

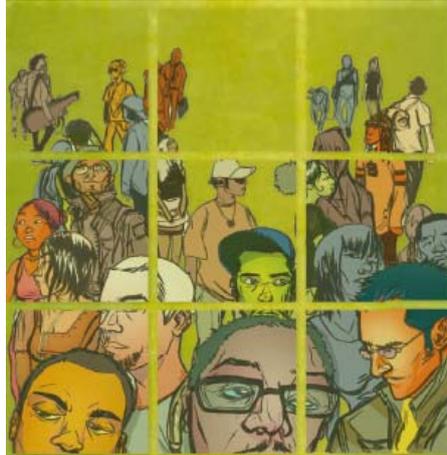


WHO Good Governance for Medicines programme: an innovative approach to prevent corruption in the pharmaceutical sector

Compilation of country case studies and best practices

Guitelle Baghdadi-Sabeti and Fatima Serhan

**World Health Report (2010)
Background Paper, 25**



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Guitelle Baghdadi-Sabeti and Fatima Serhan¹

¹ Good Governance for Medicines programme, Department of Essential Medicines and Pharmaceutical Policies (EMP), World Health Organization, Geneva, Switzerland

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Introduction

Corruption is a major obstacle to strengthening pharmaceutical systems and increasing access to quality medicines. In an effort to address this complex and multi-faceted challenge, WHO launched the Good Governance for Medicines (GGM) in 2004, its initiative to concretely address the need for transparency and preventing corruption in the health sector. Initially a pilot project in four Asian countries, the GGM grew rapidly to become a global programme implemented in 26 countries, gaining momentum in Ministries of Health (MOH).

This paper is intended to share country experiences in implementing the GGM programme in the last six years. It is based on information received from countries that have already implemented the GGM and have documented their experiences. A brief description of activities undertaken in these countries is presented below, focusing mainly on interventions at the country level that have led to changes and improvements in the pharmaceutical sector. This paper also offers a number of analyses on "best practices" and "lessons learnt" with a view to inspiring health professionals, managers and policy makers in other countries in their efforts to strengthen health and pharmaceutical systems, as well as to reach universal health coverage and increase access to quality essential medicines. It is hoped also that this paper will serve as a contribution to move forward the international anti-corruption agenda within the pharmaceutical sector and beyond.

Corruption, barrier to access to quality essential medicines

Medicines represent one of the largest components of health expenditure. The value of the global pharmaceutical market is increasing steeply over time, at a faster rate than the total health expenditure and even more than the growth of the GDP worldwide². In 2009, the total value of the pharmaceutical market was estimated at US\$837 billion³.

The sheer scale of the market makes it a very attractive target for abuse and greed is often reported as a main cause of corruption. However there are also other reasons for the sector's vulnerability. First, the pharmaceutical sector includes many stakeholders whose roles, responsibilities and accountability relationships are often not clearly defined. Information imbalances are common among different actors - for example between health care providers and patients - or between pharmaceutical companies and

² *Pharmaceutical Pricing Policies in a Global Market*. OECD Health Policy Studies, OECD, 2008

³ <http://www.imshealth.com> accessed May 14, 2010

regulators. Finally, there is a need for strong regulations, however in many countries, , regulation of the health sector is often poorly resourced and enforced.

Opportunities for corruption occur in every stage of the medicines chain before they reach the patient. Corruption can take many forms, including the falsification of evidence, the concealment of conflicts of interest, and bribery. Figure 1 illustrates key steps of the medicines chain and some examples of unethical and corrupt practices.

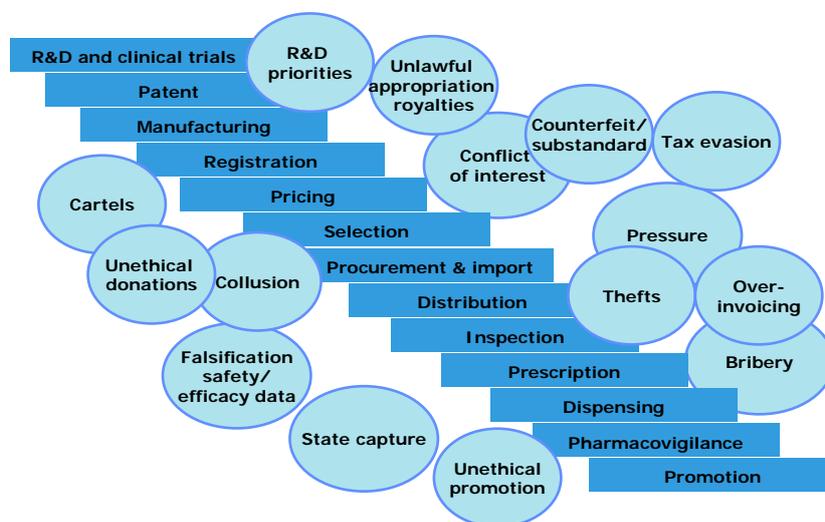


Figure 1: Unethical practices can happen throughout the medicines chain

Corruption is a matter of increasing concern for the international development agenda and is recognized as one of the biggest impediments to the world's efforts to reach the Millennium Development Goals (MDGs)⁴.

"Prices for ... medicines... are substantially much lower if procurement and distribution procedures were more efficient, corruption-free and mark-ups were reasonable." – World Health Organization Director-General Margaret Chan⁵

Corruption weakens health systems, has a direct negative impact on the quality of health services, endangers the health of entire communities, wastes limited resources and erodes public and donors'

⁴ The UN Secretary general message on the International Anti-Corruption Day, 9 December 2009

⁵ WHO Director-General Opening remarks on Creating synergies between intellectual property rights and public health, delivered at a joint technical symposium by WHO, World Intellectual Property Organization and World Trade Organization on Access to Medicines: lessons from procurement practices, Geneva, Switzerland, 16 July 2010

trust. Corruption in the health sector can be a matter of life and death. This is especially true for the poor who cannot afford to pay bribes or to use private health care⁶. Ensuring access to quality medicines is essential in reducing morbidity and mortality rates, and enhancing the quality of life. Despite many efforts to make essential medicines accessible to all, it is estimated that one third of the global population does not have regular access to them. Many factors contribute to this situation, but the lack of transparency and accountability in pharmaceutical systems are key issues⁷.

