

Governance Assessment Methods and, Applications of Governance Data in Policy- Making Workshop

Good Governance for Medicines programme

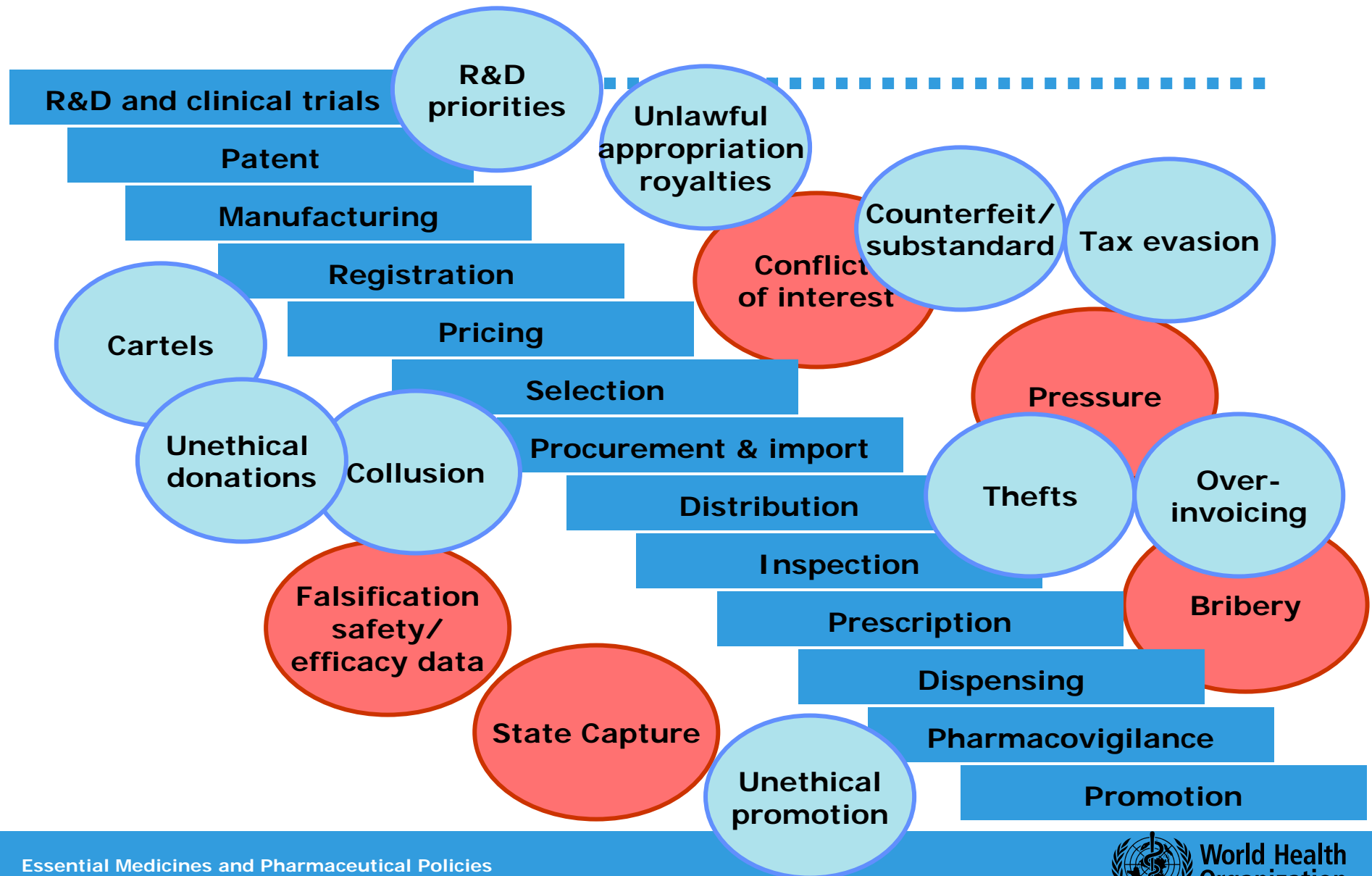
Mohamed Ramzy
WHO Regional Office for the Eastern Mediterranean

