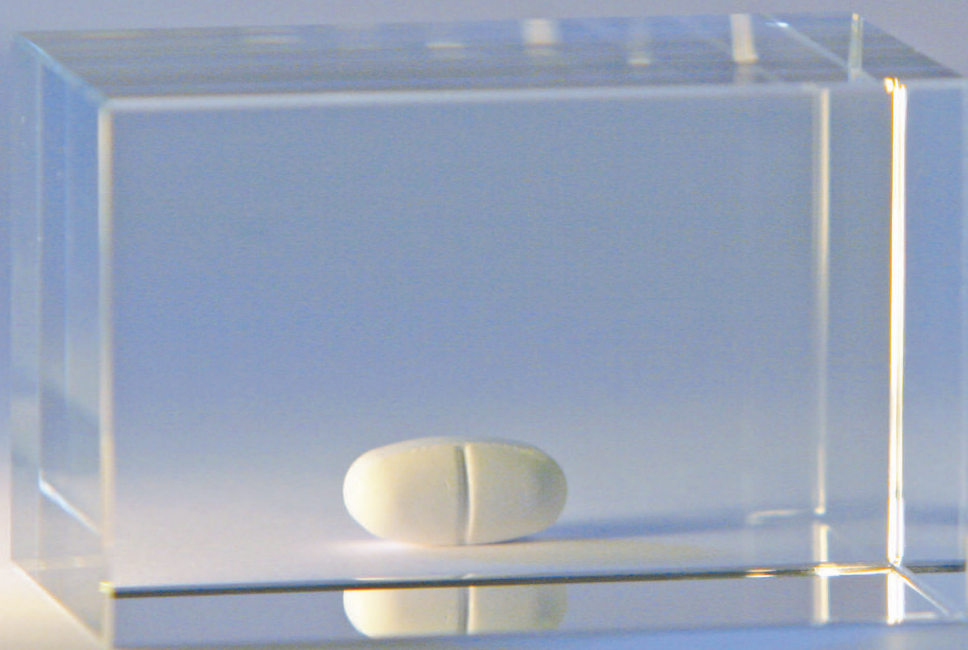


# Good Governance for Medicines

## Model Framework

Updated version 2014



World Health  
Organization



# **Good Governance for Medicines: Model Framework**

Updated version 2014



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Organization**

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## Acronyms

BERI	Business Environmental Risk Intelligence
COI	Conflict of interest
CPI	Corruption Perceptions Index
CSO	Civil society organizations
EU	European Union
GDP	Gross Domestic Product
GGM	Good Governance for Medicines programme
ICRG	International Country Risk Guide
MOH	Ministry of Health
MDGs	Millennium Development Goals
OAS	Organization of American States
OECD	Organisation for Economic Co-operation and Development
PACI	Partnering Against Corruption Initiative
UNCAC	United Nations Convention Against Corruption
WHO	World Health Organization

## CHAPTER 1

# Introduction to the Good Governance for Medicines programme

### The problem of corruption

Corruption has long plagued organized societies. From ancient China to modern-day Europe and North America, governments and societies have struggled to contain this cancer. Thousands of years of literature document the presence of corruption (1). It is found in rich and poor, developing and developed countries alike, albeit in different forms and magnitude. The corruption that prevails is a clear indicator of the profound moral crisis that many societies are experiencing. The

**"It is the bane of society... an incurable cancer... a social evil that impedes economic growth, induces inequality, deepens poverty and results in the exploitation of the poor."**

Druk Phuensum Tshogpa Manifesto 2008–2013 (3)

**"Corruption is the abuse of entrusted power for private gain."**

Definition of corruption endorsed by Transparency International (2)

social injustices and the poverty that more than half of humanity endures, together with the deterioration of public trust generated and perpetuated by corruption, have greatly diminished the capacity of society's time-honoured institutions to govern human affairs for the common good.

In essence, corruption is an act by individuals who unlawfully and wrongly use their official position to benefit themselves or someone related or close to them at the cost of others (4).

Corruption fosters an anti-democratic environment characterized by uncertainty, unpredictability, declining moral values

and disrespect for constitutional institutions and authority. It reflects a democracy, human rights and governance deficit that negatively impacts on poverty and human security. High levels of corruption can lower the level of human development by reducing economic growth, increasing poverty and inequality, raising the costs and reducing the quality of services such as health and education (5,6).

Corruption has been a matter of increasing concern for the international development agenda and is recognized as one of the biggest impediments to the world's efforts to reach the Millennium Development Goals (MDGs) (7).

**"Corruption can kill – for example, when corrupt officials allow medicines to be tampered with, or when they accept bribes that enable terrorist acts to take place... it is a major obstacle to achieving our Millennium Development Goals."**

Ban Ki-moon, United Nations Secretary-General, at the launch of the Stolen Asset Recovery Initiative, 2007

### Poor governance and corruption

Empirical research over the past decade has shown convincingly that poor governance, typically manifested by different forms of corruption, is a major deterrent to investment and economic growth and has had a disproportionate impact on the poor. In-depth case studies have given form and life to these quantitative findings and have brought home the reality that corruption is indeed harmful to the individual, family, community, and society as a whole. Globally, public awareness of the detrimental impact and severity of the problem has increased markedly, as the media, policy institutes, and nongovernmental organizations worldwide have raised concerns to unprecedented levels.

By the late 1990s, the World Bank Institute had developed a comprehensive data set covering broader governance concerns. This data set covers six dimensions of governance: control of corruption; rule of law; government effectiveness; regulatory quality, voice and accountability; political stability; and the absence of violence. They provide a picture of the overall state of governance in a country, and are derived from “several hundred individual variables measuring perceptions of governance, drawn from 37 separate data sources constructed by 31 different organizations” (8). Through aggregation of the numerous individual variables, the six indicators tend to have significantly smaller margins of error than any individual measure.

Macro-level econometric-based studies have established a strong causal link between corruption and, more broadly, poor governance on the one hand and weak private investment and growth on the other. A number of comparative country studies have also been conducted on combating corruption. While not all are statistically based, they nonetheless provide empirical analyses of reforms and strategies (9–16). As Mauro (1995) estimates, a one standard deviation increase (improvement) in the corruption index is associated with an increase in the investment rate by 2.9% of Gross Domestic Product (GDP) (17). Empirical studies by institutions like the World Bank, the International Monetary Fund and the Asian Development Bank reveal that corruption reduces economic growth in a country by 0.5-1% a year (18–20).

### Types and causes of corruption

The types and causes of corruption are diverse – socially, culturally, economically and politically. Scholarly research into the causes and consequences of corruption goes back several decades (21). Although there are many types of corruption, they can be grouped into two broad areas, often referred to as “petty” and “grand”.

*Petty corruption* is small-scale corruption practised by lower-level public servants who extort bribes for their services and who often perceive and justify their corrupt behaviour as a survival mechanism to compensate for low salaries. Petty corruption can have a profound debilitating effect on the integrity of a nation and its existence often indicates the practice of grand corruption by high-level public servants.

*Grand corruption* is large scale and often involves significant, international bribes and hidden overseas accounts. It is frequently fostered by exporters from countries (particularly industrialized countries) who may (knowingly or unknowingly) offer tax breaks for the bribes paid and refuse to regard the trans-border corruption of public officials as criminal behaviour. This type of corruption seems to be motivated more by greed than by need. Each broad area incites the other.

Within these two general levels, a variety of types of corruption can fall in either petty or grand corruption or both. These types of corruption have different causes and risk areas as was established from the findings of the Corruption Perception Survey 2007, the Corruption Perception Index<sup>1</sup> and strengthened by the enquiry/survey conducted by the Centre for Bhutan Studies, 2009 (22). Some of the most common of these are shown in the table below.

### Corruption in health

Much of the corruption found in the health sector is a reflection of general problems of governance and public sector accountability (23,24). Corruption reduces the resources effectively available for health, lowers the quality, equity and effectiveness of health-care services, and decreases the volume and increases the cost of provided services. A study carried out by the International Monetary Fund

<sup>1</sup> Transparency International has published the Corruption Perceptions Index (CPI) annually since 1995, providing ample data for those researching corruption. The 2004 update is distinguished by expansion of the index to 146 countries from 133 the previous year. The index is a composite measure of 17 data sources, each comparing overall corruption levels among countries, from 13 organizations.

TABLE 1. Types of corruption

TYPE OF CORRUPTION	CAUSES	RISK AREAS	ORGANIZATIONS AT RISK
Abuse of power	Weak recruitment system for leaders, accountability, mechanisms for detection and punishment, oversight, as well as discretionary powers, general failure in the implementation of the Code of Conduct and Ethics, weak media and a tolerant culture.	All levels	All institutions
Bribery/kickbacks	Uncontrolled discriminatory power, non-uniform application of laws, rules and norms, unclear and lengthy procedures, lack of information and transparency, failure to implement Code of Conduct and Ethics, inefficient service delivery, social demands and obligations, systemic flaws.	Contract administration Services delivery organizations Recruitment, promotions, transfer and training Adjudication of cases Elections	Central agencies Autonomous agencies Projects Judiciary Legislation
Fraud	Unlimited desires, lengthy procedures, unclear rules, weak supervision, and lack of checks and balances; general administration weakness and poor moral values.	Academic transcripts, bank guarantees Bills and other government clearances	Government departments Banks School admissions Construction and mining industries.
Collusion between public and private procurement	Non-application of the rule of rotation, lack of transparency and accountability, discretionary powers, weak oversight body, failure to implement Code of Conduct and Ethics, inefficient service delivery, poor moral values and social ties.	Government procurement system Foreign investments Processing of mining leases and rights Hiring of machinery and vehicles	Procurement section Licensing divisions Trade division Natural resources regulatory agencies

using data from 71 countries, shows that countries with high indices of corruption systematically have higher rates of infant mortality (25).

Corruption also affects the availability of funds from health budgets to pay salaries, fund operations and maintenance, leading to lower quality of care and reduced service availability (26). A study carried out in 2005 in one European country revealed that up to 9.5% of national expenditures on health care are estimated to be lost due to corruption. Not only does corruption affect health service delivery but it also has a detrimental impact on population health as shown by increased infant and child mortality indicators, even after adjusting for income, female education, health spending, and level of urbanization (27).

