
World Health Organization

John Martin

Liz Ollier

November 2012
Acknowledgments

The authors would like to thank the many people who provided them with information to undertake this evaluation in Geneva, in four participating countries and by telephone interview. Their willingness to give up their valuable time is much appreciated.
TABLE OF CONTENTS

1. INTRODUCTION .......................................................................................................................... 1
   1.1. Objectives ................................................................................................................................. 1
   1.2. Scope and Methodology ........................................................................................................... 1

2. BACKGROUND ............................................................................................................................... 3
   2.1. History of the Good Governance for Medicines (GGM) ......................................................... 3
   2.2. Rationale for GGM ................................................................................................................... 4

3. CONCLUSIONS AND RECOMMENDATIONS .............................................................................. 6
   3.1. Creating Awareness in Countries ............................................................................................. 6
   3.2. Increasing International Awareness on Transparency and Good Governance and Support for the GGM programme ......................................................................................... 6
   3.3. Achievements in Countries ....................................................................................................... 7
   3.4. Principal Conclusion - value for money has been an overarching achievement ..................... 7
   3.5. Recommendations ................................................................................................................... 8
       3.5.1. Phase I Assessment Tool and Methodology ....................................................................... 8
       3.5.2. Determinants of GGM Progress ....................................................................................... 8
       3.5.3. Key operational Factors .................................................................................................. 10
       3.5.4. Strengthening WHO’s Capacities for GGM Management ............................................. 10
       3.5.5. Recommendations on Current Critical Challenges ....................................................... 11

4. REVIEW OF PROGRAMME ........................................................................................................... 13
   4.1. Initiation and Concept .............................................................................................................. 13
       4.1.1. Challenges to the Concept and Processes ....................................................................... 13
   4.2. Global Package of Processes and Guidelines .......................................................................... 14
       4.2.1. Phase I Methodology and Tools ....................................................................................... 14
       4.2.2. Findings on Phase I Methodology and Tools ................................................................... 15
       4.2.3. Phase II Methodology and Tools ..................................................................................... 16
       4.2.4. Findings on Phase II Methodology and Tools ................................................................... 17
       4.2.5. Phase III Methodology and Tools ..................................................................................... 18
   4.3. Implementation of GGM in Countries ..................................................................................... 19
       4.3.1. Implementation at Phase I level ....................................................................................... 20
   4.4. Implementation of Phase II and Phase III .............................................................................. 23
       4.4.1. Facilitating factors ............................................................................................................. 24
5. VISITS TO THREE PHASE III COUNTRIES AND ONE PHASE II ........30
5.1. Background to Evaluation Visits .................................................. 30
5.2. JORDAN .................................................................................................... 30
  5.2.1. Process and Structure ................................................................. 30
  5.2.2. GGM Performance ................................................................. 31
  5.2.3. Conclusions .................................................................................. 32
5.3. MALAWI .................................................................................................. 32
  5.3.1. Process and Structure ................................................................. 32
  5.3.2. Conclusions .................................................................................. 33
5.4. THAILAND ............................................................................................... 33
  5.4.1. Process and Structure ................................................................. 33
  5.4.2. Conclusions .................................................................................. 34
5.5. PHILIPPINES .......................................................................................... 34
  5.5.1. Process and Structure ................................................................. 34
  5.5.2. Conclusions .................................................................................. 35
5.6. Summary of Lessons Learnt in Four Countries .................................. 36
6. GLOBAL LEADERSHIP NETWORK .................................................. 38
  6.1. Global Advisory Group (GAG) ......................................................... 38
  6.2. Global Technical Working Group ..................................................... 39
  6.3. Pool of Experts .................................................................................. 40
  6.4. Cooperation and Partnerships ............................................................ 40
7. CREATING A GGM COMMUNICATION CAPACITY .................. 42
8. STRENGTHENING WHO/GGM PROGRAMME MANAGEMENT .... 46
  8.1. Programme Validity ........................................................................... 46
  8.2. The GGM Programme Within the Wider WHO Essential Medicines and
       Health Products Department (EMP) ....................................................... 46
  8.3. Selection of Programme Countries ................................................... 47
  8.4. Engagement by WHO Regions .......................................................... 47
  8.5. Global Advisory and Technical Working Groups .............................. 48
  8.6. WHO Support to GGM at Country Level .......................................... 48
  8.7. BMZ Funding Support ....................................................................... 48
  8.8. Looking to the Future of GGM ........................................................... 49
Annex 1: Terms of Reference ................................................................. 52
Annex 2: Persons Interviewed ............................................................... 55
Annex 4: Reports of Visits to Four Countries ......................................... 61
Annex 5: Summary of Current Status of GGM Countries ....................... 78
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>WHO Regional Office for Africa</td>
</tr>
<tr>
<td>AMRO</td>
<td>WHO Regional Office for the Americas</td>
</tr>
<tr>
<td>BMZ</td>
<td>German Federal Ministry for Economic Cooperation and Development</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of interest</td>
</tr>
<tr>
<td>DFID</td>
<td>Department for International Development (UK)</td>
</tr>
<tr>
<td>DG</td>
<td>Director General</td>
</tr>
<tr>
<td>EMP</td>
<td>Essential Medicines and Health Products</td>
</tr>
<tr>
<td>EMRO</td>
<td>WHO Regional Office for the Eastern Mediterranean</td>
</tr>
<tr>
<td>EU</td>
<td>European Commission</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GAG</td>
<td>Global Advisory Group</td>
</tr>
<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, TB and Malaria</td>
</tr>
<tr>
<td>GGM</td>
<td>Good Governance for Medicines</td>
</tr>
<tr>
<td>LGU</td>
<td>Local Government Unit</td>
</tr>
<tr>
<td>MAR</td>
<td>Medicine Access and Rational Use</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>MeTA</td>
<td>Medicines Transparency Alliance</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MPC</td>
<td>Medicine Programme Coordination</td>
</tr>
<tr>
<td>NGOs</td>
<td>Non-Governmental Organizations</td>
</tr>
<tr>
<td>NPO</td>
<td>National Professional Officer</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
</tr>
<tr>
<td>SEARO</td>
<td>WHO Regional Office for South-East Asia</td>
</tr>
<tr>
<td>TO</td>
<td>Technical Officer</td>
</tr>
<tr>
<td>TWG</td>
<td>Technical Working Group</td>
</tr>
<tr>
<td>UNDP</td>
<td>United Nations Development Program</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WHR</td>
<td>World Health Report</td>
</tr>
<tr>
<td>WPRO</td>
<td>WHO Regional Office for the Western Pacific</td>
</tr>
<tr>
<td>WR</td>
<td>WHO Country Representative</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

This is the report of the evaluation of the WHO Good Governance for Medicines Programme (GGM) covering the period 2004 to 2012. It was commissioned by the Essential Medicines and Health Products (EMP) Department and undertaken in October and November 2012.

1.1. Objectives

The overall objectives of the evaluation are:

1. To provide the WHO EMP Department and the Member States providing financial support to the GGM Programme (the Federal Republic of Germany through BMZ and Kuwait), with an assessment of programme achievements, challenges and lessons learnt.
2. To identify strengths and weaknesses of the design of activities, efficiency, management and performance in order to provide the EMP Department with facts and evidence that will inform WHO strategy for future work in transparency and good governance in the pharmaceutical sector in countries.

The specific objectives of the evaluation are as follows:

- To identify key successes and outcomes of the GGM Programme at global and country levels
- To identify operational barriers and difficulties encountered at global level and in countries
- To assess achievements and lessons learnt in Phase II and Phase III countries
- To identify barriers and facilitating factors in undertaking Phase I
- To identify synergies with other programmes supporting work on good governance and transparency in medicines
- To provide recommendations on how the current GGM Programme can evolve to best contribute to future WHO work in transparency and good governance in the pharmaceutical sector
- To explore the vision of key partners and donors involved in medicines policies for improving transparency and good governance of the pharmaceutical sector, and their interest and needs for collaboration with WHO.

1.2. Scope and Methodology

The review has been the informed by the following information:

- A desk top review of GGM background documents (progress reports, meeting reports, publications, and tools and methodologies)
- Interviews of both country and WHO participants in the global GGM workshop of Phase II and III countries held in Geneva in October 2012, and a review of country reports and presentations
- A questionnaire survey of all Phase I countries
- Face to face and telephone interviews with key actors in the GGM Programme at global and country levels. These included:
  - Coordinator and Technical Officer WHO/EMP/MPC
  - WHO/EMP Director, Team coordinators and staff
  - Members of the GGM Technical Working Group (TWG) and Global Advisory Group (GAG)
  - WHO Regional Advisers for Medicines,
  - WHO National Professional Officers (NPOs), GGM focal points in countries
  - Representatives of Ministries of Health (MoH) in GGM countries
  - Development partners engaged in similar initiatives
  - Visits to three GGM Phase III and one Phase II countries in order to conduct more detailed analyses of country-specific GGM achievements and challenges through interviews with key policy-makers, GGM focal points, members of GGM task forces and steering committees, WHO Representatives (WR) and NPOs responsible for GGM support. The countries visited were Jordan, Malawi, the Philippines and Thailand.

The review was conducted by the consultants John Martin (Team Leader) and Liz Ollier during the period 8th October to 30th November 2012. Neither consultant had worked on the GGM programme although John Martin was formerly employed by WHO as Director, WHO Representation to the European Union (EU) and Liz Ollier reviewed a parallel initiative, the Medicines Transparency Alliance (MeTA) in 2010.
2. BACKGROUND

2.1. History of the Good Governance for Medicines (GGM)

WHO’s Second Medicines Strategy 2004-2007 comprises four strategic priorities the first of which is “development of national medicines policies which include promotion of ethical practices and development and use of anti-corruption measures in the pharmaceutical sector.”

This is the basis for the Good Governance for Medicines (GGM) Programme. Its principal goal is to contribute to health systems strengthening and to prevent corruption by promoting good governance in the pharmaceutical sector.

Its specific objectives are:

1. To raise awareness on the impact of corruption in the pharmaceutical sector and bring this to 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.

The programme started in 2004 as a pilot project supported by AUSaid, in four countries, the Lao People’s Democratic Republic, Malaysia, Philippines and Thailand. It is implemented through a 3-step process to institutionalize good governance in Ministries of Health, as shown below:

Phase I comprises a national assessment of transparency and vulnerability to corruption of key pharmaceutical system functions. The findings and
recommendations for action are presented in a report which provides the basis for designing interventions.

**Phase II** comprises the development of a National GGM framework which 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.

**Phase III** is the implementation phase of the national programme and focuses on translating the GGM programme into action, ensuring that it becomes institutionalized and fully integrated within the MOH.

Before the evaluation process started, GGM included 36 participating countries: 16 countries were in Phase I, 10 were in Phase II and 10 in Phase III. (see Table on page 19).

During the period of the evaluation Malawi and the former Yugoslav Republic of Macedonia adopted their GGM frameworks and therefore technically are in Phase III.

### 2.2. Rationale for GGM

The process of globalization has given rise to strong pressures for changes in international law, regulations and agreements with the aim of liberalizing trade both globally and within defined regions. Whilst the consequent “deregulation” has resulted in large increases in trade and economic growth, the downside includes increased opportunities and financial incentives for unethical behaviour and corruption. The pharmaceutical sector is an attractive target for corruption in view of its huge market value estimated, in 2009 at US$ 837 billion per year (Ref: 2010 GGM report).

During the 1990s and early years of the 21st century international organizations, their member governments and civil society have led efforts to prevent and combat corruption. Notable examples of intergovernmental conventions and informal sectoral agreements are as follows:

- The Inter-American Convention Against Corruption (OAS Convention) approved by 34 members of the Organization of American States in 1996.
- The Organization for Economic Co-operation and Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions signed by the 29 members of the OECD, along with five non-members in 1999.

GGM Programme activities are based on the following operational objectives and structure:

1. Development of a global technical package of processes and guidelines which are the basis for country support.
2. Provision of technical guidance and support to individual countries.
3. Development of a global advisory structure, both technical and strategic, and establishment of a network of committed countries, institutions and individuals to monitor and advise WHO.
4. Development of a communications capacity to provide information on programme achievements and challenges to stakeholders and the interested public through a dedicated WHO website and the publication and dissemination of country case studies and updates of the global technical package.
5. Strengthening WHO GGM programme management.

In line with previous GGM Progress Reports, this report is organized and presented in accordance with the above structure.
3. CONCLUSIONS AND RECOMMENDATIONS

3.1. Creating Awareness in Countries

At the time of preparing this report a total of 36 countries were engaged in GGM. Twelve countries are in Phase III including the former Yugoslav Republic of Macedonia and Malawi, both of which progressed from Phase II to Phase III during the evaluation. Eight countries are in Phase II and 16 in Phase I. The latter include the following countries/territories in EMRO, Bahrain, Egypt, Kuwait, Islamic Republic of Iran, Iraq, Morocco, Mozambique, Oman, Palestine, Sudan, Tunisia and Yemen.

The GGM approach involves many national participants, including key stakeholders in the pharmaceutical sector. Thus GGM Phase I has undoubtedly increased awareness on the impact of corruption and the value of transparency and good governance. The subsequent Phase II process has engaged even more people in each country with an assumed additional impact both on awareness and commitment to the subsequent national implementation plan.

3.2. Increasing International Awareness on Transparency and Good Governance and Support for the GGM programme

A large number of experts from a wide range of institutions around the world participated in preparation and review of the GGM instruments. This, in itself, increased international interest and awareness in the value of good governance for medicines as well as support for the GGM methodology.

The programme confirmed international credibility for its aims and approaches by attracting senior international experts to join its Global Advisory Group. The fact that they agreed to serve speaks highly of the credibility achieved by GGM.

The programme attracted endorsement and funding by respected international and regional development agencies. These were BMZ, AusAID, UK Department for International Development (DFID), European Commission and Kuwait.

Programme publications available on the WHO/GGM website have promoted awareness on transparency and good governance at international level and in countries as well as providing guidance on implementing the GGM process and examples of good practice.

GGM briefings at international events effectively promoted the programme. These included two World Health Assemblies and a number of major anti-corruption conferences including Transparency International conferences in Athens, Greece, and Bangkok, Thailand, and a UN Conference Against Corruption in Doha, Qatar.
3.3. Achievements in Countries

Phase II and Phase III countries reported that GGM achievements include improvements in medicines procurement practices; revision of pharmaceutical laws and regulations; increased transparency in many functions of the medicines system including registration and licensing; major advances in the management of conflict of interest; and increased public availability of information on medicines policy and governance including through websites created by ministries of health and medicines regulatory authorities.

Additional value of the GGM approach was revealed in the four countries visited, as follows:

- **Country ownership**

  Thailand continues to provide an example of GGM best practice. The GGM process is firmly embedded in the wider national efforts to maintain universal access to essential medicines and has high-level leadership and support. These are very important attributes in ensuring sustainability.

- **Promoting integrity-based systems**

  In Malawi, the Phase I assessment helped build stakeholder consensus on fundamental, underlying system weaknesses. An important achievement was the explicit awareness that ethical standards were lacking and consensus that improved integrity should be an aim of the implementation framework.

  In Jordan, Phase III has led to impressive outputs including development of Conflict of interest guidelines and management policy (see country report).

- **Engaging civil society**

  All countries with the exception of Jordan demonstrated the potential of civil society engagement as a GGM stakeholder. In Jordan, the absence of civil society involvement was acknowledged.

3.4. Principal Conclusion - value for money has been an overarching achievement

The budget for the entire programme for the period 2011-12 amounts to Euros 800 000 from BMZ and US$252 000 from Kuwait. When the above achievements are matched with the funds available to WHO it is clear that GGM has provided very significant value for money.
3.5. Recommendations

3.5.1. Phase I Assessment Tool and Methodology

- Countries reported that the assessment tool is facilitative, focussed and easy to use. It has proven effective in engaging all major national stakeholders in the GGM process and acts as a means to increase awareness, stimulate dialogue and identify shortfalls. The fact that it is not perceived as an audit is helpful.
- The evaluation revealed two principal criticisms of the instruments: (a) that it is not rigorous, robust and scientific since it is based on the opinions of key informants and uses an arbitrary scoring system and (b) it does not make adequate use of other WHO instruments used in assessments of national pharmaceutical systems.

Recommendations:

- WHO should better explain the focus and value of the instrument with regard to achieving the fundamental GGM requirement of full engagement of all key national stakeholders. This will also require translation into national languages in order to facilitate understanding and effective application.
- The GGM Global Advisory Group (GAG) and the GGM technical group should routinely review GGM instruments to ensure that they draw due benefit from other proven pharmaceutical systems assessment methodologies and incorporate improvements based on application in countries.

3.5.2. Determinants of GGM Progress

- GGM performance in countries is greatly enhanced where there is high priority and support for good governance and anti-corruption, especially where such processes take place across many sectors.

Recommendations:

- WHO should promote high-level endorsement and support for GGM by national good governance commissions.
- WHO should promote policy and operational linkages between GGM and broader cross-sectoral good governance programmes.