1-4 June 2009
Cairo Egypt

Objectives

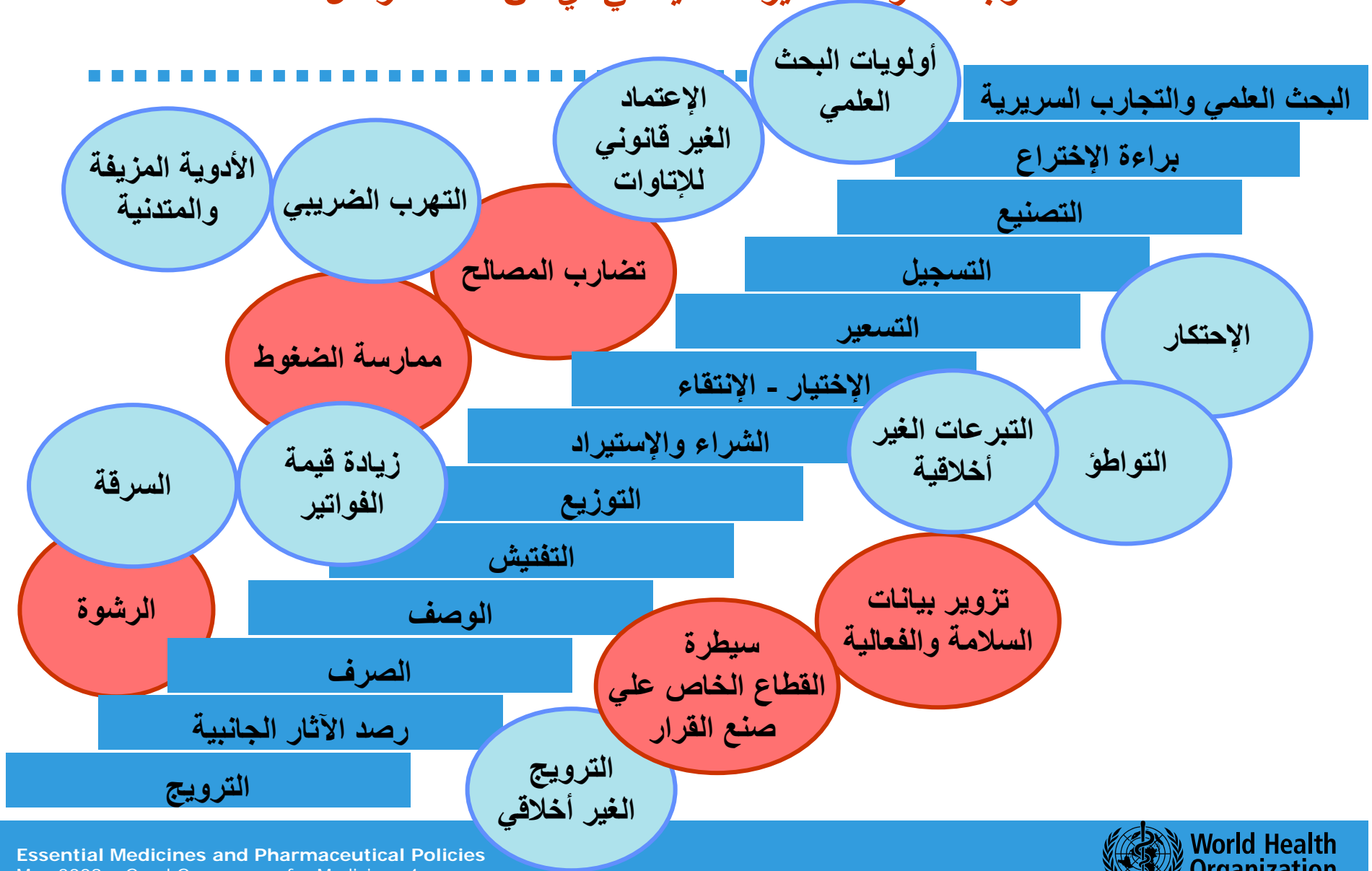
- 1. Briefly introduce WHO's Good Governance for Medicines (GGM) programme**
- 2. Share experience on WHO's transparency assessment methodology**
- 3. Share insights and reflections on translating assessment results into policies**

