Good Governance for Medicines programme in the Eastern Mediterranean Region

World Health Organization

Adi Nuseirat
Technical Officer, Essential Medicines and Pharmaceutical Polices
WHO Regional Office for the Eastern Mediterranean

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Presentation Outline

- The need for Good Governance for Medicines
- WHO Good Governance for Medicines Program – GGM
- Status of implementation of GGM in the East Mediterranean Region and the results

Low Access to Medicines…

45%

Surveys in 40 developing countries have shown availability of only 45% of medicines out of 30 essential medicines

…despite high % of spending

20-60%

of MoH recurrent health budget on medicines

60-70%

of out of pocket expense on medicines

Wastage and corruption

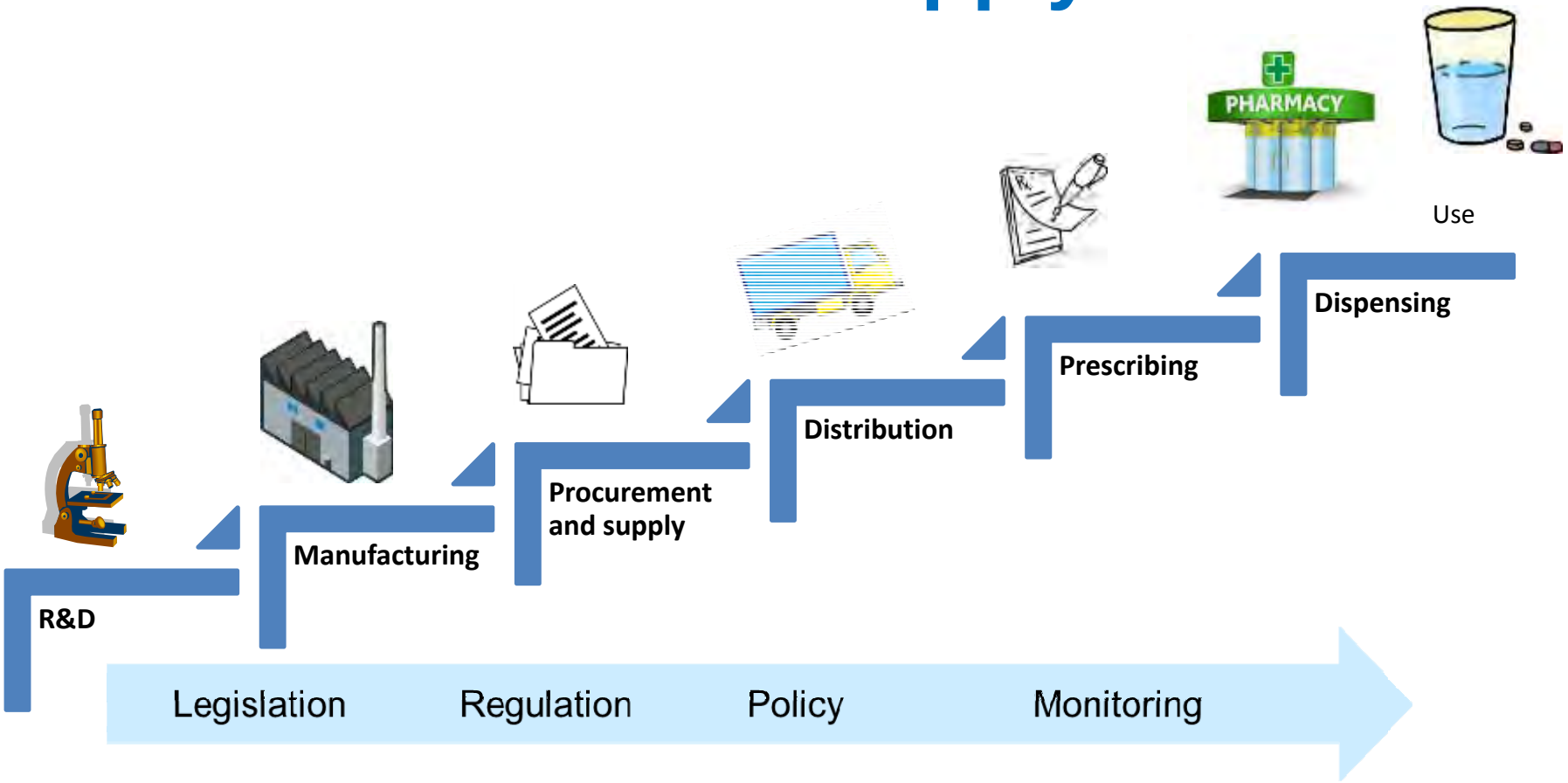
3/10

leading causes of health system inefficiencies are medicines related

2/3

of scarce medicine supplies in hospitals are “lost” to theft and corruption.

Pharmaceutical Supply Chain



Inefficiencies ⇔ **Corruption**

Good Governance for Medicines is needed to…

- **improve transparency, accountability, effective, efficient and ethical management of pharmaceutical systems**
- **avoid wastage or misuse of public or donor funding in pharmaceutical sector**
- **improve public trust and confidence in health system**

WHO GGM Programme

supporting policy-makers & managers in 37 countries

To contribute to health systems strengthening by reducing/preventing vulnerability to corruption in the pharmaceutical sector.

Specific objectives

- **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

1. Registration **2.** Licensing **3.** Inspection **4.** Promotion **5.** Clinical Trials
6. Selection **7.** Procurement **8.** Distribution

