Good Governance in the Pharmaceutical Sector

Deirdre Dimancesco
Department of Essential Medicines and Health Technologies
What is governance?

- Process of decision-making and implementation
- Manner how power is exercised in management of country's economic and social resources for development (World bank)
- Exercise of political, economic and administrative authority in management of country’s affairs at all levels (UNDP)
- Good governance refers to management of government that is free of abuse and corruption, and following rule of law
- Good governance characterized by: participation, transparency, responsiveness, accountability, consensus, rule of law, effectiveness and efficiency, equity and inclusiveness, etc.
Governance and the Sustainable Development Goals

- Recognition of the critical role of governance
  - Transparency was raised in relation to every major development challenge.
  - Strong consensus on the need for mechanism for citizen engagement.

Goal 16: Promote just, peaceful and inclusive societies

- Promote the rule of law
- Substantially reduce corruption and bribery in all their forms
- Develop effective, accountable and transparent institutions
- Ensure responsive, inclusive, participatory and representative decision-making at all levels
- Ensure public access to information and protect fundamental freedoms
WHO

WHO Constitution

"informed opinion and active co-operation on the part of the public are of utmost importance in the improvement of the health of the people"
Governance and Universal Health Coverage

- UHC is about choices
  - Which services can be provided?
  - Who should be covered?
  - How to reduce out-of-pocket payment?
  - Where will the money come from?

- Decisions and their enforcement should take place through robust public procedures and participation mechanisms => involving civil society and other stakeholders
Why is Good Governance in the pharmaceutical sector is needed?

- To improve transparency, accountability, effective, efficient and ethical management of pharmaceutical systems
- To improve health service delivery through improved access to quality-assured medicines and rational use
- To avoid wastage or misuse of public or donor funding in pharmaceutical sector
- To improve public trust and confidence in health system
WHO Good Governance for Medicines Programme:

- **Goal**
  - To contribute to health systems strengthening and to prevent corruption by promoting good governance in pharmaceutical sector

- **Specific objectives**
  - To raise awareness on impact of corruption in pharmaceutical sector and get this on national health policy agenda
  - To increase transparency and accountability in medicine regulatory and supply management systems
  - To promote individual and institutional integrity in pharmaceutical sector
  - To institutionalize good governance in pharmaceutical systems by building national capacity and leadership
WHO Good Governance for Medicines programme

PHASE I
National transparency assessment

PHASE II
Development national GGM framework

PHASE III
Implementation national GGM programme

Clearance MOH

Assessment report
GGM framework officially adopted
GGM integrated in MoH plan

TBS, 17-21 October 2016
12 Years of GGM

- Implemented in 2004
- 37 countries have participated
- Supported by Government of Kuwait, Germany, Australia

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bahrain</td>
<td>Afghanistan</td>
<td>Benin</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Cameroon</td>
<td>Bolivia</td>
</tr>
<tr>
<td>Colombia</td>
<td>Cambodia</td>
<td>Jordan</td>
</tr>
<tr>
<td>Ecuador</td>
<td>Costa Rica</td>
<td>Laos</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Egypt</td>
<td>Lebanon</td>
</tr>
<tr>
<td>Iraq</td>
<td>Indonesia</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Papua New Guinea</td>
<td>Kenya</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Moldova</td>
<td>Kuwait</td>
<td>Malawi</td>
</tr>
<tr>
<td>Morocco</td>
<td>Palestine</td>
<td>Magnolia</td>
</tr>
<tr>
<td>Yemen</td>
<td>Mozambique</td>
<td>Syria</td>
</tr>
<tr>
<td></td>
<td>Sudan</td>
<td>Thailand</td>
</tr>
<tr>
<td></td>
<td>Tunisia</td>
<td>Macedonia</td>
</tr>
</tbody>
</table>
Common strengths in all Countries

- Political commitment to improve access to medicines
- Presence of medicines laws and regulation
- Active technical committees in various functions
- National Essential Medicines Lists (EML) in place
- System of medicine distribution & licensing
- Qualified human resources
Common gaps identified

- Policy for managing conflict of interest
  - Declaration; Management; Sanctions on violation
- Written guidelines on committee membership (incl. rotation policies)
- SOPs (for decision-making process)
- Public availability of information
- Guidelines on interaction between public officials and private sector
- Independent complaints mechanism and protection of whistle-blowers
- Civil society engagement
- Socialization of Codes of Conduct (CoC)
- Limited resources
Progress in countries to date-1

- GGM tasks forces/committees created at national level
- National and regional workshops to:
  - Disseminate and validate assessments' findings
  - Develop and adopt national GGM programmes
- Increased awareness of impact of corruption in pharmaceutical sector and importance of having Good Governance
  - Public accessibility of information
  - National assessments done and published
  - Increased political will to implement GGM programme
  - Collaboration between various stakeholders (MOH, other ministries, anti-corruption commission, NGOs, private sector...)
- Implementation of assessments' recommendations:
  - Creation or improvement of SOPs, update of EML
  - Development conflict of interest policies

TBS, 17-21 October 2016
Progress in countries to date-2

- Increased promotion of individual and institutional integrity in the pharmaceutical sector
  - National GGM Framework developed, adopted and published
  - Creation of Code of conduct for people working in the public pharmaceutical sector
  - Continuous training workshops on moral leadership and GGM at national and regional level

- Increased Transparency and Accountability in Medicine Regulatory and Supply Systems
  - Various laws, regulations, SOPs created or reviewed/updated
  - Management of conflicts of interest put in place for various committees
  - Whistle-blower protection, increase in number of corruption cases investigated
  - Appeal mechanism put in place

TBS, 17-21 October 2016
Common challenges faced in implementation

- **Cultural and behavioural**: resistance to change, passive attitude or tolerance
- **Political**: instability, change in government
- **Managerial**: lack of staff, rotation, lack of financial resources
- **Structural**: more difficult if basic systems not in place
- **Technical**: integration in day-to-day affairs, new subject, access to legislation documents
- **Time**: workload, other priorities; GGM not a priority
lessons learnt

- Great interest in GGM
- Dedicated and motivated national team to tackle issues
- Involvement of high-level and technical officials is essential
- Collaboration with key stakeholders from different sectors
- Promotion of integrity together with legislative reforms
- Institutionalization needed for sustainability
Essential medicines and health products

Good Governance for Medicines (GGM)

The Good Governance for Medicines approach is to support policy-makers and national officials to understand where their strengths and weaknesses lie in the national pharmacuetic systems in order to develop and apply appropriate interventions. The programme has now been implemented in 36 countries worldwide.

Good Governance for Medicines (GGM) overview
WHO Good Governance for Medicines Model Framework
Updated version
Measuring Transparency in the Public Pharmaceutical Sec Assessment Instrument

Highlights

Good Governance for Medicines (GGM)

The need for good governance in the pharmaceutical sector

Medicines Transparency Alliance
Essential medicines and health products

Good Governance for Medicines (GGM) Overview

The 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.

Objectives:
- To raise awareness on the impact of corruption in the pharmaceutical sector and bring this to the national health policy agenda
- To increase transparency and accountability in medicine regulatory and supply management systems
- To promote individual and institutional integrity in the pharmaceutical sector

Good governance is critical to universal health coverage
- Read more…

The Good Governance for Medicines programme commemorates 10 years of