DECLARATION

I, Isabelle BURANGA on my best knowledge hereby declare and certify that the work Presented in this dissertation entitled "ASSESSMENT TO THE COMPLIANCE ON THE GOOD GOVERNANCE MEDICINES OF PHARMACEUTICAL SECTOR." Case Study *MoH, MPPD, WHOLESALERS, DPs, DHs ; PRIVATE PHARMACY* is entirely my own and original work. It has never been presented or submitted either in whole or in part to any other University or School. References in terms of books or any other written reports and electronic materials for other authors are indicated in bibliography.

Signature.....

Date.....

Isabelle BURANGA

APPROVAL

This is to certify that Isabelle BURANGA has carried out a research work titled ":

"ASSESSMENT TO THE COMPLIANCE ON GOOD GOVERNANCE OF MEDICINES IN THE PHARMACEUTICAL SECTOR."

Case Study of MOH, MPPD, wholesalers, Hospital district, DPS", Private Pharmacies.

Signature: ……

Ass. Prof. KAYUMBA Pierre Claver

Research supervisor

Date……

CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by the University of Rwanda the Thesis entitled " ASSESSMENT TO THE COMPLIANCE ON THE GOOD GOVERNANCE OF MEDICINES IN THE PHARMACEUTICAL SECTOR" Case study MoH, MPPD, WHOLESALERS, DPs, DHs, PRIVATE PHARMACIES in fulfilment of the requirements for the degree of Masters' in Pharmaceutical Quality Assurance and Quality Control.

Signature: ……

Date…….

Supervisor

DEDICATION

To the Almighty God

To my Husband and my daughter

To my dearest Parents

To my brothers

ABSTRACT

This report presents the results of transparency assessments carried out in Rwanda. It provides a comprehensive picture of the level of transparency and the potential vulnerability to corruption of four selected functions of the pharmaceutical sector which are Selection of medicines, Registration of medicines, Procurement and distribution of medicines. The methodology provides both qualitative and quantitative information. The data were collected data by conducting a series of interviews with carefully selected key informants. The information collected was then converted using a rough quantification method into a zero to 10 scales, to provide a score for each function in terms of vulnerability to corruption (minimal to extreme). The scoring indicates vulnerability in terms of the policy, the regulatory and administrative structures and the procedures at the time of the survey. The quantitative data reveals that the selection and Registration of medicines are both moderately vulnerable to the corruption; the medicines procurement received the highest scores and is minimally vulnerable to corruption; while distribution of medicines is marginally vulnerable to the corruption.

In summary, the findings and methodology that this study introduces can help health specialists and government decision makers prioritize those areas in the pharmaceutical system, which need the highest investment and regulation. This information, in turn, helps to ensure that investments in the pharmaceutical system are maximized and that access to essential medicines is improved.

TABLE OF CONTENT

LISTE OF TABLES

LIST OF FIGURES

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ABBREVIATIONS AND ACRONYMS

WHO: World health organization

NPC: National pharmacy council

KIs: key informants

MRA: Medicines Regulatory Authority

SOPs: Standards Operation Procedures

MPPD: Medical Procurement and Production Division

MoH: Ministry of Health

LMO: Logistic Management Office

GGM: Good Governance of Medicines

BUFMAR : Bureau de Formation Médical Agrée au Rwanda

NGO: No Governmental organization

DPs: District Pharmacies

DHs: District Hospitals

DFID: Department for International Development

EML: Essential Medicines List

MeTA: Medicines Transparency

UK: United Kingdom

COI: Conflict of interest

1. GENERAL INTRODUCTION

1.1 Background of the study

Medicines complement other types of health-care services in reducing morbidity and mortality rates and enhancing the quality of life. Therefore, access to health-care and essential medicines is increasingly being viewed as a fundamental human right [1]. The ability of medicines to save lives, reduce suffering and improve health depends on their being of good quality, safe, available, affordable and properly used. In many countries these conditions are far from being met and it is estimated that today almost two billion people (one third of the global population) do not have regular access to essential medicines [1].

In some of the lowest income countries in Africa and Asia, more than half of the population has no regular access on good quality essential medicines. Furthermore, one third of countries have either no regulatory authority or only limited capacity to regulate the medicines market. Unreliable supply systems persist and irrational use of medicines is a major problem worldwide [1]. Poverty, market failures and government failures, among others, contribute to these urgent challenges in the pharmaceutical sector. The latter often results, at least in part, from a lack of transparency in the pharmaceutical system, which is one of the possible reasons for the medicines gap described above. Lack of transparency in the pharmaceutical system is increasingly becoming an issue of concern because bad practices can waste resources, which in turn reduces the availability of essential medicines and so threatens the well being of populations [2].

The medicines chain involves many different steps; these include research and development of new medicines, conducting clinical trials, filing patents, manufacture, registration, selection of essential medicines, medicines procurement and distribution, inspection of manufacturers and distributors, prescribing, dispensing, pharmacovigilance and the control of medicine promotion. These are core functions in the pharmaceutical sector. Therefore, structures and processes involved in each of these functions must work optimally or access to good quality medicines is compromised [3].

Each function has different objectives and government has a unique role in each function, for instance, registration is a critical government function ensuring that the medicines registered fulfil the quality, efficacy and safety standards. The selection of essential medicines defines government or other institutional clinical and financial priorities for medicines supply, such as determination of limited formularies for reimbursement benefits as part of a health insurance scheme. An effective procurement process ensures the availability of the right medicine in the right quantity, at reasonable prices, and of assured quality standards (medicines may be acquired through purchase or donations). Distribution must ensure that medicines are stored and allocated appropriately, and transported to where medicines are dispensed to patients. Inspection is an important quality assurance activity of the medicines regulatory system whereby regulatory authority staff enters pharmaceutical manufacturing, storage and distribution premises to ensure that processes are carried out in accordance with national norms and standards, as well as with national legislation/regulation. Control of medicine promotion will ensure that promotional activities provide accurate information and that material benefits will not be offered to influence the practices of health professionals. If structures and processes are not transparent and insufficient institutional checks and balances are in place, each of the functions described is vulnerable to corruption.

All these functions are needed to be protected from unethical or corrupt practices to ensure that patients not only have the medicine they need, but also that the medicine is safe, of assured quality, is sold at a fair price, and has not been purchased or prescribed as a result of undue commercial influence [3]. With a land area of 9,633 sq mi and a population of more than 11 million, Rwanda is one of the most densely populated countries in Africa. In 2003, the total expenditure on health was 3.7% of the gross domestic product. The private expenditure was 56.5% of the total expenditure on health [4].

The pharmaceutical drugs import value provides an insight in the estimate of the market size for pharmaceuticals drugs in Rwanda. It should be noted that over 95% of medicines used in Rwanda are imported from mainly India, China, Malaysia and Europe [4]. In July 2012, the Rwanda Ministry of Health established the Logistic Management Office (LMO) to spearhead supply chain management of health commodities at all levels of care in RWANDA. The Key function of LMO is to provide guidance for the health sector, policy formulation for all areas for the pharmaceutical supply chain [3]. Therefore, the major aim of this study is to provide, to key stakeholders in the Rwandan pharmaceutical area, a picture of the level of transparency

and vulnerability to corruption in the procedures and structures of the four chosen functions of the pharmaceutical sector. Its results would help to highlight the relevance of some evidence in formulating pharmaceutical policies aiming to improve good governance for medicines in Rwanda.

1.2 Problem statement

The WHO launched Good governance for medicines Program with goal to contribute to health System Strengthening and prevent corruption by promoting good governance. The first step was to conduct a national assessment of level of transparency and potential vulnerability to corruption in Pharmaceutical Sector [5].

RWANDA is executing all pharmaceutical functions there is no appropriate authority to regulate drugs (Rwanda Medicines regulatory authority) this can make some function more vulnerable to the less transparent practices.

In this perspective, the present study attempts to assess the first quick attempt to the contribution to assess the good governance of medicines and vulnerability to the corruption of the actual 4 functions of the pharmaceutical Sector. It could provide some baseline information for policy-makers, healthcare officials, and other stakeholders to design and implement appropriate strategies to strengthen the good governance and to avoid the corruption in the Pharmaceutical Sector through the health sector in Rwanda.

1.3 Hypothesis

The lack of the good governance of medicines may cause the vulnerability to the corruption of health sector especially Pharmaceutical sectors.

1.4 Objectives of the study

1.4.1 Main objective

This study aims to collect the perceptions of pharmaceutical policy-makers and other stakeholders on the transparency of the pharmaceutical sector.

1.4.2 Specific objectives

The specific objective of the study was to assess the level of transparency and vulnerability to corruption in the procedures and structures of the following four functions of the pharmaceutical sector in Rwanda:

1. Selection of Medicines
2. Registration of Medicines
3. Procurement of Medicines
4. Distribution of Medicines

1.5 Significance of the study

Effective functioning of a pharmaceutical system is dependent on the transparency of the processes, and ability to hold individuals and entities accountable for adhering to standard procedures, norms, laws and regulations in each one of these functions [5]. The study results will give an idea and will bring us to suggest improvements by different recommendations, where applicable, to the stakeholders in health sectors and relevant authorities.

1.6 Limitations

Due to the limited time, this study focused on the Quick assessment of the good governance and the vulnerability to the corruption of the four pharmaceutical functions with special focus in five districts pharmacies, five District Hospital, the Ministry of Health, the RBC/ Medical Procurement and Production Division, two Wholesalers, three Private Pharmacy of Rwanda and one.

2. LITERATURE REVIEW

2.1 Introduction

The pharmaceutical sector and its vulnerabilities coupled with the 'medicines chain' involve many different steps. These include: research and development of new medicines; conducting clinical trials; filing patents; manufacture; registration; selection of essential medicines; medicines procurement and distribution; inspection of manufacturers and distributors; prescribing; dispensing; pharmacovigilance; and the control of medicine promotion. These are core functions in the pharmaceutical sector. The structures and processes involved in each of these functions must work optimally or, in the reverse case, access to good quality medicines is compromised [7]. Each function has different objectives and government has a unique role in each function. For instance, **registration** is a critical government function ensuring that the medicines registered fulfil quality, efficacy and safety standards.

The selection of essential medicines defines government or other institutional clinical and financial priorities for medicine supply, such as determination of limited formularies for reimbursement benefits as part of a health insurance scheme. An effective **procurement** process ensures the availability of the right medicine in the right quantity, at reasonable prices, and also of assured quality standards (medicines may be acquired through purchase or donations). Distribution must ensure that medicines are stored and allocated appropriately, and transported to where medicines are dispensed to patients. **Inspection** is an important quality assurance activity of the medicines regulatory system whereby regulatory authority staffs enter pharmaceutical manufacturing, storage and **distribution** premises to ensure that processes are carried out in accordance with national norms and standards, as well as with national legislation/regulation.