Pharmaceutical sectors is a great target to corruption and unethical practices



سلسلة الدواء

قد توجد ممارسات غير أخلاقية في أي من هذه المراحل



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

Technical guidelines

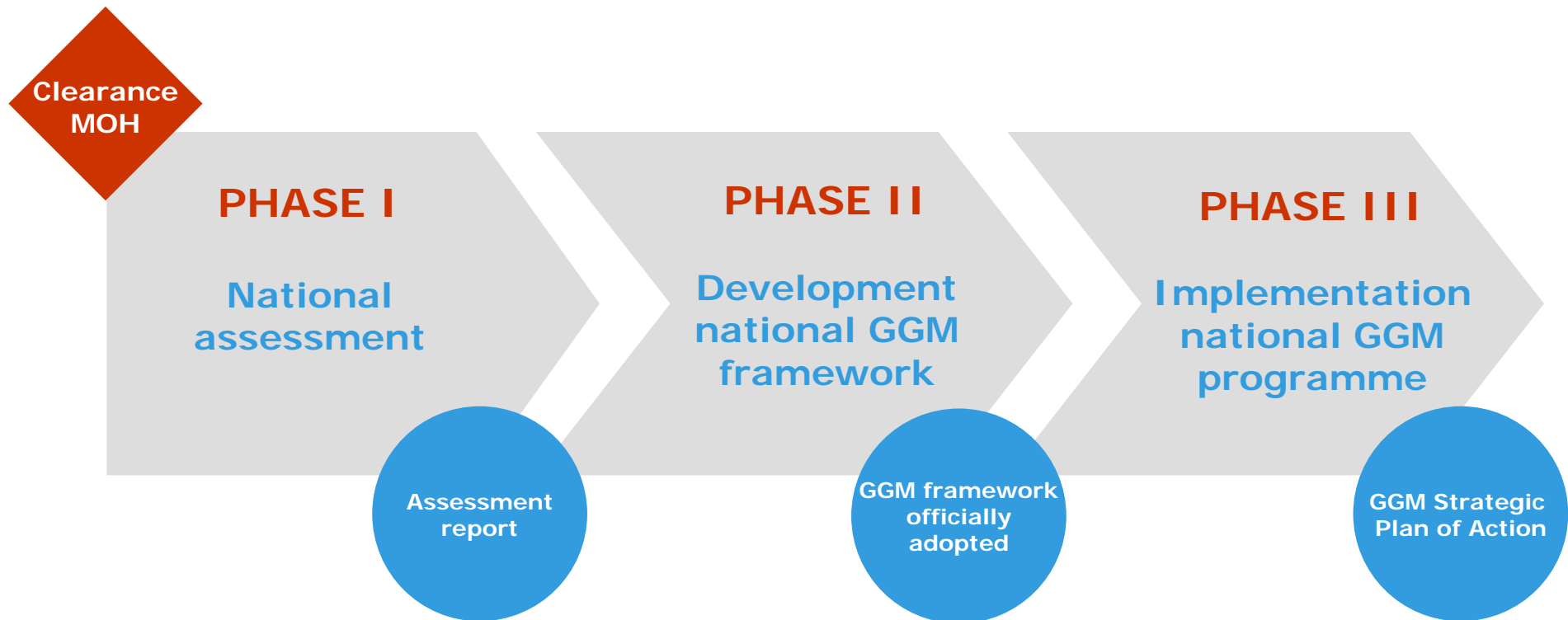
- ❑ GMP
- ❑ GCP
- ❑ Counterfeits
- ❑ Manual on Marketing Authorization
- ❑ WHO model list of EM
- ❑ Good procurement practices
- ❑ Ethical criteria
- ❑ Etc...