Globally, the World Bank (2004) estimates that more than US\$ 1 trillion is paid in bribes each year. The Asian Development Bank found that corruption adds 20–100% to the cost of procuring government goods and services in several Asian countries. There is evidence that reducing corruption can improve health outcomes by increasing the effectiveness of public expenditures (28). Research also reveals that the countries that tackle corruption and improve their rule of law can increase their national incomes by as much as four times in the long run and child mortality can fall by as much as 75% (22).

## Corruption in the pharmaceutical sector

Medicines represent one of the largest components of health expenditure. The value of the global pharmaceutical market has increased steeply over time, at a faster rate than the total health expenditure and even more than the growth of GDP worldwide (29). In 2009, the total value of the pharmaceutical market was estimated at US\$ 837 billion (30). Such large amounts of money are an attractive target for abuse, corruption and unethical practices, and the pharmaceutical sector is particularly vulnerable to such practices. Resources that could otherwise be used to buy medicines or recruit much-needed health professionals are wasted as a result of corruption, which can result in prolonged illness and even deaths.

In developing countries, pharmaceutical expenditures and drug procurements account for 20–50% of public health budgets (23,24). Making essential medicines available for everyone at affordable prices is a key condition for improving national health indicators. Inadequate provision of medicine and medical supplies has a direct bearing on the performance of the health system. Corruption in procurement/distribution of pharmaceutical and medical supplies reduces access to essential medicines, particularly for the most vulnerable groups. WHO estimates (2004) indicate that approximately 2 billion people lack regular access to medicines and that improving access to medicines could potentially save the lives of 10 million people every year (31).

Corrupt and unethical practices in the pharmaceutical sector can have a significant impact on:

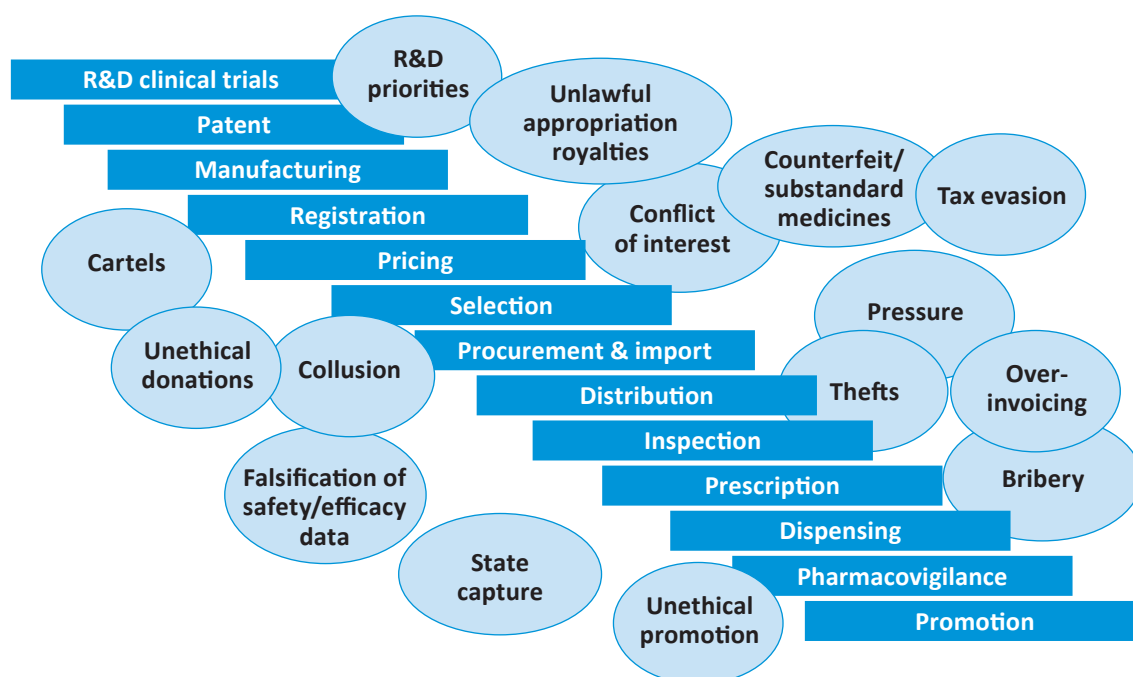
- *Health*: as the waste of public resources reduces the government's capacity to provide quality-assured essential medicines, and unsafe medical products proliferate on the market; it also leads to an increase in the irrational use of medicines;
- *Economy*: when large amounts of public funds are wasted: it is estimated that pharmaceutical expenditure in low-income countries amounts to 25–65% of total health-care expenditures. These significant amounts of money provide potential room for major financial loss;
- *Image and trust*: as inefficiency and lack of transparency reduce public institutions' credibility, erode the trust of the public and donors, and lower investments in countries.

The pharmaceutical sector is wide and complex. Also referred to as the “medicines chain”, it includes many different steps, beginning with the research and development of new medicines or chemical entities and ending with the consumption of medicines by the patient and pharmacovigilance. As shown in the figure below, each step is vulnerable to corruption and unethical practices. The pharmaceutical sector involves professionals from fields such as law enforcement authorities, regulators, physicians, nurses, pharmacists, economists, lawyers and researchers. These can serve in governments, private pharmaceutical companies, health-care facilities, academia or civil society organizations.

Poorly defined and documented processes, lack of checks and balances, unclear roles and responsibilities, as well as lack of transparency and accountability in any part of the medicines chain will increase vulnerability to corruption (32). For example: Transparency International estimates that 10–25% of all public procurement spending is fraudulent. Equally, if institutional checks are too cumbersome and slow down processes, clients may be tempted to offer bribes or gifts “to get things done”. There are numerous unethical practices that increase the vulnerability of the pharmaceutical sector to corruption and thus the risks to the health of the population. Among these are:

- **Information imbalance** between various players such as manufacturers, regulators, health-care providers and consumers. Information is not shared equally and not all players have the necessary information to make informed judgments and independent assessments of the quality, safety and efficacy of medicines.
- **Counterfeit and unregulated medicines** that are of sub-therapeutic value can contribute to the development of drug resistant organisms, increase the threat of pandemic disease spread,

FIGURE 1. Examples of unethical practices that can happen throughout the medicines chain



Source: Baghdadi-Sabeti, G. and Serhan, F. (30).

and severely damage patient health, as they might have the wrong ingredients or include no active ingredients at all and undermine public trust in important medicines (32,33).

- **Unethical drug promotion and conflict of interest** among physicians can have negative effects on health outcomes. Promotional activities and other interactions between pharmaceutical companies and physicians, if not tightly regulated, can influence physicians to engage in unethical practices (34). Studies have shown that these interactions can lead to non-rational prescribing (35) and increased costs with little or no additional health benefits. Patients' health can be endangered as some doctors enrol patients in trials even though they do not meet the trial inclusion criteria, or prescribe unnecessary or potentially harmful treatments, in order to maximize profit (36). Conflicts of interest are also a motivating force generating unethical behaviour in many other steps of the medicines' chain. A government official or expert serving on a government committee may put undue pressure or influence on the final decision to favour a particular company, instead of basing the decision on scientific evidence.
- **Bribery and gift giving** can be proactively offered or extorted by public servants. For example, suppliers can offer government officials a bribe to register medicines without the required information or to leave out findings on medicines quality in inspection reports, thus falsifying evidence. Or government officials may slow down registration procedures in order to put pressure on suppliers into paying a bribe. Other forms of corruption or unethical practices include theft in the distribution chain for personal use or diversion for private sector resale, or collusion in bid rigging during procurement by providing vendors with confidential and privileged information.

Development agencies increasingly recognize corruption as the single greatest obstacle to social and economic development, creating a vicious cycle: bad governance produces corruption and cor-



ruption destroys the basis of good governance. Corruption in the public pharmaceutical sector is endangering the health of millions of people worldwide. There is no easy and quick solution, with entrenched unethical practices throughout the interrelated stages of the medicines' chain.

### Background of anti-corruption initiatives

Since the mid-1990s, corruption and governance have become legitimate subjects of international interest and concern. Empirical research has raised public awareness worldwide of the detrimental impact of corruption on socioeconomic development and its threat to human development (1). Much of the effort put into public sector reforms during the past 15 years has been aimed in part at reducing corruption. Cross country, perception-based assessments and public opinion research show that corruption and governance are among the top concerns of people and leaders around the world, and it is now part of all national and international development dialogues and agendas (37–40).<sup>1</sup>

Many national, regional, multinational and international organizations have worked very hard and for many years individually or together on valuable initiatives to establish frameworks, policies, instruments and other necessary standards to eradicate corruption. These initiatives, which form the basis for much of the anti-corruption work that is being done today, are supported by a number of international and multinational agreements and conventions including:

- The Inter-American Convention Against Corruption approved by 34 members of the Organization of American States (OAS) in 1996;
- The Organisation for Economic Co-operation and Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions signed by the 29 members of the OECD, along with five non-members in 1999;
- The African Union Convention adopted an Anti-Corruption covenant signed in March 2003;
- The World Economic Forum Partnering Against Corruption Initiative (PACI) formally launched by Chief Executive Officers from the Engineering and Construction, Energy and Metals and Mining Industries in January 2004; and
- The United Nations Convention against Corruption (UNCAC) adopted by the United Nations General Assembly Resolution 58/4 of 31 October 2003, published in September 2004.

These anti-corruption conventions and agreements are based on international consensus regarding the laws and mechanisms that must be established and implemented at national and international levels to combat corruption. The OECD and OAS Conventions are regional in scope, while UNCAC is global in reach. The OAS Convention is the first international agreement to address corruption on all scales, and as such is more ambitious and broader in scope than the OECD Convention, which focuses primarily on legal measures to address the corrupt business practice of bribing foreign public officials. The OAS Convention directs signatory States to develop and strengthen legal mechanisms to “prevent, detect, punish and eradicate” official corruption. It differs from the OECD and

“The adoption of the United Nations Convention against Corruption will send a clear message that the international community is determined to prevent and control corruption. It will warn the corrupt that betrayal of the public trust will no longer be tolerated. And it will reaffirm the importance of core values such as honesty, respect for the rule of law, accountability and transparency in promoting development and making the world a better place for all.”

Kofi Annan, former UN Secretary General. UNCAC foreword, September 2004 (41)

<sup>1</sup> The International Country Risk Guide (ICRG), whose data have been used extensively in quantitative research, began its surveys in 1980. The Business Environmental Risk Intelligence (BERI) began to provide governance-related, survey-based indexes in the early 1980s. The Economist Intelligence Unit began providing related data around this time as well. For more recent additional sources, see Political Risk Consulting (<http://www.asiarisk.com>) and the World Economic Forum (<http://www.weforum.com>).

the United Nations anti-corruption conventions because it is “not grounded principally on trade or economic concerns, but on morality and the need to protect democratic institutions”.