Control of medicine promotion will ensure that promotional activities provide accurate information and that material benefits will not be offered to influence the practices of health professionals. If structures and processes are not transparent and insufficient institutional checks and balances are in place, each of the functions described is vulnerable to corruption. For example, suppliers may bribe government officials to register their medicines without the required information or government officials may deliberately

slow down registration procedures to solicit payments from a supplier. To influence the selection process, special interest groups may offer private incentives to public officials to include particular medicines on the essential medicines list. In the procurement process, suppliers may bribe public officials to gain monopoly positions at the tender stage. Also opportunities for the diversion of goods exist at all stages of the storage and distribution systems. All these functions need to be protected from unethical or corrupt practices to ensure that patients not only have the medicine they need, but also that the medicine is safe, of assured quality, is sold at a fair price, and has not been purchased or prescribed as a result of undue commercial influence [10].

2.2 Transparency in development work

The health sector is an attractive target for corruption, with US$ 5.3 trillion spent on health services each year and a global pharmaceutical market value of US$ 750 billion. Transparency International estimates that 10 to 25 % of public procurement spending, including in the health sector, is lost due to corruption. Corruption in the pharmaceutical sector takes various forms, such as bribery of government officials, falsification of safety data and theft in the distribution chain. Corruption negatively affects access and quality of health care. Its impact is three-fold

1. **A health impact** as the waste of public resources reduces the government′s capacity to provide good quality essential medicines, and unsafe medical products become available on the market representing potentially major financial loss [8];

2. **An economic impact** when large amounts of public funds are wasted. Indeed, it is estimated that pharmaceutical expenditures in low-income countries amount to 10-40% of total health-care expenditures [8];

3. **An image and trust impact** as inefficiency and lack of transparency reduce public institutions′ credibility, decrease donors′ trust and lower investments in countries. Increasingly, aid organizations recognize that, to be efficient and to have long-term impact, development work needs to address lack of transparency and other corruption issues. This is why two of WHO′s most recent strategies are committed to improving good governance in the public pharmaceutical sector - the WHO Global Medicines Strategy 2004-2007 and the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region 2005-2010.[8]

The World Bank has identified corruption as the single greatest obstacle to social and economic development by keeping millions of people trapped in poverty. Labelled a ″cancer″ by the same organization, it is a cross-sectoral problem affecting the public and private sectors alike. It also represents a gross departure from fundamental ethical standards. As mentioned, the pharmaceutical sector is particularly vulnerable to corruption and unethical practices. The commercial reality of the pharmaceutical market tempts the many different public as well as private actors involved. The pernicious effects of corruption arise not only from intentional mismanagement by an individual, but also from an inability to identify and ethically manage the conflicts of interest that can occur when institutions and individuals with authority interact. There is also a failure from organizational position to institutionalize procedures that will prevent corrupt behaviour.[8]

Good governance is currently also high on the health research agenda. Indeed, the Statement on Health Research issued by the Ministerial Summit on Health Research, held in Mexico City in November 2004, identifies as a priority the generation of ″relevant knowledge adhering to high ethical standards which can be used to improve the health status of populations in an equitable way. In 2006, Transparency International′s annual Global Corruption Report focused on the health sector. After almost 10 years′ experience in tackling this difficult issue using a cross-sectoral approach, the World Bank is now focusing more specifically on the pharmaceutical sector. In addition, the UK Department for International Development (DFID) has launched a new initiative, the Medicines Transparency Alliance (MeTA). Just as corruption necessarily represents a departure from ethical obligations, transparency is recognized as an essential element of ethical processes for governments (sometimes termed ″fair process″). It is also a manifestation of such basic human rights as people′s right to receive information and to participate in decisions affecting their lives.

Figure 1. The 3 phases of the GGM programme, a model operation process. [9]

The GGM programme is addressing a complex issue, which is being increasingly openly acknowledged. There is growing awareness that corruption impedes progress in reaching development goals. Interest in the programme has been higher than anticipated and momentum for change is building. The preventative and constructive approach used by the programme, of measuring vulnerability to corruption and strengthening pharmaceutical systems by increasing transparency and promoting integrity, has appealed to governments. Experience over the past six years has shown that countries progress through the programme at varying rates, influenced by such factors as political stability, readiness for change and the availability of human and financial resources. The greatest success has been in countries where there is high-level government commitment, civil society and other anti-corruption initiatives are engaged, and communication and staff training are ongoing. Good governance for medicines programmes eight lessons of success [10]:

1. There is great interest in the subject area and the preventative approach used is appealing;
2. National champions and a dedicated and motivated national GGM team enhance success;
3. Involvement of high-level and technical officials is essential for sustainability;
4.Promotion of integrity should go together with legislative reforms;
5. Collaboration with key stakeholders is valuable;
6. Effective government communication strategy is important;
7. Countries progress at different speeds influenced by a range of factors;
8. Institutionalization of GGM principles is necessary for longterm sustainability.

In the previous study of vulnerability to the corruption, KENYA have participated on the assessment this eight key pharmaceutical system functions has been assessed, namely:

medicines registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution. It was conducted using an assessment tool and model framework developed by the World Health Organization, which focuses on structures and mechanisms to prevent unethical practices in decision-making in the public pharmaceutical sector. Kenya is in the process of implementing its development blueprint - Vision 2030 – which is anchored on economic, social and political pillars, some key aspects being governance reforms as well as public sector reforms. In this regard, the Government continues to intensify efforts to bring about an attitudinal change in public service that values transparency and accountability to the citizens of Kenya. Health sector reform is in progress under the National Health Sector Strategic Plan (NHSSP II) and mechanisms for health sector governance and coordination are actively being strengthened. To guide the much-needed reforms in the pharmaceutical sector, the Government has developed the Kenya National Pharmaceutical Policy (KNPP) which enshrines 'good governance' as one of its core principles. The Pharmaceutical Strategy has provided a framework for coordinated planning, monitoring and evaluation.[10]

Methodology used

Two trained national assessors carried out the study between May and July 2008 using a standardized World Health Organization (WHO) assessment tool. A total of 113 key informants (KIs) were interviewed. Interviewees were from the Medicines Regulatory Authority (MRA) (Pharmacy and Poisons Board (PPB)), Government procurement and distribution department, other Government ministries, universities, community pharmacies, the private pharmaceutical industry, national and international nongovernmental organizations (NGOs), media and legal institutions. The quantitative indicators used were scored and a rating system was used to represent the degrees of vulnerability to corruption.

Results obtained

Registration of medicines: The average final score for registration was 4.36, indicating moderate vulnerability to corruption. The requirements for applicants are fairly well documented, including a standard application form for submission of applications for registration, guidelines on how to submit the application and a list of registered medicines. There is a committee which meets regularly to assess applications, and applicants who have their applications rejected by the committee can make formal appeals to the PPB. However,

there are no written guidelines on selection criteria for members of this committee, on the committee's composition and terms of reference, procedures on how to assess applications, how and where medicines registration officers meet with applicants and on conflict of interest (COI) with regard to registration activities.

Licensing of pharmaceutical establishments: The average final score for licensing was 5.21, indicating moderate vulnerability to corruption. There is provision in the law for licensing of pharmaceutical establishments and the MRA has a unit and a committee for licensing activities. There are written procedures on how to submit applications for licensing and how to assess applications. Although a pre-licensing inspection report is required before issuing a licence, post-licensing inspection of establishments is not regular. There is a list of licensed pharmaceutical establishments, but it is neither comprehensive nor up-to-date. There are no written guidelines on selection criteria for members of the committee for licensing or on its composition and terms of reference. There is no independent appeals system for applicants who have their applications for licensing rejected.

Inspection and market control of medicines: Inspection and market control of medicines is very vulnerable to corruption, having an average final score of 3.95. There is comprehensive provision in the medicines legislation covering inspection of pharmaceutical establishments and written standard operating procedures (SOPs) for conducting inspections. There are written guidelines for Good Manufacturing Practices (GMP) and also for Good Distribution Practices (GDP) for pharmaceutical products in Kenya, but these guidelines do not classify non-compliance with GMP or GDP. No written criteria for selection and recruitment of inspectors and no guidelines on COI exist. Written procedures to prevent regulatory capture between inspectors and the manufacturing and distributing companies inspected are also non-existent.

Drug promotion control: The average final score for licensing was 4.53, indicating moderate vulnerability to corruption. There is provision within the pharmacy legislation covering promotion and advertising of medicines, with clear penalties for anyone who breaches the law. Pre-approval of promotional material is required and there is a promotions service that vets medicines promotion advertisements, but monitoring and enforcing the provisions on this promotion are very weak. SOPs for the service for medicines promotion are being developed. However, there are no written guidelines on selection criteria for

members of the promotion service unit, nor on the composition and terms of reference of the committee. There are no written procedures to report unethical promotional practices and none for COI. Control of clinical trials: The average final score for control of clinical trials was 6.25 which indicate marginal vulnerability to corruption. There is provision for theregulation of clinical trials in the Science and Technology Act. The PPB has a committee which is responsible for reviewing applications and it also has requirements for the manufacture, importation, exportation and use of investigational products. There are guidelines on the submission of applications to the PPB to conduct clinical trials and to the various institutional ethics and research committees. There is no system for inspection of clinical trials and no written guidelines on selection criteria for members neither of the PPB and Ethics and Research Committees (ERCs) nor on COI. There are no national guidelines on principles of Good Clinical Practice and none for the establishment of an independent ethics committee.

Selection of medicines: Selection of medicines had the lowest average final score of 2.95, showing that this function is very vulnerable to corruption. The essential medicines list (EML) is in line with WHO procedures, but it was last updated in 2002. There are no written criteria for the selection process for including or deleting medicines from the national EML. A National Medicines and Therapeutics Committee (NMTC) was constituted in 2007, but it is not yet operational. There are clear criteria for the selection of NMTC members, and terms of reference describing the role and responsibilities of the NMTC have been developed, but most stakeholders are not aware of their existence. There are no written guidelines on COI and the NMTC has no SOPs for their decision-making. Procurement of medicines: The average final score for procurement of medicines was 7.01, which indicates marginal vulnerability to corruption. Transparent and explicit procedures for procurement exist and are heavily informed by the Public Procurement and Disposal Act. A description of the internal procedures to be followed by procurement staff when processing bids is available to the staff. The Procurement Office monitors supplier performance for compliance with the contract terms and it is also audited on a regular basis. There is a Tender Committee whose functions are clearly separated from the functions of the Procurement Office.

There is a formal appeals process for applicants who have their bids rejected. There are no written guidelines on COI with regard to the procurement of medicines. Distribution of medicines: Distribution of medicines had the highest of all scores, 7.82, indicating marginal

vulnerability to corruption. All procured commodities are delivered from the suppliers directly to the central warehouses where they are verified. Most medicines carry a Government identification inscription on both the primary and secondary packaging. A "master map" showing the location of medicines does not exist, but products are arranged taking into account their expiry dates. A security management system, procedure for requesting medicines, SOPs for stock management, computerized and manual information systems, a monitoring and evaluation system, and a communication system between distributions points are all in place. The warehouses are subject to regular internal and external auditing. Sanctions to be imposed on individuals for theft or corrupt practices are set out in the Public Procurement Act.