- A high-level GGM “champion” is a powerful attribute and conversely GGM struggles in the absence of high-level support.
Recommendation:

- WHO should promote endorsement and support for GGM at high levels within both the National Medicines Authority (NMRA) and Ministry of Health.

- It is difficult for GGM to have impact in countries where the National Medicines Regulatory Authority (NMRA) is weak.

Recommendation:

- The WHO Country Cooperation Strategy should include support for strengthening National Medicines Regulatory Authorities (NMRAs) in order to support implementation of the GGM process.

- GGM has made greater achievements where there has been continuity and a degree of stability amongst the membership of national GGM steering groups and task forces. Political change resulting in new appointments at senior level has often left GGM with less momentum to move forward.

Recommendation:

WHO should include this issue in future updates of the Phase II Model Framework in order to stimulate countries to anticipate such changes and identify ways to mitigate the risks that they create.

- Implementing the recommendations arising from Phase I assessments is more complex in federal systems or where there has been significant devolution. The number of stakeholders with whom engagement is necessary is greater and local politics may also hinder progress.

Recommendation:

- WHO should anticipate this complexity to ensure that all key informants from all levels are included in the Phase I Assessment and are duly represented in subsequent national GGM steering committees.

- Vocabulary can be a stumbling block. In some countries use of the term “corruption” or even “good governance” was resisted sometimes due to sensitivity to the terminology and sometimes because the basic problem was perceived to be inefficiency and weak management rather than lack of integrity.
Recommendation:

- In countries where this is perceived as an issue, WHO should seek a high-level decision on nomenclature during the initial phase of discussion on country participation in GGM.

3.5.3. Key operational Factors

- Monitoring and evaluation based on outcomes and impact is essential to provide the information needed both to steer GGM and to establish its credibility amongst sceptics.

Recommendation:

- WHO should give high priority to finalising outstanding GGM documents, including guidelines on GGM monitoring and evaluation in countries. They should include indicators of programme outputs, outcomes and impact.

- The engagement of civil society as GGM stakeholders encourages emphasis on impact and informing public opinion. This is well demonstrated in Thailand.

Recommendation:

- WHO should actively promote the identification and engagement of appropriate civil society representation in national GGM processes, including membership of GGM steering groups.

- GGM may be seen as a parallel project not integrated with country strategic and operational mechanisms. This may give rise to opposition, especially in countries with harmonised planning and implementation processes.

Recommendation:

- WHO support should include risk analysis and identification of the most appropriate location of GGM within country planning and operational mechanisms in order to promote integration where it may be appropriate.

3.5.4. Strengthening WHO’s Capacities for GGM Management

The evaluation has noted the importance of WHO’s capacities to steer, support and manage GGM at country, regional and global levels. The following recommendations are based on the findings:

- WHO staff at all levels must remain sensitive to changing country contexts in order to decide the most appropriate support to be provided. Even in countries with well-established and strong GGM mechanisms changes may take place that
undermine GGM progress. WHO must always have the necessary information and evidence to alert national GGM Steering Committees to the need for adjustments in focus and strategy, and to propose corresponding changes that may be required in WHO strategic, technical and financial support.

- WHO should acquire the capacities, skills and mind-sets necessary to ensure subtle, facilitative and tactical support to countries at critical points in GGM evolution, in addition to traditional technical cooperation. This will be dependent on careful definition of the profiles and selection criteria that will be the basis for recruitment of appropriate staff.

- WHO Country Offices should have authority to provide flexible, small-scale financial support, especially in countries that lack dedicated budgetary provision for GGM activities.

- Fulfilling the above tasks may require a WHO officer at country level with full-time responsibility for day to day GGM oversight and management. An alternative solution could be the appointment of a full time national official, from MoH or MRA, with strong backup from the WHO Country Office.

- In order to promote GGM added value at all levels of WHO, the programme should establish or strengthen operational linkages (a) to other programmes that promote good governance in medicines (such as MeTA) and (b) to wider WHO support in strengthening health systems, where GGM experiences could inform the new focus on good governance. Strengthening national health policy development processes as well as health workforce management and health systems financing are obvious examples.

- Unstable WHO funding can undermine both GGM processes in low-income countries that are dependent on WHO funding support as well as GGM inter-country and global activities. WHO should establish a risk assessment process to anticipate such problems and find solutions before damage is done.

- WHO should first seek the advice of the GAG Chair and members in the process of re-establishing a knowledgeable and enthusiastic Global Advisory Group.

3.5.5. Recommendations on Current Critical Challenges

In concluding this evaluation report it is evident to the evaluators that WHO cannot meet increasing demand for country participation in GGM without considerable strengthening of management capacity in Geneva. The following recommendations are based on the observations contained in Chapter 8.
• GGM activities should be fully integrated within the WHO medicines programme at all levels and provided with dedicated, identifiable and sustained funding support. Proper integration will promote greater complementarity between the elements of the medicines programme and add value to WHO support to countries.

• The good examples of communication, coordination and active cooperation on GGM between WHO/EMP and AFRO, EMRO and WPRO Regional Advisers should be extended to the other regions.

• GGM experiences in countries as well as the GGM methodology should be utilised to inform WHO’s new focus on health systems governance. The evaluators welcome the decision to dedicate the latter part of 2012 to consolidating the GGM programme activities, including undertaking this evaluation, in order to learn lessons and formulate a WHO vision for future work on good governance of the pharmaceutical sector.

• GGM should remain within MPC, in view of its strong focus on support to countries. It also provides opportunities to increase GGM contacts and improve coordination and complementarity with WHO partners active in work on good governance in medicines. Examples are MeTA, GFHTM and the European Commission.

• With regard to the EC/ACP/WHO Renewed Partnership, GGM methodologies should be applied more widely in participating countries and thereby access the funds necessary to deliver results. Experience from this evaluation suggests that GGM’s cost-effectiveness would be an asset in order to deliver improved transparency. Such evidence would serve as a powerful lever for approval of GGM as a core WHO approach in the context of WHO reform.
4. REVIEW OF PROGRAMME

4.1. Initiation and Concept

WHO initiated the programme in 2004, mandated by the Second Medicines Strategy 2004-2007. It formed part of WHO’s contribution to a wider health agenda focused on the Millennium Development Goals and the need to strengthen health systems.

The start-up process began as a pilot project in four Asian countries, the People’s Democratic Republic of Lao, Malaysia, Philippines and Thailand and drew upon their on-going activities. WHO work on medicines in the Western Pacific Region (WPR) already included priority on reducing vulnerability to corruption in pharmaceutical systems, subsequently formalised in the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010).

The then WPRO Regional Adviser on Medicines played a very supportive role in initiating anti-corruption and transparency activities within WHO, including resource mobilisation in the Western Pacific region, leading to financial support from AusAID. This country-based initial pilot testing was essential for developing later the global GGM programme.

The concept underlying the GGM methodology is that by helping policy-makers understand where their strengths and weaknesses lie in the public pharmaceutical system, appropriate interventions can be applied. A basic principle is transparency. This necessitates engaging all key stakeholders from the beginning in analysing the big picture of the pharmaceutical system and identifying priority for actions and a framework through which action can be planned and implementation monitored in a systematic and open manner.

This approach draws upon the already tested experiences of broad anti-corruption programmes promoted and supported by organizations such as UNDP and Transparency International which in 2006 focused its annual Global Corruption Report on the health sector.

4.1.1. Challenges to the Concept and Processes

The GGM concept has been challenged within WHO/EMP itself.

- One view reported in the evaluation interviews is that the GGM core focus on corruption has been overstated. In reality, the problems are often (a) inefficiency and (b) national policies and practices including those that encourage inflated pricing in the public sector e.g. as a means of raising MoH revenue, including for doctors’ salaries. **Thus transparency, as a means to improve system efficiency, is a more legitimate aim than preventing corruption.** This view has been endorsed by the GGM Global Advisory
Group, hence current GGM emphasis on transparency and its impact on vulnerability to unethical behaviour.

- Another view is that WHO has compromised the GGM process by placing too much emphasis on overall leadership by the MoH instead of creating a more challenging environment such as increasing transparency and promoting policy dialogue, thus encouraging accountability to a wide stakeholder profile, as adopted by MeTA. The programme response is that the ultimate aim is corrective action rather than criticism of government. As such, MoH is the responsible party.

### 4.2. Global Package of Processes and Guidelines

In order to establish a credible WHO technical support capacity that could apply to countries at various levels of socio-economic development the new programme gave early priority to developing a GGM Global Technical Package to serve as a reference tool.

#### 4.2.1. Phase I Methodology and Tools

For Phase I, WHO has developed an instrument to assess transparency and potential vulnerability to corruption in key functions of the medicine chain managed by the public sector.

Those key functions are:

- 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, It was published in 2009 and has been available on the GGM website since 2010.

The entry point for the tool is an assumption that “effective functioning of a pharmaceutical system is dependent on the transparency of the processes, and ability to hold individuals and entities accountable for adhering to standard procedures, norms, laws and regulations in each of these (above) functions”


It builds on a methodology first used for a World Bank assessment in Costa Rica in 2002 and one of its authors (Cohen-Kohler) participated in the Costa Rica exercise.
The draft was reviewed by a large number of people (63 officially acknowledged) drawn from diverse backgrounds including pharmacists and officials from the pharmaceutical sector in countries, academic experts in the fields of medicines, public health and governance, civil society including Transparency International, International Federation of Pharmaceutical Manufacturers Associations, World Bank, WHO Regional Advisers and staff of the WHO Medicines and Ethics Programmes in WHO HQ, Geneva.

An early draft went through several rounds of field testing and revisions in 19 countries between 2005 and 2007. The preparation and publication of the tool was funded by AusAID, the European Commission, BMZ and DFID.

The methodology is intended to provide both qualitative and quantitative information based on the perceptions of policy-makers and other stakeholders in national pharmaceutical systems. It aims to provide a neutral and objective platform for opening and sustaining dialogue and discussion among stakeholders. It does not set out to measure corruption per se.

To date the assessment has been completed and accepted in 22 countries and WHO has published reports containing the findings for 17 countries. They have provided valuable information enabling MoH and National Medicines Regulatory Authorities (NMRA) to identify significant deficiencies in their pharmaceuticals management systems.

The following are examples of commonly identified problems:

- Control of medicines promotion was the function most frequently identified as vulnerable to corruption.
- There is widespread lack of public access to information about the pharmaceutical sector (legislation, regulations, written procedures).
- In many countries there are no formal, written criteria to guide selection of members of key committees such as medicine selection committees.
- Medicine registration committees have a weak policy base and lack adequate operational procedures.
- In many countries there are no conflict of interest policies and they are poorly implemented where such policies are in place.

4.2.2. Findings on Phase I Methodology and Tools

Interviews conducted during this evaluation revealed two principal criticisms of the assessment instrument:

1. It is not rigorous, robust and scientific since it is based on the opinions of key informants and uses an arbitrary scoring system as a means of determining the areas of vulnerability to corruption.
2. It does not make adequate use of other longstanding WHO instruments used in assessments of national pharmaceutical systems.

These weaknesses were acknowledged by current and former GGM staff as legitimate concerns. They had also been acknowledged by the Global Technical Working Group and GAG which recommended review of the tool every two years and amendment in the light of experience.

However, they emphasised that a principal aim of the instrument is to attract all key stakeholders to engage in the entire process, not only Phase I. If transparency is the ultimate outcome, then maximum stakeholder engagement is essential, including those who might otherwise feel vulnerable to accusations and sanctions. In this regard, the instrument draws strongly upon tested, anti-corruption methods used in other sectors. As reported above, it was the subject of intense consultation and review and appears to be based on best evidence available at the time.

The second criticism was generally accepted in the sense that the tool could be technically strengthened without compromising its basic objective – transparency.

A third criticism, expressed by some respondents, was that the most recent training courses to prepare national assessors have sometimes been conducted in English when all had a common language – Arabic.

4.2.3. Phase II Methodology and Tools

Phase II comprises the development of a National GGM framework. The process 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 minimising 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.

WHO has developed a draft “Model framework for good governance in the pharmaceutical sector” 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. It is designed as a guide to countries to develop their own national GGM framework, after analysis of the results of the Phase I assessment, nationwide consultation with key stakeholders and due adaptation to specific country contexts.
4.2.4. Findings on Phase II Methodology and Tools

To date 12 countries have developed national frameworks; nine have been officially adopted (Benin, Jordan, Lao People’s Democratic Republic, Lebanon, Malawi, Malaysia, Plurinational State of Bolivia, Thailand and the Former Yugoslav Republic of Macedonia) and three have been drafted (Mongolia, Philippines and Syrian Arab Republic).

Experience from work on good governance in other sectors has shown that the coordinated application of two complementary strategies is needed in order to make a significant impact on corruption:

A “discipline-based approach,” based on legislative reform, establishing the laws and administrative structures and processes needed to ensure transparent medicines regulation and procurement systems. The "discipline-based approach" tends to be top-down. It comprises the following elements:

- Enforcement of existing anti-corruption legislation
- Mechanisms for whistle-blowing
- Sanctions of reprehensible acts based on anti-corruption legislation
- Transparent and accountable regulations and administrative procedures

A “values-based approach,” promoting institutional integrity through moral values and ethical principles and attempting to motivate ethical conduct by public servants. The “values-based approach” tends to be bottom-up and comprises:

- Key ethical principles
- Code of conduct
- Socialization of key ethical principles
- Promoting ethical leadership

The Model Framework document remains in draft form, available on the WHO/GGM website. It is anticipated that the final draft will be completed for publication by the beginning of 2013. This follows extensive reviews by the GGM Global Advisory Group, Global Technical Working Group as well as external reviewers.

The current draft acknowledges 46 reviewers, including members of staff of WHO’s medicines programme. Common criticisms were:

(a) That the text was overly academic in form
(b) The description of the values-based content appeared to be derived largely from western concepts of integrity and
(c) There is a lack of a GGM monitoring tool to track implementation in countries, particularly Impact and Outcomes indicators.
The need for outcome and impact indicators has been agreed at a number of GGM global meetings. However, the evaluators have been unable to access any record of the resulting draft indicators. It is assumed that this work was intended to be presented to a follow-up meeting of the Technical Working Group which has not taken place.

**In conclusion, it is a matter of concern that this very important work is “on hold.”**

### 4.2.5. Phase III Methodology and Tools

Phase III involves the implementation of the national programme and focuses on translating the GGM framework into action and ensuring that it becomes institutionalised and integrated within the MoH. Activities include awareness raising campaigns, revision and updating of legislation, application of new administrative procedures for increased transparency and accountability and building leadership capacity at all levels of the MoH staff to manage the promotion of good governance.

WHO has developed in 2007 and 2009 a draft “Guide to promote good governance”. It focuses on building national capacity to sustain good governance in the pharmaceutical system, and includes guidance on extending awareness beyond GGM core stakeholders and actors to include promoting health professionals at all levels of the health system as well as the general public.

However, the work on this draft was stopped in order to first document the experiences of countries that have implemented their national framework, through country case studies. A first compilation of experiences and best practices in nine countries was published in 2010. Four individual country case studies are currently under finalization.

In addition to the global technical tools and guidelines, WHO has also developed training modules designed to build the capacity of GGM national teams to lead the GGM process through each of its three phases. The most recent training workshops took place in Kuala Lumpur in June 2011 and in Amman, Jordan, in June 2012.

As has been the practice in development of the entire global package, the Phase II/III technical package and training materials were subject to review. This took place during the Kuala Lumpur workshop in June 2011. Ten country teams took part and concluded that the content was too general and recommended focus on a small number of high priority themes. These were agreed to be (a) guidance on management of conflict of interest in medicines promotion, and (b) technical assistance on developing legislative text and administrative rules to promote transparency and good governance.
4.3. Implementation of GGM in Countries

This section provides an overview of the current status of GGM in its participating countries. It includes a brief status report on Phase I countries and an analysis of progress and achievements, important obstacles and lessons learnt in Phase II and Phase III countries.

Thirty six countries/territories are currently engaged in GGM activities.

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bahrain*</td>
<td>Cameroon</td>
<td>Benin</td>
</tr>
<tr>
<td>Cambodia*</td>
<td>Costa Rica</td>
<td>Jordan</td>
</tr>
<tr>
<td>Colombia</td>
<td>Indonesia</td>
<td>Lebanon</td>
</tr>
<tr>
<td>Ecuador*</td>
<td>Kenya</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Egypt*</td>
<td>Malawi</td>
<td>Mongolia</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Morocco</td>
<td>People’s Democratic Republic of Lao</td>
</tr>
<tr>
<td>Iraq</td>
<td>Mozambique</td>
<td>Philippines</td>
</tr>
<tr>
<td>Islamic Republic of Iran</td>
<td></td>
<td>Plurinational State of Bolivia</td>
</tr>
<tr>
<td>Kuwait*</td>
<td>Oman</td>
<td>Syrian Arab Republic</td>
</tr>
<tr>
<td>Pakistan</td>
<td>The former Yugoslav Republic of Macedonia</td>
<td></td>
</tr>
<tr>
<td>Palestine</td>
<td>Zambia</td>
<td>Thailand</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Republic of Moldova</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sudan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tunisia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yemen</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: No responses to a request to provide information were received from the Phase 1 countries marked with an asterisk*
Malawi and the former Yugoslav Republic of Macedonia moved from Phase II to Phase III during the evaluation.

