



Good Governance for Medicines in Jordan



Dr. Lubna Qusous

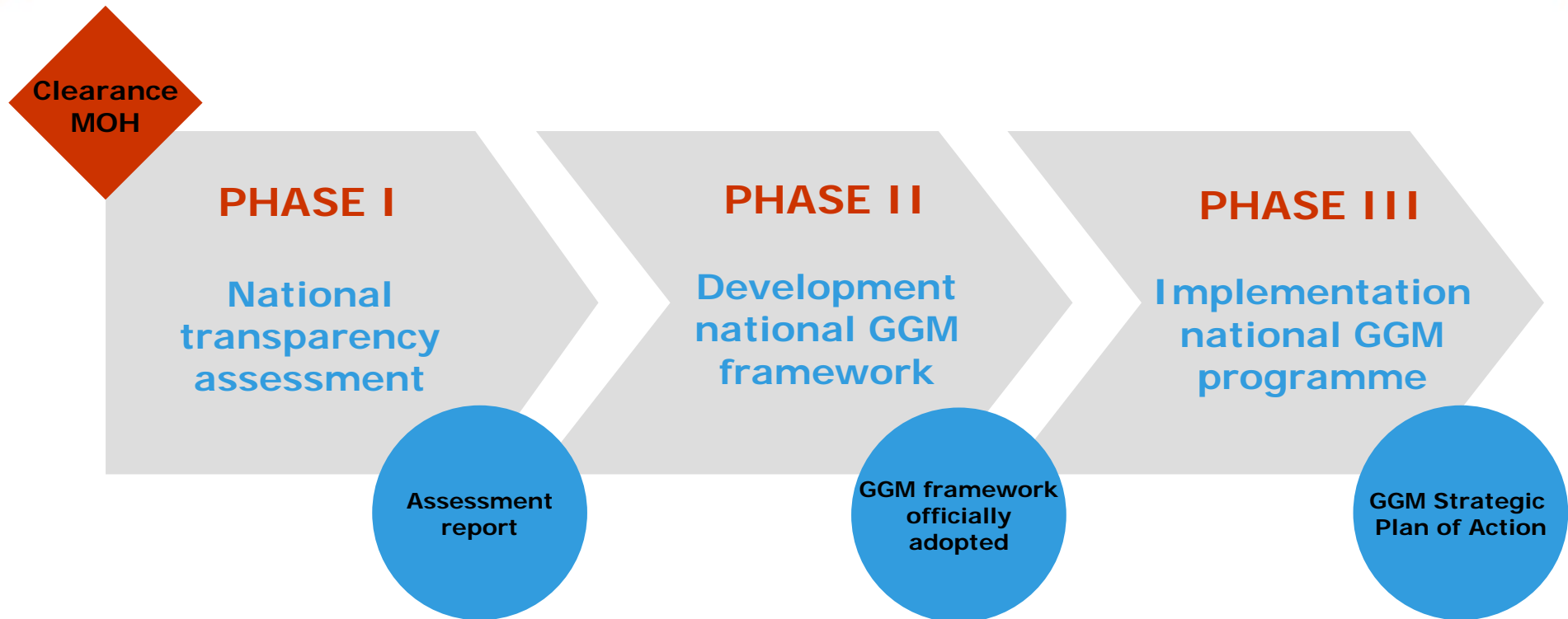
**Rational Drug Use Department
Jordan Food and Drug Administration**

www.jfda.jo

JORDAN

- Jordan is a low middle – income country
- Population in millions: 5,894,960
- 10.4 % of the Jordanian GDP is spent on health with one third of this spent on medicinal drugs.
- One quarter of the drug expenditure is spent in the public sector with the remaining three quarter spent in the private sector.
- Medicines expenditure growth 17% per annum compared to GDP growth of 3.3%.