3. METHODOLOGY

3.1 Study Design

A set of questionnaires was compiled for each function of the assessment, where four methods were used to determine the level of transparency of the practice. The methodology used in this assessment is intended primarily to collect qualitative information on selected indicators and then quantify the vulnerability to corruption by having a final score (Method 1 and 2) and perceptions of relevant health professionals in the public and private sectors (Method 3). Method 4 is used to capture additional information by using open-ended questions. The instrument for measuring transparency in the public pharmaceutical sector was used. The study is based on the assessment instrument of WHO, GGM [9].

Method1. Questions requiring a binary answer (yes/no). GGM (WHO., 2011)

Method2. Questions with sub-Questions requiring a binary answer (yes/no). GGM (WHO., 2011)

Method 3. Subjective questions probing perception. (Likert scale)

Method4. Open Questions for collecting additional information and recommendation

3.1.1 Selection Medicines Indicators

Indicator 1: Does the government have an officially adopted national essential medicines list (EML) publicly available?

Indicator 2: To what extent do you agree with the following statement: "The national essential medicines list has been developed in consultation with, and considering the opinion of all interested parties and using an evidence-based approach"?

Indicator 3: Are there clearly written and transparent rules/criteria for the selection process for including or deleting medicines from the national EML?

Indicator 4: Is the EML in line with WHO procedures?

Indicator 5: Is there a committee responsible for the selection of the national EML?

Indicator 6: To what extent do you agree with the following statement: "The committee responsible for the selection of the national EML is operating free from external influence"?

Indicator 7: Are there clear criteria for the selection of members of the selection committee?

Indicator 8: Are there written guidelines on conflict of interest with regard to the selection of essential medicines?

Indicator 9: Are there clear and publicly available SOPs that describe the role and responsibilities of the selection committee?

Indicator 10: Are the rules for decision-making clear and transparent in the SOPs?

Indicator 11: In your opinion, what types of unethical behaviour are common in the selection process in your Rwanda?

Indicator 12: If you were in a position of highest authority, what would be the first actions that you would take to improve medicine selection?

3.1.2. Medicine registration Indicators

Indicator 1: Is there an up-to-date list of all registered pharmaceutical products available in the country?

Indicator 2: If such a list exists, does it provide a minimum level of information?

Indicator 3: Are there written procedures for applicants on how to submit an application for registration of medicinal products?

Indicator 4: Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?

Indicator 5: Is there a standard application form publicly available for the submission of applications for registration of medicinal products?

Indicator 6: Are there written guidelines setting limits on how and where medicine registration officers meet with applicants?

Indicator 7: Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?

Indicator 9: Is there a written document that describes the composition and terms of reference of the committee?

Indicator 10: Are there written guidelines on conflict of interest with regard to registration activities?

Indicator 11: To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your Rwanda"?

Indicator 12: Are there clear and comprehensive guidelines for the committee′s decision-making process?

Indicator 13: Is there a formal appeals system for applicants who have their drug applications rejected?.

Indicator 14: To what extent do you agree with the following statement: "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on their final decisions"?

Indicator 15: In your opinion, what types of unethical behaviour are common in the registration system in your country?

Indicator 16: If you were in a position of highest authority, what would be the first actions that you would take to improve the registration process in your country?

3.1.3 Procurement of Medicines Indicators

Indicator 1: Does the government use transparent and explicit procedures for procurement of pharmaceutical products?

Indicator 2: Is there written guidance for procurement office staff on the type of procurement method to be used for different types of products?

Indicator 3: Is procurement done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased?

Indicator 4: Is there a formal appeals process for applicants who have their bids rejected?

Indicator 5: Is there a tender committee?

Indicator 6: Are there any specific criteria for tender committee membership?

Indicator 7: Are there written guidelines on conflict of interest with regard to the procurement process?

Indicator 8: To what extent do you agree with the following statement: "The members of the tender committee are systematically selected based on specific criteria"?

Indicator 9: Is there a computerized management information system used to report product problems in procurement?

Indicator 10: Are there SOPs for routine inspection of consignments?

Indicator 11: Is there an efficient post-tender system in place to monitor and report on supplier's performance to the tender committee?

Indicator 12: Does the procurement office undergo regular audits?

Indicator 13: To what extent do you agree with the following statement: "The procurement system in your country is operating in a totally transparent manner"?.

Indicator 14: In your opinion, what types of unethical behaviour are common in the procurement system in your country?

Indicator V.15: If you were in a position of highest authority, what would be the first actions that you would take to improve the systems and processes of procurement?

3.1.4 Distribution of Medicines Indicators

Indicator1: Is there a system in place that can expedite port clearing?

Indicator 2: To what extent do you agree with the following statement: "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process"?

Indicator 3: Is there an inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier?

Indicator 4: Is there a coding system used to identify government medicines?

Indicator 5: Is there systematic and orderly shelving of products in warehouses or store rooms?

Indicator 6: Is there a security management system in place to oversee storage and distribution?

Indicator 7: Is there an inventory management system that is used in the warehouse at each level of the distribution system?

Indicator 8: Are stock records reconciled with physical counts at least every 3 months by internal staff?

Indicator 9: Are there independent audits of warehouses by external inspectors or auditors?
Indicator 10: Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health facility?

Indicator 11: Is there a well-functioning communication system between distribution points?
Indicator 12: Does a programme exist for monitoring and evaluating the performance of the medicine distribution system?

Indicator 13: Are sanctions imposed on individuals or agencies/companies for theft or other corrupt practices associated with distribution?

Indicator 14: To what extent do you agree with the following statement: "There are very rarely leakages in the medicine distribution system in your Rwanda"?

Indicator 15: If you were in a position of highest authority, what would be the first actions that you would take to improve the systems and processes of public sector medicine distribution in Rwanda?

3.2 Study area and period

The data collection was carried out between April and June 2016. Most of the key people interviewed were from different area of Rwanda and others are located in the capital city, Kigali, where the regulators and policy-makers are and where most of the activities take place.

3.3 Selection of key Informant

For each of the six pharmaceutical functions studied, 2-11 Key Informants were interviewed to give a total of 61 informants. Their selection was carefully made based on knowledge and level of involvement in the pharmaceutical sector. The KIs were a mix of senior, middle and

junior level of personnel in the pharmaceutical sector and they represented various institutions, such as the MoH (13), MPPD(11), Wholesalers (5); DPs (13); DHs (13) and private pharmacies (5 key informant).

3.4 Data scoring and analysis

During the study period, data collection involved utilizing a diagnostic tool for interviewing a total of 61 key informants. Among them, 10 were per decision point, except for the procurement function where 11 KIs were interviewed. Each indicator required a "yes" or "no" response from the KIs determining the presence or absence of the existing practice at the department of health. On this basis, a "yes" answer is given a value of "1" and a "no" answer is given a value of "0" by the researcher. A value of "1" represents low vulnerability to corruption, while the value of "0" represents high vulnerability to corruption. The sum of all ratings is then divided by the number of indicators in a given key decision point and multiplied by 100% to get the total percentage for each section. The result (percentage) is multiplied by 10 to convert to a scale of zero to 10. Only answers to Method 1 and Method 2 questions were included in the scores.

Using Microsoft Excel, the sum of scores for all indicators for each function was then divided by the number of indicators, and multiplied by 10 to give the final score for each function on a scale of zero to 10. The 10-point rating system represented the degrees of vulnerability to corruption shown in Table 2 below.

Table 1: Vulnerability scale to the corruption

0.0-2.0	2.1-4.0	4.1-6.0	6.1-8.0	8.1-10.0
Extremely Vulnerable	Very Vulnerable	Moderately Vulnerable	Marginally Vulnerable	Minimally Vulnerable

3.6 Ethical considerations

Considering the need of confidentiality in this study, all private information's were not disclosed. However, all gaps found will urgently be communicated to the targeted sites, and public health officials for appropriate mitigation.

4. RESULTS

4.1 Summary of the results

This section of the report presents the results collected using the questionnaires, which were filled in by the 61 key informants (KIs'). It gives a narrative account of the KIs' answers for each indicator with some clarifications where necessary. The following section focuses on the qualitative results based on KI's answers and the evidence gathered throughout the study. The overall scores for each function of the assessment are summarized in Table 3. The KIs were asked to give their opinion on a series of statements and the respective responses are reported in the table below.

Table 2: Vulnerability scale scores in the four different sections

	REGISTRATION	SELECTION	PROCUREMENT	DISTRIBUTION
Indicator 1	1	1	1	1
Indicator 2	1	_	1	1
Indicator 3	1	0.6	1	1
Indicator 4	0.65	0.4	1	1
Indicator 5	0.96	1	1	1
Indicator 6	1	_	1	1
Indicator 7	1	0.3	1	1
Indicator 8	0.6	0	1	1
Indicator 9	0.8	1	1	1
Indicator 10	0	0.5	1	0
Indicator 11	_	_	1	1
Indicator 12	0.9	_	1	1
Indicator 13	_	2.15	1	1
TOTAL	8.91	6.95	13	11
FINAL SCORE	5.569	5.792	8.733	7.857
Degree of vulnerability	Moderately Vulnerable	Moderatetly Vulnerable	Minimally Vulnerable	Marginally Vulnerable

Table 3: The Perception of Key Informants (KIs)

SECTION	STATEMENT	PERCEPTION OF KIs
Registration	The members of the registration committee are systematically and objectively selected based on the written criteria in force in Rwanda	50% strongly agree or Agree
	Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decision	40% strongly Agree and Agree,40% strongly desagree and Desagree
Selection	The national essential medicines list (EML) has been developed in consultation with the opinion of all interested parties and using evidence-base approach	70% Strongly Agree or Agree
	The committee responsible for the selection of the national EML is operating free from external influence	60% agree
Procurement	The members of the tender committee are systematically selected based on specific criteria	55% Agree
	The procurement system in Rwanda is operating in a totally transparent manner	82% strongly Agree or Agree
Distribution	The port clearing is done smoothly and there is no need for bribery or gift giving to expedite the process	60% Agree
	There are very rarely leakages in the medicine distribution system	50% Agree,50% Desagree

4.2 Medicine registration

Indicator I.1: Is there an up-to-date list of all registered pharmaceutical products available in the country? There is an easily accessible, official, up-to-date list of pharmaceutical products approved for sale or distribution in RWANDA. Drugs that are not on the official list are non-approved and should not be available in the market for sale or use. Drug registration is based on an objective assessment of a drug's efficacy, safety, quality and the accuracy of the information on the product packaging.

Indicator I.2: If such a list exists, does it provide a minimum level of information? The list provides sufficient and accurate information, and includes the description of the product including the name of the product, dosage form, strength, packaging, name of manufacturer, country of manufacture, site of manufacture, date of registration, registration number, validity of registration, and whether the medicine is prescription-only.