WHO's 3-step strategy to implement GGM in Ministries of Health

In 2004 WHO launched the GGM programme⁸ as part of the broader international development and health agenda focused on the MDGs and prioritizing the strengthening of health systems. The *goal* of the GGM programme is to contribute to health system strengthening and to prevent corruption by promoting good governance in the pharmaceutical sector.

The *specific objectives* of the GGM are to:

1. raise awareness of the impact of corruption in the pharmaceutical sector and use this awareness to inform the national health policy agenda;
2. to increase transparency and accountability in medicine regulatory and supply management systems;
3. to promote individual and institutional integrity in the pharmaceutical sector;
4. to institutionalize good governance in pharmaceutical systems by building national capacity and leadership.

Reducing corruption in the pharmaceutical sector will have a lasting impact on countries' investment in health care, while improving access to quality medicines. It will also reduce the waste of public and donor funding, as well as out-of-pocket expenditure. Finally, it will improve the credibility of public institutions, which in turn increases public and donor confidence in governments.

To date the willingness of governments to implement the GGM has exceeded WHO expectations. Since its launch in four Asian countries in 2004, the GGM has gained momentum in ministries of

⁶ Global Corruption Report 2006: corruption and health. Transparency International, 2006.

⁷ WHO Factsheet n° 335. Medicines: corruption and pharmaceuticals. December 2009:

<http://www.who.int/mediacentre/factsheets/fs335/en/index.html>

⁸ WHO GGM website: <http://www.who.int/medicines/ggm/>

health and national medicines regulatory authorities and is currently running at different stages in the 26 countries⁹ across the six WHO regions.

WHO proposes a 3-step model for implementation of the GGM programme that is adapted to the country context. This includes an assessment of the level of transparency in the national system, the development of a framework (or policy document) for good governance and the implementation of the national programme.

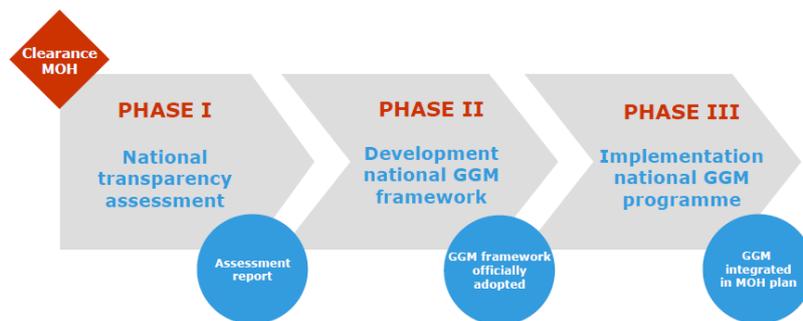


Figure 2: WHO model process to implement the GGM programme

Phase I involves a national assessment of transparency and vulnerability to corruption of key pharmaceutical system functions. Independent national assessors evaluate the country's vulnerability to corruption using the WHO standardized assessment instrument, which focuses on central functions of the pharmaceutical sector. On completion of the assessment, a report with the findings and recommendations for action is produced, providing a baseline to design interventions and monitor the country's progress over time.

Phase II concerns the development of a National GGM framework. This involves a nationwide consultation process among key stakeholders. Countries validate the results of the assessment and define the basic components necessary for good governance in their national pharmaceutical system thereby minimizing the scope for corrupt practices. The identified components are then reflected in a national GGM framework document which must be officially adopted since it provides the legal and political structure to implement them.

Phase III involves the implementation of the national programme and focuses on translating the GGM programme into action, ensuring that it becomes institutionalized and fully integrated within the MOH. This set of activities includes awareness raising campaigns, law reform, the application of new

⁹ Benin, Bolivia (Plurinational State of), Cambodia, Cameroon, Colombia, Costa Rica, Ecuador, Ethiopia, Indonesia, Jordan, Kenya, Lao People's Democratic Republic, Lebanon, Malawi, Malaysia, Mongolia, Morocco, Mozambique, Pakistan, Papua New Guinea, Philippines, Republic of Moldova, Syrian Arab Republic, Thailand, The former Yugoslav Republic of Macedonia, and Zambia.

administrative procedures for increased transparency and accountability, and building leadership capacity at all levels of ministry of health staff to manage the promotion of good governance.

GGM technical package, a concrete tool for countries on how to implement the GGM

WHO has developed a technical package to guide countries through the different phases of implementation.

For phase I, WHO has developed an *instrument to assess transparency and potential vulnerability to corruption* in key functions of the medicine chain¹⁰. The assessment has been conducted in all 26 countries and to date WHO has published the results for 14 countries¹¹. These various studies have produced valuable evidence enabling MOH and Medicines Regulatory Authorities (MRA) to identify the gaps in the systems and develop strategies to close them (see annex 1 for summary quantitative findings).

A comparative analysis of the various national assessments reveals that control of medicines promotion is often identified as the function most vulnerable to corruption. The findings also show that there is a uniform lack of public access to information about the pharmaceutical sector (legislation, regulations, written procedures) and of written selection criteria for members on drug selection committees as well as insufficient policies and procedures for drug registration committees. Other weaknesses include an absence of conflict of interest policies or poor implementation if policies are in place¹².

