

Regional Perspectives

WHO Eastern Mediterranean



Governance in Universal Health Coverage

21–22 January, 2015 - Cairo

Essential Medicines and Pharmaceutical Policies

Department of Health Systems Development



**World Health
Organization**

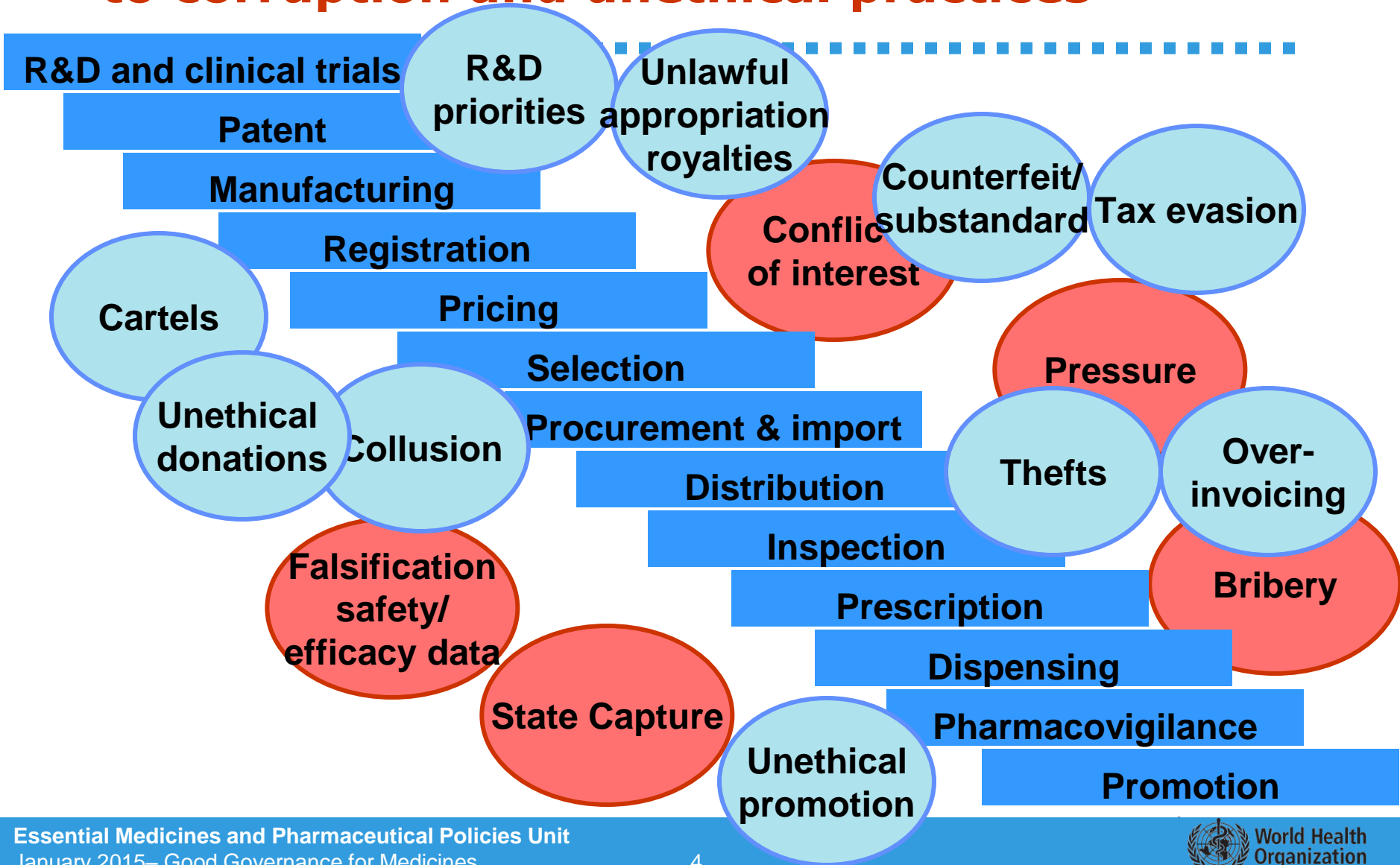
Regional Office for the Eastern Mediterranean

Classification of EMR countries by income

(World bank 2013)