4.3.1. Implementation at Phase I level

All Phase I countries were contacted by email and requested to complete a short questionnaire. A total of 11 replies were received (see table above), many after the requested deadline. The following analysis is based on the completed Phase I questionnaires.

4.3.1.1. Motivation for involvement

All countries identified the prime goal for participation as increasing governance and transparency. In addition, three mentioned reducing vulnerability to corruption. One country wished to use the Phase I assessment as an advocacy tool and several mentioned the need to tackle inefficiencies and increase and clarify accountability. Two countries highlighted weaknesses in the current regulatory framework and one felt that legislation was not being implemented. Finally, one country (Iraq) identified the desire “to be at the same level with other countries in the region who have implemented the programme” which indicates the potential of peer pressure and competition.

One country raised the issue of the language relating to governance. “There is a problem of terminology and it is better to use the term of vulnerability”. This highlights the need for cultural sensitivity both in the design of the global package but also in training sessions.

4.3.1.2. Lead agency in country

In six of the countries, support for joining GGM emanated from very senior figures in the Ministry of Health or its equivalent, mostly at ministerial or Director General level. In more than one case the lead was the Manager of the Pharmacy Department or equivalent. In one country where progress had stalled it was hoped that the creation of a new regulatory agency would facilitate future progress although no focal person had yet been identified. Already one Minister had been replaced with the expectation that GGM momentum would be adversely affected.

Note: The impact of such political and structural change has also been noted in Phase II and III countries.
4.3.1.3. Activities and achievements

Some of the countries responding have been involved in the most recent Phase I training in Jordan (Islamic Republic of Iran, Palestine, Tunisia, Yemen and Pakistan). In these newly recruited countries, the main activity in 2011-12 was limited to selection and training of assessors. In more than one country the assessors had yet to start collecting information.

Iraq had made good progress, however, and had identified 10 co-assessors to work with the four trained by EMRO and had also held a workshop to orientate officials within the MoH on governance and transparency. Likewise in Yemen and Tunisia the interviews are well under way and data analysis is currently being undertaken.

In Colombia, which joined the programme many years ago and had made little progress, there has been renewed interest in the programme after a considerable period of inactivity, which is encouraging. Interest by a newly reconstituted Ministry plus synergy with an EU programme for "Promoting trustworthiness and transparency in Colombia – trustworthiness and transparency strategy in the mining and health sector, subsector of medicines and medical and surgical supplies" led by the Transparency Secretariat under the Presidency of the Republic appears to have catalysed interest again.

Some Phase I countries that joined the programme some time ago have not yet been able to complete the assessment and/ or have it accepted by the MoH. These include Papua New Guinea and also Pakistan where the MOH was not prepared to accept the assessment. In the Republic of Moldova, progress has not been possible and this is perceived as due to lack of local investment in the process.

4.3.1.4. Challenges in implementation of Phase 1

Countries also reported a number of difficult features that have hampered GGM progress. They include fragmentation of the sector, and a federal structure in which provinces have considerable autonomy and therefore extensive advocacy and influencing is needed to gain ownership and mobilise action.

One respondent reported difficulty in interviewing senior informants because they were often absent or unavailable. This was compounded by frequent changes of personnel. In addition some informants were reluctant to provide information as they were concerned how it might be used.

A comment from Papua New Guinea highlights one of the disadvantages of confining efforts to strengthen good governance purely to pharmaceutical:
“Officers in the pharmaceutical services section felt that they were being singled out to be subjected to far more stringent orders than their counterparts in other government departments who had to abide by the fairly loose General orders. So they simply ignored the entire GGM initiative”.

4.3.1.5. Support to Phase I countries

Countries reported varying levels of support from WHO. All agreed that training had been appropriate and comprehensive. The opportunity for peer exchange of information was appreciated. The provision of briefing material for stakeholders received favourable comment. However, the respondent from Pakistan felt that WHO should proactively provide training for government officials on the subject, including information on action in other countries. One respondent felt that WHO needed to provide funding to take GGM forward in their country.

In the countries where GGM is not progressing there still appears commitment from WHO locally. This applies to the Republic of Moldova where WHO is undertaking a number of support activities which will contribute to improving governance.

4.3.1.6. Phase I country perception of GGM tools

The Phase I tool was felt to be focussed and easy to use. However, there was a view expressed that definitive answers (yes/ no) were not always possible and caution was needed in completing assessment questions to avoid misinterpretation. Participants in the most recent course expressed concern about the course being conducted in English.

4.3.1.7. Future Intent of current Phase I countries

All respondents, except three, indicated that they felt that GGM would progress in their countries. This was despite slow progress in some countries in moving towards the initial assessment. However, Iraq, which had not yet completed Phase I having received initial training in December 2010, provided a comprehensive action plan complete with target dates for key activities which was most impressive.

One country, which definitely did not envisage GGM progressing at all, cited the lack of a cultural underpinning for good governance, fragile government and lack of levers to enforce legislation. However two countries also reported serious delays in preparing for Phase II due to transfer of senior staff committed to the programme.

The respondent from Kenya (which has completed Phase I) indicated that the country did not intend progressing to Phase II as they believed it was necessary to integrate the approach into their strategic plan rather than have a separate
programme. They also indicated that given imminent decentralisation of authority, extensive preparatory work at provincial level would be required.

4.3.1.8. Future support from WHO

Country respondents recognised that they would continue to need technical support from WHO including on-going guidance on the GGM process. There were also requests for support for in-country advocacy, editing of Assessment Reports, financing of the GGM process and help in revising legislation. WHO needs to decide whether such support would be appropriate.

4.3.1.9. Conclusion of review of Phase I countries

- Progress appears to be better where there is senior level involvement from the MoH.
- Based on completed questionnaires, progress in implementing Phase I is variable – from sustained action to serious delays.
- Problems experienced in countries where political and senior staff changes are frequent were well highlighted.
- Underlying GGM principles and rationale appear to require reinforcement.
- WHO’s support role was not clearly understood by all respondents. Perhaps inevitably, some countries had greater ownership than others and were clear that GGM is a country-led process supported by WHO. The two who appeared to have less understanding of the GGM concept, gave the impression that it was a WHO-led initiative requiring greater technical and financial support in order to move forward.

4.4. Implementation of Phase II and Phase III

Countries have applied the GGM process differently with different result. In some the process is strongly country-owned and driven. Examples are Laos PDR, Mongolia, Philippines and Thailand. These countries are also more focused than others on pursuing specific outputs and outcomes, such as low price medicines and bulk procurement. They are also more interested in measuring GGM impact, in part for reasons of efficient management and in part as a means of sustaining commitment to GGM by its stakeholders.

Some other countries are dependent on WHO leadership, partly because their systems are weak, partly due to the lack of GGM champions in the MoH and partly because they are dependent on WHO presence within their GGM teams in order to provide constant technical guidance, low-key encouragement and pressure on stakeholders to maintain momentum. Availability of WHO funding for the GGM
process is also an essential element of progress in some countries, particularly in low-income countries such as Benin and Malawi.

4.4.1. Facilitating factors

It is clear from both country reports and interviews that the most important factor influencing GGM performance in countries is the level of priority and support accorded to tackling corruption in general. Where anti-corruption programmes and processes are in place across many sectors, GGM is able to achieve more progress and in a shorter time period.

**Some country GGM teams have reported benefit from engagement with other ministries**, particularly Finance and those responsible for tackling corruption, as part of a cross sector push for good governance. **Additional momentum is achieved when support emanates from high political levels**, especially from the Head of State. This includes the convening power that such support implies.

**The need to have a senior and technically knowledgeable GGM group in country was highlighted by several respondents.** There was no consistent view on composition but the inclusion of both private sector and academic members was mentioned by some countries as beneficial.

**Support from WHO both at country and regional levels appears to facilitate progress**, not just through small scale funding for meetings and support with logistics, but also for technical input and dissemination of good practice. WHO is able to benchmark progress and this can be catalytic.

Two countries identified the need for a **dedicated pharmacy specialist at local level**. Such posts were created in some countries with DFID funding, as part of the former Regional Collaboration for Action on Essential Drugs in Africa Programme. They were based within WHO as NPOs.

The incentive for GGM in some countries was clearly to match initiatives with peers regionally and globally.

**Countries have valued the Phase I tool.** It acts as a means to engage stakeholders, increase awareness, stimulate dialogue and identify shortfalls. Several countries described it as catalytic. **The fact that it is not perceived as an inspection is helpful and ownership by the country is clearly essential.**

This is in line with the analysis of GGM experiences contained in the Background Paper 25 on GGM which was prepared for the World Health Report 2010:
“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. Each country needs to assess its own situation and decide what will work best.”

The report cites further GGM experiences which reflect the findings of this evaluation, as follows:

4.4.1.1. Political and technical support

High level political support is essential to implementing GGM activities and in approving the official documents which provide the legal and political basis for progress. But political support alone is not enough. It is important to work at both the political and technical levels.

The preventive approach of the GGM Programme, aimed at increasing transparency and promoting ethical conduct has been appealing to most countries. The GGM is not about identifying bad practices or corrupt individuals/institutions, but is rather about strengthening systems so that corruption has no place.

4.4.1.2. Wide range of stakeholders

All stakeholders working in the area of health and pharmaceuticals should be engaged at an early stage, as well as those in anti-corruption/integrity/good governance initiatives.

A multi-disciplinary group should be established, including the MoH, Medicines Regulatory Authorities, National Procurement Centre/Department, Ministry of Justice, the national anti-corruption agency, Ministry of Finance, civil society, relevant NGOs, the private sector, academia and professional associations.

4.4.1.3. Structure for steering and implementing

Countries identified the need to create an appropriate structure to take responsibility for steering and implementing the GGM process in order to ensure sustainability over the mid- and long-term. Most countries have nominated two GGM Committees that complement each other’s work:

- a GGM Steering Committee headed by high-level officials which sets the strategic directions for the programme
- a Task Force responsible for coordinating, managing and monitoring the implementation of the GGM programme.
As GGM activities gain momentum and progress, it is essential to dedicate adequate human and financial resources. Unless this is done, it is very difficult to institutionalize GGM and ensure that activities are sustained over the long-term.

4.4.1.4. Transparency

It is essential to make pharmaceutical systems' procedures and information transparent by implementing the recommendations included in the transparency assessment.

- **Recommendations contained in the transparency assessment report should be implemented as soon as possible.** Improvements such as changes in terms of procedures and revision and updating of laws and regulations and other technical issues need not await completion of Phases II and III.
- **Improving the management of conflicts of interest (COI) is a concrete and tangible way to start increasing transparency and promoting ethical behaviour.** Management of COI should be applied to all committees dealing with pharmaceuticals, such as committees for registration, procurement, licensing, and essential medicines selection. It should also apply to permanent staff working in critical areas.
- **Innovative and motivational ways rather than punitive methods** should be used to encourage health institutions to comply with transparency standards (e.g. through awards).

4.4.1.5. Promoting individual and institutional integrity

- 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 everyday 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 across many topics.
- 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 needed to promote individual and institutional integrity, and involve the public.
4.4.1.6. Publication and dissemination

Publication and dissemination is a sign of transparency and underpins the ethos of GGM. **It is essential to publish the results of the transparency assessment results in a publication and validate them in workshops. The Phase II framework must be officially adopted, published and widely disseminated.**

The websites of national medicines regulatory authorities (NMRAs) and MoH provide a very important means to publish and share key documents such as legislation and other documentation. By making information available to civil society (including the media) government is allowing itself to be held to account.

4.4.1.7. Communication and advocacy

A communication and advocacy strategy with clear messages is an essential tool

- MOH and NMRA staff should be informed on the GGM programme from the beginning through seminars, workshops, intranet or newsletters.
- Opportunities for visibility should be exploited. A prime example is the annual International Anti-Corruption Day, celebrated on 9th December.

4.4.1.8. Capacity building

GGM will only be sustainable if countries **build capacity in good governance for the pharmaceutical sector.** All concerned professionals in MOH and NMRA should participate in national training workshops. GGM concepts should be included in university curricula for students in medical and pharmaceutical sciences.

4.4.1.9. Performance management and monitoring and evaluation

GGM activities should be incorporated in operational plans at all levels. This should be consolidated through a monitoring and evaluation (M&E) mechanism that is specific to the objectives set in each country.

4.4.2. Barriers to Adoption and Implementation

Several Phase II and III countries found that political changes resulting in new appointments at senior level in the MoH or equivalent, undermined priority accorded to GGM and therefore its momentum.

Many GGM countries are likely to experience a degree of political turbulence and consideration should be given to anticipating and mitigating the risks and effects. Publication and dissemination increases the extent to which politicians are likely to be held to account in the long term.
Developing and implementing GGM frameworks and action plans is more difficult in federal states or where there has been significant decentralisation. The number of stakeholders is greater and local politics may hinder progress. This problem is also present where the pharmaceutical sector is split between a number of players who are not part of the same accountability structure. For example, autonomous medical procurement, supply and distribution agencies are present in a number of countries. Whilst separation of duties is a desirable feature of a well governed sector it may also cause difficulty to reach agreement on policies which affect several organizations.

In countries with harmonised planning and implementation processes, including external partners, there may be resistance to GGM if it is perceive as a parallel project not integrated with the country strategic and operational mechanisms. This implies adopting GGM processes and avoiding separate GGM management mechanisms which may be poorly supported. **GGM implementation needs to be incorporated in national and local plans and budgets.**

**It is important to select appropriate terminology to express GGM objectives.** In some countries there has been resistance to using the term “anti-corruption” or even “good governance” because they are seen to imply wrong-doing. In others, where national leadership accords high political priority to explicit anti-corruption measures, using this term was both acceptable and useful in mobilising support, including funding.

Many Phase II and III countries expressed the view that their basic problem was inefficiency and poor management rather than corruption per se. In these countries **transparency is seen as a prerequisite for managerial effectiveness which itself is a prerequisite for good governance.**

As mentioned in the previous section, the Phase I assessment tool is seen to have both strengths and weaknesses. The most common criticism is its perceived lack of rigour in the sense that the methodology does not facilitate profound analysis of issues. This underlines the importance of well-trained and independent national assessors with both the knowledge and confidence to probe the views of key informants.

Whilst most countries have found WHO support to be helpful, a number expressed concerns about the delays in finalising the documents and guidelines contained in the global package (see section 4.1). **It was felt that there was a need for more model documents on topics such as monitoring and evaluation of GGM outcomes and impact as well as examples of practice from other countries.**
WHO delay in providing country support was also criticised as a barrier to progress. In one case, the country had been waiting for a year for the Phase I assessment to be finalised for publication. **Support needs to be timely.**

As with the examples of good practice above, these examples of problems and barriers also accord with the following findings contained in the Background Paper for the World Health Report (WHR) 2010:

- 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.
- Political challenges, including political instability and delays due to bureaucracy.
- Managerial challenges due to rotation of staff, lack of human resources or assignment of government representation to junior personnel.
- Technical challenges due to lack of experience and knowledge on the part of GGM stakeholders with regard to governance, ethics and transparency assessment.
- Time becomes an issue when the existing workload of GGM committee members slows down the implementation process and when there are other priorities in the MoH.
5. VISITS TO THREE PHASE III COUNTRIES AND ONE PHASE II

The following section provides a summary of conclusions. Detailed reports on country visits are appended as Annex 3.

5.1. Background to Evaluation Visits

In order to gain a deeper insight into the status and experiences of GGM in countries the evaluation Terms of Reference include provision for visits to three countries, subsequently extended to four. They were identified during the Global Meeting of Phase II and III countries held in Geneva in October 2012 on the basis of their country reports and presentations. They are Jordan, Malawi, Philippines and Thailand. All are longstanding GGM countries and all except Malawi are in GGM Phase III.

Note: Malawi progressed to Phase III during the country visit by the evaluator when its GGM framework was reviewed and adopted at a meeting of stakeholders.

Thanks are due to country GGM focal points and WHO Representatives for organizing the visits at very short notice.

The schedule of visits was as follows:
- Jordan 21st to 23rd October 2012
- Malawi 29th October to 2nd November 2012
- Thailand 5th to 7th November 2012
- Philippines 8th to 10th November 2012

5.2. JORDAN

5.2.1. Process and Structure

The GGM process in Jordan has closely adhered to the WHO model. The focus is on increasing transparency in administrative structures and processes of the pharmaceutical system, principally regulation and supply management. (Ref: MeTA evaluation report).

The Steering Committee (SC) comprises high-level representatives from: Ministry of Health, Ministry of Public Sector Development, Jordan Food and Drug Administration, Anti-Corruption Commission, Royal Medical Services, High Health Council, Joint Procurement Department, Jordan University Hospital, Jordan Consumer Protection Society, Jordan Pharmacy Association, Jordan Association of Pharmaceutical Manufacturers, Drug Stores Owners Association, and WHO. It is Chaired by the Director General of the FDA.
5.2.2. GGM Performance

The following is the evaluator’s assessment of performance so far:

- Phases I and II had important impacts. They succeeded in creating awareness at high levels of the importance of transparency in effective management and governance of the public medicines system. The GGM process has brought together all key national stakeholders, including representatives of local manufacturers. It has provided the rationale and impetus for them to remain engaged and to work together. According to one respondent “Before GGM there was a go-it-alone attitude, including in JFDA.”