Ethical practices

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

Good Governance for Medicines programme: a model process



PHASE I

PHASE II

PHASE III

Assessment of transparency and accountability

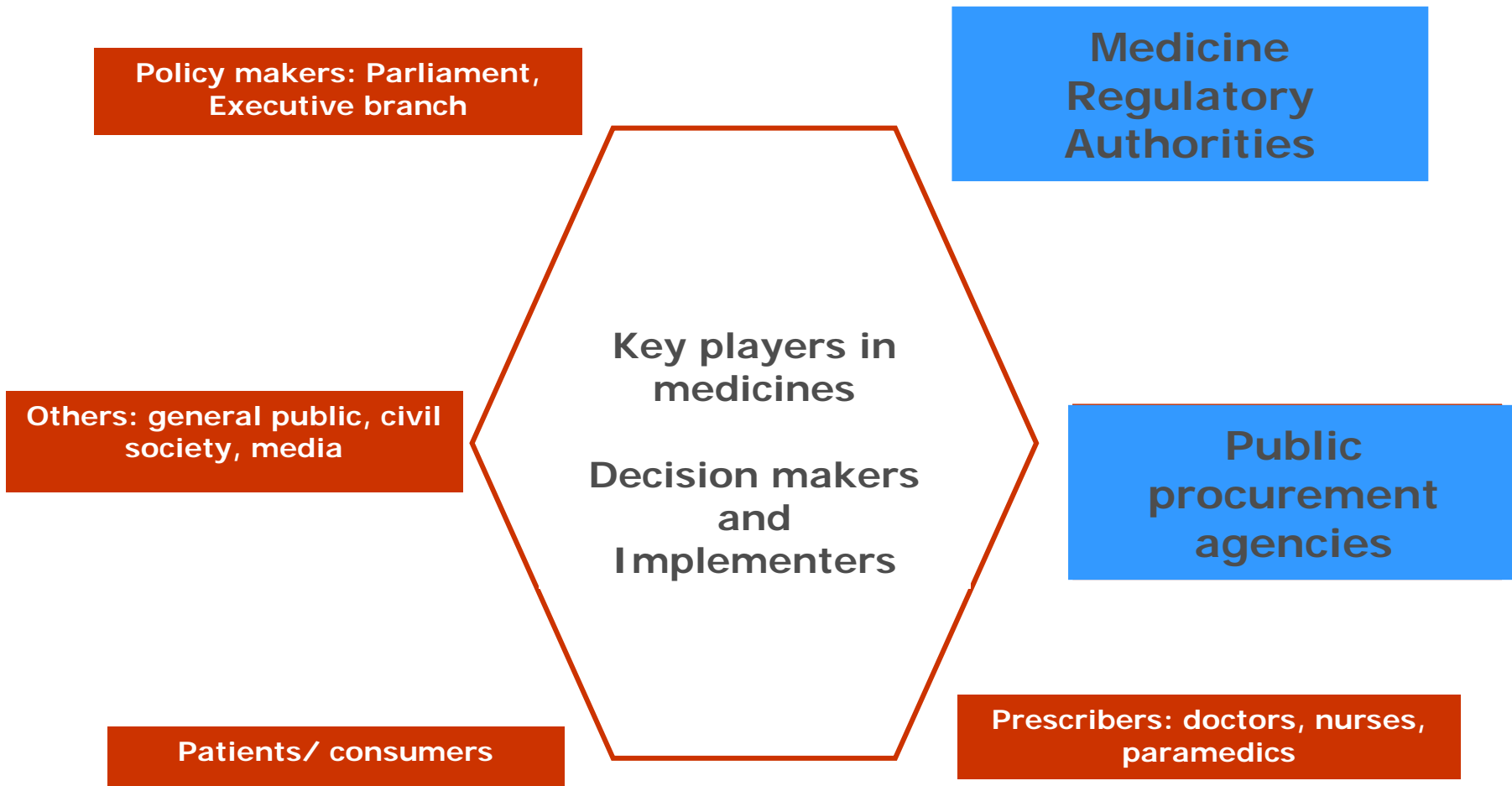


National
assessment

Assessment
report

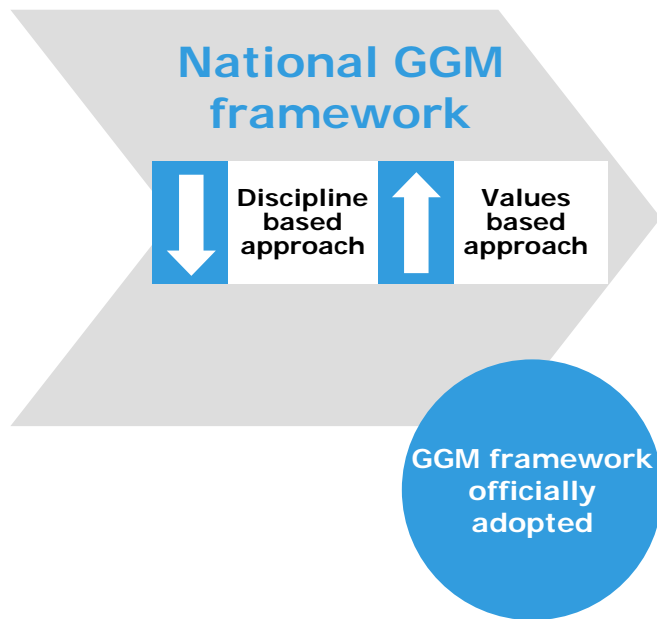
- ❑ **Assesses vulnerability to corruption of systems in place**
- ❑ **Looks at key functions of the pharmaceutical sector systems**
 - Regulation: registration, licensing, inspection, promotion, clinical trials
 - Supply: selection, procurement, distribution
- ❑ **Elements evaluated:**
 - Country's 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?





