

# WHO Good Governance for Medicines programme (GGM)

<http://www.who.int/medicines/areas/policy/goodgovernance/home/en/index.html>



## MACEDONIAN EXPERIENCES ON GOOD GOVERNANCE FOR MEDICINES PROGRAMME

# Overview

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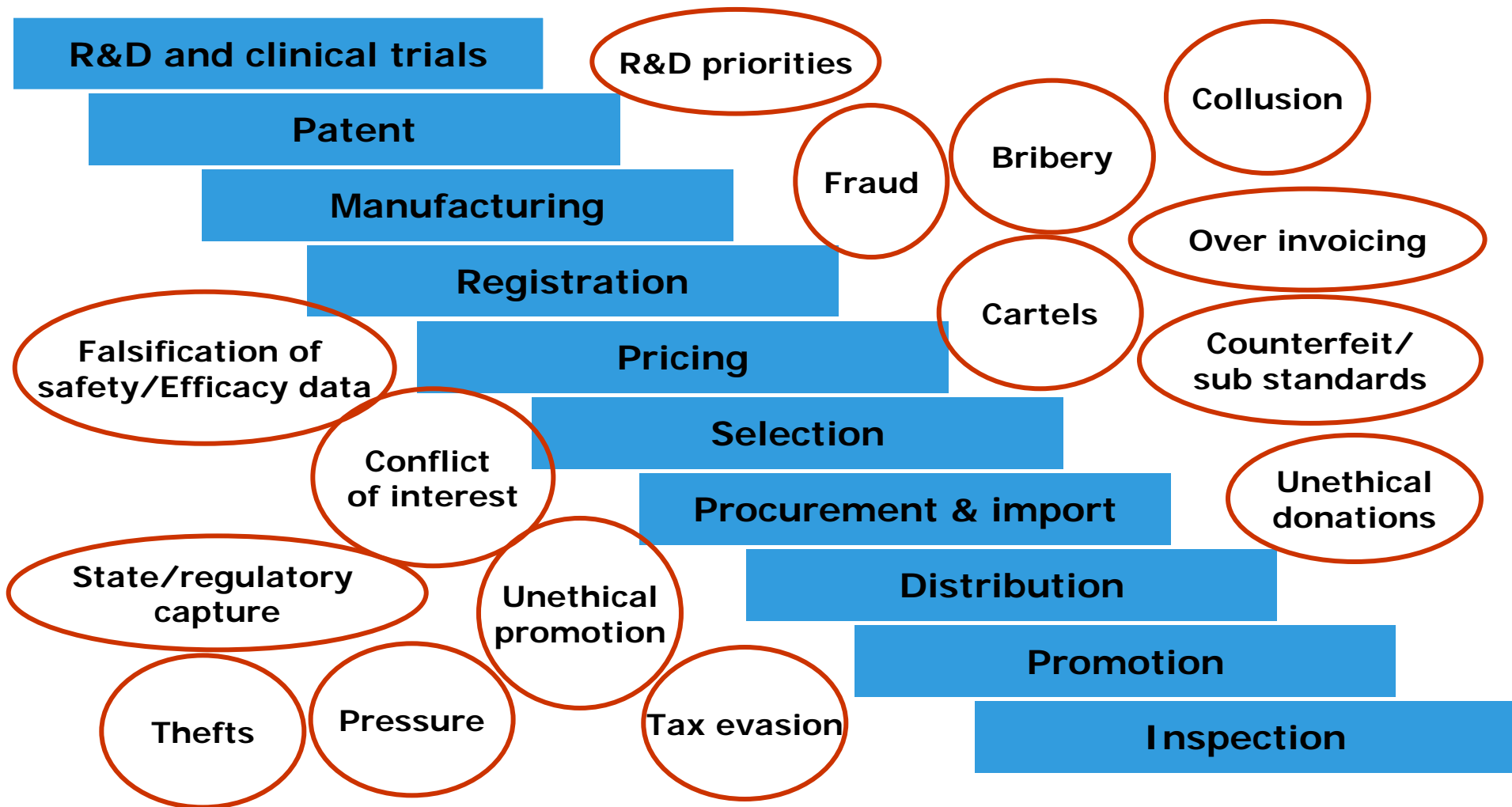


