Summary report on the

Intercountry meeting on Good Governance for Medicines for phase I countries in the Eastern Mediterranean Region

WHO-EM/EDB/124/E

Amman, Jordan
16–19 August 2015

World Health Organization
Regional Office for the Eastern Mediterranean

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1. Introduction

The WHO Good Governance for Medicines (GGM) programme was launched in 2004 with the goal of contributing to health systems strengthening and preventing corruption by promoting good governance in the pharmaceutical sector. Its objectives are to: raise awareness on 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; and institutionalize good governance in pharmaceutical systems by building national capacity and leadership. 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.

The GGM programme is implemented through a three phase process, starting with a national transparency assessment, followed by the development of a national programme for promoting good governance and then by its implementation. This process is meant to provide countries with a flexible road map to implementing the national GGM programme. It is action oriented, concrete and measurable. The process assists to institutionalize the GGM programme in national structures. Phases I and II set the foundation for the implementation of Phase III, which is considered the most critical step of the process. While Phase I provides a baseline for initiating the GGM work and evidence for policy-/decision-makers to help them prioritize and direct resources to those areas found most vulnerable, Phase II is a nationwide consultation process for developing and agreeing on a national GGM framework.

The intercountry meeting on Good Governance for Medicines for Phase I countries in the Eastern Mediterranean Region was held in Jordan, Amman, from 16 to 19 August 2015. The meeting involved

representatives from anti-corruption agencies, independent national assessors and government counterparts from six target countries including Afghanistan, Iraq, Jordan, Lebanon, Morocco and Pakistan (Libya and Yemen could not participate).

The objectives of the meeting were to:

- present results of national assessments conducted in participating countries and identify strengths, weaknesses, opportunities and threats (SWOT analysis);
- increase the capacity of national teams to move to GGM Phase II activities;
- identify and address potential bottlenecks in developing a national GGM framework; and
- develop national GGM action plans up to end 2016.

2. Summary of discussions

The first day of the meeting included sessions on a global overview of GGM, the WHO model framework for good governance in the pharmaceutical sector, the regional situation, country progress of national GGM programmes, practical advice on how to develop a national GGM framework (Phase II), a country example (Jordan) and accelerating GGM progress in the Region.

Day two included sessions on another country example (Malaysia), the elements of a GGM training curriculum for practitioners and a GGM training of trainers programme, a values-based approach in promoting good governance in the pharmaceutical sector, building GGM leadership, ethical principles and integrity, transparency, ethical leadership, conflicts of interest, and attitudes and perspectives encountered during implementation of GGM Phases II and III. Small group work focused on conflict of interest management from a country perspective.

Sessions on day three included ones on the experience of managing conflicts of interest, including in Jordan and Malaysia, a panel forum with representatives from the United Nations Development Programme Regional Project on Anti-corruption and Integrity in the Arab Countries, the Healthcare Governance and Transparency Association, the Jordanian High Health Council and the Jordanian Anti-corruption Commission on partners' efforts in promoting good governance in the health sector, and a session on developing country action plans.

On the fourth day of the meeting, field visits were organized to the Prince Hamzah Hospital and Joint Procurement Department, the Jordan Food and Drug Administration (FDA) and the Ministry of Health Central Medical Stores. Feedback from the three groups was very positive and in the discussion that followed, the good governance elements of the WHO model framework observed at the sites were highlighted.

In group work, common strengths, gaps, challenges and observations were identified for national GGM programmes in Phase I countries. The strengths included political commitment for increasing access to medicines, the presence of medicines laws in all countries and active technical committees, having registration systems in place and essential medicines lists in use, and the availability of qualified human resources.

The gaps included the lack of policies on declaring and managing conflicts of interest, a lack of enforcement of sanctions for law violations, a lack of written guidelines on membership of committees (including rotation policies), a lack of standard operating procedures, especially for decision-making processes, and a lack of public information.

Identified challenges included passive attitudes towards corruption, a resistance to change, the demands of other priorities, political instability, bureaucracy, frequent staff rotation, the integration of GGM in existing national structures and systems, the workload of staff and the novelty of good governance in the pharmaceutical sector.

The observations were that there was great interest in the subject area (more than anticipated) and an appreciation of the constructive and informative nature of the GGM approach, that country assessment could be educational for stakeholders, that some countries needed more time than others to implement GGM activities and that the institutionalization of GGM was needed to ensure sustainability.

The most vulnerable functions in Phase I countries were also identified and included registration (Afghanistan), clinical trials (Iraq, Pakistan), promotion (Iraq, Pakistan, Morocco) and selection (Pakistan, Morocco). For Phase II countries, they were identified as selection (Lebanon) and promotion (Jordan, Lebanon).

In discussion, countries emphasized the importance of sharing experiences and lessons learnt, and exchanging information on how to overcome obstacles during the development and implementation of national GGM programmes. They confirmed the importance of conflict of interest management and the need for future capacity-building and more guidance in this area. Countries felt that more guidance would be needed on country-specific issues in the near future. It was concluded that the pace of implementation of the next phase will vary between countries because of local contexts.

Countries emphasized the importance of technical support in the development and implementation of national codes of conduct for the pharmaceutical sector. The further development of country action plans

in countries was encouraged for the inclusiveness of stakeholders and better monitoring of the implementation of activities of national GGM programmes. The peer review of individual country action plans by WHO was requested, but peer review during intercountry events, such as at regional meetings, was also seen as important.

3. Recommendations

To Member States

1. GGM Phase I countries should address their identified gaps in their action plans.

2. More attention should be given to the structure, mandate and composition of a committee/board of directors/board of trustees. These committees should have in place adequate terms of reference, solid selection criteria for committee members, and standard operating procedures.

3. Countries should make extra efforts to submit their Phase I assessment reports as soon as possible in order to progress to Phase II activities.

To WHO

4. The progress made in each country should be monitored, including the development and implementation of action plans.

5. More focus should be given to disclosure policies that define the type of information that needs to be communicated to each party and in what form, as this would help minimize the abuse of confidentiality.

6. Guidance should be provided to the re-assessment exercise planned by Morocco to document the impact of constitutional and regulatory reforms on GGM as a basis for development of their GGM framework.

7. A case study should be prepared on how the Jordan FDA was established as an autonomous entity governed by a board of directors and regulatory framework, including the challenges faced and solutions found in becoming a well-functioning national regulatory authority.

8. French translation of GGM training materials should be made available for national meetings and workshops.

9. The regional GGM platform for information sharing and technical guidance should be revived.

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