
Brief summary of findings
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Brief summary of findings

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Introduction

The principal purpose of the first comprehensive evaluation of the World Health Organization (WHO) Good Governance for Medicines (GGM) programme covering the period 2004–2012 was to analyse experiences and identify in-country lessons after eight years of implementation. Given the WHO commitment to the goal of universal health coverage, and the central role of good governance in its achievement, the basic objectives of the GGM programme are highly pertinent and timely.

The evaluation provides an opportunity to inform future work of countries, WHO and partners towards improving governance of the pharmaceutical sector.

Background

The importance of good governance for medicines is self-evident. According to the 2010 World health report, global health expenditure has reached US$ 4.1 trillion per year. Expenditure on pharmaceuticals accounts for some US$ 880 billion of this total.

In most countries expenditure on pharmaceuticals comprises a large proportion of total health expenditure, both public and private. Effective management of pharmaceutical systems is therefore an essential element of wider health systems governance in order to ensure universal access to affordable, quality medicines and to prevent losses that may occur, including through unethical practices.

The basis for the GGM Programme is a series of WHO Medicines Strategies, beginning with the Second Strategy (2004–2007). The first of its four strategic priorities included “Promotion of ethical practices and development and use of anti-corruption measures in the pharmaceutical sector.”

The specific objectives of the GGM Programme are to:

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

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2 IMS 2011 reference
How the GGM approach works

The concept underlying the GGM approach is that by supporting policy-makers and national officials to understand where the strengths and weaknesses lie in national pharmaceutical systems, appropriate interventions can be developed and applied.

A basic principle is the need for transparency in all the stages of the medicines chain from research, to procurement and delivery of medicines to health institutions.

The programme is implemented through a three-phase process aimed at institutionalizing good governance in ministries of health and national regulatory bodies, as shown below (Figure 1).

**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 that provides the basis for designing and developing interventions.

**Phase II** comprises the development of a national GGM framework, which involves a nationwide consultation process among key stakeholders. Results of the assessment are validated and define the basic components necessary for good governance in respective national pharmaceutical systems.

**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 ministry of health.
At the time of the evaluation a total of 36 countries and territories were engaged in the GGM programme (see Table 1).

Currently twelve countries are in Phase III, eight countries are in Phase II and Phase I includes 15 countries as well as Occupied Palestinian Territory (Figure 2 on opposite page).

The GGM methodology builds on the experiences of work on good governance in other sectors, including broad anti-corruption programmes promoted and supported by organizations such as the United Nations Development Programme (UNDP) and Transparency International. These have shown that the coordinated application of two complementary strategies is needed in order to make a significant impact on governance:

- ‘Discipline-based’ approaches – based on legislative reforms, and establishing the laws, administrative structures and processes that are required to ensure transparent medicines regulation, procurement and supply systems.
- ‘Values-based’ approaches – promotes institutional integrity through ethical principles and motivating ethical conduct by public servants.
FIGURE 2 Regional distribution of countries and territories in the GGM programme.
Evaluation methodology

The evaluation comprised interviews with key actors from participating countries; a survey of 11 Phase I countries; interviews with participants from Phase II and III countries; telephone interviews with key actors in the programme at global and country levels; interviews with WHO Regional Advisers for Medicines and staff in the Essential Medicines and Health Products Department in WHO/HQ (Geneva); and interviews with representatives of development partners that have supported the programme during its evolution since 2004. These included the German Federal Ministry for Economic Cooperation and Development (BMZ), the Government of Kuwait, the European Commission, the Australian Government Overseas Aid Program (AusAID) and the UK Department for International Development (DFID).

Principal findings and conclusions of the evaluation

i. Phase II and Phase III countries reported a range of concrete outcomes. These include improvements in medicines procurement practices; revision of pharmaceutical laws and regulations; increased transparency in specific functions of regulatory mechanisms including registration and licensing; major advances in management of conflict of interest; and increased public availability of information on medicines policy and governance, e.g. through creation of dedicated websites by ministries of health and regulatory authorities.

ii. The GGM programme has created awareness in participating countries about the impact of weak governance, including unethical behaviour, on the capacity of countries to achieve universal access to affordable and quality medicines.

iii. The programme has also created awareness of the value of transparency and has promoted key national stakeholders’ commitment to create and sustain transparency in key stages of the medicines development, registration and supply chain.

iv. The programme has increased international awareness of the value of transparency and good governance for medicines. This has been achieved through the engagement of a large number of experts from a wide range of institutions, both in developing and refining the GGM methodology and in supporting countries to adapt and implement it.

v. Overall the programme has demonstrated significant value for money. This is evidenced particularly in the most recent phase of the programme when documented achievements are compared with programme funding.

vi. The three-phase methodology has proved to be of value to participating countries. The Phase I assessment tool, in particular, 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 regarded as helpful.

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4 Colombia, Ethiopia, Iraq, Islamic Republic of Iran, Pakistan, Occupied Palestinian Territory, Papua New Guinea, Republic of Moldova, Sudan, Tunisia and Yemen.