Development of National GGM Framework



- ❑ Developed through a national consultation process with all stakeholders

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

PHASE I

PHASE II

PHASE III

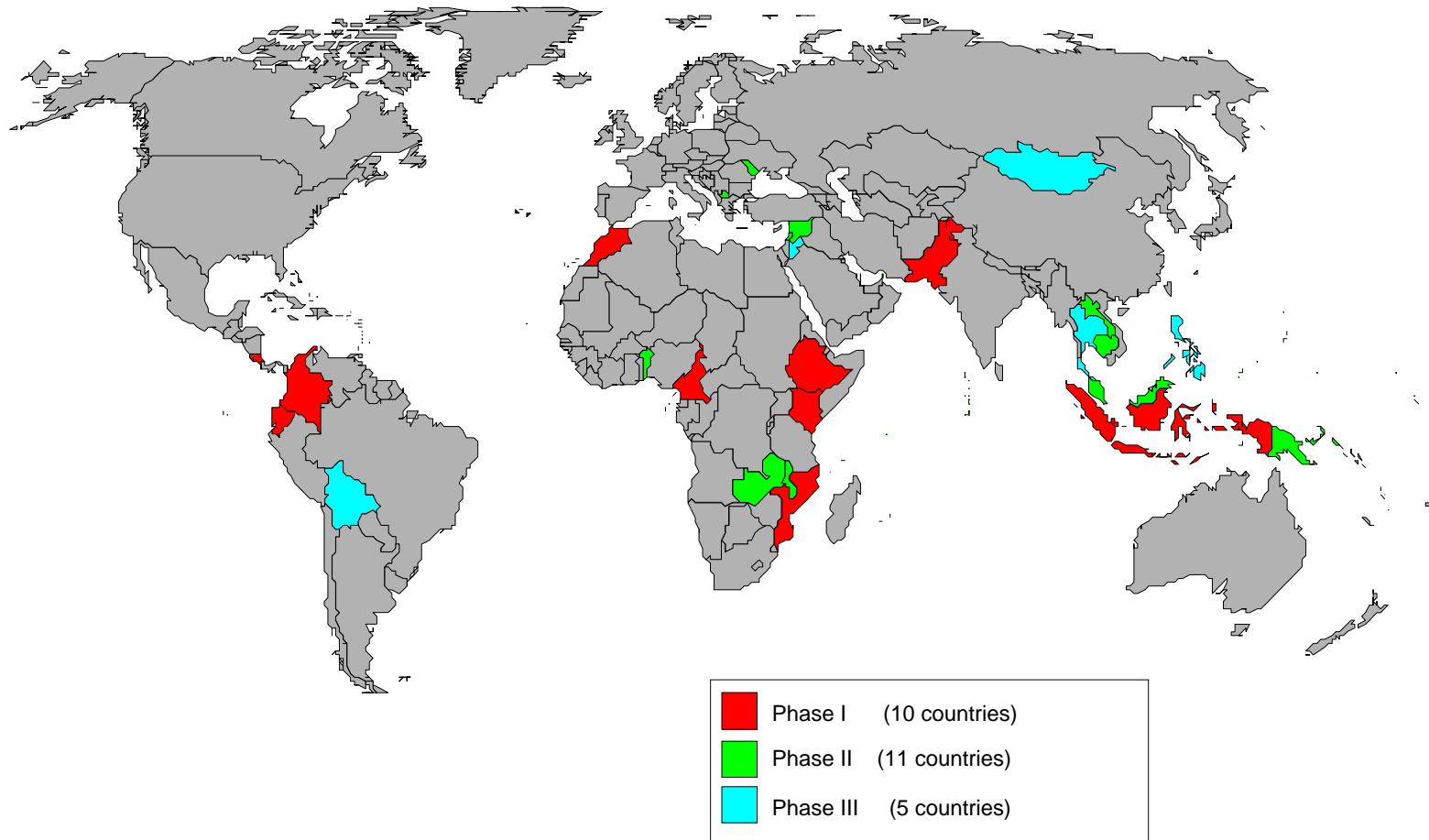
Implementation of National GGM Programme

