Ethical Infrastructure
for Good Governance in the
Public Pharmaceutical Sector

Working draft
for field testing and revision
November 2006

Dr Eloy Anello
(WHO consultant)

World Health Organization

Department of Medicines Policy and Standards (PSM)

Contents

1.   The problem of corruption

Increasingly development agencies recognize corruption as the single greatest obstacle to economic and social development. The hyper-corruption that prevails in many countries is a clear indicator of the profound moral crisis that civilization is experiencing. The social injustices and the scandalous 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 time-honoured institutions of society 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.

Transparency International defines corruption as: *"the abuse of entrusted power for private gain."* 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 reflection document focuses on the values approach for promoting ethical practices in the governance and management of pharmaceuticals within ministries of health. It fully recognizes the need to coordinate and integrate such endeavours with existing legislative efforts to establish a legal framework and ethical infrastructure that adequately address the problem of corruption within the context of each country.

Although this document's primary focus is on the components related to the values approach, some key components of the disciplinary approach will be briefly discussed. For example, the research instrument for measuring transparency[1] focuses mainly upon the components related to the disciplinary approach to existing policies and relevant administrative procedures. The recommendations arising from the transparency assessment should be implemented first. The complementary nature and mutual dependence of these two approaches must be taken into account in developing an effective ethical infrastructure.

1.1   Specific case of the pharmaceutical sector

Globally more than US$ 3 trillion is spent on health services each year, with pharmaceutical expenditure accounting for up to 25-65% of total health expenditure in some developing

---

[1]   WHO. Measuring transparency to improve good governance in the public pharmaceutical sector. Working document, 2006.

countries. Such large amounts of money are an attractive target for abuse, making the pharmaceutical sector highly vulnerable to corruption and unethical practices, in part due to the high market value of pharmaceutical products.

Other factors making the pharmaceutical sector particularly vulnerable to corruption include:

- the information imbalances 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
- the high degree of government involvement in regulation of the pharmaceutical sector
- poorly defined and documented processes
- limited or too many institutional checks
- inappropriate incentive structures.

1.2 Types of unethical behaviour

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 contracting a particular company
- practices nepotism when hiring personnel
- receives post-employment benefits from a contracted company.

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 bribes, kickbacks and/or gifts for the following unethical behaviour:

- Allowing pseudo-trials of medicines funded by pharmaceutical companies that are really for marketing purposes (unethical promotion)
- Speeding up the process of drug registration
- Biased certification and licensing procedures
- Suppression of drug quality inspection findings
- Collusion in bid rigging during procurement by providing vendors with confidential and privileged information related to the bidding process
- Gratuitous payment made to a person for referral of business
- Selection of a specific medicine for the essential medicines list
- Providing procurement contracts
- Not holding accountable suppliers who fail to deliver.

Theft:

- 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.

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. Thus, 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.

1.3 Impact on the health system and health status

As stated, the pharmaceutical sector is particularly vulnerable to corruption and unethical practices. Transparency International estimates that, on average, 10 to 25% of public procurement spending, including that in the health sector, is lost 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.

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.

2. Application of a moral and ethical framework to the pharmaceutical sector

Potential and existing unethical practices in the governance of the pharmaceutical sector have been found throughout the medicine chain. The medicine 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. The basic areas of the medicine chain are:

- Research and development
- Clinical trials

- Patent application
- Manufacturing
- Registration
- Inspection
- Promotion
- Pricing
- Selection
- Procurement
- Distribution
- Prescription and consumption.

WHO and other organizations have prepared technical guidelines and manuals on the various areas of the medicine 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.

2.1 The ethics infrastructure

For a framework of moral values and ethical principles to have a significant and sustainable impact on the professional conduct of public servants an "ethics infrastructure" is required. The basic components of this are:

- A framework of moral values and ethical principles
- A code of conduct
- A programme for the socialization of an ethical framework and code of conduct
- Established anti-corruption legislation
- Established administrative procedures
- Mechanisms for whistle-blowing (ombudsman)
- Sanctions on reprehensible acts
- Mechanisms for collaboration between existing anti-corruption agencies
- Management, coordination and evaluation of an ethical infrastructure

The first three components on the list are based on the values approach and the remaining six on the disciplinary approach. To be effective in addressing the problem of corruption, an ethical infrastructure must integrate both approaches in a coherent and balanced system.