- The findings of the Phase I assessment already prompted the FDA to revise the regulations pertaining to medicines promotion and advertising; to develop clear written criteria for selection of members committees, starting with the essential medicines selection committee; to initiate a Conflict of Interest process, starting with the development of forms for members of committees. Interviews confirmed that the subsequent Phase II workshops to review findings helped achieve consensus amongst other stakeholders on the importance of pursuing Conflict of Interest as a GGM priority.

- Phase III has resulted in the following outcomes:
  - Compilation of anti-corruption legislation and policies
  - Publication of a document (October 2012) that compiles for the first time anti-corruption legislation and institutional policies that contain both laws and sanctions
  - Development of a whistle-blowing mechanism and a document that spells out safeguards for whistle-blowers
  - Adoption of a code of conduct for pharmacists working in the public sector
  - Development of Conflict of Interest guidelines, management policy and review of declaration forms

Discussion with members of the Steering Committee and Task Force revealed a sense of satisfaction and pride with what has been achieved so far. Phases I to III have successfully created the right environment, process and consensus on an agenda in the short term. However, from their perspectives of expected outcomes, there was also a strong consensus that “GGM is just beginning.”

The challenge will be to maintain momentum – what one respondent described as “GGM Phase IV”.
5.2.3. Conclusions

Discussants felt that the following issues should be included in plans for future action:

- Engaging relevant civil society organizations should be a priority for the next phase.
- The Task Force should draft a strategic plan aimed at strengthening GGM sustainability and maintaining its momentum and credibility. Priority activities in the short term would include:
  - Strengthen GGM institutionalisation including (1) establishing a small GGM team to provide back-up to the national focal point (2) creating a GGM budget line to provide small amounts of flexible financing as needed and (3) integrating GGM and MeTA planning and management. This has direct implications for WHO Jordan which provides technical and administrative back-up for both.
  - Engage doctors in the GGM process both by organizing awareness and training activities for doctors, including on Conflict of Interest, and encourage a more active participation in the Steering Committee by the Jordanian Medical Association.
  - Give priority to monitoring and evaluation of GGM with an emphasis on measuring outcomes and impact. This would include defining a set of impact indicators.
  - Encourage networking and sharing of good practice between GGM countries. One of the innovation could be for WHO to support peer review visits to countries for purposes of sharing experiences and public endorsement of good performance.

5.3. MALAWI

5.3.1. Process and Structure

The creation of GGM was preceded by the so-called Medicines Leakage Study in 2006 (Assessment of Drug and Medical Supplies Leakages from Medical Stores and Public Health Facilities) which focused on losses of medicines during the processes of procurement and distribution which fell under the responsibility of the then Central Medical Stores. During his participation in the 2006 World Health Assembly the Minister of Health requested WHO support through GGM.

The GGM process has moved forward very slowly. Stakeholders have been “informed” rather than “engaged” through occasional meetings of the Task Force.

Nevertheless it was reported at the Global Meeting of Phase II and III Countries, Geneva, October 2012, that there have been a number of tangible GGM achievements during 2011 and 2012, despite the limited momentum of the process. Above all, the Ministry of Health finalised a draft GGM Implementation Framework.
with WHO support in May 2012. It was discussed and adopted at a meeting of stakeholders on 1st and 2nd November 2012. The meeting was attended by the evaluator.

**It is an opportune time to revive GGM in Malawi.** The current government is said to be committed to good governance and fighting corruption. This can facilitate GGM action, at least in the short term.

### 5.3.2. Conclusions

GGM has been able to survive and move forward slowly to Phase III under very difficult circumstances. That, in itself, is an achievement.

- Longstanding participation by stakeholders in the GGM Committee has been an important factor in sustaining momentum.
- Implementation of the three phases of GGM has achieved a modest increase in awareness on the importance of transparency but participation and sharing of information has not been extensive.
- A national “GGM champion” has been lacking and it is evident that MoH high-level commitment is necessary to enable the fruits of GGM to permeate the weak health system governance.
- The process has been highly dependent on WHO support.

**The time is ripe for GGM revival.** Head of State commitment to fighting corruption and progress on medicines including reform of the Central Medical Stores are positive developments in an on-going difficult environment. Endorsement of the GGM framework and plan of action can serve as the lever for GGM revival and the signal to stakeholders that there is viable path to follow. However GGM stakeholders have become accustomed to working in a low-key and fatalistic manner. There is a pressing need to inject more vigour, focus and a strong sense of purpose into their agenda.

**Action by WHO** at local, regional and global levels will be required to create the necessary momentum.

### 5.4. THAILAND

#### 5.4.1. Process and Structure

In 2004, Thailand became one of the four GGM pilot countries. There was consensus amongst respondents that the time has come to update both the GGM framework and the strategy for its implementation. All respondents acknowledged that GGM has established the necessary structure and process but much more
attention should be given to defining concrete outcomes and monitoring and evaluating GGM impact.

The time is ripe due to the high priority given to fighting corruption by the recently elected government. GGM should benefit by linking action on transparency in pharmaceuticals management to the national anti-corruption activities. One opportunity is to share GGM experiences and, in particular, demonstrate the value of the two-pronged discipline- and values-based approaches.

5.4.2. Conclusions

- Thailand continues to provide an example of GGM best practice. It is country-led rather than WHO-driven, an essential attribute in ensuring sustainability.
- The value of WHO support is acknowledged - timely and responsive to country demand.
- There is a consensus on the part of many stakeholders that a review of GGM strategy is needed in order to identify the tactics and actions necessary to help stem the increasing cost of medicines. The time is opportune in view of the importance of good governance stressed by the current government.
- Stakeholder institutions are strong and the GGM structure is impressive. Nevertheless there are signs, such as a reduction in the quality of routine reporting to the Pharmacy Information System, that reinforcement of key processes is necessary.
- There appears to be a plethora of committees and working groups operating at policy level, with some evidence of duplication and working at cross purposes. Streamlining will be required in order to provide the clarity and focus required to inform high-level strategic vision and decision-making.
- WHO needs to analyse and reflect on such challenges in order to identify effective future support to GGM in such country contexts.

5.5. PHILIPPINES

5.5.1. Process and Structure

Philippines was one of four pilot countries included in the launch of the GGM programme in 2004. The incentive for wide stakeholder engagement provided by the GGM Phase I was an important influence in attracting participation at both national and local government levels.

Respondents acknowledged that the Phase I and II processes were successful in (a) raising awareness and (b) mobilising many people in the various stakeholder institutions related to medicines procurement, regulation and supply. Implementation of the Phase III framework has been less successful.
In effect, the GGM process has been “on hold” since the last meeting of its Steering Committee in 2011. Nevertheless, and despite the lack of momentum, many respondents believe that the time is ripe for GGM revival.

**Restarting GGM after a year’s inactivity will not be sufficient in itself to address the serious obstacles to achieving universal access to essential medicines in the Philippines.** The nature of the obstacles, including political influence, unethical behaviour and a fragmented health system, require a process that is accorded high-level priority, status and support. All are currently lacking.

As in the Malawi case, **there is an important role for WHO** at local, regional and global levels in order to help create the necessary momentum. One possible focus could be development and implementation of a Conflict of Interest policy, including a high-profile communications element to oversee and report both progress and obstacles to the public. Civil society would be an important ally.

WHO also has an instrumental role to play in building complementarity between a revived GGM process and implementation of MeTA Phase 2.

### 5.5.2. Conclusions

Good governance faces major difficulties in the Philippines arising from its geographical structure and decentralised system.

In that context, the GGM process has successfully created considerable awareness in favour of transparency in the pharmaceuticals system and a network of stakeholders with important members including civil society.

The absence of a “GGM champion” and strong Department of Health support has impeded progress, including at Local Government Unit (LGU) level where strong national oversight has been missing.

The weakness of the FDA has left a serious void in national medicines regulatory capacity.

Whilst a GGM framework has been adopted its implementation has been weak, exacerbated by a one year gap since the last meeting of the GGM committee.

MeTA has established an influential network that should have been better linked to the GGM process in the interests of complementarity.

Despite these problems, some individual GGM stakeholders, such as NCPAM, have continued to achieve significant results.
Events including the current government anti-corruption drive and the appointment of a new FDA Director General are creating the rationale and supportive environment for a revival of the GGM process.

WHO has a critical role to play in nurturing the revival process. An initial element would be a diplomatic initiative to urge the necessary high-level commitment and commit WHO support. A second task is to facilitate a situation analysis by stakeholders in order to identify concrete activities, strategies for their implementation and impact indicators.

5.6. Summary of Lessons Learnt in Four Countries

1. High-level commitment coupled with a stable GGM steering mechanism, comprising a wide range of stakeholders, are important determinants of GGM impact and sustainability.
2. In these ideal circumstances the GGM instruments, especially Phases I and II can achieve important impacts – widespread awareness, rationale and impetus for stakeholders to remain engaged and work together and consensus on GGM priorities, agenda and expected outcomes.
3. Where health systems are weak and/or where countries are decentralised, a much greater effort is required in order to achieve a critical level of momentum to enable GGM to progress.
4. Longstanding membership of GGM committees by stakeholder representatives creates stability and can ensure GGM survival in difficult country circumstances where support is lacking or lukewarm.
5. A high-level GGM champion is a powerful attribute and conversely GGM struggles in the absence of high-level support.
6. Reaching GGM Phase III is seen as a beginning and a point when careful consideration of focus, targets and expected outcomes is required.
7. Monitoring and evaluation based on outcomes and impact is essential to provide the information needed both to steer GGM and to establish its credibility amongst sceptics.
8. The engagement of civil society as GGM stakeholders encourages emphasis on impact and informing public opinion.
9. WHO must remain sensitive to changing country contexts in order to choose the most appropriate support to be provided to countries. A basic criterion is country status as “country-led” or “WHO-led.”
10. WHO support should be sensitive to signs that GGM review is necessary, including in countries with well-established and strong GGM mechanisms.
11. WHO should develop the capacities, skills and mind-sets necessary to ensure subtle, facilitative and tactical support to countries at critical points in GGM evolution, in addition to traditional technical cooperation. Flexible, small-scale financial support is also often required, especially in WHO-led processes.
12. An overall view of achievements and comparing activities with inputs indicates that GGM has been very cost-effective.
13. It is difficult for GGM to have an impact in countries where the NMRA is weak.
14. GGM should be linked both to other GG programme and to wider WHO support in medicines and strengthening health systems. Complementarity should be a goal reflected in the WHO Country Cooperation Strategy (CCS).
6. GLOBAL LEADERSHIP NETWORK

The network has three components i.e. a Global Advisory Group (GAG) established in 2007; a network of individuals with technical expertise and experience from GGM in their own countries; and cooperation with institutions active in international good governance activities within and beyond the health sector.

6.1. Global Advisory Group (GAG)

The GAG model is well-established in WHO at global level and many WHO technical programmes have established GAGs to provide expert technical opinion and strategic and policy guidance to programme managers. They often also play an informal role as programme advocates both within and outside WHO.

The GGM programme’s Global Advisory Group was established in 2007. Minor membership changes took place in 2008 followed by the creation of a new GAG in 2009 as well as a separate Technical Working Group. GAG membership subsequently evolved to include 10 experts from institutions with an interest in good governance in the pharmaceutical sector - Transparency International, the World Bank; donor community, civil society, and the private sector. The United Nations Development Programme (UNDP) and the Global Fund to Fight AIDS, TB and Malaria (GFATM) joined in 2010. Dr Kerstin Leitner, former WHO-ADG and adviser to Transparency International was appointed as the first GGM GAG Chair.

Review of the CVs of GAG members available on the WHO/GGM website confirms their seniority, wide international experience and credibility in the area of good governance in general and medicines.

The fact that they agreed to become GAG members speaks highly of the importance they attached to their responsibilities as well as the credibility achieved by GGM during its early years.

According to its Terms of Reference the GAG provided general advice and guidance to WHO on the Good Governance for Medicines (GGM) programme. This included review of the global package of tools and policy documents developed for the GGM programme, information on entry points for action against corruption across sectors, and in the pharmaceutical sector, and examples of good practice. Some members, particularly the Chair, undertook to provide advice and assist with resource mobilisation.

Respondents reported that the group membership was updated in 2009, coinciding with the beginning of serious financial constraints within WHO as a consequence of
the current economic crisis. It affected both GGM and the WHO medicines programme (EMP) as a whole. Resources to fund GAG meetings, including their heavy travel costs, were curtailed. Members committed to using electronic communication to offset the pressure on face to face discussion.

The most recent GAG consultation was an e-discussion in early 2011 to agree how the programme could adjust to its serious shortage of funds. It was concluded that:

- The number of new countries should be limited through careful selection procedures. A key criterion should be proven support for good governance in medicines on the part of national authorities.
- Participating countries should be encouraged to seek ways of establishing self-sufficiency on the part of their national GGM programmes. GAG advised the creation of country level partnerships with institutions committed to promoting good governance, such as local chapters of Transparency International and UNDP. This arrangement might help to substitute for limited WHO technical and financial back up.
- It was also agreed that countries which had successfully achieved Phase III should “graduate” from GGM and perhaps maintain contact through the global network of GGM countries, past and present.
- In an evaluation interview (October 2012) the GAG Chair, Dr Leitner, expressed the following views:
  - GGM has always been demand driven and influenced by the geographical priorities of some of its funders. Consequently, the GGM programme lacks global outlook and coverage and has become imbalanced in terms of country participation – it started in Asia with AusAID funding, added Plurinational State of Bolivia with locally raised DFID funding (due to an enthusiastic champion and global GGM expert based in Bolivia) and subsequently has included many EMRO countries due to the influence of Kuwait funding. Central and South Asia are largely missing and Africa, Europe and Latin America are under-represented.
  - It would be a good idea to convene another GAG meeting soon as a means of demonstrating to WHO senior management GGM’s continuing credibility and momentum, impact in countries and high country demand to join.

6.2. Global Technical Working Group

This informal group was established in 2009, in order to provide technical support to the WHO secretariat, principally to review and improve GGM instruments and the technical package and to help plan activities in regions. Its members were selected from the GAG. It last met in April 2011 in Geneva.
It includes experts from national ministries of health, medicine regulatory authorities, anti-corruption agencies, industry associations, academia and international organizations. To date participants have met in training sessions, regional meetings, and at one global event. GGM progress reports indicate that an e-platform to facilitate the exchange of information has been developed.

A meeting was held in Tunisia in 2010 to share the experiences of seven phase III countries and three Phase II countries nearing Phase III. This was seen as the first of a series of focused regional and thematic workshops. It agreed that a priority theme for a subsequent meeting should be the development of monitoring and evaluation instruments capable of analysing country performance and self-reporting.

According to evaluation interviews, the group met quite regularly until 2011 and then “began to wither” as a consequence of unstable funding and its effects on staff morale as well the delay in replacing the HQ Responsible Officer for GGM and the shortage of staff following the transfer of the GGM Programme from MAR to the MPC unit.

6.3. Pool of Experts

The GGM Progress Report 2010 refers to the creation of “a pool of experts, combining knowledge and skills relating to pharmaceutical management and good governance.” Its purpose is reported to be to help build capacity in countries, through a combination of training and coaching for national GGM teams. The pool includes medical doctors, pharmacists, public health and anti-corruption specialists working in ministries of health, pharmaceutical services, universities and civil society organizations. They were trained in workshops which took place in Geneva in mid-2009.

The evaluators have been unable to obtain any systematic reporting, either on the status of this group or its achievements. However, during the country visit to Jordan, it was revealed that the GGM focal point in the WHO Country Office, as well as his senior colleague responsible for MeTA, have both been deployed as GGM resource persons in EMRO inter-country workshops and in the GGM assessment in the Republic of Moldova.

6.4. Cooperation and Partnerships

The 2011 Progress Report indicates that GGM/WHO has developed collaborations with Transparency International, the World Bank, DFID, U4 Anti-Corruption Resource Centre, UNDP, academia, and Procurement Watch (Philippines). The evaluators were unable to find details.
The report also includes the following examples of GGM activities carried out in the period 2010/2011 with the stated aim of strengthening cooperation with a view to establishing more structured future partnerships:

- Participation in UNDP MENA conference Building Strategic Anti-corruption Partnerships in the Arab Region, 26-27 October 2010, Amman, Jordan.
- Participation in Transparency International Anti-Corruption Conferences in Athens, Greece (2008) and Bangkok, Thailand, 8-November 2010, including a) moderating a session on corruption in health in collaboration with UNDP, and b) presenting the GGM programme in collaboration with Transparency International.
- UNCAC first meeting in Jordan (2006 or 2007) and second meeting in Doha, Qatar (2009)
- Participation in WHO-EMRO GGM Inter-country Training Workshop on Assessment Instrument, 13-15 December 2010, Cairo, Egypt.
- International Anti-corruption Day 9 December 2010 - Lebanon presented GGM country experience.
- Meeting with BMZ, March 2011.
- GGM technical group meeting, April 2011
- GGM meeting with academia and civil society organizations involved in anti-corruption, July 2012
- Collaboration with Alliance for Health Policy and Systems Research — on-going.
- Collaboration with the Medicines Transparency Alliance (MeTA)
- Participation during 2012 in two UNDP workshops on anti-corruption initiatives in the education, water and health sectors and membership of a panel in a recent anti-corruption conference in Brasilia (October 2012).
7. CREATING A GGM COMMUNICATION CAPACITY

The aim of this element of the GGM structure and strategy is to strengthen communications capacity in order to a) provide information both globally and to countries, including stakeholders and the interested public, through a dedicated WHO website and b) to publish and disseminate country case studies and updates of the global technical package. The stated aims are to promote understanding of the need for good governance and to provide information on the GGM programme objectives, methods, achievements and challenges.

