

A Framework for Good Governance in the Public Pharmaceutical Sector

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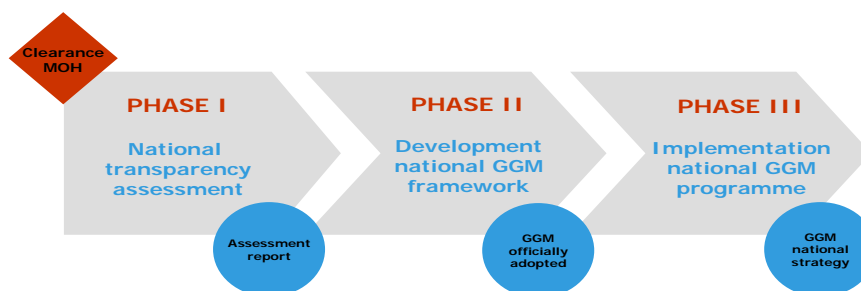
1. Good Governance in the Public Pharmaceutical Sector

Good governance is an essential factor for economic growth and sustainable development at all levels and within all sectors of society. The social and economic chaos, corruption and violence that proliferate in failed states clearly demonstrate the results that ensue when bad governance prevails. There are many different definitions of governance and good governance in the literature (see Annex A). Although the definitions do not always use the same terminology, 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. The term **Good Governance** is increasingly used to emphasize the need for governance to operate with due regard for the rule of law and especially in a manner that is free of corruption. There is also growing consensus on the major characteristics of good governance. Good governance is participatory, consensus oriented, accountable, transparent, responsive, effective and efficient, equitable and inclusive and follows the rule of law.

The establishment of a national integrity system is a basic prerequisite for good governance (1,2). Good policies can be subverted by corrupt practices, and so there is a need for an effective integrity system to ensure ethical practice in the implementation of policies. An integrity system is based upon a set of elements that ensure that governance reflects the characteristics of “good governance” and complies with established moral values and ethical principles in formulating and implementing policies and enforcing laws.

Concretely, governance is about decision-making processes related to policy formulation and the way policies are implemented to assure effective and ethical management. If decisions are made with respect for the major characteristics of good governance and in line with an established ethical framework, then the implementation of policies in the various sectors such as health, education and agriculture, will lead to social well being and economic progress.

In an attempt to curb corruption in pharmaceutical systems, WHO established the Good Governance for Medicines (GGM) programme. The programme's goal is to reduce corruption in pharmaceutical systems through the application of transparent, accountable administrative procedures and the promotion of ethical practices. The GGM is implemented in a 3-step approach as shown below.



WHO has developed a technical package to help countries establish GGM programmes at national level. For Phase I, an assessment instrument "*Measuring transparency in the public pharmaceutical sector*" provides a methodology to measure the level of transparency and the vulnerability to corruption in key functions of the pharmaceutical system. For Phase II this document serves as a model for countries to develop their own national GGM framework, after wide consultation with key stakeholders and contextualization to national situations.

In the GGM programme, the focus is on the fundamental need to have good laws, regulations, policies and procedures in place to improve the management of the medicines chain and a corrupt-free environment to promote access to good-quality medicines. While corruption persists in pharmaceutical systems, it is almost impossible to ensure access to good-quality medicines for all members of society, and so improve people's health and well-being. The GGM programme's primary emphasis is on prevention of corruption and on improving systems, rather than on hunting down culprits.

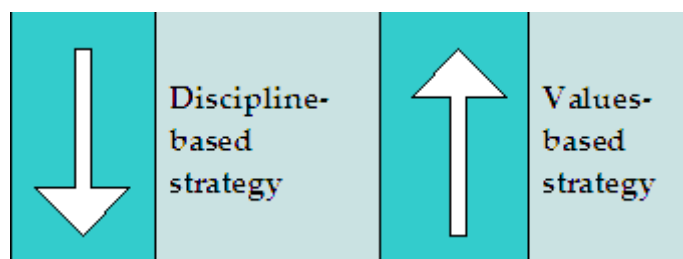
Therefore, in the GGM programme, *Good governance refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, in particular medicine regulatory systems and medicine supply systems, in a manner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

2. The Problem of Corruption

Increasingly development agencies recognize corruption as the single greatest obstacle to economic and social development (3). Corruption is at the heart of an entrenched vicious cycle: bad governance produces corruption (4) and corruption destroys the basis of good governance (3,5).

The hyper-corruption that prevails in many countries is a clear indicator of the profound moral crisis that many societies are experiencing. The 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. Corruption vitiates and destroys the key ingredients of social capital, without which the machinery of governance cannot function. In the light of these considerations, it has become a moral imperative that all sectors of society address and resolve the problem of corruption.

“Corruption takes many forms. It has a supply side (private bribers) and a demand side (public officials). There is grand corruption, involving high-level officials with discretionary authority over government policy, and petty corruption, involving lower-level officials who control access to basic services such as education and electricity. Ultimately, addressing all aspects of the issue is vital because they feed into one another” (5). Transparency International defines corruption as: “*the abuse of entrusted power for private gain*” (6). Efforts to address the issue of corruption in the public sector have focused on the application of two basic strategies. One strategy has been a legislative reform approach, which establishes laws against corruption with appropriate punitive consequences for violations. This approach is often referred to as the “discipline approach”, which attempts to deter corrupt practices through the fear of punishment. The second strategy, often termed the “values approach”, attempts to increase institutional integrity by promoting moral values and ethical principles as a way of motivating public servants to behave ethically. Experience with these two strategies has shown that neither is sufficient if used alone and coordinated use of both is required to have a significant impact on establishing ethical practices within an institution.



This document discusses both approaches, although more details are provided on components of the values approach. It emphasizes the importance of the values approach for promoting ethical practices in the governance and management of pharmaceuticals within ministries of health. At the same time the author fully recognizes the need to coordinate and integrate this approach with existing efforts to establish and enforce a legal framework that adequately addresses the problem of corruption within the context of each country.

The assessment instrument for measuring transparency, used during Phase I of the GGM, focuses mainly upon the components related to the disciplinary approach such as existing laws, regulations, policies and relevant administrative procedures. The technical recommendations arising from the transparency assessment should become an integral part of Phases II and III of national GGM programmes, and should be implemented in conjunction with the process of socializing the system of values and principles adopted by the national GGM framework. The complementary nature and mutual dependence of these two approaches must be taken into account in developing an effective national framework for good governance in the pharmaceutical sector.

3. Background to the Current Anti-corruption Movement

To understand the context in which the GGM programme is operating, it is useful to briefly review the historical background of the current anti-corruption movement and the existing Conventions related to it.

During the colonization period, Europeans in general adopted the “rule of geographical morality”(7,8) to justify the corrupt practices performed in their public and private dealings within the colonies. The “rule of geographical morality” is defined as “the norm by which a citizen of a country of the North may engage in acts of corruption in any country of the South, including bribery and extortion, without the attachment of any moral condemnation to those acts” (7). It is important to acknowledge that “the rule of geographical morality” is based on a world view that non-Christian, non-Western and non-white individuals are fundamentally immoral and corrupt when measured by European standards” (7). This rule, grounded in racist attitudes and beliefs, has been used by the North to justify its exploitation of the South for centuries and unfortunately its legacy continues to haunt the current anti-corruption movement.

During the decolonization period (1960-70), Western intellectuals developed the revisionist discourse and notions regarding corruption, based on concepts of cultural relativism. Revisionism perceives corruption as making a positive contribution to economic development and asserts “the unavoidable character of corruption at certain stages of development and the contributions of the practice to processes of modernization and development” (9). Revisionists argue that what is called corruption in developing countries of the South is nothing more than “violation(s) of western norms” (10). The amorality of the revisionist approach to corruption allowed transnational corporations and others to hide behind cultural relativism in order to justify their involvement in corrupt acts, including bribery of public officials in the former colonies” (7).

The current anti-corruption movement began to emerge after the end of the Cold War within the context of the process of globalization. It emphasizes the economic cost of corruption and relies on empirical evidence to prove that corruption “slows economic growth and serves as a heavy tax on investment” (11). The movement uses empirical evidence to prove that “corruption undermines political development and impedes the development of democracy and its institutions, as well as the promotion of the rule of law” (7). The Asian Development Bank (ADB) uses its research findings to refute the revisionist hypothesis:

“Graft and corruption have strongly affected development efforts negatively, belying the so-called “revisionist hypothesis” prevalent in the West which considers corruption as either a necessary step in the development process or a means of speeding it up. Instead (our research) found that corruption leads to unfair and inequitable distribution of scarce public resources, and the leakage of revenue from government coffers to private hands. Less directly, but no less perniciously, corruption leads to loss of confidence in government” (12).