The process of enforcing UNCAC began in December 2005. Over 140 signatory States participated in the UNCAC conferences held in Indonesia in January 2008 and in Qatar in November 2009. One of the key issues addressed was the need to establish adequate mechanisms to monitor the enforcement of the Convention, a need shared by the OAS and OECD, although valuable experience has been gained and is being shared between regions. Systematic monitoring and reporting by civil society organizations (CSOs) and by the press are essential to promote awareness of corruption issues and to mobilize the public support and political will necessary for the successful enforcement of these conventions. Governments must demonstrate to the public the measures and mechanisms that are being applied to enforce the conventions, to prevent corruption, and to ensure legal cooperation among states.

It is within the context of this movement and its spirit of reform that the Good Governance for Medicines (GGM) programme draws great support for its activities in promoting good governance in the pharmaceutical sector, and builds upon the legal framework and mechanisms of enforcement established by the anti-corruption conventions ratified by the signatory States.

### **Overview and progress of the Good Governance for Medicines programme worldwide**

In an attempt to curb corruption in the pharmaceutical systems, the World Health Organization (WHO) established the Good Governance for Medicines programme (42). The GGM programme focuses on the fundamental need to have in place laws, regulations, policies and procedures based on ethical principles to improve the management of pharmaceutical systems and create a corrupt-free environment to promote access to quality-assured medicines. Its primary emphasis is on prevention of corruption and on improving systems.

Good governance is an essential factor for sustainable development and economic growth at all levels and within all sectors of society. There are many definitions of governance and good governance. Yet, there is an emerging general consensus that governance is about managing the resources and affairs of society to promote the well-being of its members.

In the WHO GGM programme, good governance refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, especially in medicine regulatory and supply systems, in a manner that is transparent and accountable, and follows the rule of law and minimizes corruption.

#### ***General objective***

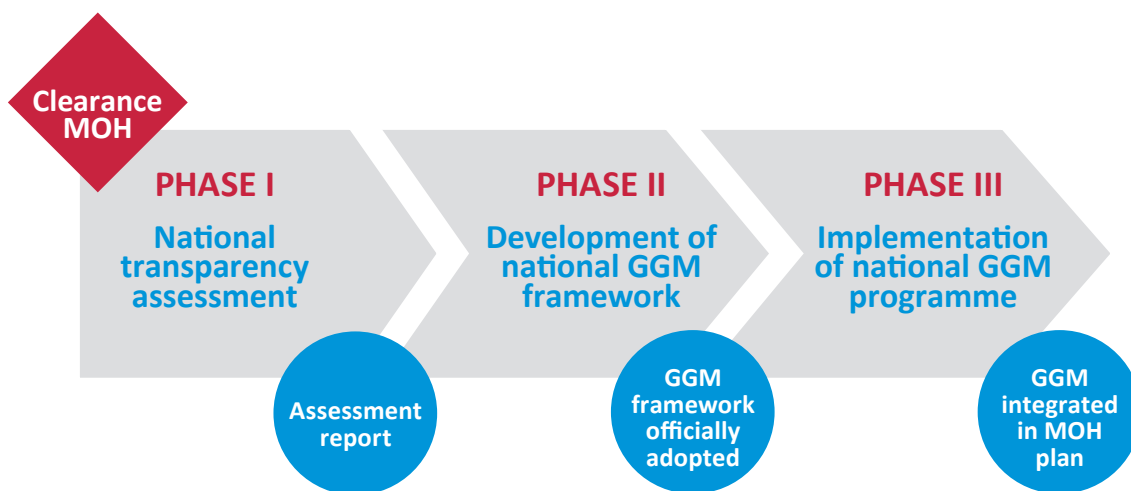
The general objective of the GGM is to contribute to health systems strengthening and prevent corruption by promoting good governance in the pharmaceutical sector.

#### ***Specific objectives***

- i) To raise awareness of the impact of corruption in the pharmaceutical sector and use this awareness to inform the national health policy agenda;
- ii) To increase transparency and accountability in medicine regulatory and supply management systems;
- iii) To promote individual and institutional integrity in the pharmaceutical sector; and
- iv) To institutionalize good governance in pharmaceutical systems by building national capacity and leadership.

The GGM programme is implemented in a 3-step strategy to institutionalize good governance in ministries of health, as shown in Figure 2 below:

FIGURE 2. WHO model process to implement the Good Governance for Medicines programme



Following the launch of the GGM programme in 2004 as a pilot project in four countries, the programme has been very successful and currently comprises 36 countries. A detailed description of the GGM process is provided below.

### Phase I

For Phase I, a standardized assessment instrument entitled *Measuring Transparency in the Public Pharmaceutical sector* provides the methodology to measure the level of transparency and vulnerability to corruption in key functions of the pharmaceutical system (43). Independent national assessors evaluate the country's vulnerability to corruption using the WHO standardized assessment instrument, which focuses on key functions of the pharmaceutical sector. On completion of the assessment, a report with the findings and recommendations for action is produced, providing a baseline to monitor the country's progress over time. The assessment has been conducted in 26 countries and to date WHO has published the results for 14 countries (44). The country studies as well as transparency monitoring carried out in 15 countries in 2010 have produced valuable data enabling ministries of health and medicines regulatory authorities to identify gaps in the system and develop strategies to close them (30). For a comparative analysis of transparency assessment reports, please consult the GGM chapter of the 2011 World Medicines Situation (31) or the individual country assessment reports available on the GGM website (44).

### Phases II

For Phase II, this model framework serves as a guideline for countries to develop their own national GGM framework, after analysis of the results for the Phase I assessment, based on a nationwide consultation with key stakeholders and contextualization to national situations. It integrates the top-down and bottom-up approaches necessary to promote good governance and to reduce corrupt practices. This document, once adapted to the national context, should be officially adopted to guarantee institutionalization within the legal, ethical and political structure of the ministry of health (MOH). To date 11 countries have developed their national frameworks: 8 have been officially adopted (Benin, Bolivia (Plurinational State of), Jordan, Lao People's Democratic Republic, Lebanon, Malaysia, Thailand and The Former Yugoslav Republic of Macedonia) and 5 have been drafted (Malawi, Mongolia, Philippines, Republic of Moldova, and Syrian Arab Republic).

### ***Phase III***

This Phase involves implementation of the national programme and focuses on translating the guidelines of the Model Framework for GGM into action, institutionalizing the programme and ensuring that it is fully integrated within the MOH of each country. To date, seven countries are in phase III of the implementation of GGM (30).

Worldwide, the programme is being increasingly adopted based on an apparent great need in the subject area. Its preventive and constructive approach is appealing as well as its focus on processes and systems. The progress of each country from one phase to the next depends on “champions” that are dedicated to the success of the programme and that have strong ethical leadership and governance, an active and dedicated GGM team, high political will and support, GGM integrated in other structures, collaboration with key stakeholders and anti-corruption movements. Challenges experienced are a passive attitude towards corruption, resistance to change, political instability, bureaucracy, high rotation of staff, and other priorities.

GGM is also contributing to WHO’s current health systems strengthening by promoting transparency and leadership, thus preventing corruption in the medicines sector and maximizing the use of limited resources. GGM is the first global initiative in this field. Countries’ interest in implementing GGM is much higher than anticipated (36 countries currently applying the programme). The GGM programme focuses on strengthening knowledge, values, attitudes and ethical behaviours that help each individual raise his/her level of consciousness in order to prevent corruption. It also helps create legal and social mechanisms that enhance these ethical behaviours. The increase in the level of consciousness and ethical leadership will help promote higher standards of transparency in areas such as governance, medicines and technology, information management and recruitment of human resources. This, in turn, will have an impact on financing and service delivery.

GGM has developed a technical package of tools, guidelines and training materials that provide universal and internationally recognized standards for governments to adapt and use depending on their local context. The GGM promotes transparency and leadership in the key medicine areas of development of national medicines policy, access, quality assurance and rational use of medicines.

This document was prepared for the use of health professionals, decision-makers, managers, policy-makers and MOH personnel involved in GGM in their countries. It can be used as a guide or model for their country GGM frameworks and programmes. The successful examples included in this document are from countries in phases II and III of the programme and are only a few of many to inspire and help the GGM teams worldwide in their anti-corruption efforts.

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## CHAPTER 2

# Basic components of the model framework

The model *framework for good governance for medicines* is intended to be a guideline and can be adapted by each country according to their needs. It includes the basic components required by the GGM programme and steps necessary to achieve these. The basic components of the GGM framework are divided in two strategies that are complementary:

- **Values-based strategy:** this strategy attempts to increase institutional integrity by promoting key ethical principles and moral values as a way of motivating key actors to behave ethically. It is a bottom-up approach within institutions, based on consensus-building of shared ethical principles. Participation of key actors in the process of consensus-building generates a sense of ownership and personal identification.
- **Discipline-based strategy:** this is essentially a top-down legislative process that establishes anti-corruption laws, policies and administrative procedures, and attempts to impose compliance with them through legal sanctions.

Experience with these two strategies has shown that a complementary use of both is required in order to have a significant impact on establishing ethical practices within institutions and governments. There are 10 basic components of the model framework, each of which belongs to one of the strategies listed below.