High-income	Upper-middle-income
<ul style="list-style-type: none"><input type="checkbox"/> Bahrain<input type="checkbox"/> Kuwait<input type="checkbox"/> Oman<input type="checkbox"/> Qatar<input type="checkbox"/> Saudi Arabia<input type="checkbox"/> UAE	<ul style="list-style-type: none"><input type="checkbox"/> Iran, Islamic Republic<input type="checkbox"/> Jordan<input type="checkbox"/> Lebanon<input type="checkbox"/> Libya<input type="checkbox"/> Tunisia
Lower-middle-income	Low-income
<ul style="list-style-type: none"><input type="checkbox"/> Djibouti<input type="checkbox"/> Egypt<input type="checkbox"/> Iraq<input type="checkbox"/> Morocco<input type="checkbox"/> Pakistan<input type="checkbox"/> Palestine<input type="checkbox"/> Sudan<input type="checkbox"/> Syrian Arab Republic<input type="checkbox"/> Yemen	<ul style="list-style-type: none"><input type="checkbox"/> Afghanistan<input type="checkbox"/> Somalia

The pharmaceutical sector is a great target to corruption and unethical practices



Is poor governance an obstacle to social and economic development?

❑ Health and pharmaceutical sectors attractive targets

➤ US\$ 6.5 trillion spent on health services annually

➤ Global pharmaceutical market: > US\$ 950 b

❑ No global estimate on financial losses, but:

➤ 10 to 25% procurement spending lost into corruption

➤ Some countries report losses:

- 2/3 medicines supplies lost in hospitals
- 10% national expenditures on health care



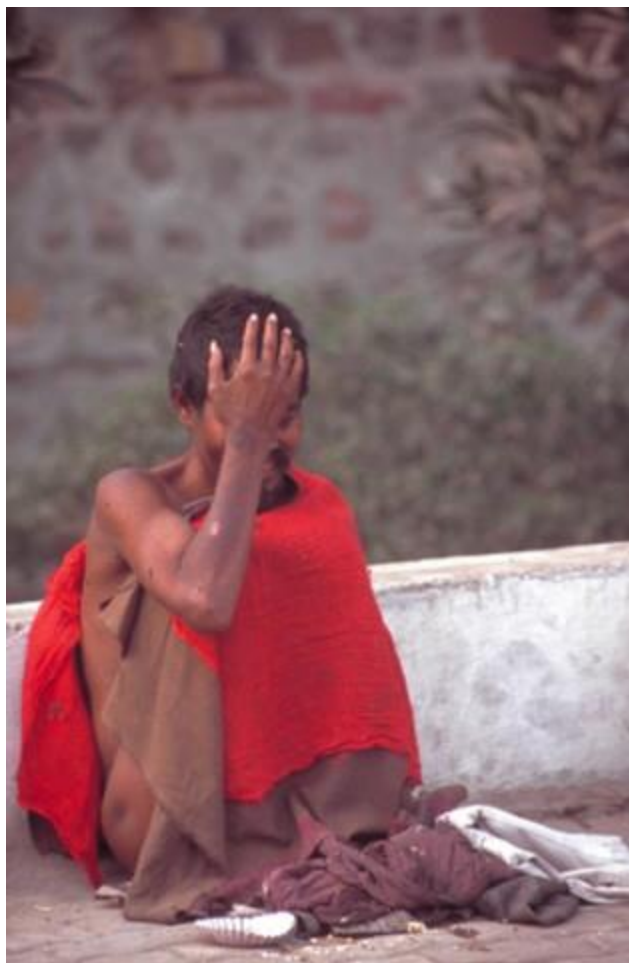


Why is the pharmaceutical system vulnerable to corruption?

- ❑ **High market value**
- ❑ **High need for control/regulation**
 - **Poorly defined and documented processes**
 - **Lack of check and balances**
 - **Too many institutional checks**
- ❑ **Information imbalance between the various players to**
 - **make independent assessments**
 - **Informed judgments**
- ❑ **Inappropriate incentive structures**

[Remember: difficulty to differentiate corruption to inefficiency]

Unethical practices can have significant impact on the health system



❑ Health impact

- Unsafe medicines on the market
- Lack EM in health facilities
- Irrational use of medicines

❑ Economical impact

- Waste limited public/donor funding
- Not stable environment
- Not easy to conduct business

❑ Image and trust impact

- Erodes public trust
- Reduces credibility of health profession

Corruption requires two parties: the corrupter and the corruptee



"Whose is the greater blame?"