**Corruption in the pharmaceutical sector**

**WHO's Good Governance for Medicines programme  
(WHO's GGM programme)**

**Macedonian experiences on WHO's GGM programme**

# Unethical practices can be found throughout medicines chain are very diverse



# Corruption identified as the single greatest obstacle to economic and social development

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- ❑ US\$ 3 trillion spent on health services annually
- ❑ Global pharmaceutical market: > US\$ 600b
- ❑ 10 to 25% procurement spending lost into corruption (including health sector)
- ❑ Some countries report that 2/3 medicines supplies lost through corruption and fraud in hospitals
- ❑ Low quality trials exaggerate the benefits of treatment by an average of 34%
- ❑ Bribery of high officials in regulatory authorities has led to unsafe medicines circulating on the market resulting in deaths

# Unethical practices can have significant impact on the health system

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## ❑ Health impact

- Lack EM → increases morbidity & mortality
- Unsafe medicines on the market
- Irrational use of medicines

## ❑ Economical impact

- Pharma. expenditure low-income countries:
  - 10-40% of public health budget
  - 20-50% of total health care expenditures
- Poor most affected → inequalities

## ❑ Image and trust impact

- Reduces government capacity
- Reduces credibility of health profession
- Erodes public trust

## Why is the pharmaceutical system vulnerable to corruption?



- ❑ Market volume and economic interests
- ❑ Information imbalance to make independent assessments on quality, safety & efficacy of medicines
- ❑ High degree of government involvement in its regulation
- ❑ Poorly defined and documented processes
- ❑ Limited or too many institutional checks
- ❑ Inappropriate incentive structures
- ❑ Difficulty to differentiate corruption to inefficiency

# Numerous technical guidelines already exist... the challenge is the balanced integration of appropriate ethical practices

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## 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...

# Overview

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Corruption in the pharmaceutical sector



WHO's Good Governance for Medicines programme

Macedonian experiences on WHO's GGM programme

# WHO *Good Governance for Medicines* Programme

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## □ Goal

- To curb corruption in pharmaceutical sector systems through the **application of transparent and accountable administrative procedures** and the promotion of **ethical practices** among health professionals.

## □ Specific objectives

- To **increase the awareness** of all stakeholders on the potential for corruption in the pharmaceutical sector and its impact on health systems functioning.
- To **increase transparency and accountability** in **medicines regulatory systems** and **supply management systems**.
- To **build national capacity for good governance in medicines regulation and supply management systems**.

# TRANSPARENCY

## U4-Utstein Anti-Corruption Resource Center

<http://www.u4.no./document/faqs5.cfm>

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- **Transparency means** clearness, honesty and openness.
- **Transparency is the principle** that those affected by administrative decisions should be informed, and the duty of **civil servants, managers and trustees to act visibly, predictably and understandably.**
- **Transparency** thus **encompasses access**, relevance, quality and reliability and describes the increased flow of timely and reliable economic, social, and political information.