MOH Clearance

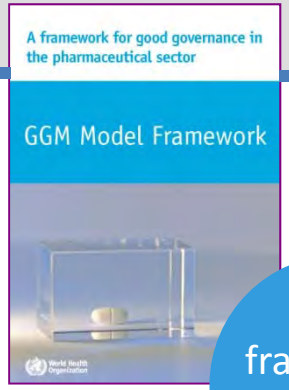
PHASE I

National transparency assessment

Assessment report

PHASE II

Development national GGM framework



GGM framework officially adopted

PHASE III

Implementation national GGM programme

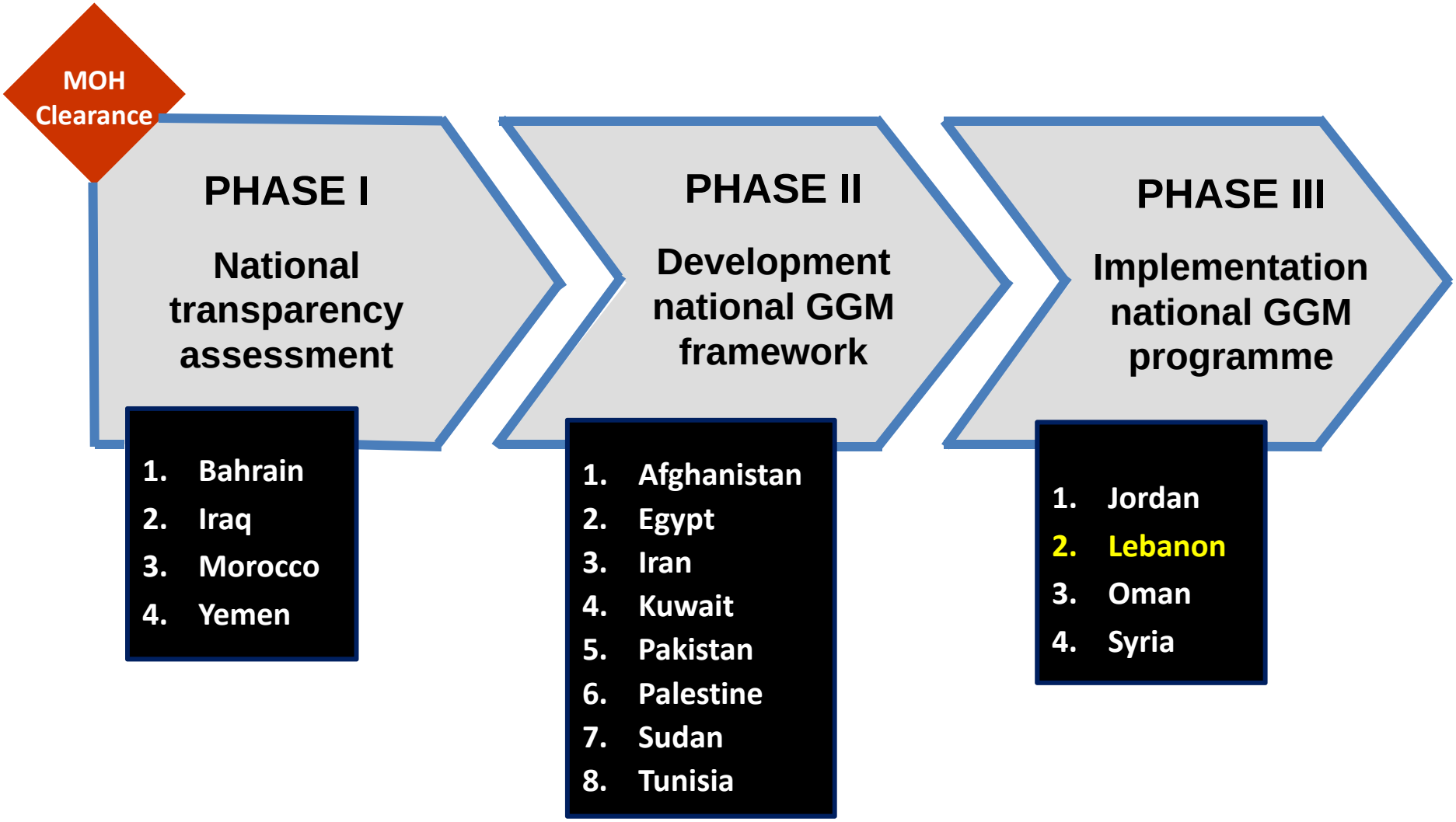
GGM integrated in MoH plan

Eastern Mediterranean Region

World Health Organization

GGM Implementation in EMR

Since 2007 – 16 countries



Summary of Assessment Scores

Function	AFG	EGY	IRA	IRQ	JOR	KUW	LEB	MOR	OMA	PAK	PAL	SUD	TUN	YEM
Registration	0.64	6.03	3.94	6.21	7.52	6.08	6.52	6,01	5.38	4.94	3.23	3.53	6,22	2.4
Licensing	4.34	5.95	5.84	8.33		7.66		6,79	6.18	7.96	5.3	5.44	6,77	5.1
Inspection	1.64	6.07	6.11	8.26	5.78	5.97	7.28	5,70	3.86	6.08	5.81	2.71	5,37	3.4
Promotion	1.06	4.13	4.54	3.72	1.87	7.49	4.9	3,82	0.32	4.07	1.93	1.44	3,68	0.58
Clinical trials	0.76	6.11	7.15	2.08		6.48		4,18	1.69	4.05	0		5,36	0
Selection	3.65	3.78	4.54	5.31	7.71	5.28	4.37	3,19	4.35	3.85	4.63		5,03	1.8
Procurement	2.61	6.79	4.97	7.45	8.59	7.49	6.7	6,54	6.24	5.31	6.85	6.04	6,83	5.4
Distribution	3.33	6.23	6.88	7.84	8.41	9.18	8.37	7,20	8.15	7.6	6.47	6.86	7,83	6.6

0.0—2.0	2.1—4.0	4.1—6.0	6.1—8.0	8.1—10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally Vulnerable