The current anti-corruption movement is supported by a number of international and multinational initiatives including:

- The Inter-American Convention Against Corruption (OAS Convention) approved by 34 members of the Organization of American States in 1996
- The Organization 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 United Nations Convention against Corruption (UNCAC) adopted by the UN General Assembly on 31 October 2003 that entered into force on 14 December 2005.
- The World Economic Forum Partnering Against Corruption Initiative (PACI) that was formally launched by Chief Executive Officers from the Engineering & Construction, Energy and Metals and Mining industries in January 2004.

These anti-corruption conventions and initiatives 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 the UN Declaration is global in reach. Over 10 years have elapsed since the initiation of the OAS and OECD Conventions.

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 that 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” (13) official corruption. The OAS Convention is different from the OECD and the UN Anti-corruption Conventions because it is “not grounded principally on trade or economic concerns, but on morality and the need to protect democratic institutions” (7).

The primary aim of the OECD Convention is to establish the criminalization of bribery of foreign public official and to convince countries to legislate and implement laws to this standard. The 2007 Progress Report of the OECD, prepared by Transparency International, states that “Eight years after the Convention entered into force, its success is not yet assured. There is now significant enforcement in 14 countries, compared to 12 in the 2006 report and eight in the 2005 report. However, there has been little or no enforcement in 20 countries, demonstrating a serious lack of political commitment by over half of the signatories” (14). By 2007 there were 150 cases of corruption investigated and only a few convictions.

The process of enforcing UNCAC began in December 2005 and so is relatively recent. Over 140 signatory States participated in the UNCAC Conference held in Indonesia in January 2008. One of the key issues addressed was the need to establish adequate mechanisms for monitoring the enforcement of UNCAC, a need shared by the OAS and OECD Conventions, although valuable experience has already 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 the mechanisms that are

being applied to enforce the Conventions and to prevent corruption and the mechanisms for legal cooperation among states. Transparency International (14) recommends “government reports be based not only on a description of legal changes carried out but also on State practices and statistical information reflecting concrete results.” Systematic and rigorous peer review among signatories is also necessary. In order to avoid duplication of efforts, effective coordination between the Conventions must be established. Stronger measures are needed to ensure compliance by governments that have not shown the political will to prosecute foreign bribery.

Despite existing deficiencies and obstacles, the anti-corruption movement has gradually gained momentum during the last decade and it appears that significant progress will continue into the future. It is within the context of this movement and its spirit of reform that the GGM Programme draws great support for its activities in promoting good governance in the public pharmaceutical sector and builds upon the legal framework and mechanisms of enforcement established by the anti-corruption Conventions that have been ratified by the signatory States. Padideh Ala’i (7) affirms in her study that “the anti-corruption movement has come to the recognition that the moral aspect of corruption must be addressed and that any anti-corruption campaign cannot succeed until it addresses the internal, or moral and ethical, causes of corruption as well as the external, or economic and political, causes of corruption.”

4. Petty and Grand Corruption

There are two general types of corruption, often referred to as “petty” and “grand”. Petty corruption is a sort of small-scale corruption practiced 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. Although this type of corruption may seem of minor significance when compared to grand corruption, it can have an upward spiral effect when supervisors and higher-level officials demand a share of the bribes extorted. Petty corruption can have a profound debilitating effect on the integrity system of a nation and its existence is often a sign indicating the existence of grand corruption practiced by high-level public servants.

Grand corruption is large-scale and often involves large, international bribes and hidden overseas accounts. It is frequently fostered by exporters from countries (in particular, the 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. Both types of corruption, petty and grand, feed on each other and both must be vigorously addressed and eliminated.

5. The Specific Case of the Pharmaceutical Sector

Globally more than US\$ 3 trillion is spent on health services each year. The value of the global pharmaceutical market is estimated at over US\$ 600 billion. Such large amounts of money are an attractive target for abuse, making the pharmaceutical sector highly vulnerable to corruption and unethical practices. For instance, Transparency International estimates that 10 to 25% of public procurement spending is lost to corruption, and in some countries up to two thirds of often scarce medicine supplies at hospitals are lost through corruption and fraud.

This is in part due to the *high market value* of pharmaceutical products as described above. Also, the pharmaceutical sector is *highly regulated*. Poorly defined and documented processes, lack of checks and balances, as well as lack of transparency will increase vulnerability to corruption. Equally, if institutional checks are too cumbersome and slow down processes, clients may be tempted to offer a bribe or a gift "to get things done". Another factor making the pharmaceutical sector particularly vulnerable to corruption is the *information imbalance* between the 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.

5.1 Types of unethical behaviour

The pharmaceutical sector is a wide and complex sector - also referred to as the 'medicines chain' - and 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. Each step is vulnerable to corruption and involves different professional expertise, such as the medical profession (nurses, pharmacists, physicians, etc.), economists, lawyers and researchers. These can serve in governments, private pharmaceutical companies, academia or civil society organizations.

The medicines chain includes the following steps:

- Research and development of new medicines or chemical entities
- Conducting clinical trials
- Filing patents
- Manufacturing
- Registration
- Price fixing
- Licensing of professionals and establishments
- Selection of essential medicines
- Procurement
- Distribution
- Inspection of establishments
- Prescription
- Dispensing
- Pharmacovigilance
- Medicines promotion

Management of conflicts of interest

Conflicts of interest are often the motivating force generating unethical behaviour. Three types are frequently encountered in public institutions that tolerate corrupt behaviour, namely when a public servant:

- has vested personal interests in a particular company
- practices nepotism or cronyism when hiring personnel
- receives post-employment benefits from a contracted company.

When a government official or an expert serving on a government committee, for example for the registration of medicines, or the selection of essential medicines or tender committee, has a conflict of interest, he/she may put undue pressure and influence on the final decision of that committee to favour a particular company, instead of basing the decision on scientific evidence. Such practices include:

- special interest groups offering "incentives" to individuals or pressurizing public officials to include particular medicines on lists of medicines that may be procured or using misinformation to influence decision-making on procurement
- falsifying safety/efficacy data resulting from clinical trials.

Public institutions often limit their concern about unethical practices to these three forms of corrupt behaviour, by establishing policies and procedures that attempt to prevent these types of conflict of interest. Unfortunately other forms of corrupt practices exist that are sometimes ignored by public institutions, and which become part of the unofficial institutional culture. The following list represents the types of unethical behaviour that are at the heart of corruption in the management of pharmaceuticals.

Accepting or extorting bribes, kickbacks and/or gifts:

Bribery and gift giving are probably the most common forms of corruption in any sector and the pharmaceutical sector is no exception. They can be proactively offered to or extorted by public servants, for speeding up services or simply for making some services happen, for ignoring some information or the omission of other important information, or falsifying data.

Bribes or gifts can be offered at any step of the medicines chain, for example:

- **Registration:**
 - by suppliers to government officials to register medicines even though the required information has not been provided
 - by suppliers to government officials to speed up the process of drug registration
 - government officials will slow down registration procedures in order to pressurize suppliers into paying a bribe.
- **Selection of essential medicines:**
 - by suppliers to selection committee members to include the medicines they manufacture or import on the national essential medicines list.
- **Inspection:**
 - not including findings on medicines quality in inspection reports

- certification of a manufacturer that is not compliant with good manufacturing practices.
- **Medicines promotion:**
 - offering of bribes by suppliers to government officials to approve, for example, an unethical promotion campaign or materials
 - offering of bribes by companies to government officials to gain authorization for "pseudo" clinical trials that are a cover for marketing.
- **Procurement:**
 - bribery of public officials by suppliers to gain a monopoly position at the tendering stage or providing procurement contracts
 - not holding accountable suppliers who fail to deliver
 - gratuitous payment made to a person for referral of business.

Other forms of corruption or unethical practices

Mismanagement of conflict of interest and bribery are unethical practices that can be found throughout the medicines chain. Other abuses in pharmaceutical systems are also reported, which are in fact more specific to some steps of the chain, including:

- **Theft in the distribution chain:**
 - theft of medicines for personal use or diversion for private sector resale
 - pocketing money from the sale of medicines that were supposed to be supplied free of charge.
- **Collusion in procurement and price fixing:**
 - collusion in bid rigging during procurement by providing vendors with confidential and privileged information relating, for example, to price.
- **Favouritism:**
 - officials may favour the recruitment and/or promotion of family members (*nepotism*) or friends (*cronyism*) instead of basing their decision on professional merit
 - the same favours can be applied to selecting experts on committees.
- **State capture**
 - as in any other sector, outside interests can "bend" pharmaceutical laws, policies and regulations to their financial benefit through corrupt transactions with public officers and politicians. These laws and regulations can be extremely detrimental to public health objectives and outcomes.