Indicator I.3: Are there written procedures for applicants on how to submit an application for registration of medicinal products? The written procedures for applicants on how to submit an application for registration of medicinal product are clear but was not yet published in the official gazette. They describe the process to follow for submitting an application, the data to be submitted, and the timeframe for processing an application. There are written procedures that describe the process to be followed in assessing submitted applications, which mention the time frame for processing and specify the issues to be considered in assessing submissions. However, these procedures are not publicly accessible and do not provide guidance on report writing , the fees, and the criteria for drug registration.

Indicator I.4: Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products? There are written procedures that describe the process to be followed in assessing submitted applications, which mention the time frame for processing and specify the issues to be considered in assessing submissions. However these procedures are not publicly accessible and do not provide guidance on report writing.

Indicator I.5: Is there a standard application form publicly available for the submission of applications for registration of medicinal products? There is a standard application form made publicly available for the submission of applications for the registration of medicinal products. This document is available on the LMO (Rwanda MHO/Logistic Management Office) website. It requires a description of the product, such as

the name of the product (brand name and International Non-proprietary Name INN) and the composition per unit dose. It includes a brief summary of the manufacturing method; the specifications of pharmaceutical ingredients and excipients; the Summary of Product Characteristics (SPC), including the pharmacological action, therapeutic classification, indications and contraindications; and details of the packaging material and labelling.

Indicator I.6: Are there written guidelines setting limits on how and where medicine registration officers meet with applicants? There are written guidelines for setting limits on where medicines registration officers meet the applicants. However, the guidelines don't include the number of registration officers present, to avoid any real or perceived conflict of interest in the outcomes of the meetings (usually one officer meets the applicant); and there are no minutes of the meetings that include the names of those in attendance.

Indicator I.7: Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products? There are functioning formal committees responsible for assessing applications for registration of pharmaceutical products according to the Department of Pharmacy Regulation, to ensure that the applications submitted for registration are assessed for efficacy, safety, quality, accuracy and completeness of product information. These committees are: the technical committee for the registration of new medicines (originators); the studying the medicinal plants and herbs committee; the bioequivalence studies committee; and the re-registration of registered products committee.

Indicator I.8: Are there clear written criteria for selecting the members of the committee? There are written criteria for selecting the members of two of the registration committees according to the Department Pharmacy regulations (technical committee for the registration of originators and generic medicine committee). It specifies the professional qualifications required, the required research experience in the area of expertise and gives a time-frame for serving as a committee member. It also specifies the technical skills and work experience related to the area and organizational affiliation to be considered when selecting members. However, it does not require declaration of conflict of interest (e.g. investment in a pharmaceutical company, spouse working in a pharmaceutical company, payment received from companies or individuals, etc.). The other registration committees, the studying the medicinal plants and herbs committee, and the vaccines committee, do not have clear written criteria for selecting their members.

Indicator I.9: Is there a written document that describes the composition and terms of reference of the committee? Technical committees have a written and but not yet publicly accessible document, available as part of the drug and pharmacy law, which describes the committee membership, roles and responsibilities. However, the committees do not include the accountability of the members.

Indicator I.10: Are there written guidelines on conflict of interest with regard to registration activities? There are no written guidelines on conflict of interest and a conflict of interest declaration form does not exist with regard to registration activities.

Indicator I.11: To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"?50% agreed or strongly agreed with the statement "The members of the registration committee are systemically and objectively selected based on the written criteria in Rwanda.

Indicator I.12: Are there clear and comprehensive guidelines for the committee′s decision-making process? Two of the registration committees, the technical committee for the registration of originators and the generic drug committee, according to the Drug and Pharmacy Law, have clear and comprehensive guidelines for their decision-making processes,

Indicator I.13: Is there a formal appeals system for applicants who have their drug applications rejected? There is an appeal mechanism, available at Rwanda MOH, to manage concerns and complaints from companies and drug stores.

Indicator I.14: To what extent do you agree with the following statement: "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on their final decisions"? 40% agreed or strongly agreed with the statement "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on their final decisions".

Indicator I.15: In your opinion, what types of unethical behaviour are common in the registration system in your country? These can include bribery, material gifts, favouritism (family, friends), conflict of interest (e.g. investments in pharmaceutical companies), etc.

The common types of unethical behaviour in the registration system in Rwanda:

- 3 key informants though that the common types can be conflict of interest

- 3 key informants though that the common types can be favouritism
- 2 key informants though that the common types can be material gifts

Indicator I.16: If you were in a position of highest authority, what would be the first actions that you would take to improve the registration process in your country?

a) The first actions that the KIs would take to improve the registration process in Rwanda regarding the quality of services offered by public institutions would be to:

- Train employees of the public institution.
- Recruit qualified personnel.
- Build the experience of the staff and form in-house committees.
- The members of technical committees must be from registration staff.
- Adopt the support of external experts in the field of assessment.
- Follow and comply totally with the East Africa guidelines regarding the documents needed for registration.
- Enhance the registration process by increasing the number of committee members.
- Increase the number of registration employees and increase the number of pharmacists allowed to receive applications, thus facilitating and accelerating the process of appointments.
- Adopt the international procedures for registration.
- Decrease the technical requirements for registration/re-registration of products (this was an opinion from private sector).

b) The first actions that the KIs would take to improve the registration process in Rwanda regarding transparency in the services offered by public institutions would be to:

- Publish all requirements, processes and procedures.
- Publish SOPs.
- Increase knowledge of the services offered and the way in which people work in order to increase awareness.
- Clarify the procedures of registration to the public.
- Enable submission of files on the website.
- Provide guidelines on conflict of interest and rules for the acceptance of gifts.
- Ensure that the appeal committee is different from the registration committee.
- Make sure that the manufacturer or the agent is in direct contact with the pharmacist who accepts/refuses the file.

- Accept applications electronically, particularly changes that occurred to the product.
- Ensure that the committees responsible for registration of medicines declare any conflict of interest issues.

4.3 Selection

Indicator IV.1: Does the government have an officially adopted national essential medicines list (EML) publicly available? The national essential medicines which is available is not adopted it is a draft one dated of 2013; but it helps the government to purchase appropriate drugs for their population.

Indicator IV.2: To what extent do you agree with the following statement: "The national essential medicines list has been developed in consultation with, and considering the opinion of all interested parties and using an evidence-based approach"? 70% agreed or strongly agreed with the statement.

Indicator IV.3: Are there clearly written and transparent rules/criteria for the selection process for including or deleting medicines from the national EML? The government have clear guidelines that specify what criteria are applied for medicines to be included in or deleted from the MOH/Department of Pharmacy. The inclusion of new medicines should be based on studies that confirm that the medicine is necessary for the health needs of the population and is cost-effective, and the deletion of a drug from the Medicines Regulation Authority is based on evidence that the drug is inappropriate or not cost-effective for the population's health needs. However, the committee of selection does not include a person who is experienced in pharmacoeconomics.

Indicator IV.4: Is the EML in line with WHO procedures? The products are listed by generic name, pharmacological category, and by level of health care. We do not have national treatment guidelines for all common diseases in Rwanda.

Indicator IV.5: Is there a committee responsible for the selection of the national EML? A selection committee is appointed to give technical advice on the revision and update of the Essential medecines selection. It includes physicians of different specializations and pharmacists.

Indicator IV.6: To what extent do you agree with the following statement: "The committee responsible for the selection of the national EML is operating free from external influence"? 60% agreed with the statement "The committee responsible for the selection of the national EML is operating free from external influence".

Indicator IV.7: Are there clear criteria for the selection of members of the selection committee? The criteria for selecting committee members are not made publicly available. However, the criteria define the professional requirements, and the committee only includes experts from the medicine and pharmacy fields. The criteria do not require declaration of conflict of interest, and membership is not time-limited.

Indicator IV.8: Are there written guidelines on conflict of interest with regard to the selection of essential medicines? There are no written guidelines on conflict of interest and a conflict of interest declaration form does not exist.

Indicator IV.9: Are there clear and publicly available SOPs that describe the role and responsibilities of the selection committee? There are clear and publicly available SOPs that describe the rules for the decision-making process. Decision is made by majority of the members. If the numbers of members who accept adding or selecting the medicine equal the number of the members who refuse it, the decision of the chairperson of the committee is considered.

Indicator IV.10: Are the rules for decision-making clear and transparent in the SOPs? The rules for decision-making defined in the SOPs require that: decisions are made by all members in a democratic manner; minutes of meetings are produced and approved by the members; consultations are held with interested parties; final decisions for selecting medicines are taken independently; decisions on the selection process are made publicly available.

Indicator IV.11: In your opinion, what types of unethical behaviour are common in the selection process in your country? These can include bribery, material gifts, favouritism (family, friends), conflicts of interest (e.g. investments in pharmaceutical companies), pressure on consultants by companies, etc.

The common types of unethical behaviour in the selection process in Rwanda:

- (4 of our respondings thought that in the procurement process material gift)
- (3 of our respondings thought that in the procurement favouritism)

- conflict of interest (1)

Indicator IV.12: If you were in a position of highest authority, what would be the first actions that you would take to improve medicine selection?

a) The first actions that the KIs would take to improve medicine selection in terms of the quality of services offered by public institutions would be to:

- Ensure that choosing a medicine is dependant on cost-effectiveness studies.
- Publish the national standard treatment guidelines and ensure that they are linked to the rational medicine list.
- Ensure medicine selection is based on the scientific (generic) name.
- Set treatment guidelines for chronic diseases and ensure that doctors to stick to it Ensure that the selection committee must include a qualified member with a PhD in pharmacoeconomics.
- Make membership of the selection committee limited in time.
- Ensure a member from private sector is present on the selection committee.

b) The first actions that the KIs would take to improve medicine selection in terms of transparency in the services offered by public institutions would be to:

- Publish all the scientific information for the reasons of choosing these medicines.
- Set written guidelines on conflict of interest.
- Change the committees of selection every year.
- Train members to review on a cost-effectiveness basis.
- Set laws to force all doctors in the public sector to stick to the list.
- Ensure the rules for decision-making in the SOPs are clear and transparent to the public.

4.6 Procurement

Indicator V.1: Does the government use transparent and explicit procedures for procurement of pharmaceutical products? YES.The government has an explicit document that describes the procurement process for pharmaceutical products under the Joint Procurement Law of Medicines and Medical Supplies (2002).

This document is publicly available and requires: the use of generic names; the advertisement of tenders; that contract specification is made publicly available; criteria for adjudication of

tenders are included as part of the tender package; information on the tender process and results are made public; and a description of the internal process to be followed by the procurement staff on how to process the bids and the other entities of the public sector only stick to 80%–90% of it.

