

Measuring transparency to improve good governance
in the public pharmaceutical sector in Malawi



MALAWI



**World Health
Organization**

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Abbreviations

CHAM	--	Christian Health Association of Malawi
CMS	--	Central Medical Stores
COI	--	Conflict of Interest
DFID	--	Department for International Development
EHP	--	Essential Health Package
EML	--	Essential Medicines List
GDP	--	Good Distribution Practices
GGM	--	Good Governance for Medicines
GMP	--	Good Manufacturing Practices
GNP	--	Gross National Product
GoM	--	Government of Malawi
HTSS	--	Health Technical Support Services
IBRD	--	International Bank for Rehabilitation and Development
ICR	--	International Competitive Bidding
IDA	--	International Dispensary Association
IPC	--	Internal Procurement Committee
IT	--	International Transparency
KI	--	Key Informant
MBB	--	Medical Buying Board
MedCo	--	Medicines Committee
MESL	--	Malawi Essential Surgicals List
MI	--	Management International
MNDL	--	Malawi National Drugs List
MoH	--	Ministry of Health
MoF	--	Ministry of Finance
MSF	--	Médecins Sans Frontières
MSH	--	Management Sciences for Health
NA	--	National Assessors
NCB	--	National Competitive Bidding
NI	--	National Investigators
NSO	--	National Statistical Office
ODPP	--	Office of the Director for Public Procurement
PMPB	--	Pharmacy, Medicines and Poisons Board
POW	--	Programme of Work
SBD	--	Standard Bidding Documents
SOP	--	Standard Operating Procedures
SWAp	--	Sector Wide Approach
TC	--	Tender Committee
TN	--	Technical Note
UNICEF	--	United Nations Children's Fund
WHO	--	World Health Organization

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Executive summary

The Good Governance for Medicines (GGM) assessment, aimed at measuring the extent of vulnerability to corruption in Malawi, is the first of its kind, both in the country and in Africa. The study was instituted to measure the level of transparency in the country's pharmaceutical sector. Measuring corruption in this sector is a very complex process. In recognizing this, WHO initiated a GGM programme and developed tools to help countries carry out assessments to measure the levels of transparency and of vulnerability to corruption and to develop and implement national programmes.

WHO has identified the three phases necessary for a country to address the problem of corruption in the pharmaceutical sector. Phase I involves conducting a national assessment of transparency and potential vulnerability to corruption, phase II is the development of a national GGM programme through a nationwide consultation process and Phase III is the implementation and promotion of the programme.

The Government of Malawi, through the Ministry of Health, requested that WHO provide support in introducing a GGM programme in Malawi. This study concerns the first phase of undertaking a national assessment to assist in measuring the level of corruption in the pharmaceutical sector. In this phase, the level of transparency and potential vulnerability to corruption in a few key functions in the sector, i.e. medicines registration, control of medicine promotion, inspection of establishments, selection of essential medicines, and procurement of medicines, was assessed.

The national assessment was carried out by independent national assessors (NAs), using the standardized WHO assessment instrument¹. The NAs collected information through a combination of desk research and semi-structured interviews with 57 key informants (KIs), organized the data, and analysed it to generate the results, which are presented in this report. (Of the interviews, 10 were concerned with registration, 12 with promotion, 10 with inspection, 15 with selection, and 21 procurement).

Malawi has a daunting task in combating corruption and bribery in the pharmaceutical sector. The study results show that generally the sector suffers from extreme vulnerability to corruption (i.e., a score of 3.36 on a 1.00 to 10.00 rating scale). Some key functional areas exhibit very low levels of transparency due to poor good governance mechanisms while other areas barely have any mechanisms for transparency and good governance. To illustrate this, assessment indicators showed that registration scored 4.84 on the 1.00 to 10.00 rating scale, showing moderate vulnerability to corruption; promotion scored 1.39, showing extreme vulnerability to corruption; inspection scored 5.98, indicating that this key function is also moderately vulnerable; the score for selection was 1.59, meaning it is extremely vulnerable to corruption; and finally procurement scored 3.20 indicating that this area is very vulnerable to corruption.

¹ Measuring transparency to improve good governance in the public pharmaceutical sector, working document January 2006

The resulting recommendations include some that are specific to each functional area, however the NAs found that others cut across all functional areas in the pharmaceutical sector.

These include that:

- there should be increased information-sharing within the pharmaceutical sector through training and motivation of those directly or indirectly involved with medicines;
- Government should provide Standard Operating Procedures (SOPs) and guidelines on conflict of interest (COI) in written form (including procedures to be followed in the process of declaring COI and clear, simple forms to be completed by those involved). These prerequisites should be publicly available and easily accessible;
- Government should ensure the promotion of proper, publicly available and speedy public tendering procedures for medicines;
- Government should ensure that there is improved communication with all institutions involved in medicine registration, promotion, inspection, selection, procurement and distribution.

In summary, the results of this assessment show that key functions of the pharmaceutical sector in Malawi are very vulnerable to corruption, mainly because of a number of lapses in the good governance for medicines mechanisms. The legislation providing for these mechanisms is contained in publicly available documents and should be easily accessible. However, access to the documents is limited by the fact that they are not disseminated widely and in some cases are being sold to stakeholders. The function most vulnerable to corruption in Malawi's pharmaceutical sector is drug promotion, followed by drug selection, procurement and registration. Only drug inspection is of moderate vulnerability in the sector.

1. Introduction

1.1 Background

Medicines or pharmaceuticals account for the largest expenditure from both public and donor funding in the health sector globally. Such large amounts of money are an attractive target for abuse, making the pharmaceutical sector highly vulnerable to corruption and unethical practices. Determining the level of this corruption is not an easy task, but Transparency International (TI) estimates that in some countries up to two thirds of medicines supplies at hospitals are lost through corruption and fraud.

The World Bank identified corruption as the single greatest obstacle to economic and social development and its impact on the pharmaceutical sector can be three-fold:

- **Health impact** – wastage of public resources reduces Government capacity to provide access to good-quality essential medicines, while at the same time the risk of unsafe medical products on the market increases due to counterfeiting and/or bribery;
- **Economic impact** – pharmaceutical expenditure in low-income countries may represent up to 50% of total health care costs, which means that corrupt pharmaceutical practices are extremely detrimental to national health budgets;
- **Government image and trust impact** – inefficiency and lack of transparency reduce the credibility of public institutions, and erode public and donor confidence in Government capacity to deliver on promises.

In order to implement a Good Governance for Medicines programme at country level, WHO has identified a three-step approach as follows:

- **Step one** – National assessment of transparency and vulnerability to corruption of national public procurement systems and of national medicines regulatory authorities;
- **Step two** – Development of a national GGM programme via a consultative process; and
- **Step three** – Implementing and promoting the national GGM programme by training national officials in the public pharmaceutical sector on good governance principles.

Malawi has just undergone the first step in the implementation of a GGM programme. This is a report of the first step, which is the assessment of transparency and vulnerability of the pharmaceutical system to corruption. It includes explanations of the aim and objectives of the national assessment exercise, the methodology used in the study, the major findings and recommendations on how to improve transparency and good governance in medicines in Malawi.

1.2 Aim and objectives of the assessment

The aim of the assessment was to measure the extent of good governance and assess the levels of transparency and extent of vulnerability to corruption and unethical practices in the pharmaceutical sector in Malawi. In the assessment, instruments designed and developed for this purpose by the World Health Organization (WHO) were used. The assessment instrument contains five questionnaires, each focusing on one function of the pharmaceutical sector (*see Annex I*).

The objectives of the assessment included the task of conducting a literature review relating to the pharmaceutical sector in Malawi, conducting interviews of key informants (KIs) in the sector in order to obtain their perspectives on the levels of transparency and vulnerability to corruption, and analysing the information with a view to obtaining a comprehensive picture of the level of transparency and vulnerability to corruption in the five functions of the pharmaceutical sector, namely:

- i. registration of medicines
- ii. control of medicine promotion
- iii. inspection of establishments
- iv. selection of essential medicines
- v. procurement of medicines.

1.3 Methodology

1.3.1 Data and information collection method

The assessment methodology used in this study was designed and developed for use by WHO. As part of the methodology, questionnaires were used to collect quantitative and qualitative data from key informants in various stakeholder institutions/organizations (*see Annex II*). The assessment instrument used contained five questionnaires, one for each function, namely: registration, inspection, promotion, selection and procurement. The quantitative data was used to measure the level of transparency in the areas mentioned above. The qualitative data was collected to help confirm the findings from the quantitative data and to help in developing recommendations on how to improve good governance for medicines in Malawi.

Prospective institutions to provide KIs were selected at a stakeholders' orientation workshop. A list of 57 key informants was later drawn up by the national assessors. The choice of KIs was based on their assumed first-hand knowledge and/or involvement in the areas under study. The KIs for each function included both senior and junior professionals and represented both the public and private sectors, including civil society organizations. Some KIs were interviewed for more than one function because of the nature of their position in the chosen institution.

1.3.2 Data analysis and scoring

Four methods of data analysis and interpretation were used to determine the level of transparency:

Method 1: All questions that required a binary answer (yes/no) were subjected to this method of analysis. A “yes” was given a value of 1 and a “no” was given a value of 0. A value of 1 represents low vulnerability to corruption if it is supported by a publicly available document. A value of 0 represents high vulnerability to corruption. Where a KI responded with a “yes” but no evidence was found, a score of zero was given.