Obviously these types of corrupt behaviour are not limited to the governance and management of pharmaceuticals. Unfortunately all sectors of society are vulnerable to some degree to such unethical practices. The development of an ethical framework for the governance and management of the pharmaceutical sector may be relevant for other sectors, just as the experience gained in other sectors in addressing ethical issues may provide important inputs in the area of pharmaceuticals.

5.2 Impact on the health system and health status

As stated, the pharmaceutical sector is particularly vulnerable to corruption and unethical practices. Determining the extent of this corruption is difficult, especially at the global level but some studies reveal figures at the national level. 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. Resources that could otherwise be used to buy medicines or recruit much-needed health professionals are wasted as a result of corruption, which reduces the availability of essential medicines and can cause prolonged illness and even deaths.

Corrupt and unethical practices in the pharmaceutical sector can have a significant impact on the health system and the health status of the population:

- a *health impact* as the waste of public resources reduces the government's capacity to provide good-quality essential medicines, and unsafe medical products proliferate on the market; it also leads to an increase in the irrational use of medicines
- an *economic impact* 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, representing potentially major financial loss
- an *image and trust impact* as inefficiency and lack of transparency reduce public institutions' credibility, erode the trust of the public and donors, and lower investments in countries.

6. Integrity System for Good Governance

Entrenched unethical practices in the governance of the pharmaceutical sector have been found throughout the medicines chain. The medicines chain consists of a series of sequential and interrelated stages and areas. Each area is potentially vulnerable to corruption, if proper procedures and ethical practices are not introduced and established. All the functions need to be protected from unethical practices to ensure that patients not only have the medicine they need, but also that the medicine is safe, of good quality, has an affordable price and has not been purchased as a result of undue commercial influence.

WHO and other organizations have prepared technical guidelines and manuals on the various areas of the medicines chain, which propose practical procedures for improving the efficiency and effectiveness of governance in the pharmaceutical sector. Many proposed procedures and policies are implicitly designed to prevent unethical practices and corruption, but in most cases the moral and ethical underpinnings of these procedures are not made explicit. To prevent and combat corruption effectively, these technical guidelines need to operate within an explicit framework of moral values and ethical principles that encourage ethical practices.

The concept of a “national integrity system” as promoted by Transparency International (TI) is an holistic approach that draws together “various strands and actors that collectively comprise the nation’s integrity system” (1) and is based on partnerships and coalition-building to contain corruption. As stated by Jeremy Pope, TI’s founder, “By adopting an holistic approach and by co-opting all the principal actors into the process of anti-corruption reform, a country or community can enhance its capacity to curtail corruption to manageable levels. But none of this can be tackled without enlightened and determined political leadership, without high levels of public awareness and support, and without a motivated and well-led private sector. In many countries, the most difficult element in the equation is that of developing a vibrant civil society willing and able to play a meaningful role in shaping its environment.” The development of a national integrity system as promoted by TI is probably the most comprehensive approach to reducing corruption in a sustainable manner. The TI Source Book for National Integrity System flags six areas for reform:

- Leadership
- Public programmes
- Government reorganization
- Law enforcement
- Public awareness
- The creation of institutions to prevent corruption.

The term “framework for good governance”, as used in this document, refers to the basic components required by the GGM programme to prevent and address the problem of corruption in the pharmaceutical sector, and does not refer to all the components of a “national integrity system” as proposed by TI. This is because some of the components are beyond the scope and influence of the GGM programme, such as those related to an elected legislature, an independent judicial system, and the role of an Auditor General. Nonetheless, the GGM programme does deal with aspects of each of the areas in need of reform identified

by TI. The framework proposed in this document integrates the top-down and bottom-up approaches necessary to promote good governance and to reduce corrupt practices. The basic components of the framework of the GGM programme are:

Values approach:

1. A system of moral values and ethical principles
2. A code of conduct
3. A programme for the systematic socialization of the moral values, ethical principles and code of conduct
4. Promotion of moral leadership

Disciplinary approach

a) outside the pharmaceutical sector

5. Established anti-corruption legislation
6. Mechanisms for whistle-blowing (ombudsman)
7. Sanctions on reprehensible acts based on anti-corruption legislation

b) within the pharmaceutical sector

8. Established management procedures, including internal and external financial audits
9. Collaboration between anti-corruption agencies, civil society organizations and the private sector
10. Management, coordination and evaluation of the good governance programme.

To be effective in addressing the problem of corruption, the GGM framework must integrate both the values approach and the discipline approach in a coherent and balanced system. The first component on the list is the system of moral values and ethical principles, which is considered to be the heart of the GGM framework.

Fukuyama (15) states that the “most effective organizations are based on communities of shared ethical values.” Bernardo Kliksberg (3) affirms that good governance is built upon “social capital” consisting of the basic elements of trust, associativity and good citizenship practices, all of which are the results of a shared system of moral values that motivate ethical behaviour. Thus, it is asserted that faithfulness to shared moral values and obedience to ethical principles form the basis of genuine transparency and accountability, which are essential for combating corruption and for the performance of good governance.

7. The Process of Constructing a Framework

The discipline approach to addressing corruption 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. The values approach has tended to be a bottom-up approach within institutions, based on consensus building on shared moral values and ethical principles. Participation of public servants in the process of consensus building generates a sense of ownership and personal identification with the moral values and ethical principles adopted, which is essential for creating the intrinsic motivation necessary for self-imposed adherence to the norms promoted by the framework.

Construction of a national framework for good governance in the public pharmaceutical sector requires consensus building through a consultation process about which components should be included. Formulating a national framework requires:

1. Participation of key actors and stakeholders in the review and analysis of the moral values, ethical principles and code of conduct proposed in this document, as a reference point for consideration and consultation.
2. Participation of key actors and stakeholders in the construction of a national framework designed to improve governance and management in the pharmaceutical sector. Existing legislation and relevant work done by other agencies should be considered as reference points in this process.
3. Official adoption and promotion, by the ministry of health, of a national framework for good governance for the pharmaceutical sector.

The basic need for consensus building makes it advisable to circulate a copy of the established framework periodically for review and revision. This would assure genuine participation and would motivate renewed commitment to applying the framework in the performance of public duties.

Cultural diversity tends to generate different nuances of understanding about the meaning of moral values. Nonetheless, for certain moral values there are relatively high degrees of consensus on their relevance and importance in addressing the issue of corruption. The components of the proposed framework were derived from a process of consensus building involving representatives of the pharmaceutical sectors and health ministries from eight Asian countries at a GGM seminar in Malaysia in 2006. The proposed framework is not considered final but is a working document designed to stimulate reflection and discussion as part of a consensus-building process in ministries of health.

8. Components of a Framework for Good Governance in the Public Pharmaceutical Sector

Despite the growing recognition that good governance requires an integrity system based on moral values and ethical principles, to date universal consensus has not been reached regarding which specific values and principles should be incorporated into the framework. The measures promoted by the anti-corruption movement reflect implicit values and principles that should be made explicit so that they can be consciously incorporated into an official framework along with other components that have been agreed upon through a consultative process of consensus building.

8.1 Moral values and ethical principles

The following statement by John Fletcher Moulton stimulates reflection as to the nature of self-imposed obedience to moral values and ethical principles and the challenge it represents to individual and collective integrity and to the development of true civilization:

“The real greatness of a nation, its true civilization is measured by the extent of this land of obedience to the unenforceable. It measures the extent to which a nation trusts its citizens, and its existence and area testify to the way they behave in response to that trust. Mere obedience to law does not measure the greatness of a nation. (Such obedience) can easily be obtained by a strong executive, and most easily of all from a timorous people. Nor is the license of behaviour which so often accompanies the absence of law, and which is miscalled liberty, a proof of greatness. The true test is the extent to which the individuals composing the nation can be trusted to obey self-imposed law.”ⁱ

Moral values relate to what is believed to be good and of primary importance to human civilization, and are often articulated as ideals. Moral values inform judgment by defining right from wrong, and good behaviour from bad. Ethical principles are the operational expression of moral values and provide guidance to decision-making and action. Along this same line of reasoning, Carol W. Lewis relates these concepts to public service: “ethical principles are guides to action; they operationalize values and cue behaviour befitting public service” (16).

