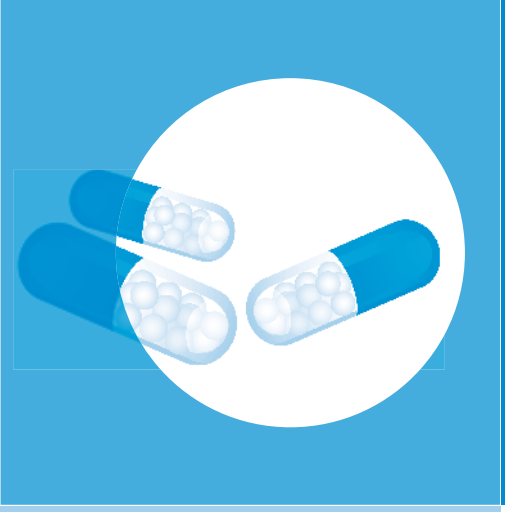


Good Governance for Medicines

Progress Report 2010

World Health Organization

"Don't let corruption kill development" - highlights one of the biggest impediments to the world's efforts to reach the Millennium Development Goals." – United Nations Secretary-General Ban Ki-moon[1]

"Prices for… medicines… are substantially much lower if procurement and distribution procedures were more efficient, corruption-free and mark-ups were reasonable." – WHO Director-General Margaret Chan[2]

Improving access to quality health care has been identified as an international development priority. Strengthening health systems is one of the areas of focus for bringing about this change. Pharmaceuticals are an important element of a functioning health system. They complement other types of health-care services, and can reduce illness and death rates and enhance quality of life. Yet, despite many efforts to make the most essential medicines accessible to all, an estimated one third of the global population does not have regular access to them. Many factors contribute to this tremendous challenge; lack of transparency and accountability being one of them.[3]

The health sector is an attractive target for corruption, with US$ 5.3 trillion spent on health services each year and a global pharmaceutical market value of US$ 750 billion. Transparency International estimates that 10 to 25 % of public procurement spending, including in the health sector, is lost due to corruption. Corruption in the pharmaceutical sector takes various forms, such as bribery of government officials, falsification of safety data and theft in the distribution chain. Corruption negatively affects access and quality of health care. Its impact is three-fold:

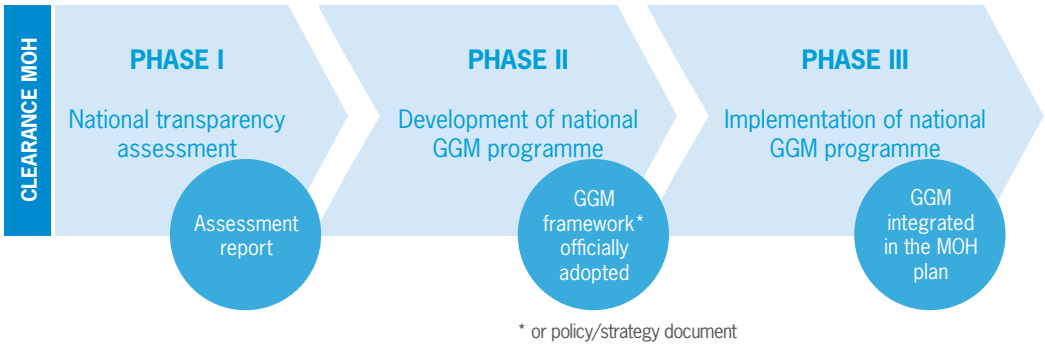
- health — loss of government capacity to provide access to good-quality essential medicines. More unsafe medical products on the market due to counterfeiting and/or bribery of officials;
- economic — low-income countries are hardest hit. Pharmaceutical expenditure may represent up to 50% of national health care costs, so corruption losses are extremely detrimental;
- trust — abuse and lack of transparency reduce the credibility of public institutions and erode public and donor confidence in governments.