For phase II, WHO has developed a draft *model framework for good governance in the pharmaceutical sector*¹³ defining the basic components necessary for good governance, such as a code of conduct, collaboration with other anti-corruption and good governance initiatives, and a whistle blowing mechanism. To date 11 countries have developed national frameworks – five have been officially adopted (Bolivia (Plurinational State of), Jordan, Lebanon, Malaysia and Thailand) and six have been drafted (Lao People’s Democratic Republic, Mongolia, Philippines, Republic of Moldova,

¹⁰ Measuring transparency in the public pharmaceutical sector: Assessment instrument. WHO/EMP/MAR/2009.4

<http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeasTranspENG.PDF>

¹¹ All published country assessments are available on

<http://www.who.int/medicines/areas/policy/goodgovernance/documents/en/index.html>

¹² For a comparative analysis of transparency assessment reports, please refer to the 2010 World Medicines Situation (GGM chapter) or to individual country assessment reports available on

<http://www.who.int/medicines/areas/policy/goodgovernance/documents/en/index.html>

¹³ A framework for good governance in the pharmaceutical sector: working draft for field testing and revision:

<http://www.who.int/medicines/areas/policy/goodgovernance/WHO-GGMframework.pdf>

Syrian Arab Republic and The former Yugoslav Republic of Macedonia). Experience has shown that in order to have a significant impact on corruption the coordinated application of two complementary strategies are needed:

- A "discipline approach," based on legislative reform, establishing the laws and administrative structures and processes needed to ensure transparent medicines regulation and procurement systems. The "discipline approach" tends to be top-down.
- A "values approach," promoting institutional integrity through moral values and ethical principles and attempting to motivate ethical conduct by public servants. The "values approach" tends to be bottom-up.

For Phase III, WHO has developed a *guide to promote good governance*. The guide for phase III is a working document and assists countries in implementing the national framework. It promotes awareness among health professionals and the general public on the potential for corruption and its impact on health system functioning, and focuses on building national capacity to sustain good governance in the pharmaceutical system. It is currently being revised in the light of various successful experiences. Additionally, the achievements, the best practices and the lessons learnt described in the subsequent paragraphs are intended to serve as a guide for action for all countries interested in promoting anti-corruption efforts in their pharmaceutical agenda.

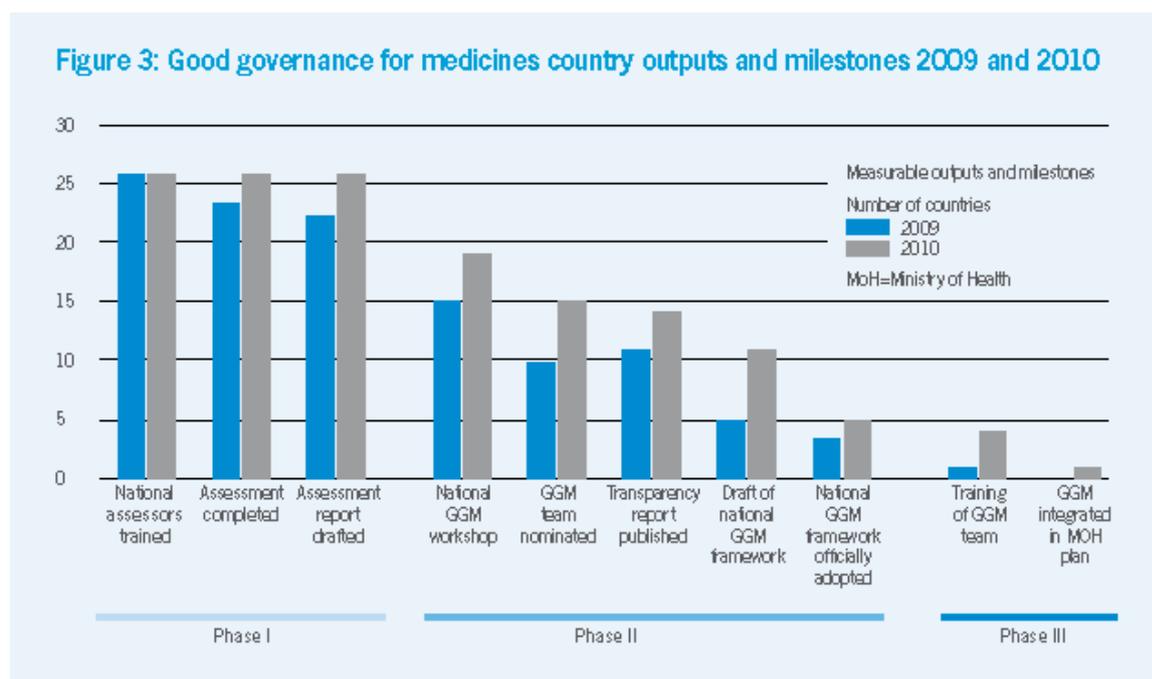
To date, 7 countries are in phase III of the implementation namely, Bolivia (Plurinational State of), Jordan, Lebanon, Malaysia, Mongolia, Philippine and Thailand. Combating corruption and promoting good governance in the pharmaceutical sector requires a long-term strategy for action. While structural and procedural changes are an important step, to be effective the programme must also address some practices that may be part of the culture and the locally accepted way of doing business.

In addition to technical tools and guidelines, WHO has developed *training modules for each of the three phases*, which are designed to build the capacity of the GGM national teams to accompany them through the implementation of related activities. Progress in implementing the GGM programme varies from country to country, depending on the political situation, the availability of human resources, as well as the cultural or social context. Nevertheless, momentum for change is increasing and the GGM programme often becomes one of the top priorities items on the MOH agenda, especially in phase III countries.

The impact of the GGM programme is already visible in countries

As already stated, having started with just four pilot countries in 2004, the GGM programme now has twenty-six countries at different stages of implementation. Interest in the programme has exceeded expectations. Good governance has been identified as a national health priority by ministries of health in most participating countries and is increasingly being institutionalized. Due to limited resources, WHO's priority of the last two years has been to entrench the programme in participating countries and consolidate results rather than to expand to reach new countries. The programme aims to have all countries move to phase III and fully institutionalize the good governance principles within their national health systems.

WHO has established an annual monitoring and reporting system for participating countries to report on their activities. A summary of key country outputs and milestones that underline progress in the three phases are presented in Figure 3.



The impact of the GGM programme is already visible in different areas of the pharmaceutical sector. For example successes include more transparent medicine procurement leading to fairer competition between suppliers and savings, the revision of national pharmaceutical laws and regulations to meet internationally recognized standards, more transparent procedures for selection of essential medicines, market authorization and licensing of pharmaceutical activities and information related to the medicines chain publicly available on MOH websites.

