discussed below.[1] Country examples of specific regulatory and supply management systems and processes are also illustrated in boxes throughout the chapter.

---

[1] Of the 26 national assessments, 14 have been published to date. The other 12 are being cleared by the government or the report is being finalized by the NAs. In this chapter countries have been named if the report has already been published (whether positive or negative findings). For non-published information we are using only the positive and validated results from countries.

1.2.4 Registration of medicines

In terms of the systems for medicines registration, identified common weaknesses include a lack of written terms of reference for government committee members who determine which medicines should be registered in the market and an absence of both selection criteria and conflict of interest policies for committee members. Even in those countries where procedures for conflict of interest disclosures had been established, many were neither mandatory nor sufficiently comprehensive to have a meaningful impact. For example, in the Philippines, while public sector representatives are covered by a conflict of interest policy, at the time of the study (2005), consultants employed in the private sector were not (*12*). As many as 14 countries reported that there is a perception that gifts and other benefits offered to public officials in charge of medicines registration have had an influence on decision-making. A similar number of countries do not have a formal appeal process for medicines that were refused registration.

Conflict of interest disclosures in many countries were neither mandatory nor comprehensive.

Among the reporting countries, Thailand provides a good practice model, as medicine registration is well documented, the requirements are standardized and public information is readily available.[1]

1.2.5 Licensing of pharmaceutical establishments

So far, assessment of the effectiveness of pharmaceutical sector licensing systems has been limited, this being an area of regulatory activity that has only recently been added to the good governance assessment methodology (see Table 1.1). However, in the six countries that have conducted this part of the assessment, there does appear to be some degree of regulation of the activities of pharmaceutical agents and pharmaceutical companies. All countries scored moderately or marginally vulnerable. Legislation governing the licensing of pharmaceutical agents and companies exists in all six countries and companies are inspected regularly. For example, Costa Rica has adopted legislation requiring the licensing of local medicine manufacturers, and all importing and exporting agents and distributors, as well as the inspection of premises and facilities used to manufacture, store or distribute medicines. There is also a standard checklist which has to be used to assess each application for the relevant licence. However, in most countries, criteria for membership of committees responsible for licensing were poorly documented and opaque. The absence of conflict of interest policies was also highlighted as an area of concern.

1.2.6 Inspection of facilities

Inspection of manufacturing and distribution centres was identified as another high risk area in medicine regulation that is prone to corruption. Table 1.1 shows that among the 21 countries in which the inspection system has been assessed, 3 (14.3%) were found to be "very" vulnerable to corruption and of the remaining of 18 countries, 10 (55.6%) were found to be "moderately" vulnerable to corruption. On the basis of these data, it would appear that in general inspection systems are not well organized and are operating below par.

Lack of procedures and documentation is common.

A common finding was the general lack of proper procedures and documentation relating to the inspection of facilities; either such information was not available or, where it did exist, it was not easily accessible by the public. In one African country, Benin, for example, there was

---

[1] For example, information about the requirements needed to register medicines is available on a web site: (http://www.fda.moph.go.th).

no written record of the criteria used to select and recruit inspectors, a critical mechanism for ensuring independence and honesty in the inspection process. In another country, a critical gap in the inspection process was the absence of any statutes for pharmaceutical inspection.

BOX **1.2**

> ### Jordanian legislation on inspection of medicine manufacturers
>
> In Jordan, comprehensive provision in the legislation covering the inspection of medicine manufacturers and distributors was described as beneficial. This provision includes written guidelines on the classification of good manufacturing practices non-compliance (which describe the types of deficiencies and the corresponding measures to be taken by the national medicines regulatory authority) and written standard operating procedures for inspectors on how to conduct an inspection. There are also stipulations that the inspection findings and conclusions be subject to an internal review by the head of the inspection department.