2.2 The process of constructing a framework

The discipline approach to addressing corruption is essentially a top-down legislative process that establishes anti-corruption laws 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 and

ethical framework, which is essential for creating the intrinsic motivation necessary for self-imposed adherence to the norms promoted by the framework.

Construction of a national ethical framework requires consensus-building through a consultation process about which moral values and ethical principles should be included. Formulating a national ethical framework requires:

1. Participation of key actors and stakeholders in the review and analysis of the ethical framework 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 ethical framework and code of conduct 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 ethical framework and code of conduct for the pharmaceutical sector.

The basic need for consensus-building on moral values and ethical principles makes it advisable to circulate a copy of the established framework for review and revision periodically. This is in order to assure genuine participation and to 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 elements of the proposed framework were derived from a process of consensus-building in which representatives of the pharmaceutical sectors and health ministries from 11 Asian countries participated[2]. The proposed framework is not considered a finished piece, but a working document designed to stimulate reflection and discussion within a consensus-building process in ministries of health.

3. Elements of an ethical framework

3.1 Moral values and ethical principles

The following statement by John Fletcher Moulton[3] stimulates reflection as to the nature of self-imposed obedience to moral values and ethical principles and the challenge it represents to individual integrity and to the development of true civilization:

---

[2]   These consultations were held during two bi-regional workshops on promoting ethical practices in medicines registration and procurement, organized by WPRO from 31 May-2 June 2005 and 14-16 June 2006, in Penang, Malaysia, and Manila, the Philippines, respectively.

[3]   Fletcher, Moulton John (1844-1921). Renowned judge and barrister, appointed Counsellor of the United Kingdom during the reign of King Edward VII in 1906. Quote from a public speech given in 1920.

"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."

Moral values have to do with 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"[i].

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.

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. It can empower public servants with a 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"[ii]).

> **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.

> **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.

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.

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.

3.2 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."[4]

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. Justice 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. The application of the principle of consultation in the collective decision-making process is the operational expression of justice in human affairs[iii], 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 moral responsibility to see through one's own eyes and not through the eyes of others, and 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

> **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." (J. Rawls). 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.

---

[4] Rawls, John. *A Theory of Justice*. Revised ed. Cambridge, Harvard University Press, 1999, pg. 3-4.

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. Formal procedures 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 a person's or 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.

3.3 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

> **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. Those 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.

3.4   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

> **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.

3.5 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 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 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.

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 framework 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.

4.   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. The governments that have established such codes of conduct and the other elements of an ethical infrastructure are listed as 10 countries with very low levels of corruption in studies by Transparency International.[iv]

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 <u>not</u> 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 medicine chain would result in the prevention of unethical practices and corruption.

The administrative structures and procedures for managing the medicine 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 administrative procedures. Annex A provides an outline of the initial phase of this type of analysis applied to three areas of the medicine chain: registration, selection and procurement.

5. Other components of ethical infrastructure

5.1 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 by so doing 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.

The mechanisms for whistle-blowing are a key element of an ethical infrastructure, requiring further analysis and discussion that goes beyond the scope of this document. Likewise other components of an ethical infrastructure require analysis and development. These include control of reprehensible acts, and coordination, management and evaluation of an ethical infrastructure, and the socialization of an ethical framework and code of conduct, which are briefly described in the following paragraphs.

5.2 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 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.

5.3 Coordination, management and evaluation programmes

The effective coordination, management and evaluation of programmes that socialize an ethical framework and code of conduct within an institution require the services of trained human resources and adequate logistical support. A department of human resource management within an institution often administers this type of programme. In some cases governments have established inter-institutional offices that promote programmes in various government agencies. Ideally, both levels should establish a formal structure for coordinating intra-institutional and inter-institutional efforts. In some countries, these structures have been the given the name "ethics committee" or "anti-corruption agency", and have been granted the overall responsibility for implementing the ethical infrastructure. Suggested terms of reference (TOR) for this type of structure are included in Annex B.