The good governance for medicines programme (GGM) leads WHO's efforts to reduce corruption in the health sector. Its goal is to contribute to health systems strengthening and to prevent corruption by promoting good governance in the pharmaceutical sector. While many anti-corruption initiatives focus on the macro-level, some programmes are improving their results by using complementary sector-specific approaches. The GGM aims to complement broader anti-corruption efforts by focusing on the pharmaceutical sector.

WHO's strategy to implement GGM at the country level

WHO proposes a three-step programme that is adapted to meet the specific context in each participating country, as described in figure 1. It includes an assessment of the level of transparency in the national system, the development of a framework for good governance, and the implementation of the national programme. In 2010, the GGM is active in 26 countries.

Figure 1: The three phases of the GGM programme, a model operational process



* or policy/strategy document

Progress to date – 2010

I – GGM TECHNICAL PACKAGE AND TRAINING MATERIALS

WHO has developed a complete technical package to guide countries through each of the three phases of the good governance for medicines programme:

a) Phase I - *WHO transparency assessment instrument*[4]: The assessment instrument measures the level of transparency and vulnerability to corruption in the following functions of the pharmaceutical sector:

- regulation – registration of medicines, control of their promotion, inspection and licensing of establishments, and control of clinical trials;
- supply management – selection, procurement and distribution of essential medicines.

The use of this instrument allows countries to identify strengths and weaknesses in a given pharmaceutical system, and to make recommendations as to how to address them. After testing and refinement based on experience, the instrument is now available on the GGM web site.

b) Phase II - *GGM model framework for good governance in the pharmaceutical sector*[5]: The model framework assists phase II countries in developing their national GGM frameworks. The model comprises two strategies:

- Discipline-based strategy – a top-down approach establishing legislative and administrative procedures and structures to enhance and enforce measures against corruption in the pharmaceutical sector.
- Values-based strategy – a bottom-up approach building institutional integrity through the promotion of moral values and ethical principles.

Experience has shown that the coordinated use of both strategies yields the best results. The model framework also provides a review of the basic components necessary for good governance in the pharmaceutical sector, such as updating or establishing regulations and administrative procedures, a whistle-blowing mechanism, a code of conduct and a good governance for medicines implementing task force.

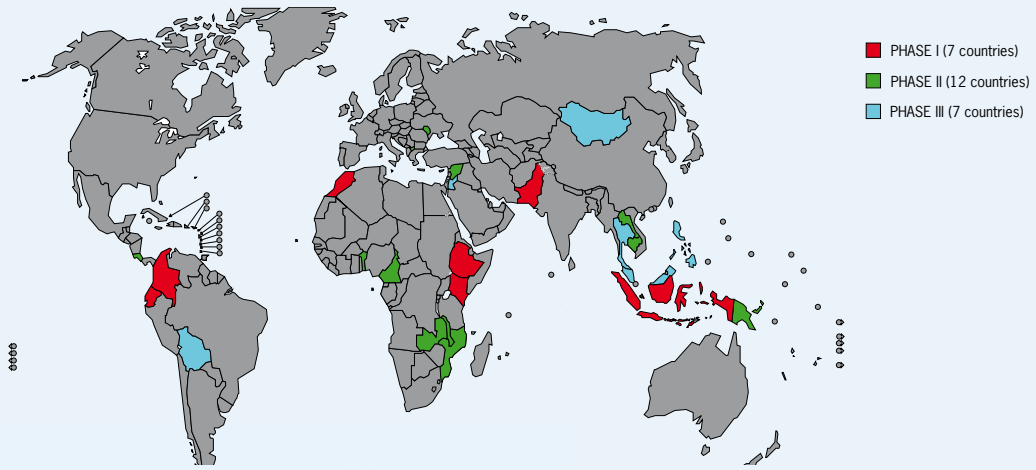
c) Phase III - *Guide for promoting good governance in the pharmaceutical sector*:

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. The WHO guide for phase III assists countries in implementing the national framework: promoting awareness among health professionals and the public on the potential for corruption and its impact on health system functioning, and building national capacity for sustaining good governance in the pharmaceutical system. The guide is a working document used by participating countries. The programme is currently collecting examples of successful experiences and best practices of promoting good governance from countries and plans to publish a compilation.