1.2.7 Control of medicines promotion

As mentioned above, medicines promotion control emerged as one of the weakest functions of the pharmaceutical sector. A lack of resources was identified as being the main reason for the high vulnerability to corruption and unethical practices in 20 of the 25 countries that undertook an assessment of this area of activity. Insufficient or no staff, no unit dedicated to the task of monitoring promotional activities, and no standard operating procedures were also frequently cited as being problematic. Although many countries have passed legislation on marketing standards, in many cases, it lacks depth and breadth; the existing laws do not cover all aspects of promotion and it is easy to find loopholes to exploit. The public and even health professionals are often unaware that such legislation even exists. Moreover, sanctions for breaches of the law are poorly enforced. For example, many countries have no formal legal procedures for making complaints about unethical promotional campaigns and practices, and in some only advertising of non-prescription medicines in the mass media is regulated.

BOX **1.3**

> ### Macedonian legislation on medicines promotion
>
> In one European country Macedonia, current legislation bans the advertising of prescription medicines. It is strictly forbidden to publicly advertise a non-prescription medicinal product by associating it with its therapeutic characteristics; overstating its positive effects; exaggerating and describing effects of a medicinal product in an inappropriate manner; comparing it with other medicinal products; or misleading medicinal product users in any other way.

1.2.8 Control of clinical trials

As a standard method for analysing systems for regulating clinical trials has been developed and added to the Good Governance assessment tool only recently, only six countries have completed this part of the programme. Nevertheless, a number of common weaknesses have emerged, including a general absence of systems and procedures for the inspection of clinical trials, a lack of transparency concerning committee membership and very limited conflict of interest policies..

1.2.9 Selection of essential medicines

A positive finding to emerge from the review of national good governance assessments is that, overall, countries are using national essential medicines lists commensurate with WHO standards to guide their medicines selection and procurement. However, public access to information relating to the processes used to update national medicines lists was found to be limited in many of the participating countries.

Governance of selection committee was poor, with no defined terms of reference, no conditions and duration of tenure.

A number of other common, systematic weaknesses were identified. For instance, in many cases national essential medicines lists are not developed in consultation with core stake-holders and not disseminated sufficiently widely. Updating is irregular and is often too infrequent. In common with other areas of activity in the pharmaceutical sector, committee governance was found to be poor. For example, many countries do not have clearly defined and publicly available terms of reference that detail the responsibilities of the essential medicines selection committee members, and the terms and conditions and the duration of their period of tenure on the committee. How committee members are selected is often not specified. While some countries have made efforts to ensure that there are conflict of interest forms available, their use is not necessarily mandatory; this can lead to situations in which an appointed medicine selection committee member could have ties to a manufacturer or a supplier. In the Lao People's Democratic Republic, for example, at the time of the assessment (2005) there were no laws or regulations prohibiting members of the medicine selection committee from accepting support in kind or in cash from pharmaceutical companies. In approximately one quarter of the countries, there are no written criteria for the selection process for including or deleting medicines from the national essential medicines list. In Malaysia, at least at the time of the assessment (2005), almost all information relating to the process of medicines selection was not made public.

1.2.10 Procurement of pharmaceuticals

Surprisingly, vulnerability to corruption in procurement was revealed to be low. Only four (16%) out of 25 countries had procurement systems that were classed as "moderately" vulnerable to corruption and only one was found to be "very" vulnerable to corruption. Most countries claim to have instituted formal systems to regulate and monitor how procurement and tendering take place. In addition, written standard operating procedures are common-place and tendering committees for the most part well established.

BOX **1.4**

> ### Kenyan procurement procedures
>
> A good example was found in Kenya where there are transparent and explicit procedures for procurement, which are heavily informed by the Public Procurement and Disposal Act. A description of the internal process the procurement staff follows is available so that all employees are familiar with the due process of procurement. The procurement office monitors supplier performance for compliance with the contract terms and it is also audited on a regular basis. There is a tender committee whose functions are clearly separated from the functions of the procurement office. There is also a formal appeals process for applicants who have their bids rejected.

Despite these notable successes, several examples of weaknesses in the tendering system and process – generally regarded as an area that is very susceptible to bribery – were exposed. Some countries admitted to having no clear criteria upon which to base procurement committee membership. Procurement committee governance, as in many other areas of activity, tends to be limited by a lack of publicly-available, transparent terms of reference for members and for the committee itself. Malawi is just one example of a country in which basic procurement and tender documents are not made public (*13*).In Cambodia, there are no standard operating procedures for the procurement of medicines.