Implementation
national GGM
programme

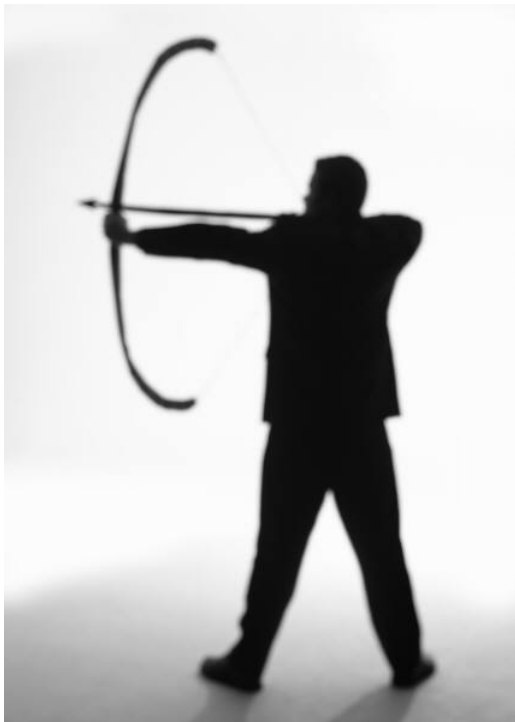
Communication
plan

- ❑ 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

Countries efforts focus on moving from phase I to phase III



Objectives of transparency assessment study

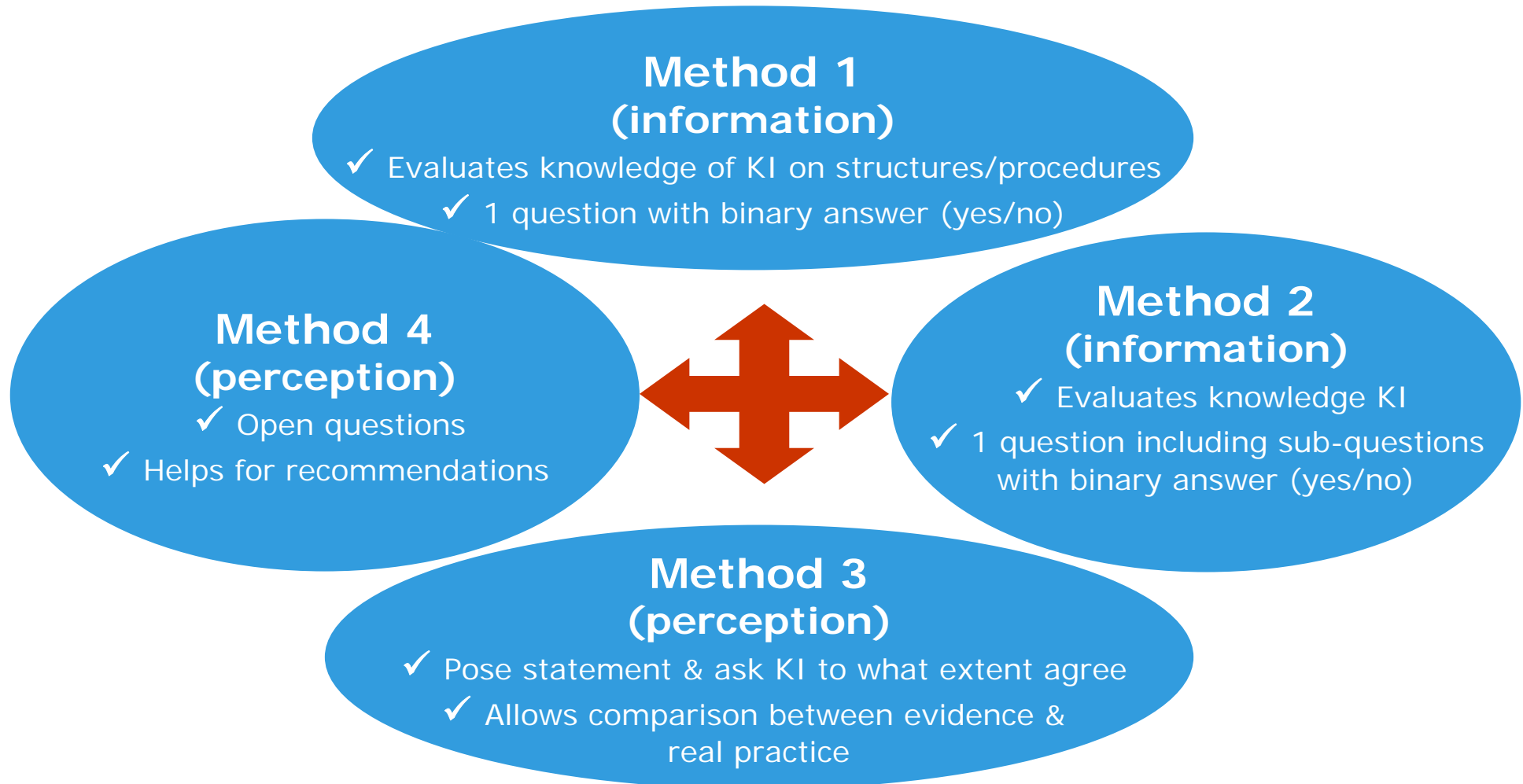


- ❑ Provide countries picture of level of transparency and vulnerability to corruption of 8 functions:
 - Regulation: registration, licensing, inspection, promotion, clinical trials
 - Supply: selection, procurement, distribution
- ❑ Recommendations to increase transparency and accountability in pharmaceutical public sector
- ❑ Initiate establishment of GGM programme in countries

Assumption

- ❑ The more transparent any system is, the less vulnerable to corruption it will be
 - Presence of publicly available and easily accessible documents = sign of transparency → reduces vulnerability to corruption (and vice versa)
 - Awareness about their existence suggest they have been disseminated and used on practice

Questions use 4 different methods



Rating indicators method 1

- ❑ **1 question with binary answer: Yes or No**
 - Yes (existence of document) = 1 ⇔ low vulnerability to corruption
 - No (document does not exist) = 0 ⇔ high vulnerability to corruption
 - Transcribe 1 or 0 on consolidation sheet
- ❑ **Use *interpretation guidelines* in the manual for each indicator**
- ❑ **Transcribe score calculated (0 or 1) on scoring sheets**
- ❑ **Needs to be supported by evidence**

Rating indicators method 2

- ❑ Each question has several criteria
- ❑ Binary answer for each criteria
- ❑ On questionnaire calculate scoring for each answer
 - Disregard all invalid answers (D.K., N.A.)
 - **Score = total "yes"/total valid answers**
 - If more than half are D.K. or N.A. → disregard whole question for this KI
- ❑ Transcribe score calculated (between 0 and 1) on score sheet

Example method 2

- ❑ **Indicator: Are there clear written criteria for selecting the members of the essential medicines committee?**