### ***Values-based strategy***

1. Key ethical principles
2. Code of conduct
3. Socialization of key ethical principles
4. Promoting ethical leadership

### ***Discipline-based strategy***

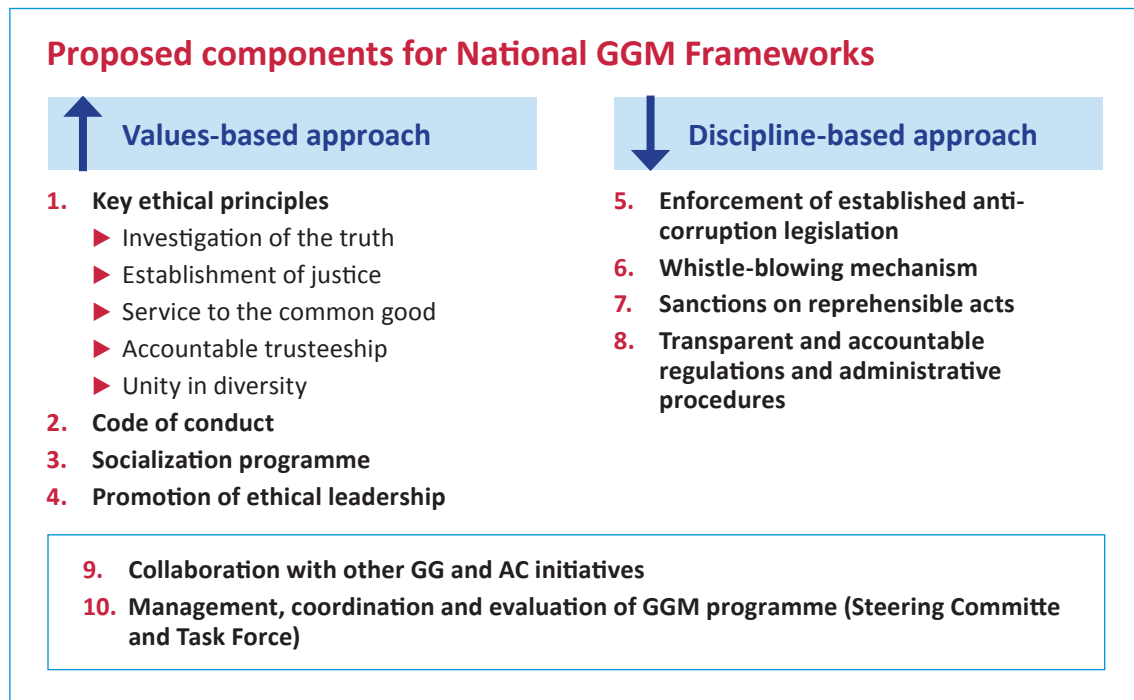
5. Enforcement of existing anti-corruption legislation
6. Mechanisms for whistleblowing
7. Sanctions on reprehensible acts based on anti-corruption legislation
8. Transparent and accountable regulations and administrative procedures

There are also two cross cutting components that need to be integrated within both strategies:

9. Collaboration among anti-corruption agencies, civil society organizations and the private sector
10. Management, coordination and evaluation.

These 10 components are further explained below.

FIGURE 3. Complementary GGM strategies



## Values-based strategy

### 1. Key ethical principles

Cultural diversity tends to generate different nuances of understanding about the meaning of ethical principles and moral values. Nonetheless, there are relatively high degrees of consensus on their relevance and importance in addressing the issue of corruption. This consensus is the basis of the key ethical principles of the GGM programme. Each key ethical principle has a set of moral values that are seen more clearly when practising the capabilities of *ethical leadership*. Five key ethical principles were selected through consultation and consensus as those that would help address the prevailing weaknesses that create vulnerability to corruption, i.e.:

- **Investigation of the truth:** Independent investigation of the truth, based on facts and evidence, requires detachment from all previously acquired knowledge, concepts, ideas or prejudices. Individuals must be able to strive to see with their own eyes and to know from their own knowledge, analysing and evaluating information that is presented. Then, whether the new information, concepts, or principles are accepted, partially accepted, with reserved judgment or rejected, they will be able to give a coherent explanation supporting their action. This is the basis for trust, integrity and honour – for both the individual and society. Additionally, it requires consistence between words and actions.
- **Establishment of justice:** Justice relates to the exercise of impartial judgment in determining the truth of facts and principles in collective decision-making. Fairness refers to justice and personal moral responsibility for the individual. It requires the application of the two pillars of reward and punishment.
- **Service to the common good:** Any person in power should fulfil the ethical imperative to use his/her official position to serve the public good. True service is characterized by wisdom and does not create dependency, but rather frees people from it. It does not seek to bind, but to



emancipate. It respects the dignity of each person, and its purpose is to empower those who are served. Therefore, it is not concerned solely with satisfying the immediate needs of the members of the organization or community, but rather with assisting each member to develop the capabilities needed in order to contribute to personal material, intellectual and spiritual well-being and that of the family, the organization, and the community. Selfless leadership implies detachment from the expectation of recognition from others as a reward for services offered and resisting the temptation of magnifying the contributions given. Invisible leadership implies giving ample credit to those who share in the work, or the group as a whole.

- **Accountable trusteeship:** An institution cannot be effective without an adequate degree of public trust, which is only granted to people and organizations that demonstrate trustworthiness through transparency and responsible management of what is entrusted to them. Public servants are trustees of public resources and are accountable to the society they serve.
- **Unity in diversity:** Though actors and stakeholders might be diverse in their backgrounds, cultures and languages, they need to be united in a shared belief and vision that corruption is detrimental not only for the individual or for a specific programme but for the society as a whole. Key actors need to act together to eradicate corruption and use their differences to enrich the anti-corruption work they are engaged in. Unity in diversity requires a fundamental capability, which is consultation.

Each of these key ethical principles has a set of values and capabilities that requires ample training in their proper use. It also requires reflection and change in terms of the mental models or mind frames that might hinder or enhance their implementation. The GGM programme is elaborating a training manual that includes various areas that could be used for this purpose.

## **2. Code of conduct**

Some governments have established codes of conduct based on moral values and ethical principles as a measure to prevent unethical behaviour by public servants in the performance of their duties. Studies by Transparency International indicate that governments that have established a framework for good governance based on a code of conduct, ethical principles and other key components of an integrity system are listed among the 10 countries with very low levels of corruption. There is a logical and consistent link between values, principles and a code of conduct. The code of conduct attempts to articulate in concrete terms the application of ethical principles.

## **3. Socialization of key ethical principles**

In the context of this document the term “socialization” refers to the process by which moral values, ethical principles and a code of conduct can be learnt, internalized, applied and promoted by a group of key actors until they become fully integrated into the institutional culture. This requires constant communication strategies and training. For more detail on this, see GGM training materials.

## **4. Promoting ethical leadership**

In the current anti-corruption discourse, increasing mention is made of the importance of leadership and good governance in promoting reform. It has been aptly stated that the current global leadership crisis is not due to a lack of people wanting to lead, but rather to the lack of people willing to exercise ethical leadership. It must be emphasized that ethical leadership is not limited to individuals in positions of authority within an organization, but rather a concept based on the notion of shared leadership that encourages and enables every individual of an organization and community to exercise this leadership within their sphere of responsibility and influence at whatever level that may be.



## Discipline-based strategy

### 5. Enforcement of existing anti-corruption legislation

The GGM programme draws on existing anti-corruption legislation in each country to support the integrity system and implementation of administrative and technical measures. Thanks to the activities of the anti-corruption movement and international anti-corruption conventions, there is an emerging spirit in many countries of reform and a growing receptivity to address the problem of corruption (Box 1). The objectives of the GGM programme aim to promote the enforcement of existing legislation, to protect whistleblowers and to sanction those who commit corrupt acts.

An important example is to have an established form that covers different types of conflict of interest (COI) and to enforce a legal requirement on declaration of interests including sanctions in case of non-declaration or falsified or incomplete declaration as explained in Annex 1. An example of a COI Form can be seen in Annex 2.

#### **BOX 1. LEGAL INCORPORATION OF THE CODE OF CONDUCT AND DECLARATION OF CONFLICT OF INTERESTS IN MONGOLIA**

The Declaration of Conflict of Interests form for external experts of drug registration in the Health Department is being implemented since 2009. The amendment to the Drug Law was approved by Parliament in 2010 and incorporated the Conflict of Interest declaration forms for members of the Drug Committees. The Code of Conduct for Inspectors was approved by the General Agency for Specialized Inspections director order N370, 2006. The Code of Conduct for pharmacists was adopted during the first Assembly of the Mongolian pharmacists in 2006. Registration for a special permission to conduct professional activities in the medical field and the licensing to import medical equipment and pharmaceuticals can be completed by using the Licemed website since 2008. The Government has approved the law for tenders, and all hospitals and other institutions procuring medicines must follow the specific tender documents.

### 6. Mechanisms for whistleblowing

A *whistleblower* is someone who sheds light on something that is hidden. This “hidden” thing is usually a corrupt, fraudulent or illegal act. It has different meanings in different contexts. For GGM, the concept of whistleblowing is to bring forth that hidden act without being punished or reprimanded. A dialogue usually follows once a complaint is filed against somebody within an institution to further investigate the allegation. Once the allegation is proven to have merit, the matter is handled through the courts or through the ombuds system. Most cases of responsible whistleblowing are courageous acts performed by public servants who place the public interest above personal self-interest and so assume the risks of retaliation in various forms. These risks require that a mechanism for whistleblowing be set up in order to protect the whistleblower from victimization and retaliation by those who perform corrupt practices. These mechanisms comprise:

- Internal disclosure within the organization, anonymously, confidentially or openly, by a peer employee.
- External disclosure through a complaint by someone outside the institution. This may be a supplier/contractor, the private sector, or other stakeholders such as CSOs or academia privy to the details of the corrupt act. The disclosure can be made openly, confidentially or anonymously. This mechanism requires adherence to a proper procedure in filing a complaint, failing which it may not be acted upon promptly by the proper officials.

- Public disclosure during which the disclosure is acted upon in a forum such as a public hearing. Usually the media covers such events and, in some cases, also affect the outcome or increase public interest in the complaint.

The challenge is to choose the mechanism that is right and comfortable for the whistleblower, while at the same time protect public servants from irresponsible and unethical whistleblowing that could damage their reputation and career due to false allegations. For this reason there should be rigorous prerequisite conditions for acceptable whistleblowing. For example, they should only be considered when they:

- deal with serious problems
- are supported by unequivocal evidence
- have exhausted internal channels
- are likely to obtain satisfactory results.

## **BOX 2. LEGISLATION REGARDING WHISTLEBLOWING IN MALAYSIA**

Under the Government Transformation Programme, various initiatives were put in place to ensure that the fight against corruption was effective. Strategies were formulated on three focused areas most prone to corruption, namely the regulatory and enforcement agencies, government procurement and “grand or political corruption”. Whistleblower legislation passed in 2010, and improved transparency in government contracts, were key components of this effort. The government is also working to pass legislation to require those suspected of corruption to be brought to trial within one year. Performance will be assessed using Transparency International’s Corruption Perception Index.

## **7. Sanctions on reprehensible acts**

The control of reprehensible acts requires the establishment of policies and procedures regarding the gradation of measures that will be applied in dealing with acts of corruption. The measures are usually grouped in two basic categories:

- a) Internal sanctions implemented by the institution;
- b) External legal sanctions implemented by the legal system and law enforcement.