Indicator V.2: Is there written guidance for procurement office staff on the type of procurement method to be used for different types of products? **YES,** There are several types of procurement methods used to purchase pharmaceutical products, which fall into one of four basic categories: open tender, restricted tender, competitive negotiations and direct procurement. The procurement method chosen for each product aims to obtain the lowest possible purchase price for assured quality products. Written guidance is available for procurement office staff on what procurement method to use for the different types of products to be purchased.

Indicator V.3: Is procurement done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased? Medicine procurement is based on objective, expected health needs, and on budget availability to reduce the risk of over-supply, under-supply, or unnecessary supply of pharmaceuticals.

Indicator V.4: Is there a formal appeals process for applicants who have their bids rejected? An appeal mechanism works in the following way: If a firm is unsuccessful in its bid for a tender, a representative from the firm can file a protest based on the firm's view that the tender excludes it unfairly or that the tender process was flawed. This appeal process is available online.

Indicator V.5: Is there a tender committee? Yes, If so are the key functions of the procurement office and those of the tender committee clearly separated? A tender committee is available. Its main role is to review information on suppliers and determine which suppliers should participate in the tender, if a restricted tender is used, and which suppliers should receive contracts. Staff from the procurement office, whose main role is to collect information on needs, manage the tender process and monitor the supplier's performance.

Indicator V.6: Are there any specific criteria for tender committee membership? The criteria that the government has for selecting tender committee members is written in an article of the Joint Procurement Law of Medicines and Medical Supply. They are appointed for their professional expertise. The members should have skills that complement each other, including senior government officials in departments served by the procurement system, and

representation from client facilities (governmental hospitals). The membership rotates periodically every 2 years and is renewable for one time. The criteria do not require that each member should declare conflict of interest. The criteria for committee membership are publicly available.

Indicator V.7: Are there written guidelines on conflict of interest with regard to the procurement process? There are no written guidelines on conflict of interest with regard to the procurement process.

Indicator V.8: To what extent do you agree with the following statement: "The members of the tender committee are systematically selected based on specific criteria"? 55% agreed with the statement "The members of the tender committee are systemically selected based on specific criteria".

Indicator V.9: Is there a computerized management information system used to report product problems in procurement? The management information system is computerized and it includes product records, and monitors supplier and facility performance. It also records all quality assurance information for products purchased, and tracks the status for each order, including the quantities actually purchased compared with the original estimates made.

Indicator V.10: Are there SOPs for routine inspection of consignments? In Rwanda, each drug shipment should be physically inspected. This involves checking adherence to contract specifications. Additionally batch samples should be sent to quality control laboratories using random sampling for known suppliers and systematic sampling for new ones. All documents including inspection reports and laboratory testing results should be archived in the procurement office.

Indicator V.11: Is there an efficient post-tender system in place to monitor and report on supplier's performance to the tender committee? It includes that the procurement committee should be composed of member of procurement ;office monitors; supplier performance and compliance with the contract terms. The monitoring system tracks the supplier's lead-time, delivery status, shelf life, and packaging of products. Product quality is also tracked, and suppliers with poor performance are blacklisted for a certain period of time.

Indicator V.12: Does the procurement office undergo regular audits? The procurement office should undergo external auditing through the Auditoriat general at least once a year, and its results are made publicly available in the parliament of Rwanda. The annual audit should

report on the operating costs of the procurement office, pharmaceutical products tendered, quantities of the products procured, and the contracts awarded. Results of tenders are available in all official documents and the awarded suppliers are notified.

Indicator V.13: To what extent do you agree with the following statement: "The procurement system in your country is operating in a totally transparent manner"? 82% agreed or strongly agreed with the statement "The procurement system in Rwanda is operating in a totally transparent manner".

Indicator V.14: In your opinion, what types of unethical behaviour are common in the procurement system in Rwanda? These can include bribery, material gifts, favouritism (family, friends), conflict of interest (e.g. investments in pharmaceutical companies), etc.

The common types of unethical behaviour in the procurement system in Rwanda:

- 6 of our respondings thought that in the procurement process material gift can be common
- 3 of our respondings thought that in the procurement process bribery can be common
- 2 of our respondings thought that in the procurement process , travelling can be common
- 1 of our respondings thought that in the procurement process favouritism can be common.

Indicator V.15: If you were in a position of highest authority, what would be the first actions that you would take to improve the systems and processes of procurement?

a) The first actions that the KIs would take to improve the systems and processes of procurement in terms of the quality of procurement services would be to:

- Train employees of the public institution.
- Recruit qualified personnel.
- Re-structure the procurement department to include the following key functional areas: specification section; accountancy section; quality assurance section; including audit; procurement section; receiving and checking section; and information technology support.
- Review procedures to ensure that prospective suppliers are pre-qualified, and that their performance is monitored for product quality, service reliability, delivery time and financial viability, and appropriately recorded in a retrievable database.

- Simplify the procurement process to have a positive impact on the system and improve effectiveness. This could be achieved by: requiring a more evidence-based approach to medicine selection for procurement; and rationalization of medicine requirements,

b) The first actions that the KIs would take to improve the systems and processes of procurement in terms of transparency in procurement services would be to:

- Set written guidelines on conflict of interest with regard to the procurement process.
- Ensure that the submission of the tenders' process can be done online on the website and that the results are posted on the website.
- Ensure that the members of the tender committee are required to declare any conflict of interest issues.
- Enforce the blacklisting of non-performing or poor performing suppliers. This should be regularly updated and a copy of the list forwarded to the procurement department.

4.7 Distribution

Indicator VI.1: Is there a system in place that can expedite port clearing? The medical stores have a person that is responsible for port clearing and there is a computerized system to monitor port clearing activities.

Indicator VI.2: To what extent do you agree with the following statement: "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process"? 60% agreed with the statement "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process".

Indicator VI.3: Is there an inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier? There is a designated staff member responsible for checking receipts against the packing list when supplies arrive at the warehouse. The responsible person should prepare documentation through a receiving report on the basis of the invoice specifying the types, quantities and condition of the supplies received.

Indicator VI.4: Is there a coding system used to identify government medicines? Government medicines can be identified by imprints on containers and external packaging.

Indicator VI.5: Is there systematic and orderly shelving of products in warehouses or storerooms? Products in warehouses are organized systemically by dosage forms: tablets and

capsules, injections, syrups and suspensions, creams and ointments, etc. These dosage forms are arranged according to therapeutic action. A computerized system is used to control expiry dates of medicines entered alphabetically or by manufacturer (MPPD, SAGE SYSTEM), etc.

Indicator VI.6: Is there a security management system in place to oversee storage and distribution? There is no effective security management system to oversee storage and distribution. There are regulations for monitoring entry and exit to warehouses; to ensure limited access to unauthorized persons; and, to ensure that controlled substances (narcotics) are separated and secured. However, there is an alarm system for security breaches and there is a CCTV physical search done for those leaving the warehouse.

Indicator VI.7: Is there an inventory management system that is used in the warehouse at each level of the distribution system? There are inventory records and procedures in the warehouses at various levels of the distribution system. The inventory control system provides information on the following elements: the average working stock; the amount of safety stock; the frequency of reordering; the quantity of reordering; the average inventory; and the lead time.

Indicator VI.8: Are stock records reconciled with physical counts at least every 3 months by internal staff? The warehouse staffs continuously produces up-to-date records of current stock levels reconciled with the physical count of selected medicines.

Indicator VI.9: Are there independent audits of warehouses by external inspectors or auditors? The warehouses are subjected to external auditing by the Auditoriat General at regular time intervals, and random auditing by the Ministry of Health. When asked, the warehouse supervisor should be able to provide the date of the last audit that was conducted and show: a report of the warehouse audit; that the audit was carried out at least once a year; and that the audit was carried out by an independent party (Auditoriat General).

Indicator VI.10: Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health facility? A computerized system provides information on medicines that have left the warehouse to health facilities, including: type of medicines that have left the warehouse; quantity of medicines that have left the warehouse; the person who verified the amounts; the intended recipients of these medicines; and the date that the medicines arrived at the designated health facility.

Indicator VI.11: Is there a well-functioning communication system between distribution points? The communication system between distributions points include: a manual/document exchange system between distribution points at all levels; telephone contact between all levels of the distribution points; and fax contact between all levels of the distribution points. However, a computerized system does not exist.

Indicator VI.12: Does a programme exist for monitoring and evaluating the performance of the medicine distribution system? There is no programme that exists for monitoring and evaluating the performance of the medicine distribution system.

Indicator VI.13: Are sanctions imposed on individuals or agencies/companies for theft or other corrupt practices associated with distribution? Sanctions are imposed on individuals for theft or corrupt practices. There are procedures in place for the application of sanctions for corrupt behaviour. The type of sanctions to be applied depends on the nature and gravity of the act of corruption. Evidence exists that individuals have been sanctioned for corrupt behaviour in the past.

Indicator VI.14: To what extent do you agree with the following statement: "There are very rarely leakages in the medicine distribution system in your country"? 50% agreed with the statement. "There are very rarely leakages in the medicine distribution system in Rwanda"

Indicator VI.15: If you were in a position of highest authority, what would be the first actions that you would take to improve the systems and processes of public sector medicine distribution in your country?

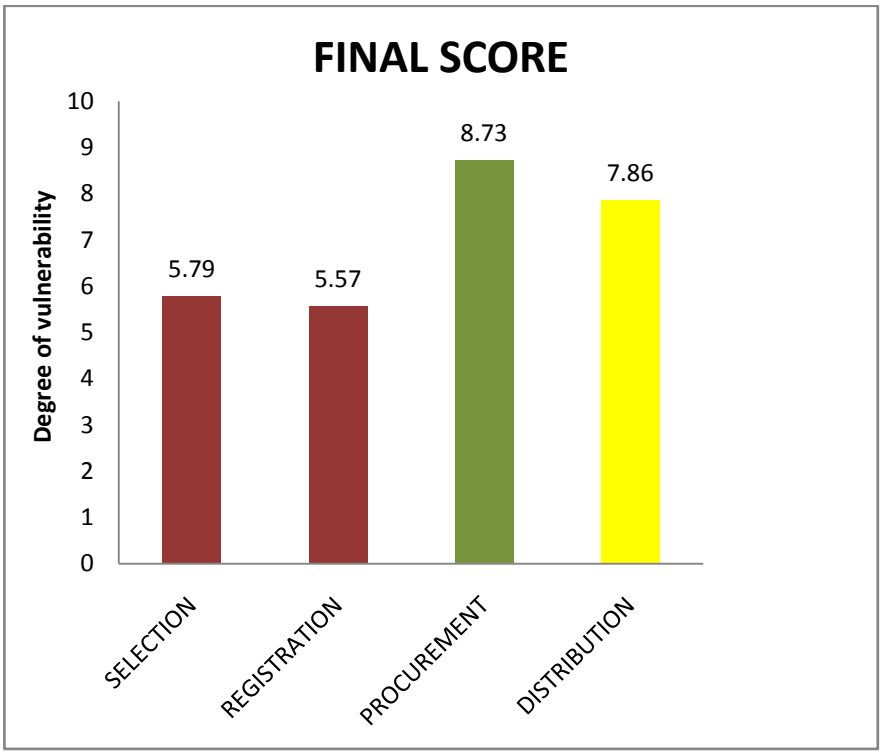
a) The first actions that the KIs would take to improve the systems and processes of public sector medicine distribution in Rwanda in terms of the quality of services offered by the public institutions would be to:

- Train the employees of the public institution.
- Recruit ethical and qualified personnel.
- Introduce more effective security management to oversee storage and distribution
- Introduce a computerized system for the communication between distribution points.

b) The first actions that the KIs would take to improve the systems and processes of public sector medicine distribution in Rwanda in terms of the transparency of the services offered by the public institutions would be to:

- Submit reports identifying weakness of the distribution system and these weaknesses must be reported to the public.