	No	Yes	D.K.
1. Written criteria	0	①	
2. Criteria publicly available	0	①	
3. Specify professional qualification required	0	①	
4. Specify the technical skills and work experience related to the area	0	①	
5. Require declaration of conflict of interest (e.g. investment in pharmaceutical business)	①	1	
6. Give a timeframe to serve as a committee member	0	1	✓
Total	1	4	1

<i>Total yes</i>	4
<i>Total valid answers</i>	5
<i>Scoring (total yes/total valid answers)</i>	0.8

Rating indicators method 3

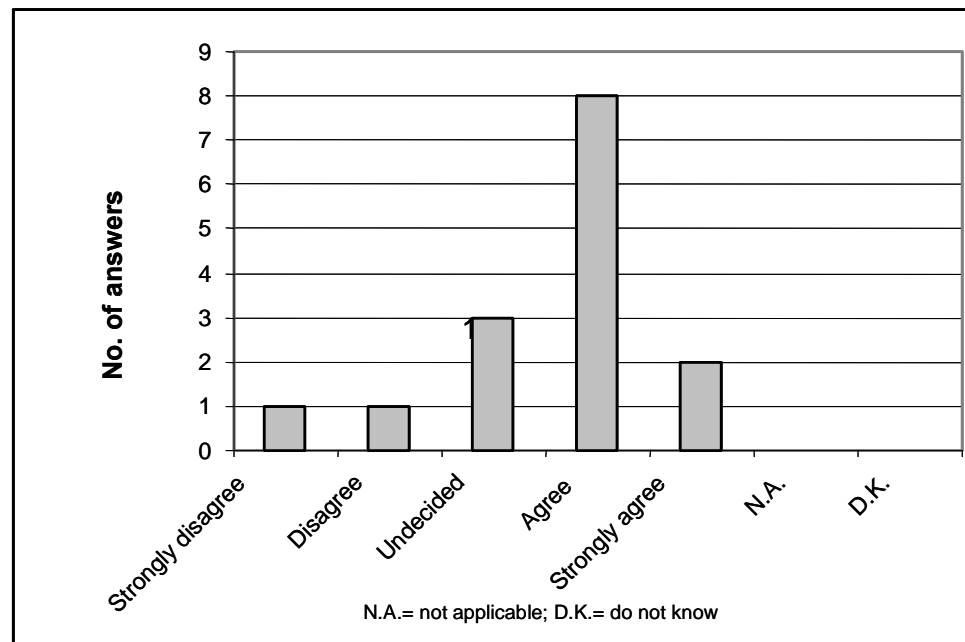


- Asks KI level of agreement with a statement
- Remember may be **sensitive**
- Uses Likert scale

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.

Example method 3

- ❑ To what extent to you agree with the following statement: "the members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"?



Rating indicators method 4

- ❑ Open questions → mainly for narrative report
- ❑ Brings additional information useful for recommendations

Score each function to define level "vulnerability to corruption" (Annex 5)



- ❑ For each indicator (method 1 & 2)
 - Transcribe rate for each KI on score sheet
 - Calculate average rating (possible range between 0 and 1)

- ❑ For each function
 - Calculate score → "*vulnerability to corruption*"
 - 10-point scoring system

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

Example of scoring registration function

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	Total	Average per question**
<i>Profession*</i>	G	G	G	G	N	P						
Indicator I.1	1	1	1	1	1	1					10.00	1.00
Indicator I.2	1	1	0.88	1	1	1					9.38	0.94
Indicator I.3	1	1	1	1	1	1					9.57	0.96
Indicator I.4	0.83	0.50	0.50	0.50	1	0.67					5.57	0.56
Indicator I.5	1	1	1	1	1	1					9.88	0.99
Indicator I.6	1	1	1	1	1	D.K	D.K	1	D.K	1	7.00	1.00
Indicator I.7	1	1	1	1	1	1	1	1	1	1	10.00	1.00
Indicator I.8	0.63	0.63	0.63	0.38	0.63	0.60	0.50	0.63	0.85	0.5	5.95	0.60
Indicator I.9	0.75	0.75	0.75	0.63	0.63	0.60	0.71	0.57	0.5	0.50	6.22	0.62
Indicator I.10	0	0	0	0	0	0	0	0	0	0	0.00	0.00
Indicator I.11												
Indicator I.12	0.86	0.57	0.57	0.57	0.57	0.57	0.57	0.57	0.57	0.57	3.71	0.37
Indicator I.13	1	1	1	1	1	1	1	1	1	1	10	1
Indicator I.14												
Indicator I.15												
Indicator I.16												
											Total	9.03
											***Final score registration	7.52

The Total for each line is given by the sum of KI's scores.