## **BOX 3. SANCTIONS FOR CORRUPTION IN THE PHARMACEUTICAL FIELD: SYRIAN REPUBLIC**

In April 2010, the Government of Syria issued Presidential Decree 24 for the year 2010 on regulation of production and supply of medicines, replacing decree 40 of 1949 and law 67 of 2001. This new Decree, which now has the power of law, addresses several recommendations reported in the 2009 assessment of transparency and vulnerability to corruption in the Syrian pharmaceutical sector. The Decree also includes measures to control counterfeit pharmaceutical products and sanctions on violators. Sanctions include 5–10 years of hard labour, imprisonment and a minimum fine of 5 million Syrian liras (over US\$ 100 000). If medicinal products have led to death or permanent disability, punishment is increased to 20 years and a minimum fine of 10 million Syrian liras. The Decree provides the legal background for MOH inspectors to access pharmaceutical establishments and grants them judiciary authority in enforcing the related laws.

Decisions regarding the type of sanctions to be applied depend on the nature and gravity of the act of corruption. In general, serious acts of corruption should be dealt with using external measures implemented by the judicial system and law enforcement. Conventions related to the anti-corruption movement criminalize acts of corruption and propose legal sanctions for such acts. The existing legal and administrative sanctions in each country should be studied to make sure that they provide adequate deterrence, thus making corruption a “high-risk” and “low-profit” undertaking (i.e. increasing both the risk of being detected and the likelihood of appropriate punishment thereafter).

#### **8. Transparent and accountable regulations and administrative internal and external financial audits**

Governments have a responsibility to create sound institutional structures, processes, and policies to reinforce outcomes that promote public welfare. As part of this effort, anti-corruption measures that include transparent and accountable regulations/procedures, if implemented successfully, can improve access to medicines, saving public money and the credibility of governments or other organizations. Governments have two core responsibilities in the pharmaceutical system.

**First**, they are responsible for regulating the manufacture, distribution, sale, and use of pharmaceutical products, which includes regulating all actors involved in the pharmaceutical sector.

**Second**, where governments provide drug coverage, public purchasers are responsible for the selection, purchase, and logistical management of medicines for use through the public health-care system.

Both roles are of equal importance for good governance in the pharmaceutical system and to ensure access to essential medicines for the population. Specific regulations and procedures need to be created or enforced for each vulnerable area. Internal and external periodic auditing of the financial management of the pharmaceutical sector must also be implemented as a mechanism to diminish corruption.

#### **BOX 4. THE LEBANESE REGULATIONS ON INSPECTION AND DRUG CONTROL**

**Drug control:** Strengthening pharmaceutical inspection capabilities centrally and regionally include: contracting with 18 new pharmacist inspectors; training pharmacist inspectors locally and abroad; close cooperation with the Division of Research for smuggling at the Lebanese Customs and the Criminal Investigation Department in the Internal Security Forces; preventing the retail of smuggled pharmaceutical products or counterfeits; withdrawing these from the market; informing the relevant authorities (particularly WHO) and publishing related decisions. Also, pharmaceutical regulations include contributing to an awareness campaign on smuggled and counterfeit medicines; publishing the cost of medicines on the web site for pharmacists and citizens; and monitoring compliance with the official price. As an additional mark approved by its members, the insertion of Lebanese Pharmaceutical Importers Associations hologram was instituted to ensure an uninterrupted chain of responsibilities from the producer to the citizen.

**Disciplinary audit bureau (financial audit):** This administrative court manages the finances to ensure the safety of public funds and those deposited in the Treasury.

#### **9. Collaboration among anti-corruption and transparency initiatives: strengthening linkages**

The GGM programme cannot achieve its objectives without effective collaboration and coordination of efforts. It is important that the MOH is proactive – from the beginning and at every stage of the programme – in establishing alliances and strengthening linkages with other agencies that promote good governance and/or work on the problem of corruption at the local, national and international

levels (see Annex 3 for list of possible stakeholders). Clearly the public and private sectors and civil society must join forces to solve the problem of corruption, thus showing unity in diversity. WHO is a global public institution that has the mandate to serve its Member States and their MOH throughout the world. Thus, the GGM programme focuses primarily on the role of the MOH in taking measures within the public pharmaceutical sector to establish good governance and to prevent corruption.

Collaborative agreements should be established that clearly define roles and responsibilities for each partner, mechanisms of communication and coordination, and protocols for information and resource sharing. These agreements can assist in avoiding overlap and the duplication of efforts, and allow the GGM programme to benefit from advances made by other agencies. Entering into collaborative agreements will require political will and leadership from the MOH and other agencies.

**Political will:** Obviously, the GGM programme contributes to the objectives of the anti-corruption movement and at the same time draws valuable support and leverage from its agencies and activities and from the enforcement of its conventions. The minimum political support required for the success of the GGM programme consists of official approval of the MOH for the implementation of the programme in the pharmaceutical sector and of allocation of funds in the MOH annual operating budget for the sustained operation of the programme.

#### **BOX 5. POLITICAL WILL IN JORDAN**

The MOH and the Jordan Food and Drug Administration has demonstrated commitment and political will from the beginning of the GGM programme by involving not only the health sector but several other ministries, senior officials from public and private pharmaceutical organizations, representatives from consumer groups, local agencies concerned with good governance and others. It has also worked closely with other good-governance initiatives in the medicines sector, such as the Medicines Transparency Alliance programme, financing entities and other global stakeholders to increase good governance.

#### **10. Management, coordination and evaluation**

Management, coordination and evaluation of the GGM programme needs to be carried out from the beginning and during the whole process. It includes improving the management system, fund-raising and resource mobilization, as well as constant monitoring and evaluation.

- a) **Improving the management system:** The GGM programme initiates a transparency assessment to identify points in the management system of the medicines chain that are vulnerable to corruption, among other things. The transparency assessment report is formally presented to the MOH for review and discussion. It provides excellent input for building awareness in the MOH on the problem of corruption and the measures that can be taken to reduce and to prevent it in the future. As the focus of the assessment is systems improvement for good governance, rather than the identification of criminals, the assessment report provides a positive entry point to address the difficult issue of corruption in a non-threatening manner.
- b) **Monitoring and evaluation of the GGM programme:** The effective coordination, management, monitoring and evaluation of a GGM programme requires a team of trained human resources and adequate logistical support. If a MOH does not have a system that promotes transparency and good governance practices, the GGM programme Task Force team should be given the authority and support necessary to carry out activities pertaining to such a system that has direct bearing on the GGM programme. In any event, the GGM programme must be able to respond to the needs of other departments within the MOH, which requires additional personnel and logistical support. The responsibilities and activities of the Task Force during the

first three stages of the GGM programme require a team composed of two types of professionals: one that has expertise in evaluating and managing the medicines chain and another that has expertise in facilitating the process of socializing key ethical principles and leadership, and designing and implementing training programmes for personnel in management and leadership positions. Terms of reference should be prepared for this Task Force and ongoing monitoring and evaluation carried out to ensure improvements in addressing the problems.

- c) **Fundraising and resource mobilization:** Initially, it is important for each country to map its current and future possible donors. Sustainability of the GGM programme requires a thorough analysis of cost-effectiveness and minimum financial resources. Inclusion of the GGM programme in an annual national budget clearly indicates strong government commitment and ensures the future institutionalization and sustainability of the programme.

### **BOX 6. MANAGEMENT AND COORDINATION OF FUNDING THE GGM PROGRAMME IN THE PHILIPPINES**

Implementation of the GGM programme in the Philippines is funded both by WHO and the government budget. Major events such as the GGM awards and the development of the GGM manuals are at this time funded by WHO, while other activities that are part of good governance reforms and integrity development initiatives are funded by the Government. Improvements in procurement and drug management, rational use and access are funded separately by the Government with support from development partners such as the World Bank and the European Commission. At this stage of implementation, and the establishment of the National Center for Pharmaceutical Access and Management – which is taking on the technical secretariat work for the programme – the majority of the funding will be given by this office with the support of major initiatives such as the GGM programme from WHO and MeTA.

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## CHAPTER 3

# Process for developing national good governance for medicines framework

The construction of a framework for Good Governance in the pharmaceutical sector requires consensus-building through a national consultation process involving all relevant stakeholders. It also requires adequate training to be able to critically analyse and reflect on all the necessary elements that should be incorporated in the framework. With the experience of countries that are currently implementing the GGM programme, this revised and updated process in the development of a national GGM framework will serve as a guideline for the phases required, especially phases II and III. It is important to note that the steps can be carried on in a parallel or circular way. Also, the experience gained by applying the framework will add new elements that each country can incorporate in updated versions of their framework.

The *Model Framework for Good Governance in Medicines* has been used by countries that have initiated Phase II of the GGM programme. Examples of successful development of a national framework for each country coming from GGM country case studies are summarized in this chapter. To date eight countries have officially adopted national GGM frameworks, each of which has had its challenges in its development and implementation. Despite these obstacles, most have persevered and found creative ways of overcoming barriers.

Figure 4 outlines the steps necessary for developing a national GGM framework.

FIGURE 4. Six steps to achieve good governance for medicines



### Step I: GGM Information meeting and presentation of the national transparency assessment results

The objective of this step is to give information and share the GGM programme and its three phases with key stakeholders. In this meeting the results of the Transparency Assessment for Phase I are presented, reviewed and validated. In this first stage, it is also important to officially nominate both the Task Force and the Steering Committee.

- **Task Force:** Members may include as many different key stakeholders as possible at the local, regional and national levels to ensure that all sides of the issue are taken into account.
- **Steering Committee:** Members include as many decision-makers at the highest levels as possible, including the Minister of Health.

A date is set for the first national GGM workshop. The Task Force and Steering Committee will organize and make the necessary arrangements, invitations and agenda for this workshop.