This component builds upon a previous strategy which was developed with the support of the EMP communications officer and successfully sharpened key GGM messages and included preparation of some advocacy tools. The background document prepared for the WHR 2010 (see above) is an important example of this earlier work.

BMZ provided financial support for this element during the period 2011-12. It included support to strengthen the information exchange platform as a means of improving sharing of information between countries. According to the 2011 Progress Report, “GGM staff piloted the use of EZCollab in place of MedNet as a communication platform in the EMRO region. The pilot group reported a positive result.” The evaluators were unable to access any additional information on this achievement. The extension of this platform to the Global GGM network was discussed during the global meeting in October 2012.

Review of GGM progress reports and the WHO/GGM website confirm that the programme has always accorded priority to communications. The approaches used have been similar to other WHO technical programmes and include:

- A global website that describes the programme rationale, aims and objectives; contains copies of programme publications that are available for download; and includes links to the websites of partner organisations, and
- Publication of technical papers and information articles in recognised journals, especially WHO flagship publications.
- Participation in technical conferences
- The GGM website currently contains the following:
  - “Two pager policy briefs” on GGM rationale and objectives (Curbing Corruption in Medicines Regulation and Supply, 2010) and a flyer explaining the GGM Assessment Instrument, 2010)
  - GGM progress report 2010
  - Copies of the core GGM instruments i.e. Assessment Instrument and GGM Model Framework, 2009
  - Reports of the findings of 5 country-specific transparency assessments-Benin, Jordan, Lebanon, Malawi and the Syrian Aran Republic. Cameroon
and Zambia assessments have been published but are not yet on the web. The Kenya report is in process of publication.

- Measuring transparency in medicines registration, selection and procurement: four country assessment studies - Lao PDR, Malaysia, the Philippines and Thailand
- Measuring transparency to improve good governance in the public pharmaceutical sector: a comparative analysis of five country studies - Bolivia, Cambodia, Indonesia, Mongolia and Papua New Guinea
- Thailand a country case study: good governance and preventing corruption, June 2010
- Medicines: corruption and pharmaceuticals, Fact Sheet No. 335, WHO Media Centre, December 2009.

GGM publications include:
- Background document on GGM for the World Health Report 2010
- Chapter on GGM programme in the World Medicines Situation 2011

Participation in conferences, includes co-hosting and participation in international technical meetings that promote wider programme visibility, increase technical knowledge and awareness with regard to programme aims and experiences, and increase programme credibility through the quality of presentations and discussions and the standing of key presenters, discussants and participants. The following examples were noted:

- Presentation of abstracts on GGM at the third International Conference for Improving the Use of Medicines, Antalya, Turkey, 14-18 November 2011.
- GGM Global Stakeholders Meeting, Transparency for Change, Bangkok, December 2007, in cooperation with the Ministry of Public Health, Thailand

From the above, it is evident that the programme has invested considerable effort in a conventional WHO-style communications process. A notably strategic success was the contribution of a background paper for the World Health Report 2010 which was dedicated to Health Systems Financing. This publication enabled a wide, mainly public health readership, to learn about GGM and how it fits within the bigger picture of strengthening health systems.

A second example is the conference in Bangkok in 2007 (see above) which attracted high-level participants from countries, global institutions including the World Bank and civil society including Transparency International and, by its very nature, probably succeeded in boosting GGM credibility as well as advancing knowledge on promoting transparency and preventing corruption.

The GGM Technical Working Group, which last met in Geneva in April 2011 to assess programme progress and provide guidance on future priorities, expressed the view that greater efforts were needed.
“WHO should give more attention to communicating GGM key governing principles and examples of their application in order to raise public awareness on the content of the GGM framework and how it can guide programme implementation in countries. In this regard a communication brief should also be prepared with the aim of conveying key messages about GGM objectives, methods and achievements.”

Recognising the GGM resource constraints, members agreed to share responsibility for developing GGM communications and advocacy tools with the secretariat. An example was support by the Alliance for Health Policy and System Research as follows:

- Conducting the Second GGM Transparency Assessment in 2010. Its aim was to monitor progress in implementing the recommendations contained in national GGM assessment studies. It is reported that 15 out of the 26 GGM countries responded and the report should have been a very important product for GGM global advocacy and information to interested countries. Unfortunately clearance for publication by participating countries has proved difficult to obtain due to sensitivity arising from the analysis that appeared to rank country performance rather than assessing progress by each country against its own first round performance. Rather than abandon the work or publish a document two years after the assessment, the option is being studied of carrying out a third assessment in 2013 in order to ensure that the final report will be timely and up to date.

- Preparing of a GGM policy brief which aims to provide a succinct presentation of GGM aims, processes and achievements for national policy makers as a means of promoting better understanding and high-level support for GGM in countries. A first draft was felt to be too focused on promoting the GGM programme and lacking in evidence and information drawn from country experiences. A second draft is in preparation.

The evaluators suggest that, whilst voluntary support by GGM collaborators for drafting important documents for publication is a good thing in principle, in practice it appears difficult for GGM managers to enforce deadlines and edit and finalise drafts for publication in a timely manner. There are several examples of important documents remaining in draft form for unacceptably long periods.

It is difficult to identify the precise objectives, expected results and plan of action for this GGM element:

- Nevertheless, the programme has obviously devoted considerable effort to the preparation of publications and establishing its website.
- Many of the publications are of high quality and there is evidence that updating has been carried out on those which contain information on programme experiences.
- The publications comprising the GGM technical package are essential tools. In this regard the model framework has remained as an unfinished draft for too long. It is understood that it will be finalised before the end of 2012 and this is of great importance.
- Productivity seems to have reached its peak during the period 2007-10. It is likely that subsequent efforts have been undermined by the turnover of WHO/HQ key GGM staff and the shifting responsibilities for GGM within EMP.
- Agreement by volunteer TWG members to assist in drafting of GGM documents is an admirable example of the GGM spirit. In practice, it appears to pose difficulties for GGM management to bring key documentations to successful and timely publication.
8. STRENGTHENING WHO/GGM PROGRAMME MANAGEMENT

Previous sections of this report have traced the evolution of the GGM programme since its creation in 2004, identified its achievements and analysed difficulties encountered en route.

The purpose of this section is to examine the management of the programme by WHO and to offer reflections on the part of the evaluators on possible future directions and the implications for WHO support.

8.1. Programme Validity

The programme’s policy base is the Second WHO Medicines Strategy 2004-2007. One of its four strategic priorities is development of medicines policy, including “promotion of ethical practices and development and use of anti-corruption measures in the pharmaceutical sector.”

The two subsequent strategies provide continuity whilst the successive WHO Programme Budgets describe how the policy will be implemented. WHO’s Programme Budget is a mandatory instrument both for management of the budget by the secretariat as well as for oversight and accountability to Member States. In the current budget 2012-13, GGM is placed under OWER 11.1 which relates to WHO’s sixth health systems building block, comprising work on medical products, vaccines and technologies. This area of work has been accorded priority both on the basis of its contribution to achievement of MDG8 and as an explicit DG priority.

8.2. The GGM Programme Within the Wider WHO Essential Medicines and Health Products Department (EMP)

Despite the validity conferred by successive medicines strategies and a place in the WHO programme budget, the programme has reportedly always suffered from shortage of funds and uncertain status within the wider medicines programme.

Several respondents noted that perpetual instability of funding for the entire Medicines Programme caused stress and competition within the department. In this environment, it was their perception that GGM has never been institutionalised nor fully integrated within EMP. Several WHO respondents have noted the potential for GGM activities to complement other elements of the medicines programme in countries.

GGM start-up in 2004 was overseen by the office of the-then Director, albeit without a formal programme title. It was transferred to MAR in 2006. Day to day management was the responsibility of a Technical Officer who fulfilled the role of GGM “champion” within the department until her transfer to another programme in 2011.
Subsequently, management responsibility was transferred to the Medicines Access and Rational Use team (MAR) and then, from 1st January 2012, to the Medicines Programme Coordination team (MPC).

8.3. Selection of Programme Countries

Expansion of the number of programme countries was constrained by funding as well as distortions arising from geographical priorities of some of the few programme donors, notably AusAID (at the beginning) and Kuwait (currently).

At the time of its launch, WHO intended that the programme should “help poor countries struggling with procurement.” Limited funds restricted engagement with poor countries and country selection was opportunistic, guided by the advice of interested Regional Advisers. In effect, it encouraged cooperation with middle-income countries such as Thailand, Malaysia and Philippines. Subsequent the participation and rapid progress by Bolivia and Mongolia were the results of leadership by influential nationals. The first very poor country to be involved was Malawi, which requested WHO support following a study of “leakages” of medicines in its distributions system.

8.4. Engagement by WHO Regions

Regional interest in GGM has been variable. In part, this is a reflection of restrictions on GGM funding in the early years.

WPRO and EMRO have been engaged and supportive since the programme was launched. As previously reported, the programme start-up benefited from strong support on the part of the WPRO Regional Adviser who advised on the selection of four pilot countries and was instrumental in obtaining funding from AusAID.

The former AFRO and EMRO Regional Advisers were very positive GGM supporters and active, both within their region as well as in global GGM activities. Other regions have been more passive although there are now GGM countries in all WHO regions.

It is notable that the new EMRO Regional Director attended the recent GGM inter-country training programme in Amman, Jordan, in June 2012. It is too early to say if this will lead to greater high-level support for GGM within EMRO.

Meantime, shortage of funding for the entire EMP programme has led to postponement of the annual meeting of Regional Advisers and EMP staff. This meeting is a basic component of global management and coordination of the medicines programme, including GGM. The last meeting took place in early 2011.
8.5. Global Advisory and Technical Working Groups

As reported in Section 6.1, the high standing of the GAG members and the enthusiasm of both groups played significant roles in creating GGM credibility and productivity, especially with regard to development and testing of the global package of instruments for guiding countries through the three GGM phases.

Respondents noted how their ability to function was undermined by the shortage of programme funding and the climate of uncertainty about GGM sustainability on the part of GGM staff. After approximately two years of effective work, they gradually became dysfunctional. Their most recent meetings took place in 2011.

8.6. WHO Support to GGM at Country Level

The evaluation has established that the quality of support by WHO country offices is an important determinant of GGM progress. A committed GGM focal point can play a key role in helping to shape and steer the national GGM programme. According to the information supplied by GGM countries, it is evident that current WHO support is variable in quality.

8.7. BMZ Funding Support

BMZ funding has been instrumental in permitting the programme “to go global” by engaging countries from all WHO regions and strengthening the management capacity at global level. Respondents reported that the number of GGM countries doubled as a result of the first phase of BMZ funding. However, Germany indicated that the duration and amount of funding would remain limited and this stimulated staff to search for additional donors, including through personal contacts as well as WHO’s institutional methods. It was on this basis that Kuwait funds were mobilised, facilitating an increase in GGM countries in EMR. They also supported the salary of one HQ staff member and contributed to costs of travel to countries during a one-year period when BMZ funding was unavailable.

BMZ has provided Euros 800 000 in budget support to the programme for the period 2010 and 2011, which was then extended to 2012. It has been allocated to GGM activities as follows:
<table>
<thead>
<tr>
<th>PROGRAMME COMPONENT</th>
<th>2010 Euros</th>
<th>2011 Euros</th>
<th>TOTAL Euros</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. GGM Technical Package</td>
<td>33 000</td>
<td>33 000</td>
<td>66 000</td>
</tr>
<tr>
<td>2. Country Support</td>
<td>49 000</td>
<td>74 000</td>
<td>123 000</td>
</tr>
<tr>
<td>3. GGM Leadership Network</td>
<td>131 000</td>
<td>106 000</td>
<td>237 000</td>
</tr>
<tr>
<td>4. Communication and Advocacy</td>
<td>43 000</td>
<td>43 000</td>
<td>86 000</td>
</tr>
<tr>
<td>5. Management Support</td>
<td>98 000</td>
<td>98 000</td>
<td>196 000</td>
</tr>
<tr>
<td>6. Programme Support Costs</td>
<td>46 000</td>
<td>46 000</td>
<td>92 000</td>
</tr>
<tr>
<td>7. TOTAL</td>
<td>400 000</td>
<td>400 000</td>
<td>800 000</td>
</tr>
</tbody>
</table>

The activities supported by these funds and examples of their outcomes and achievements are described in the preceding sections of this report, which is structured according to the five programme components listed above.

First of all it is clear that the spread of BMZ funding has sustained both country and global elements of the programme. Secondly, the evaluators conclude that overall GGM has provided considerable value for money when the relatively modest volume of funding is compared with activities and their outcomes. This conclusion remains valid even when additional funding from the Government of Kuwait is included. This amounts to approximately Euros 250 000 (equivalent), mainly to support activities in EMRO countries, as well as salary support and travel costs for GGM at HQ.

8.8. Looking to the Future of GGM

The evaluation confirms a growing need in countries to strengthen transparency and good governance for medicines. The recent experiences of corruption affecting supply of medicines by the Global Fund to certain countries are a sharp reminder of reality in this regard.
It is evident that current WHO capacity will not permit a strong and sustainable GGM programme without full-time senior staffing and stable funding at global level and better communication and coordination between the three levels of WHO (country, regional and HQ). This, in turn, is dependent on (a) full integration of GGM activities within the WHO medicines programme at global level and (b) adequate, sustained funding support. Proper integration will promote greater complementarity between the elements of the medicines programme and add value to WHO support to countries.

The current WHO reform, provoked by the serious lack of funds across the entire organization, may provide additional opportunities to properly embed GGM activities within future WHO work on transparency and good governance.

In particular, it is intended that work on strengthening health systems will be expanded to include a new focus on better health systems governance. GGM experiences in countries together with the GGM assessment instrument have the potential to inform and add value to this work. A particular example is the human resources function of ministries of health, including its links to other institutions such as civil service commissions and ministries of higher education. The complementary GGM discipline and values-based approaches could offer a valuable tool for improving transparency and strengthening institutional and individual integrity.

In this context, the evaluators welcome the decision to dedicate the latter part of 2012 to reviewing and consolidating the GGM programme activities on the basis of the following principles:

- No new countries in 2012 except in EMRO Region
- Support to countries to complete their current GGM phase, with priority to Phases II and III
- Refinement of the GGM technical package
- Completion of pending publications
- Maintenance relations with other transparency initiatives, especially MeTA

This process should also take stock of current thinking on good governance within the WHO secretariat.

In the meantime, it is logical that GGM should remain within MPC, in view of its strong focus on support to countries. It also provides opportunities to increase GGM contacts and improve coordination and complementarity with WHO partners active in work on good governance in medicines. Two examples are MeTA and the European Commission.
WHO is a MeTA partner and MPC is responsible for managing WHO’s technical support to MeTA in cooperation with Health Action International. Earlier reference has been made to MeTA in relation to GGM activities in Jordan and the Philippines. **In both countries, there is scope for increasing the complementarity between GGM and MeTA activities.** At global level, there may be additional scope to take due account of the experiences and lessons from their respective activities in other countries and to use this information to improve the quality of the respective country programmes as well as to improve complementarity in those countries where they are both active.

MPC is also responsible for coordinating EMP cooperation with the European Commission for the implementation of the Renewed EU/ACP/WHO Partnership in strengthening pharmaceutical systems and improving access to quality medicines in African ACP countries. Activities include promoting transparency, accountability and good governance in the pharmaceutical sector in the 15 participating countries, of which a few are also GGM countries.

**There is potential to apply GGM methodologies more widely in participating countries and thereby access the funds necessary to deliver results. Experience from this evaluation suggests that GGM’s cost-effectiveness would be an asset in order to deliver improved transparency. Such evidence would serve as a powerful lever for approval of GGM as a core WHO approach in the context of WHO reform.**
Annex 1: Terms of Reference

WHO Good Governance for Medicines Programme Evaluation

Terms of Reference

Background

Guided by its Medicines Strategy 2004-2007, the World Health Organization (WHO) initiated the Good Governance for Medicines (GGM) Programme in 2004. Its goal is to contribute to health systems strengthening and to prevent corruption by promoting good governance in the pharmaceutical sector.

The GGM Programme has been managed by the Medicines Programme Coordination team (MPC) in the Essential Medicines and Health Products Department in WHO since November 2011. Before that the coordination of the Programme was done by the Medicines Access and Rational Use team (MAR).