Training modules: In addition to the technical tools and guidelines, WHO has developed training modules for each of the three phases that are delivered to participating countries as they enter each phase. The modules aim at building the capacity of GGM national teams to implement the related activities and ensure the sustainability of the programme.

II – PROGRESS IN COUNTRIES

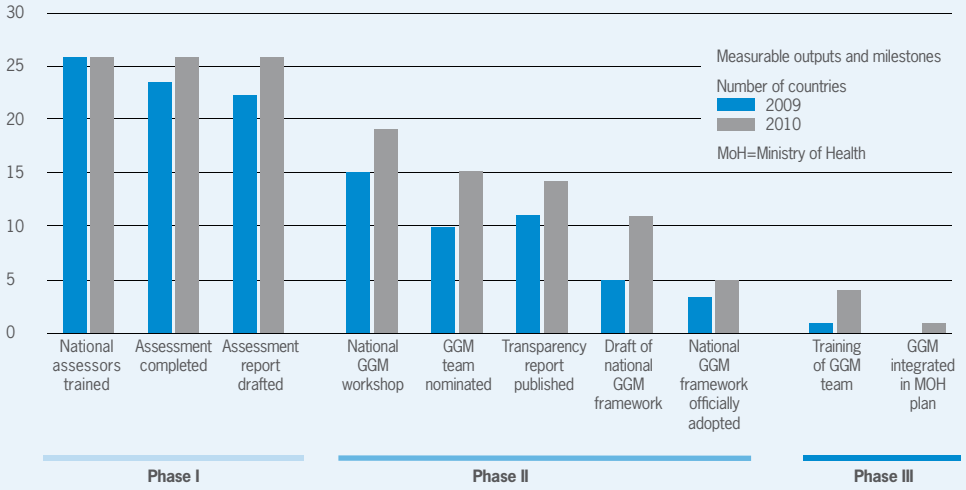
Figure 2: Current GGM phases in participating countries



Having started with just four pilot countries in 2004, the good governance for medicines programme now has 26 countries at different stages of the three-phase programme.[6] Interest in the programme has exceeded expectations. Many countries have adopted GGM and are moving successfully from one phase to the next. 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 gain results rather than to expand to reach new countries. The programme aims to have all countries move to phase III and institutionalize the good governance principles within their national health systems. Figure 2 shows the current GGM programme phases in the 26 participating countries.

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

Figure 3: Good governance for medicines country outputs and milestones 2009 and 2010