#### BOX 7. EXAMPLE OF GGM STEP I: JORDAN

In November 2008 the results of the transparency assessment were presented to key stakeholders, the MOH and the Jordan Food and Drug Administration. The debate that resulted extended beyond the health sector to involve others from government, civil society bodies, and all interested in fighting corruption and ensuring better health for Jordanian citizens. Thus, the Minister of Health in Jordan officially appointed the following two committees:

1. **The Steering Committee** of good governance for medicines, which was headed by the Jordan Food and Drug Administration Director General, officials from the public and private pharmaceutical sectors holding vital positions in the medicine sector, high-level policy-makers, and a representative of the consumers group. These were responsible for the overall establishment, adoption and management of policies and procedures for the control of reprehensible acts, whistleblowing mechanisms, implementation and evaluation of the national GGM programme.
2. **A Task Force** was made up of mid-level professionals from key government representatives of the pharmaceutical sector, civil society and local agencies concerned with good governance. Its main tasks included: a) managing the national consultation process to share results of the national assessment of transparency and vulnerability to corruption in the public pharmaceutical sector; b) following up recommendations made in the national assessment reports and by the Steering Committee; and c) coordinating the development, adoption, and socializing the national ethical framework and code of conduct.

#### BOX 8. EXAMPLE OF GGM STEP I: BOLIVIA

In 2007 a national workshop presented the transparency assessment and recommendations with the participation of key MOH and Ministry of Transparency and Anti-corruption dignitaries, representatives from the MOH Pharmaceutical Health Unit, national and local health authorities, public and private pharmaceutical senior officials, academic field representatives and other key stakeholders. The MOH nominated a Task Force to coordinate the programme and implement the necessary recommendations.



## Step II: First national GGM workshop to initiate the country GGM framework

The WHO model GGM framework is presented and studied, followed by training for a Steering Committee, Task Force and other key stakeholders on the values- and discipline-based strategies (with their 10 components), on how to integrate these components to address gaps in the system and on searching the best ways of collaboration. This training is divided in two parts and should include:

### Part 1

- a) Raising consciousness about the importance of key ethical principles, values and capabilities, and understanding mind frames or mental models that hinder or enhance these principles. Failing the necessary time for training, an extra training session should be programmed as soon as possible before the second national workshop.
- b) Discipline-based strategy and its components.
- c) Understanding how these strategies together can address vulnerability to corruption in the medicines chain.

### Part 2

- a) Forming subcommittees with key collaborators and stakeholders to apply the two strategies to address vulnerability to corruption found in the national transparency assessment. Each subcommittee should have a Task Force member to ensure proper follow up; a Secretary and Chairperson should also be appointed.
- b) Analysis by each subcommittee of a medicines chain area most vulnerable to corruption together with specific recommendations made by the national transparency assessment in order to develop an action plan to strengthen the area and make it less vulnerable to corruption. Subcommittees will thus need to research existing laws, regulations and legislation for current needs.
- c) Identification by subcommittees of key ethical principles and functional mental models that require reinforcement in order to reduce vulnerability to corruption in their corresponding area.
- d) Listing key stakeholders with whom collaboration will lead to the necessary changes.
- e) Analysis and inclusion of all activities required to complete this task and describe their description in the corresponding section of the Action Plan together with the responsible institutions or persons, and the timelines for finishing these activities.
- f) Mention of the monitoring and evaluation process or instrument that will be used to follow up the implementation of this specific task and its frequency (monthly, annually, etc.).
- g) Presentation of work done by subcommittees and feedback from the larger group. The secretary of each subcommittee will take notes on the feedback given by the group at large.

The following tables are examples of how an action plan can incorporate the above tasks for part 2 of Step II.

TABLE 2. Example of an action plan (1)

RELEVANT AREA OF THE MEDICINES CHAIN	DISCIPLINE-BASED COMPONENTS	KEY ETHICAL PRINCIPLES AND FUNCTIONAL MENTAL MODELS REQUIRING REINFORCEMENT	COLLABORATION NEEDED	PROCESS	RESPONSIBLE OFFICES	TIMELINE	FOLLOW-UP AND EVALUATION MECHANISM
Registration	<p><b>Transparent and accountable regulations:</b> Law or Decree for registration and import of medicines</p> <p><b>Sanctions:</b> Fines or confiscating medicines not registered</p>	<p><b>Key ethical principles:</b> Establishment of Justice (laws with sanctions: punishment and rewards)</p> <p>Accountable trusteeship (transparency by registering all medicines available and making list available to all)</p> <p><b>Functional mental models:</b> Service to the common good</p>	<p>Key stakeholders involved in export/import of medicines</p> <p>Public and private pharmaceutical sector</p>	<p>Workshops to reinforce and integrate key ethical principles and functional mental models</p> <p>Consensus-building with key stakeholders to draft law and sanctions</p> <p>Law in pharmaceutical legislation</p> <p>Socializing and promoting law with all</p>	MOH GGM Task Force	3 months	Evaluate changes with GGM monitoring and evaluation instrument (biannually)

TABLE 3. Example of an action plan (2)

RELEVANT AREA OF THE MEDICINES CHAIN	DISCIPLINE-BASED COMPONENTS	KEY ETHICAL PRINCIPLES AND FUNCTIONAL MENTAL MODELS REQUIRING REINFORCEMENT	COLLABORATION NEEDED	PROCESS	RESPONSIBLE OFFICES	TIMELINE	FOLLOW-UP AND EVALUATION MECHANISM
Inspection and market control	<p><b>Management, coordination:</b> Strengthen pharmacy inspection capabilities centrally and regionally</p> <p><b>Sanctions:</b> Fines or closure of establishments that do not comply</p>	<p><b>Key ethical principles:</b> Investigation of the truth (inspecting with the purpose of discovering the truth)</p> <p>Establishment of Justice (laws with sanctions: rewards and punishments)</p> <p>Accountable trusteeship (transparency by publishing inspection results and list of registered medicines, prices and others)</p> <p><b>Functional mental models:</b> Service to the common good</p> <p>Investigation of the truth</p>	<p>Public and private pharmaceutical sector</p> <p>Customs, police force and other law-enforcing agencies to prevent entry of counterfeit and substandard medicines</p> <p>General public and health professionals (denounce non-registered, illegal or counterfeit medicines)</p> <p>Media and other organizations</p>	<p>Training in ethical leadership and inspection techniques</p> <p>Awareness campaigns about smuggled and counterfeit medicines</p> <p>Established alert systems</p> <p>Publicly available list of approved facilities and medicines for procurers and end-users</p>	MOH Customs officials Media	4 months	Annual evaluation of GGM monitoring and evaluation instrument

**Step III: Second national GGM workshop** to socialize the work that began during the first national workshop by the subcommittees formed, and continued after, to incorporate feedback given by the group and further research done by each. Additional training can be given in this workshop, if necessary. At this point, the first draft of the national GGM framework is initiated. Work is continued by subcommittees after the workshop and shared with the group at large and the Steering Committee so that they can all give feedback (via e-mail or other means as convenient). Once all feedback is sent, the Task Force consolidates it into a final document and resends this to all for final approval.

**BOX 9. EXAMPLE OF GGM STEP II/III: LEBANON**

The working teams in the national workshops studied the model framework carefully and divided the work among the members. Each was asked to do a literature review to search what was available in general or specifically in the Lebanese law and policies of the Ministry, related to a specific area missing in the Transparency Assessment. The focus of the work was integral, both on the discipline-based strategy (regulations and administrative procedures) and the values-based strategy. The framework components were rearranged according to priority. The final framework included all legislations, laws and administrative procedures related to good governance, sanctions, and mechanisms to promote transparency and the code of conduct. Moreover, the document covered mechanisms for reporting breaches, suggested cooperation with other initiatives of good governance, and encouraged collaboration with institutions that fight corruption via administrative, judicial, social, and media means.

**BOX 10. EXAMPLE OF GGM STEP II/III: PHILIPPINES**

A national workshop undertaken to develop the GGM framework included the discipline- and values-based strategies by building “accountable systems” through which “accountable individuals” can work. A personnel order named members of the ethical framework (equivalent to Task Force) to develop the advocacy mechanism and training programme to socialize the framework. An agreement was also reached on key principles and core values, similar to those listed in the model framework. Most components of the framework are also part of the 22 ‘doables’ of the Integrity Development Plan mandated by the Presidential Anti-Graft Commission such as the norms of behaviour (code of conduct), whistleblowing mechanism, gift policy, and public disclosure. These may be customized for medicine registration, selection and procurement if necessary.

**BOX 11. EXAMPLE OF GGM STEP II/III: THAILAND**

The Thai GGM framework draws from the WHO model framework and integrates a top-down and bottom-up approach. A national workshop was organized to prepare the framework. The values-based strategy included the moral values and ethical principles, a code of conduct, and promotion of moral leadership, while the discipline-based strategy incorporated a system of whistleblowing, transparent and accountable regulations and administrative procedures, management, coordination and evaluation of the good governance programme.

**Step IV: Third national GGM workshop:** This step socializes the final national GGM framework document with all key stakeholders and receives final approval from the Steering Committee for its publication.

**BOX 12. EXAMPLE OF GGM STEP IV: JORDAN**

In April 2010, Jordan completed and published its national GGM framework. The document included methodological goals, expected outputs of the programme, and defined good governance, its requirements and characteristics. It also included the elements that need to be in place at the country level such as moral values and ethical principles necessary for building good governance in the pharmaceutical sector. In addition, it includes international anti-corruption initiatives and conventions as well as procedures and initiatives carried out in Jordan. Based on the result of transparency assessment, a work plan was prepared to guarantee the application of recommendations in phase III. This framework has been socialized in various encounters.

**Step V: GGM framework training workshop:** This involves sharing the final published document with all stakeholders at the local, regional and national levels, accompanied by training on all components of the framework and how best to use the document for phase III of the GGM programme in their country.

**BOX 13. EXAMPLE OF GGM STEP V: MALAYSIA**

In November 2009, the Malaysian GGM framework was published, the key components of which were moral values, ethical principles and the do's and don'ts for the five areas in the pharmaceutical sector, namely registration, selection, procurement, inspection and promotion. Also, various seminars, training workshops and awareness campaigns on integrity and good governance were carried out throughout the country by hospitals and institutions alone or in collaboration with other agencies. The Public Service Department issued brochures entitled 'My Integrity' to all public servants. An audit value management system had been implemented to evaluate the effectiveness of the various programmes introduced to instil ideal values to the public personnel.

**BOX 14. EXAMPLE OF GGM STEP V: MONGOLIA**

In January 2010, a seminar on "Enhancing the participation of private organizations in the promotion of the GGM programme and transparency in the health sector" was organized with the participation of many key stakeholders from different sectors. The seminar's purpose was to enhance knowledge and awareness about the GGM programme among private pharmaceutical organizations; to improve their participation and collaboration towards GGM; to identify barriers of complying with regulations and rules; and to discuss challenges and identify further actions for improvement. Also included was training in ethical leadership capabilities among directors, managers and executives of pharmaceutical companies.