The framework proposed in this document is based on four moral values that are believed to be essential for good governance: justice, truth, service to the common good and responsible trusteeship. Obviously there are many other moral values related to various aspects of human existence. But in order to provide a relatively clear and simple framework that can guide our learning about ethical governance in the pharmaceutical sector, these four values were selected because they were identified as core values that directly address prevailing moral weaknesses that create vulnerability to corruption.

ⁱ John Fletcher Moulton (1844-1921) was a renowned judge and barrister, appointed Counsellor of the United Kingdom during the reign of King Edward VII in 1906. This is a quote from a public speech given in 1920.

Under each moral value, basic ethical principles and precepts that are derived from them are listed. Some ethical principles are clearly derived from a specific moral value, while others may have their roots in more than one. This does not pose a problem. The purpose of grouping the principles under specific moral values is to facilitate an understanding of the moral grounding and orientation of ethical principles. When one perceives the relationship between an ethical principle and a cherished moral value, this awareness can generate the intrinsic motivation necessary for sustained application of ethical principles in the governance of the pharmaceutical sector and in other sectors as well. A conscious and sincere commitment to moral values is a source of motivation that is capable of sustaining efforts and perseverance in serving the common good. The power of intrinsic motivation should not be underestimated. Intrinsic motivation can empower public servants with a deep personal commitment to ethical principles that enables them to resist the materialistic inducements offered by corrupt practices.

The following conditions are considered to be basic requirements that ethical principles should fulfil in order to effectively guide decision-making. (Adapted from conditions proposed by John Rawls in his book *A Theory of Justice*) (17) .

- > **Principles should be general.** They should be stated in a general manner that does not limit their application with reference to specific individuals or associations. "Principles must be capable of serving a public charter of a well-ordered society in perpetuity and the knowledge of them must be open to individuals of any generation. Thus to understand these principles should not require a knowledge of contingent particulars, and surely not a reference to individuals or associations."
- > **Principles should be universal in application.** "They must hold for everyone in virtue of their being moral persons." In this context, the term "moral persons" refers to individuals who are committed to the application of principles based on moral values in making decisions and implementing them.
- > **Principles should be publicly known and accepted.** They should be accessible to public knowledge and subject to public scrutiny and debate. "The difference between this condition and that of universality is that the latter leads one to assess principles on the basis of their being intelligently and regularly followed by everyone. But it is possible that all should understand and follow a principle and yet this fact not be widely known or explicitly recognized."
- > **Principles should impose an ordering on conflicting demands.** "This requirement springs directly from the role of principles in adjusting competing demands." The ordering of competing demands requires the judicious prioritizing of values and the application of principles.
- > **Principles should have a condition of finality.** "The parties are to assess the system of principles as the final court of appeal in practical reasoning. There is no higher standard to which arguments in support of claims can be addressed; reasoning successfully from these principles is conclusive." This requires the development of the capability of moral reasoning, which is the capability to reason from abstract

general ethical principles to resolve conflicts that arise from moral dilemmas and ethical problems.

These five conditions assist in understanding the nature of ethical principles and may be used as criteria to assess the adequacy, relevance and validity of the ethical principles proposed in this document. These conditions provide a basis for understanding the main differences between an organization's ethical principles and administrative procedures. Ethical principles are more general and universal in nature, whereas administrative procedures are more specific and context bound. Ethical principles provide the framework for the development of practical operational procedures that accord with ethical practice and good governance.

A common challenge facing public servants in applying principles in formulating policies and in addressing specific issues is the lack of capacity for moral reasoning, which entails the ability to reason from a general abstract principle through to its application to a specific concrete problem. The capacity for moral reasoning is a basic capacity of moral leadership and it can be developed through training courses.

The ethical framework proposed in this document should not be considered definitive. It is rather a work in progress that can be used to stimulate reflection and consultation among key actors in the process of constructing national ethical frameworks adapted to the context and needs of specific countries, and articulated in a language and style that are culturally appropriate.

The application of all the values and principles delineated in this ethical framework are conducive to good governance. Some of the ethical principles specifically address issues related to transparency and accountability, which are necessary for preventing corrupt practices. Although the meaning and purpose of the values and ethical principles listed below may be clear and evident, brief clarification will be provided for each.

8.1.1 Justice/fairness

The following quote by John Rawls invites profound reflection on the nature of justice:

“Justice is the first virtue of social institutions, as truth is of systems of thought. A theory however elegant and economical must be rejected or revised if it is untrue; likewise laws and institutions no matter how efficient and well-arranged must be reformed or abolished if they are unjust... Therefore in a just society the liberties of equal citizens are taken as settled; the rights secured by justice are not subject to political bargaining or to the calculus of social interest... Being first virtues of human activities, truth and justice are uncompromising (17).”

Justice relates to the exercise of impartial judgment in determining the truth of facts and principles in making decisions that guide action. Justice is based on the two pillars of reward and punishment and is concerned with giving each his or her fair due of reward and/or punishment. The institutions of society should govern by principles of justice. For example, the application of the principle of consultation in the collective decision-making process is an operational expression of justice in human affairs (18), in that the consultative process allows for the diversity of perspectives and information to be considered in the making of just

decisions. The attainment of unity in diversity in society depends in great measure on the degree of the population's participation in collective decision-making through a consultative process. Thus, the consultative process is recognized as an essential requirement of just governance.

Fairness is the operational expression of justice on the individual level. The institutions of society administer justice on a collective level, while individuals attempt to be fair in their judgment and behaviour within their personal sphere of influence. Being fair implies the fulfilment of the individual moral responsibility to investigate truth independently and objectively in order to know through one's own knowledge and not through the knowledge of another. This concept of justice invokes the moral imperative to overcome prejudice and to search for truth in all things.

Ethical principles of justice/fairness (see Annex B)

- > Rule of law
- > Accountability for the proper exercise of authority and use of public resources
- > Equity in administering rewards and punishments
- > Equality of rights and opportunities
- > Participation in the consultative process for collective decision-making
- > Merit system in contracting personnel

8.1.2 Truth

This framework does not attempt to define truth, but rather emphasizes the vital importance of fulfilling the basic moral responsibility to search for truth, to recognize it once found and to faithfully abide by it in all human affairs. Faithfulness to truth is the basis of trustworthiness, integrity and honour for both the individual and society as a whole. This framework proposes that the search for truth should be made in at least two basic categories. The first is the search for the facts of contingent reality. Evidence-based decision-making is founded on the search for truth in the realm of provable facts. The second category has to do with the search for truth in the realm of ethical principles and moral values that are relevant to good governance. Unfortunately this category is often neglected in the decision-making process, which can lead to unethical and immoral behaviour. When the moral question is raised in the consultative process and the search for and application of ethical principles are pursued, a new dynamic is set in motion that can enhance the quality and wisdom of decisions and subsequent actions. Transparency and honesty regarding the facts and principles considered in the decisions related to the administration of public resources greatly enhance public trust.

Ethical principles of truth (see Annex C)

- > Truthfulness in reporting the facts
- > Honesty in managing resources
- > Evidence-based decision-making
- > Transparency of decision-making and resource management for public scrutiny
- > Safeguards for whistle-blowers

8.1.3 Service to the common good

Society should expect a public servant to fulfil the moral imperative to use his/her official position to serve the public interest. The honour and distinction of a public servant is based on having rendered outstanding and valuable services to the common good. This precept applies equally to public institutions and to the individual. Personal and institutional commitment to the core moral value of serving the common good is a source of intrinsic motivation, which is capable of sustaining the efforts and perseverance often required to promote social transformation and development. When a public servant uses his/her public position to serve personal self-interests, this behaviour tends to destroy the basis of public trust, which is an essential ingredient of the social capital required for effective governance. Disinterested and effective service to the common good is the ultimate basis of public trust.

Consensus-building on what is the common good is an evolving process. The common good is generally defined in terms of shared values, and as these change over time, the collective consensus regarding the common good will also change and evolve. A significant role of moral leadership in society has to do with constructing consensus on the shared core values that define the common good. A public servant has the moral responsibility to assure that services respond to the common good and to the highest interest of society. The quality of public servants' spirit of service forms an integral part of this value.