** The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded

Example of scoring registration function

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	Total	Average per question**
<i>Profession*</i>	G	G	G	G	N	P	P	P	P	P		
Indicator I.1	1	1	1	1	1	1	1	1	1	1	10.00	1.00
Indicator I.2	1	1	0.88	1	1	1	0.88	0.88	0.88	0.88	9.38	0.94
Indicator I.3	1	1	1	1	1	1	1	0.86	0.86	0.86	9.57	0.96
Indicator I.4	0.83	0.50	0.50	0.50	1	0.67	0.33	0.50	0.40	0.33	5.57	0.56
Indicator I.5	1	1	1	1	1	1	1	1	1	1	9.88	0.99
Indicator I.6	1	1	1	1	1	1	1	1	1	1	7.00	1.00
Indicator I.7	1	1	1	1	1	1	1	1	1	1	10.00	1.00
Indicator I.8	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	0.63	5.95	0.60
Indicator I.9	0.75	0.75	0.75	0.63	0.63	0.60	0.71	0.57	0.57	0.50	6.22	0.62
Indicator I.10	0	0	0	0	0	0	0	0	0	0	0.00	0.00
Indicator I.11												
Indicator I.12	0.86							0	0.29		3.71	0.37
Indicator I.13	1							1	1		10	1
Indicator I.14												
Indicator I.15	see text in narrative report											
Indicator I.16	see text in narrative report											
											Total	9.03
												7.52

Method 3 question. The KI is asked his/her level of (dis)agreement in respect to a given statement.

Method 4 questions: An open-ended question is asked to the KI.

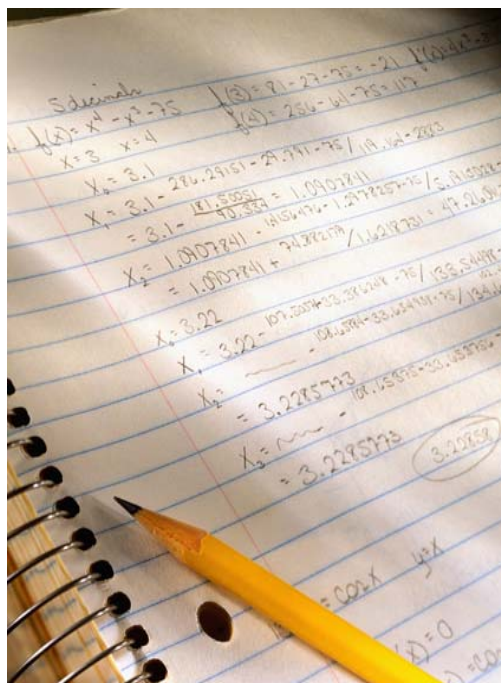
***Final score registration

Example of scoring registration function

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	Total	Average per question**
<i>Profession*</i>	G	G	G	G	N	P	P	P	P	P		
Indicator I.1	1	1	1	1	1	1	1	1	1	1	10.00	1.00
Indicator I.2	1	1	0.88	1	1	1	0.88	0.88	0.88	0.88	9.38	0.94
Indicator I.3	1	1	1	1	1	1	1	0.86	0.86	0.86	9.57	0.96
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Indicator I.5	1	1	1	1	1	1	1	0.875	1	1	9.88	0.99
Indicator I.6	1	1	1	1	1	D.K	D.K	1	D.K	1	7.00	1.00
Indicator I.7	1	1	1	1	1	1	1	1	1	1	10.00	1.00
Indicator I.8	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	5.95	0.60
Indicator I.9	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	6.22	0.62
Indicator I.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Indicator I.11	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Indicator I.12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.71	0.37
Indicator I.13	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10	1
Indicator I.14	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Indicator I.15	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Indicator I.16	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total												9.03
***Final score registration												7.52

***** The final score is given by summing up all the averages for each question (orange boxes) and dividing the result by the number of method 1&2 indicators (12 in this example). This number is then multiplied by 10 to be represented in a 0-10 scale.**

Analysing results and report writing



❑ **Annex 4: Annotated content list for final report**

❑ **Analytical framework**

➤ **Quantitative (scoring of vulnerability to corruption)**

➤ **Qualitative**

- Summarise relevant information from notes taken during interviews
- Compare answers with evidence found
- Compare method 1&2 with method 3 (perception of KIs → see table 1)

❑ **Recommendations for actions**

➤ **Flow naturally from questions scoring low**

➤ **Analysis of answers to open ended questions**

Selecting key informants: influences directly the quality of the findings

- ❑ Knowledgeable and interest in pharmaceutical sector
- ❑ Multi-perspective
 - Mix of senior, middle managerial and junior level personnel
 - Different institutions and organizations: MOH, MRA, procurement office, committee members, industry, associations, academia, CSOs, etc. (see box 2, page 12)
- ❑ Minimum of 10-15 interviews per function → saturation (no new information is coming from interviews)
- ❑ KIs can be interviewed for several functions (but counted only once in total number of KIs)

For more information ...

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