Figure 2. Representation of Final Score Vs. the degree of vulnerability



5. Data analysis and interpretation

5.1 Summary

The following sections provide specific analysis of the results obtained during the interviews with the key informants. It is important to highlight that data were collected during the interviews and through the analysis of the information supplied by KIs. The results are presented in the areas of registration, promotion, inspection, selection, procurements and distribution of medicines. The study revealed that the areas of medicines registration and selection are marginally vulnerable to corruption, medicine inspection is moderately vulnerable to corruption, medicine procurement are minimally vulnerable and the distribution are margiinally vulnerable to corruption, while medicine promotion is extremely vulnerable to corruption.

5.1.1 Medicine registration

The decision area corresponding to medicine registration received an average indicator score of 5.569 indicating moderate vulnerability to corruption. The area of medicine registration is well documented and but the requirements for the registration of new medicines are not yet well standardized. There is a fair access to information and there is an up-to-date list of all registered pharmaceutical products, which provide sufficient information about these medicines. The procedures for applicants on how to submit an application for registration of medicinal products are clearly written but not yet publicly accessible. There is a standard application form publicly available for the submission of applications for registration of medicinal products and a formal appeals process to manage complaints from companies and medicine stores. This area's principle weaknesses are that there are no written guidelines on conflict of interest regarding the registration activity and the members of registration committees are not required to declare any conflict of interest issues; most of the registration committees have no clear comprehensive guidelines for the committees' decision-making process; there are no clearly written or publicly accessible procedures for assessors on how to assess applications submitted for the registration of medicinal products; and finally, the criteria for selecting the members of some registration committees are not made clear enough to the public.

5.1.2 Selection

The decision area corresponding to medicine selection received an average indicator score of 5.792 indicating moderately vulnerability to corruption. The first essential medicines list which is updated is available through the public health system, and helps the government to purchase appropriate medicines for the population. The government has clear guidelines that specify what criteria are applied to medicines to be included in or deleted from the EML. The inclusion of a new medicine should be based on studies that confirm that the medicine is necessary for the health needs of the population and is cost-effective; However, the committee of selection does not include a member who is experienced in pharmacoeconomics consequentlty it is easily accessible to all health professionals.

In addition, the products are listed by generic name, pharmacological category, and by level of health care. A selection committee is appointed to give technical advice on the revision and update of the EML, which should be revised every 2 years. It includes physicians from different specializations and pharmacists. This area's principle weaknesses are that there are no written guidelines on conflict of interest regarding the selection of rational medicines. The criteria for selecting committee members are not made publicly available, and the committee only includes experts from the medical and pharmacy fields. The criteria do not require members to declare issues of conflict of interest, and membership is not time-limited.

5.1.3 Procurement

Procurement of pharmaceuticals in public health obtained the highest rating of all six areas, earning 8.733 and thereby highlighting the high level of transparency that characterize the procedures of this area and indicating a minimal vulnerability to corruption. The government has transparent and explicit procedures that describe the procurement process for pharmaceutical products. There are written guidelines for procurement office staff on the type of procurement method to be used for different types of products, and the procurement method chosen for each product aims to obtain the lowest possible purchase price for assured quality products. A formal appeals process is available for applicants who have their bids rejected. There are clear and specific criteria for tender committee membership. The membership rotates periodically every year. There are SOPs for routine inspection of consignments and the procurement office undergoes regular external auditing through the Auditoriat General. In other words, the MPPD's principle weaknesses are that there are no

written guidelines on conflict of interest with regard to the procurement process. In addition, the criteria for tender committee membership do not require that members declare issues of conflict of interest. Also, not all medicines procured are from the national essential medicines list.

5.1.4 Distribution

The decision area corresponding to distribution of pharmaceuticals in public health received an average indicator score of 7.85 indicating marginally vulnerability to corruption. The government medicines can be identified by imprints on containers and external packaging and there is systematic and orderly shelving of products in warehouses. There are inventory records and procedures in the warehouse at various levels of the distributing system and the warehouses are subjected to internal and external auditing. A computerized system provides information on medicines that have left a warehouse to health facilities. Sanctions are imposed on individuals for theft or corrupt practices. This area's principle weaknesses are that there is no effective security management to oversee storage and distribution and there is no programme for monitoring and evaluating the performance of the medicine distribution system.

6. Conclusions and recommendations

6.1 Conclusions

In the past few decades, RWANDA MoH has taken large steps towards improving its management structures for medicines. The establishment of two autonomous structures, the LMO (Logistic Management Office) and the MoH Pharmaceutical Department was a progressive step backed and supported by political leadership. These two agencies, among others, have improved the transparency of medicines governance and decreased the system′s vulnerability to corruption. Further action is still needed to improve the system. This is especially true in the area of promotion, which requires the enforcement of new regulations that cover all medicine promotion activities, and the establishment of a committee that will be responsible for controlling and monitoring medicine promotion. In addition, to continually improve the pharmaceuticals management system, effort is needed to promote a culture of transparency across the different professions in the pharmaceutical field. An ethical infrastructure document could be a useful tool to achieve this. However, such a document would need to be established in wide collaboration with various stakeholders. Even if the ethical infrastructure were initiated for the public sector, involvement of other actors who are users of the system would be beneficial to the process.

6.2 Recommendations

This study aimed to do an assessment on the quality of the transparency of the Rwandan pharmaceutical system to corruption. Accordingly, the following recommendations attempt to address the areas where transparency is lacking within certain functions of the system. The recommendations are not tailored to address weaknesses in the system as a whole; rather, they are the sum of opinions of respondents from this assessment activity and within its scope.

6.2.1 Medicine registration

a) Ensure the committees responsible for registration of medicines declare conflict of interest.

b) Publish all requirements, process and procedures for medicine registration and SOPs and clarify the procedures of registration to the public.
c) Increase the types of services offered on the Health sector website.
d) Develop expertise and train Rwandan officials and staff on good governance and ethical practices in drug management.
e) Ensure submission of files through the website. Applications should be accepted electronically, as well as the changes that occurred to the product.
f) Ensure members of the appeal committee are different from those of registration committee.
g) Recruit qualified personnel.
h) Train the pharmacists of the registration department.
i) Adopt external experts in the field of assessment.
j) Enhance digital filing of administrative and technical documents.
k) Increase the number of registration employees and the number of pharmacists allowed to receive applications, thus facilitating and accelerating the process of appointments
l) Control of medicine promotion

6.2.2 Selection

a) Publish all the scientific information pertaining to the reasons for choosing the medicines.
b) Develop and enforce the standard form for conflict of interest and guidelines for the relationship between members of the medicine selection committee and pharmaceuticals.
c) Change the committees of selection every year.
d) Train members to review on a cost-effectiveness basis.
e) Establish laws to force all doctors in the public sector to stick to the list.
f) Ensure the rules for decision-making in the SOPs are clear and transparent to the public.

6.2.3 Procurement

a) Establish written guidelines on conflict of interest with regard to the procurement process.

b) Ensure the process of submission of tender is online and the results are posted on the website.
c) Require members of the tender committee to declare conflict of interest.
d) Include the following key functional areas in the structure of the procurement department: specification section; accountancy section; quality assurance section, including audit section; procurement section; receiving and checking section; and, information technology support.
e) Restrict public sector tender procurement to the Rational Drug List.
f) Review procurement procedures to ensure that prospective suppliers are pre-qualified, and their performance is monitored for product quality, service reliability, delivery time and financial viability. All information must be appropriately recorded in a retrievable database.
g) Update the blacklist of non-performing or poor-performing suppliers regularly and forward a copy of the list to the procurement department.
h) Simplify the procurement process to have a positive impact on the system and improve effectiveness. This can be achieved by: requiring a more evidence-based approach to medicine selection for procurement; and rationalization of medicine requirements, i.e. reducing the chemical entity in each therapeutic group.

6.2.4 Distribution

a) Submit reports identifying the weakness of the distribution system and inform the public of these reports.
b) Put in place more effective security management to oversee storage and distribution.
c) Introduce a computerized system for communication between distribution points.

6.2.5 General recommendations

a) Revise laws, administrative structures and procedures based on the findings of the assessment and discussions during the national workshop to ensure transparent medicines registration, promotion, inspection, selection, procurement and distribution.
b) Develop a national ethics infrastructure for promoting good governance in medicines regulation and procurement through a consultation process.

c) Officially adopt the national ethics infrastructure, giving political backing to government officials to take the necessary actions to promote good governance in the pharmaceutical sector.
d) Socialize the national ethical framework and the codes of conduct by training government officials to generate civil servants' sense of ownership and personal identification with an ethical framework.
e) Nominate a working group that will be responsible for coordinating and managing the implementation of the Good Governance for Medicines project in the public sector, at the national level.