Numerous technical guidelines already exist... the challenge is to balance them with ethical practices

Technical guidelines

- ❑ **GMP**
- ❑ **GCP**
- ❑ **Counterfeits**
- ❑ **Manual on Marketing Authorization**
- ❑ **WHO model list of EM**
- ❑ **Good procurement practices**
- ❑ **Ethical criteria**
- ❑ **Etc...**



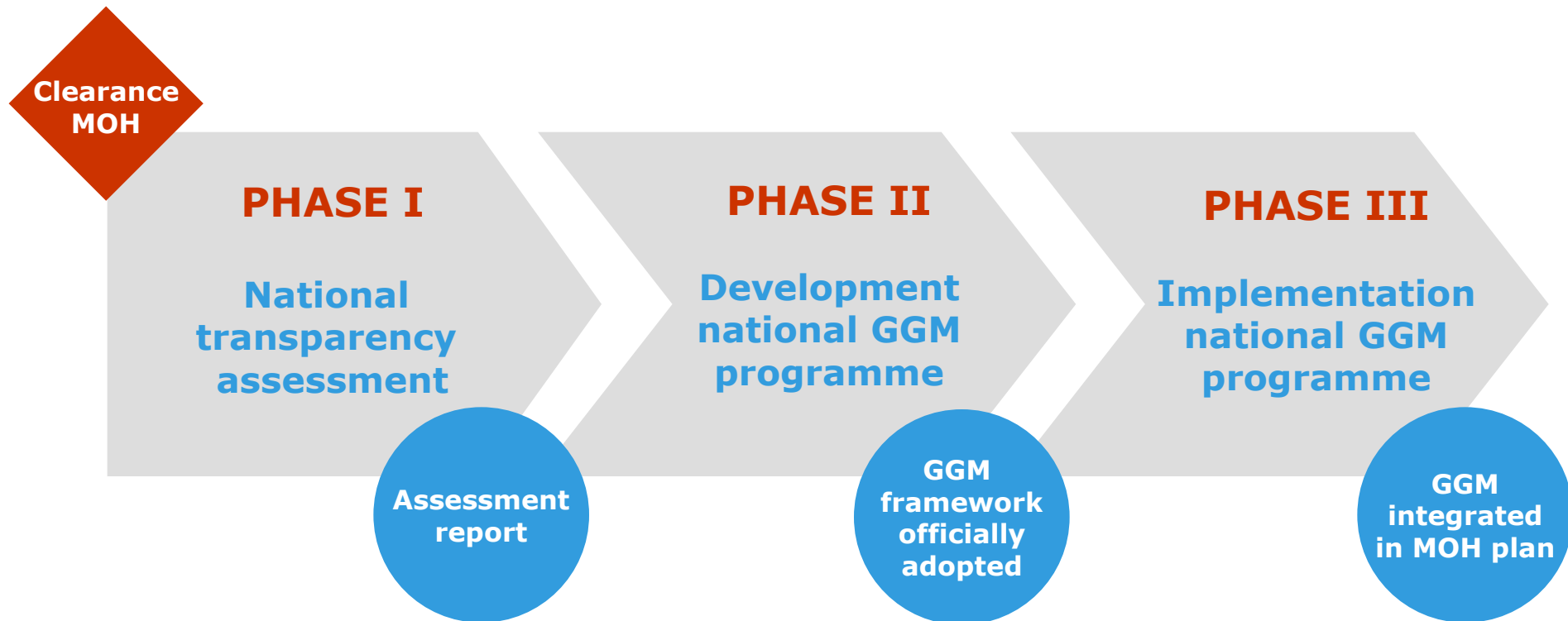
Ethical practices

- ❑ **Accountability**
- ❑ **Transparency**
- ❑ **Efficiency and effectiveness**
- ❑ **Responsiveness**
- ❑ **Forward vision**
- ❑ **Institutional pluralism**
- ❑ **Participation**
- ❑ **Rule of law**
- ❑ **Etc...**