Countries also report improved management of conflict of interests and a new culture of transparency in their institutions. The following country examples illustrate some of the GGM programme's impact on increasing transparency and improving practices in the medicines chain. They include examples from all phase III countries and two phase II countries¹⁴.

When asked "what was the main reason your country wanted to implement the GGM programme?" national counterparts from Ministries of Health provided the following answers:

- Reducing corruption was recognized as the missing link to achieve development and health goals
- To improve access to essential medicines, especially for the vulnerable populations
- Further promote the development of the pharmaceutical sector and systems
- Have a systematic approach to institutionalize transparency, efficiency, cost containment and governance in all pharmaceutical functions
- Well structured model process for implementation
- Opportunity with concrete tools and strategy to implement government anti-corruption priority
- Prevent instances of corruption
- Build capacity in pharmaceutical sector on societal issues and health systems of the country
- Increase awareness on the impact of corruption
- Regaining MOH stewardship in health
- Development and maintenance of a sound health system with high standards
- Be part of a network of countries working on this issue to exchange experiences and learn from each other

Box 1: Why countries want to promote good governance in the pharmaceutical sector.

Bolivia (Plurinational State of)

GGM was started in 2006 with the national transparency assessment as part of the efforts to improve governance. A ministerial decree resolution was issued in March 2007 approving GGM phase III implementation. The Pharmaceutical and Health technology unit of the MOH (UNIMED) is the key responsible agency for the implementation of the GGM programme and focuses currently, internally and throughout the country, on the establishment of the Quality Management System with Standard Operating Procedures (SOP) for application of all norms, as well as the socialization of ethical values within UNIMED.

There is a project agreement between the Ministry of Health and Sports, WHO regional office and Núr University to work with the university students for promotional and socialization activities. The new agreement will involve the Transparency Unit of the Ministry of Health and the Vice Minister of Transparency and Anticorruption. Meanwhile a series of national training workshops in phase II and III have been held to train professional pharmaceutical personnel on transparency, good governance and moral leadership.

¹⁴ This information below on country activities is based on information available in WHO/HQ at the time of the drafting of this paper and certainly does not cover all activities on-going at the moment in all countries. More will be reported on a regular basis as information become available and shared with WHO.

In phase III there was a strong communications strategy which included: newsletters written in a simple and comprehensible language (in Quechua, Aymara and Spanish) to promote good governance within health care professionals. Key messages included: "Transparency for change". There were also radio spots and posters.

Work has also been done on the implementation of the transparency assessment studies recommendations (conducted in 2006 and 2009), resulting in:

- the posting of a number of documents on the website making them available to the public;
- the re-design of the UNIMED webpages;
- the development of an "act of conformity" to ensure that inspectors declare conflicts of interest;
- the development of a manual for the procurement of medicines which is in conformity with the norms established by the Ministry of Finance.

The socialization of the GGM in different provinces has started with Santa Cruz, and the GGM country team is involving university students from La Paz and Santa Cruz who are interested in the promotion and socialization process. The GGM team has been able to overcome a number of challenges including change of government, passive attitudes towards corruption and resistance to change, as well as rotation of staff. Challenges were overcome by constant communications with key institutions and individuals, creating a multi-disciplinary team, and the involvement of Civil Society Organizations (CSO). All these activities serve to promote an institutional culture based on ethical principles and transparency.

Jordan

GGM started in 2007 with the national transparency assessment. The Jordan Food and Drug Administration (JFDA) is the key body responsible for the implementation of the GGM programme in the country. Jordan has both a GGM Steering Committee (headed by high-level officials responsible for setting the strategic directions of the GGM in the country, including approval and adoption of all documents) and a GGM Task Force which is responsible for the coordination, management and evaluation of the national GGM programme.

The GGM Task Force members, composed for the majority of JFDA staff, took on the GGM tasks in addition to their numerous other duties. Despite some preliminary resistance - mainly due to the fact that integrating anti-corruption and good governance measures in pharmaceutical activities was unfamiliar - the GGM programme has progressed quite smoothly in Jordan.

One of the 1st tasks undertaken by the GGM team was to develop the national GGM framework which was officially approved in 2009. It is available in Arabic and English. The GGM framework was officially launched in 2010, during a national workshop where the implementation plan was also presented. The programme runs parallel to the Medicines Transparency Alliance (MeTA), another initiative seeking to improve access to quality essential medicines by increasing transparency and accountability in the pharmaceutical sector. Activities of the GGM programme and MeTA are mutually supportive (e.g. sharing instruments, reports, data, people involved).

Since the GGM programme was introduced in Jordan, the JFDA has been very active in implementing the recommendations included in the transparency assessment and the changes reported include:

- a revision of the provisions on medicines promotion and advertising which now cover a wider range of different forms of promotion, and which also foresee an enforcement mechanism stating the sanctions in cases of violation;
- the development of clear criteria for the selection of members of the essential medicines selection committee.

Lebanon

Over the past few decades Lebanon has endured recurrent conflicts and instability that have severely impacted the health sector. As a result, in the 1990s Lebanon was faced with a weakened primary health care system, unrestricted growth of high technology health sector and high cost pharmaceuticals where the private sector played a prominent role. As part of its commitment to health system strengthening, the government adopted the GGM programme in 2007. Despite the challenging political situation faced by Lebanon at the time of GGM programme initiation, the MOH showed considerable commitment at a high level to institutionalize both transparency and accountability concepts in every aspect of medicine policy and management practice within the ministry.

The transparency assessment of the pharmaceutical sector identified a number of gaps which resulted in a number of changes at different levels. One of the gaps identified and immediately tackled was related to the national Good Manufacturing Practices (GMP) standards which was dated 1983. A national GMP committee was formed by ministerial decree no. 212/1, dated 18 March 2008, to update the national GMP. This committee included members from the private and the public sectors; the private experts represented academia, pharmaceutical manufacturers, and pharmacists. The revised GMP guidelines, officially adopted on 28 May 2009, are based on WHO GMP guidelines, the GGM transparency assessment findings and adjusted to the Lebanese law of pharmacy.