**Step VI: Institutionalizing the national GGM framework and programme** by including it in the existing MOH guidelines and in the national annual planning and budget, to ensure its sustainability.

**BOX 15. EXAMPLE OF GGM STEP VI: PHILIPPINES**

Currently, the National Center for Pharmaceutical Access and Management, which is funded by the MOH, assumes the technical secretariat work for the GGM programme. The awards programme is another initiative that institutionalizes transparency and good governance in regard to the regulation, supply and overall management of medicines in the public and private sectors. It encourages local government units, national health facilities and the private sector to develop innovative initiatives that provide models of good governance.

**BOX 16. EXAMPLE OF GGM STEP VI: MALAYSIA**

The development of the GGM framework in line with the National Integrity Plan – a countrywide plan to reduce corruption and increase ethical practices – is among the key steps taken towards institutionalizing GGM. Successes in this area have been achieved through a combination of various programmes put in place by the Government, in addition to the GGM programme, including the Government Transformation Programme and the national mission for achieving vision 2020 – designed to help Malaysia become a fully developed nation. Most of the funding is also from government sources.

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## CHAPTER 4

# Challenges and successes in developing a national Good Governance for Medicines framework

The development of the GGM national framework in various countries has experienced common challenges and successes, some of which are mentioned below.

### Common challenges

- Political instability and changes in government
- Poor understanding of the culture of transparency and good governance
- Resistance to change
- Access to legislation documents
- Maintaining motivation of Task Force experts
- Low priority of the Good Governance for Medicines programme for ministries of health
- Lack of adequate monitoring and evaluation tools for follow-up
- Integrating this programme within existing efforts in the same area given different players and priorities (for some countries)

### Common successes

- Involvement of many different key stakeholders and their commitment from the beginning of the programme (national and local authorities, public and private institutions, academia, civil servants, nongovernmental organizations, consumers and others)
- GGM perceived as a catalyst for change
- Increase in level of public awareness about ethical leadership and good governance
- Increase in transparency and ethics of procedures, legislation and practices, thus addressing gaps encountered in transparency assessment
- Ethical leadership applied and more visibly seen
- Successful collaboration and partnerships
- Information made accessible and available
- Standard operating procedures created in several functions to increase transparency of decision-making processes

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## CHAPTER 5

# Conclusions

Corruption in any one of the critical decision points in the pharmaceutical system can be harmful to a country's ability to improve the health of its population as it limits access to quality-assured medicines and reduces the gains associated with their proper use. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard medicines, or waste resources on the wrong kind of medicines. Good governance is therefore a *sine qua non* for ensuring better access to essential medicines. Greater transparency and accountability in the pharmaceutical system will help to improve access to medicines. Honest assessment of the institutional robustness at all core decision points in the pharmaceutical system is an initial necessity. Governments need to know what areas of the system are less than optimal and vulnerable to corruption.

The first step towards stopping corruption in the pharmaceutical sector is to understand its structure, actors, and motivations, and to identify the key points where corruption can occur. Based on this, priority measures to stop corruption at these points should be identified for the short, medium, and long-term. Priorities should be based on the extent to which the identified corruption is a threat to safety and health in the first instance, and secondly, its economic implications. Irrespective of what priorities are made, transparency and accountability mechanisms are critical at every point in the pharmaceutical system to encourage movement towards stopping corruption sooner rather than later.

The development and management of the GGM programme within the pharmaceutical sector of the Ministry of Health of each country requires ethical leadership for its sustained and effective operation. There is no easy and quick solution to the problem of corruption in the pharmaceutical sector. Establishing ethical leadership and good governance throughout the discipline-based components in this sector requires analysis, reflection and systematic work, such as that mentioned in this framework. It will require investment of public resources for the development and socialization of its components, and the provision of an adequate operational budget for its implementation. Political will is vital if the required investment is to occur.

A public servant's faithful application of a model framework and sustained compliance to a code of conduct requires the development of intrinsic motivation based on a personal commitment to the underlying ethical principles. This type of commitment empowers and motivates a public servant to "walk the talk" and to "become the change he seeks to create".<sup>1</sup> Such an approach will require moral courage to take bold initiatives and to persevere throughout the process of change and to assume the risks that are required in establishing good governance in the pharmaceutical sector.

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<sup>1</sup> Saying attributed to Mahatma Gandhi.



# Annexes

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## ANNEX 1

# Conflict of interest

The reality of human diversity is such that conflicts of interest may exist in any human interaction, whether at individual, family, organization or national level. An individual may be confronted with potential, apparent or real conflict of interest in the exercise of his/her professional responsibilities. There is nothing fundamentally unethical in finding oneself facing a potential conflict of interest. The manner in which individuals manage the perceived conflict of interest will determine whether they have been ethical in their decisions and action.

There is an inherent tension between altruism and self-interest. This type of tension can exist in the interactions between individuals and in some cases between organizations interacting in society. Thus, when a public organization such as a ministry of health (MOH) – whose altruistic mission is to serve the common good in terms of public health – interacts with a commercial enterprise, whose mission is to maximize profits for its owner(s), a tension emerges due to the potential conflict of interest between two types of organizations motivated by very distinct goals. This does not mean that a commercial enterprise is incapable of expressing altruism and philanthropy, in complement with a MOH's mission, but that a conflict of interest could emerge, especially if the means used by the enterprise to generate profit has proven to be harmful to the common good.

Some social analysts take the position that public service organizations must maintain a distance from private interests “because an organization like the United Nations is driven, to some extent, by a set of ethical principles while a business is largely driven by the profit motive and the interests of shareholders. Tensions and conflicts of interest, therefore, are likely to arise when private interests exert undue influence over the decision-making processes of a public-interest organization and engage in what has been called ‘institutional capture’” (45).

It is generally assumed that the fulfilment of the profit motive is the primary purpose for the existence of commercial enterprises. The fundamental question is: can a non-profit public service institution (such as a MOH) interact with a commercial enterprise in a collaborative relationship by means of which both entities can fulfil their missions without any apparent or real conflicts of interest that could be detrimental to either or both entities? If the answer is no, then there would be no point in developing guidelines for working with the private sector. If the answer is yes, then there must be ways of structuring the relationship and designing projects with commercial enterprises that will not jeopardize the interests of a MOH. The next question is how to do it? The capability of negotiating, structuring and designing conflict of interest-free agreements and interactions needs to be developed in MOH staff.

### Definition of conflict of interest

It is often unclear what is referred to by the term ‘conflict of interest’. More serious than a mere conflict of views and opinions, it is a situation that can lead to a penal fault such as corrupt practice, misappropriation of corporate funds, ‘insider dealings’; thus it is important to understand the meaning of the term and its relevance to a MOH's collaborative interactions with governments and commercial enterprises.

There are *two categories* of conflict of interest pertinent to a MOH that require definition: individual and organizational.

**Individual (or personal):** consists of the types of conflict of interest that arise when a MOH staff member, in his/her relations and interactions with a commercial enterprise or other private entity, uses his/her professional position to influence MOH decisions and activities in ways that could lead directly or indirectly to financial gain and/or other benefits for the staff member or his/her family to the detriment of the MOH's interests.

This category has to do with the "abdication of professional duty by an individual staff member in pursuit of personal gain" (46). If the employee chooses to abdicate official responsibility to take advantage of the situation for personal gain this would be a clear conflict of interest, which could lead to a penal fault. The responsibility for the types of conflict of interest in this category falls primarily on the shoulders of the MOH employee. However, if the employee does not take advantage of the situation, this does not mean the issue of conflict of interest is eliminated. In this case, the MOH is responsible as an institution (legal entity) to establish and implement principles, guidelines and procedures that effectively manage and eliminate potential situations of conflict of interest from its internal organizational environment and from its collaborative interactions with other entities.

**Institutional (or organizational):** consists of the types of conflict of interest that arise when a MOH staff member through his/her actions creates a situation in which a MOH enters into a collaborative interaction with a commercial enterprise or other private entity in a manner that puts the interests of the outside organization above a MOH's public health mission and objectives, although the staff member as such would not gain any personal benefit.

This type of conflict of interest is not necessarily the result of a conscious and deliberate intention on behalf of the staff member, but rather the result of the staff member's inexperience and/or naiveté in dealing with commercial enterprises and other private entities and in negotiating agreements. A MOH, as a legal institution, is responsible for these types of conflict of interest if it allows such situations to arise by failing to provide adequate procedures, guidelines, orientation and training to employees; such guidance would enable them to negotiate more effectively with private entities through well designed collaborative interactions that would protect and promote the interests and objectives of a MOH.

This is why institutional policies related to the management of conflict of interest are necessary. Guidelines, a declaration of interest form, organizational screening procedures, etc. are necessary means for managing conflict of interest. This Annex 1 for Managing Conflict of Interest facilitates the orientation and training of MOH employees.

### Individual level

The individual types of conflict of interest are more conventional, and those that first come to mind when considering the issue. The following examples reflect a conscious and deliberate "abdication of professional duty by an individual in pursuit of personal gain" (2) to the detriment of a MOH's interests.

- Self-dealing
- Accepting benefits
- Influencing peddling
- Using MOH resources for private advantage
- Seeking and/or accepting post-employment.

### **Institutional level**

Some MOH staff members provided the following examples that form the institutional type of conflict of interest. The examples are presented in a generic form without specific details to avoid sensitivities.

- Procurement of products
- In-kind donations
- Donation of funds
- Formulation of treatment guidelines
- Misuse of MOH emblem and programmed logos
- Co-sponsoring of meetings, seminars or conferences
- Attendance of industry personnel in MOH meetings
- Divulging confidential information.
- Endangering public health policy.

### **Prevention of conflict of interest**

The application of the principles, guidelines and approval procedures delineated in this Reference Manual is the best measure to prevent and manage conflict of interest when interacting with commercial enterprises. The best means of protection against unwarranted external influences upon a MOH are the institutional measures established to protect its integrity and independence, coupled with the ethical and competent management by MOH staff of the various forms of conflict of interest.

Ultimately, the most effective safeguards against conflict of interest are the MOH staff members themselves working in an organizational environment and culture that fosters commitment to the institution and that does not tolerate the ethical laxity that gives rise to conflict of interest. Of course this implies a continuous process of institutional learning and the development of personnel in key positions who are willing to exercise ethical leadership in protecting and promoting the best interests of their MOH in its service to the public good.