Method 2: Questions that included a series of sub-questions or criteria were scored using this method. Each of the criteria was formulated to require a binary answer (yes/no). Each “yes” was given a 1 and each “no” a 0. If the KI did not know the answer, there was an option of assigning “don’t know” (DK). The total “yes” answers were counted and then divided by the total number of valid answers. The total DK answers were subtracted from the total of criteria available for each indicator, which gave the total of valid answers. The final rating for the indicator was calculated by dividing the total of “yes” responses by the total of valid answers.

Method 3: This method was used for subjective questions which probed the perceptions of the KIs. Asking for the perceptions of KIs brings valuable insight into the transparency level of each of the functions. This method was used as a cross-triangulation technique to back or refute the data collected with methods 1 and 2. Answers to these questions were arranged on a scale of 1-5 and presented using a bar chart.

Method 4: This method used open questions that gave the KIs an opportunity to provide additional input, as well as their opinions on the issues put forward. The responses to these questions are important because they provide insight as to what recommendations can be put forward for consideration. They also provide qualitative information to confirm the findings in methods 1 and 2.

1.4 Assumptions and limitations

The assessment assumed that the selected KIs are knowledgeable, experienced, and involved in the area in which they have been selected for interview. It was also assumed that the KIs would be able to provide honest and rational answers to questions covering each indicator. It was expected that the KIs would be able to back up their answers/replies with evidence/documentation confirming the availability of rules, regulations and procedures.

The exercise had to be conducted within the available time the respondents set aside from their normal work. However, it was observed that time was a constraint to some KIs and therefore they tended to rush through the exercise. Some of the replies to the questions, especially to sensitive ones, were not fully honest and seemed to be influenced by fear of exposure or repercussions, despite the assurances given. There was a problem of uniformity of responses to qualitative questions; some of the respondents did not prioritize their answers.

In some instances the questionnaires seemed not well adapted for the Malawian situation, i.e., they were not country-specific and as such some of the questions were not directly applicable to Malawi. Indicator 1.6, under registration, is a case in point: the questionnaire asks about the existence of written guidelines setting limits on how and where medicine registration officers meet with applicants. In Malawi, all official Government business is done in Government offices and no one questions it.

2. Overview of the pharmaceutical sector in Malawi

2.1 Health-care services in Malawi

Formal health-care services in Malawi are generally classified into two categories -- public and private. The public health sector comprises the Ministries of Health and Local Government, as well as other Government institutions, including the Malawi Defence Forces, the Malawi Police Service, and the Malawi Prison Service. Private health-care providers include the non-profit category, within which fall the Christian Health Association of Malawi (CHAM) affiliates, the profit-making private practitioners and hospitals. The last category of the health sector is that of traditional healers and traditional birth attendants (NAC, 2000, p 4). The Ministry of Health provides about 60% of the total national health-care services; CHAM and nongovernmental organizations (NGOs) 37%; the army and the police 2%; and the Ministry of Local Government 1% (MoH, 1999, p7).

The Ministry of Health (MoH) is therefore the prime contributor of health-care delivery services through the majority of hospitals, clinics, dispensaries and health posts. The Ministry obtains its funding from the Ministry of Finance (primarily from internal revenue and donors). The Christian Health Association of Malawi (CHAM) is the second-largest contributor to these services and therefore complements the work of the MoH in the delivery of these services. CHAM receives annual financial support from the Ministry of Health, primarily for payment of staff salaries. CHAM also gets its funding from a variety of local and foreign sources, including charging user fees for a wide range of its health services and also gets revenue from drug sales (OPC, 1999, p276). These health service providers procure essential medicines from varying sources from both developed and developing countries. Funding agencies largely determine where the essential medicines will be procured, in line with their set conditions. In terms of volume, the majority of drugs consumed in the public and private sectors appear to be sourced from generic manufacturers in the developing world.

2.2 Background to the pharmaceutical sector in Malawi

The National Drug Policy (1991) provides a framework for the pharmaceutical sector in Malawi. The aim of the policy is "to develop within the available resources the potential drugs have to control common diseases and alleviate suffering" by a ready and constant availability of essential medicines that are of high quality, safe, efficacious and sold at an affordable price to the individual and community, using the Essential Health Package (EHP) as a strategy. The MoH is committed to providing the EHP through effective registration of drugs, control of medicines promotion, inspection of establishments, selection of essential medicines, and their procurement and distribution in order to increase drug availability to

the population in general, and to pregnant women and children under five in particular. The provision of essential drugs to its people is one of the core obligations of any government.

The pharmaceutical sector operates in a country classified as one of the poorest in the world, with a per capita GNP of US\$210 from the 1999 estimate (NAC, 2000, p2). The last population and housing census indicates that Malawi had a population of 9.9 million (currently estimated to be between 12 and 13 million) with an annual growth rate of 2% per year (NSO, 2000). Eleven percent of the population lives in the major urban centres, with the rest in rural areas. Malawi is a landlocked country with a narrow economic base, no significant mineral resources and high external trade costs (University of Keele, 1996, p 1), making it heavily dependent on donor support.

2.3 The pharmaceutical sector in Malawi

The pharmaceutical sector in Malawi covers the operations of the MoH, the Pharmacy, Medicines and Poisons Board (which is a regulatory authority), other Government institutions and departments, such as the Central Medical Stores and hospitals, CHAM-affiliated health facilities, private hospitals, retail pharmacies, drugstores, manufacturers and wholesale distributors. The organizational structure of the pharmaceutical sector is depicted in Annex C. The pharmaceutical sector in Malawi is therefore largely influenced by the MoH, which centrally procures medicines for all Government hospitals through the Central Medical Stores (CMS). CMS procures, stores and distributes the bulk of medicines and supplies used in the public health system. The sources of essential medicines for private hospitals are varied and depend on the type of drug to be procured. The majority of the medicines procured by Central Medical Stores are produced outside the country. Domestic generic manufacturers also supply medicines to the MoH, although only in small quantities. The procurement of medicines by CMS is governed by the Public Procurement Act No. 8 of 2003.

The Public Procurement Act seems to reflect a deliberate government policy to encourage domestic manufacturers or suppliers to supply goods to the government. Section 31(17) of the Procurement Act stipulates that “in the evaluation of tenders, a procuring entity may apply the margin of price preference in favour of domestic bidders.” The CHAM-affiliated health facilities, private hospitals and nongovernmental organizations (NGOs) are not bound by the Government procurement regulations. CHAM procures its essential drugs mainly through the International Dispensary Association (IDA) and the CMS. NGOs either procure from local wholesale distributors or import directly. Médecins Sans Frontières (MSF)(Luxembourg), for example, sources about 90% of its drugs from Europe and has been very restrictive in buying medicines from the developing world (Robert Lewis-Lettington & Chikosa Banda, “A Survey of Policy and Practice on use of Access to Medicines in Malawi”, DFID, 2004, p1).

Private hospitals procure medicines as individual institutions that are profit-making entities. They do not usually abide by MoH policies in procurement of medicines, i.e. procurement through tenders or procuring generic medicines.

Prior to 2004, through the National Health plans, the Programme of Work (POW 2004-2010), and the Essential Health Package, Malawi made some great efforts in focusing on improving the health status of the population, but the resurgence of diseases such as TB and malaria

and the escalation of the HIV/AIDS pandemic has put tremendous pressure on the health systems, resulting in a shortage of health workers and consistent shortages of essential drugs. A diagrammatic view of the players in the pharmaceutical sector is provided in Annex III.

2.4 Challenges facing the sector

One of the major challenges in the public health system is therefore the consistent shortage of essential drugs and medical supplies at service delivery points. This is exacerbated in part by chronic under-funding of the health sector and inefficient procurement and distribution systems, as well as unethical practices that include corruption and pilferage. Malawi is also faced with a limited pharmaceutical manufacturing base and therefore significantly depends upon the importation of medicines from foreign manufacturers. Local manufacturers produce a limited range of medicines and on a small scale. Over-reliance on importation of medicines is a potential problem because of the inherent problems that this can bring, for example, what to do with medicines of poor quality; what to do in cases where consumption of a particular medicine suddenly goes up.

Other obstacles in the sector include the inadequate capacity of the Pharmacy, Medicine and Poisons Board to enforce legislation and regulations relating to control of medicines in Malawi.

The prevailing problems in the pharmaceutical sector include the fact that the majority of people are poor and cannot afford to pay for quality drugs. Although Government provides free health services, it has had problems providing quality health services because of inadequate financing (MoF, *PSRSP*, p 86). However, due to the relatively high cost of medicines, and considering that access to medicines is important in providing quality health services, Government has begun to put in place mechanisms to ensure the availability and accessibility of essential drugs. One mechanism is to understand the level of vulnerability to corruption and extent of transparency in the key functions of the pharmaceutical sector.

