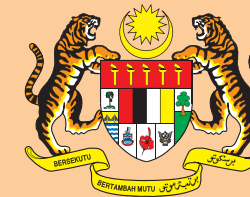


Framework For Good Governance In The Public Pharmaceutical Sector Ministry Of Health Malaysia

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Ethical Framework for Good Governance in Medicine

FIRST EDITION

November 2009

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PREFACE

Malaysia was one of the first four countries to participate in the project organised by the World Health Organization on good governance for medicine. The first phase of the project is the assessment of the ethical practices in medicine registration, selection and procurement was done in December 2004. It was to determine the degree of vulnerability to corruption in the registration, selection and procurement processes of pharmaceuticals and to highlight areas where the current system is most prone or vulnerable to corruption.

The second phase of the program is the development of Good Governance for Medicine (GGM) framework , the basic components needed in the GGM programme to address and prevent corruption in the pharmaceutical sector. The framework proposed here integrates two basic strategies necessary to promote good governance and to reduce corrupt practices.

In September 2006, a Good Governance for Medicine steering committee was formed at the Pharmaceutical Services Division which was headed by the Senior Director of the Pharmaceutical Services Division. A working group/ task force was formed in January 2007 to look into the development of a framework for good governance for medicine; the basic components needed in GGM programme to address and prevent corruption in the pharmaceutical sector.

Finally a workshop was held to develop the framework in April 2007. This framework went through several series of updating before it was finally accepted. The next phase will be the implementation of the GGM programme

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1 INTRODUCTION

Recognising corruption as a global menace, the United Nations General Assembly adopted the Convention against Corruption in December 2003. It is a comprehensive treaty, which called upon member states to address this menace in both the public and private sector.

The world spends more than US\$3 trillion on health services each year. The estimated health budget lost to corruption is as high as 10% in some countries¹. This amount could otherwise be used as resources to purchase medicines or recruit the much-needed professionals for health services. The global expenditure on pharmaceuticals is 25% – 65% of the total health expenditure². Such large amounts of money make the pharmaceutical sector attractive to corruption and unethical practices. It can manifest in various ways such as officials or politicians accept kickbacks in medicines procurement, omnipresent bureaucracy and doctors succumbing to pressure and influence from drug companies to prescribe their drugs.

Despite international aid and programmes devoting to improve pharmaceutical access, this issue of accessibility of medicines is still a major challenge globally. There is a worrying gap in access whereby it is estimated that one-third of the global population lacks regular access to essential medicines. The determinants that contribute to this gap include corruption, market failures, government inefficiencies and poverty.

In an attempt to curb corruption in the pharmaceutical industries, WHO established the Good Governance for Medicines (GGM) programme in order to reduce corruption in pharmaceutical systems. It was implemented in 3 phases:

- (i) National assessment of ethical practices in medicines registration and procurement to improve transparency and good governance in pharmaceutical system
- (ii) Development of GGM framework and
- (iii) Implementation of GGM programme

The necessity to combat corruption in the health sector, particularly for the pharmaceutical system is recognized by the international community and governments. This project currently operates in nineteen countries in Asia and Latin America. The Global Corruption Report produced by Transparency International in 2006 also focused on the health sector. The World Bank is now focusing more specifically on the pharmaceutical sector after almost 10 years' experience in tackling this issue with cross-sectoral approach.

2 THE MALAYSIAN PERSPECTIVE IN ENHANCING INTEGRITY

Malaysia, as a developing country, which has achieved successes in many fields, now aims to become a fully developed nation in its own mould by 2020. The country's transformation towards a developed nation is not solely based on economic and technological progress but also on its progress in the social, cultural, intellectual and spiritual fields. To achieve this transformation it is absolutely necessary to enhance ethics and integrity in the society's culture.

The public sector, being the main engine for the national development, is also responsible for the management and administration of public resources. Therefore, ethical practices and integrity must be reflected in all undertakings. The integration, internalisation and upholding of good moral values and the endeavour to be free of corruption and abuse of power should continuously be strengthened. The government had introduced various programmes since independence, aimed at enhancing good moral values and integrity in the public service. Since the 1980s in particular, greater attention has been given to the concepts of 'Clean, Efficient and Trustworthy', 'Integration of Islamic Values', 'Excellent Work Culture', 'Code of Work Ethics', 'Client's Charter' and quality initiatives such as ISO Certifications.

Since independence, Malaysia had taken serious efforts to combat corruption. Through the Parliament, the government passed the Prevention of Corruption Act in 1961 replacing the Prevention of Corruption Ordinance 1950 and now Malaysia Anti-Corruption Commission had replaced the Anti-Corruption Act 1997. The Public Complaints Bureau (PCB) was established as one of the mechanisms through which members of the public can lodge complaints on malpractices and abuse of power in the public service. Malaysia's Corruption Perception Index (CPI) remain at 5.1 in year 2008, showing no improvement since year 2007. But there was a minimal positive change of CPI from 5.0 in 2006 to 5.1 in 2007. But in terms of country ranking, Malaysia showed a decline from number 43rd in 2007 to 47th out of 180 countries in year 2008.

Since the piece meal approach in the effort to combat corruption has not been fully successful in the last 5 decades, a national comprehensive plan known as the National Integration Plan (NIP) was established. The main purpose of the plan is to coordinate all sectors in the enhancement of integrity as a way of life among the people.

The overall objective of the NIP is to fulfil the fourth challenge of Vision 2020, which is "to establish a fully moral and ethical society whose citizens are strong in religious and spiritual values and imbued with the highest ethical standards."

3 GOOD GOVERNANCE IN PUBLIC PHARMACEUTICAL SECTOR

In the public health sector, the health and safety of the people must be of the utmost priority. Honesty and transparency are among the main thrusts in making decisions related to the administration of public resources.

Good governance is one of the most important factors in improving the health services. Governance can be seen as the exercise of economic, political and administrative authority to manage a country's affairs at all levels. It comprises the mechanisms, processes and institutions, through which citizens and groups articulate their interests, exercise their legal rights, meet their obligations and mediate their differences.

Good governance is an essential factor for economic growth and sustainable development at all levels. It involved participatory, transparent, accountable, effective and equitable and promotes the rule of law. Good governance ensures that political, social and economic priorities are based on broad consensus in society and that the voices of the poorest and the most vulnerable are heard in decision-making over the allocation of development resources.

Public pharmaceutical service must ensure an equitable and timely supply of safe, effective and quality medicines at the most reasonable cost to the population. To achieve this, it is important that the management of the entire pharmaceutical sector involving principal key points such as registration, inspection, promotion, selection, procurement and distribution of medicinal substances, is done cost-effectively. It is also pertinent that elements of honesty, transparency and ethical principles are incorporated in the routine processes of these various key points. Trustworthiness, fairness, equity and sincerity are the ethical principles that must be instilled in all personnel to prevent bribery and pilferages that can be detrimental to the efficiency of the system.