Specific objectives of the GGM Programme are:

1. To raise awareness on the impact of corruption in the pharmaceutical sector and bring this to 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

GGM started as a pilot project in four Asian countries and has rapidly become a global programme. The GGM Programme is implemented via a three-step process that is adapted to meet the specific context in each participating country. It includes an assessment of the level of transparency in the national system (phase I), the development of a national framework for good governance (phase II) and the implementation of the national programme (phase III). Tools and training material have been developed to support countries in the first two phases. Currently 36 countries are part of the Programme: 16 countries are in Phase I, 10 are in Phase II and 10 are in Phase III.

More information on the GGM Programme can be found on the GGM website:


Purpose and scope of GGM Programme evaluation

The overall objective of the GGM Programme evaluation is to provide the WHO EMP Department and the Federal Republic of Germany through BMZ with sufficient evaluation of the Good Governance for Medicines Programme. November 2012  

information about the GGM Programme achievements, challenges and for informing strategy for future implementation.

The specific objectives of this evaluation are as follows:

- To identify key successes/outcomes of the GGM Programme at global and country levels
- To identify barriers/difficulties at global level and in countries when implementing the GGM Programme
- To assess achievements in the pharmaceutical sector in Phase III countries and learn lessons
- To identify synergies with other programmes/work on good governance and transparency in countries that are relevant and have a potential impact for improving access to medicines
- To give recommendations on how the current GGM Programme can evolve to best contribute to future WHO work on transparency and good governance of the pharmaceutical sector
- To explore the vision of key partners and donors involved in medicines policies for improving transparency and good governance of the pharmaceutical sector and their interest and needs for collaboration with WHO.

Methodology and approach

- Desk top review of GGM background documents (progress reports, meeting reports, publications, tools…)
- Development of a questionnaire to be sent to all GGM countries
- Face to face and telephone interviews with a list of key actors in the GGM Programme at global and country levels (EMP coordinators, GGM coordinators, members of the GGM technical working group, WHO Regional Advisers for medicines, WHO National Professional Officers, GGM focal points in countries, representatives of Ministry of Health, donor representatives…)
- In country visits up to 3 Phase III countries (across the different WHO regions) to meet with key policy makers, GGM focal points, members of GGM task forces and steering committees, WHO NPOs and representatives
- Participation in the global GGM workshop of Phase II and III countries in Geneva in October 2012.

Evaluation programme

The evaluation of the GGM Programme will be done by two consultants who will share the work (Dr John Martin and Ms Elizabeth Ollier) during a two month period starting at the end of September 2012.
Dr John Martin will be the team leader. His tasks will be:

- To lead the evaluation process and coordinate the work with Ms Liz Ollier and the Medicines Programme Coordination Team (MPC)
- To review previous GGM monitoring reports in order to identify key activities supported by BMZ funding and to summarize their outcomes
- To consult with Ms Ollier, based upon her rapid review of GGM aims, tools and processes, in order to (a) agree those aspects of the programme to be reviewed in depth and (b) finalize the review instruments i.e. a short questionnaire to be sent to programme countries and a semi-structured follow-up questionnaire for interviews with key country and WHO actors
- To attend the GGM Global Workshop in Geneva (9th to 11th October) including conducting interviews with selected participants in coordination with Ms Ollier, and identifying several best practice countries for follow-up visits
- To carry out telephone interviews with focal points representing selected Phase I, II and III countries and WHO staff involved in the GGM Programme at global, regional and country levels
- To carry out country visits in coordination with WHO Regional Office focal points
- To prepare an Evaluation Report and present its findings and recommendations at a joint meeting of BMZ and WHO staff.

Ms Liz Ollier’s tasks will be:

- To undertake a scan of the aims, tools and processes to inform the areas the evaluators want to look at in detail.
- To draw up a short questionnaire to be used with all the Phase II and III countries attending the workshop. Ideally this questionnaire should be sent out in advance (probably mid/late September) in the hope that the majority might reply in writing and give the evaluators a chance to identify those they particularly want to interview
- To attend the workshop and to work in parallel both listening to presentations from the countries but also undertaking one to one interviews based on a semi-structure follow-up questionnaire
- Subsequently to undertake further telephone interviews (including some with Phase I countries) and to document these, identify any emerging themes and lessons to feed into the report.

Required results

- An evaluation report including final recommendations
### Annex 2: Persons Interviewed

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboudi Sawsan (Dr)</td>
<td>Department of Procurement and Supply/ MOH Jordan</td>
</tr>
<tr>
<td>Ala Virginia (Dr)</td>
<td>NCPAM Philippines</td>
</tr>
<tr>
<td>Artavatkun Witit (Dr)</td>
<td>Managing Director  Govt Pharmaceutical Organisation Thailand</td>
</tr>
<tr>
<td>Aungkasuvapala Narongsakdi (Dr)</td>
<td>Chairman Government Pharmaceutical Organisation Thailand</td>
</tr>
<tr>
<td>Baghdadi-Sabeti Guitelle (Dr)</td>
<td>Ex GGM Programme co-ordinator</td>
</tr>
<tr>
<td>Batayneh Mahmoud (Dr)</td>
<td>Director General/ Joint Procurement Department Jordan</td>
</tr>
<tr>
<td>Belisario Carole (Ms)</td>
<td>Diaspora for Good Governance, Philippines</td>
</tr>
<tr>
<td>Bigdeli Maryam (Dr)</td>
<td>Alliance for Health Policy and Systems Research</td>
</tr>
<tr>
<td>Bin Shahna Mohamed</td>
<td>RO EMRO</td>
</tr>
<tr>
<td>Birmingham Maureen (Dr)</td>
<td>WHO Representative Thailand</td>
</tr>
<tr>
<td>Boazza Omar (Dr)</td>
<td>MOH Morocco</td>
</tr>
<tr>
<td>Busool Abla (Dr)</td>
<td>Jordan University</td>
</tr>
<tr>
<td>Name</td>
<td>Affiliation</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Cecile Sison (Ms)</td>
<td>MeTA Philippines</td>
</tr>
<tr>
<td>Chafulumira Abdon (Dr)</td>
<td>MOH Malawi</td>
</tr>
<tr>
<td>Chafulumiro Francis (Mr)</td>
<td>Dep Chief Pharmacist GGM Focal Point Malawi</td>
</tr>
<tr>
<td>Chisale Moses (Dr)</td>
<td>Ex GGM focal point AFRO</td>
</tr>
<tr>
<td>Dauphin Catherine (Ms)</td>
<td>Former WHO NPO Philippines</td>
</tr>
<tr>
<td>De Jonchere, Kees (Dr)</td>
<td>Director WHO/EMP</td>
</tr>
<tr>
<td>Desta Abayneh (Dr)</td>
<td>TO AFRO</td>
</tr>
<tr>
<td>Dimancesco Deirdre (Ms)</td>
<td>TO/MTC (MeTA)</td>
</tr>
<tr>
<td>Dodoli Wilfred (Mr)</td>
<td>WHO NPO Malawi</td>
</tr>
<tr>
<td>Eksaengsri Achara (Dr)</td>
<td>Director Research and Development Institute Thailand</td>
</tr>
<tr>
<td>Eloundou Christelle (Ms)</td>
<td>MOH Cameroon</td>
</tr>
<tr>
<td>Fitzgerald, James (Dr)</td>
<td>RO PAHO/AMRO</td>
</tr>
<tr>
<td>Forte Gilles (Dr)</td>
<td>MPC co-ordinator</td>
</tr>
<tr>
<td>Guerro Melissa (Dr)</td>
<td>NCPAM Philippines</td>
</tr>
<tr>
<td>Hadidi Ikhlas (Dr)</td>
<td>Director/ Drug Directorate/ JFDA</td>
</tr>
<tr>
<td>Hamra, Rasha (Dr)</td>
<td>MoH Lebanon</td>
</tr>
<tr>
<td>Name</td>
<td>Position/Department</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Hartigan-Go Kenneth (Dr)</td>
<td>Director General FDA Philippines</td>
</tr>
<tr>
<td>Hogerzeil, Hans (Dr)</td>
<td>Former Director EMP</td>
</tr>
<tr>
<td>Homoud Lama (Dr)</td>
<td>Director/ Pharmacy Directorate/ MOH Jordan</td>
</tr>
<tr>
<td>Jaffar Sawsan (Mrs)</td>
<td>MOH Oman</td>
</tr>
<tr>
<td>Jaghbeer Maha (Dr)</td>
<td>Registration Department/ JFDA</td>
</tr>
<tr>
<td>Javroongrit Yuppadee (Ms)</td>
<td>Pharmacist Thai FDA</td>
</tr>
<tr>
<td>Kaupa Feston (Dr)</td>
<td>CEO Central Medical Stores Trust Malawi</td>
</tr>
<tr>
<td>Keohavong Bounxou (Dr)</td>
<td>MOH People’s Democratic Republic of Lao</td>
</tr>
<tr>
<td>Kiatying-Angsulee Niyada (Dr)</td>
<td>Manager Drug System Monitoring and Development Programme Thailand</td>
</tr>
<tr>
<td>Kresham Ethar (Dr)</td>
<td>Inspection Department/ JFDA</td>
</tr>
<tr>
<td>Laing, Richard (Dr)</td>
<td>EMP/MPC</td>
</tr>
<tr>
<td>Leitner Kerstin (Dr)</td>
<td>Chair GAG</td>
</tr>
<tr>
<td>Loko Christian (Pr)</td>
<td>MOH Benin</td>
</tr>
<tr>
<td>Macé Cécile (Dr)</td>
<td>TO/MPC</td>
</tr>
<tr>
<td>Mathiya Wilford (Mr)</td>
<td>Acting Registrar, Pharmacy Medicines and Poisons Board Malawi</td>
</tr>
<tr>
<td>Name</td>
<td>Organization/Title</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Musopole Ipyana (Mr)</td>
<td>Anti Corruption Bureau Malawi</td>
</tr>
<tr>
<td>Mwansambo Charles (Dr)</td>
<td>Permanent Secretary Malawi</td>
</tr>
<tr>
<td>Nafa Sana (Dr)</td>
<td>WHO Jordan</td>
</tr>
<tr>
<td>Nuseirat Adi (Dr)</td>
<td>WHO Jordan</td>
</tr>
<tr>
<td>Obeidat Hayel (Dr)</td>
<td>Director General/ Jordan FDA</td>
</tr>
<tr>
<td>Ondari Clive (Dr)</td>
<td>MAR Co-ordinator</td>
</tr>
<tr>
<td>Ouladi Didar (Dr)</td>
<td>Nur University, Bolivia</td>
</tr>
<tr>
<td>Palakornul Duangta (Ms)</td>
<td>Chief Pharmacist</td>
</tr>
<tr>
<td>Purevsuren Sodnomtseren (Dr)</td>
<td>University of Mongolia</td>
</tr>
<tr>
<td>Qusos Lubna (Dr)</td>
<td>Head of Quality Control Drug Lab/ Jordan FDA</td>
</tr>
<tr>
<td>Rago Lembit (Dr)</td>
<td>WHO/EMP/QSM</td>
</tr>
<tr>
<td>Raichki Renata (Pr)</td>
<td>University Ss Cyril and Methodius Macedonia</td>
</tr>
<tr>
<td>Ramzy Ismail Mohammed (Dr)</td>
<td>TO EMRO</td>
</tr>
<tr>
<td>Rhaouti Mohamed (Dr)</td>
<td>Ex-President National Council of Pharmacists Morocco</td>
</tr>
<tr>
<td>Ronquillo Kenneth (Dr)</td>
<td>Director HR, DoH and GGM/TWG Integrity Dev Cluster Philippines</td>
</tr>
<tr>
<td>Name</td>
<td>Organization</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Rushdi Mariam (Dr)</td>
<td>Jalan University Malaysia</td>
</tr>
<tr>
<td>Sabbagh Mohammed (Dr)</td>
<td>Drugstores Owners Association Jordan</td>
</tr>
<tr>
<td>Saif Jamal Abu (Dr)</td>
<td>Jordan High Health Council</td>
</tr>
<tr>
<td>Saleh Rafat Abu (Dr)</td>
<td>Jordan Pharmacy Association</td>
</tr>
<tr>
<td>Sattin, Eric (Mr)</td>
<td>European Commission</td>
</tr>
<tr>
<td>Saulog Vanessa (Dr)</td>
<td>DoH Philippines</td>
</tr>
<tr>
<td>Sautenkova, Nina (Dr)</td>
<td>Acting Regional Adviser, EURO</td>
</tr>
<tr>
<td>Serhan Fatima (Dr)</td>
<td>WHO/FWC/IVB/EPI</td>
</tr>
<tr>
<td>Sintavanarong Pradit (H.E Dr)</td>
<td>Minister for Public Health Thailand</td>
</tr>
<tr>
<td>Susonwanich Netnapis (Ms)</td>
<td>Asst Sec General National Health Security Office Thailand</td>
</tr>
<tr>
<td>Tharatep Chanvit (Dr)</td>
<td>Deputy Permanent Secretary, MoPH, Thailand</td>
</tr>
<tr>
<td>Tisocki Klara (Ms)</td>
<td>Regional Advisor EMP/WPRO</td>
</tr>
<tr>
<td>Van Lerberghe, Wim (Dr)</td>
<td>Director HDS/HSS</td>
</tr>
<tr>
<td>Vera Theresa (Dr)</td>
<td>Director Procurement DOH Philippines</td>
</tr>
<tr>
<td>Yoongthong Worasuda (Dr)</td>
<td>MoPH Thailand</td>
</tr>
<tr>
<td>Zoubi Esraa (Dr)</td>
<td>Registration Department/ JFDA</td>
</tr>
</tbody>
</table>
Annex 3: References

- Measuring Transparency in the Pharmaceutical Sector; Assessment Instrument, WHO/EMP/MAR 2009
- Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector, Jordan, WHO/EMRO 2008
- Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector in Malawi, WHO/PSM/PAR 2008
- Thailand; Drug Policy and Use of Pharmaceuticals in Health Care Delivery, WHO/SEARO, August 2012
- Good Governance for Medicines, Progress Report 2010, WHO 2010
- Contractual Agreement between World Health Organization and Government Federal Republic of Germany, 2010
- WHO/Government of the Federal Republic of Germany Collaboration on Good Governance in Medicines; Progress Report Year 1, December 2011
- Good Governance for Medicines, Draft Evaluation Strategy Consultation Report; WHO/GGM, February 2010
- WHO/BMZ Collaboration on Good Governance in Medicines, Report of Meeting of GGM Phase III Countries, Kuala Lumpur, Malaysia, July 2011, WHO/GGM 2011
- WHO Programme Budget 2012-13, WHO 2011
Annex 4: Reports of Visits to Four Countries

Introduction:

In order to gain a deeper insight into the status and experiences of GGM in countries the evaluation Terms of Reference include provision for visits to three countries, subsequently extended to four. They were identified during the Global Meeting of Phase II and III countries held in Geneva in October 2012 on the basis of their country reports and presentations. They are Jordan, Malawi, Philippines and Thailand. All are longstanding GGM countries and all except Malawi are in GGM Phase III.

Note: Malawi progressed to Phase III during the country visit by the evaluator when its GGM framework was reviewed and adopted at a meeting of stakeholders.

Thanks are due to country GGM focal points and WHO representations for organising the visits at very short notice.

The schedule of visits was as follows:

- Jordan 21st to 23rd October 2012
- Malawi 29th October to 2nd November 2012
- Thailand 5th to 7th November 2012
- Philippines 8th to 10th November 2012

JORDAN

BACKGROUND

Jordan spends 8.6 per cent of annual GDP on health services, equivalent to US$ 322 per capita. Expenditure on pharmaceuticals consumes 35.9 per cent of total health expenditure, representing 3 per cent of GDP. Around 38 per cent of medicines expenditure takes place in the public sector. (Source: NHA data). Despite this relatively high expenditure access to medicines remains an important problem in Jordan.

In 2003 Jordan established a national Food and Drug Administration as a means of improving efficiency and transparency in medicines regulation and supply. In 2007 the Ministry of Health requested Jordan’s participation in WHO GGM with a particular aim of measuring transparency and vulnerability to corruption within six essential functions of the public pharmaceutical system. These are registration, promotion, inspection, selection, procurement and distribution of medicines.
PRECEDING REGIONAL AND NATIONAL ANTICORRUPTION ACTIVITIES

In line with international thinking and action with a view to improving good governance and preventing corruption, there have been a number of regional good governance initiatives involving the Arab states since 2000. Jordan has played a leading role in a number of them, particularly “the good government initiative of development service in the Arab countries” launched in Jordan in February 2005 and also the project to support implementation of the UN Convention against corruption in Arab countries, launched in Jordan in 2008. Jordan, itself, starting with its 1952 constitution, has introduced a large number of anti-corruption laws and mechanisms including most recently establishment of the Anti-corruption Bureau in 2005.

GGM PROCESS AND OUTCOMES

The GGM process in Jordan has closely adhered to the WHO model.

Phase I:

Assessment was conducted in October-November 2007 using the WHO standardized assessment instrument. The primary purpose was not to measure corruption per se but to examine how resistant or vulnerable the system is towards unethical practices.