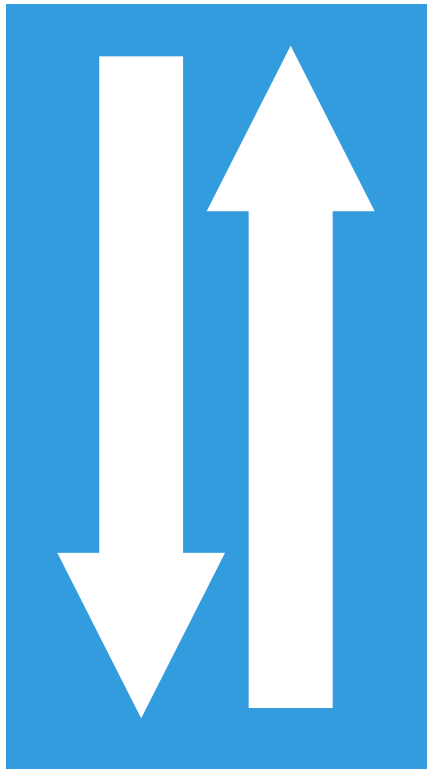
WHO Good Governance for Medicines Programme

- ❑ **Launched in 2004**
- ❑ **Launched in EMRO in 2007**
- ❑ **16 countries from EMRO**
- ❑ **37 countries globally**
- ❑ **Momentum building over the years**

Good Governance for Medicines programme: a model process



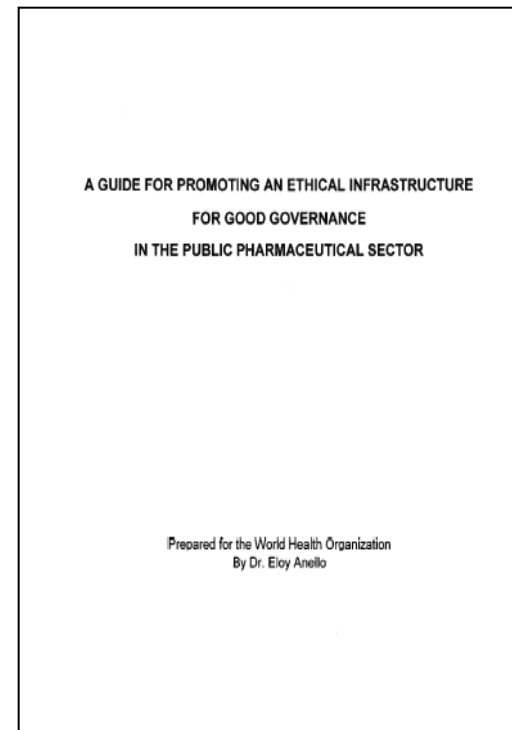
Efforts to address corruption need coordinated application of two basic strategic approaches



- ❑ **"Discipline-based approach" (top-down)**
 - **Laws, policies and procedures against corruption and for pharmacy practice with adequate punishment for violation**
 - **Attempts to prevent corrupt practices through fear of punishment**

- ❑ **"Values-based approach" (bottom-up)**
 - **Promotes institutional integrity through promotion moral values and ethical principles**
 - **Attempts to motivate ethical conduct of public servant**

GGM technical package further refined



Progress in EM Region (GGM implementation)

Phase I	Phase II	Phase III
Afghanistan	Egypt	Jordan
Bahrain	Islamic Republic of Iran	Lebanon
Iraq	Kuwait	Syrian Arab Republic
Morocco	Oman	
Pakistan	Palestine	
Yemen	Sudan	
	Tunisia	

Preliminary findings

Country/ Function	A	B	C	D	E	F	G	H	I	J	K	L	M	Ave	Rank
Registration	0.6	6.0	7.5	6.1	6.5	6.0	4.4	4.3	3.2	3.5	5.1	6.2	2.4	4.8	4
Licensing	4.3	6.0		7.7		6.8	6.2		5.3	5.4	7.4	6.8	1.1	5.7	6
Inspection	1.6	6.1	5.8	6.0	7.3	5.7	3.9	5.2	5.8	2.7	5.9	5.4	3.4	5.0	5
Promotion	1.1	4.1	1.9	5.6	4.9	3.8	0.3	2.1	1.9	1.4	4.5	3.7	0.6	2.8	1
Clinical Trials	0.8	6.1		6.5		4.2	1.7		0.0		3.4	5.4	0.0	3.1	2
Selection	3.7	3.8	7.7	5.3	4.4	3.2	4.4	4.4	4.6		5.7	5.0	1.8	4.5	3
Procurement	2.6	6.8	8.6	7.5	6.7	6.5	6.2	5.5	6.9	6.0	6.3	6.8	5.4	6.3	7
Distribution	3.3	6.2	8.4	9.2	8.4	7.2	8.2		6.5	6.9	6.6	7.8	6.6	7.1	8

Sample findings: Registration

- 2 out of 13 countries have written guidelines setting limits on how and where medicine registration officers meet with applicants.
- 1 out of 13 countries had a written document that describes the composition and terms of reference of the registration committee, which conforms to the following minimum criteria:
 - up-to-date
 - publicly accessible
 - lists committee members by name and their expertise
 - includes the roles and responsibilities of its members
 - their accountability and financial benefits if any
- 1 out of 13 countries had a clear and comprehensive guidelines for the committee's decision making process.