Overall Rank

Function	AFG	EGY	IRA	IRQ	JOR	KUW	LEB	MOR	OMA	PAK	PAL	SUD	TUN	YEM	Rank
Promotion	3	2	2	2	1	5	2	2	1	3	2	1	1	2	**1**
Selection	7	1	3	3	4	1	1	1	4	1	4		2	3	**2**
Clinical trials	2	6	7	1		4		3	2	2	1		3	1	**3**
Registration	1	4	1	4	3	3	3	5	5	4	3	3	5	4	**4**
Inspection	4	5	6	7	2	2	5	4	3	6	6	2	4	5	**5**
Procurement	5	8	4	5	6	6	4	6	7	5	8	5	7	7	**6**
Licensing	8	3	5	8		7		7	6	8	5	4	6	6	**7**
Distribution	6	7	8	6	5	8	6	8	8	7	7	6	8	8	**8**

Common gaps identified

- **Policy for managing conflict of interest**
  - ⇨ **Declaration; Management; Sanctions on violation**
- **Public availability of information**
- **Written guidelines on committee membership**
- **SOPs (for decision-making process)**
- **Independent complaints mechanism and protection of whistle-blowers**
- **Civil society engagement**
- **Socialization of Codes of Conduct (CoC)**
- **Limited resources**

GGM Assessment in Lebanon

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A World Health Organization resource

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+ Subjects & Keywords

Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector, Lebanon
(2009; 79 pages)

Abstract

This report presents the results of a transparency assessment carried out in Lebanon.

It gives a comprehensive assessment of the level of transparency and the level of vulnerability to corruption within the six primary functions of the pharmaceutical sector – registration, inspection, promotion, selection, procurement and distribution of medicines.

The methodology provides both qualitative and quantitative information. Three national investigators, selected by the Ministry of Health, collected data by conducting a series of interviews with 50 carefully selected key informants. The information collected was then converted using a rough quantification method into a zero to 10 scale, to provide a score for each function in terms of vulnerability to corruption (minimal to extreme). The scoring indicates the vulnerability in terms of the policy, the regulatory and administrative structures and the procedures at the time of the survey.

Measuring transparency to improve good governance in the public pharmaceutical sector

LEBANON

General Findings

- Pharmaceuticals constitute a high share of total health expenditure in Lebanon
- Different stakeholders are involved: powerful private sector
- No modern drug regulatory authority structure
- Relatively all laws & regulations are old; pharmacy law 1994
- Lack of publically available information …transparency

Scoring

Function	Score	Degree of vulnerability
Registration	6.52	Marginally
Promotion	4.9	Moderately
Inspection	7.28	Marginally
Selection	4.37	Moderately
Procurement	6.7	Marginally
Distribution	8.37	Minimally
Total	6.36	Marginally

Registration: Strengths

- List of all registered pharmaceutical products with relevant information is available on the website
- Standard application form for submission of application with registration requirements; check list available on the website
- Formal technical committee; professionals from relevant parties with technical skills, meets on regular basis
- Result given in written, with reasons for rejection

Registration: Weaknesses

- No documented Standard Operating Procedure; decision based on judgment of the committee members
- Lack of detailed terms of reference; lack of description of duties, responsibilities & accountability of the members
- No pre-defined registration timeline;

  Queuing System
- No Conflict of Interest forms signed

Achievements in Registration

- Development of written documents for registration in 2012:

- Detailed checklists and application forms
- SOPs for technical committee &
- Terms of references including: roles, responsibilities
- Publishing agenda of technical committee
- Minutes of meetings with decisions and justifications on MOH Website
- Online tracking system