# TRANSPARENCY

## U4-Utstein Anti-Corruption Resource Center

<http://www.u4.no./document/faqs5.cfm>

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**.. Transparency enables institutions and the public:**

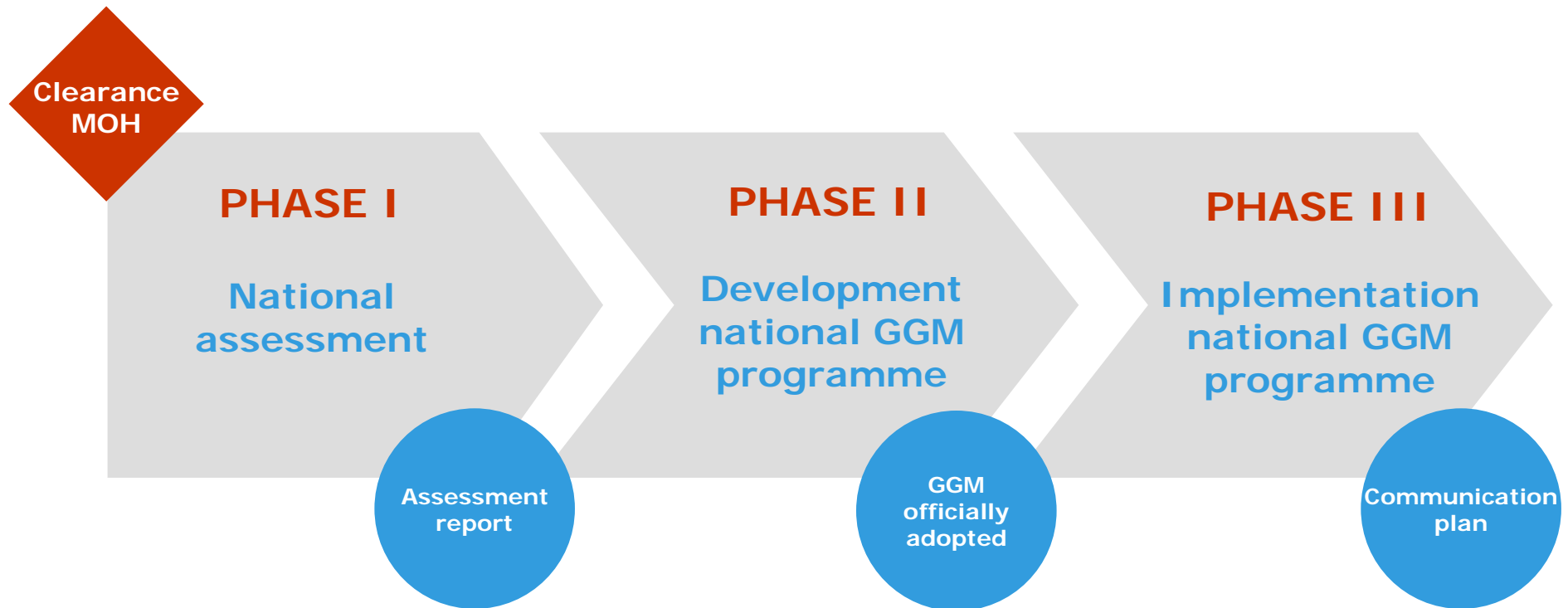
- to make informed political decisions,
- to improves the accountability of governments
- to reduces the scope for corruption.

**Transparency is also essential to the economy:**

- it improves resource allocation
- enhances efficiency and
- increases growth prospects.

