WHO events addressing public health priorities

Good governance for medicines: moving towards a national framework

Background

Access to and affordability of essential medicines are integral to universal health coverage, particularly as a large part of private and public health expenditure is on medicines. The value of the global pharmaceutical market is therefore immense and the pharmaceutical sector as a result is very open to abuse, corruption and unethical practices. Indeed corruption in procurement/distribution of pharmaceutical and medical supplies and lack of transparency and checks and balances make medicines one of the common causes of inefficiency in health systems.

The WHO Good Governance for Medicines (GGM) programme was launched in 2004 to contribute to health systems strengthening and prevention of corruption by promoting good governance in the pharmaceutical sector. It aims to: raise awareness on the impact of corruption in the pharmaceutical sector; 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. It supports 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 3-phase process, starting with a national transparency assessment, followed by the development of a national programme for promoting good governance and then by 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. Phase I provides a baseline for initiating the GGM work and evidence for policy-makers and decision-makers to help prioritize and direct resources to the most vulnerable areas. Phase II is a nationwide consultation process for developing and agreeing on a national GGM framework. Phases I and II set the foundation for the implementation of Phase III, the most critical step.

Advancing GGM in the Region

Several countries of the Region have already conducted national transparency assessments and received technical support on GGM Phase I. Progress has varied among the 16 participating countries. In 2014, a meeting was held for best performing Phase II countries to assist national GGM teams in progressing to Phase III and with a focus on managing conflict of interests. Following on from this, to support countries in Phase I to progress to Phase II, an intercountry meeting on Good Governance for Medicines for Phase I countries in the Eastern Mediterranean Region was held in Amman from 16 to 19 August 2015. The participants included representatives from anti-corruption agencies, independent national assessors and government counterparts from six target countries: Afghanistan, Iraq, Jordan, Lebanon, Morocco and Pakistan.

This meeting was designed to allow maximum interaction between country groups to facilitate inter-country learning and to share collective experiences in conducting national assessments and developing national frameworks. The specific 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;
- develop national GGM action plans up to end of 2016.

Strengths, gaps and challenges in Phase I countries

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).

Strengths identified during the meeting included political commitment for increasing access to medicines, the presence of medicines laws in all countries, active technical committees having registration systems in place and essential medicines lists in use, and the availability of qualified human resources.

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

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Box 1 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

1. The progress made in each country should be monitored, including the development and implementation of action plans.
2. 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.
3. 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.
4. 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.
5. French translation of GGM training materials should be made available for national meetings and workshops.
6. The regional GGM platform for information sharing and technical guidance should be revived.

of committees (including rotation policies), a lack of standard operating procedures, especially for decision-making processes, and a lack of public information.

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

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

The way forward

During the discussions, 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 and that the pace of implementation of the next phase will vary from country to country because of local contexts.

The importance of technical support in the development and implementation of national codes of conduct for the pharmaceutical sector was also emphasized. The further development of country action plans was encouraged for the inclusiveness of stakeholders and better monitoring of the implementation of activities in national GGM programmes.

At the conclusion of the meeting, a number of recommendations were drawn up addressed to Member States and WHO. These are aimed at facilitating countries in the Region in moving forward in the process towards Phase II and Phase III of the GGM programme (Box 1).