3. Findings of the assessment

3.1 Registration of medicines

The Pharmacy, Medicines and Poisons Act No 15 of 1988, under Part IV to Part VII, provides for the registration of all medicinal products for human or veterinary use circulating in the country regardless of whether these are for use in the public or private sector, whether procured or donated. Therefore in Malawi it is a legal requirement that all medicines should be registered by the Pharmacy, Medicines and Poisons Board. Importation, manufacturing, wholesaling, retailing or dispensing of unregistered medicines is a serious offence under this Act (Section 35). According to the Act, The Board is supposed to maintain a register of all registered medicines, and their manufacturers and marketing agents in Malawi. The objective of registration is to protect patients by ensuring that all medicinal products circulating in the country are safe, efficacious and of good quality. In order to assess the level of transparency and extent of vulnerability to corruption for the registration function, 10 KIs were interviewed. There were 16 indicators related to the registration of medicines, 13 of which were analysed using methods 1 and 2, and which directly contributed to the final rating of the level of vulnerability to corruption for registration as seen in Annex IV, Table 1.

Indicator I.1: The PMPB maintains a register of all medicines registered in the country in an electronic database. The comprehensive list is not accessible to the general public. On occasions where one makes a special request to the PMPB on the registration status of a particular medicine or group of medicines, the PMPB will provide such information free of charge. Most of the respondents (70%) said that a list of registered products is available at the PMPB.

Indicator I.2: No evidence of an up-to-date list was found by the assessors. (As already pointed out, the PMPB has a database of all registered medicines in the country and it provides information on the registration status of medicines on request.) The database is compiled using products by applicant and therefore is not easy to manipulate. Other information, i.e., registered medicines by therapeutic class, has to be manually compiled by the registration pharmacist. However, 55 % of the KIs interviewed for registration provided what they thought was the basic level of information found on such a list. This could be due to the fact that most of the KIs came from institutions that have had a product registered by the PMPB and so are aware of the kind of information that is demanded for registration. A list of products by applicant that is provided by the PMPB contains the following information: licence number, trade name (including a brief product description), generic name and scheduling level (i.e., prescription or OTC, etc.).

Indicator I.3: On written procedures for applicants on how to submit an application for registration of medicinal products, 70% of the respondents were aware of such procedures. The PMPB has a booklet, "A Guide to the Registration, Licensing and Scheduling of Medicinal Products in Malawi", which is available for sale. The booklet describes both the process to follow in submitting an application and the registration process, but it does not specifically mention how long the process takes nor the actual fees involved. Of the respondents, 60% did not know whether or not the procedures mention a time frame for processing the application.

Indicator I.4: Responses on the availability of written procedures for assessors on how to assess applications for registration were split equally among the three possible answers, but the PMPB does not in fact have written procedures on how to assess applications. One has to note that such procedures are part of the PMPB's internal standard operating procedures and would not necessarily be available to the public. Only PMPB staff would be privy to this information. In the guide to registration and licensing of medicinal products in Malawi, there is mention of how the application will be handled, i.e., pre-checking by registration section, quality analysis at the National Drug Quality Control Laboratory and then what the Medicines Committee will look for before approving a medicine for registration.

Indicator I.5: A standard application form publicly available for submission of applications for registration of medicinal products was said to be accessible from the Pharmacy, Medicines and Poisons Board by 63% of the respondents; 28.7% did not know of the existence of such a form, while 5% said that such a form does not exist at all. The PMPB has a standard application for a product licence form which is available to the public free of charge. An order version of the form is available on the PMPB's website. The form contains a description of the product and brief manufacturing and quality control information but does not ask for pharmacological action nor contra indications.

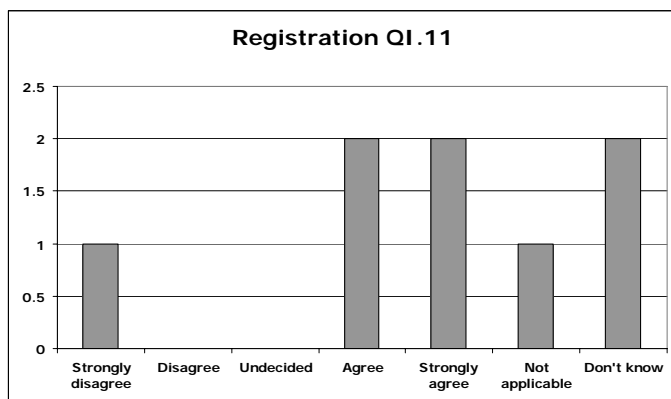
Indicator I.6: There are no written guidelines on how and where medicine registration officers meet with applicants, according to 60% of the respondents; 30% said they did not know of such guidelines, and 10% were sure that such guidelines were available at the PMPB. There are no such written guidelines, but it is well-known that applications are submitted to the PMPB office and not to the registration officer. Applicants do not usually come in direct contact with the registration officer during the registration process. This indicator is essentially not applicable to the Malawi scenario. The registration process in Malawi is such that registration officers and applicants do not meet to discuss the application. The applicant submits the application through the registrar or deputy registrar. The registration officers process and submit the registration application for approval to the Medicines Committee, which gives the recommendation for approval.

Indicator I.7: The PMPB has a Medicines Committee (Medco) whose main function is to assess applications for registration and make recommendations to the Board for registration. The establishment of such a committee is provided under Section 12(1) of the Pharmacy, Medicines and Poisons Act No 15 of 1988. Of the respondents, 90 % knew that there is a committee responsible for assessing applications for registration of medicinal products, while 10 % did not know.

Indicator I.8: The Pharmacy, Medicines and Poisons Act clearly spells out the composition of the Board and how these members will be selected – i.e., appointment by the Minister of Health. The act also provides for the establishment of a Medicines Committee but it does not specify who should be on such a committee. Section 12 (2) of the act only mentions that the chairman of the Board shall be a member of every committee established under the Act. Of the KIs, 37.5% said such criteria do not exist, while 23.75% said that it is available and 38.75 % did not know if such criteria exist.

Indicator I.9: Even though the Pharmacy, Medicines and Poisons Act clearly spells out the composition of the Board members, it does not spell out the composition and the selection procedures for members of the various committees of the Board, such as the medicines/registration committee. It also briefly provides the terms of reference for the three committees established under the act. However, 41.25% of the respondents said that there is a document describing the composition and terms of reference of the committee. Another 41.25 % had no idea whether this document exists, and 17.5 % said the document was not available.

Indicator I.10: Not surprising that no one of the respondents could say whether written guidelines on conflict of interest (COI) with regard to registration activities exist in Malawi. A majority 61.4% said that there are no guidelines, and only 27.1% did not know. In the Pharmacy, Medicines and Poisons Act, there is no reference to conflict of interest in the conduct of the members of the various committees.

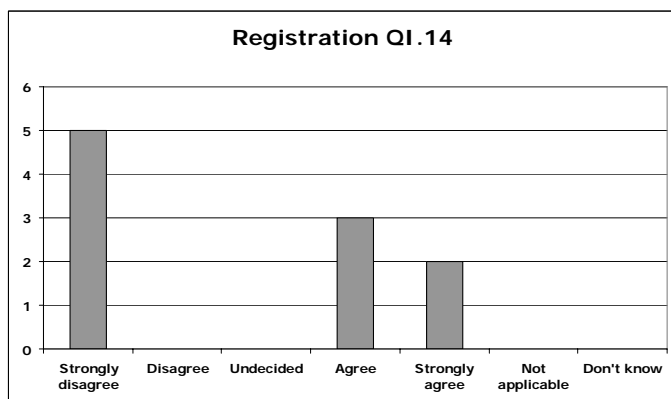


Indicator I.11: Of the respondents, 60% agree that a criterion for selecting members of the registration committee which results in the selection process being systematic and objective exists; 35% do not agree with this and only 25% did not know. There are no criteria for the selection of committee members available. The PMPB secretariat draws the members from both the public sector and the private

pharmaceutical sector and they are approved by the Board. Figure 1: (Responses to Indicator I.11)

Indicator I.12: Of the key informants, 35% said they do not know if there are clear and comprehensive guidelines for the committee's decision making process; 27.5% of the key informants said such guidelines exist, while 25% said that these guidelines do not exist. In the Guide to the Registration, Licensing and Scheduling of Medicinal Products in Malawi, section 2.4 outlines the criteria for consideration of applications by the MedCo. The primary criteria include quality, safety, efficacy, therapeutic appropriateness and cost and number of identical products on the market. Whether these guidelines are strictly followed by the MedCo could not be ascertained during the assessment.

Indicator I.13: A majority of the respondents (60%) said there was a process for appealing the decision of the committee when registration of medicinal products has been denied, while 40% said such a mechanism does not exist. Section 2.6 of the Guide to the Registration, Licensing and Scheduling of Medicinal Products in Malawi gives guidance on how applicants can appeal if they have been aggrieved by a decision of PMPB regarding the registration and licensing of a medicinal product.



Indicator I.14: Of the respondents, 50% strongly disagreed with the statement that "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decisions"; 30% agreed with the above statement, while 20% strongly agreed with the statement.

Indicator I.15: Of the key informants, 44% said that favouritism is the most common unethical behaviour. Another 44% mentioned bribery as another common unethical behaviour, while 11% said that since they are not directly involved in the registration process they don't know what kind of unethical behaviours are common in registration activities.

Indicator I.16: This question sought suggestions from the respondents on what should be the first action undertaken to improve the registration process in Malawi in terms of the quality of services offered by public institutions and transparency in the services offered by public institutions.