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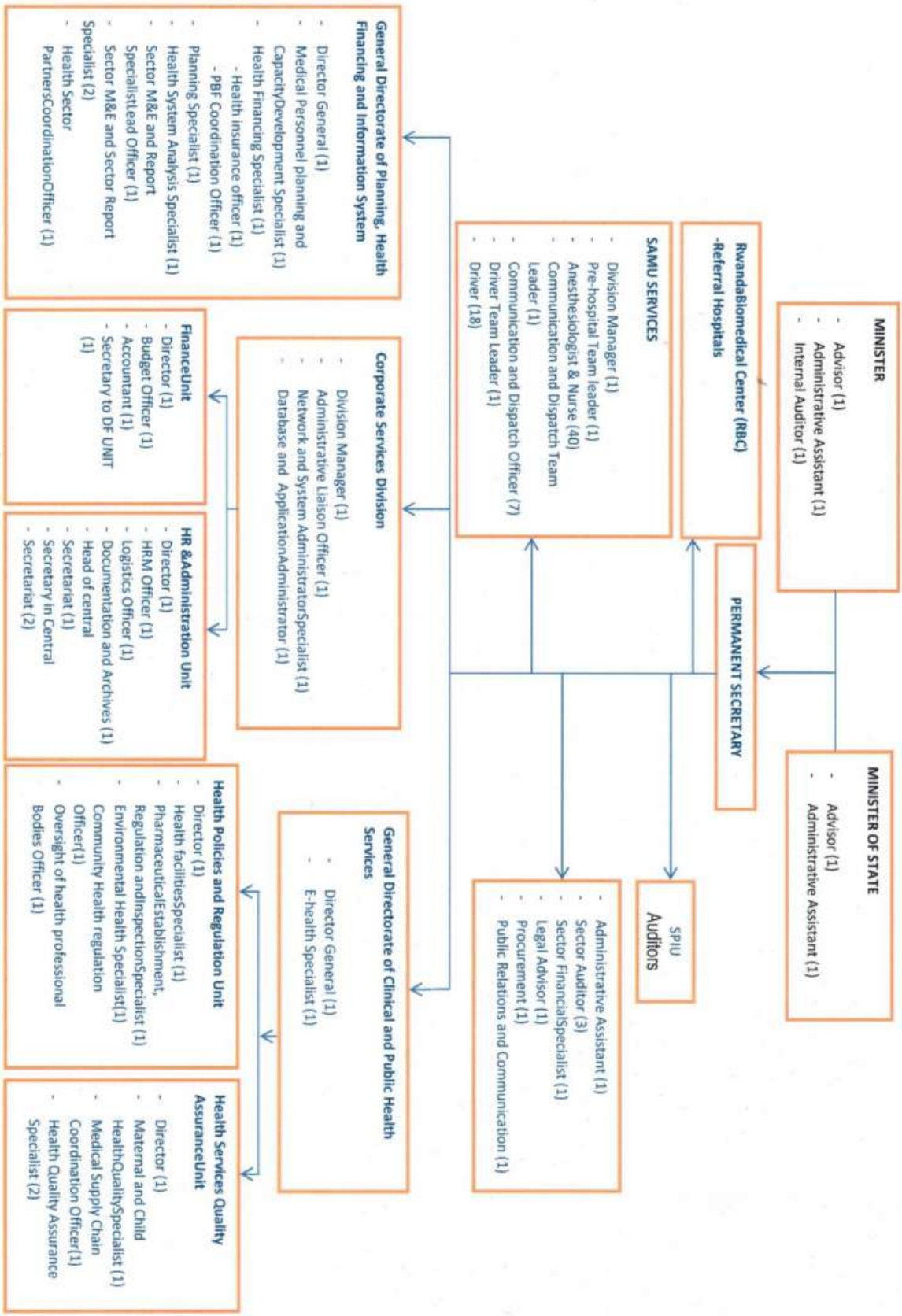
Appendixes

Appendix 1: Ministry of Health - Organizational Chart



Appendix 2: Questionnaires

QUESTIONNAIRE ON REGISTRATION OF MEDICINES

PRELIMINARY INFORMATION

Date: _____

Key informant number: _____

The key informant works in:

Government (public sector)	†
Private sector	†
Nongovernmental organization	†
International governmental organization	†
Media	†
Other (please specify):_____	†

Measuring transparency in the public pharmaceutical sector:

Assessment instrument

I.1 Is there an up-to-date list of all registered pharmaceutical products available in the country?

No	Yes	D.K.
0	1	

I.2 If such a list exists, does it provide a minimum level of information?

	No	Yes	D.K.
1. Product description: name of product	0	1	
2. Primary packaging any identifying mark			
3. Name of manufacturer	0	1	
4. Country of manufacture	0	1	
5. Site of manufacture	0	1	
6. Date of registration	0	1	
7. Validity of registration	0	1	
8. Conditions for registration (ex Prescription only or OTC)	0	1	
Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

I.3 Are there written procedures for applicants on how to submit an

application for registration of medicinal products? If so:

		No	Yes	D.K.
1.	Written procedures	0	1	
2.	Publicly accessible	0	1	
3.	Describe the process to follow in submitting an application	0	1	
4.	Mention timeframe for processing	0	1	
5.	Mention fees	0	1	
6.	Mention data to be submitted	0	1	
7.	Mention criteria for registration	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

I.4 Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products? If so:

		No	Yes	D.K.
1.	Written procedures	0	1	
2.	Publicly accessible	0	1	
3.	Describe the process to follow in assessing submissions	0	1	
4.	Mention timeframe for processing	0	1	
5.	Specify issues to be considered in assessing submissions	0	1	
6.	Provide guidance on report writing	0	1	
	Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

I.5 Is there a standard application form publicly available for submission of applications for registration of medicinal products? If so:

		No	Yes	D.K.
1.	Publicly accessible	0	1	
2.	Readily available at government office	0	1	
3.	Requires description of the product: name of product (brand name & INN), composition per unit dose	0	1	
4.	Brief summary of method of manufacture	0	1	

5.	Specification of pharmaceutical ingredients and excipients	0	1	
6.	Summary Product Characteristics (SPC): Pharmacological action, therapeutic classification, indications, contraindications, etc.	0	1	
7.	Packaging material and inserts	0	1	
8.	Labelling	0	1	
	Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

I.6 Are there written guidelines setting limits on how and where medicines registration officers meet with applicants?

No	Yes	D.K.
0	1	

I.7 Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?

No	Yes	D.K.
0	1	

I.8 Are there clear written criteria for selecting the members of the committee? If so:

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

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

I.9 Is there a written document that describes the composition and terms of reference of the committee? If so:

	No	Yes	D.K.
1. Up-to-date document	0	1	
2. Publicly accessible	0	1	
3. Includes names of the members	0	1	
4. Includes duties, responsibilities and obligations of the members	0	1	
5. Includes the accountability of the members	0	1	
6. Includes quorum requirement	0	1	
7. Includes membership terms/rotation requirements	0	1	

8. Includes the financial benefits of the members, if any	0	1	
Total			

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

I.10 Are there written guidelines on conflict of interest (COI) with regard to registration activities? If so:

	No	**Yes**	**D.K.**
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for members of registration committee exists	0	1	
3. Include rules on the acceptance of gifts	0	1	
4. Include rules on reporting conflict of interest	0	1	
5. Include a mechanism protecting informers of COI	0	1	
6. Include actions to be taken in case of failure to comply with policy	0	1	
7. Evidence of enforcement of these regulations	0	1	
Total			

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

I.11 To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"? (see question 8)

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

I.12 Are there clear and comprehensive guidelines for the committee's decision-making process? If so:

	No	Yes	D.K.
1. Available in writing			
2. Available publicly			
3. Describe clearly the mandate of the committee	0	1	
4. Describe the number of meetings it should convene	0	1	
5. Describe procedures for decision-making	0	1	
6. Include clear time limits for decision-making process for the committee	0	1	
7. Describe the reporting structure	0	1	
8. Decisions of meetings need to be publicly available	0	1	
Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

I.13 Is there a formal appeals system for applicants who have their medicine applications rejected?

No	Yes
0	1

I.14 To what extent do you agree with the following statement: "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decisions"?

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

I.15 To what extent do you agree with the following statement: "The registration committee meets on a regular basis and keeps minutes for its meetings"?

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

I.16 In your opinion, what types of unethical behaviour are common in the registration system in your country?

I.17 If you were in a position of highest authority, what would be the first action that you would take to improve the registration process in your country?

QUESTIONNAIRE ON SELECTION OF MEDICINES

PRELIMINARY INFORMATION

Date: _____

Key informant number: _____

The key informant works in:

Government (public sector)	†
Private sector	†
Nongovernmental organization	†
International governmental organization	†
Media	†

Other: (please specify)_____ †

VI.1 Does the government have an officially adopted national essential medicines list publicly available?

No	Yes	D.K.
0	1	

VI.2 To what extent do you agree with the following statement: "The national essential medicines list has been developed in consultation with all interested parties and using an evidence-based approach"?

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

VI.3 Are there clearly written and publicly available guidelines for the selection process for including or deleting medicines from the national EML? If so:

	No	Yes	D.K.
1. Available in written format in the public domain	0	1	
2. Define criteria for inclusion of new medicines	0	1	
3. Define criteria for rejection of new medicines	0	1	
4. Define criteria for eliminating medicines on existing EML	0	1	
5. Only medicines with sound and adequate evidence of efficacy and safety are included	0	1	
6. Based on priority health needs of the country	0	1	
7. Based on cost-effectiveness	0	1	
Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VI.4 Is the EML in line with WHO procedures? If so:

	No	Yes	D.K.
1. Published and easily accessible	0	1	
2. Disseminated widely to relevant health professionals	0	1	
3. By generic names	0	1	
4. By level of health care	0	1	
5. Linked to national standard treatment guidelines	0	1	
6. Revised within past 5 years	0	1	
Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

VI.5 Is there a committee responsible for the selection of the national EML?

No	Yes	D.K.
0	1	

Questionnaire forms

Selection of medicines

VI.6 To what extent do you agree with the following statement: "The committee responsible for the selection of the national EML is operating

free from external influence"?

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

VI.7 Are there clear criteria for the selection of members of the selection committee? If so:

	No	Yes	D.K.
1. Criteria publicly available	0	1	
2. Criteria clearly written	0	1	
3. Criteria easily accessible	0	1	
4. Define the professional requirements			
5. Membership includes experts from different fields	0	1	
6. Require declaration on COI	0	1	
7. On a rotation basis or limited in time	0	1	
Total			

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

VI.8 Are there written guidelines on conflicts of interest (COI) with regard to selection of essential medicines? If so:

	No	Yes	D.K.
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for members of selection committee exists	0	1	
3. Include rules on the acceptance of gifts	0	1	
4. Include rules on reporting conflict of interest	0	1	
5. Include a mechanism protecting informers of COI	0	1	

6. Include actions to be taken in case of failure to comply with policy	0	1	
7. Evidence of enforcement of these regulations	0	1	
Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VI.9 Are there clear and publicly available Terms of reference (TORs) that describe the role and responsibilities of the selection committee? If so:

	No	**Yes**	**D.K.**
1. Clear TORs	0	1	
2. TORs publicly available	0	1	
3. Describe the rules for decision-making process	0	1	
Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VI.10 Are there written SOPs for decision-making process of the committee? If so:

	No	**Yes**	**D.K.**

1.	Decisions made by all members in a democratic manner	0	1	
2.	Minutes of meeting produced and approved by members			
3.	Require consultation with interested parties	0	1	
4.	Final decision for selecting medicines done independently	0	1	
5.	Decisions on selection process publicly available	0	1	
6.	Decisions disseminated widely	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VI.11 In your opinion, what types of unethical behaviour are common in the selection process in your country?

VI.12 If you were in a position of highest authority, what would be the first action that you would take to improve medicine selection in your country?