Ethical principles of service to the common good (see Annex D)

- > Consensus-building in relation to the common good
- > Application of human development indicators
- > Inclusiveness
- > Spirit of service
- > Respect for human dignity

8.1.4 Trusteeship

Good governance is based on public trust. A public institution cannot fulfil its role effectively without an adequate degree of public trust, which is granted to public servants and institutions that have demonstrated trustworthiness. An implicit social covenant/moral contract between public servants and society exists, and this has two parts. Society expects public servants, as trustees of public resources, to be trustworthy in the use of the power, authority and resources entrusted to their charge in serving the highest public interest. In turn, society has the responsibility to recognize the merit of trustworthy public servants and to provide them with adequate and fair remuneration in appreciation of their services.

Ethical principles of trusteehip (see Annex E)

- > Legal contract between government and public servant
- > Responsible stewardship
- > Efficient and effective service of the public interest
- > Transparency regarding possible and apparent conflict of interest
- > Recognition of merit and adequate remuneration
- > Safeguards for whistle-blowers

Although these four moral values and list of ethical principles may appear to be formidable and challenging to apply in an institutional context that traditionally tolerates corruption, the

magnitude of the task should not paralyse efforts for change. The systematic and faithful application of such principles will require public servants to exercise moral leadership in the process of transforming the institutions of society. Only through the exercise of genuine moral leadership, within an institution that is fully committed to implementing a system of moral values and ethical principles, will it be possible to eradicate corruption and renew institutional integrity and public trust. Such leadership will require the moral courage to persevere and to assume the risks that such a process of change will entail in establishing good governance. The process of institutional transformation and the subject of moral leadership are discussed in a later section on the socialization of the ethical framework and code of conduct.

8.2 A 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 (14) 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. The following code of conduct addresses the common types of corrupt behaviour listed above. The normative base for the code of conduct is the framework of four moral values and the principles derived from them.

- A public service is a trust that requires a public servant to place faithfulness to his/her moral contract with society and obedience to the laws and ethical principles above private gain.
- A public servant shall fulfil his/her lawful obligations to the government and the public with professionalism and integrity.
- A public servant shall perform his/her official duties with justice, truthfulness and with a spirit of service to the common good (public interest).
- A public servant shall perform his/her official duties with honesty, transparency and accountability.
- A public servant shall respect the rights of the public and of his/her colleagues.
- A public servant shall disclose unethical practice and corruption to appropriate authorities.
- A public servant shall avoid any actions that may create the appearance of violating the law or ethical principles promoted by this code of conduct.

A public servant who fulfils this code of conduct would as a consequence avoid situations of conflict of interest and unethical behaviour that lead to corruption. This code of conduct attempts to use language that is affirmative in describing the expected behaviour of a public servant, and states what a public servant should do.

Some government agencies stipulate explicitly in their code of conduct what a public servant should not do in relation to the types of unethical and corrupt behaviour that often prevail.

Although these rules are implicit in the code of conduct above, they are made explicit to avoid any ambiguity or misinterpretation. Examples of some of the most noteworthy are:

- A public servant shall not hold financial interests that conflict with the conscientious performance of official duties.
- A public servant shall not give preferential treatment to any private organization or individual.
- A public servant should not engage in financial transactions using non-public government information or allow the improper use of such information to further any private interest.
- A public servant shall not bring his/her institution into disrepute through his/her private activities.
- A public servant shall avoid any actions that create the appearance that they are violating the law or the ethical principles promoted by this code of conduct.

Public servants' conscientious adherence to an appropriate code of conduct in the performance of their public duties in each stage and area of the medicines chain would result in the prevention of unethical practices and corruption.

The administrative structures and procedures for managing the medicines chain should be framed within a moral and ethical framework. This requires a rigorous level of analysis and moral reasoning for appropriate application of ethical principles in the design and operation of procedures. This task should be a central activity in securing ethical coherence between the code of conduct and procedures and practices.

8.3 The socialization of moral values, ethical principles and code of conduct

The term “socialization” is used in sociology to refer to “the process by which we learn to become members of society, both by internalizing the norms and values of society, and also by learning to perform our social roles (as worker, citizen, and so forth).”¹ In the context of this document the term refers to the process by which moral values, ethical principles and a code of conduct can be learned, internalized, applied and promoted by a group of key actors within the pharmaceutical sector of ministries of health until they become fully integrated into the institutional culture. Some of the key elements of the process are:

- Consciousness-raising on the need for moral values, ethical principles and a code of conduct.
- Transformation of dysfunctional mental models that get in the way of individual and collective learning (change of prevailing mentality).
- Conscious and willing adoption and internalization of moral values, ethical principles and code of conduct on personal and collective levels through processes of consultation and learning.
- Development of intrinsic motivation for the consistent application of moral values, ethical principles and code of conduct in personal and professional life.

¹ Gordon Marshall

- Advocacy of moral values, ethical principles and code through the genuine moral leadership of key actors.

a) Consciousness-raising activities

A major element of the socialization process concerns raising the awareness of key actors about the importance of the issue of corruption, and the need to develop and apply moral values, ethical principles and code of conduct. Some activities that could facilitate consciousness-raising on the issues are:

1. Share information related to the findings of the transparency study that depict the nature and dimensions of the issues.
2. Facilitate critical thinking and consultation about the key issues.
3. Stimulate an acute awareness of the gap between what is and what should be: current reality and ideal reality.
4. Promote a growing sense of moral imperative to assume individual and collective responsibility to improve the situation.

b) Transforming dysfunctional mental models

The collective mentality that prevails within an institution on the issue of corruption can often become a formidable obstacle to positive change, especially when it consists of dysfunctional mental models (19) that sustain patterns of unethical practices and an institutional culture that tolerates corruption as an inevitable evil.

Activities that can facilitate the process of transforming dysfunctional mental modelsⁱ that could hinder the socialization process of moral values, ethical principles and code of conduct are:

1. Raise awareness of specific dysfunctional mental models that will hinder the adoption of moral values, ethical principles and code of conduct.
2. Facilitate critical analysis of the elements of a dysfunctional mental model: underlying assumptions, concepts, prejudices, beliefs, attitudes, etc. This activity will provoke a sort of existential crisis regarding prevailing dysfunctional ways of thinking and behaving, which should foster openness to change.
3. Facilitate critical analysis and construction of new conceptual frameworks to replace dysfunctional mental models related to corruption, moral values, ethical principles, moral leadership, etc.
4. Adopt and apply new conceptual frameworks that foster the process of learning and transformation.

c) Development of intrinsic motivation

The application of moral values, ethical principles and observance of a code of conduct require intrinsic motivation based on personal commitment to the moral values and ethical principles upon which the framework and code are derived. This type of commitment coupled with conscious knowledge about the serious harm produced by corruption can serve to motivate sustained efforts towards change. The development of intrinsic motivation

requires the systematic and sustained promotion of the framework and code through diverse activities, such as:

1. Conferences and workshops
2. Pamphlets that explain the ethical framework and code of conduct
3. Articles in newspapers and institutional bulletins
4. Posters
5. Formal recognition and appreciation of ethical conduct
6. Educational videos
7. Periodic motivational talks by institutional authorities

8.4 Moral leadership training

The exercise of highly committed leadership is essential for the effective functioning of an integrity system and the application of a framework for good governance. In the current anti-corruption discourse increasing mention is being made regarding the vital importance of leadership in promoting reform. Different terms are used in reference to the type of leadership required, such terms as ethical leadership, values based leadership and principled-based leadership are being used. The underlying concepts behind these terms have common ground in that they emphasize the importance of the moral dimension of leadership. This common base reaffirms the growing consensus that moral leadership is needed for promoting good governance and for fighting against corruption (20).

The proposed conceptual framework of moral leadership is straightforward and simple. It consists of six basic elements and capabilities that have characterized great leaders from the diverse nations of the world, those social actors who left their tracks in history by contributing to positive social transformation in the development of human civilization (21,22).

The basic elements of the conceptual framework are:

- > An overarching life orientation of service to the common good (23)
- > Bold initiative and sustained perseverance in promoting processes of personal transformation and processes of social transformation
- > A humble learning attitude in fulfilling the moral responsibility to search for truth and to faithfully apply it in all the dimensions of one's life (24)
- > Commitment to moral values and ethical principles that are conducive to the betterment of the world (25, 26)
- > Belief in the potential goodness and nobility of human nature
- > Capacity for transcendence and renewal through vision.