Following are the suggestions:

- a) For quality of services offered by public institutions, respondents felt that Government should develop clear registration procedures, ensuring procedures are followed, and ensure compliance with quality standards; reducing bureaucracy in order to achieve efficiency in the service; provide adequate training to personnel involved in drug evaluation, and ensure members of PMPB have the necessary knowledge and qualifications for the job; disseminating registration procedures to the public and recruit more pharmacists to increase staff numbers at PMPB to cover registration functions and to improve quality of service.
- b) In order to increase transparency in the services offered by public institutions, Government should ensure the Medicines Committee is staffed by professionals so that work is done professionally following guidelines and professional; make clear what criteria are to be used for registering medicines; improve the integrity of PMPB staff in drug registration with clear criteria for choosing Board members; ensure annual list of registered pharmacists and medicines is published; PMPB to make registration forms available to clearing agencies; and make public aware of PMPB functions so that people know drugs have to be registered. Government should also ensure the relationship between PMPB and the police is clear – PMPB is to work hand in hand with other agencies such as MRA; disseminate to the public the functions of PMPB, and PMPB to facilitate MRA to control which drugs can come in to the country (i.e. provide up-to-date information on the registered drugs and suppliers; provide clear guidelines and train MRA on how to handle drugs at entry points; and have an updated website that details the registration status of medicinal products in Malawi.

3.2 Control of medicine promotion

WHO defines drug promotion as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products." By definition the aim of promotion is to stimulate product sales.

For Malawi, the Pharmacy, Medicines and Poisons Act No. 15 of 1988 under section 52 to 54 provides for the control over sale of medicinal products and over promotional activities in form of advertisements of medicinal products through issuing of regulations by the Minister. This is very important to the nation as it leads to better prescribing, more rational use of medications and/or improved cost-effectiveness. Excessive promotional activities may lead to widespread prescribing and use before the safety profile of the medicinal products is fully understood (Drug Promotion, WHO, 2005, p 1). Control of drug promotional activities may be helpful in that it will ensure that medicinal products that have not gone through the regulatory authorities are not promoted. The Medicines Committee of the Board is responsible for the monitoring of the drug promotional activities which include advising the Board on all matters in respect of promotion of sales of medicinal products.

For medicine promotion, the questionnaire was administered to 12 KIs and this provided information used to measure the level of transparency and vulnerability to corruption in so far as control over promotion of medicinal products is concerned. Out of the 12 respondents, only 5 were able to provide responses which were substantiated by evidence as indicated in Annex IV, Table 2.

Indicator II.1: As to whether there is provision in the medicines legislation/regulations covering promotion and advertising – only 4 out of 12 respondents (33%) had any knowledge about the existence of such provisions. Even those who knew of them stated that access to the documents containing those provisions was limited, i.e., the Pharmacy, Medicines and Poisons Act No. 15 of 1988 can be accessed through purchase.

Indicator II.2: As to whether the provisions on drug promotion and advertising include explicit mention of advertising to professionals and the public, qualification and training of medical representatives, restrictions on monitoring samples, scientific symposia/meetings, post-marketing scientific studies, fees and consultancies, packaging, labeling and package inserts, promotion of exported drugs, restrictions and limits on gifts and gimmicks, etc., only one respondent from the media, one from the private sector, and one from Government responded by stating that they had some knowledge of the mention of promotion and advertising in the provisions, representing only 8%. The rest of the respondents were utterly ignorant of any mention of these in the provisions in the legislation. Despite the mention of advertising in the legislation, the provisions do not refer to specific target groups such as professionals or the public, and there is no mention of samples or studies and the like.

Indicator II.3: Of 12 respondents, 10 indicated some knowledge of the need for pre-approval of promotional and advertising materials, representing (63%) of the answers from the questions in the indicator. These comprised six private sector informants, two media informants, one from a nongovernmental organization and one from a Government organization. However, only 2 out of 12 respondents (16%) knew that there were regulations under Section 52 of Pharmacy, Medicines and Poisons Act 35:01 (Fees and Forms) (Amendment December 1998), Regulation No. 40A of 1988 (Part V, Regulation No 34.) that provides restriction on advertising of medicinal product on pre-approval of promotional and advertising materials.

Indicator II.4: Of the respondents, 6 out of 12 were knowledgeable about the enforcement mechanisms on promotion and advertising of medicines, and other infringements and its sanctions in case of violations, representing 50%. These came from the three private sector respondents, two from media respondents and one from a non-governmental organization. Under section 65, Sub Section (1), the act stipulates, “Any person who is guilty of an offence under this Act for which no penalty has been provided shall be liable to a fine not exceeding fifty thousand kwacha and to imprisonment for a term not exceeding five years”.

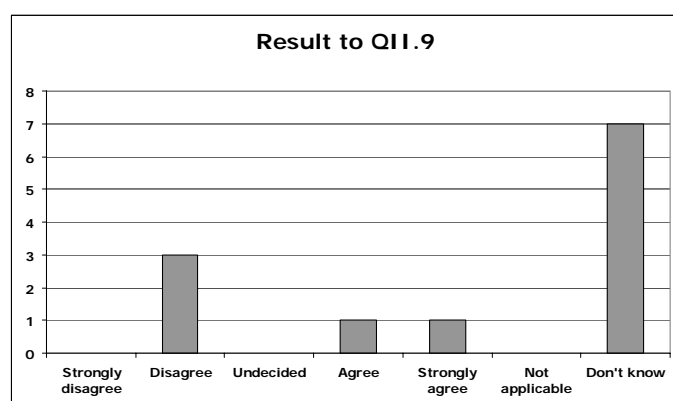
Indicator II.5: As to whether there is a formal complaint procedure for reporting unethical practices, only 2 out of 12 respondents expressed knowledge of the complaint procedures being in place, and about whether they were publicly available. The act provides for general appeals through the High Court. The respondents who knew about it represented 16%. The rest were utterly ignorant as to the existence of this provision.

Indicator II.6: As to whether there is a service or committee responsible for monitoring and enforcing the provisions on drug promotion, only one nongovernmental organization KI and 2 private sector KIs expressed knowledge of existence of a Medicines Committee for monitoring and enforcement of provisions on drug monitoring (representing only 18%), while the rest had no knowledge whatsoever.

Indicator II.7: As to whether there are written and publicly available Standard Operating Procedures (SOPs) guiding the service responsible for pre-approving or monitoring drug promotion and advertising – only one respondent, from the private sector expressed agreement about the existence of SOPs for services for pre-approving or monitoring drug promotion. Since the respondent could not produce evidence of their existence, the score was 0.

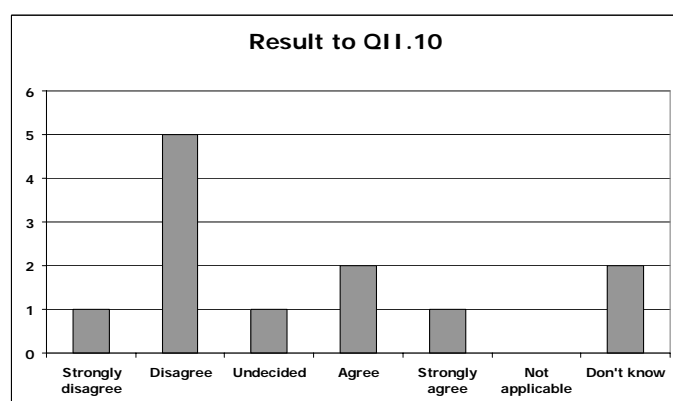
Indicator II.8: As to whether there are written guidelines on conflict of interest (COI) with regard to control of medicine promotion activities – only one media respondent answered as having some idea of the existence of the guidelines on conflict of interest and answered some of the questions relating to this indicator, representing only 4%. The rest had no idea.

To confirm these findings, i.e., very low transparency in relation to control over drug promotion, the responses from the KIs on indicators II.9 and II.10, using method 3 of the guidelines, are bar graphs as illustrated below:



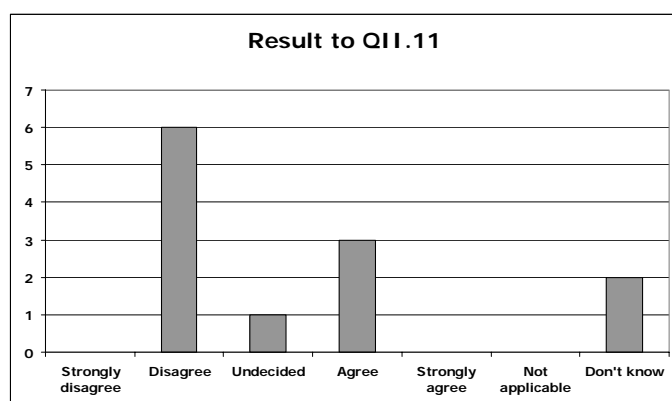
Indicator II.9: Here, the answers indicate that three out of five KIs (60%) disagree with the statement that “the legal provisions on drug promotion have been developed in broad consultation with all interested parties”, and only two out of five KIs (40%) either agree or strongly agree with the statement. There were more KI who did not know about how the legal provisions were developed, i.e. 7

out of 12 KIs (58%). This means that many respondents think that the legal provisions were basically developed without wide consultation.