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Drugs Registration

تسجيل الأدوية والمستحضرات المصنّفة بحكم الدواء

1. قرار وزير الصحة رقم 504 تاريخ 1/7/1999 المتعلق بتنظيم قبول طلبات تسجيل الأدوية
2. النظام الداخلي للجنة الفنية للدواء
3. دليل إجراءات تسجيل الأدوية والمستحضرات الصيدلانية في لبنان NEW
4. قرار وزير الصحة رقم 476 تاريخ 21/4/2012 المتعلق بتأليف اللجنة الفنية
5. جدول تقديم طلبات تسجيل الأدوية لعام 2012 بحسب التسلسل الزمني
6. جدول طلبات تسجيل الادوية بانتظار إنتهاء دراسة التكافؤ الحيوي (قبل 2012)
7. قرار وزير رقم 733 تاريخ 2012/6/5 يتعلق بنشر جداول أعمال وقرارات اللجنة الفنية على موقع الوزارة الإلكتروني
8. قرار وزير رقم 1619 تاريخ 2012/10/9 يتعلق بالمستحضرات المصنّفة بحكم الدواء
9. لائحة المستحضرات المصنّفة بحكم الدواء
10. أعمال اللجنة الفنية

جدول أعمال اللجنة الفنية فى تاريخ 5/9/2014

الموافقة على محضر الإجتماع السابق

Pharmacy TWFS nb.	Import/Export nb.	Import/Export Date	Tradename	Strength	Form	Presentation	Agent	Manufacturer	Ingredient	Country	N/P
20141121528	751	24/7/2014	Invokana	300mg	film coated tablets	30	Monaco S.A.L.	Janssen Ortho LLC	canagliflozin	USA	New
20141121529	752	24/7/2014	Invokana	100mg	film coated tablets	30	Monaco S.A.L.	Janssen Ortho LLC	canagliflozin	USA	New
201411215281	753	24/7/2014	Giotrif	20mg	film coated tablets	28	Monaco S.A.L.	Boehringer Ingelheim Pharma GmbH &CO kg	afatinib	Germany	New
201411215283	754	24/7/2014	Giotrif	30mg	film coated tablets	28	Monaco S.A.L.	Boehringer Ingelheim Pharma GmbH &CO kg	afatinib	Germany	New
201411215280	755	24/7/2014	Giotrif	40mg	film coated tablets	28	Monaco S.A.L.	Boehringer Ingelheim Pharma GmbH &CO kg	afatinib	Germany	New
201411215282	756	24/7/2014	Giotrif	50mg	film coated tablets	28	Monaco S.A.L.	Boehringer Ingelheim Pharma GmbH &CO kg	afatinib	Germany	New