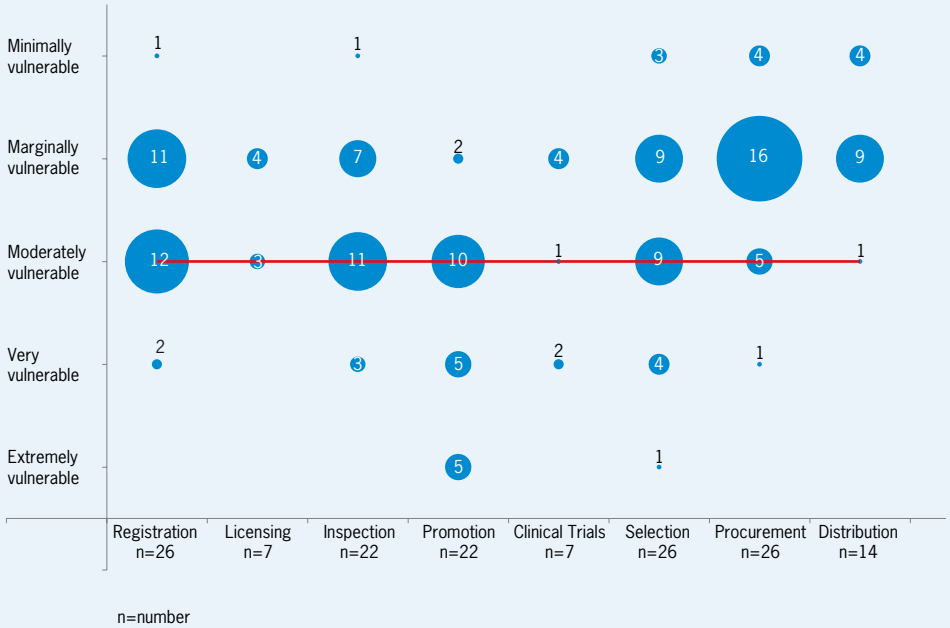


1 – Country progress: phase I transparency assessment

Assessing the level of transparency and vulnerability to corruption is the first step in building good governance in the pharmaceutical sector. Independent national assessors, key government officials and WHO country staff from all participating countries have completed a national transparency assessment. The findings have enabled ministries of health and national drug regulatory authorities to identify weaknesses in their systems and move on to phase II to develop strategies to address them. WHO encourages countries to publish the assessment results showing a "vulnerability to corruption" score for each of the functions measured. To date, WHO has published the results from 14 country assessments following their validation and approval by national governments and stakeholders. Two more countries have recently received official publication clearance.

Some common trends among countries' assessment results have emerged, as shown in figure 4. Most countries have transparent and competitive procurement procedures, with a post-tender mechanism to monitor suppliers' performance. Most have a national essential medicines list with transparent procedures for the selection of medicines. **Common weaknesses among countries include a lack of conflict of interest guidelines for all functions across pharmaceutical systems**, an absence of a responsible unit within the medicines regulatory authorities for monitoring medicines promotion, or a lack of publicly available terms of reference for the committee responsible for overseeing medicines registration or selection.

Figure 4: Country transparency assessment results on the level of vulnerability to corruption in the pharmaceutical sector.



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2 – Country progress: phase II consultation and development of framework

Once countries' strengths and weaknesses have been identified through the transparency assessment, WHO recommends that countries hold a workshop with key stakeholders to validate the assessment results and consult on the components that need to be included in the national GGM framework document.

After the national workshop, the ministry of health nominates a GGM team, which has two responsibilities. First, the team works with all key stakeholders to develop a national framework document that addresses the weaknesses identified in the national assessment and to promote good governance in the pharmaceutical sector. Second, the team manages, coordinates, and evaluates the GGM programme throughout its implementation. Once the national framework document has been adopted by the ministry of health and other key stakeholders, the GGM team has the legal and political backing to proceed to phase III: implementation and promotion of good governance principles and mechanisms. 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, Syrian Arab Republic and The former Yugoslav Republic of Macedonia).

Phase II country example: Republic of Moldova

The Republic of Moldova is one of two countries in the WHO European Region to join the GGM programme. The national team and the National Medicines Agency are committed to its implemention. The team has worked with pharmacists in the field to address all weaknesses in regulations and standard operating procedures revealed by the transparency assessment. A key success is the Ministry of Health's approval of a guide on medicines procurement, a code of ethics for medical and pharmaceutical workers, and monitoring of drug promotion.

Phase III country example: Lebanon

In Lebanon, one of the gaps identified and tackled was the national good manufacturing practices guideline. The national framework recommended that the national good manufacturing practices be updated as the last standards were established in 1983. As a result, a national committee, including experts from the private and the public sectors, reviewed and revised the guideline and a new version was officially adopted by the Government and published in 2009. The revised good manufacturing procedures are based on WHO guidelines and the transparency assessment findings and are adjusted to be consistent with Lebanese pharmacy laws.

3 – Country progress: phase III implementation of national programme

The aim of phase III is to ensure that concrete actions are developed and implemented and that anti-corruption efforts are sustainable. The implementation of the national programme requires a long-term strategy to ensure the recommendations made in the transparency assessment and framework development processes are pursued. The sustainability of good governance for medicines depends on its institutionalization in countries.