Governance refers to the processes and systems by which decisions are made and the methods by which a society or entity is controlled or administered. It is a wider concept than anti-corruption. The purpose of good governance is to achieve a series of good results and to avoid bad circumstances. This is explained in detail in **APPENDIX 1**.

The pharmaceutical sector is particularly vulnerable to corruption and unethical practices in part due to the high market value of pharmaceutical products. Other factors, which contribute to vulnerability to corruption, include:

- high market volume and economic interests
- information imbalance to make independent assessment of quality, safety and efficacy of medicines
- high degree of government involvement in regulation of pharmaceutical sector

- poorly defined and documented processes
- limited or too many institutional checks
- inappropriate incentive structures
- difficulty in differentiating between corruption and inefficiency

In view of this and in the quest to expand access to essential medicines, the WHO launched the WHO Medicine Strategy for 2004-2007 with emphasis on the promotion of ethical practices, development and use of anti-corruption measures in the pharmaceutical sector as part of the strategies.

4 OBJECTIVES OF THE GOOD GOVERNANCE PROGRAMME

This programme is established with the following objectives:

- to inculcate and enhance integrity among public servants dealing in all areas involved in pharmaceuticals.
- to promote transparency, accountability and ethical practices among health professionals in the public pharmaceutical sector
- to raise awareness of the potential for corruption in the pharmaceutical sector
- to minimise corruption by promoting and implementing good governance within the public pharmaceutical sector

5 GGM PROGRAMME IN MEDICINE

Components of a good governance programme include:

- An ethical framework of moral values and ethical principles
- A code of conduct
- Transparent and accountable regulations and administrative procedures
- Mechanism for whistle-blowing (ombudsman)
- Sanctions on reprehensible acts
- Collaboration with other good governance and anti-corruption initiatives
- GGM implementing task force

The first two components are based on value approach whilst and the remainder are disciplinary approach. To be effective in addressing the problem of corruption, an ethical infrastructure must integrate both approaches in a coherent and balanced manner. It is pertinent that good governance should exist in public and private pharmaceutical sectors.

At the initial stage the focus will be on developing a framework of ethical principles, moral values and the code of conduct in five areas of the pharmaceutical system namely registration, inspection, promotion, selection and procurement as in **APPENDIX 2**.

The ethical framework proposed is based on 4 core moral values that are believed to be essential to good governance which can help a person resist the materialistic inducement offered by corrupt practices. The core values are justice, truth, service to the common good and trusteeship as in **APPENDIX 3**.

This framework is to create awareness on areas of vulnerability, addresses procedures and policies and the relevant ethical principle necessary to guide in decision-making. Technical guidelines and manuals on the processes of pharmaceutical system should be supplemented with an ethical framework to prevent and combat corruption effectively.

The entire pharmaceutical system consists of a series of sequential and interrelated stages and areas. The basic areas of the pharmaceutical system are:

- Research and development
- Clinical trials
- Patent application
- Manufacturing
- Registration
- Inspection
- Promotion
- Pricing
- Selection
- Procurement
- Distribution
- Prescription and consumption
- Disposal

6 CODE OF CONDUCT

Apart from the 4 core moral values described above, public servants should have a stated code of conduct so that they are clear on what should and should not be done. Code of conduct is a set of rules outlining the responsibilities of or proper practices for an individual or organisation.

For public servants involved in the pharmaceutical system, the Code of Conduct is based on moral values and ethical principles which serve as a guide to prevent unethical behaviour in performing their duties. A public servant who fulfils this code of conduct would avoid situations of conflict of interest (COI) and unethical behaviour that can lead to corruption.

A public servant should reflect the interests of the public and the profession as a whole in the activities. The set of values that conduct and guide the behaviour of public servants includes:

- **Selflessness**

Public servants should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family or their friends.

- **Integrity**

Public servants should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

- **Objectivity**

In carrying out public business, including making public appointments, awarding contracts or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

- **Accountability**

Public servants are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

- **Openness**

Public servants should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

- **Honesty**

Public servants have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

- **Leadership**

Public servants should promote and support these principles by leadership and example.

In principle, a public servant should instil the following values within himself/herself:

- Shall fulfil his/her lawful obligations to the government and the public with professionalism and integrity.
- Shall perform his/her official duties with justice, truthfulness and with a spirit of service to the common good (public interest).
- Shall perform his/her official duties with honesty, transparency and accountability.
- Shall respect the rights of the public and of his/her colleagues.
- Shall disclose unethical practice and corruption to appropriate authorities.
- Shall avoid any actions that may create the appearance of violating the law or ethical principles.
- Shall not hold financial interests that conflict with the conscientious performance of official duties.
- Shall not give preferential treatment to any private organization or individual.
- Should not engage in financial transactions using non-public government information or allow the improper use of such information to further any private interest.
- Shall not bring his/her institution into disrepute through his/her private activities.
- Shall avoid any actions that create the appearance that they are violating the law or the ethical principles promoted by this code of conduct.

Adherence to the code of conduct in performance of their public duties would result in the prevention of unethical practices and corruption.

6.1 Unethical Practices

Conflict of interest (COI) may become the driving force for unethical practices. This may occur when a public servant has vested personal interests in contracting a particular company and/or receives post-employment benefit from a contracted company.

The following unethical practices that may also lead to corruption have also been identified to exist in the management of pharmaceuticals:

- a) **Bribes** in the form of incentives, monetary inducement, kickbacks and/or gifts
 - to allow pseudo-trials of medicines to be carried out, funded by pharmaceutical companies, that are really for marketing purposes (unethical promotion)
 - for falsification of data submitted on safety, quality and efficacy
 - for speeding up the process of drug registration by compromising critical steps
 - for biased certification and licensing procedures
 - for suppression of drug quality inspection findings
 - for collusion in bid rigging during procurement by providing vendors with confidential and privileged information related to the bidding process

- for gratuitous payment made to a person for referral of business
- for selection of a specific medicine for the essential medicines list based on favour
- for providing procurement contracts to friends and relatives
- for not holding accountable, suppliers who fail to deliver

b) **Theft**

- of medicines for personal use or diversion for private sector resale
- of money made from the sale of medicines that were supposed to be supplied free of charge

6.2 Impact of Unethical Practice on Health System

Transparency International estimated that in some countries up to two thirds of medicines supplies at hospitals are lost through corruption and fraud. The impact on the pharmaceutical sector is three-fold:

- a) **health impact** – wastage 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 that can cause prolonged illness and even deaths
- b) **economic impact** – pharmaceutical expenditure in low income countries may represent up to 50% of total health care costs, which means that corrupt pharmaceutical practices are extremely detrimental to national health budgets
- c) **government image and trust impact** – inefficiency and lack of transparency reduce the credibility of public institutions, and erode public and donors' confidence in governments' capacity to deliver on promises.