A group of experts from the MOH, academia and the pharmaceutical sector were also nominated in the GGM Task Force, which is responsible for the overall monitoring and implementation of activities. The group developed the national GGM framework, based on the WHO GGM framework model, and it was recently adopted by the MOH. It includes a national code of conduct, compilation of regulations and administrative procedures, mechanisms for collaboration with other good governance and anti-corruption initiatives, whistle-blowing mechanisms and sanctions for reprehensible acts that work within the framework of Lebanese laws.

Other key changes based on the transparency assessment recommendations include:

- Creation of a new committee responsible for the revision of the national essential medicines list (EML). The new EML is currently being developed.
- MOH tender list prepared using generic names since end of 2008.
- Draft of ethical code for medicine promotion developed and placed on the MOH website to be reviewed by all stakeholders before being finalized.
- The development of written procedures, terms of reference, roles, responsibilities and professional qualifications of members for all committees.
- The enforcement of a conflict of interest form as of 21 October 2010, to be filled by all members of MOH committees dealing with pharmaceuticals, including the registration, pricing and GMP (Good Manufacturing Practices) committees.

The challenges faced include poor understanding of transparency and good governance, fear of being evaluated (during phase I), and resistance to change. Despite these challenges, the MOH commitment, the dedication of the GGM programme team, the involvement of the public and private sectors, have all helped to reach the goals set.

Malaysia

Malaysia was one of the first four Asian countries to join the GGM programme in 2004. A strong pharmaceutical system was already in place and the GGM programme was introduced to complement many other governmental initiatives to increase transparency in the health systems. Success is evident in the key steps undertaken to institutionalize the GGM and in its adoption by the Malaysian Pharmaceutical Services Division (PSD). The key steps towards institutionalizing the GGM in Malaysia include to date:

- Development of the GGM framework, in line with the National Integrity Plan which is the mother of all integrity plans.

- Establishment of the GGM Steering Committee.
- Establishment of the GGM Task Force.

Despite the number and diversity of stakeholders in the pharmaceutical sector, the MOH is committed to fighting corruption and it is reported that the number of public servants caught in corrupt activities has decreased in the past 3 years. Activities designed to increase awareness of the potential for corruption in the pharmaceutical sector have been conducted, including seminars, workshops and awareness campaigns. A series of brochures on integrity have been issued for all public servants and an audit value management system has been put in place.

The increased level of transparency is evident with the constant enhancement of administrative procedures throughout the medicines chain. Changes introduced to date include:

- Online services, including registration of medicines.
- Information available on the MOH website, such as the list of essential medicines and registration forms for medicines
- Implementation of conflict of interest policy for various committee members has been enforced since 2008
- The results of tenders are posted on the web;
- Transparency is on the agenda of the hospital drug committee meetings.

It should be noted that the changes are the result of a combination of various programmes put in place by the government, in addition to the GGM programme, including the Government Transformation Programme and the national mission for achieving vision 2020 – designed to help Malaysia become a fully developed nation.

Republic of Moldova

The Republic of Moldova joined the GGM programme in 2008 and is one of the two countries in the European region implementing the GGM. The GGM national team, nominated by the MOH, has shown very high commitment to follow through with GGM implementation despite the political instability following the presidential election in 2009. The National Medicines Agency is leading the implementation process. The GGM team started working with pharmacists to develop regulations, SOP for each function that revealed weaknesses in the national transparency assessment report. Educational materials and educational activities to promote the GGM programme have also been disseminated. To date, success is reflected in the MOH orders to approve a guide on medicines procurement, a code of ethics for medical and pharmaceutical workers and the monitoring of drug promotion.

Key changes in improving transparency since the assessment was done include:

- in the area of licensing of pharmaceutical establishments, a formal committee that assesses applications is now in place and written guidelines for assessing applications have been developed;
- written guidelines on conflict of interest (COI) with regard to the procurement process have been developed;
- new inspection guidelines on Good Manufacturing Practices (GMP) have been developed, especially with regard to the classification of GMP non-compliance that describe the types of deficiencies and corresponding measures to be taken by the MRA are in place.

Challenges met by the team since the GGM was introduced in 2008 have included: GGM team members being too busy with other duties; resistance to change and the indifference of some stakeholders. The need for long-term planning has also presented a challenge. Obstacles have been overcome by: persistent communication to gain high-level support; beginning on the technical level to save time and move ahead; committing extra time to the GGM.

Mongolia

In 2005, WHO initiated the GGM programme in Mongolia. GGM implementation is monitored by the Ethical Committee of the MOH. The Government has integrated the GGM within its project “Support to integrity and transparency efforts till 2013”, and nominated the National Anti-Corruption Agency as the main implementing organization with the collaboration of the MOH and the State Specialized Inspection Agency.

The success of the programme has been evident in the increased transparency in the MOH procedures. Regulations and guidelines such as the Mongolian National Standards (MNS) on drug registration and prescribing, general principles for pharmacy and for drug wholesalers were reviewed and updated. In 2007 the MOH and PMD (Pharmaceuticals and Medical Devices Department) established an online registration system for "Licensing and Special Permission of Drugs and medical Devices" that was updated in August 2008 with the support of UNDP to improve related information.

Meanwhile, various educational activities developed around the GGM have been encouraged. For example a workshop promoting transparency and accountability in the health sector was held late 2009. The concept of “Moral leadership” was introduced to the MOH officials and health professionals and an action plan to socialize the national GGM framework was developed. Most recently, the MOH organized a training workshop to enhance the awareness of stakeholders from the private sector on the GGM programme and to improve their participation and collaboration to help achieve its goals. It

engaged directors, managers and executives of private pharmaceutical companies, such as manufacturing companies, retail pharmacies and wholesalers from both urban and rural areas.