5.4 The socialization of an ethical framework 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)." (Gordon Marshall) In the context of this document the term refers to the process by which an ethical framework and 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 an ethical framework and 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 an ethical framework and code of conduct on personal and collective levels through processes of consultation and learning.
- Development of intrinsic motivation for the consistent application of an ethical framework and code of conduct in personal and professional life.
- Advocacy of a framework 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 an ethical framework 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 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 models that could hinder the socialization process of an ethical framework and code of conduct are:

1. Raise awareness of specific dysfunctional mental models that will hinder the adoption of an ethical framework 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 to apply an ethical framework

The application of an ethical framework 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

d) Advocacy through moral leadership

Possibly the most effective means of promoting the adoption and application of a new ethical framework and code of conduct is through the moral leadership of the key actors. Their example in applying the ethical framework and code of conduct in their professional and personal lives sets the standard for all to follow. If they demonstrate in action that they are

"walking the talk", it will convey a powerful message throughout the institution that all are expected to do the same. In this process, moral leadership refers to a leadership that reflects the following characteristics:

- Promotes justice as the organizing principle of society and the basis of unity in diversity.
- Fulfils the moral responsibility to search for truth and to apply it in the processes of decision-making and action.
- Has a proactive commitment to serving the common good.
- Fulfils the moral responsibilities of trusteeship in carrying out the duties of a public servant.
- Is proactively engaged in processes of personal and social transformation.

The socialization process of an ethical framework and code of conduct is complex and requires effective planning and implementation to be successful. The official granting of institutional priority and commitment is essential for this to move forward and progress. Fortunately a growing number of countries are acknowledging the vital need to promote ethical practices in the governance and management of pharmaceuticals in the public sector.

6.   Conclusion

The development and management of an ethical infrastructure within the pharmaceutical sector of a ministry of health is a process that requires the concomitant development of the components of the infrastructure, 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 ethical infrastructure, 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.

Annex A:

Registration

The registration of medicines is a critical governmental function that ensures that the medicines registered fulfil quality, efficacy and safety standards.

Need for written criteria and a description of the process of drug registration available for public scrutiny

Procedures and policies	Relevant ethical principles
• Application using standard forms and procedures	• Equality of rights and opportunities • Equity
• Evaluation of the products in terms of quality, safety and efficacy	• Honesty in reporting the facts • Evidence-based decision-making
• Evaluation of the applicant (manufacturers/importers/wholesalers) in terms of compliance with standard practice, e.g. Good Manufacturing Practices	• Honesty in reporting the facts • Evidence-based decision-making • Equity
• Grant authorization approval or reject application	• Evidence-based decision-making • Equity
• Approved product placed on list of authorized products	• Efficient and effective service in the public interest

• Authorization granted for:
    • Marketing or free distribution
    • Entitlement, such as fast-track reimbursement
	• Equity
	 • Recognition of merit

Need for clearly documented administrative/management procedures and policies

Procedures and policies	Relevant ethical principles
• Terms of reference of each unit and post	• Accountability • Transparency
• Defined relationships among units and posts	• Transparency
• Lines of reporting/approvals/clearance	• Accountability • Transparency

Need to establish a clearinghouse for public information on registered medicines

Procedures and policies	Relevant ethical principles
• Information – references/data - available in public domain	• Transparency • Efficient and effective service in the public interest
• Communication in service by phone, fax, web site, email, public comments, hearing, etc.	• Transparency

Examples of potential corrupt practices in the registration of medicines:

- Suppliers may bribe government officials to register their medicines without providing the necessary information.
- Government officials may deliberately slow down registration procedures to solicit payment from a supplier.

Selection

The selection of essential medicines defines the government's priorities for medicine supply and medicine benefits as part of health insurance schemes. What are essential medicines?

Concept: A limited range of carefully selected essential medicines leads to better health care, better drug management, and lower costs.

Definition: Essential medicines are those that satisfy the priority health care needs of the population (Report to WHO Executive Board, January 2002).

Need for clear, written selection criteria available for public scrutiny

Procedure and policies	Relevant ethical principle
• Take into account disease prevalence	• Evidence-based decision-making
• Sound and adequate evidence on efficacy and safety	• Honesty in reporting the facts • Evidence-based decision-making
• Comparative cost-effectiveness (within same therapeutic category)	• Efficient and effective service of the public interest
• Local considerations • Local manufacturing • Facilities for storage • Treatment facilities and personnel experience	• Declaration of conflict of interest (COI) • Honesty • Transparency • Trusteeship

Procedure and policies	Relevant ethical principle
• Mostly single compounds, fixed-dose combinations only when proven advantage	• Evidence based decision making • Transparency • Human well-being indicators

Need for clear and written selection process available for public scrutiny

Procedures and policies	Relevant ethical principle
• Consultative and transparent process	• Consultation as means of collective decision-making • Transparency

• Independent membership of the Selection Committee
  o Terms of reference
  o Careful consideration of conflict of interest (COI forms)
  o Experts from different fields (medicine, nursing, pharmacology, pharmacy, consumer groups, health workers)
  o Rotating basis
	• Transparency
	• Consultative process
	• Declaration of COI
	• Evidence-based decision-making
	• Inclusiveness