The code of conduct which describes the procedures and policies in the five areas of the pharmaceutical system is stated in **APPENDIX 4**.

7 CONCLUSION

The leaders of public and private pharmaceutical sector organizations have to shoulder the challenge and responsibility of fostering good governance. They need to provide the leadership, direction and control for the organizations they serve. They must be seen to carry out these in accordance with the prevailing rules and regulations to best meet public interest-

Good Governance emphasizes on:

- Focusing on the organization's purpose and outcomes for the public and service consumers
 - Performing effectively in clearly defined functions and roles
 - Promoting integrity and good values for the whole organization and practicing these in the day to day operation
 - Taking informed, transparent decisions and managing risk
 - Developing the capacity and capability of the governing body to be effective
 - Engaging stakeholders and be accountable in all matters pertaining to service delivery
-
- **Focusing on the organization's purpose and outcomes for the public and service consumers**

Organizational objectives should be clear to the governing body and they are used as a basis for planning. There should also be a mechanism to constantly review all procedures and decisions taken in the course of service delivery, to ensure that they are done in the interest of the public, in particular the users of the services concerned. The organization's vision and mission must be accepted by all in the organization and constantly reminded to all members of the organization to ensure they are translated into actions and be seen in the outcomes of the services.

- **Performing effectively in clearly defined functions and roles**

The organization must have clearly defined functions and roles for its staff and committees and that the public and clients must be made aware of them. The organisation should also apply principles of collective responsibility and equal status in discussion in tackling issues of service delivery.

- **Promoting integrity and good values for the whole organization and practicing these in the day to day operation**

Directors and top managements must take a lead in fostering ethics and values for the organization and its staff. The whole organization should demonstrate commitment to good values and at the same time shows clear rejection of unethical behaviour and misconduct.

- **Taking informed, transparent decisions and managing risk**

Transparent decisions that are clearly explained are more likely to be understood by staff, the public and stake holders, and hence can be implemented effectively. The top management should justify and be clear about delegation of power and types of decision that are being delegated and also what are being reserved for the central management.

- **Developing the capacity and capability of the governing body to be effective**

The top management has the responsibility to make sure that the appointed personnel has the skills, knowledge and capability to perform well the specified tasks given to them. A relevant skill assessment and enhancement system should be in place whereby any short fall in performance can be addressed swiftly. Strong commitment to develop competency in the organization to serve the client is imperative and of great importance.

- **Engaging stakeholders and be accountable in all matters pertaining to service delivery**

The top management should make clear to the organization to whom it is accountable and the scope of its accountability. There is a need to be particularly active in developing an open channel of communication with the public and consumers. In this respect, it should be made clear that the organization as a whole seeks and welcomes feedback and ensures that it responds to comments in a positive manner.

Areas of Ethical Framework

DRUG REGISTRATION

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

A) DRUG REGISTRATION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Selection of applications for review <ul style="list-style-type: none"> Distribute applications to evaluators for review based on set criteria (Vulnerability: Queue jumping, give preferential treatment, delay, mishandle)	<ul style="list-style-type: none"> Manipulation Bias Prejudice Conflict of Interest Collusion Corruption Pressure Procrastination 	<ul style="list-style-type: none"> Openness and transparency Fairness/ Neutrality Accountability Trustworthiness Sincerity Discerning No COI Integrity Honesty
2	Evaluation of the products in terms of quality, efficacy and safety <ul style="list-style-type: none"> acceptance of product information (vulnerability: acceptance of incomplete, inaccurate, falsified data) guidelines, procedures, timelines, client's charter (vulnerability: non-adherence) independence of analyst, evaluators and panel of experts (vulnerability: subject to influenced by parties with vested interest; influenced by perks, monetary or otherwise e.g. gifts and sponsorships from interested parties) consideration for evidence based assessment (vulnerability: ignore pertinent information which has bearing on decision for registration) 	<ul style="list-style-type: none"> Corruption Bias Prejudice Conflict of Interest Collusion Pressure Deliberate mishandling Manipulation 	<ul style="list-style-type: none"> Knowledge Skills Competency Objectivity Discerning Rational Fairness Just Unbiased Analytical Accountable Transparent No COI Professionalism Honesty/ Trustworthiness Confidentiality Attitude Aptitude Vigilance Credibility Reliability Commitment Impartial

A) DRUG REGISTRATION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
3	<p>Granting of authorization approval or rejection of application</p> <ul style="list-style-type: none"> • Empowerment to approve or reject applications (Vulnerability: subject to influence by parties with vested interest) • Selection of Drug Control Authority (DCA) members (Vulnerability: selection of cronies/nepotism) • Terms of Reference (TOR) to describe roles and responsibilities of the committee (vulnerability: manipulate TOR to suit vested interests) • Declaration of COI (vulnerability: not mandatory, false declaration) • DCA decision making process (vulnerability: no clear guidelines, not transparent) • Final decision by DCA (vulnerability: susceptible to pressure and influence) • Dissemination of DCA decisions (vulnerability: withhold, delay, do not inform stakeholders, not timely delivery of decisions) • Making known basis for DCA decision (rejection, conditions, new policies) (vulnerability: no transparency) • Appeal process on DCA decisions (Vulnerability: not transparent, manipulation, withhold information, delay) 	<ul style="list-style-type: none"> • Manipulation • Bias • Prejudice • Conflict of Interest • Collusion • Corruption • Pressure • Procrastination 	<ul style="list-style-type: none"> • Conscience • Transparent • Objectivity • Discerning • Rational • Fair • Just • Unbiased • Accountability • No Conflict of Interest • Commitment • Honesty/ Trustworthiness • Impartial
4	<p>Registry of authorized products</p> <ul style="list-style-type: none"> • Updating registry in a timely manner with current and correct information (Vulnerability: delay, withhold, not transparent, inaccurate information, misleading) 	<ul style="list-style-type: none"> • Corruption • Manipulation 	<ul style="list-style-type: none"> • Honesty • Transparent • Integrity • Accountability

A) DRUG REGISTRATION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
5	<p>Issuance of relevant product certifications e.g. Product Registration Certificate, Certificate of Pharmaceutical Product, Certificate of Free Sale, Clinical Trial Import Licence, laboratory analysis results</p> <ul style="list-style-type: none"> • Generate the relevant documents based on correct and accurate information • Within stipulated timelines • Issue documents to authorised parties (Vulnerability: falsify information in the document, withhold, delay the issuance/ delivery) 	<ul style="list-style-type: none"> • Conflict of Interest • Corruption • Collusion 	<ul style="list-style-type: none"> • Honesty • Transparent • Integrity • Accountability
6	<p>Issuance of Information to stakeholders and public</p> <ul style="list-style-type: none"> • Make public relevant documents e.g. guidance documents for drug registration process, policies list of DCA members, product sanctions, safety and quality issues, product withdrawals, punitive actions, adulterated products • Information should be current, accurate and timely (Vulnerability: falsify information, withhold, delay, manipulate, selective) 	<ul style="list-style-type: none"> • Bias • Corruption • Conflict of Interest • Prejudice • Pressure 	<ul style="list-style-type: none"> • Transparent • Honest • Impartial

B.1) INSPECTION OF MANUFACTURERS

B.2) INSPECTION OF PREMISES FOR ISSUING POISON LICENCE

Inspection is an important area of the medicines regulatory system whereby staff of the regulatory authority enter premises where medicines are manufactured, stored and distributed to ensure that processes are carried out in accordance with national norms and standards, as well as with national legislation.