Other notable developments were: the introduction of elements of the national GGM framework into the new pharmacy curriculum of the School of Pharmacy and the renewed Drug Law which was approved by the Parliament of Mongolia in 2010, incorporating a new COI declaration for the Drug Committees. It should be noted that the declaration of COI for external experts of drug registration in the Health Department was developed earlier and has already been implemented since 2009, before the Law was approved by the Parliament.

The Philippines

Philippines started the GGM programme in 2004 and was among the first four countries to join the programme. The GGM complements other initiatives already undertaken through anti-corruption initiatives and the health sector agenda on better medicines access.

Recent GGM activities include the development of a manual for good governance in registration, selection and procurement of medicines. The manual establishes the criteria, indicators and operational standards for these three medicines functions. The GGM in Philippine is a collaborative work between the MOH, anti-corruption agencies, NGOs, UN agencies, academia, WHO and donors.

In August 2008, Philippines launched a GGM awards system, in collaboration with the MeTA (Medicines Transparency Alliance) initiative as an advocacy and compliance mechanism. The awards aim to institutionalize transparency and good governance in regard to the regulation, supply and overall management of medicines in the public and private sectors. It encourages local government units, national health facilities and the private sector to develop innovative initiatives that provide models of good governance. In January 2010, three awards were given to those who have satisfactorily conformed to a number of transparency standards used to improve their systems, to recognize their efforts on good governance and transparency in medicine.

Thailand

In 1997, Thailand was in economic crisis with the devaluation of the Thai Baht. Hospitals under the Ministry of Public Health (MOPH), providing 70-80% of health and medical services, were expected to become bankrupt within two years. In addition: medicine prices were increasing; hospitals were purchasing medicines at different prices from the same companies; pharmaceutical companies offered incentives to physicians to prescribe their products; and physicians often prescribed medicines by trade name rather than generic name.

In 2004, Thailand decided that the WHO Good Governance for Medicines programme (GGM) would support the MOPH goals to increase transparency and ensure access to medicines while saving precious resources. In response, the government introduced pharmaceutical management reform: limiting the type and amount of medicines hospitals stocked, establishing provincial group medicines purchasing schemes and setting up a pharmacy information centre to share information among hospitals.

Now less than five years later, a number of GGM related achievements can already be counted. 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, resulting in lower costs for quality medicine procurement. National pharmaceutical laws and regulations have also been reviewed, while a national database on good governance in drug systems that contains all publications and articles on corruption and a collection of unethical practices and corrupt cases has been developed.

Newsletters, public communications including media, brochures, and websites have been issued; minutes from national medicine committee meetings are publicly available and good governance has been added to the curriculum of Faculties of Pharmacy. A GGM-related topic "Stopping Unethical Drug Promotion To Prevent Economic Loss from Rising Healthcare Costs" was been recently adopted at the Thai National Health Assembly. Curbing the influence of pharmaceutical firms on doctors topped the agenda. Last but not least, members of various Committees dealing with pharmaceuticals are now requested to declare their conflict of interest

The former Yugoslav Republic of Macedonia

The Government of the former Yugoslav Republic of Macedonia has identified the fight against organized crime and corruption as their top priority. This may be one of the important factors driving progress with the GGM programme since it started in 2007 despite political instability and a change of government. The GGM technical team was officially nominated and fully active in 2009. The team showed significant commitment to sharing the results of the assessment, developing the national GGM framework where the major focus has been the compilation of the laws and regulations covering the pharmaceutical sector.

The team has met a number of challenges including the usual resistance to these new concepts. At the same time the highest authorities show continual support for the GGM programme as it has demonstrated to be motivating in terms of overall strategic impact. It has a clear capacity-building

dimension and is perceived to have tremendous potential to contribute to improving overall pharmaceutical functions.

Since the transparency assessment was conducted the GGM team identified a number of priority areas for improvement including the management of conflicts of interests. The country is currently in phase II and will move to phase III as soon as the GGM framework is officially adopted.

Common challenges faced in implementing the GGM programme

Decades of efforts by other institutions such as the World Bank, UNDP and Transparency International have paved the way for sector specific initiatives such as the GGM. Increased awareness of the need to tackle this sensitive subject and the desire of a majority of honest health professionals weary and frustrated on a daily basis by corruption, makes it a less taboo area than one might anticipate. However addressing corruption with a sector specific approach, such as the health/pharmaceutical sector, is rather new. As expected in most initiatives involving a cultural change, the GGM country teams that are in the frontline face a number of challenges in initiating and implementing the GGM. The most frequently encountered challenges are summarized below.

- a. Cultural and behavioural: the most commonly reported challenge is resistance to change and to new concepts such as transparency and good governance. A passive attitude towards or tolerance of corruption is often evident.
- b. Political challenges, including political instability and delays due to bureaucracy.
- c. Managerial challenges arise as a result of rotation of staff, lack of human resources (the GGM programme needs at least one full time person in the MOH if GGM activities are to be sustained) or if the governmental involvement is undertaken at too junior a level.
- d. Technical challenges arise where governance is a new area for country counterparts and needs to be integrated in all pharmaceutical affairs (mainly as far as this concerns the health sector), where discussions regarding ethics are unfamiliar and where the implementation of transparency assessment recommendations is protracted.
- e. Time becomes an issue when the existing workload of GGM committee members slows down the implementation process, when there are other priorities in the MOH. The complexity and in-depth nature of the GGM process requires long-term planning and a sustained effort is needed to keep motivation and interest.

- f. Lack of resources can become an issue in the form of a lack of funding and/or a shortage of human resources.

Lessons learnt and "best practices" from the country interventions

There is no fixed or simple formula for preventing corruption and promoting good governance in the pharmaceutical sector. The GGM technical package provides countries with a framework for action and helps them to remain focused on the GGM objectives. At the same time it leaves sufficient scope and flexibility for countries to choose their own specific approaches. The diversity of activities reported for each country in the previous section demonstrates well how GGM country teams have creatively explored the most acceptable ways to operationalize the project and make it acceptable in the local context.