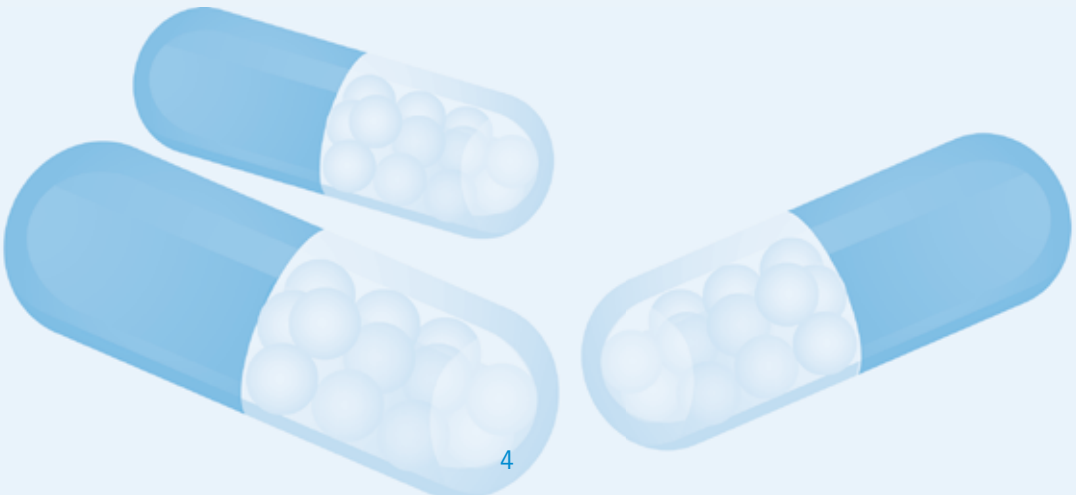
Seven countries are in phase III of implementing the programme (Bolivia (Plurinational State of), Jordan, Lebanon, Malaysia, Mongolia, Philippines and Thailand). These countries have developed an action plan to promote their national good governance for medicines programme. In Thailand, GGM has been institutionalized within the Ministry of Health. Bolivia (Plurinational State of), Malaysia and Mongolia have also begun this process.

After six years of implementation, successes are visible in countries. Medicine procurement practices have been enhanced, national pharmaceutical laws and regulations have been revised, pharmaceutical activities, such as registration and licensing, are more transparent, management of conflict of interest is improved, and more information regarding medicines is publicly available on ministry of health web sites.

Phase III country example: Thailand

After five years, Thailand is in GGM phase III and there are already a number of significant achievements.

- **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 has been developed, containing publications and articles on corruption, unethical practices and cases of corruption.
- **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 curricula of 15 faculties of pharmacy.



III – GGM LEADERSHIP AND NETWORK

Global advisory group

The GGM programme is guided by its global advisory group, which provides overall strategy and policy guidance. The group includes 10 people who meet using e-tools in an effort to reduce meeting-related costs. The group is diverse, with representation from a wide range of anti-corruption agencies, such as Transparency International, the United Nations Development Programme, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the World Bank; the donor community; civil society; and the private sector. The guidance and support of the global advisory group has proven a valuable resource.

Global network

In the process of establishing the WHO good governance for medicines programme and its subsequent exponential growth, an active network has developed. This informal global network provides a forum for exchanging best practices and lessons learnt among participating countries and a broad range of parties interested in anti-corruption efforts, including experts from national ministries of health, drug regulatory authorities, anti-corruption agencies, industry associations and international organizations. These people have met in training sessions, regional meetings, and one global event. An e-platform to further facilitate the exchange of information is being developed.