B.1) INSPECTION OF MANUFACTURERS			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Scheduling of assessment	<ul style="list-style-type: none">• Manipulation (Frequency, Announce – Lead Time / Unannounced)• Pressure	<ul style="list-style-type: none">• Integrity• No Conflict of Interest• Rotation of Lead Auditor• Impartiality
2	Establishment of team	<ul style="list-style-type: none">• Manipulation• Selection Criteria (Auditor, specific to the assigned task)• Pressure	<ul style="list-style-type: none">• Trustworthy• Knowledgeable (competency)• Fair• Responsible• Integrity• No Conflict of Interest• Impartiality
3	Creating assessment plan	<ul style="list-style-type: none">• Manipulation (targeted audit, duration of audit)	<ul style="list-style-type: none">• Trustworthy• Knowledgeable (competency)• Fair• Responsible• Integrity• No Conflict of Interest
4	Team meeting	<ul style="list-style-type: none">• Manipulation (steering the team)	<ul style="list-style-type: none">• Trustworthy• Fair• Responsible• Integrity
5	Conduct of opening meeting	<ul style="list-style-type: none">• Manipulation (Steering the audit Atmosphere)	<ul style="list-style-type: none">• Trustworthy• Fair• Responsible• Integrity• Ability to Communicate

B.1) INSPECTION OF MANUFACTURERS

No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
6	Conduct of assessment of facilities	<ul style="list-style-type: none"> • Manipulation (COI, to report or not to report findings) • Bribery • Collusion • Bias 	<ul style="list-style-type: none"> • Trustworthy • Knowledgeable (competency) • Fair • Responsible • Integrity • No Conflict of Interest • Accountable • Critical • Transparent • Analytical • Accurate • Efficient • Confidentiality • Ability to Communicate • Impartial
7	Categorising deficiencies according to risk and assigning assessment rating	<ul style="list-style-type: none"> • Manipulation (COI, to write or not to write findings as per the actual risk – negotiation) • Bribery • Collusion • Bias 	<ul style="list-style-type: none"> • Knowledgeable (competency) • Impartial • Fair • Responsible • Integrity • No Conflict of Interest • Accountable • Critical • Transparent • Analytical • Accurate • Confidential • Confidence
8	Team meeting prior to exit meeting	<ul style="list-style-type: none"> • Manipulation (casting doubts amongst team members) 	<ul style="list-style-type: none"> • Trustworthy • Knowledgeable (competency) • Fair • Responsible • Integrity • No Conflict of Interest • Accountable • Critical • Transparent • Analytical • Accurate • Efficient • Confidential • Ability to Communicate

B.1) INSPECTION OF MANUFACTURERS			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
9	Exit meeting	<ul style="list-style-type: none"> • Manipulation (Steering the conclusion of the audit) 	<ul style="list-style-type: none"> • Integrity • Confidential • Ability to Communicate • Impartial
10	Writing of Report	<ul style="list-style-type: none"> • Manipulation (Steering the audit compliance rating) 	<ul style="list-style-type: none"> • Integrity • Knowledgeable • Accurate • Efficient • Transparent • No Conflict of Interest • Confidential
11	Presenting of finding in committee meeting	<ul style="list-style-type: none"> • Manipulation (Steering the committee to concur with the proposed audit compliance rating) • Bribery 	<ul style="list-style-type: none"> • Integrity • Knowledgeable (competency) • Accurate • Efficient • Transparent • No Conflict of Interest • Confidential • Ability to Communicate • Impartial
12	Decision Making of internal committee	<ul style="list-style-type: none"> • Manipulation (lobbying in the committee decision) • Pressure 	<ul style="list-style-type: none"> • Integrity • Knowledgeable (competency) • Transparent • No Conflict of Interest • Confidential • Ability to Communicate • Impartial
13	Final Decision of approving committee	<ul style="list-style-type: none"> • Manipulation (lobbying in the committee decision) 	<ul style="list-style-type: none"> • Integrity • Knowledgeable • Transparent • No Conflict of Interest • Confidential • Ability to Communicate
14	Issuance of licence	<ul style="list-style-type: none"> • Collusion 	<ul style="list-style-type: none"> • Integrity • Transparent • Impartial

B.2) INSPECTION OF PREMISES FOR ISSUING POISON LICENCE			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Licence application <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Bribery Acceptance of gift Corruption Favouritisms Bias COI Collusion Procrastination 	<ul style="list-style-type: none"> Competency Knowledgeable Trustworthy Confidentiality Integrity Accountability Honesty No conflict of interest
2	Inspection for issuing licence. <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Bribery Accepting gift Corruption Favouritism Bias COI Collusion Procrastination Incompetence 	<ul style="list-style-type: none"> Competency Knowledgeable Trustworthy Confidentiality Integrity Accountability Honesty No conflict of interest
3	Inspection report <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Fabrication of report Corruption Favouritism Bias COI Procrastination Incompetence 	<ul style="list-style-type: none"> Competency Knowledgeable Trustworthy Confidentiality Integrity Accountability Honesty No conflict of interest
4	Issuing licence <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Bribery Accepting gift Corruption Favouritism Bias COI Collusion Procrastination Incompetency 	<ul style="list-style-type: none"> Competency Knowledgeable Trustworthy Confidentiality Integrity Accountability Honesty No conflict of interest
5	Appeal of licence application rejection <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Bribery Accepting gift Corruption Favouritism Bias Conflict of Interest Collusion Procrastination Incompetence 	<ul style="list-style-type: none"> Competency Knowledgeable Trustworthy Confidentiality Integrity Accountability Honesty No conflict of interest

C) PROMOTION

All educational and persuasive activities by importers, manufacturers and distributors the effect of which is to induce the prescribing, supply and purchase of medicinal drugs. Control of drug promotion will ensure that promotional activities provide accurate information and material benefits will not be offered to influence the practice of health care professionals.

C) PROMOTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Entertaining by sale representatives	<ul style="list-style-type: none"> • Conflict of Interest • Misleading information • Incompetence 	<ul style="list-style-type: none"> • Unbias • Trustworthy • Availability of scientific study • Reliable, truthful, accurate, informative • Knowledgeable • No Conflict of interest • Impartiality • Integrity
2	Receiving sponsorship from company		
3	Advertisement through Adver-torial, testimonials and use of public icon	<ul style="list-style-type: none"> • Conflict of interest • Bias • Irresponsible 	<ul style="list-style-type: none"> • Transparent • Responsibility • Reliable • Knowledgeable • Trustworthy • Integrity
4	Policy on misleading advertisement		
5	Application of advertisement	<ul style="list-style-type: none"> • Favouritism 	<ul style="list-style-type: none"> • Validity of information • Transparency of document • Reliability

C) PROMOTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
6	Advertisement screening and evaluation of supporting documents	<ul style="list-style-type: none"> • Bribery • Manipulation of data • Falsification • Favoritism • Conflict of Interest • Political and management pressures 	<ul style="list-style-type: none"> • Competency • Knowledgeable • Trustworthy • Confidentiality • Integrity
7	Advertisement Approval by the Medicines Advertisement Board (MAB)	<ul style="list-style-type: none"> • Bribery • Favoritism • Conflict of Interest • Political and management pressures 	<ul style="list-style-type: none"> • Fairness • Competency • Knowledgeable • Trustworthy • Confidentiality • Integrity • Transparency
8	The MAB may, in its discretion, issue or refuse to issue such approval or may cancel any such approval previously issued.	<ul style="list-style-type: none"> • Bribery • Favoritism • Conflict of Interest • Political and Management Pressures 	<ul style="list-style-type: none"> • Integrity • Transparency • Trustworthy
9	Advertisement Investigation and Prosecution	<ul style="list-style-type: none"> • Bribery • Favoritism • Conflict of Interest • Political and management pressures 	<ul style="list-style-type: none"> • Fairness • Knowledgeable • Trustworthy • Confidentiality • Integrity • Transparency

D) SELECTION

The selection of medicines into the formulary which forms the basis for the procurement

D) SELECTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Preparation of applications (Proforma applications): <ul style="list-style-type: none"> • By Specialists/ Consultants/Pharmacist • Standard application form • Submission of evidence-based clinical paper by the proposer • Endorsement by Head of Department 	<i>Collusion/Manipulation</i> <ul style="list-style-type: none"> • Pharmaceutical companies decide on the drugs and prepare the Proforma for the doctors. • There is no consideration of budget, drug requirement, morbidity, disease burden. Bias/ Bribery/(COI) <ul style="list-style-type: none"> • Samples given freely to the specialists resulting in indiscriminate use • Aggressive promotion of products contributes to inappropriate prescribing trends. • Marketing strategies to meet the sales target Bribery <ul style="list-style-type: none"> • Incentives • Free gifts • Sponsorships (holiday trips, conferences/ seminars) • Payment for signing the proformas by Consultants/ Specialists 	<ul style="list-style-type: none"> • Efficiency • Timeliness • Trustworthiness • No COI • Knowledgeable • Transparency • Unbiased • Analytical • Critical • Accountability • Responsible • Integrity • Accuracy

D) SELECTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
2	Secretariat of Pharmacy & Therapeutic (P & T) Committee (Pharmacy) <ul style="list-style-type: none"> • Register proforma • Screening of proforma • Appraisal of literature • Comparison with existing drugs in formulary, price, adverse events, usage 	COI/ Bribery/ Collusion/ Manipulation <ul style="list-style-type: none"> • Pressure by pharmaceutical sales representatives: - <ul style="list-style-type: none"> - to expedite the process - aggressive promotion of drug use by giving samples Bias/Bribery/COI <ul style="list-style-type: none"> • Acceptance of non evidence-based literatures to support the products In competency <ul style="list-style-type: none"> • Inadequate knowledge and training of personnel involved in literature appraisal. Bias/Manipulation/COI <ul style="list-style-type: none"> • Fabrication and omission of clinical data submitted (after registration) on safety, quality and efficacy. 	<ul style="list-style-type: none"> • Trustworthiness • Honesty • Professionalism • Accountability • Knowledgeable • Efficiency • Responsiveness • Openness and Transparency • Discerning • Neutrality

D) SELECTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
3	<p>Review of applications by Expert Committee Ministry of Health (MOH) Drug Working Committee:</p> <ul style="list-style-type: none"> Assessment of comparative efficacy, safety and cost effectiveness and formulation of recommendation Making of Recommendation Discussion and recommendation by Expert Committee 	<p><i>COI/ Bribery/ Collusion/ Manipulation</i></p> <ul style="list-style-type: none"> Pressure by pharmaceutical sales representatives <ul style="list-style-type: none"> - to expedite the process influence the committee members on final decision aggressive promotion of drug use by giving samples <p>Bias/COI</p> <ul style="list-style-type: none"> Provision of non evidence-based literatures to support the products <p>Bias/Manipulation/ COI/ Inappropriate selection</p> <ul style="list-style-type: none"> Fabrication and omission of clinical data submitted (after registration) on safety, quality and efficacy. 	<ul style="list-style-type: none"> Transparency Truthfulness in reporting facts Declaration of COI Trustworthiness <ul style="list-style-type: none"> - openness - sincerity Efficient and effective service in the public interest Accountability in the exercise of authority Critical Analytical

D) SELECTION			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
4	<p>P&T Committee</p> <p>Decision making based on the followings:-</p> <ul style="list-style-type: none"> • disease prevalence • Sound and adequate evidence on efficacy and safety • Comparative cost effectiveness (within same therapeutic category) • Local considerations <ul style="list-style-type: none"> - Treatment facilities and personnel experience • Link to evidence-based treatment recommendations • Review and compilation by the secretariat 	<p><i>COI/ Bribery/ Collusion/ Manipulation</i></p> <ul style="list-style-type: none"> • Pressure by pharmaceutical sales representatives <ul style="list-style-type: none"> - to expedite the process • influence the committee members on final decision • aggressive promotion of drug use by giving samples <p><i>Bias/COI</i></p> <ul style="list-style-type: none"> • Acceptance/provision of non evidence-based literature to support the products <p>Bias/ Manipulation/ COI/ Inappropriate selection</p> <ul style="list-style-type: none"> • Fabrication and omission of clinical data submitted (after registration) on safety, quality and efficacy. 	<ul style="list-style-type: none"> • Evidence-based decision making • Truthfulness in reporting the facts • Efficient and effective service in the public interest • Declaration of COI • Transparency • Trusteeship • Consultation as means of collective decision making

E) PROCUREMENT

The procurement process ensures the availability of the right medicine in the right quantity, at reasonable prices and of assured quality standards.