Each country needs to assess its own situation and decide what will work best. The **nine good practices** discussed in this section are based on an analysis of the various country experiences that have determined successful implementation of the GGM. They are all **mutually supportive**, and it is evident that the application of all or at least most of them will work better than simply adopting one or two interventions. This list of good practices is not intended to be exhaustive and will undoubtedly need to be revised regularly in the light of future experiences.

1. Gain political and technical support to facilitate process

- High level political support is essential to implementing activities related to the GGM programme and in approving the official documents which provide the legal and political basis for progress.
- If there is initial resistance due to various issues (other priorities, emergencies, common resistance to change, fear of stepping into a sensitive subject), continuous communication with senior executives is needed emphasizing also the political gains for supporting the GGM implementation.
- The preventive approach of the GGM programme, aimed at increasing transparency and promoting ethical conduct has been appealing to most MOH. The GGM is not about identifying bad practices or corrupt individuals/institutions, but is rather about strengthening systems so that corruption has no place.
- Political support alone is not enough. It is important to work at both the political and technical levels.

2. Identify and nominate a responsible structure for the GGM to ensure sustainability over the mid- and long-term.

- It is essential to identify from the outset the suitable 1) national assessors who need to produce quality assessment report and 2) and GGM focal point (an individual or unit) in the MOH or the Medicines Regulatory Authority (MRA) that will be responsible for GGM-related activities. This will enable smooth implementation and progress of GGM-related activities, as well as the institutionalization of the programme. Ideally the focal point should be an already existing structure (e.g. MRA) or committee (e.g. ethics committee). This focal point, nominated officially, will work closely with the GGM Steering Committee and GGM Task Force.
- Most countries have nominated 2 GGM Committees that complement each others work: a GGM Steering Committee headed by high-level officials which sets the strategic directions for the programme; and a Task Force responsible for coordinating, managing and monitoring the implementation of the GGM programme. Alternatively, some countries, especially those with limited human resources, chose to merge the roles of the Task Force with those of the focal point.
- It is important to acknowledge that in some instances the motivation of the "national champions" was so strong that they were ready to work extra time. It has been extremely touching to see the level of dedication of GGM team members in pushing forward the anti-corruption agenda in their countries. But it is also important to note that this is not sustainable in the long term. As GGM activities gain momentum and progress, it will be essential to dedicate adequate human and financial resources. Unless this is done, it will be very difficult to institutionalize GGM and ensure that activities are sustained over the long-term and reach the goals established at the outset.

3. Publish and disseminate - this is a sign of transparency.

- It is essential to publish the results of the transparency assessment results in a publication and validate them in workshops.
- Officially adopt and publish a national GGM framework, and promote its dissemination.
- Make easy gains to increase transparency by using the MOH or MRA website, both for providing services and for sharing key documents or information.

4. Engage and collaborate with a wide range of stakeholders to build trust and widen ownership

- Involve, at early stage, all stakeholders working in the area of health and pharmaceuticals, as well as in anti-corruption/integrity/good governance initiatives.
- Create a multi-disciplinary group with various partners including the Ministry of Health, Medicines Regulatory Authorities, Ministry of Justice, the national AC agency, Ministry of Finance, relevant NGOs, the private sector, and academia.
- Countries can go as far as having a high-level inter-institutional agreement, but here again one can face some resistance as a culture of collaboration is not always in place, even within various units of the same institution. This can be overcome by clear and regular communication, inviting all parties in national workshops including sessions specially designed to promote and learn collaboration.

5. Make pharmaceutical systems' procedures and information transparent by implementing the recommendations included in the transparency assessment.

- Start implementing the recommendations included in the transparency report as soon as possible. There is no need to wait for phase II or III, as a number of valuable changes, especially in terms of procedures, can already be made and are technical matters.
- Revise and update the laws, regulations and procedures as needed and that have been identified as gaps by the assessment to make them stronger and more comprehensive.
- The website has proven to be a very efficient and practical vehicle to increase transparency in MOH and MRA, both in terms of procedures and services, such as those for registration of medicines and licensing of establishments, and also for sharing information such as making an essential medicines list publically and easily available.
- Improving the management of conflicts of interest (COI) is a concrete and tangible way to start increasing transparency and promoting ethical behaviours, since COI is essentially an ethical concern. Management of COI should be applied to all committees dealing with pharmaceuticals, such as committees for registration, procurement, licensing, and essential medicines selection.
- Roll out procurement transparency principles and procedures to hospitals and other health facilities in provinces throughout the country.
- Use innovative and motivational ways to encourage health institutions to comply with transparency standards (e.g. through awards or label).

6. Focus on the culture of the institutions, as much as on enhancing systems by integrating integrity and moral leadership in all affairs.

- Corruption is generally accepted to be a moral issue and any initiative aimed at tackling corruption needs to have a moral and ethical framework.
- Improving only the systems and procedures will not be sufficient and needs to be complemented by the promotion of individual and institutional integrity
- Moral values and ethical principles can sometimes be perceived as conceptual and their concrete application in every day life is not always easy to grasp. This is the reason why the GGM programme frames integrity and moral leadership as broadly applicable cross-cutting issues and incorporates the promotion of ethics and values in training as a broadly relevant issue (introduced in all training session, rather than taught as a separate module).
- The development or revision of a code of conduct is also a helpful tool to highlight norms that need to be applied.
- Communication and advocacy campaigns are also needed to promote individual and institutional integrity, and involve the public.

7. Develop a sound and comprehensive communications and advocacy strategy with clear messages.

- With the help of communications experts identify your target audiences and develop clear communications messages for each. Target audiences can include high-level officials, MOH and MRA staff/professionals, and also the general public.
- Brief MOH and MRA staff on the GGM programme from the beginning through for example seminars, workshops, intranet or newsletters.
- Make use of advocacy and education materials such as newsletters, radio jingles, posters, and others.
- Reach out to the media to ensure coverage of GGM issues and activities.
- Celebrate International Anti-Corruption Day, held every year on 9 December.