Each of these elements requires a discussion and exposition that goes beyond the intention and scope of this reflection document. Although these elements may appear to be too idealistic and impractical for today's world, yet history demonstrates that these six characteristics are the key ones that distinguished the lives of those who have led processes of positive social change and development. It has been aptly stated that the current leadership crisis in the world is not due to a lack of people who want to lead, but rather to the lack of people willing to exercise moral leadership. The application of this conceptual framework requires the development of 18 specific capabilities that are grouped in three

categories (39):

- > Capabilities that facilitate personal transformation
- > Capabilities that enhance interpersonal relationships and team work
- > Capabilities that facilitate social transformation.

The development and exercise of these capabilities empower individuals to become effective change agents (see Annex F: Capabilities of moral leadership (21)). When the capabilities are exercised within the context of the conceptual framework, they are then endowed with moral quality. These same capabilities can be used to promote corrupt practices. This is why both the conceptual framework and the capabilities must be developed together through a series of seminars and training workshops.

It is important to emphasize that the exercise of moral leadership is not limited to those individuals in positions of authority within an organization, but rather it is a concept based on the notion of shared leadership that encourages and enables every individual of an organization and community to exercise moral leadership within his/her sphere of responsibility and influence at whatever level that may be. Experience in moral leadership training among CSOs and municipal governments has demonstrated that those public servants who strive to exercise moral leadership in their lives become motivated to apply an ethical framework and to comply with a code of conduct and thus set an example for others to follow.

8.5 Enforcement of existing anti-corruption legislation

The GGM programme draws on the existing anti-corruption legislation in each county for support of the integrity system and the implementation of administrative and technical measures. Thanks to the activities of the anti-corruption movement and the international anti-corruption Conventions, in many countries there is an emerging a spirit of reform and a growing receptivity to address the problem of corruption.

It is not an objective of the GGM programme to promote the establishment of anti-corruption legislation, but rather to promote the enforcement of existing legislation to protect whistle-blowers and to sanction those who commit corrupt acts. It is necessary to assess the anti-corruption legislation of each country to determine its adequacy as a deterrent to corrupt practice.

8.6 Whistle-blowing

Most cases of responsible whistle-blowing 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 whistle-blowing is set up to protect the whistle-blower from victimization and retaliation by those who perform corrupt practices. On the other hand the mechanism should protect public servants from irresponsible and unethical whistle-blowing that could damage their reputations and careers due to false allegations.

For this reason there should be rigorous conditions set for acceptable whistle-blowing, and the following have been proposed:

- Deal with serious problems
- Be supported by unequivocal evidence
- Come only after internal channels have been exhausted
- Be likely to obtain satisfactory results.

In some countries a Public Sector Integrity Commissioner has been appointed, who provides a place for "blowing the whistle" outside a person's own department or agency but still within public services. Therefore, depending on countries, such a mechanism can be either set up within the pharmaceutical services, or within the Ministry of Health or also outside health services.

The mechanisms and procedures for whistle-blowing are a key component of an integrity system, which require further analysis and discussion that goes beyond the scope of this document.

8.7 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: 1) those consisting of internal sanctions implemented by the institution and 2) those consisting of external legal sanctions implemented by the legal system and law enforcement. 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. The Convention's related to the anti-corruption movement criminalize acts of corruption and propose legal sanctions for such acts. The existing legal and administrative sanctions should be studied to be 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) (14).

8.8 Improving the management system

The GGM programme initiates a transparency assessment in order to identify weak points in the management system of the medicines chain that are vulnerable to corruption. The report of the transparency assessment 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 it 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 report of the assessment provides a positive entry point to address the difficult issue of corruption in a non-threatening manner.

On the basis of the findings produced by the transparency assessment, administrative and technical recommendations are presented to the MOH for review, approval and implementation. One of the principal objectives of the socialization process of the GGM programme is to provide the technical support and training needed to improve the public

pharmaceutical sector's management system. Although the context of each MOH is different there are some weaknesses that seem to be common and that require the application of standard administrative and technical measures for improvement.

The internal and external auditing of the financial management of the public pharmaceutical sector must would have to be in accordance with standards established by government legislation and good auditing procedures.

8.9 Inter-institutional collaboration in the anti-corruption movement

The GGM programme cannot succeed in achieving its objectives without effective collaboration and coordination of efforts with other agencies. The GGM programme Task Force will have to be proactive in establishing alliances and partnerships with other agencies that are promoting good governance and/or are working on the problem of corruption. Collaborative agreements should be established that clearly define roles and responsibilities of each partner, mechanisms for communication and coordination, and protocols for information and resource sharing. Collaborative agreements can assist in avoiding overlap and the duplication of efforts. Such agreements would allow the GGM programme to benefit from the advances made by other agencies. Entering into collaborative agreements will require political will and leadership from the MOH and other agencies.

8.10 Management and evaluation of the GGM programme

The effective coordination, management and evaluation of a GGM programme within a MOH require a team of trained human resources and adequate logistical support. If a MOH does not have a system in place promoting transparency and good governance practices, then the GGM programme Task Force team should be given the authority and support necessary to carry out those activities pertaining to the integrity system that have direct bearing on the GGM programme. But, eventually the GGM programme would have to develop capacity to respond to the needs of other departments within the MOH, which would require additional personnel and logistical support. The set of responsibilities and activities of the GGM 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 the other that has expertise in facilitating the process of socializing institutional values and in designing and implementing training programmes for personnel in management and leadership. Suggested terms of reference (TOR) for this type of Task Force are included in Annex B.

9. The Role of Civil Society Organizations and the Media

Civil society organizations (CSOs), such as Transparency International, Procurement Watch, Oxfam G.B. and others, have provided valuable institutional moral leadership in the anti-corruption movement. They have raised their voices as whistle-blowers when necessary and have played important roles as independent monitors and assessors of the enforcement process of the anti-corruption Conventions. CSOs should be encouraged and supported to continue playing these vital roles. Although the voice of CSOs has become stronger during the last decade, the capacity of the State to listen and respond to the voice of civil society must also be strengthened so that collaborative efforts can emerge to promote good governance.

Another important role of CSOs is the promotion of values in society related to human rights, the environment and social well-being. In one sense, CSOs fulfil the role of moral conscience in society and safeguard society from the abuses of government and the private sector.

An independent free press and other forms of media such as radio and television play an important role in raising public awareness about the gravity of the problem of corruption and in keeping the public informed about the progress or lack of progress in enforcing the anti-corruption Conventions. Informed public opinion can be a powerful force in mobilizing political will for change. Political leaders in democratic governments are learning that they cannot ignore the voice of the people and expect to win elections.

10. Role of 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 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 are not overly 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 they 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 are only elements of a marketing strategy to improve corporate image.

Clearly the public sector, civil society and the private sector must join forces to solve the problem of corruption. WHO is a global public institution that has the mandate to serve its Member States and their ministries of health throughout the world. Due to this mandate, the GGM programme has focused primarily on the role of MOHs in taking measures within the public pharmaceutical sector to establish good governance and to prevent corruption, and has left the job of working with the corporate world to those anti-corruption agencies best suited for this task. Therefore the focus and scope of this reflection document has been limited to the public pharmaceutical sector.

11. Political Will

As mentioned previously, the lack of political will shown by the majority of signatory States to enforce the legal standards stipulated by the OECD Convention has been a major obstacle to the success of the anti-corruption campaign. Although there has been a gradual increase each year in the number of signatory States complying with the Convention, acceleration of this trend will require mobilization of political will in each of them. Obviously the same is true for the enforcement of the OAS and the UN Anti-corruption Conventions. Such mobilization requires a series of activities carried out by diverse stakeholders, for example:

- Systematic monitoring of the enforcement process by CSOs in each country and progress reports made available for public scrutiny. Press coverage regarding the problem of corruption and the progress of the enforcement process to build public awareness and demand for enforcement.
- Peer group pressure among signatory countries for enforcement.
- Stronger enforcement measures established and applied by OAS, the OECD, Committee on International Business Enterprises (CIME) and the UN Office on Drugs and Crimes (UNODC) in regards to their respective Conventions.
- Development of moral leadership capabilities of public servants through training workshops.
- Operation of an national integrity system that fosters the good governance of public institutions.
- Systematic promotion and socialization of moral values and ethical principles with public institutions.
- Technical support provided by OAS, OECD and UNODC and other programmes.
- The creation of a partnership between government and civil society (including the private sector, professions and religious organizations).

The mobilization of political will is a complex process consisting of diverse influences and forces operating simultaneously. Leadership is required to facilitate the alignment of these forces into a sustainable and effective anti-corruption campaign capable of mobilizing sufficient political will for its success at national level.