E) PROCUREMENT			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
1	Review drug selection <ul style="list-style-type: none"> Deciding on the types of drugs to be procured. Procurement will be based primarily drug listed in the MOH Formulary and drugs with prior approval for non-Formulary. Procurement will be based on registered product. 	<ul style="list-style-type: none"> COI Bribery Collusion Preference Manipulation 	<ul style="list-style-type: none"> Equity Efficient Timely Trustworthy No COI Knowledgeable Transparent Precise Analytical Critical Accountable Responsible Integrity
2	Determine quantities needed <ul style="list-style-type: none"> Based on end user usage- Based on usage pattern and constant monitoring of drug movement. 	<ul style="list-style-type: none"> Manipulation Inducement Pressure Collusion 	<ul style="list-style-type: none"> Equity COI Knowledgeable Transparent Precise Analytical
3	Reconcile needs and funds <ul style="list-style-type: none"> Procurement must based on availability of operating funds 	<ul style="list-style-type: none"> Obligation Manipulation of funds Pressure Inducement 	<ul style="list-style-type: none"> Equity COI Knowledgeable Transparent Precise Analytical
4	Choose procurement method <ul style="list-style-type: none"> Follow Treasury Instructions, Treasury Circulars that are in effect 	<ul style="list-style-type: none"> Manipulation Integrity 	<ul style="list-style-type: none"> Compliance Efficient Knowledgeable Transparent

E) PROCUREMENT			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
5	Locate and select supplier <ul style="list-style-type: none"> Selection will be made from the suppliers who are registered with the MOF under the drug category according to the purchase limit set by the Treasury Instructions and circular 	<ul style="list-style-type: none"> Bribery COI Collusion Manipulation 	<ul style="list-style-type: none"> Trustworthy COI Knowledgeable Transparent Fair Analytical Accountable Integrity
6	Specify contract quotation terms <ul style="list-style-type: none"> Issuance of letter of award according to terms and conditions agreed between KKM and suppliers 	<ul style="list-style-type: none"> Manipulation Bribery 	<ul style="list-style-type: none"> Timely Efficient Knowledgeable Transparent Accurate Precise
7	Issue purchase order <ul style="list-style-type: none"> Based on requirements and availability of funds Based on 'best value for money' and quality 	<ul style="list-style-type: none"> COI 	<ul style="list-style-type: none"> Timely Efficient Transparent Accurate
8	Monitor order status <ul style="list-style-type: none"> Monitoring order status periodically to ensure continuous supply 	<ul style="list-style-type: none"> COI Collusion 	<ul style="list-style-type: none"> Timely Efficient Analytical Trustworthy Effective Assertive
9	Receive, check and storage of stock <ul style="list-style-type: none"> It is mandatory that stocks received should be checked immediately to ensure compliance to terms of contract/ quotation All stocks received must be stored immediately and update into inventory system/stock card Every consignment must be accompanied with Certificate of Analysis 	<ul style="list-style-type: none"> Manipulation Bribery Collusion 	<ul style="list-style-type: none"> Knowledgeable Accountable Integrity Trustworthy Accurate Responsible Reliable

E) PROCUREMENT			
No.	PROCEDURES & POLICIES	ISSUES (Areas of Vulnerability)	RELEVANT ETHICAL PRINCIPLE
10	Make a payment <ul style="list-style-type: none"> Payment should be made within stipulated time frame after receiving complete documentation from supplier. 	<ul style="list-style-type: none"> Manipulation Collusion Bribery 	<ul style="list-style-type: none"> Timely Accountable Integrity Trustworthy Accurate Responsible Efficient
11	Collect consumption information <ul style="list-style-type: none"> Consumption information based on indents and end-user estimation for all drugs should be collected for planning purposes. 	<ul style="list-style-type: none"> Manipulation COI 	<ul style="list-style-type: none"> Timely Reliable Validity Analytical Accurate Teamwork Efficient
12	Periodic auditing and inspection of consignments and store <ul style="list-style-type: none"> This is part of ongoing check and balance incorporated in Treasury Instructions and in contractual clauses/ contract management. External auditors should conduct an audit at least once a year. 	<ul style="list-style-type: none"> COI Collusion 	<ul style="list-style-type: none"> Trustworthy Teamwork Accountable

Elements of an ethical framework

The moral values have to do with what is believed to be good and of primary importance to human civilization, and are often articulated as ideas. Moral values inform by defining right from wrong and good behaviour from bad. Ethical principles are the operational expression of the moral values and provide guidance to decision-making and action.

The ethical framework proposed is based on 4 core values that directly address prevailing moral weakness that are predisposing factors to corruption. Compliance to these 4 core values can help a person resist the materialistic inducement offered by corrupt practices.

The core values are:

- I. Justice
- II. Truth
- III. Service to the common good
- IV. Trusteeship

(I) Justice

Justice relates to the exercise of impartial in determining the truth of facts and principles in making decisions that guide action whereas 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 judgement and behaviour within their personal sphere of influence.

- **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.

- ▶ **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.

(II) Truth

Faithfulness to truth is the basis of trustworthiness, integrity and honour for both the individual and society as a whole. 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.

- **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.

(III) Service to the common good

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.

Consensus built 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.

- **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 fulfill 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.

(IV) 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.

The code of conduct in the five areas of the pharmaceutical system

A DRUG REGISTRATION: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
1	Application using standard forms and procedures.	<ul style="list-style-type: none"> • Inculcate values of integrity and commitment, as part of our work culture. Be responsive and sensitive to the needs of the public. • Instil the desire for continuous improvement through updating of knowledge and lifelong learning. • Ensure decisions are transparent, just, evidence based and adhering to laws, regulations, established criteria, policies and procedures. • Maintain confidentiality at all times • Be vigilant and maintain credibility • Make available relevant and pertinent information to stakeholders and the public in an effective, efficient, transparent and timely manner such as <ul style="list-style-type: none"> - Clear and comprehensive guidelines - Registry of approved products sanctions • Have open and effective channels/avenues for communication for the public and stakeholders and ensure that staffs are approachable, friendly, sincere and helpful. 	<ul style="list-style-type: none"> • Abuse/misuse power • Neglect or disregard professional responsibilities • Succumb to pressure • Have any conflict of interest • Indecisive practices • Practise favouritism • Enjoy lifestyle beyond your means
2	Selection of applications for review.		
3	Evaluation of the products in terms of quality, efficacy and safety - Includes evaluation of the dossier, lab testing, compliance to Good Manufacturing Practice (GMP) and applications for variations post registration, evaluation of Adverse Drug Reactions) ADR reports.		
4	Grant authorization approval or reject application.		
5	Registry of authorized products.		
6	Issuance of the Product Registration Certificate including certification for export.		
7	Information on product sanctions, safety and quality issues, product withdrawals, punitive actions, adulterated products		

A DRUG REGISTRATION: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
		<ul style="list-style-type: none"> • Establish effective channels for internal communication for the dissemination of information to promote a creative, innovative and responsible culture amongst the workforce • Establish mechanisms for the detection, correction and prevention of weaknesses and non-compliance in the work processes • Increase motivation and productivity of staff members • Make available avenues for appeal with clear guidelines for the appeal process • Have clearly defined, transparent and unambiguous TOR's to ensure awareness of roles and responsibilities of <ul style="list-style-type: none"> - Staff - Committees • Declaration of conflict of interest for member of DCA, Panel of experts etc. • Acceptance of gifts and sponsorships from interested parties should adhere to clearly defined guidelines and in accordance with the General Orders and relevant government circulars. 	