Discussions with senior officials during the country visit confirmed their judgement that the assessment instrument had the necessary qualities to engage the principal national stakeholders in a constructive manner, recognising the sensitivity of the issues involved. This was an important condition for achieving an implicit secondary goal to provide an entry point for establishing a national programme on good governance for medicines. The initial assessment would serve as a baseline from which to monitor progress in improving transparency and good governance over time.

The focus of GGM in Jordan is on increasing transparency in administrative structures and processes of the pharmaceutical system, principally regulation and supply management. (Ref: MeTA evaluation report).

The assessment concluded that the area of medicines promotion was the most vulnerable to corruption whilst procurement and distribution were minimally vulnerable due to transparency mechanisms that had already been established.

Interviews confirmed that the momentum created by the assessment prompted a number of positive actions in the short term. These included development of Conflict of Interest forms which became obligatory for members of a small number of important committees and the development of some prototype standard operating procedures.

**Phase II:**

This phase involved a nationwide consultation process among key stakeholders which took place in February 2008. They validated the results of the assessment and defined the basic elements necessary for a programme to improve governance in the national pharmaceutical system.

It was agreed to establish two national committees - GGM Steering Committee and Task Force Committee - to (a) develop policies and strategies for strengthening good governance across the entire public medicines system, and (b) to guide, coordinate, manage and evaluate the GGM programme in Jordan.

The Steering Committee comprises high-level representatives from: Ministry of Health, Ministry of Public Sector Development, Jordan Food and Drug Administration, Anti-Corruption Commission, Royal Medical Services, High Health Council, Joint Procurement Department, Jordan University Hospital, Jordan Consumer Protection Society, Jordan Pharmacy Association, Jordan Association of Pharmaceutical Manufacturers, Drug Stores Owners Association, and WHO. It is Chaired by the Director General FDA.

**Phase III:**

This phase is on-going and focuses on translating the GGM programme into action, ensuring that it becomes institutionalized and fully integrated within the MOH and the public pharmaceutical sector. Its current agenda comprises the following:

- Adoption of a Code of Conduct for pharmacists working in the public sector
- Establishing cooperation and coordination with other anti-corruption agencies especially the national anti-corruption commission and projects, especially the Medicines Transparency Alliance (MeTA)
- Publication (October 2012) and promotion of a resource document (including e-version) that for the first time compiles in one source all existing anti-corruption legislation and associated institutional policies that include anti-corruption laws and sanctions
- Development of a “whistle-blowing mechanism” and guidelines for the protection of whistle-blowers
- Development of a Conflict of Interest management policy, including review and monitoring of declarations
• Establishment and adoption of clear criteria for selection, Terms of Reference, and duration of tenure of members of all committees related to the public pharmaceuticals sector

**Cooperation with MeTA (Medicines Transparency Alliance)**

Note: background to MeTA is included under Section 4.6, GGM programme management. WHO was a sponsoring partner and is now an implementing partner with Health Action international (HAI). It works in seven countries, three of which are also GGM countries, (Jordan, Zambia and Philippines)

MeTA Jordan conducted a pilot phase from early 2009 until the end of 2010. It was the first forum in Jordan to engage all stakeholders in medicines – public, private and civil society. In line with MeTA International, its aims are to improve transparency in all elements of the supply chain from policy development and implementation through procurement, promotion and distribution.

According to respondents, MeTA was concerned that GGM’s base in the Food and Drug Administration and oversight by the Ministry of Health might influence its objectivity. Accordingly MeTA maintained a distance from GGM activities, including locating its secretariat in the High Health Council, a small, official body dedicated to health policy issues which functions as a think tank.

In view of the strong stakeholder engagement in the GGM process, described above, including high-level political approval, it is apparent that MeTA was seen to function in parallel and to have missed an opportunity for synergy with GGM.

MeTA Phase 2 will extend from October 2012 until September 2013. Its secretariat has relocated to the JFDA and its implementation is being guided by WHO and HAI. These measures are expected to increase the effectiveness and sustainability of the programme by bringing it close to mainstream action on medicines overseen by FDA, including complementarity with GGM. This aim will be assisted by the fact that the local WHO staff responsible for support to MeTA are also closely engaged in GGM.

**GGM performance so far – the evaluator’s assessment**

• Phase I and II had important impacts. They succeeded in creating awareness at high levels of the importance of transparency in effective management and governance of the public medicines system. The GGM process has brought together all key national stakeholders, including representatives of local manufacturers. It has provided the rationale and impetus for them to remain engaged and to work together. According to one interviewee “Before GGM it was go-it-alone, including JFDA.”
The findings of the Phase I assessment already prompted the FDA to revise the regulations pertaining to medicines promotion and advertising; to develop clear written criteria for selection of members committees, starting with the essential medicines selection committee; and to initiate a Conflict of Interest process, starting with the development of forms for members of committees. Interviews confirmed that the subsequent Phase II workshops to review findings helped achieve consensus amongst other stakeholders on the importance of pursuing Conflict of Interest as a GGM priority.

Phase III has resulted in the following outcomes:

- Compilation of anti-corruption legislation and policies
- Publication of a document (October 2012) that compiles for the first time anti-corruption legislation and institutional policies that contain laws and sanctions
- Development of a whistle-blowing mechanism and a document that spells out safeguards
- Adoption of a code of conduct for pharmacists working in the public sector
- Development of Conflict of Interest guidelines, management policy and review of declaration forms

Discussion with members of the Steering Committee and Technical Working Group revealed a sense of satisfaction and pride with what has been achieved so far. Phases I to III have successfully created the right environment, process and consensus on agenda in the short term. However, from their perspectives of expected outcomes there was also a strong consensus that “GGM is just beginning.”

The challenge will be to maintain momentum – what one interviewee described as “GGM Phase IV”. Discussants felt that the following issues should be included in plans for future action:

- Engaging relevant civil society organizations should be a priority for the next phase
- The TWG should draft a strategic plan aimed at strengthening GGM sustainability and maintaining its momentum and credibility. Priority activities in the short term would include:
  - Strengthening GGM institutionalisation including (1) establishing a small GGM team to support both the Technical Working Group and Steering Committee; (2) creating a GGM budget line to provide small amounts of flexible financing as needed and (3) integrating GGM and MeTA planning and management. This has direct implications for WHO Jordan that provides technical and administrative back-up for both.
- Engaging doctors in the GGM process both by organizing awareness and training activities for doctors, including on Conflict of Interest, and encouraging a more active participation in the Steering Committee by the Jordanian Medical Association.

- Giving priority to monitoring and evaluation of GGM with an emphasis on measuring outcomes and impact. This would include defining a set of impact indicators.

- Encouraging networking and sharing of good practice between GGM countries. One of the innovation could be for WHO to support peer review visits to countries for purposes of sharing experiences and public endorsement of good performance.

MALAWI

Background

Malawi is a low-income country which is highly dependent on external assistance by international partners. Current financial support is said to constitute 60 per cent of the annual public sector budget. At the same time health is the biggest spending sector and public sector medicines spending absorbs the biggest portion of the health budget.

Strengthening the national health system is a government and partner priority. There is an on-going health sector SWAp mechanism in place. It includes a working group dedicated to strengthening the public pharmaceutical sector which has a background of longstanding irregularities and unethical behaviour and has received adverse publicity in both the domestic and foreign press.

There was a transfer of political power to a new President, earlier in 2012. The current political environment is marked by widespread public concern about high prices and low salaries in the wake of currency devaluation under IMF supervision. There is also widespread concern about shortage of medicines in public health facilities, especially in Rural Health Centres and District Hospitals, and public perception that corruption is a principal cause.

The origins of GGM

The creation of GGM was preceded by the so-called Medicines Leakage Study in 2006 (Assessment of Drug and Medical Supplies Leakages from Medical Stores and Public Health Facilities) which focused on losses of medicines during the processes of procurement and distribution which fell under the responsibility of the then Central Medical Stores.

During his participation in the 2006 World Health Assembly the Minister of Health requested WHO support through GGM.
**The Phase I Transparency Assessment** took place in 2007. It examined those components of the medicines chain that had not been included in the Leakage Study i.e. medicines registration, control of medicines promotion, inspection of establishments, selection of essential medicines and procurement.

Findings pointed to extreme vulnerability of almost all these functions. Only inspection scored as moderately vulnerable. Whilst legislation existed it was often out of date and provisions were largely unknown to stakeholders; operational procedures in all functions either did not exist or were vague and outdated; and governance mechanisms had lapsed.

A cross-cutting finding was the absence of a sense of ethical standards, the absence of a meaningful code of conduct, written Standard Operating Procedures and guidelines on conflict of interest.

The Phase I Assessment was not immediately followed up by Phase II as recommended by WHO. The formal reason was said to be the need to await the reorganisation of Central Medical Stores as recommended by the Leakage Study and supported by external partners.

Other reasons were reported to include suspicion on the part of stakeholders, that the process would lead to “finger pointing” and consequent blockage by individuals said to be hostile to GGM aims. By implication the Ministry of Health preferred to maintain the on-going “laissez-faire” approach.

**The GGM process**

The GGM process has moved forward very slowly. Nevertheless there have been a number of tangible GGM achievements during 2011 and 2012, including the continuing engagement both by national and partner stakeholders and improved information sharing during development of Standard Operational Procedures recommended by the Phase I assessment.

The Ministry of Health finalised a draft GGM Implementation Framework with WHO support in May 2012. It was discussed and adopted at a meeting of stakeholders in November 2012.

**REVIVING GGM – the evaluator’s assessment**

It is an opportune time to revive GGM in Malawi. The current government is said to be committed to good governance and fighting corruption. This can facilitate GGM action, at least in the short term.

At the same time the drastic restructuring of the Central Medical Stores, implemented in response to the “leakage study” has been largely completed but needs close
oversight and encouragement. Meanwhile the national regulatory authority PMPB is in acute need of support and lacks both technical and ethical capacity. The GGM process, well led, could provide an important complement to conventional technical and financial support provided by external partners.

GGM is currently driven by a national GGM Committee. Members are Ministry of Health, Ministry of Finance, Central Medical Stores Trust (CMST), Pharmacy, Medicines and Poisons Board (PMPB), Anti-Corruption Bureau (ACB), Department of Human Resources, Malawi Health Equity Network and WHO. The Committee appears to combine the roles of GGM Technical Working Group as well as the Steering Committee.

It is not evident that any of them fulfils the criteria of a “GGM champion” as seen in some high-performing GGM countries. Therefore strong but subtle support on the part of WHO will be required in order to sustain and strengthen national ownership of the process.

An additional potentially important oversight mechanism is the SWAp-related Drugs and Medical Supplies Technical Working Group which includes all SWAp partners – DFID, USAID, NORAD, GIZ, UNICEF and WHO. Its Co-Chairs are the Ministry of Health and USAID. It maintains a passive interest in GGM activities, which might be upgraded to more active support.

Its rationale is to provide one single steering and oversight mechanism with regard to partner support to strengthening the medicines system. In principle GGM visibility and potential future funding can benefit from such a mechanism rather than having a dedicated Steering Committee. (Unfortunately the evaluator was unable to meet any partner representative during his brief visit).

WHO support

The evaluator noted that WHO technical, political and financial support has played a critical role in keeping GGM alive in Malawi. A national NPO has specific responsibility for managing WHO technical support in the area of medicines, including GGM, which he combines with malaria programme activities.

WR Malawi is supportive of GGM and was instrumental in arranging a number of interviews with senior MoH officials during the evaluator’s visit.

A consequence of this strong support is that a number of stakeholders perceive GGM as a WHO programme rather than a national process. Changing this perception will be a WHO challenge for the short term since weak national ownership to date can be seen to have retarded progress and reduced potential GGM impact. It is a delicate issue since GGM would probably not survive in the absence of WHO
encouragement, “pushing” and funding of strategic events, such as the recent stakeholders meeting to finalise the GGM framework.

THAILAND

Background

Thailand suffered an economic crisis beginning in 1997. The public health system came under serious stress due to increasing medicines prices accentuated by devaluation of the Thai Baht. Hospitals under the Ministry of Public Health, providing 70-80% of health and medical services, were projected to be bankrupt within two years.

The high cost of medicines was exacerbated by individual hospitals purchasing medicines at different prices from the same companies; pharmaceutical companies offering incentives to physicians for prescribing their products; and by physicians who prescribed trade name medicines rather than generics.

The government response was pharmaceutical management reform. It included limiting the type and amount of medicines stocked by hospitals, establishing provincial group medicines purchasing schemes and setting up a pharmacy information centre to share information about prices among hospitals.

In 2004, Thailand became one of the four GGM pilot countries with the aim of using programme support to pursue their goals of increasing transparency and ensuring access to medicines whilst containing costs.

GGM in Thailand

The programme has benefited from a “GGM champion” who has overseen GGM activities since its beginning. He has recently been promoted to the post of Deputy Permanent Secretary in the Ministry of Public Health.

Good governance was a MoPH goal even before Thailand’s participation in the WHO programme. But action was sporadic and fragmented, not systematic. It was also based almost exclusively on a “discipline approach.” Early exposure to the WHO methodology revealed the potential value of introducing a strong “values-based” dimension. The Phase I assessment demonstrated the big picture of medicines management issues and helped underline the rationale for the two-pronged approach.

In hindsight “the discipline approach alone is inefficient. It needs a lot of rules and power of implementation for modest outcome. The values base encourages awareness and readiness to take action on the part of committed personnel throughout the health system.”
In the subsequent period of five years, the following achievements were attributed to the GGM process:

- A pooled medicines purchasing scheme by hospitals was established with an agreed list of medicines and suppliers, resulting in lower costs for quality medicine procurement
- National pharmaceutical laws and regulations were reviewed and updated
- A national database on good governance in drug systems was established, containing all publications and articles on corruption and a collection of examples of unethical practices was prepared for purposes of advocating the importance of transparency
- The minutes from national medicine committee meetings were made publicly available and good governance was added to the curriculum of Faculties of Pharmacy

**The need to adapt to changing circumstances**

Access to quality affordable medicines is not a problem in Thailand at the present time. The system of pooled procurement for public sector facilities continues to work well. Even so government is very concerned by high and increasing medicines expenditure. The fact that there are some 200 million OPD visits and 7 to 10 million admissions in public sector facilities every year provides a picture of the volume of medicines consumption.

Whilst GGM continues to demonstrate positive outcomes there are signs that Thailand needs to stake stock of the next generation of challenges and adapt the GGM strategy accordingly.

The National Ethical Framework on Drug Promotion was published in 2011. And in 2012 the Pharmacy Information System helped detect the theft of pseudoephedrine involving 14 hospitals, leading to the dismissal of five hospital pharmacists.

Nevertheless evaluation interviews revealed common concern that concerted action is needed to tackle the underlying causes of rising costs.

Costs are rising despite strong control mechanisms including NHSO (National Health Security Organisation) budget allocations directly to hospitals; central pooled procurement, including an emphasis on generic medicines; production and supply of many common medicines by GPO (Government Pharmaceutical Organisation); the Pharmacy Information System and peer review in hospitals. A principal culprit is seen to be the fee-for-service system for civil servants and their families (CSMBS). It covers approximately 10 million people yet its costs are equal to those of the remainder of the entire public system.
Several respondents referred to the growing fragmentation of the pharmaceutical management system. There is a large number of specialist committees concerned with the many functions of the medicines chain. In addition the Ministry of Public Health has set up a number of parallel working groups to advise government on cost control, quality and other governance issues. This has led to duplication of effort, lack of clarity and difficulties for the senior managers of the pharmaceutical system maintaining a clear view of events.

Additional problems include:

- High turnover of staff (pharmacists) at all levels. This has diluted commitment to transparency and good governance which, in turn, is undermining the quality of reporting to the Pharmacy Information System and provides space for unethical practice (e.g. by hospitals that have an interest in wishing to conceal theft, as in the case of the pseudoephedrine scandal)
- Promotion of medicines by transnational companies through gifts and incentives to doctors such as funding for research and financial support for attendance at international “scientific” meetings etc. It distorts codes of conduct
- Loss of transparency at hospital level. Undergraduate training does not equip doctors with understanding and a sense of duty with regard to information sharing.
- Bad prescribing practice on the part of many university teaching hospital specialists who tend to reject generics in favour of high-cost brand name medicines. This sets a very poor example for undergraduates and junior doctors

**Updating the GGM framework and strategy**

There is consensus that the time has come to update both the GGM framework and the strategy for its implementation. The focus should be on the challenges noted above. All respondents acknowledged that GGM has established the necessary structure and process but much more attention should be given to defining concrete outcomes and monitoring and evaluating GGM impact.

The time is ripe due to the high priority given to fighting corruption by the recently elected government. GGM should draw benefit by linking action on transparency in pharmaceuticals management to the national anti-corruption activities. One opportunity is to share GGM experiences and, in particular, demonstrate the value of the two-pronged discipline- and values-based approaches.

In the view of the -FDA (Food and Drug Administration) “the right stakeholders are already engaged and committed.” They are: Ministry of Public Health, Ministry of Agriculture, Ministry of Education, Ministry of Foreign Affairs, Ministry of Commerce, Thai Pharmaceutical Manufacturers Association, the Association of Pharmacists,
doctors’ representatives and consumer associations, notably the Thai Health Promotion Foundation which links with the National Health Assembly.