1.2.11   Distribution of pharmaceuticals

Distribution, like procurement, reveals high transparency scores in most countries. The current good governance assessment methodology examines the robustness of systems for medicines procurement and distribution largely from the point of view of the purchase and subsequent delivery to, and management within, central warehouses. The methodology does not cover the distribution of medicines to regional warehouses and health facilities. This may explain the high scores, as leakages and diversions of medicines once they have left the central warehouse are not captured. An example of good practice is provided by Jordan, where not only are medicines purchased by the government easily identified (by special imprints on both containers and packaging), but there is also a systematic and orderly shelving of products in the warehouses (*14*).Stock is routinely inventoried and procedures are in place for monitoring movements in and out of the warehouses to other parts of the distribution system. In addition, the distribution warehouses are regularly subjected to internal and external auditing. A computerized system provides up-to-date-information on stock levels to health facilities. Sanctions are imposed on any individuals found guilty of theft or other corrupt practices.

Elsewhere, however, deficiencies in distribution system functions were noted. In as many as eight countries, key informants (KIs) reported that gift-giving is needed to expedite the medicine distribution process and the port clearing process. In Lebanon, the national assessor (NA) found that there was no security management system at the central drug warehouse. In addition, even though the country has multiple levels and points of distribution, there was no computerized program to link these.

1.3   REVIEW OF LESSONS LEARNED

To date, 26 countries worldwide have either finalized or will soon complete their good governance assessments (see Table 1.2) (*10*).This level of response to the launch of the good governance for medicines initiative has far exceeded expectations. It indicates that not only is there real interest in addressing corruption in the health sector but also that this issue is increasingly being recognized as something that is detrimental to the intended public health outputs of the pharmaceutical sector.

A number of useful lessons have been learned that will hopefully help make the implementation of the GGM programme more seamless in the future. They include the following:

- Countries with a dedicated, well-resourced team generally fare better in terms of advancing the GGM programme; also high-level political support is essential for the sustainability of the programme. Both need to go hand-in-hand.

- An infrastructure that allows close collaboration between relevant governmental institutions and key stakeholders of the pharmaceutical sector is another contributory factor

to successful implementation of the GGM programme. These include anti-corruption agencies, the private sector, civil society organizations and academia.

■ Preventing corruption and promoting good governance and integrity in the health sector is a new area of work for health professionals in most countries. There is a need to build capacity and new leadership combining both pharmaceutical management and good governance skills so that good governance is naturally integrated in daily activities. GGM training workshops ensure that these new issues are promoted not as theoretical models, but in concrete terms to facilitate application.

■ The speed of progress will vary depending on country contexts. This is not an issue. What matters is that change is sustained over time and that countries keep progressing until good governance is institutionalized and becomes an integral part of pharmaceutical management.

■ The importance of follow up and institutionalization of the GGM programme cannot be underestimated. Unless national governments take steps to implement the recommendations made in the GGM assessment reports, and integrate the promotion of good governance in national plans of action, there is little hope of progress in the global fight against corruption.

Thailand is one country that has reached phase III, with a number of significant achievements as shown in the box below.

BOX **1.5**

Good governance and ensuring access to medicines: Thailand

In 2004, Thailand decided that the WHO Good Governance for Medicines programme would support its goals of increasing transparency and ensuring access to medicines while saving precious resources.

Progress after five years
Lower costs for quality medicine procurement: the number of hospitals with best practices in medicines procurement has increased. A pooled medicines purchasing scheme by hospitals has been established, with an agreed list of medicines and suppliers.

National attention focused on the problem: national pharmaceutical laws and regulations have been reviewed. A national database on good governance in drug systems, containing publications and articles on corruption, unethical practices and corrupt cases has been developed.

Information more readily available: newsletters, public communications, including media, brochures, and web sites have been created. The minutes from national medicine meetings are publicly available and the topic of "good governance" has been added to the curriculum of 15 Faculties of Pharmacy.

Positive effects beyond the Ministry of Public Health
■ Cooperation of the Ministry of Public Health with universities and the Food and Drug Administration of Thailand, as well as internationally with other GGM participating countries.