B.1 INSPECTION OF MANUFACTURERS & ISSUING MANUFACTURERS LICENCE: <i>Code of conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
1	Scheduling of assessment	<ul style="list-style-type: none"> Inculcate values of integrity and commitment, as part of work culture Rotate Lead Auditor (as per quality manual) Ensure Auditors understand that they are governed by government orders such as declaration of assets and code of conduct of good behaviour Schedule assessment to follow risk assessment approach which is integrated in the inspectorate quality system Ensure adherence to written procedures and guidelines as well as international guide of inspection and classification of findings (PIC/s format) Maintain confidentiality Be diplomatic, stay composed and vigilant Ensure composition of the team be built on the capacity & capability of the team members against the audited area Ensure the committee members comprise of the technical bearers of the organisation with a lead auditor Ensure that the final deciding committee are elected as per the national legislation 	<ul style="list-style-type: none"> Should not indicate the intent of malice & persecution Should not imply pre decision endorsement (Superficial <i>audit</i>) Should not be influenced by the organisation being inspected Should not succumb to pressures which might influence judgement (close collaboration with key personnel, unethical directives of top management) Should not be easily influenced to re-categorise deficiencies rating Avoid passive behaviour Should not fail to stand up for your rights and express your needs, wants, views and feelings Should not be easily influenced by team leader Should not use the power and influence of skills in communication to exert or revert decision Should not display Aggressive Behaviour
2	Establishment of team		
3	Creating assessment plan		
4	Team meeting		
5	Holding of opening meeting		
6	Conducting assessment of facilities		
7	Categorising deficiencies according to risk and assign assessment rating		
8	Team meeting prior to exit meeting		
9	Exit meeting		
10	Writing of Report		
11	Presenting finding in committee meeting		
12	Decision making of internal committee		
13	Final Decision of approving committee		
14	Issuance of licence		

B.1 INSPECTION OF MANUFACTURERS & ISSUING MANUFACTURERS LICENCE: <i>Code of conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
		<ul style="list-style-type: none"> • Ensure that the issuance of license follow the national law and client charter • Instil the desire for continuous improvement through updating of knowledge and lifelong learning • Make advice, if required, with intent to serve public interest without compromising the credibility of inspectors • Be mindful of the power and influence of body language 	<ul style="list-style-type: none"> • Should not ignore, disregard or discount needs, wants, views and feeling of others • Do not violate the trust of the organisation • Do not advise to gain personal benefit • Do not use gestures which can mean different things to different races and cultures

B.2 INSPECTION OF PREMISES FOR ISSUING POISON LICENCE: <i>Code of conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
	Licence application <ul style="list-style-type: none"> Type A (Pharmacist) Type B (Poison chemicals) Sodium Hydroxide permit 	<ul style="list-style-type: none"> Adhere to the relevant Acts And Regulations Follow the guideline Uphold professionalism 	<ul style="list-style-type: none"> Free from personal interest COI Abuse of power Display aggressive behaviour
2	Inspection of premise and report writing	<ul style="list-style-type: none"> Adhere to the relevant Acts And Regulations Follow the guideline Uphold the professionalism 	<ul style="list-style-type: none"> Free from personal interest COI Abuse of power Display aggressive behaviour
3	Approval and licensing	<ul style="list-style-type: none"> Adhere to the relevant Acts And Regulations Follow the guideline Uphold the professionalism 	<ul style="list-style-type: none"> Free from personal interest COI Abuse of power Display aggressive behaviour

C PROMOTION: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
1	Entertaining to sales representatives	• No personal interest	• Have personal interest
2	Receiving sponsorship from company	• Sponsorship with approval	• Engage in any commitment
3	Advertisement through Advertorial, testimonials and use of public icon	• Compliance to the relevant Acts	• Accept gift
4.	Policy on misleading advertisement	• Compliance to the relevant policies and guidelines	• Accept sponsorship
		• Inculcate moral values among staff	• Breach the legal contract between government and public servant ("Aku Janji "
		• Inculcate integrity, accountability	• Endorsement by politicians
		• Uphold professionalism	
		• Follow Standard Operating Procedure and Advertisement Policy and Guideline	
5	Public Trust of approved advertisement		• Abuse and misuse of power
6	Application submission for Advertisement: <ul style="list-style-type: none"> • Application form • Product registration certificate • Indication Certificate • Company registration • Processing Fee • Advertisement format and other supporting document 		• Be unprofessional • Be influenced by negative factors.

C PROMOTION: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
7.	Advertisement: Screening and evaluation <ul style="list-style-type: none"> Evaluate and screen advertisement format submitted and all supporting documents. 	<ul style="list-style-type: none"> Fairness Knowledgeable Vigilance 	<ul style="list-style-type: none"> abuse power be influenced by negative factors have personal interest be unprofessional
8.	Approval of advertisement Medicines Advertisement Board	<ul style="list-style-type: none"> Uphold professionalism 	
9.	The MAB may, in its discretion, issue or refuse to issue such approval or may cancel any such approval previously issued.	<ul style="list-style-type: none"> Adhere to Act & Regulations 	
10.	Advertisement Investigation and Prosecution		

D	SELECTION: <i>Code of Conduct</i>		
No.	PROCEDURES & POLICIES	DO'S	DON'TS
1	Preparation of Proformas	<ul style="list-style-type: none"> • Consultant/specialist/ pharmacist must prepare the proforma • Accept standard application forms approved by MOH to ensure equality of rights and opportunities 	<ul style="list-style-type: none"> • Allow pharmaceutical companies to interfere with selection procedures. • Accept proformas directly from the pharmaceutical companies • Sign on proforma prepared by company
2	Secretariat of Pharmacy & Therapeutic Committee (Pharmacy)	<ul style="list-style-type: none"> • Have a registry of proforma for retrieval of records • Source unbiased drug information which is evidence-based • Follow the criteria set for qualifying drugs to be presented for selection meeting • Used evidenced-based information in the comparative write-up • Have clearly written and transparent rules/criteria for the selection process for listing or deleting products from the formulary. • Prepare clear criteria and TOR for selection committee and the technical committees 	<ul style="list-style-type: none"> • Be influenced or dictated by the pharmaceutical companies. • Succumb to other pressures, which might influence judgment. • Speed up the process of drug selection in favour of the interested parties. • Select a specific drug to be discussed in favour of any interested parties. • Suppress information on drug quality, safety and efficacy findings. • Unnecessarily delay the selection process • Present to meeting a specific drug in favour of any interested parties.