# *Good Governance for Medicines programme:* a model process

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PHASE I

PHASE II

PHASE III

# Assessment of transparency and accountability

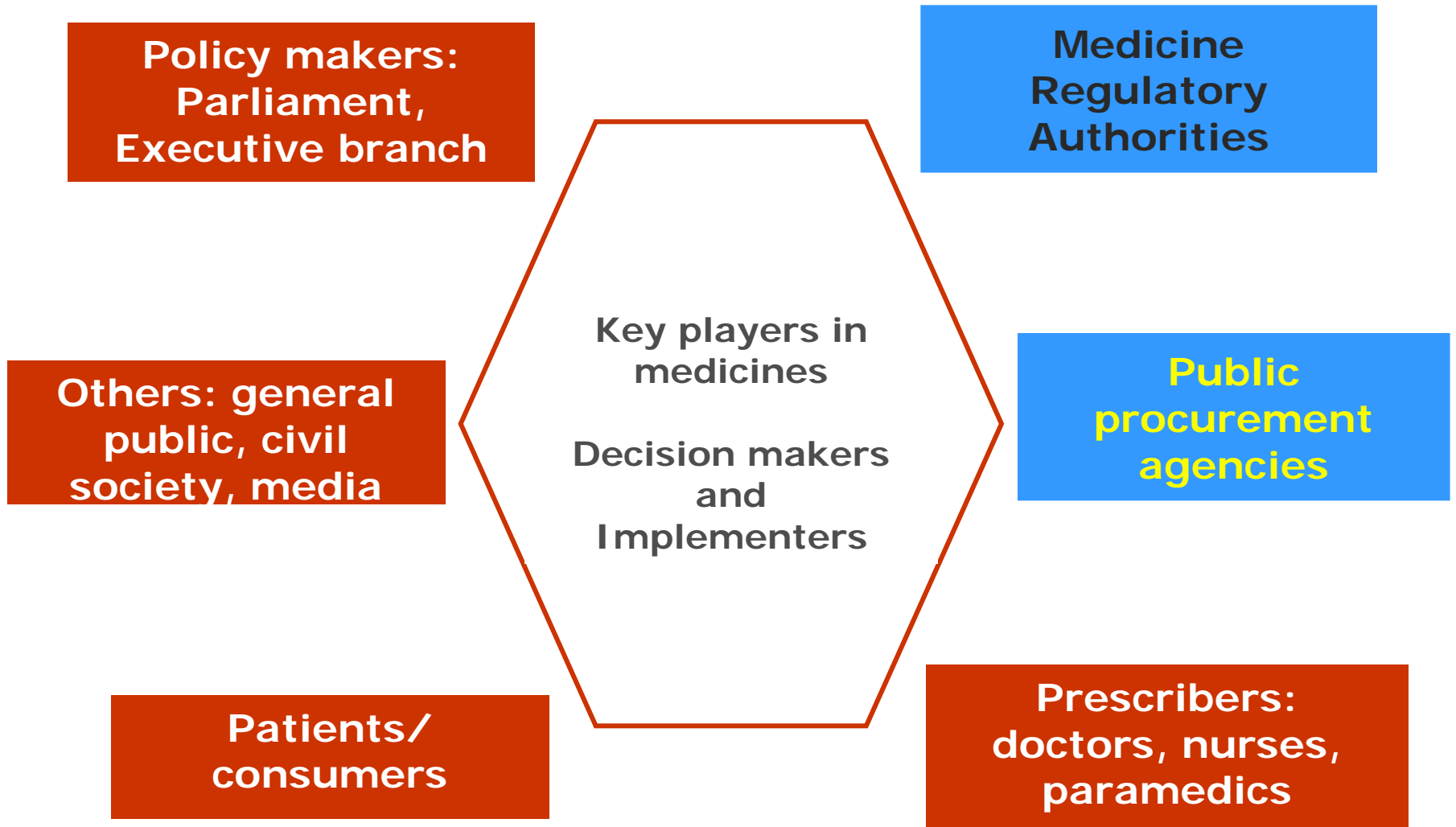
National  
assessment

Assessment  
report

- ❑ **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

# Key players in medicines: Who and What do we assess?

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# Development of National GGM Programme

PHASE I

PHASE II

PHASE III

## National GGM programme



Discipline based approach



Values based approach

GGM officially adopted

- ❑ Developed through a national consultation process with all stakeholders
- ❑ Components of GGM programme:
  - Ethical framework of moral values & ethical principles
    - Justice/fairness
    - Truth
    - Service to common good
    - trusteeship
  - Code of conduct
  - Transparent and accountable regulations and administrative procedures
  - Collaboration mechanism with other GG & AC initiatives
  - Whistle-blowing mechanism
  - Sanctions on reprehensible acts
  - GGM implementing task force