To enable participating countries to learn from the experiences of phase III countries and to improve the overall GGM programme, a meeting was held in Tunisia in 2010. The meeting of seven phase III countries and three phase II countries nearing phase III, provided an opportunity to exchange experiences in curbing corruption and promoting good governance in the pharmaceutical sector. Nearly 30 participants, including national officials involved with the implementation of GGM in their countries, as well as a wide range of key stakeholders, attended this meeting. **Participants reported that a culture of transparency is now emerging in their institutions**. Focused regional and thematic workshops, such as the one held in Tunisia, will be planned in the future.

Pool of experts

A pool of experts, combining knowledge and skills relating to pharmaceutical management and good governance, has been created. The pool includes medical doctors, pharmacists, public health and anti-corruption specialists working in ministries of health, pharmaceutical services, universities and civil society organizations. These experts can be deployed to help build capacity in countries, through a combination of training and coaching for national GGM teams. It is expected that this new resource will improve the programme's sustainability in countries.

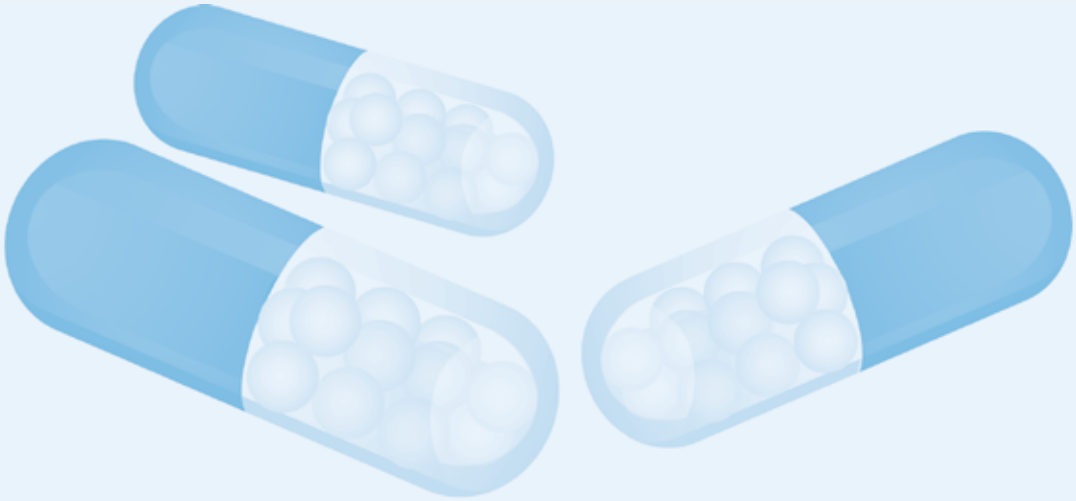
Lessons learnt

The GGM programme is addressing a complex issue, which is being increasingly openly acknowledged. There is growing awareness that corruption impedes progress in reaching development goals. Interest in the programme has been higher than anticipated and momentum for change is building. The preventative and constructive approach used by the programme, of measuring vulnerability to corruption and strengthening pharmaceutical systems by increasing transparency and promoting integrity, has appealed to governments.

Experience over the past six years has shown that countries progress through the programme at varying rates, influenced by such factors as political stability, readiness for change and the availability of human and financial resources. The greatest success has been in countries where there is high-level government commitment, civil society and other anti-corruption initiatives are engaged, and communication and staff training are ongoing.

Good governance for medicines programme's eight lessons of success:

1. **There is great interest in the subject area and the preventative approach used is appealing;**
2. **National champions and a dedicated and motivated national GGM team enhance success;**
3. **Involvement of high-level and technical officials is essential for sustainability;**
4. **Promotion of integrity should go together with legislative reforms;**
5. **Collaboration with key stakeholders is valuable;**
6. **Effective government communication strategy is important;**
7. **Countries progress at different speeds influenced by a range of factors;**
8. **Institutionalization of GGM principles is necessary for long-term sustainability.**