Indicator II.10: As regards Indicator II.10, the answers showed that 6 out of 10 KIs (60%) strongly disagree or disagree with the statement that “Civil society or nongovernmental organizations have a great influence on improving the control of drug promotion in Malawi” and only three (30%) agree with the statement. This means that generally civil society has very little influence and control on

drug promotion, probably due to very little awareness as to its role and responsibility.



Indicator II.11: Here, the answers indicate that 6 out of 10 KIs (60%) disagree with the statement that “the provisions on drug promotion are well respected in Malawi”, and 3 out of 10 (30%) agree with the statement while one (10%) is undecided. There are still 2 out of 12 KIs (16%) who do not know whether there is respect for the drug promotion provisions. This is tantamount to thinking that even if the

provisions for drug promotion were available in the legislation, there was very little respect for those provisions by the stakeholders.

Interpretation of Indicator II.12

In answer to the question of what types of unethical behaviour are common in drug promotion in Malawi, the 12 respondents chose the following:

No.	Unethical Behaviour	Involving Health Professionals and Institutions	Involving Regulatory Services Offered by Public Institutions
1.	Bribery	3 (25%)	
2.	Material gifts	0 (0.0%)	
3.	Favouritism (to family/friends)	4 (33%)	1 (8.3%)
4.	Conflict of interest (e.g., investment in pharmaceutical companies)	3 (25%)	
5.	Other	5 (41.6%)	1 (8.3%)

Interpretation of responses to Indicator II.13

The question asked various KIs, if they were in the position of highest authority, what action they would recommend as a priority:

A. To improve the quality of the drug promotion process and service by:

- Stamping out corruption
- Forming regulatory committees that are neutral and independent
- Increasing interaction with firms/companies
- Publicizing regulations/ procedures laws widely
- Sensitizing the public to proper drug usage and promotion
- Promoting airtime in the media to sensitize the public about drugs
- Increasing information on drugs; train and motivate those involved
- Improving communication
- Avoiding delays in distribution of drugs
- Conducting inspections regularly

- Promoting public tendering
- Empowering inspectors
- Developing proper SOPs for inspectors

B. To improve drug promotion through increased transparency by:

- Forming committees that are neutral and independent with standards
- Monitoring committees' work and publicizing it
- Having clear guidelines
- Putting systems in place
- Having regulatory bodies that are nonpartisan
- Promoting interaction with all promotional agencies
- Making adequate rules, regulations, and laws and circulating them
- Ensuring disclosure of drug side effects
- Making documents available to all users and involving all parties

3.3 Inspection of establishments

The purpose of inspection of establishments in the pharmaceutical sector is to ensure that operations are carried out in accordance with the approved norms, standards and guidelines.

The Pharmacy, Medicines and Poisons Act No 15 of 1988, Part X, is dedicated to inspections. It outlines how inspectors will be appointed, their mandate in entering premises and the mode of inspection. Ten key informants were interviewed on registration and Table 3 in Annex IV summarizes their responses to the 11 indicator questions.

The Pharmacy, Medicines and Poisons Board also has a Guide to GMP Inspector Manual which provides guidance to its inspectors when conducting inspections especially in facilities that manufacture pharmaceutical products.

Indicator III.1: Respondents were aware of the existence of a regulation that governs inspection of medicinal products in Malawi. All the respondents (100%) said that the Pharmacy, Medicines and Poisons Act provides for the inspection of medicine manufacturers and distributors whether they be wholesale, retail, or clinics. This is provided for under Part X, Section 59 to Section 65.

Indicator III.2: The provision for inspection in the act, Section 60 (1 and 2) gives authority to inspectors to enter any premises that store, manufacture, distribute and dispense drugs. The majority of the key informants are aware of this fact. Although most KIs could not produce the act or regulations governing inspection of premises by the Pharmacy, Medicines and Poisons Board, 87.5% answered affirmatively to the provision being comprehensive enough. All KIs said the regulation gives power to inspectors to enter any premise where medicinal products are produced, packaged, stored, and distributed and also provides for special identification of the inspectors. Of the KIs, 20% did not know whether the duties and roles of the inspectors are defined.

Indicator III.3: Neither the Pharmacy, Medicines and Poisons Act nor the Regulations 1988 No 4A contain guidelines on classification of Good Manufacturing Practices (GMP) or Good Distribution Practices (GDP) non-compliance that describe the types of deficiencies and the

corresponding measures to be taken by the PMPB. The PMPB is currently in the process of adapting the WHO guidelines for use in Malawi.

Although 61.7% of KIs confirmed that there are written guidelines on GMP and GDP, none of them could produce a copy. Neither is there a copy at the PMPB that outlines the classification of GMP deficiencies and what corresponding actions will be taken by the PMPB. Of the KIs, 60% said there is no appeal system for companies that do not agree with the GMP/GDP findings of the PMPB.

Indicator III.4: There are no guidelines to prevent regulatory capture and this was confirmed by 50% of the respondents. Of the respondents, 38% did not know if such guidelines exist, while 11% said a mechanism for preventing regulatory capture exists. Rotation of inspectors is a fairly new concept within the Pharmacy, Medicines and Poisons Board and has so far been done once, when inspectors from the southern region of Malawi inspected establishments in the central region and vice versa. No external audit of inspectors has ever taken place but with the initiation of standardization of the SADC regulatory authority operations, this might become operational quite soon.

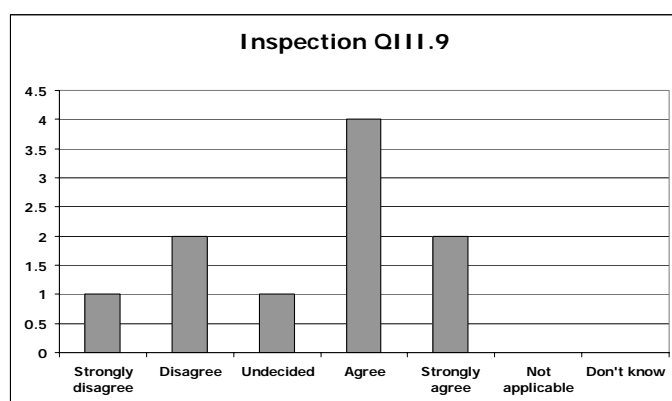
Indicator III.5: Guidelines on conflict of interest in inspection are very important in Malawi since most of the inspectors are not full-time employees of the Pharmacy, Medicines and Poisons Board. The inspectors are mostly from the private pharmaceutical sector. There are no written guidelines on conflict of interest according to 70% of the KIs, while 30% of the respondents did not know whether or not these are available. Only 1.43% could give an affirmative answer on conflict of interest guidelines and this was only on the fact that there is evidence of enforcement of these regulations through prosecution of some individuals in the pharmaceutical sector at the Anti-Corruption Bureau. But such evidence was not found by the assessors at the PMPB. This indicator gave most of the KIs an opportunity to express their lack of confidence in the PMPB's inspections. Since inspectors do not declare any conflict of interest, the KIs were of the opinion that objectivity is compromised in most of the inspection exercises, especially in cases where an inspector has to inspect the premises of a fellow inspector.

Indicator III.6: The responses to this indicator allude to the fact that the respondents have confidence in the PMPB. Inspection findings are subject to an internal review as evidenced by the fact that after an inspection the PMPB secretariat officially informs the institution of the results of the inspection. This is according to 70% of the respondents, while 10% did not know whether this happens and 20% said it does not happen. The inspectors submit reports to either the MedCo or the Pharmacy Committee, which makes recommendations to the Board for approval or rejection. This provides a forum for reviewing the inspectors' findings and conclusions.

Indicator III.7: There are written procedures on how inspectors should conduct themselves, but these are internal documents of the PMPB and as such are not available to the general public. The PMPB has been using guidelines from regulatory authorities within neighbouring countries, i.e., the Uganda National Drug Authority, and is currently in the process of reviewing these documents to customize them for Malawi. Written standard operating procedures (SOPs) for inspectors on how to conduct inspections are available (62% responded that this was so). The procedures include a checklist to be used by inspectors at the facility being inspected, and this may explain the high proportion of respondents aware

of the standard operating procedures. A good proportion (24%) said they did not know whether these were available, and 14% said these are not available at all.

Indicator III.8: The PMP Act 1988 only stipulates that inspectors will be pharmacists but does not indicate the minimum number of years' experience they must have nor does it require that the inspectors be recommended by certain institutions. Of the respondents, 48% said that guidelines on recruitment of inspectors are available, while 25% said they do not exist and 28% did not know.



Interpretation of Indicator III.9 The statement, "The integrity of inspectors is not at all influenced by personal gains, such as bribes, gifts, material or other benefits", drew a variety of responses. Of the respondents, 40% agreed with the statement and 20% strongly agreed with the statement, while a minor 10% strongly disagreed with the statement and 20% disagreed with the statement; 10% could not

decide whether they agreed or disagreed with the statement.

Responses to Indicator III.10

Favouritism and conflict of interest were the two most mentioned examples of unethical behaviour in the area of inspection of premises. Other unethical conduct included concealment of material gifts received and bribery, and the least-mentioned was the pilferage of unregistered medicines by distributors/suppliers, mostly from the private sector.