In public institutions where corruption has become a serious problem, one of the key obstacles in addressing the issue of conflict of interest is often referred to as a ‘culture of tolerance’. This term refers to an institutional culture that tolerates the existence of apparent and/or real conflict of interest as a normal state of affairs, in which staff members are not inclined nor encouraged to assume the moral responsibility to ‘blow the whistle’ when ethical principles are violated. Staff members are often unaware that their passive tolerance is a form of irresponsibility towards and complicity with the corrupt practices based on conflict of interest. They fail to recognize that their personal integrity is at risk, as well as the institutional integrity of the MOH.

In such cases a training programme for staff is necessary to develop awareness and understanding regarding the issue and the capabilities necessary to manage situations of conflict of interest effectively. The development of the capability to apply ethical principles in the management of collaborative interactions with external agencies is of high priority.

### **Principles for managing interactions**

The following principles provide a framework for managing interactions with commercial enterprises in a manner that prevents conflict of interest:

- **Mission congruence principle:** Interactions with a commercial enterprise should lead to public health gains in accordance with the mission and objectives of a MOH, and the gains should be worthy of and commensurate to the effort involved in establishing and maintaining the interaction.

- **Selective association principle:** A MOH should avoid association with onerous and disreputable commercial enterprises. Only those and other private agencies approved by the Office of Resource Mobilization are acceptable for interaction. The mission of a collaborating commercial enterprise should not be contrary to the public health mission of a MOH, such as those of the tobacco and the armament industry.
- **Non-exploitation principle:** A MOH's name and logo, and/or any other institutional patrimony or asset, should not be subject to exploitation by a commercial enterprise.
- **Safeguarding the MOH's normative functions principle:** The integrity and independence of the normative functions of a MOH must be vigilantly and rigorously protected from any unwarranted and unethical influence by a commercial enterprise.
- **Non-privileged advantage principle:** A MOH's interactions with a commercial enterprise should not provide the enterprise with a privileged competitive advantage or monopoly. Private sector entities should not be privy to information that is considered by MOH as confidential and/or classified.
- **Intellectual property rights principle:** Legal arrangements for intellectual property rights regarding the products of an interaction should be agreed upon and formalized prior to engaging in a proposed interaction.
- **Transparency principle:** All interactions and agreements between a MOH and a commercial enterprise should be transparent and open for disclosure and public scrutiny. The periodic monitoring of interactions and audit of conflict of interest should be performed to secure and maintain transparency.
- **Conflict of interest disclosure principle:** MOH personnel who have a direct role in making institutional decisions on equipment or drug procurement must disclose to the purchasing unit, prior to making any such decision, any financial interest they or their immediate family have in companies that might substantially benefit from the decision. Such financial interests could include equity ownership, compensated positions on advisory boards, a paid consultancy, or other forms of compensated relationship. The purchasing unit will decide whether the individual must recuse him/herself from the purchasing decision. All members of the procurement unit and committees should be required to disclose all personal and professional relationships with industry prior to joining and annually thereafter.
- **Accountability principle:** MOH personnel with responsibility for decision-making and actions related to interactions with a commercial enterprise will be held accountable for compliance to the principles, policies, guidelines and procedures, as delineated by the MOH, and non-compliance should be sanctioned.

These principles should be presented to the proposed collaborator as a MOH's ground rules of interaction. It should be made clear to the collaborating agency that all interactions with the MOH must comply with these principles and that they are non-negotiable.

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ANNEX 2

**Declaration of Interests for WHO Experts**



## **DECLARATION OF INTERESTS FOR WHO EXPERTS**

WHO's work on global health issues requires the assistance of external experts who **may have interests related to their expertise**. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a **potential conflict of interest** (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interest (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards **and** any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department).

Please complete this form and submit it to WHO Secretariat if possible at least 4 weeks but no later than 2 weeks before the meeting or work. You must also promptly inform the Secretariat if there is any change in this information prior to, or during the course of, the meeting or work. All experts must complete this form before participation in a WHO activity can be confirmed.

Answering "Yes" to a question on this form does not automatically disqualify you or limit your participation in a WHO activity. Your answers will be reviewed by the Secretariat to determine whether you have a conflict of interest relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g. nature and magnitude of the interest, timeframe and duration of the interest).

The Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the conflict of interest may be applied. The Secretariat (i) allows full participation, with public disclosure of your interest; (ii) mandates partial exclusion (i.e., you will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., you will not be able to participate in any part of the meeting or work).

All potentially significant interests will be **disclosed** to the other participants at the start of the activity and you will be asked if there have been any changes. A summary of all declarations and actions taken to manage any declared interests will be **published** in resulting reports and work products. Furthermore, if the objectivity of the work or meeting in which you are involved is subsequently questioned, the contents of your DOI form may be made available by the Secretariat to persons outside WHO if the Director-General considers such disclosure to be in the best interest of the Organization, after consulting with you. Completing this DOI form means that you agree to these conditions.

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the Secretariat may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name: Institution: Email:
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**Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):**

\_\_\_\_\_

\_\_\_\_\_

*Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.*

*The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.*

## EMPLOYMENT AND CONSULTING

*Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?*

- 1a Employment Yes ☐ No ☐
- 1b Consulting, including service as a technical or other advisor Yes ☐ No ☐

## RESEARCH SUPPORT

*Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?*

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes ☐ No ☐
- 2b Non-monetary support valued at more than US \$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes ☐ No ☐

Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?

## INVESTMENT INTERESTS

*Do you have current investments (valued at more than US \$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.*

- 3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes ☐ No ☐
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company) Yes ☐ No ☐

## INTELLECTUAL PROPERTY

*Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?*

- 4a Patents, trademarks, or copyrights (including pending applications) Yes ☐ No ☐
- 4b Proprietary know-how in a substance, technology or process Yes ☐ No ☐

## PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)

- 5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes ☐ No ☐
- 5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work? Yes ☐ No ☐

## ADDITIONAL INFORMATION

- 6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage? Yes ☐ No ☐
- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes ☐ No ☐
- 6c Excluding WHO, has any person or entity paid or contributed towards your travel costs in connection with this WHO meeting or work? Yes ☐ No ☐

6d Have your received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this WHO meeting or work? Yes ☐ No ☐

6e Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes ☐ No ☐

**7. TOBACCO OR TOBACCO PRODUCTS** (*answer without regard to relevance to the subject of the meeting or work*)

Within the past 4 years, have you had employment or received research support or other funding from, or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity? Yes ☐ No ☐

**EXPLANATION OF "YES" RESPONSES:** If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.

Nos. 1 - 4: Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)

**Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details**

**CONSENT TO DISCLOSURE.** By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

**DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.**

**Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.**

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

Signature \_\_\_\_\_

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## ANNEX 3

# List of key stakeholders in the pharmaceutical sector

- Ministry of Health (e.g. health service department, pharmaceutical units, national programmes for disease control, medical stores, procurement division);
- Medicine Regulatory Authority (registration, inspection, control of promotion, licensing and clinical trial units/departments, etc.);
- Procurement agencies, importers and distributors both from the private and the public sector (including tertiary-care hospitals, primary care facilities, pharmaceutical brokers and consolidators, hospital pharmacists);
- Members of committees, such as tender committees, therapeutics committees, selection of essential medicines committees, at national and local level;
- Ministries of finance, industry and commerce, customs and importation;
- Local anti-corruption organizations/commission;
- National quality control laboratories;
- Audit departments (internal, external, and state auditors);
- Pharmaceutical industry (multinational and national) and associations;
- Nongovernmental organizations, such as those engaged in health service activities, patient advocacy groups, “watch dog” organizations;
- International donor organizations, such as the World Health Organization, the United Nations Children’s Fund, the United Nations Development Programme, the World Bank and the Global Fund;
- Academic institutions (national colleges, state universities and research institutes);
- Professional associations (medical, pharmacy, biochemist associations, etc.);
- Media (if knowledgeable about the pharmaceutical sector);
- Ethics committees, institutional review boards;
- Health insurance funds.

### Other important stakeholders

**Civil society and the media:** Civil society organizations (CSOs), such as Transparency International, Procurement Watch and Oxfam GB, have provided valuable institutional moral leadership in the anti-corruption movement. They have raised their voices as whistleblowers when necessary and have played important roles as independent monitors and assessors of the enforcement process of anti-corruption conventions. CSOs are important in the **promotion of values** in society related to human rights, the environment and social well-being, good governance and others. In one sense, CSOs fulfil the role of moral conscience in society and safeguard society from the abuses of government and the private sector.

Also important is an **independent free press** and other forms of **media** such as radio and television that work with the key ethical principle of **investigation of the truth**. They will help raise public awareness about the gravity of the problem of corruption and keep the public truthfully informed about the progress or lack of progress in enforcing anti-corruption laws and conventions. They will

also help advocate for the good governance for medicines programme and other anti-corruption movements. Informed public opinion can be a powerful force in mobilizing political will for change.

**Transnational corporations:** By definition, acts of corruption involve two actors: a corruptor and a corruptee. Both parties are responsible for a corrupt act that they jointly commit. In the bribery of foreign public officials, the corruptor is generally a transnational corporation and the corruptee is a public official with discretionary decision-making powers. The initiator of the corrupt action could be either the representative of a corporation who offers a bribe or a public official who demands the payment of a bribe. In general the anti-corruption movement addresses both sides of the corruption equation. The Organisation for Economic Co-operation and Development (OECD) Convention focuses on the criminalization of bribery of foreign officials by European corporations as a deterrent to this corrupt practice. During the last 10 years, over 150 cases have been investigated under the OECD Convention and a few have resulted in convictions. Although these numbers may not be impressive, they do communicate a clear message to the corporate world that the increasing enforcement of the Convention is a reality that will shape the future of international business practices with which it will have to conform. As anti-corruption conventions have clearly rejected the rule of geographical morality and cultural relativism as justifications for corruption, transnational corporations can no longer use them to try to rationalize the bribing of foreign officials. Some corporations have actively joined in the promotion of the OECD Convention and many have developed codes of ethics and internal mechanisms to monitor and sanction corrupt behaviour by their employees. These measures represent the beginning of a positive trend that hopefully will gain momentum, although some critics suspect that these anti-corruption measures taken by transnational corporations are symbolic and only elements of a marketing strategy to improve corporate image.

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