5 Interviews took place during a workshop held in Geneva (October 2012).
Lessons learnt (2004–2012)

Implementation by Phase II and Phase III countries

Countries have applied the GGM process differently and with varying results. The process is strongly country-owned and addresses specific areas of pharmaceutical systems in some settings, as seen in Laos People’s Democratic Republic, Mongolia, Philippines and Thailand. These countries are strongly focused on pursuing specific outputs and outcomes, such as low price medicines and efficiencies through bulk procurement. They are also interested in measuring GGM impact, partly for reasons of achieving efficient management and also as a means of sustaining commitment to GGM by stakeholders.

Other countries require support from WHO and other partners partly because their pharmaceutical systems are still fragile and they have not identified champions for promoting good governance in the pharmaceutical sector. They may also be dependent on external 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 financial support for the GGM process is also an essential element of progress in some countries, particularly in low-income countries.

Weaknesses and vulnerabilities

i. Regulation and control of medicines promotion was most frequently identified as vulnerable to corruption.

ii. There is a widespread lack of public access to information about the pharmaceutical sector (e.g. medicines pricing, information on quality and suppliers etc.).

iii. Lack of formal, written criteria to guide selection of members of key committees such as medicine selection committees is a common challenge.

iv. Medicine registration committees frequently have a weak policy base and lack adequate operational procedures.

v. Conflict of interest policies are lacking in many countries, and may be poorly implemented in those where they do exist.

Factors that facilitate effective GGM implementation

i. 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 already in place across many sectors, GGM is able to achieve significant progress and more rapidly.

ii. Some countries reported benefit from engagement with other ministries, particularly finance and those responsible for tackling corruption, as part of cross-sector advocacy for good governance.
iii. 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.

iv. The need to have a senior and technically knowledgeable in-country GGM group – including the private sector and academia – was highlighted by several countries.

v. Support from WHO at both the country and regional levels appears to facilitate progress, not only through small-scale funding for meetings and support with logistics, but also for technical input and dissemination of good practice. WHO benchmarking of progress can be catalytic in this regard.

**Respondent views about GGM methodology in practice**

i. The evaluation found a general consensus that the GGM three-phase approach provides countries with a practical framework for identifying system vulnerabilities and planning appropriate mitigation responses. At the same time, it leaves sufficient scope and flexibility for adaptation to specific country circumstances.

ii. Countries particularly valued the Phase I assessment tool. It acts as a means to engage stakeholders, increase awareness, stimulate dialogue and identify shortfalls. Several countries described it as “catalytic”. Essential country ownership is promoted by the lack of perception of the assessment tool as an inspection and/or audit.

iii. The preventive approach of the GGM programme, aimed at increasing transparency and promoting ethical conduct, appeals to many countries. GGM is not about identifying bad practices or corrupt individuals/institutions, but is rather about strengthening systems so that governance can be improved and vulnerabilities reduced.

iv. Capacity building is essential in order to make good governance in medicines sustainable in countries. A number of countries recommended that all concerned stakeholders in ministries of health and national regulatory authorities should participate in national training workshops on good governance. Some also suggested that GGM concepts should be included in university curricula for students in medical and pharmaceutical sciences.

v. It is important to select appropriate terminology to express GGM objectives. In some countries there has been resistance to using the terms ‘good governance’ and ‘anti-corruption 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 mobilizing support, including funding.

vi. Many Phase II and III countries expressed the view that their basic problem was inefficiency and poor management rather than explicit corruption. In these countries transparency is seen as a prerequisite for managerial effectiveness, which itself is a prerequisite for good governance.
Future WHO work on promoting good governance

The evaluation confirmed a growing need in countries to strengthen transparency and good governance throughout the pharmaceutical sector. It concluded that the GGM approach is an essential component of the next generation of WHO action aimed at achieving universal access to affordable, quality-assured medicines. It also confirmed the need for stronger and more consistent support from WHO and its partners – in terms of dedicated staff and budget – at both global and regional levels.

The methodology should be further developed to include indicators of impact, in order that countries and WHO will have a robust framework for monitoring and measuring progress.

WHO reform could provide opportunities to properly embed GGM-related activities within future WHO work on transparency and good governance.

The evaluation noted the WHO commitment that extending work on strengthening health systems should include a new focus on better health systems governance. It recommended that GGM experiences in countries – together with the transparency assessment tool – should 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 offer valuable concepts for improving transparency and strengthening institutional and individual integrity.

It also recommended that WHO increase contacts, and improve coordination with key partners that are already active in work on good governance in the pharmaceutical sector and establishes synergies between GGM work and programmes such as the Medicines Transparency Alliance (MeTA) and the EU/ACP/WHO Partnership for strengthening pharmaceutical systems in Africa.

Finally, dialogue with broader health and development partners revealed a potential interest in the wider application of the GGM approach, particularly for risk assessment and strengthening other elements of the wider health system.

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