Responses to Indicator III.11

This indicator solicited thoughts from the KIs on priority actions that should be instituted to improve the inspection process in terms of:

a) The quality of inspection services offered by public institutions

The respondents mostly said that there is a need to train inspectors so that they behave professionally and are aware of their ethical obligations.

- The tools used in inspections should be updated.
- Criteria to be used in the recruitment of inspectors should be developed to ensure that people of integrity and self-discipline are recruited.
- The numbers of inspectors should be boosted so that they spend adequate time doing inspections.
- There should also be peer review of inspectors from other countries so that the quality of the inspection provided does not fall below international standards.
- Inspections should be regular, especially where inefficiencies were initially detected.
- The use of part-time inspectors will be discouraged so that bias on inspection issues and the decisions taken is eliminated.

b) Transparency in the inspection services offered by public institutions

- There is a need to let institutions know what procedures and guidelines are used in the inspection so that they are not caught unawares during inspections.
- Inspectors should be rotated so that inspectors from one region do inspections in another region.
- Inspectors should be made to declare gifts offered during inspection visits.
- The findings of inspection visits should be made public.
- Part-time inspectors should be eliminated.
- An inspection schedule should be developed and circulated to the concerned parties well in advance.

3.4 Selection of essential medicines

Drug selection deals with the choice of essential medicines that define the Government's priorities for medicine supplies in the public sector and also the reimbursement benefits for medicines as part of health insurance.

Drug management in Malawi and drug supply management in particular, is supported by a legislative and regulatory framework. This framework is encompassed in the Malawi National Drug Policy (NDP), 1991. A number of regulations were put in place to enable the enactment and enforcement of the NDP, such as the Pharmacy, Medicines and Poisons Act, 1988 and the Dangerous Drugs Act. These acts ensure compliance with various aspects of laws related to handling and use in Malawi.

Drug selection in Malawi is based on WHO's Essential Medicines List. WHO defines essential medicines as those that satisfy the priority health care needs of the population (Report to WHO Executive Board, January 2002). Essential medicines are further defined as a limited range of carefully selected essential medicines which lead to better health care, better drug management and lower costs.

The drug selection assessment instrument had 10 indicators with two open-ended questions. Of the 10 indicators, eight were analysed using methods 1 and 2, and the remaining two indicators were assessed using method 3, which was used as a cross-triangulation technique.

A total of 15 Key Informants were assessed in the area of drug selection. Six of the KIs came from the Government, five were from nongovernmental organizations and the remaining four from the private sector. The scoring and rating of this function can be found in Annex IV, Table 4.

Indicator IV.1: This assesses whether the Government of Malawi has an officially adopted national essential medicines list which is publicly available. About 60% (9 out of the 15 KIs) indicated that the Government has an officially adopted, publicly available national essential medicines list, while 40% of the KIs (or six) indicated negatively. Of the nine that responded positively, three were from government, five from nongovernmental organizations and one from the private sector. The six negatives were split in half between Government and the private sector.

In essence the Government has an Essential Medicines List (EML), which is known as the Malawi National Drug List (MNDL). However, this list was last revised in 1998 i.e., 10 years ago and is therefore outdated. It should be revised regularly. As to whether the MNDL is publicly available, the findings indicate that the MNDL is not readily available. The MNDL has been out of print for a long time. Obtaining a copy from any of the institutions visited proved futile.

However, the selection of drugs for procurement the public sector is still based to some extent on the MNDL and more recently the Essential Health Package (EHP) under the Sector Wide Approach (SWAp).

Indicator IV.3:

This indicator attempts to ascertain whether there are clearly written and transparent rules or criteria for the selection process, for including or omitting medicines from the EML. About 53% of the KIs indicated some knowledge of the existence of the rules or criteria, while 47% indicated otherwise. Four KIs were definite that rules or criteria existed, while the remainder (seven) gave ambiguous responses. Four KIs from Government and two from the private sector indicated that the list of rules or criteria did not exist. In addition, the issue of enforcement as a challenge was raised, and the issue of whether the selection of medicines was based on cost-effectiveness should be investigated further.

In essence, neither rules nor criteria exist for the process of including or omitting medicines from the national EML.

Indicator IV.4: This indicator attempts to ascertain whether the EML is in line with WHO procedures. Overall, 60% agreed that EML was indeed in line with WHO procedures. However, 40% indicated otherwise or were doubtful. What clearly came out was that the EML has not been revised for a very long time and as such might not be up to date. Some KIs perceived that the procedures were not widely disseminated to health professionals due to lack of an enforcement mechanism.

The review process of the MNDL in 1998 was cognizant of the WHO procedures and thus development was in line with the WHO framework. The MNDL 1998 version was widely disseminated soon after the review process. Funds were allocated from WHO through the MOH to print and disseminate the list mostly to institutions that deal with the pharmaceutical products one way or the other. The MNDL has since disappeared from most of the institutions and is no longer in print.

Indicator IV.5: This indicator seeks to ascertain the presence of a committee responsible for selection of the national EML. About 67% of the responses (10 KIs) indicated knowledge of and confirmed the presence of a selection committee. While 33% (five KIs) indicated that they were unaware of the existence of the selection committee.

Although the National Drug Committee is legislated in the National Drug Policy, the committee operates in an ad hoc fashion, or as a task force. Meetings are not regular. It is chaired by the deputy director of pharmaceuticals in the MOH. Currently, disease programmes within the MoH (i.e., the National Malaria Control Programme or the National TB Programme) will undertake the revision or selection of medicines used in the programme as and when the need arises.

Indicator IV.7: In ascertaining whether there is a clear criteria used in choosing members of the selection committee, about 58% of the KIs responded that they were not aware of the existence of the selection criteria and 42% indicated that some sort of criteria existed but perhaps not in a written form. Thus, the criteria are not easily accessible nor publicly available.

No written criteria for the selection of members of the Selection Committee exist. The MOH, through the Deputy Director of Pharmaceuticals, extends invitations to experts from various fields in the health sector to attend.

Indicator IV.8: This indicator discusses whether written guidelines on conflict of interest (COI) with regard to selection of essential medicines exist. About three KIs, representing 18%, expressed knowledge of the guidelines. However, the KIs were quick to add that since a form for declaration of COI for the selection committee does not exist, committee members make verbal declarations of COI. The majority of the KIs (82%) expressed total ignorance of the existence of guidelines on COI.

Written guidelines on COI do not exist. Declaration of COI has been basically left to an official's personal integrity and candour. Some of the professionals and experts invited to sit on the Drug Selection Committee come from the private sector and have interests in the pharmaceutical sector (i.e., own a pharmaceutical business or are involved in research being sponsored by a pharmaceutical company) and so the issue of COI is extremely pertinent.

Indicator IV.9: This indicator ascertains whether there are clear and publicly available Standard Operating Procedures (SOPs) that describe the role and responsibilities of the Selection Committee. A mere 20% (or three KIs) expressed knowledge of the existence of the SOPs. The larger number of KIs (12, or 80%) was not aware of the SOPs or emphatically said the SOPs did not exist.

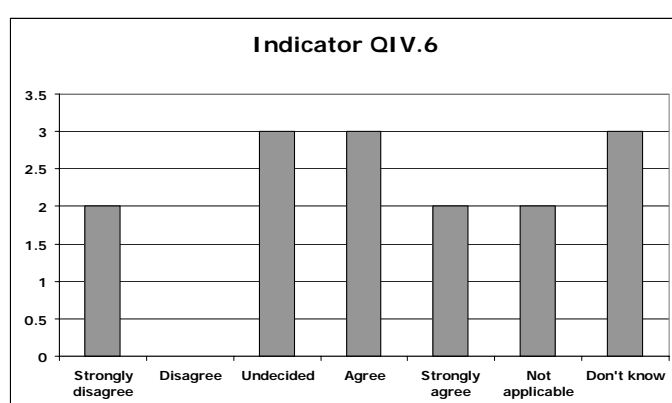
SOPs describing the role and responsibilities of the Selection Committee do not exist. The National Drug Policy only makes mention of the formulation of the National Drug Selection Committee, but it does not define the roles and responsibilities or composition.

Indicator IV.10: This indicator determines whether rules for decision-making in the SOP are clear and transparent. About 34% of KIs indicated some knowledge of the manner in which the selection committee makes decisions. About two thirds (or 66%) of the KIs expressed lack of knowledge on this area.

As for the previous indicator, the SOPs do not exist; hence the rules for decision-making do not exist.

Indicator IV.2 discusses the issue of the development of the EML through a consultative process. Ten out of 15 KIs (representing about 67%), responded that they either strongly agreed (six) or agreed (four) that the EML had been developed through wide stakeholder consultation process. The remaining five (representing 34%) disagreed with the statement (i.e., three disagreeing and two strongly disagreeing).

It is, however, interesting to note that three of the KIs whose answers were either strongly disagree or disagree were from Government institutions, namely Central Medical Stores (CMS) and Kamuzu Central Hospital. Therefore, it can be deduced that even though the statement scores a high percentage based on the knowledge of the KIs, the responses from the Government KIs give a picture of the reality on the ground -- that original EML was indeed developed based on a consultative process. No other review of the EML has taken place in the last eight years.