Good Governance for Medicines programme: a model process



PHASE I

PHASE II

PHASE III



Assessment of transparency and accountability October - November /2007

- Assesses vulnerability to corruption of systems in place
- Looks at key functions of the pharmaceutical sector systems

Regulation: registration, inspection, promotion

Supply: selection, procurement, distribution

•Elements evaluated:

- Country's regulations and official documents
- Written procedures and decision-making processes
- Committees, criteria for membership and conflict of interest policy
- Appeals mechanisms and other monitoring systems

National
assessment

Assessment
report

General Findings

Area	Total indicators	Number of Key Informants	Score on 10 point scale	Degree of vulnerability to corruption
Registration	16	10	7.52	marginally
Promotion	12	10	1.88	extremely
Inspection	11	10	5.79	moderately
Selection	12	10	7.71	marginally
Procurement	15	11	8.59	minimally
Distribution	15	10	8.41	minimally
Total	66	61	6.65	marginally

General Findings

Area	Strength	Weakness
Registration	<ul style="list-style-type: none"> - Documented and standardized. - Fair access to information - Formal appeals process - Specialized TC 	<ul style="list-style-type: none"> - No written guidelines on COI - For some committees: No clear criteria for selecting the members & no written guidelines for the committees decision-making process
Promotion	Pre-approval of promotional and advertising materials for public is officially required	<ul style="list-style-type: none"> - Lack of legal coverage - No sanctions for breaching the law - Pre-approval of promotional and advertising materials are not officially required.
Inspection	<ul style="list-style-type: none"> - Comprehensive provision in the medicines legislation - Written guidelines on classification of GMP - Written SOPs for inspectors on how to conduct inspection 	<ul style="list-style-type: none"> - No written guidelines COI - No clear criteria for selection and recruitment of inspectors. - No written procedures to prevent regulatory capture - No appeal system for companies.

General Findings

Area	Strength	Weakness
Selection	<p>JRDL is available in a printed format- and in the website of the JFDA</p> <p>Clear guidelines for addition-deletion- for medicines from the list</p> <ul style="list-style-type: none"> - 17 selection committees is appointed to give technical advice on the revision and updating of the RDL 	<ul style="list-style-type: none"> - No written guidelines on COI - Membership is not time-limited. - The criteria for selecting drugs are not publicly available - Only includes experts from medicine and pharmacy field.
Procurement	<p>transparent procedures for procurement- of pharmaceutical products</p> <p>Formal appeals process -</p> <ul style="list-style-type: none"> - Clear and specific criteria for tender committee membership. 	<ul style="list-style-type: none"> - No written guidelines on COI - Not all medicine procured are from a national rational drug list.
Distribution	<p>Medicines can be identified by imprints- on containers and external packaging.</p> <p>There is systematic and orderly shelving- of products in warehouses.</p> <p>The warehouses are subjected to internal and external auditing.</p> <ul style="list-style-type: none"> - A computerized system 	<ul style="list-style-type: none"> - There is no effective security management to oversee storage and distribution - There is no programme exist for monitoring and evaluating the performance of the medicine distribution system.

Areas of Improvement

Registration	<ul style="list-style-type: none"> - Conflict of interest policy - Committee composition & TOR
Promotion	<ul style="list-style-type: none"> - Complete provisions to cover all Activities related to drug promotion
Inspection	<ul style="list-style-type: none"> - Conflict of interest policy - Clear criteria for selection of inspectors
Selection	<ul style="list-style-type: none"> - Conflict of interest policy - Selection criteria for members
Procurement	<ul style="list-style-type: none"> - Conflict of interest policy - Audit results publicly available

General Recommendations



- Revision of the laws and procedures
- There should be written guidelines on COI
- Publish all available regulations, guidelines, SOPs concerning each area to the public.
- Develop and adopt a framework for good governance in the public pharmaceutical sector
- Develop expertise-train Jordanian officials and staff on good governance and ethical practices in drug management

PHASE I

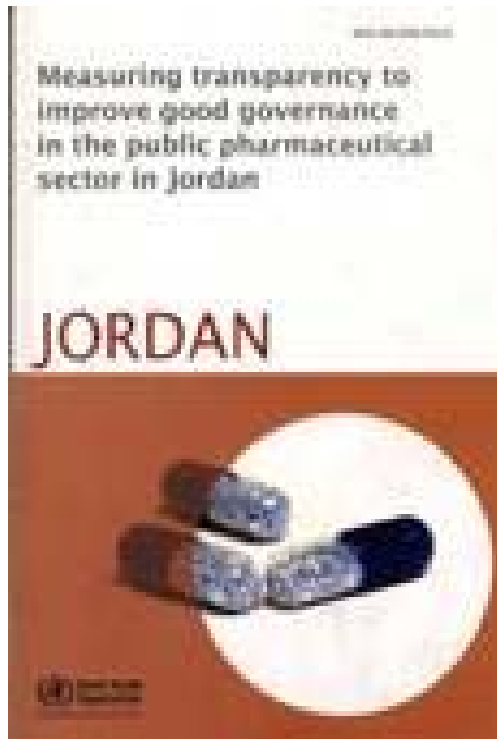
PHASE II

PHASE III

Assessment of transparency in Jordan



- The results of the assessment and recommendations were disseminated to the stakeholders through a national workshop in February/2008
 - Assessment report was published and disseminated in January 2009
 - Improvements in the procedures of the pharmaceutical sector took place