PHASE I

PHASE II

PHASE III

# Implementation of National GGM Programme

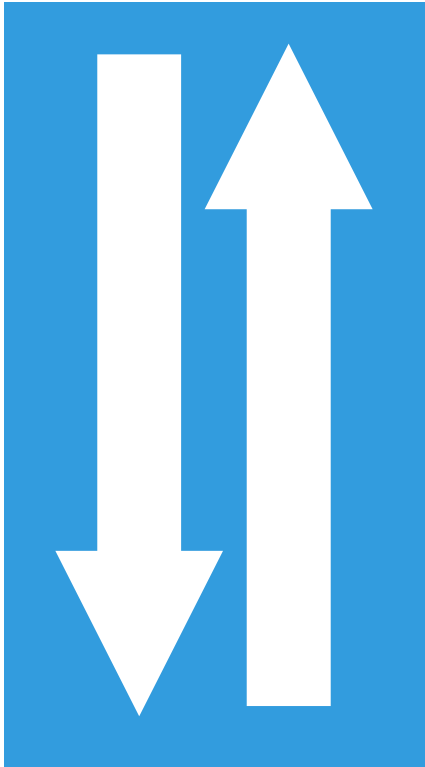
Implementation  
national GGM  
programme

Communication  
plan

- ❑ **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

# Efforts to address corruption need coordinated application of two basic strategies

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- ❑ "Discipline-based approach" (top-down)
  - Laws, policies and procedures against corruption and for pharmacy practice with adequate punitive consequence 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

# Overview

Corruption in the pharmaceutical sector

WHO's Good Governance for Medicines programme



Macedonian experiences on WHO's GGM programme

PHASE I

PHASE II

PHASE III

# Assessment of transparency and accountability

24.10 - 23.11. 2007

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## □ Key functions of the pharmaceutical sector systems

Macedonian  
National  
assessment

Assessment  
report

### ➤ Regulation:

- Registration
- Inspection
- Promotion

### ➤ Supply:

- Selection
- Procurement
- Distribution

PHASE I

PHASE II PHASE III

# Assessment of transparency and accountability

24.10 - 23.11. 2007


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## □ Elements evaluated:

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Macedonian  
National  
assessment

Assessment  
report



**You really understand a system when you are able to  
represent it using a mathematical equation**

**Lord Kelvin**



### Vulnerability scale SCORE

<b>Function</b>	<b>Total indicators</b>	<b>Number of KIs</b>	<b>Score on 10 point scale</b>	<b>Degree of vulnerability to corruption</b>
Registration	16	18	5.86	Moderately
Promotion	12	11	4.73	Moderately
Inspection	11	10	6.49	Marginally
Selection	12	9	6.48	Marginally
Procurement	15	17	6.69	Marginally
Distribution	16	12	7.62	Marginally
<b>Total</b>	82	84	<b>6.31</b>	Marginally

# REGISTRATION

## Strengths

- **Transparent written information about the registration procedure**
- **Standard application form available in official publications and on the web site**
- **Professional experience of the Registration Committee members is taken into consideration**
- **The Registration Committee meets twice a month**
- **The Registration Committee prepares an official written document which contains all the decisions and it is signed by all members**
- **A system for formal appeals is developed**

# DRUG PROMOTION CONTROL

## *Strengths*

- ❑ Advertising of medicinal products (MP) that are **subject to medical prescription** in the media and which address the general public **are forbidden**
- ❑ It is forbidden to address children while advertising MP
- ❑ It is forbidden to publicly advertise MP that have no Marketing Authorization
- ❑ The acquisition of additional knowledge does not exceed the limit of scientific-expert objectives and it is targeted to persons prescribing or dispensing MP
- ❑ Advertising of MP subject to medical prescription is allowed in terms of providing information in line with the summary of the product characteristics (SmPC)