The GGM programme is focused on promoting good governance in the public pharmaceutical sector within Ministries of Health (MOH). 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 on behalf of the MOH for the implementation of the programme in the public pharmaceutical sector and of the allocation of funds in MOH annual operating budget for the sustained operation of the programme. The ideal scenario would be to attain “a clear commitment by political leaders to combat corruption wherever it

occurs and to submit themselves to scrutiny (revisiting the need for immunities and privileges°which°may°shield°some°from°legal°process)”(14).

12. Conclusion

The development and management of an integrity system within the pharmaceutical sector of a ministry of health is a process that requires the concomitant development of the components of the integrity system, the administrative capabilities, and the moral leadership necessary for its sustained and effective operation. There is no easy and quick solution to the problem of corruption in the pharmaceutical sector. Establishing ethical practices in the governance of this sector requires the creation of an effective integrity system, which necessitates the 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 in resources is to occur.

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

¹ Saying attributed to Mahatma Ghandi

GOVERNANCE & GOOD GOVERNANCE SOME DEFINITIONS

<p>World Bank</p>	<p>Governance can be broadly defined as the set of traditions and institutions by which authority in a country is exercised. This includes (1) the process by which governments are selected, monitored and replaced, (2) the capacity of the government to effectively formulate and implement sound policies, and (3) the respect of citizens and the state for the institutions that govern economic and social interactions among them.</p> <p>The Worldwide Governance Indicators (WGI) project reports aggregate and individual governance indicators for 212 countries and territories over the period 1996–2006, for six dimensions of governance:</p> <ul style="list-style-type: none"> - Voice and Accountability - Political Stability and Absence of Violence - Government Effectiveness - Regulatory Quality - Rule of Law - Control of Corruption <p>http://info.worldbank.org/governance/wgi2007/</p>
<p>OECD</p>	<p>Good Governance is about achieving better policy outcomes and building trust in government.</p> <p>http://www.oecd.org/dataoecd/23/58/39790456.pdf</p>
<p>WHO Health Systems</p>	<p>Leadership and governance involves ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system-design and accountability</p> <p>http://www.who.int/healthsystems/topics/en/index.html</p> <p>The leadership and governance of health systems, also called stewardship, is arguably the most complex but critical building block of any health system. It is about the role of the government in health and its relation to other actors whose activities impact on health. This involves overseeing and guiding the whole health system, private as well as public, in order to protect the public interest. It requires both political and technical action, because it involves reconciling competing demands for limited resources, in changing circumstances, for example, with rising expectations, more pluralistic societies, decentralization or a growing private sector. There is increased attention to corruption, and calls for a more human rights based approach to health. There is no blueprint for effective health leadership and governance. While ultimately it is the responsibility of government, this does not mean all leadership and governance functions have to be carried out by central ministries of health.</p> <p>http://www.who.int/healthsystems/strategy/everybodys_business.pdf</p>

<p>Wikipedia</p>	<p>The terms <u>governance</u> and good governance are increasingly being used in <u>development</u> literature. <u>Governance</u> describes the process of decision-making and the process by which decisions are implemented (or not implemented). Hereby, public institutions conduct public affairs, manage public resources, and guarantee the realization of human rights. Good governance accomplishes this in a manner essentially free of abuse and <u>corruption</u>, and with due regard for the <u>rule of law</u>.</p> <p>Good governance defines an ideal which is difficult to achieve in its totality. However, to ensure sustainable human development, actions must be taken to work towards this ideal. Major donors and international financial institutions, like the <u>IMF</u> or <u>World Bank</u>, are increasingly basing their <u>aid</u> and loans on the condition that reforms ensuring good governance are undertaken.</p> <p>http://en.wikipedia.org/wiki/Good_governance</p>
<p>U4 Utstein</p>	<p>For most donors, good governance equals democratic government, and anti-corruption work tends to be placed within an overall strategy of assistance for democratisation efforts, which also includes related themes such as enhanced participation, strengthening of the rule of law, multi-party elections, institution building and making governments more accountable to their electorates. This is not to suggest that all donors share the same priorities or that approaches towards good governance within the donor community are identical, but there are similarities. These include helping to promote competition among political parties, high levels of participation and sufficient levels of civil^oand^opolitical^oliberties.</p> <p>Good governance is also about effective and efficient management - the way that governments manage their resources and responsibilities.</p> <p>Frequently Asked Questions: http://www.u4.no/helpdesk/faq/faqs4.cfm</p>
<p>UNESCAP</p>	<p>Good governance has 8 major characteristics. It is participatory, consensus oriented, accountable, transparent, responsive, effective and efficient, equitable and inclusive and follows the rule of law. It assures that corruption is minimized, the views of minorities are taken into account and that the voices of the most vulnerable in society are heard in decision-making. It is also responsive to the present and future needs of society.</p> <div data-bbox="363 1429 1380 2004" data-label="Diagram"> <p>The diagram consists of a central octagon with the words 'GOOD GOVERNANCE' written inside. Surrounding the octagon are eight text labels, each positioned near one of the octagon's vertices. Starting from the top and moving clockwise, the labels are: 'Consensus oriented', 'Accountable', 'Transparent', 'Responsive', 'Equitable and inclusive', 'Effective and Efficient', 'Follows the rule of law', and 'Participatory'.</p> </div> <p>http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing/gg/governance.asp</p>

Annex B

Ethical principles of justice/fairness

- > **Rule of law:** a legal order is a system of public rules “addressed to rational persons for the purpose of regulating their conduct and providing a framework for social cooperation. When these rules are just they establish a basis for legitimate expectations. They constitute the grounds upon which persons can rely on one another and rightly object when their expectations are not fulfilled”(17). The governance and administration of any social enterprise must be realized within the framework provided by the rule of law. This precept establishes the obligation of individual and collective obedience to the system of public rules that define the legal limits of what can and cannot be done. Obviously, disobedience to the law leads to corrupt and criminal behaviour. Thus, a first question that should be asked when formulating governance policies and administrative procedures is whether or not they fulfil the legal requirement of the rule of law.

- > **Accountability for the proper exercise of authority and use of public resources:** a basic precept of justice is that people should be held legally and morally accountable for the fulfilment or lack of fulfilment of their contractual responsibilities. Such accountability provides a means of safeguarding society from possible abuses of authority and mismanagement of public resources by public servants. Formal procedures and contracts must be established to assure responsible, transparent and legal accountability.

- > **Equity in administering rewards and punishments:** justice is built upon the fair administration of reward and punishment in accordance with the merit of an individual’s or an organization’s behaviour. Thus the equitable degree of reward or punishment may vary in accordance with the just assessment of each case, on the principle of each according to their due.

- > **Equality of rights and opportunities:** this principle provides a "level playing field" for all without any bias caused by favouritism or prejudice. It protects the right of each to participate and allows for an equal starting point of opportunity. The application of this principle secures equal access to public services to all members of society. The universal application of this principle would prevent the injustices resulting from the various forms of prejudice prevailing in society.

- > **Participation in the consultative process for collective decision-making:** consultation is the operational expression of justice in human affairs, because it is through the consultative process that the diversity of views and voices within a social organization can be heard and taken into account in the process of collective decision-making. This allows decisions to reflect truthfully and justly the needs and aspirations of the members of the society. It is only just that the members of a society have the means to participate in making the decisions that affect their lives. The application of the principle of consultation provides such a means.

- > **Merit system in contracting personnel:** the public suffer a serious injustice when unqualified and incompetent people are hired to perform public services. Such hiring practices, when based on political cronyism and/or nepotism, are a form of corruption that tends to lead to other forms of corruption related to mismanagement of public resources and abuse of authority. The disciplined and systematic application of the principle of merit in contracting public employees can have a significant effect in preventing corruption in this area, and can assist significantly in improving the efficiency, effectiveness and quality of public services.