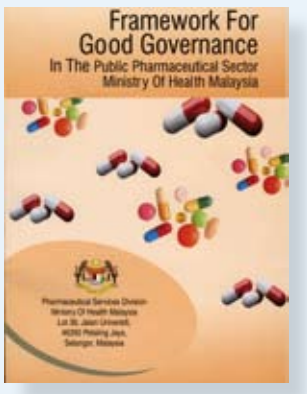
The way forward and next steps

In early 2010, WHO officials met with participating country representatives and civil society partners to evaluate the first five years of the programme. Discussions focused on how WHO could strengthen its technical guidance to countries and adjust its current strategy to improve national programme sustainability. Six priorities were identified for the next few years.

Priorities for the global good governance for medicines programme 2010-2012

1. Country support: Identify best practices and case studies, and continue country support to consolidate the work. New countries entering the programme will be on a self-funded basis
2. International health agenda: Collaborate with other key international players to increase awareness of what can be done to prevent corruption and to integrate anti-corruption measures in the international health agenda
3. Mainstream and institutionalize GGM: Work with participating countries to institutionalize the programme and possibly widen its application to include the whole health sector, not just medicines
4. Communications: Continue implementing and building on GGM global communications, particularly using e-platforms for sharing and exchanging information and best practices
5. Monitoring and evaluation: Ensure a strong monitoring and evaluation framework for the programme to maintain integrity and trust
6. Resource mobilization: Pursue stable funding through enhanced resource mobilization efforts to secure the future of the programme.

Sharing information and experiences between participating countries has provided an important learning platform. WHO will continue to facilitate this exchange of experiences, ensure systematic evaluation and reflection on how best to increase transparency, and build capacity to promote good governance in the pharmaceutical sector.



GGM publications – NEW in 2009-2010

GGM Technical Package
Measuring transparency in the public pharmaceutical sector. Assessment instrument – phase I
http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF
WHO Framework for good governance in the pharmaceutical sector – phase II
http://www.who.int/medicines/areas/policy/goodgovernance/GGMframework09.pdf
A compilation of best practices – phase III (in preparation)

Country Reports
Measuring transparency to improve good governance in the public pharmaceutical sector - Benin
http://www.who.int/medicines/areas/policy/goodgovernance/benin_report/en/index.html
Measuring transparency to improve good governance in the public pharmaceutical sector – Lebanon
http://www.who.int/medicines/areas/policy/goodgovernance/measuringtransparencylebanon/en/index.html
Measuring transparency to improve good governance in the public pharmaceutical sector - Syrian Arab Republic
http://www.who.int/medicines/areas/policy/goodgovernance/measuringtransparencysyria/en/index.html

Other related documents available through the WHO homepage:
Curbing corruption in medicines regulation and supply
http://www.who.int/medicines/areas/policy/goodgovernance/ENCurbingCorruption4May2010.pdf

Assessment instrument flyer
http://www.who.int/entity/medicines/areas/policy/goodgovernance/ENAssessmentInstrument4May2010.pdf
WHO fact sheet – Medicines: corruption and pharmaceuticals
http://www.who.int/mediacentre/factsheets/fs335/en/index.html
WHO country feature – Thailand a country case study: good governance and preventing corruption
http://www.who.int/features/2010/medicines_thailand/en/index.html

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Additional information:
Visit: www.who.int/medicines/ggm
Email: ggminfo@who.int
Good governance for medicines programme
Department of Essential Medicines
and Pharmaceutical Policies
World Health Organization

[1] UN Secretary-General's comment on the theme of International Anti-Corruption Day, 9 December 2009 http://www.un.org/News/Press/docs/2009/sgsm12660.doc.htm
[2] WHO Director-General's 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 http://www.who.int/dg/speeches/2010/access_medicines_20100716/en/index.html
[3] http://www.who.int/mediacentre/factsheets/fs335/en/index.html
[4] www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspeng.pdf
[5] www.who.int/medicines/areas/policy/goodgovernance/GGMframework09.pdf
[6] 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.