■ The GGM made possible the exchange of information and experiences that has helped in introducing new ideas and ways of doing things.

■ There is a more systematic approach and strategy, and a clear direction with goals to meet against a timeline and a greater focus on transparency

TABLE **1.2**   **GGM milestones: programme status as of June 2010**

GGM phase	Milestones	Number of countries
Phase I	National assessors trained	26
	Transparency assessment completed	25
	Transparency assessment report drafted	25
Phase II	National GGM workshop	19
	National GGM team nominated	15
	Transparency report officially published	14
	Draft national GGM framework	11
	National GGM framework officially adopted	5
Phase III	Approved national GGM plan of action	5
	Training of national GGM team	4

1.4   **FUTURE CHALLENGES AND PRIORITIES**

Improvement in committee governance in every area of the pharmaceutical sector is needed in almost every country.

It is particularly noticeable that in every area of the pharmaceutical sector and in almost every country, there is a need for improvements in committee governance arrangements. The types of measures that need to be introduced typically include justification for committee membership, terms of reference for committee members, conflict of interest policies, and descriptions of the purpose of the committees. Improved coordination and communication between pharmaceutical departments would also pay dividends in terms of improved pharmaceutical governance. For the most part, these much-needed reforms are low cost and fairly easy to implement, yet their potential impact, in terms of improving transparency in the pharmaceutical sector and ultimately access to medicines, is likely to be significant. The deciding factor is rather government willingness to make the necessary changes, backed by a commitment to see them through.

Future challenges include ensuring that countries' initial enthusiasm and commitment to improving their governance is sustained and that countries progress their GGM programmes, within a reasonable timeframe, from Phase I through to Phase III, while recognizing that in times of economic hardship governance is more likely to have to complete with many other demands on resources. Highlighting the clear connections between good governance, reduced levels of corruption and economic benefits will help to strengthen the case for investment in good governance. WHO is committed to working with countries to help them advance their GGM programmes.

The second major challenge is building sufficient capacity nationally to promote good governance in pharmaceutical systems. Even though 26 countries have committed to GGM programmes, more training is required in countries in leadership, integrity, communications and advocacy campaigns, and other anti-corruption components necessary for good governance initiatives. These need to be tailored to the pharmaceutical sector and once in place will ensure the continuity of GGM efforts.

Thirdly, lessons learned need to be reported and disseminated more widely, so that countries can benefit from the experience of others. This type of information also helps WHO refine and further improve the relevance of its good governance policy guidance and technical documents. Increased use of modern communications technology tools, such as electronic discussion groups, should be made as these provide governments and GGM focal points with ready lines of communication, helping to keep the issue "alive" and encourage "cross-country" learning.

Finally, the reality is that without ongoing donor commitment, the gains made by the WHO Good Governance for Medicines programme in countries will not be sustained. It is important to foster global advocacy for good governance in the pharmaceutical sector. The rationale for investing in good governance in this sector is compelling: it is essential if countries are to make the health gains associated with improved access to quality medicines and their rational use. It is also essential to ensure that donor funding is not wasted and reaches those it is intended for.

REFERENCES

1. *Spending on health. Fact Sheet No. 319*. Geneva, World Health Organization, 2004. Available at: **http://www.who.int/mediacentre/factsheets/fs319/en/index.html**

2. *Handbook: Curbing corruption in public procurement*. Berlin, Transparency International, 2006. Available at: **http://www.transparency.org/publications/publications/other/procurement_handbook**

3. IMPACT. *Counterfeit Drugs Kill!* Geneva, World Health Organization, 2008. Available at: **http://www.who.int/impact/FinalBrochureWHA2008a.pdf**

4. Empowering the poor to fight corruption [PovertyNet web site]. Washington, DC, The World Bank, 2009. **http://go.worldbank.org/APAR27YJ50**, accessed 8 May 2010

5. UN Secretary-General's message on International Anti-corruption Day, 9 December 2009. **http://www.un.org/News/Press/docs/2009/sgsm12660.doc.htm**

6. Cohen JC, Mrazek M, Hawkins L. Corruption and pharmaceuticals: Strengthening good governance. In: Campos JE, Pradhan S, eds. *The many faces of corruption: Tracking corruption at the sectoral level*. Washington, D.C., World Bank Publications, 2007:30.