# INSPECTION

## *Strengths*

### *Strengths*

□ **The highest level of legislation/regulation profiles covering**

**1. Medicines manufacturers**

**2. Distributors inspections**

**3. Internal audit of inspection**

**New law on INSPECTION promulgated in May, 2010**

## DRUG SELECTION

### *Strengths*

- EML-NF is in line with the recommended WHO procedure
- More or less linked to national standard treatment guidelines
- The EML-NF was revised during the past 5 years
- Committee members are distinguished professionals selected on the basis of their expertise and position

# PROCUREMENT

## *Strengths*

- ❑ **Procurement process is defined by the Law on Public Procurement**
- ❑ **Procedures for procurement of the pharmaceutical products are competitive**
- ❑ **Transparent and official invitations for bidders for showing interest to participate in the procurement procedure**
- ❑ **All activities related to conducted public procurement procedures are integrated in a written annual summary report prepared by an audit agency**
- ❑ **Written COI documents are signed by all members of the Committee**
- ❑ **A system for formal appeals was developed**

## *DISTRIBUTION*

### *Strengths: GDP*

- ❑ The employees **practice regular monitoring of the stock**, almost every second month and regular monitoring of the warehouse, at the end of the fiscal year
- ❑ A revision of operation (financial and stock counting) is conducted **by an independent inspection / audit**
- ❑ The computer-based **IT system** of management promotes accountability for every product
- ❑ All activities are integrated in a written annual summary report prepared by an audit agency
- ❑ Well established and operational communication between all interested parties

## RECOMENDATIONS

- ❑ **Establishment of advanced training programs for inspectors**
- **Attendance at the ECA qualification and training programs for inspectors**
- **Open competition for the Committees member selection**
- **Completely eliminate or if possible, minimize the political influences, favouritism, conflict of interests and pressure by pharmaceutical companies**
- **Establishing a specialized pharmaceutical department/office within the Custom Administration**
- **Written COI documents should be signed by all members of the Committees**
- **To clearly establish SOPs and TOR for all functions in the pharmaceutical sector**