Activities to achieve phase II plan

- Conducting a National Multi-Stakeholders workshop to disseminate results of the transparency assessment;
- Nominating and selecting National GGM Team Steering Committee and the task force (TOR);
- Committing to meet on weekly basis and the TF members prepared the GGM Framework over their regular duties
- training and building capacity of a national core team
- Finalization and getting consensus and approvals for the GGM Framework
- Set a plan for Phase III, socialization and dissemination of the Framework.

GGM Steering Committee

- Members are high level policy makers
- Responsible for the overall management, adoption and evaluation of the GGM programme
- Ensure implementation of recommendations made in assessment report
- Ensure that the national Framework for Good Governance in the public pharmaceutical sector is officially adopted
- Ensure the establishment of policies and procedures for the control of reprehensible acts
- Ensure the establishment of a whistle-blowing mechanism
- Ensures the establishment and implementation of a GGM programme (phase III)

GGM Task Force

The GGM Task Force main tasks include:

1. Manage the national consultations process necessary to:
 - a. Share the results of the national assessments of transparency and vulnerability to corruption in the public pharmaceutical sector and
 - b. Develop and implement the national GGM framework that approved by the steering committee
2. Follow-up and act upon the recommendations made in the national assessments report and by the steering committee.
3. Coordinate the development, adoption, and socializing the national ethical framework and the code of conduct



Jordan GGM Framework Partnership

- Ministry of Health.
- Ministry of Public Sector Development.
- Jordan Food & Drug Administration.
- Anti Corruption Commission.
- Royal Medical Services.
- High Health Council.
- Joint Procurement Department.
- Jordan University Hospital.
- World Health Organization.

Jordan GGM Framework

Sequence of the document



1. Introduction to GGM Framework

1. GGM Framework purpose, guiding principles and requirements
2. Scope and mandate to improve transparency and accountability
3. Mechanisms and approaches (desk review, national GGM team dynamics, authority gained by SC high level representation)
4. Output and expected impact (deliverables: document, competent team, better access to quality affordable medicines, more efficiency in the public sector resources and to have a good model in the region)

Jordan GGM Framework

Sequence of the document



2. Governance and AC

- definition, requirements, local and global initiatives International, regional, bilateral and UN agreements and treaties in addition to AC work in Jordan to date:
 - Law of litigation No 16 of 1960
 - Jordan Constitution in 1952
 - The Inspection and Control Bureau in 1992.
 - The Economic criminals law in 1993.
 - Anti Corruption Department in the Intelligence department in 1996.
 - Higher Committee for transparency and accountability in 2002.
 - The national committee against corruption , nepotism & favoritism to implement Jordan First Initiative in 2002.
 - The Anti-corruption Commission in 2006
 - The Ombudsmen Bureau in 2008 (harmful actions and inactions)

Jordan GGM Framework

Sequence of the document



3. *Good Governance in the Ph. Sector*

- medicine chain cycle and management functions
 - R&D
 - Clinical research
 - Production, registration and pricing
 - Licensing and certification to individuals and institutions
 - Inspection
 - Selection, procurement & distribution
 - Prescription and dispensing practices
 - Pharmacovigilance
 - Promotion
- expected types of corruption; conflict of interest, bribery, promotion, tenders and distribution.
- impact of corruption on health systems and health outcomes, directions and actions for future protection
- Directions for strengthening and protection

Jordan GGM Framework

Sequence of the document



4. Integrity system in Jordan and in the Ph. Sector.

- National integrity system components (leadership, restructuring, rule of law, public awareness and AC bodies)
- GGM Framework in the Ph. Sector approach in Jordan
 - **Elements of GGMF**
 - 1. Ethical framework of moral values & ethical principles
 - Justice/fairness
 - Truth
 - Service to common good
 - trusteeship
 - 2. Code of conduct developed in Jordan in 2002
 - 1. Duties & responsibilities of the Public servant
 - 2. Respect and equity consideration in providing services
 - 3. Confidentiality and disclosure
 - 4. Acceptance of gifts, privileges and other benefits
 - 5. Conflict of interest