7. Cohen JC, Mrazek M, Hawkins L. Tackling corruption in the pharmaceutical system worldwide with courage and conviction. *Clinical Pharmacology and Therapeutics*, 2007, 81(1):445–449.

8. *WHO Medicines Strategy: Countries at the core 2004–2007*. Geneva, World Health Organization, 2004. Available at: **http://apps.who.int/medicinedocs/en/d/Js5571e/**

9. Medicines Transparency Alliance web site: **http://www.medicinestransparency.org/about-meta/**

10. Baghdadi G, Cohen-Kohler JC, Wondemagegnehu E. *Measuring transparency in the public pharmaceutical sector: Assessment instrument*. Geneva, World Health Organization, 2009. Available at: **http://www.who.int/entity/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG**

11. *Good Governance for Medicines programme. Progress Report. February 2009*. Geneva, World Health Organization, 2009. Available at: **http://www.who.int/entity/medicines/areas/policy/goodgovernance/ggmprogressreport_feb09.pdf**

12. *Measuring transparency in medicines registration, selection and procurement: Four country assessment studies (Lao People's Democratic Republic, Malaysia, Philippines, Thailand)*. Geneva, World Health Organization, 2006. Available at: **http://www.who.int/entity/medicines/areas/policy/goodgovernance/Transparency4CountryStudy.pdf**

13. *Measuring transparency to improve good governance in the public pharmaceutical sector in Malawi*. Geneva, World Health Organization, 2008. Available at: **http://www.who.int/entity/medicines/areas/policy/goodgovernance/ MeasuringTransparencyMalawi/en/index**

14. *Measuring transparency to improve good governance in the public pharmaceutical sector: Jordan*. Cairo, World Health Organization Regional Office for the Eastern Mediterranean, 2006. Available at: **http://www.emro.who.int/publications/Book_Details.asp?ID=968**

ABBREVIATIONS

GGM	Good governance for medicines
KI	Key informant
NA	National assessor

Annex 1

Country	WPRO						SEARO		AFRO						EMRO					PAHO				EURO	
	A	B	C	D	E	F	A	B	A	B	C	D	E	F	A	B	C	D	E	A	B	C	D	A	B
Registration	5.1	6.8	7.7	5.6	6.8	4.3	6.9	7.2	4.0	5.5	4.7	4.3	4.8	7.0	6.5	6.0	5.1	7.5	5.7	6.2	8.6	6.1	4.4	5.8	6.8
Promotion	5.1		4.4			1.7		7.6	1.3	2.6	2.0	4.5	1.4	5.1	4.9	3.8	4.5	1.9	3.6	4.7	4.7	5.0	3.8	4.7	2.4
Inspection of Production	5.0		6.3			2.6		8.7	4.4	4.6	3.7	4.0	4.3	8.0	7.3	5.7	5.9	5.8	7.1	4.3	6.2	7.8	6.0	6.5	5.3
Selection	6.2	6.2	4.8	6.1	5.8	4.5	8.0	5.5	4.2	3.9	3.7	3.0	1.6	5.2	4.4	3.2	5.7	7.7	6.7	8.0	7.6	8.3	7.2	6.5	4.9
Procurement	5.4	8.5	6.9	6.9	7.2	6.6	7.1	7.0	5.9	5.1	4.7	7.0	3.5	6.7	6.7	6.5	6.3	8.6	7.5	8.1	6.2	8.1	6.0	6.7	7.1
Distribution									9.2	4.6	6.6	7.8		9.6	8.4	7.2	6.6	8.4		7.8			7.1	7.6	7.7
Licensing											5.8	5.2				6.8	7.4			6.3					4.5
Clinical Trials											3.6	6.3				4.2	3.4			7.9					7.9

Legend

- 0.0–2.0: Extremely vulnerable
- 2.1–4.0: Very vulnerable
- 4.1–6.0: Moderately vulnerable
- 6.1–8.0: Marginally vulnerable
- 8.1–10.0: Minimally vulnerable
- Not measured