مقررات اللجنة الفنية فى تاريخ 5/9/2014

الموافقة على محضر الإجتماع السابق

Pharmacy TWFS nb.	Import/ Export nb.	Import/Export Date	Tradename	Strength	Form	Presentation	Agent	Manufacturer	Ingredient	Country	result
201411121528	751	24/7/2014	Invokana	300mg	film coated tablets	30	Marvaco S.A.L.	Janssen Ortho LLC	canagliflozin	USA	قرار بالتسجيل
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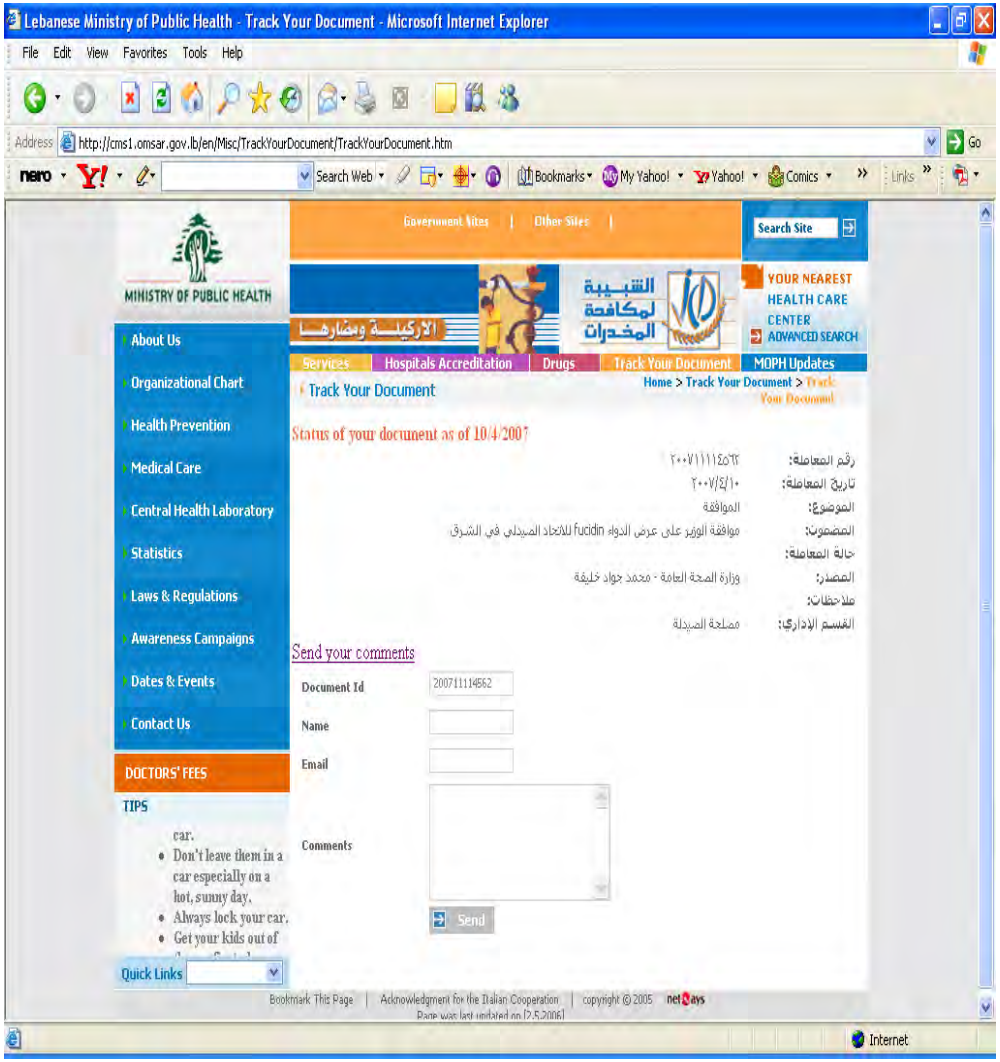

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Other Key Achievements Based on Assessment

- MOH Tender list prepared using generic names since end of 2008
- Update of national GMP in 2009
- Conflict of Interest Declaration by all committee members as of October 2010
- EML updated in 2014
- Development of ethical code for medicine promotion
- Guidelines for Good Storage and Distribution Practices of Pharmaceutical Products in Lebanon 2014
- Good Cold Chain Management for Temperature Sensitive Pharmaceuticals 2015

- https://youtu.be/xOMBhaTYxUo

Progress in EM 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
  - ⇨ 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:

- ⇨ Public accessibility of information
- ⇨ Creation or improvement of SOPs, update of EML
- ⇨ Development conflict of interest policies
- ⇨ No gift policy bill

Progress in countries to date-2

- **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
  - Information publicly available to increase transparency
  - Whistle-blower protection, increase in number of corruption cases investigated
  - Increased accessibility of medicines at lower costs
  - Appeal mechanism put in place
- **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

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
- Time: workload, other priorities; GGM not a priority

Key observations and lessons learnt

- An evaluation of the GGM Programme, performed in 2012, confirmed that the GGM Programme has made important contributions to an increased awareness of transparency and good governance in the pharmaceutical sector both in countries and globally;
- A positive impact on medicines policies and practices; revisions of pharmaceutical laws and regulations; improved availability of information and management of conflict of interest.
- GGM programme did not address the need for **clear and practical guidance** to address particular aspects of governance such as, for example: how to improve transparency, manage conflicts of interest, engage with civil society, and strengthen legislative frameworks.

Next steps

- Continue and expand country support
- Facilitate sharing of experiences among countries
- Finalize guidance documents: conflict of interest, code of conduct
- Finalize the revision of the WHO transparency assessment instrument

http://www.emro.who.int/entity/essential-medicines/index.html


Thank you