QUESTIONNAIRE ON PROCUREMENT OF MEDICINES

PRELIMINARY INFORMATION

Date: _____

Key informant number: _____

The key informant works in:

Government (public sector)	†
Private sector	†
Nongovernmental organization	†
International governmental organization	†
Media	†
Other: (please specify)_____	†

VII.1 Does the government use transparent and explicit procedures for procurement of pharmaceutical products? If so:

		No	Yes	D.K.
1.	Written procedures publicly available	0	1	
2.	Describe the internal process to be followed by staff on how to process the bids	0	1	
3.	Require the use of generic names	0	1	
4.	Require procurement to be based on the national essential medicines list	0	1	
5.	Require advertisement of tenders	0	1	
6.	Require that contract specifications be publicly available	0	1	
7.	Require that criteria for adjudication of tender be included as part of the tender package	0	1	
8.	Require that contract awards be recommended by the tender committee	0	1	
9.	Require that information on tender process and results are made public (to the extend permitted by law)	0	1	
	Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

VII.2 Is there written guidance for procurement office staff on the type of

procurement method to be used for different types of products?

No	Yes	D.K.
0	1	

VII.3 Is procurement done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased?

No	Yes	D.K.
0	1	

VII.4 Is there a formal appeals process for applicants who have their bids rejected?

No	Yes	D.K.
0	1	

VII.5 Is there a tender committee (TC)? If so are the key functions of the procurement office and those of the tender committee clearly separated?

		No	Yes	D.K.
1.	There is a TC formally established	0	1	
2.	TC responsible for suppliers' selection for restricted tenders	0	1	
3.	TC responsible for contract decisions	0	1	
	Total			

Total yes	
Total valid answers	
Scoring (total yes/total valid answers)	

VII.6 To what extent to you agree with the following statement: "Decisions of the tender committee are always taken into account in the procurement process"?

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

VII.7 Are there specific criteria for tender committee membership? If so:

		No	Yes	D.K.
1.	Criteria publicly available	0	1	
2.	Criteria clearly written	0	1	
3.	Require professionals with specific functions or skills	0	1	
4.	Require representation from senior government officials	0	1	
5.	Require representation from end-user facilities	0	1	
6.	Require that membership changes periodically	0	1	
7.	Require that members declare COI	0	1	
	Total			

Total yes	
Total valid answers	
Scoring (total yes/total valid answers)	

VII.8 Are there written guidelines on conflicts of interest (COI) with regard to the procurement process? If so:

	No	Yes	D.K.
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for procurement office staff exists	0	1	
3. Form for declaration of COI for members of tender committee exists	0	1	
4. Include rules on the acceptance of gifts	0	1	
5. Include rules on reporting conflict of interest	0	1	
6. Includes a mechanism protecting informers of COI	0	1	
7. Include actions to be taken in case of failure to comply with policy	0	1	
8. Require to be signed by both procurement office staff and tender committee members.			
9. Evidence of enforcement of these regulations	0	1	
Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

VII.9 To what extent do you agree with the following statement: "The members of the tender committee are systematically selected based on specific criteria (see question VII.7)"?

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

VII.10 Is there a computerized management information system used to report product problems in procurement? If so:

	No	Yes	D.K.
1. Management information system exists	0	1	
2. Includes product records	0	1	
3. Monitors suppliers performance	0	1	
4. Monitors facilities (clients) performance	0	1	
5. Records quality assurance information	0	1	
6. Tracks status for each order	0	1	
7. Tracks quantities purchased compared with estimates	0	1	
Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VII.11 Are there Standard Operating Procedures (SOPs) for routine inspection of consignments? If so:

		No	Yes	D.K.
1.	Each shipment physically checked	0	1	
2.	Samples taken and sent to quality control laboratories randomly for all consignments	0	1	
3.	Samples taken and sent to quality control laboratories systematically for new suppliers	0	1	
4.	Inspections reported in documents and archived in the procurement office	0	1	
	Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

VII.12 Is there an efficient post-tender system in place to monitor and report on suppliers' performance to the tender committee? If so:

		No	Yes	D.K.
1.	Supplier's performance monitored at least annually	0	1	
2.	Monitoring system tracks supplier's lead-time	0	1	
3.	Monitoring system tracks the shelf-life	0	1	
4.	Monitoring system tracks the packaging of products	0	1	
5.	Procurement agency has a list of previous suppliers	0	1	
6.	Suppliers with poor performance are identified and blacklisted	0	1	

Total			

Total yes

Total valid answers Scoring

(total yes/total valid answers)

VII.13 Does the procurement office undergo regular audits? If so:

		No	**Yes**	**D.K.**
1.	Audit compulsory by law	0	1	
2.	Done on an annual basis	0	1	
3.	Results publicly available	0	1	
4.	Audit conducted by an independent unit (internal or external)	0	1	
5.	Reports operating costs of procurement office	0	1	
6.	Reports pharmaceutical products tendered	0	1	
7.	Reports quantities of the products	0	1	
8.	Reports the beneficiaries	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VII.14 To what extent do you agree with the following statement: "The procurement system in your country is operating in a totally transparent manner"?

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

VII.15 In your opinion, what types of unethical behaviour are common in the procurement system in your country?

VII.16 If you were in a position of highest authority, what would be the first action that you would take to improve the systems and processes of procurement?

QUESTIONNAIRE ON DISTRIBUTION OF MEDICINES

PRELIMINARY INFORMATION

Date: _____

Key informant number: _____

The key informant works in:

Government (public sector)	†
Private sector	†
Nongovernmental organization	†
International governmental organization	†
Media	†
Other: (please specify)_____	†

VIII.1 Is there system in place that can expedite port clearing?

No	Yes	D.K.
0	1	

VIII.2 To what extent do you agree with the following statement: "port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process"

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

VIII.3 Is there an inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier? If so:

		No	Yes	D.K.
1.	A separate space for checking the arrived goods	0	1	
2.	Designated person(s) responsible for checking receipts against packing list	0	1	
3.	Documentation-based invoice	0	1	
4.	Oversight system	0	1	
	Total			

Total yes		
Total valid answers		
Scoring (total yes/total valid answers)		

VIII.4 Is there a coding system used to identify government medicines?

No	Yes	D.K.
0	1	

VIII.5 Is there systematic and orderly shelving of products in warehouses or store rooms? If so does it require:

	No	Yes	D.K.
1. Classified by alphabetical or therapeutic order	0	1	
2. Existence of a master map showing location of medicines	0	1	
3. Placed taking into account the expiry date	0	1	
Total			

Total yes	
Total valid answers	
Scoring	
(total yes/total valid answers)	

VIII.6 Is there a security management system in place to oversee storage and distribution, if so including, as a minimum, the following elements?

		No	Yes	D.K.
1.	Monitoring of entry and exit to warehouses	0	1	
2.	controlled substances (such as narcotics) should be separated and secured			
3.	locks with controlled key distribution			
4.	Limited access to non-staff persons	0	1	
5.	Alarm system for security breaches	0	1	
6.	Search done by security personnel when leaving the warehouse	0	1	
	Total			

Total yes		
Total valid answers		
Scoring (total yes/total valid answers)		

VIII.7 Are there SOP for stock management at each level of the distribution system?

No	Yes	D.K.
0	1	

VIII.8 Is there an inventory management system at each level of the distribution system and which provides information, as a minimum, on the following elements?

		No	Yes	D.K.
1.	The average working stock for each product	0	1	

2.	The amount of safety stock for each product	0	1	
3.	The frequency of reordering	0	1	
4.	The quantity of reordering for each product	0	1	
5.	The average inventory for each product	0	1	
6.	The lead time			
7.	The expiry date	0	1	
	Total			

Total yes		
Total valid answers		
Scoring		
(total yes/total valid answers)		

VIII.9 Are stock records reconciled with physical counts at least every 3 months by internal staff?

No	Yes	D.K.
0	1	

VIII.10 Are there independent audits of warehouses by external inspectors or auditors? If so:

		No	Yes	D.K.
1.	Evidence/report of warehouse audit	0	1	
2.	Audit takes place at least once a year	0	1	
3.	Audit carried out by an independent party	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VIII.11 Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health facility, and which provides the following information for medicines that have left the warehouse?

		No	Yes	D.K.
1.	Type of medicines that have left the warehouse	0	1	
2.	Quantity of medicines that have left the warehouse	0	1	
3.	The person who verified the amounts	0	1	
4.	The intended recipient of these medicines	0	1	
5.	The time and date that the medicines arrived at the appropriate health facility	0	1	
6.	Documentation of any problems or irregularities with the supplies received	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VIII.12 Does the health facility have an appropriate procedure for requesting medicines? If so, does it include the following:

		No	Yes	D.K.
1.	The medicine to be supplied (INN)	0	1	
2.	Dosage form	0	1	
3.	Strength	0	1	
4.	Quantity	0	1	
5.	The requisition should be checked by the responsible person, dated and signed	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VIII.13 Are there appropriate written guidelines on transportation and delivery of the medicines from/to the warehouse? If so, do they include the following:

		No	Yes	D.K.
1.	Problems of adverse transportation conditions (exposure to excessive heat, moisture, sunlight)	0	1	
2.	Problems of theft during transportation and methods for protection	0	1	
3.	Mechanism to prevent swapping of consignment during transportation	0	1	
4.	Request that the person responsible for transportation sign a receipt	0	1	
	Total			

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

VIII.14 Is there a well-functioning communication system for ordering, re-ordering and complaints between the suppliers and the end-users?

No	Yes	D.K.
0	1	

VIII.15 Does a programme exist for monitoring and evaluating the performance of the

medicine distribution system? If so:

		No	Yes	D.K.
1.	Monitoring and evaluation programme exists	0	1	
2.	Done by an independent authority (e.g. MOH , external auditors, etc)	0	1	
3.	Monitoring is regular, systematic and documented	0	1	
4.	Evaluation carried out at least every two years	0	1	
5.	Reports identifying weaknesses and making recommendations publicly available	0	1	
6.	Evidence that weaknesses are addressed exists	0	1	
7.	Reports are posted publicly	0	1	
	Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VIII.16 Are sanctions imposed on individuals or agencies/companies for theft or corrupt practices associated with distribution? If so:

		No	Yes	D.K.
1.	Policies and/or procedures foreseeing the application of sanctions for corrupt behaviour exist	0	1	
2.	They include the type of sanctions to be applied depending on the nature and gravity of the act of corruption	0	1	
3.	There is evidence that individuals are sanctioned for corrupt behaviour	0	1	
	Total			

Total yes
Total valid answers
Scoring
(total yes/total valid answers)

VIII.17 Does the MS/health facility have appropriate procedures for disposal of expired and/or spoiled medicines? If so, do they include the following:

		No	Yes	D.K.
1.	Mechanism to notify MRA about expired or spoiled medicines	0	1	
2.	Committee responsible for the supervision of disposal of medicines	0	1	
3.	Minute taken on the disposal and signed by the members of the committee	0	1	
4.	List of disposed medicines	0	1	

Total			

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

VIII.18 To what extent do you agree with the following statement: "there are very rarely leakages in the medicine distribution system in your country".

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

VIII.19 If you were in a position of highest authority, what would be the first action that you would take to improve the systems and processes of public sector medicine distribution in your country?