Indicator IV.6 is to do with whether the selection committee responsible for the EML operates free from external influence. The responses were a mixed bag: two of the KIs (or 13.3%) strongly disagreed, three (or 20%) were undecided, another three (or 20%) agreed, and two (or 13.3%) strongly agreed. However, three (or 20%) did not know and interestingly two others felt that this statement was

not applicable.

Indicator IV.11: This question helps assess KIs perceptions on issues to do with unethical behaviours that are common in the selection process.

Some of the KIs perceptions and observations include the following:

- Previously during the Kamuzu Banda regime, drugs were purchased directly from reputable suppliers and manufacturers. During the Muluzi era, individuals and bogus companies were involved in the provision of pharmaceutical drugs. This trend exacerbated bribery and favouritism.
- The selection process is deliberately rushed and procedures are flouted in the process, in that drugs are being bought on an emergency basis – hence procedures are being bypassed.
- Favouritism is shown to friends and those with similar political inclinations.
- The SOPs should be documented.
- A transparent selection process should be developed to harmonize and establish one committee.
- Conflict of interest is by far the biggest unethical behaviour.
- There is a clear indication that unqualified persons have been given licenses to run pharmaceutical businesses.

Indicator IV.12: This question asks the KIs what they would do, about two issues, if they were in a position of highest authority.

a. The quality of services offered by public institutions:

- Follow WHO guidelines and use evidence-based decisions to select high quality, affordable drugs.
- Be open -- make the names of those who sit on the selection committee public knowledge.
- A need of a quantification survey is needed, in order to include the private sector (currently, no one can assess what is dispensed by the private sector).
- Strengthen the capacity of CMS and PMPB.
- The mandate of the Tender Committee should be revised so as to include civil society representation.

b. Transparency in the services offered by the public institutions:

- Be a part of the decision-making process in the drug selection
- Try and publicise drugs on the EML and if they are not available, make the public aware. This will prevent unscrupulous individuals in the pharmaceutical sector from taking advantage of the situation for personal gain.
- Make the guidelines and procurement act operative.
- Establish structures and trim current establishment to fit structure.
- Establish accountability and supportive structures for drugs monitoring and supervision.
- Relevant health sector organs should conduct the monitoring and supervisory roles.

After carefully analyzing the responses and the scores from the 15 KIs, drug selection obtained the lowest score compared to the other components. The final score for drug selection was **1.59**. This score falls within the 0.0 – 2.0 category, which indicates being extremely vulnerable.

3.5 Procurement

The strategic objectives of pharmaceutical procurement are: to procure the most effective drugs in the right quantities; select reliable suppliers of high-quality products; ensure timely delivery; and achieve the lowest possible total cost(WHO/EDM/PAR/99.5).

In Malawi, the public sector drug procurement is done by the Central Medical Stores (CMS). For both the public and private sectors, procurement and donations are limited to those items registered for use in Malawi unless approved by the Ministry of Health (MoH). Procurement is also restricted to products currently registered and marketed in the country of origin.

In this study, 15 indicators having to do with the procurement function were measured. Of these, 11 key indicators were analysed using methods 1 and 2, referred to on page 3, and directly contributed to the final rating of the level of vulnerability to corruption for procurement (see Annex IV, Table 5).

The study collected information from 21 key informants. Of the 21, 13 were from Government institutions, 3 were from private organizations, one from an international agency, and four from nongovernmental institutions, both local and international.

Indicator V.1: This indicator ascertains the use of transparent and explicit procedures for procurement of pharmaceutical products. The procurement system in Malawi is covered by a legal framework comprising The Public Procurement Act (No. 8 of 2003) that provides the legal basis of the public procurement system of the Government of Malawi (GoM); the Public Procurement Regulations that provide a more detailed framework of rules to implement the objectives of the act and govern all public procurement; the Desk Instructions that provide step-by-step procedures for all aspects of the procurement cycle; and the Standard Documents, which are working documents for the implementation of public procurement activities. The use of the Standard Documents is mandatory for all procuring entities. The legal framework provides general comprehensive guidelines, principles applicable to the procurement of goods, works and services (not specifically pharmaceuticals).

For the procurement of health sector goods, the GoM currently uses World Bank Guidelines – Standard Bidding Documents (SBD) and its companion Technical Note (TN) prepared by the Bank for use by borrowers and their implementing agencies in the procurement of pharmaceuticals, vaccines, and condoms through international competitive bidding (ICB). The procedures and practices presented in these SBD are mandatory for use in projects financed in whole or in part by the World Bank in accordance with the provisions of the latest edition of the Guidelines: Procurement under IBRD Loans and IDA Credits-May 2004.

The GoM Ministry of Health (MoH) also uses procurement guidelines contained in the Procurement Manual for the implementation of Programme of Work (POW) for the Health Sector Wide Approach. The Procurement Manual was meant to provide guidance in the procurement of goods, works and services under the Health SWAp and compliments the Procurement Act. The POW has been divided into six components or programme areas, one of which is Pharmaceutical and Medical Supplies (MoH: February 2007).

An average of 43% (or 9 out of 21 KIs) interviewed said the Government uses transparent and explicit procedures. About 52% (or 11 out of 21 KIs) interviewed did not have any idea at all.

Nearly all (except one) of the KIs who said yes could not produce evidence. In some institutions, copies of the documents mentioned herein are available, but it was difficult to get a copy for the mere reason that these are paid documents. In other institutions, evidence never existed at all. The indicator, therefore, scored very low, and the low score is indicative of the lack of transparency of the procedures in so far as pharmaceutical procurement is concerned.

One critical observation made during the assessment is that the GoM lacks adequate print capacity to make available enough copies of the guidelines to satisfy all those who need them. Many times the documents are out of stock at the GoM stores. National assessors also found that the leeway given to the GoM to adopt other procedures for the procurement of those goods and works not financed by a World Bank loan creates loopholes that lead to systematic abuse of the procurement function.

Indicator V.2: In terms of written guidance for procurement office staff on the type of procurement method to be used for various types of products, there are provisions made in all the legal documents highlighted in this section regarding the methods of procurement.

Section 3.13 of the World Bank's Technical Note gives guidelines, for selecting a procurement method for each pharmaceutical product group. These guidelines apply to all goods and works financed in whole or in part by bank loans (Procurement under IBRD Loans and IDA Credits-May 2004). For the procurement of those contracts for goods and works not financed by a bank loan, the borrower may adopt other procedures.

The Memorandum of Understanding signed between development partners and GoM requires that all goods, works and services below the thresholds for International Tendering be procured in accordance with the GoM Procurement Act of 2003. Procurement methods for goods and works include International Competitive Bidding (ICB), National Competitive Bidding (NCB), Shopping (also called Request for Quotations), and Direct Contracting. These are all based on the amounts of money involved and not on different types of products. Parts V and VI of the Public Procurement Act 2003 also provide, respectively, explicit provisions regarding methods of procurement and their conditions for use and main principles and procedures for methods of procurement.

However, a meagre 5% of those interviewed (or 1 out of 21 KIs), acknowledged the existence of these guidelines, while 52% said no and those who did not know comprised of 43% (see table 3 below).

All KIs except one were unable to provide evidence, and the indicator was rated zero. The mere fact that individual institutions have to buy the procurement guidelines prevents some organizations from taking the initiative to procure them.

One observation made is that after the documents are purchased, they are kept in drawers for protection. They are never read or passed on to those who may need to apply the principles and procedures in their procurement activities. Other institutions do not find it sufficiently urgent to buy the guidelines from the GoM stores. In addition, the World Bank Guidelines are available only at the national level; one can expect to see them at Central Medical Stores (CMS) and not at the operational level.

Indicator V.3: None of the documents studied so far makes use of the objective quantification method to determine the quantity of pharmaceuticals to be purchased, except the World Bank Technical Note; Section 4.2, Subsection 4.2.1 recommends a quantification methodology appropriate for pharmaceuticals. Among the methodologies are: The consumption method, which employs data on past use (adjusted for stock outs and projected changes in drug utilization) to project future needs; the morbidity method, which bases the estimate on the expected number of attendances, the incidence of common diseases, and current standard treatment guidelines; and the adjusted consumption method, which applies the pattern of drug use in a "standard" supply system to the target system. These guidelines are available only at the central level.

Of the KIs interviewed, 52% (or 11 out of 21) indicated that objective quantification methods are used to determine quantities of medicines to be procured, while 10% said no and 38% did not know.

Unfortunately, the World Bank Guidelines are available only at the central level and cannot be accessed at the operational level. In the light of the absence of evidence and guidelines specific to pharmaceutical products at the operational level other than CMS, it was observed that some KIs' responses on this indicator were based only on assumptions.

The Drug Leakage Study findings (MoH: August 2006) recognizes that although estimates for quantification of drug requirements are based on documentation of yearly consumption, the procurement of drugs in Malawi is, to a large extent, determined by the availability of funds..

Indicator V.4: This indicator discusses if there is a formal appeals process for applicants who have their bids rejected. The Public Procurement Act, 2003 sets conditions for both the procuring entity and bidders and for a formal appeals process for applicants whose bids are rejected. Section 38 (4) of the act and the accompanying Regulation 192 (11) recognizes the fact that a supplier or bidder who has been excluded from public procurement may appeal to the Minister. Detailed review procedures, however, are contained in Schedule D of the Public Procurement Regulations 2004.