D	SELECTION: <i>Code of Conduct</i>		
No.	PROCEDURES & POLICIES	DO'S	DON'TS
3	Review of applications by Expert Committee (MOH Drug Working Committee)	<ul style="list-style-type: none"> • Establish clear criteria and TOR for membership. • Committees must be composed of impartial persons with the appropriate technical skills and on rotating basis • Have a mandatory declaration COI • Formulate a code of conduct for members • Recommend new products based on cost-effectiveness and health needs • Recommendation is based on discussion and acceptance by key members and voting system 	<ul style="list-style-type: none"> • Practise favouritism when selecting members in the committee. • Be influenced/dictated by the pharmaceutical companies • Allow other pressures to influence judgement and decision. • Hold any financial/other interests (vested personal interests) that conflict with the decision making • Give preferential treatment to any pharmaceutical companies or individuals • Engage in financial transactions that may affect the decision making • Allow the improper use of the information to further any private interest

D SELECTION: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
4	P&T Committee and Decision making	<ul style="list-style-type: none"> Establish clearly written and transparent rules/criteria for the selection process for listing or deleting products from the MOH formulary. Establish a clear criteria and TOR for membership. Members will be selected based on technical expertise Have membership of the selection committee on a rotating basis to avoid favouritism and biased decision Formulate a code of conduct for members Drug selection committees must be composed of impartial persons with the appropriate technical skills Have mandatory declaration of COI. The selection of the new products into the formulary must be based on cost-effectiveness and health needs Have final selection criteria based on discussion and acceptance by members, and voting system should be in place to ensure a fair selection. List all drugs in the MOH 	<ul style="list-style-type: none"> Practise favouritism when selecting members in the committee. Accept direct sponsorship from pharmaceutical companies Allow other pressures, to influence judgement and decision. Hold financial/other interests that conflict with the decision making Be influenced/dictated by the pharmaceutical companies Give preferential treatment to any pharmaceutical companies or individuals Allow the improper use of the information to further any private interest Accept commissions for prescribing /selecting a particular drug or a drug from a particular company .Allow pharmaceutical companies to interfere with selection procedures

E PROCUREMENT: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
1	Review drug selection	<ul style="list-style-type: none"> • There must be a quotation / tender/technical specification and evaluation committee whose terms of reference are clearly defined. The committees shall conduct its business in an unbiased manner. • Have specific criteria for quotation/ tender/technical specification and evaluation committee membership • Mandatory declaration of Conflict Of Interest by members of the committees. 	<ul style="list-style-type: none"> • Do not unnecessarily delay the selection process.
2	Determine quantity needed to procure	<ul style="list-style-type: none"> • Determine the quantity of pharmaceuticals to be purchased objectively 	<ul style="list-style-type: none"> • Do not over estimate or under estimate quantities.
3	Reconcile needs and funds	<ul style="list-style-type: none"> • Fund allocation should be done through consensus by a competent committee. 	<ul style="list-style-type: none"> • Should not be a one-man decision.
4	Choice of procurement method	<ul style="list-style-type: none"> • Have written guidance for staff in the procurement office on the type of procurement method to be used for different types of products. • Parties shall comply with all relevant laws, rules and regulations. • The key functions of the procurement unit and those of the quotation/ tender/technical specification evaluation committee must be clearly separated and defined. 	

E PROCUREMENT: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
5	Locate and select supplier	<ul style="list-style-type: none"> • The process for awarding quotation/ contracts shall be transparent and accountable and must follow SOP. • Prepare a list of qualified suppliers/ vendors. • Ensure that the suppliers are chosen based on merit and to avoid conflict of interest, inappropriate gift, entertainment and any other kinds of favouritism that might compromise the selection process. • Have a formal appeals process for applicants that have their bids rejected. 	<ul style="list-style-type: none"> • Do not confine the selection of suppliers to specific suppliers. • Do not give one supplier's confidential business information (proposed rates, winning bid information, etc) to another.
6	Specify contract terms	<ul style="list-style-type: none"> • Quantity, product specification, lead time, price per unit, packaging, sources and distribution centres shall be clearly specified. 	<ul style="list-style-type: none"> • Do not breach the specified contract terms.
7	Issue order	<ul style="list-style-type: none"> • Issue orders for appropriate quantity that is really needed. • Have SOP and transparency in issuing of LPOs 	<ul style="list-style-type: none"> • Do not order beyond actual needs.
8	Monitor order status	<ul style="list-style-type: none"> • Monitor and report on suppliers' performance to the Quotation Tender Committee. 	<ul style="list-style-type: none"> • Don't ignore delays in supply. • Don't select suppliers who consistently fail to fulfil performance targets.

E PROCUREMENT: <i>Code of Conduct</i>			
No.	PROCEDURES & POLICIES	DO'S	DON'TS
9	Receive and check drugs	<ul style="list-style-type: none"> • Have SOP for receiving checking and storing drugs received. • There must be a management information system to report product problems in procurement. 	<ul style="list-style-type: none"> • Do not accept any drugs which do not conform to the specifications
10	Payment process	<ul style="list-style-type: none"> • Have SOP and transparency in making payment. 	<ul style="list-style-type: none"> • Do not make unnecessary delay of payment upon receipt of complete documentations.
11	Collect consumption information	<ul style="list-style-type: none"> • Have a information system for consumption of drugs. • Data collected must be reliable and have analytical value • Regular audits/check at end user to be carried out to verify the usage 	<ul style="list-style-type: none"> • Do not rely solely on information supplied by end users.
12	Periodic auditing and inspection of consignments	<ul style="list-style-type: none"> • Standard Operating Procedures (SOPs) for routine inspection of consignments • Procurement unit must undergo regular audits and be audited periodically 	<ul style="list-style-type: none"> • Do not appoint personnel who have conflict of interest as auditors.

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ACKNOWLEDGEMENT

THE PHARMACEUTICAL SERVICES DIVISION,
MINISTRY OF HEALTH MALAYSIA,
WOULD LIKE TO THANK TO ALL THOSE ARE INVOLVED
EITHER DIRECTLY OR INDIRECTLY IN THE
PREPARATION OF THIS FRAMEWORK.