# The components of a national GGM Framework

**1. Ethical framework of moral values & ethical principles**

- Justice/fairness
- Truth
- Service to common good
- Trusteeship

**2. Code of conduct**

**3. Socialization programme**

**4. Promotion of Moral Leadership**

**5. Established anti-corruption legislation**

**6. Whistle-blowing mechanism**

**7. Sanctions on reprehensible acts**

**8. Transparent and accountable regulations and administrative procedures**

**9. Collaboration with other GG & AC initiatives**

**10. Management, coordination and evaluation of GGM programme (Steering Committee & task force)**

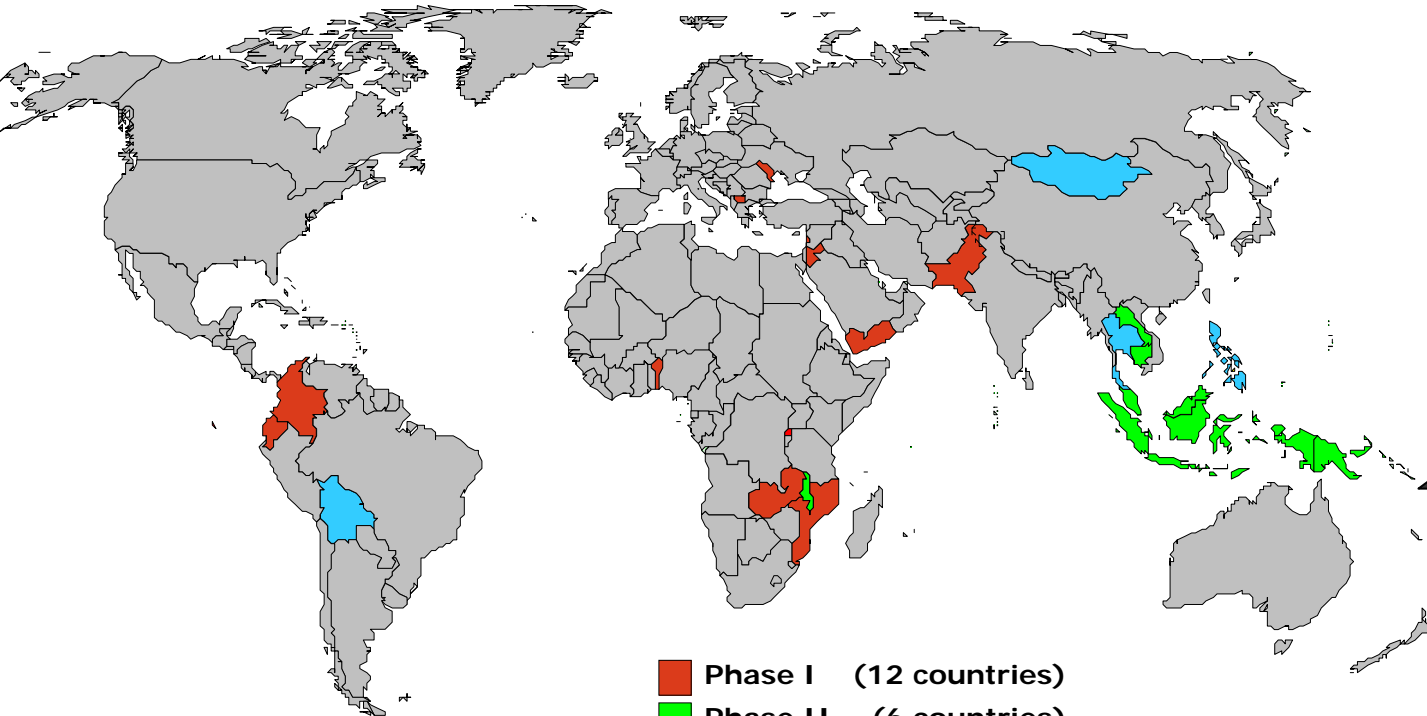


**Values based approach**



**Discipline based approach**

# Bottom-up approach in implementation of project and policy development



- Phase I (12 countries)
- Phase II (6 countries)
- Phase III (4 countries)

Questionnaire 1

**Objective:** To assess the level of compliance in the pharmaceutical sector with a focus on the areas: registration, promotion, inspection, selection of essential medicines and environment.

**QUESTIONNAIRES ON REGULATION PRACTICES**

- SECTION ONE: REGISTRATION
- SECTION TWO: CONTROL OF SALES PROMOTION
- SECTION THREE: INSPECTIONS

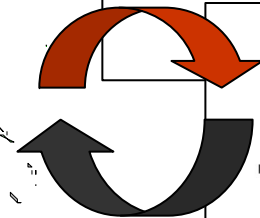
**PRELIMINARY INFORMATION**

Date: \_\_\_\_\_

Key informant number: \_\_\_\_\_

The key informant works in:


- Government (public sector)
- Private sector
- Non-governmental organization
- Inter-national governmental organization
- None



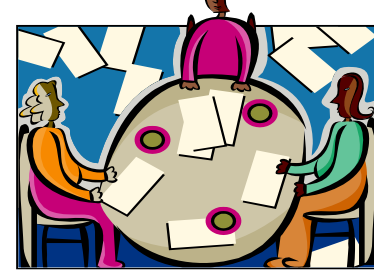
**Ethical Infrastructure for Good Governance in the Public Pharmaceutical Sector**

*Working draft for field testing and revision*  
November 2006

Dr Eloy Anello  
(WHO consultant)

 World Health Organization

Department of Medicines Policy and Standards (PSM)



- 1. Do you believe that corruption exists in the pharmaceutical sector in your country?**
- 2. What are the most common forms?**
- 1. What are the possible causes?**



**Questions ?**

**Thank you for your attention!**