• Standard application form	• Equality of rights and opportunities
• Link to evidence-based treatment recommendations	• Evidence-based decision-making
• Rapid public dissemination (e.g. electronic access)	• Efficient and effective service in the public interest • Transparency
• Regular review and update (2 years)	• Evidence-based decision-making • Trusteeship

Steps in review of applications: example of the WHO Model List of Essential Medicines

Procedures and policies	Relevant ethical principle
• Summary of application posted on WHO Medicines web site	• Transparency
• Specialist assessment of comparative efficacy, safety and cost-effectiveness	• Transparency • Truthfulness in reporting facts • Declaration of COI
• Review of assessments by Expert Committee member ("presenter"); formulation of draft recommendation	• Transparency • Truthfulness in reporting facts • Declaration of COI
• Review of draft recommendation by relevant Expert Advisory Panel members; and posted on the WHO Medicines web site	• Consultative process in collective decision-making • Declaration of COI • Transparency
• Review by presenter, prepares final draft recommendation	• Efficient and effective service in the public interest
• Discussion, recommendation by Expert Committee	• Accountability in the exercise of authority

Examples of potential unethical practices in the selection of medicines:

- Manufacturers or importers may offer incentives to public officials to include a particular medicine on the essential medicines list
- Committee members with a conflict of interest can influence final decisions
- Failure to use evidence by the selection committee

These potential vulnerabilities to corruption can be overcome and prevented by the rigorous application of the procedures and ethical principles stipulated.

Procurement

The procurement of medicines requires not only estimation of the quantities needed but also the choice of the right medicines for the epidemiological profile of the population. Procurement is the process of acquiring supplies from private and public suppliers and/or through various sources, such as manufacturers, distributors, agencies, etc.

Good procurement of medicines is a complex process, which ensures the availability of the right medicines, in the right quantities, at the lowest possible cost, at the right time and at recognized standards of quality.

Need for competent professional staff committed to ethical practices

Procedures and policies	Relevant ethical principles
• Appointment by merit system staff with appropriate professional expertise	• Recognition of merit • Efficient and effective service in the public interest
• Staff must be honest and free of COI	• Declaration of COI • Honest reporting of facts • Transparency • Rule of law
• Provision of incentives and adequate salaries	• Recognition of merit and the provision of adequate remuneration

Need for a clear policy on the quantification methodology that limits the interest of individuals and/or groups to inflate estimates

Procedures and policies	Relevant ethical principles
• Procurement of the most-effective medicines in the right quantities	• Evidence-based decision-making
• Assurance of value for money	• Accountability

Need for transparent written procedures that describe procurement processes and criteria to award contracts that are available for public scrutiny

Procedures and policies	Relevant ethical principles
• Transparent procurement procedures	• Transparency
• Separation of responsibilities among different individuals	• Accountability • Declaration of COI
• Competitive procurement	• Rule of law • Evidence-based decision-making • Equality of rights and opportunity
• Selection of reliable suppliers	• Evidence-based decision-making

Procedures and policies	Relevant ethical principles
	• Recognition of merit and provision of adequate remuneration
• Monitoring performance of suppliers to assure timely delivery	• Rule of law • Evidence-based decision-making • Accountability

Example of unethical practices:

• Suppliers may bribe public officials to gain monopoly positions in the tender process.

Annex B:

Terms of reference (TOR) for an ethics committee[5]

The ethics committee will be responsible for the overall coordination, management and evaluation of the ethics medicines programme[6]. 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 ethical infrastructure;
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 ethical 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;
6. Ensure the establishment of a whistle-blowing mechanism;
7. Ensure the establishment of policies and procedures for the control of reprehensible acts.

---

[5] The name of this committee will change from country to country. Other possible names include "transparency committee", "anti-corruption committee", or "good governance committee".

[6] The name of the programme will also be different from one country to another. They may be called "good governance for medicines programme", "transparency programme" or "anti-corruption programme".

References

i   Lewis, W. Carol; *The Ethics Challenge in Public Service*, Jossey-Bass Publishers, San Francisco, 1991

ii   Rawls, John; *A Theory of Justice*, Revised Edition, Harvard University Press, 1999, pg. 113-118

iii   Bahá'í International Community; *The Prosperity of Humankind*, BIC New York, 1995

iv   www.transparency.org