Sample findings: Distribution of medicines

- ❑ **7 out of 12 countries had an inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier.**
- ❑ **7 out of 12 countries had a systematic and orderly shelving of products in warehouses or storerooms.**
- ❑ **5 out of 12 countries had a security management system in place to oversee storage and distribution.**

Sample findings: Control of medicines promotion

- ❑ **None of the 13 countries had clear written criteria for selecting the members of the service/committee**
- ❑ **None of the studied countries had written guidelines on conflict of interest with regard to the control of medicine promotion activities.**
- ❑ **None of the studied countries had a formal complaints procedure to report unethical promotional practices.**

Common strengths

- ❑ **Political commitment to increasing access to medicines**
- ❑ **Presence of medicines laws in all countries**
- ❑ **Active technical committees in various functions**
- ❑ **Registration systems**
- ❑ **Essential medicines lists**
- ❑ **Qualified human resources**

Common gaps

- ❑ **Policy for managing conflict of interest**
 - **Declaration**
 - **Management**
 - **Sanctions on violation**
- ❑ **Written guidelines on membership in committees (including rotation policies)**
- ❑ **Standard operating procedures (especially for decision making process)**
- ❑ **Public availability of information**

Common gaps (cont'd)

- ❑ **Control of medicines promotion**
 - **Direct to consumer**
 - **Medical professionals**
- ❑ **Civil society engagement**
- ❑ **Presence of suitable codes of conduct**
 - **Civil service**
 - **Professional association**
 - **Manufacturers association**
- ❑ **Socialization of codes of conduct**

Common gaps (cont'd)

- ❑ **Sanctions on reprehensible acts**
- ❑ **Enforcement mechanisms**
- ❑ **Guidelines on interaction between public officials and private sector**
- ❑ **Independent complaints mechanism**
- ❑ **Protection of whistle blowers**
- ❑ **Limited resources**

Increasing transparency and accountability in pharmaceutical systems – country support

- ❑ **New and experimental field**
 - **Not limited to developing countries**
 - **Is not isolated from overall governance system**
 - **Encourages sharing views and experiences across countries**
- ❑ **Growing roster of human resources**
- ❑ **Technical documents in Arabic**
- ❑ **Stakeholder involvement from outside the medicines sector**
- ❑ **Sum of WHO technical support \approx sum of lessons learned in countries**

Key factors of success

- ❑ **National "champions" (dedicated & motivated national GGM team)**
- ❑ **Selection of national assessors**
- ❑ **Active GGM teams (strong technical team)**
- ❑ **High-level political will & support**
- ❑ **Collaboration with key stakeholders extremely valuable (e.g. anti-corruption agencies)**
- ❑ **GGM integrated in existing structures and committees**

Some common challenges

- ❑ **Passive attitude towards corruption & resistance to change**
- ❑ **Political instability**
- ❑ **Bureaucracy**
- ❑ **Rotation of staff**
- ❑ **Integration of GGM in existing national structures**
- ❑ **Governance is new area**
- ❑ **Existing workload and other priorities**
- ❑ **Etc.**

EMR Challenges

- ❑ **Political climate**
- ❑ **Weak CSOs**
- ❑ **High turn over of public officials**
- ❑ **Constraints on WHO regional/country office capacity**
- ❑ **Limited financial and human resources**

Some observations



- ❑ **Great interest in subject area (more than anticipated)**
- ❑ **Preventive and constructive approach appealing**
- ❑ **Assessment can be educational**
- ❑ **Some countries need more time than others**
- ❑ **Institutionalization needed to ensure sustainability**

More information

- ❑ **On EMR medicines situation and EMP work**

 - ➔ www.emro.who.int/emp

- ❑ **On WHO GGM Programme**

 - ➔ www.who.int/ggm

Special thanks to...

- ❑ **Government of the State of Kuwait**
- ❑ **Government of the Federal Republic of Germany (Federal Ministry for Economic Cooperation and Development – BMZ)**

for financially supporting the GGM



TRANSPARENCY FOR CHANGE

وشكراً

Thank you