Jordan GGM Framework

Sequence of the document



5. *Socialization of the programme*

- ❑ Raising awareness, dissemination of TA results, encourage critical thinking and discussions, situation analysis and setting targets and promote individual responsibility and moral values practices
- ❑ Transformation of dysfunctional mental models and supporting the culture for good practices and moral values (awards ceremonies and incentive linked to performance and moral practices)

6. *Promotion of Moral Leadership*

1. basic elements of the conceptual framework
2. Capabilities grouped in categories that facilitate personal transformation in a healthy relationships and team work in addition to the capabilities needed for social transformation
3. Activities to be taken

Jordan GGM Framework

Sequence of the document



7. *Enforcement of existing Anti-corruption laws*

- UN Treaty for Anti corruption in 2004
- Related legislations in Jordan
 - AC Law No 62 in 2006
 - JFDA Law No 41 in 2008
 - Public health Law No 47 in 2008
 - Medicine and Pharmacy law No 80 in 2001
 - Criminal Law
 - Pharmacy licensing law No 43 in 1972
 - Bureau of Audit Law
 - Administration inspection court law in 1992
 - Ombudsmen law No. 11 year 2008
 - General procurement law No 32 in 1993 and its amendments
 - Civil Service Bylaws No 30 year 2007
 - Joint Procurement Law No 91 year 2002

Strengthening institutions and departments working on Anti-corruption in Jordan

Jordan GGM Framework

Sequence of the document



- **Whistle Blowing**
 - Strict criteria for WB
 - Clear mechanisms
 - Protection & security for reporter
- **Sanctions on reprehensible acts**
 - Internal sanctions by the government entity
 - Sanctions by the AC agencies and legislative courts

Jordan GGM Framework

Sequence of the document



8. Improving management system

Criteria for selecting committee members

GGM Framework implementation

Policies and mechanisms to ensure implementation
of SC recommendations

Monitoring plan for enforcement of GGM SC
resolutions

Jordan GGM Framework

Sequence of the document



9. **Inter-institutional Collaboration**

Audit department in MOH, JFDA

Ministry of Public Sector Development

AC Commission

Audit Bureau

Ombudsmen Bureau

10. **Management & evaluation of GGM programme**

full time staff

Setting targets and indicators

Jordan GGM Framework Sequence of the document



- ***Role of Media and Civil Society***
 - Empowerment, involvement and building their capacity to act as a watch dog and pressure groups
 - Involvement in raising awareness and education of the public
- ***Role of private sector***
 - Corrupted –corruptor responsibility (AC bodies)
- ***Political will and commitment***
 - Regular monitoring –advocacy events
 - Building local capacity to institutionalize the moral values
 - Partnership between government and civil society
 - Financial support to implement and sustain GGM framework.

Progress

- In January 2009 a Phase III training workshop was held for the first time in Jordan. It focused on anti-corruption & pharmaceutical sector legal frameworks, implementation of the recommendations included in the transparency assessment (Phase I) & moral leadership capabilities.
- Among 26 countries globally including 5 countries in EMR, 10 countries are in phase I, 11 countries in phase II and 5 in phase III including Jordan.
- Jordan recently finalized the national GGM framework, and is the 1st EMR country to enter the implementation phase (phase III). .

PHASE I

PHASE II

PHASE III

Implementation of National GGM Programme

Implementation
national GGM
programme

GGM Strategic
Plan of Action

- Strengthening systems by increasing transparency and accountability
- Promoting awareness (general public & health professionals)
 - Dissemination of information (newsletter, website, etc.)
 - Social marketing (radio, TV jingles, posters, etc.)
 - Critical thinking and discussions (seminars, conferences)
- Building capacity (managers and public policy makers)
 - Technical training programme
 - Leadership training programme

Suggested Activities in Jordan for Phase III



- Training of the national GGM team, briefing sessions for government officials, production of advocacy materials
- Implementing recommended changes in related laws & procedures to increase transparency
- Adoption of a code of conduct for civil servants working in the pharmaceutical sector
- Development of a COI guidelines
- Introducing the GGM concept into university curricula.



Thank you!