8. Build capacity in good governance for the pharmaceutical sector, for the present and the future.

- Train leaders or experts consisting of professionals combining both the knowledge and skills of the pharmaceutical sector and of good governance, and who will promote the GGM programme at the country level (e.g. members of the GGM Task Force and Steering Committee)
- Plan national training workshops for all concerned professionals in MOH and MRA, across the country.
- Introduce GGM concepts in university curricula for students in medical sciences.

9. Implement a monitoring and evaluation mechanism to measure progress.

- Develop a monitoring and evaluation (M&E) mechanism that is specific to the objectives set in each country.
- As a first step countries can conduct the transparency assessment on an annual basis to assess how the transparency in pharmaceutical functions is progressing.

Because of

- ✓ national "champions" that are persistent and dedicated
- ✓ political will and technical support
- ✓ selection of national assessors (reputation, good collaboration with MOH) and of the GGM team.
- ✓ strong collaboration with Anti-Corruption agency, other MOH departments, pharmaceutical stakeholders, CSO, UNDP, etc.
- ✓ GGM is integrated into existing structures, and committees.
- ✓ the time-frame for implementation is adapted to each country's context
- ✓ effective communication within the MOH and by the government
- ✓ the government's willingness to institutionalize the GGM
- ✓ integrity is promoted together with legislative reforms

Box 2 Why things worked well?

Need to institutionalize good governance and anti-corruption efforts

Corruption is a multi-faceted and complex challenge, often rooted in culture. It can occur in all sectors and the pharmaceutical sector is no exception. There are no quick fixes and any policy reform intending to genuinely root out corruption will require a long-term and comprehensive strategy, including a combination of activities ensuring that all aspects are covered.

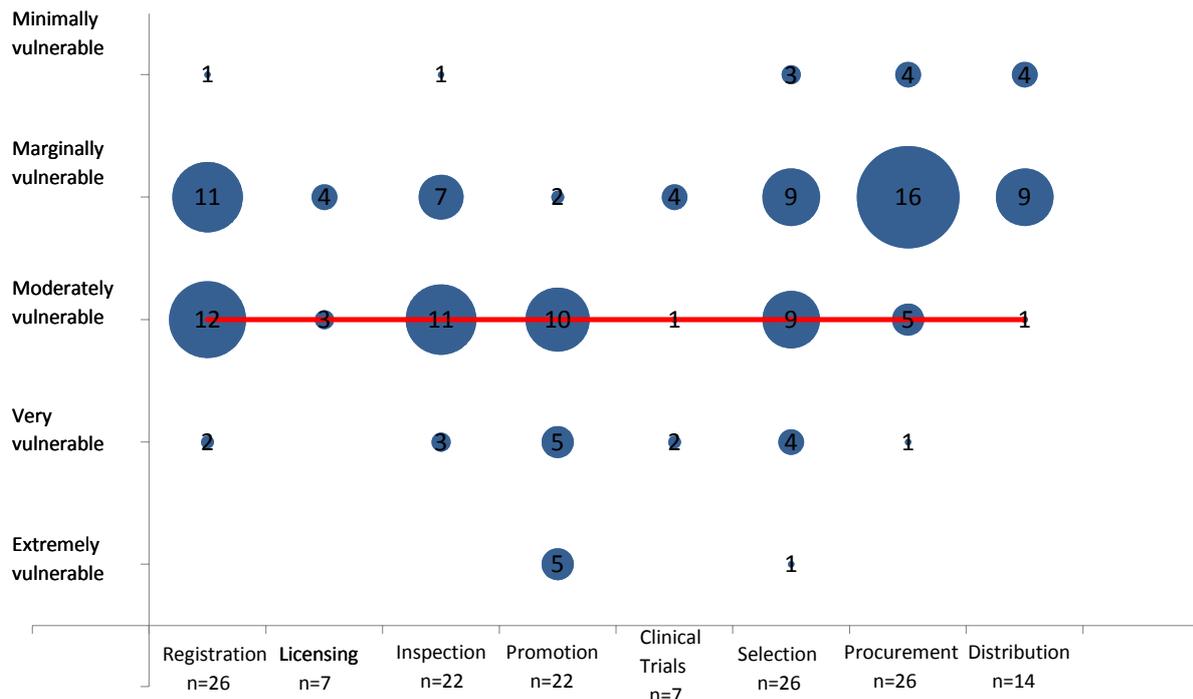
To ensure the sustainability of the GGM programmes in countries and a decent chance that efforts will continue over the long term, it is vital to institutionalize the GGM in the government structures and plans of action. The term institutionalization usually refers to the process of embedding something (for example a concept, a social role, particular values and norms, or modes of behaviour) within an organization, social system, or society as an established custom or norm within that system. Therefore institutionalization is an ongoing process in which a set of activities, structures, and values becomes an integral and sustainable part of an organization.

Institutionalizing the GGM programme in countries will not only ensure its long term sustainability, but it will also legitimize the programme, ensure its continuity despite political and management changes and establish good governance and anti-corruption practices as part of the culture. Concretely the institutionalization of GGM in national structures means that:

1. Written legal and policy documents supporting GGM are issued, including the official clearance to conduct transparency assessment and official nomination of the national assessors and the official adoption of documents (transparency assessment report & national GGM framework).
2. Resources and structures needed to support and maintain GGM activities are in place, including a GGM Steering Committee and Task Force, a unit with dedicated full time staff and equipment, and the inclusion of the GGM activities in the national plan of action, with appropriate budget & an M&E mechanism.
3. Core values are communicated and socialized to become part of the culture through norms, guidelines and procedures; training (GGM phase II & III) and advocacy (media, campaigns, awards, etc.)

Annex 1: Summary of quantitative findings in 26 countries

Rating national pharmaceutical sectors according to vulnerability to corruption



Country transparency assessment results on the level of vulnerability to corruption in the pharmaceutical sector.

Of the twenty-six countries with either completed reports or draft reports, the licensing and clinical trials functions were only examined in six countries. This is because the assessment instrument continues to evolve to capture more information and to better suit country needs.