Annex C

Ethical principles of truth

- > **Truthfulness in reporting the facts:** at the heart of corruption is the intentional misrepresentation of truth. Social progress and development cannot be achieved by decisions based on lies. The effective planning and evaluation of a project or programme must be based on a truthful presentation of relevant facts and indicators. The truthful presentation of facts in financial reporting is absolutely essential in monitoring and verifying the integrity of financial management. Truthfulness is the foundation stone of trustworthiness.
- > **Honesty in managing resources:** the old dictum that honesty is the best policy is still true today, but unfortunately not universally applied. Stealing, the acceptance of bribes and lying are forms of dishonesty that contribute to corruption. When a public servant steals public resources, he/she is essentially committing a dishonest act that claims ownership of a resource that does not rightfully belong to him/her. Dishonest behaviour by public servants creates public distrust towards the institutions that are supposed to serve society.
- > **Evidence-based decision-making:** decisions that affect the public interest should be substantiated by appropriate, reliable and provable evidence. Rigorous truth seeking should be exercised in gathering the facts and in identifying the principles upon which decisions should be made.
- > **Transparency of decision-making and resource management for public scrutiny:** the processes and procedures for decision-making and for resource management should be documented and made accessible for public scrutiny. Such transparency enhances public trust, allows for the opportune identification of potential vulnerability of the integrity system to possible acts of corruption and permits the timely application of corrective measures.
- > **Safeguards for whistle-blowers:** whistle-blowing on acts of corruption often entails personal risks for the whistle-blower. Individuals, who have the integrity and moral courage to stand up against corruption by stating the truth, should be protected from possible retaliation towards them and their families by those who are corrupt. Such safeguards will encourage honest and truthful public servants to come forward with vital information necessary to combat corruption.

Ethical principles of service to the common good

- > **Consensus-building in relation to the common good:** the application of the principle of building consensus regarding the common good is essential for creating the basis for unity in diversity within society. A clear notion of the common good is necessary to orient the governance of social institutions and for the formulation of social policies. Each social institution must fulfil its role in serving the common good. Social service projects and programmes should ultimately be evaluated in terms of the degree to which they serve the common good and in terms of their coherence with the values that define the common good. Obviously corruption does not serve the common good, but rather undermines it. Commitment to upholding the common good should be public servants' primary motive for combating corruption.
- > **Application of human development indicators:** the evaluation of service to the common good should be based on human development indicators such as those used by the United Nations Development Programme to evaluate the development progress of nations. Unfortunately the evaluation of socio-economic development programmes and projects tends to restrict the focus to assessing indicators related to economic growth, which do not measure impact in terms of human development and service to the common good.
- > **Inclusiveness:** public services should be inclusive and should serve all equally. This requires a fundamental recognition by public institutions and public servants of the reality of the oneness of humanity. Such recognition and sincere acknowledgement of the implications of the oneness of humanity require an essential restructuring of society, as they do not allow for any discrimination caused by prejudice (whether in terms of gender, ethnicity, religious difference, social class, etc.). The principle of inclusiveness relates to basic social justice in service to the common good.
- > **Spirit of service:** if public servants are to effectively serve the common good they must develop a true spirit of service. This requires a fundamental change in the bureaucratic mentality that prevails in most public institutions. Acts of corruption are the opposite of work completed in the spirit of service.
- > **Respect for human dignity:** public services should not be provided in a manner that destroys the sense of human dignity. People should not be made to feel ignorant or inferior when receiving services. They should not be coerced to pay bribes in order to receive public services, as this practice makes them participants in corruption, which erodes their human dignity. If a public service is offered in a manner that destroys human dignity, then in reality it is not a public service. People should be served in a manner that genuinely respects and enhances their human dignity

Ethical principles of trusteeship

- > **Legal contract between government and public servant:** as an employee of the government a public servant enters into a legal contract to perform professional services on behalf of the public interest. By entering into a contractual relationship with the government, the public servant is held legally accountable to fulfil the terms of the contract related to his/her professional services under the rule of law. The implications of the legal dimension of the principle of trusteeship are important when dealing with issues of corruption.
- > **Responsible stewardship:** the principle of stewardship makes explicit an implicit moral covenant that exists between society and a public servant to render responsible stewardship in exercising public authority and managing public resources. The implicit moral covenant that underlies responsible stewardship commits, on the one hand, the public servant to serve the highest interest of society and the common good to the best of his/her knowledge and capacity and, on the other, commits society to appreciate and support these services both monetarily and morally. It is the commitment to fulfil the role of responsible stewardship that often motivates a public servant to become a whistle-blower and to stand against corrupt practices.
- > **Efficient and effective service of the public interest:** the fulfilment of the role of trusteeship requires the efficient and effective use of public resources in the service of the public interest and the common good. This principle runs contrary to corrupt practices that utilize public resources for personal interests rather than for the public good. The systematic monitoring and evaluation of the efficient delivery of services and their impact are an essential responsibility of trusteeship.
- > **Transparency regarding possible and apparent conflict of interest:** the effective exercise of the role of trusteeship can be undermined when potential and/or real personal conflicts of interest exist. Transparency in terms of potential personal conflicts of interest of a public servant in performing his/her functions is essential. Mechanisms and procedures must be established to secure transparency, such as official Conflict of Interest declarations.
- > **Recognition of merit and adequate remuneration:** a justification commonly given for the unethical practice of extracting bribes in public institutions in many countries is the low remuneration that public employees receive. Public employees often rationalize the unethical practice by seeing it as a means of augmenting their low salaries. Unfortunately this type of corruption is often tolerated by the institutional culture of public institutions. For this situation to change, governments and society at large need to value and appreciate the trusteeship role exercised by public servants and to provide adequate remuneration for their services. The salaries of civil servants and political leaders should adequately reflect the responsibilities of their posts and should be as comparable as possible with those in the private sector.

Capabilities for moral leadership

An active conception of moral leadership encompasses a new concept of the moral person, beyond a traditional passive definition to one of an individual who has become a social actor and is consciously and actively engaged in the processes of personal and social transformation.

Capabilities for moral leadership consist of an integration of concepts, skills, attitudes, and qualities which enable and empower one to carry out actions contributing to transformation and the promotion of the common good. They can be categorized into three groups: personal, interpersonal and social. Within these groups, 18 capabilities have been identified. As they are closely interrelated, these divisions and the order in which the capabilities have been listed are of a somewhat arbitrary nature. Although not meant to be a definitive list, the capabilities listed are presented as highly relevant to the development of moral leadership.

1. Capabilities that facilitate personal transformation

- > The capability to evaluate ones strengths and weaknesses without involving the ego: self-evaluation
- > The capability to learn based on the systematic reflection on action within a coherent and evolving conceptual framework
- > The capability to take initiative in a creative and disciplined manner
- > The capability to persevere in achievement of goals and objectives
- > The capability to oppose ones lower passions and negative impulses by concentrating ones mind on higher and noble purposes

2. Capabilities that facilitate interpersonal relationships (team work)

- > The capability to participate effectively in consultation for collective decision-making
- > The capability to build consensus in constructing a shared vision
- > The capability to encourage the heart of others (motivate and inspire)
- > The capability to mediate the resolution of conflicts
- > The capability to promote unity in diversity

3. Capabilities that facilitate social transformation

- > The capability to promote and establish justice
- > The capability to comprehend and transform relationships of domination towards relationships of collaboration, complementarity and mutual service
- > The capability to understand and interpret current events within an appropriate historical perspective
- > The capability to construct consensus about the common good by means of dialogue and consultation

Terms of reference (TOR) for a GGM Task Force

The GGM Task Force will be responsible for the overall coordination, management and evaluation of the national GGM programme. Its main tasks will include:

1. Manage the national consultations process necessary to:
 - a. Share the results of the national assessments measuring transparency and vulnerability to corruption in the public pharmaceutical sector and
 - b. Develop the national GGM framework
 - c. Implement the national GGM programme.
2. Follow-up and act upon the recommendations made in the national assessments report measuring transparency and vulnerability to corruption.
3. Coordinate the development and adoption of the national GGM framework for promoting good governance in the public pharmaceutical sector.
4. Coordinate the development and adoption of the code of conduct.
5. Socialize the national ethical framework and the code of conduct.

Some countries have decided to have two types of responsible groups for their national GGM programme:

- A *GGM Steering Committee*, headed by high-level officials from the Ministry of Health, such as the Minister of Health and/or Head of the Medicines Regulatory Authority. Other members represent the key functions of the various stakeholders in the pharmaceutical sector (Head of Procurement Office, private sector representative, consumers' representative, etc.). The Steering Committee sets the strategic directions of the GGM work in the country, including approval and adoption of all documents (e.g. transparency assessment report, national GGM framework, national GGM plan of action) and other deliverables prepared by the national GGM Task Force.
- A *GGM Task Force*, appointed by the Ministry of Health and the GGM Steering Committee will be responsible for the coordination, management and evaluation of the national GGM programme as mentioned in the above TOR. The members of this Task Force usually, but not always, include the national assessors who carried out the transparency assessment during Phase I, representatives from the key functions of the MOH pharmaceutical services (policy, regulation and procurement) and WHO country office staff.

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