The role of WHO

All respondents acknowledged the value of WHO’s low key technical and strategic roles, rather than as a provider of funds. Support to the GGM process should not lose sight of other useful WHO inputs such as the recent study by the SEARO Regional Adviser on Drug Policy and Use of Pharmaceuticals in Health Care Delivery in Thailand.

Inter-country networking, both regional and global, is valuable both to well developed countries like Thailand and poor countries. In the context of GGM, WHO should strengthen this role in the future by creating an inter-country network for the purposes of sharing experiences, promoting good governance standards and supporting technical work, especially on methods for evaluating GGM impact.

Conclusions:

- Thailand continues to provide an example of GGM best practice. It is country-led rather than WHO-driven, an essential attribute in ensuring sustainability.
- The value of WHO support is acknowledged - timely and responsive to country demand.
- There is a consensus on the part of many stakeholders that a review of GGM strategy is needed in order to identify the tactics and actions necessary to help stem the increasing cost of medicines. The time is opportune in view of the importance of good governance stressed by the current government.
- Stakeholder institutions are strong and the GGM structure is impressive. Nevertheless there are signs, such as a reduction in the quality of routine reporting to the Pharmacy Information System, that reinforcement of key processes is necessary.

PHILIPPINES

Background

The country has a population of approximately 95 million and comprises more than 7000 islands. Governance is based on a federal system with decentralisation to 16 regions, 82 provinces, 135 cities and 1493 municipalities.

One consequence of this complexity is that the national health system is fragmented. National and local service delivery functions are poorly coordinated, including procurement and supply of medicines. Regulation and governance agreed at national
level is obstructed and space is provided for unethical practices, such as selling of medicines by doctors.

At the level of provinces and Local Government Units (LGUs) supply of medicines is under the control of the local political leadership and is reportedly often subject to political influence.

**GGM implementation**

Philippines was one of four pilot countries when WHO launched the GGM programme in 2004 (see introduction).

Early emphasis on transparency and good governance was introduced to bring a systematic and analytical view to procurement, regulation and supply.

Subsequent participation in the WHO programme was seen as a means of reinforcing national commitment to equitable access to medicines by promoting transparency both as a managerial tool and a guard against unethical behaviour. The emphasis which the GGM methodology places on engagement of all stakeholders as well as the opportunity to share experiences with other countries were important incentives for participation by both national and local levels.

The GGM Phase I assessment took place in 2004 and the results were finalised and shared during 2005. The subsequent Phase III framework was endorsed in 2006. The membership of the GGM Steering Committee was approved in 2006 but according to respondents it was too large and has never been able to function properly.

Phase I and II processes were successful in (a) raising awareness and (b) mobilising many people in the various stakeholder institutions related to medicines procurement, regulation and supply.

Implementation of the Phase III framework is reportedly less successful. Nevertheless, an early achievement was the development of a GGM manual for promoting and measuring improvements in efficiency and transparency with regard to selection, procurement and distribution of medicines in health facilities at provincial, district and local levels. The manual established criteria, indicators and operational standards for these three functions.

It was the basic tool used in a GGM awards scheme launched in 2008 by the Department of Health in collaboration with MeTA as an advocacy and compliance mechanism targeting health facilities in Local Government Units. Three awards were presented at a well-publicised event in Manila in January 2010. It is intended that the scheme will be gradually extended to all LGUs and linked to the LGU Scorecard and
Seal of Good Housekeeping Scheme overseen by the Department of Local Government.

The expected outcomes are defined as (a) improving the health system through improved transparency and accountability (b) improving the motivation and performance of health workers and consequently (c) improving service delivery.

Other achievements noted by respondents are:

- Introduction of the Medicines Access Scheme which aims to reach the poorest people with “a complete outpatient regimen for the leading causes of morbidity and mortality.” In practice this includes low-cost medicines for common infections, hypertension and diabetes (ComPack)
- Launch of the Philippines National Drug Policy and strategy (2011-2016)
- Update of the National Formulary scheduled to be published in 2013. It is reported that 30 preparatory meetings of the expert committee have taken place during 2012
- Development of a database of drug procurement prices in health facilities to determine the Allocation Budget Ceiling (ABC) for medicines in the public sector. It is intended to be used in future by all government health facilities as the basis for bidding and procurement and by the national health insurance agency in the reimbursement of medicines. Guidelines for implementation are reported to be under preparation

GGM Current Status – the evaluator's assessment

In effect the GGM process has been “on hold” since the last meeting of its Steering Committee in 2011. The progress reported above is more the result of previously agreed DoH and NCPAM commitments than the fruits of the labour of the totality of GGM stakeholders.

GGM leadership has been unstable and subject to shifts. Before joining the WHO programme, responsibility for taking forward good governance lay with the Food and Drug Administration (FDA). Subsequently GGM was transferred to the Department of Health (DoH) and then to NCPAM. Both had a high turnover of senior staff, many of whom reportedly had little experience of medicines and had other priorities.

Nevertheless, and despite the lack of momentum many respondents believe that the time is ripe for GGM revival for the following reasons:

- President Aquino’s election platform accorded high priority to fighting corruption. Now that he is in office there is an opportunity for GGM to gain high-level political support. This can serve as a stimulus to the DoH to give strong support to GGM which has been lacking in the past.
The Food and Drug Administration (FDA) has appointed a new and dynamic Director General. The new leadership needs to be supported and, if successful, can reciprocate by delivering an institution that is fit for the purpose. FDA has a critical role to play but is seriously undermined by inadequate resources, low credibility and a longstanding lack of trust on the part of other stakeholders. One respondent described it as “under capture by local manufacturers and political interests.” Its inability to routinely assess the quality of generic medicines, principally due to the lack of a quality control laboratory capacity, has had a particularly serious effect. It has led to a widespread lack of confidence in generics on the part of many doctors. This situation has been exploited by brand name manufacturers in order to promote their high-cost products.

NCPAM senior management capacity has been boosted by the return from postgraduate training of one of its Directors who is widely respected as a dynamic leader. NCPAM is responsible for the procurement and supply of affordable medicines to peripheral health facilities, especially through the ComPack scheme (see above). An impact survey in 2010 showed that availability of ComPack medicines in rural health centres had increased from 25 to 56 per cent. It is intended to boost this further by targeting availability at district hospitals during 2013. A viable GGM would be an important ally in this endeavour.

The start-up of Phase 2 of the MeTA programme began in October 2012. Whilst it is not seen as an implementing agent, MeTA is regarded as an influential mechanism for promoting awareness on the needs and benefits of transparency and good governance and its local Council comprises many influential individuals active in the pharmaceutical sector. WHO will play a technical advisory role in the Phase 2 programme, thereby presenting an opportunity to promote stronger complementarity with GGM.

The role of WHO in GGM revival

Restarting GGM after a year’s inactivity will not be sufficient in itself to address the serious obstacles to achieving universal access to essential medicines in the Philippines. The nature of the obstacles including political influence, unethical behaviour and a fragmented health system require a process that is accorded high-level priority, status and support. All are currently lacking.

As in the Malawi case, there is an important role for WHO at local, regional and global levels in order to help create the necessary momentum. An initial element would be a diplomatic initiative to urge the necessary high-level commitment and commit WHO support. A second task is to facilitate a situation analysis by stakeholders in order to identify concrete activities, strategies for their implementation and impact indicators. One possible focus could be development and implementation of a Conflict of Interest policy, including a high-profile
communications element to oversee and report both progress and obstacles to the public. Civil society would be an important ally.

WHO also has an instrumental role to play in building complementarity between a revived GGM process and implementation of MeTA Phase 2.

**Conclusions:**

- The GGM process has successfully created considerable awareness in favour of transparency in the pharmaceuticals system and has established a network of stakeholders with important members including civil society.
- The absence of a “GGM champion” and strong DoH support has impeded progress, including at LGU level where strong national oversight has been missing.
- The weakness of the FDA has left a serious void in national medicines regulatory capacity
- Whilst a GGM framework has been adopted its implementation has been weak, exacerbated by a one year gap since the last meeting of the GGM committee.
- MeTA has established an influential network that should have been better linked to the GGM process in the interests of complementarity
- Despite these problems some individual GGM stakeholders such as NCPAM have continued to achieve significant results
- Events including the current government anti-corruption drive and the appointment of a new FDA Director General are creating the rationale and supportive environment for a revival of the GGM process. WHO has a critical role to play in nurturing the revival process

**Summary of lessons learnt in four countries**

1. High-level commitment, coupled with a stable GGM steering mechanism, comprising a wide range of stakeholders, are important determinants of GGM impact and sustainability.
2. In these ideal circumstances the GGM instruments, especially Phases I and II can achieve important impacts – widespread awareness, rationale and impetus for stakeholders to remain engaged and work together and consensus on GGM priorities, agenda and expected outcomes.
3. Where health systems are weak and/or where countries are decentralised, much greater effort is required in order to achieve a critical level of momentum to enable GGM to progress.
4. Longstanding membership of GGM committees by stakeholder representatives creates stability and can ensure GGM survival in difficult country circumstances where support is lacking or lukewarm.
5. A high-level GGM champion is a powerful attribute and conversely GGM struggles in the absence of high-level support.
6. Reaching GGM Phase III is seen as a beginning and a point when careful consideration of focus, targets and expected outcomes is required.

7. Monitoring and evaluation based on outcomes and impact is essential to provide the information needed both to steer GGM and to establish its credibility amongst sceptics.

8. The engagement of civil society as GGM stakeholders encourages emphasis on impact and informing public opinion.

9. In addition to GGM Steering Committees and TWGs, there is a case to be made in favour of a small dedicated GGM team to take responsibility for maintaining day to day oversight and follow-up.

10. WHO must remain sensitive to changing country contexts in order to choose the most appropriate support to be provided to countries. A basic criterion is country status as “country-led” or “WHO-led.”

11. WHO support should be sensitive to signs that GGM review is necessary, including in countries with well-established and strong GGM mechanisms.

12. WHO should develop the capacities, skills and mind-sets necessary to ensure subtle, facilitative and tactical support to countries at critical points in GGM evolution, in addition to traditional technical cooperation. Flexible, small-scale financial support is also often required, especially in WHO-led processes.

13. An overall view of achievements and comparing activities with inputs indicates that GGM has been very cost-effective.

14. It is difficult for GGM to have impact in countries where the MRA is weak.

15. GGM should be linked both to other GG programme and to wider WHO support in medicines and strengthening health systems. Complementarity should be a goal reflected in the CCS.
Annex 5: Summary of Current Status of GGM Countries

This table is sourced from GGM Country Situation August 2012, WHO/MCT 2012

<table>
<thead>
<tr>
<th>GGM Countries</th>
<th>Region</th>
<th>Starting date</th>
<th>Countries status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bahrain</td>
<td>EMRO</td>
<td>2012</td>
<td>Phase I</td>
<td>Training Phase I done in June 2012</td>
</tr>
<tr>
<td>Benin</td>
<td>AFRO</td>
<td>2007</td>
<td>Phase III</td>
<td>National Framework published, launch of framework and follow-up of March workshop under discussion</td>
</tr>
<tr>
<td>Bolivia</td>
<td>AMRO</td>
<td>2006</td>
<td>Phase III</td>
<td>Proposed activities received for 2012</td>
</tr>
<tr>
<td>Cambodia</td>
<td>WPRO</td>
<td>2006</td>
<td>Phase I</td>
<td>No activities planned for 2012</td>
</tr>
<tr>
<td>Cameroon</td>
<td>AFRO</td>
<td>2007</td>
<td>Phase II</td>
<td>Assessment report under publication, Phase II training to be done, Framework to be developed</td>
</tr>
<tr>
<td>Colombia</td>
<td>AMRO</td>
<td>2007</td>
<td>Phase I</td>
<td>Finalisation of the transparency assessment in 2012</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>AMRO</td>
<td>2008</td>
<td>Phase II</td>
<td>No activities planned for 2012</td>
</tr>
<tr>
<td>Country</td>
<td>Region</td>
<td>Year</td>
<td>Phase</td>
<td>Status</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------</td>
<td>-------</td>
<td>--------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Ecuador</td>
<td>AMRO</td>
<td>2007</td>
<td>I</td>
<td>No activities planned for 2012</td>
</tr>
<tr>
<td>Egypt</td>
<td>EMRO</td>
<td>2010</td>
<td>I</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>AFRO</td>
<td>2007</td>
<td>I</td>
<td>Put on hold until country comes back to WHO AFRO and HQ</td>
</tr>
<tr>
<td>Indonesia</td>
<td>SEARO</td>
<td>2006</td>
<td>II</td>
<td>GGM process stopped but anti-corruption activities done at country level</td>
</tr>
<tr>
<td>Iraq</td>
<td>EMRO</td>
<td>2010</td>
<td>I</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Islamic Republic of Iran</td>
<td>EMRO</td>
<td>2012</td>
<td>I</td>
<td>Training Phase I done in June 2012</td>
</tr>
<tr>
<td>Jordan</td>
<td>EMRO</td>
<td>2007</td>
<td>III</td>
<td>Implementation on-going</td>
</tr>
<tr>
<td>Kenya</td>
<td>AFRO</td>
<td>2008</td>
<td>II</td>
<td>Assessment report under publication, Phase II training to be done</td>
</tr>
<tr>
<td>Kuwait</td>
<td>EMRO</td>
<td>2010</td>
<td>I</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Lao People's Democratic Republic</td>
<td>WPRO</td>
<td>2005</td>
<td>III</td>
<td>National framework still to be adopted</td>
</tr>
<tr>
<td>Country</td>
<td>Region</td>
<td>Year</td>
<td>Phase</td>
<td>Status</td>
</tr>
<tr>
<td>-----------</td>
<td>--------</td>
<td>------</td>
<td>--------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lebanon</td>
<td>EMRO</td>
<td>2007</td>
<td>Phase III</td>
<td>Implementation on-going</td>
</tr>
<tr>
<td>Malawi</td>
<td>AFRO</td>
<td>2007</td>
<td>Phase II</td>
<td>Phase II training already done, framework to be developed</td>
</tr>
<tr>
<td>Malaysia</td>
<td>WPRO</td>
<td>2005</td>
<td>Phase III</td>
<td>Plan of activities received for 2012</td>
</tr>
<tr>
<td>Mongolia</td>
<td>WPRO</td>
<td>2005</td>
<td>Phase III (without adoption of the framework)</td>
<td>GGM Programme still to be adopted, activity for 2012</td>
</tr>
<tr>
<td>Morocco</td>
<td>EMRO</td>
<td>2007</td>
<td>Phase II</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Mozambique</td>
<td>AFRO</td>
<td>2007</td>
<td>Phase II</td>
<td>Transparency assessment report received under review</td>
</tr>
<tr>
<td>Oman</td>
<td>EMRO</td>
<td>2010</td>
<td>Phase II</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Pakistan</td>
<td>EMRO</td>
<td>2007</td>
<td>Phase I</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Palestine</td>
<td>EMRO</td>
<td>2012</td>
<td>Phase I</td>
<td>Training Phase I done in June 2012</td>
</tr>
<tr>
<td>Country</td>
<td>Region</td>
<td>Year</td>
<td>Phase</td>
<td>Status</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>----------</td>
<td>-------</td>
<td>-------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>WPRO</td>
<td>2005</td>
<td>Phase I</td>
<td>No activities planned for 2012</td>
</tr>
<tr>
<td>Philippines</td>
<td>WPRO</td>
<td>2005</td>
<td>Phase III</td>
<td>No plan of activities for 2012 due to a NPO change</td>
</tr>
<tr>
<td>Republic of Moldova</td>
<td>EURO</td>
<td>2008</td>
<td>Phase I</td>
<td>Phase II training to be done</td>
</tr>
<tr>
<td>Sudan</td>
<td>EMRO</td>
<td>2010</td>
<td>Phase I</td>
<td>Training for Phase II already done</td>
</tr>
<tr>
<td>Syrian Arab Republic</td>
<td>EMRO</td>
<td>2007</td>
<td>Phase III</td>
<td>Difficult context currently</td>
</tr>
<tr>
<td>Thailand</td>
<td>SEARO</td>
<td>2005</td>
<td>Phase III</td>
<td>Plan of action received for 2012</td>
</tr>
<tr>
<td>Tunisia</td>
<td>EMRO</td>
<td>2012</td>
<td>Phase I</td>
<td>Training Phase I done in June 2012</td>
</tr>
<tr>
<td>Yemen</td>
<td>EMRO</td>
<td>2012</td>
<td>Phase I</td>
<td>Training Phase I done in June 2012</td>
</tr>
<tr>
<td>The former Yugoslav Republic of Macedonia</td>
<td>EURO</td>
<td>2007</td>
<td>Phase II</td>
<td>Plan of activity received for 2012</td>
</tr>
<tr>
<td>Zambia</td>
<td>AFRO</td>
<td>2007</td>
<td>Phase II</td>
<td>Assessment report under publication, Phase II training done, Framework to be developed</td>
</tr>
</tbody>
</table>