Of the KIs interviewed, 62% (or 13 out of 21) indicated that procedures do exist whereby applicants who have their bids rejected can file a protest against the rejection; 38 (or 8 out of 21) KIs did not know about this.

Indicator V.5: This indicator discusses a Tender Committee (TC) and clear separation of the key functions of the procurement office and those of the TC. The Public Procurement Act 2003, Public Procurement Regulations 2004, and Desk Instructions for Public Procurement all make provisions for the establishment, in all ministries, departments and parastatal organizations, of Internal Procurement Committees (IPC), which in the context of pharmaceuticals, is called a Medical Buying Board; IPCs function in the same way as TCs. Provisions are also made for the establishment of the procurement offices, referred to in the Public Procurement Act 2003 as specialized procurement units. The two offices are different and have different functions; Part III of Public Procurement Act 2003 is dedicated to these two important offices. Page 5 of 9 of the Desk Instructions outlines a summary of the roles of each key body –the functions are clearly distinguished.

Of the KIs interviewed, an average of 52% (or 11 out of 21) indicated the existence of formally established TCs, which are responsible for suppliers' selection for restricted tenders and for contract decisions. On average about 43% (or 9 out of 21) KIs interviewed expressed no knowledge of this.

In the case of the Ministry of Health, the issue of the TC was problematic when it came to distinguishing between the TC, the Medical Buying Committee (MBC), the IPC, and the procurement unit.

However, in accordance with the provisions in the Procurement Act No. 8 of 2003, tender evaluation and awarding of any drug supply contract whose value is above MK800,000, is done by the MBC.

The MBC is a formally established TC under the Ministry of Health for pharmaceutical procurement. It is made up of:

- The Secretary for Health
- Directors from the Ministry of Health including the director for HTSS, director of nursing
- A representative from the Ministry of Finance (Treasury)

- A representative from CHAM
- A representative from PMPB
- A representative from CMS
- A representative from the Office of the Directorate of Public Procurement (ODPP).

Indicator V.6: Criteria for Tender Committee membership are clearly presented by the Public Procurement Act 2003, Public Procurement Regulations 2004 and the Desk Instructions for public procurement. However, the law does not provide for representation from client facilities, nor require that membership changes periodically. Nevertheless, it requires professionals with specific functions or skills, representation from senior Government officials and also that those members declare conflict of interest.

On average 26% (or 6 out of 21) KIs who were interviewed said specific criteria for TC membership do exist. About 67% of KIs interviewed (or 14 out of 21), expressed ignorance at the presence of these criteria. For those who said yes, most of them could not provide evidence and the indicator was given a low score.

The large percentage of respondents who did not know criteria exist is in itself a sign of lack of transparency in the selection of members for the TCs.

In the above indicator, some respondents displayed ignorance by either saying that criteria for TC membership does exist or does not, but when their responses were cross-compared with indicator V.8 ("To what extent do you agree with the following statement: 'The members of the TC are systematically selected based on specific criteria'"), the same respondents either said that they did not know or that they agree. This kind of response confirmed the ignorance projected in indicator V.6, and the indicator was rated zero.

Indicator V.7: This indicator treats written guidelines on conflicts of interest with regard to the procurement process, the Public Procurement Regulations Part X, Accountability and Transparency in Public Procurement. Division I, Measures to Promote Transparency, Regulation 168 (i) calls for information on conflict of interest declaration, if a bid was rejected in the circumstances referred to in section 18 (4) (a) of the act. Under the same Part X, Division II, Accountability, Regulation 175 (1) calls for all members of an Internal Procurement Committee, before commencing evaluation and comparison of bids, to, sign a declaration of interest to the effect that they have no relationship with bidders of the types stipulated therein. Regulation 176 provides for identification of activities on behalf of the procuring entity subject to conflict of interest restrictions.

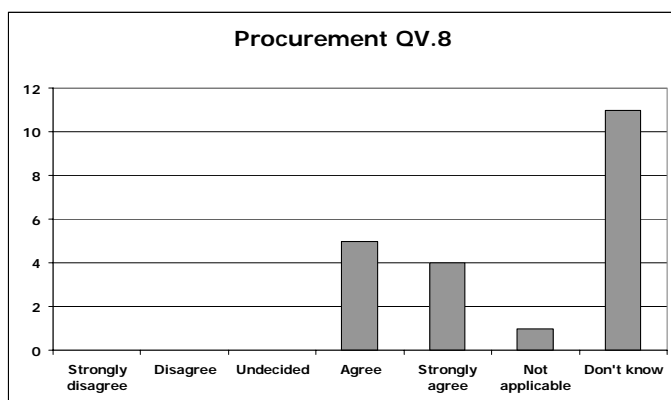
The procurement laws fall short of providing for: Criteria 2, 4, and 5, "form for declaration of COI for members of the TC, rules on reporting COI and mechanisms protecting informers of COI", respectively. However, the guidelines do include: Criteria 3, 6 and 7, "rules on acceptance of gifts on Regulation 181 of the Regulations about disclosure of offer of inducement, and actions to be taken in case of failure to comply with policy. E.g. Section 19 (2) of the Act says: Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine of K50, 000 and to imprisonment for two year."

The number of respondents who did not know about the existence of written guidelines on conflict of interest with regard to the procurement process was almost 100%.

It was observed during the assessment study that despite the comprehensiveness of the laws on procurement, accessibility of the guidelines is a major setback. Guidelines are available on paper but stakeholders who are supposed to apply them do not know they exist. No form for declaring interest was available at the time of the assessment. Interestingly, indicator V.14 about KI opinion on "what types of unethical behaviour are common in the procurement system in Malawi", COI scored 47%. Although this figure doesn't look alarming, it does indicate a significant and systematic threat to the procurement system.

It was understood from the Drug Leakage Study that the initial evaluation of tenders is done by CMS usually involving three staff members who scrutinize the submitted tenders and prepare the initial tabulation on which MBC bases its evaluation. By implication the MBC's evaluation is based on secondary rather than primary data thereby casting doubts on the objectivity of the evaluation exercise. It was further observed that the three CMS members of staff were deemed to be an interested party in the drug and supplies system and therefore their initial involvement in tender evaluations raise issues of conflict of interest, the study team concluded.

The Drug Leakage Study found that the Chairperson for the MBC is the Secretary for Health. Although this may seem logical since the Secretary for Health is responsible for the efficient and effective running of the entire ministry's operations, including drug supply management, the fact that the Secretary for Health is the Chairperson of the MBC and is at the same time an interested party, means that COI comes into play, and hence compromises the independence of the MBC.



Indicator V.8: When asked to express their opinion as to whether the members of the TC are systematically selected based on specific criteria, 42% of KIs interviewed (or 9 out of 21), agreed or strongly agreed with the statement; 52% (or 11 out of 21) said they did not know; and only 5% (or 1 out of 21) said that the statement was not applicable.

Criteria do exist as provided for by the Procurement Act and the accompanying Regulations and Desk Instructions. However, people have no access to these documents because they are not made available at a particular organization.

Most respondents contradicted themselves by giving either positive or negative responses that were contrary to their first responses to indicator V.6. The indicator was therefore given a low score.

Indicator V.9: This indicator deals with the question of computerized management information systems used to report product problems in procurement. It was encouraging to note that the Public Procurement Law (Act 2003 and Regulations 2004) has made some provisions regarding the use of modern technology and communications in the procurement system on Section 17 of the act and Section 16 (1) of the regulations.

About 14% of KIs interviewed (or 3 out of 21), said there is a computer management information system in use to report product problems, while 24% of KIs (or 5 out of 21), said the system is not computerized. However, an average of 62% of KIs (13 out of 21), expressed ignorance at the use of computerized management information systems.

The management information system in Malawi is just developing, and currently the manual system is in use in most organizations. Regulation 16 (1) of the Public Procurement Regulations 2004 confirms this statement when it says that ".the Director of Public Procurement shall devise, and facilitate the implementation of, strategies for introducing and spreading the use of information and communication technology in the procurement process". This statement shows that the procurement system in Malawi is in a transition to full institutionalization.

Indicator V.10: This indicator discusses Standard Operating Procedures (SOPs) for routine inspection of consignments: the purpose of the Desk Instructions for Public Procurement is to enhance efficiency, economy, transparency and accountability in public procurement. They apply to all procurement carried out by procuring entities, using public funds. They cover the whole procurement cycle from initiation through contract completion. Inspection of consignments is, therefore, covered by the current Desk Instruction 21: Administering a Contract: Guidance Note 2 – Contract Administration for Goods.

Nevertheless, only about 33% of KIs interviewed (or 7 out 21), said SOPs do exist, 14% of KIs (3 out of 21) said that SOPs do not exist, and 57% of KIs (12 out of 21) did not know SOPs exist.

If Desk Instructions apply to all procurement carried out by procuring entities using public funds, and they cover the whole procurement cycle from initiation through contract completion, one must expect to find these guidelines at every level of procurement operations. The Desk Instructions for Public Procurement cost MK3290 and when purchased by public institutions they are protected because they are expensive. This makes the guidelines inaccessible to those who should apply them.

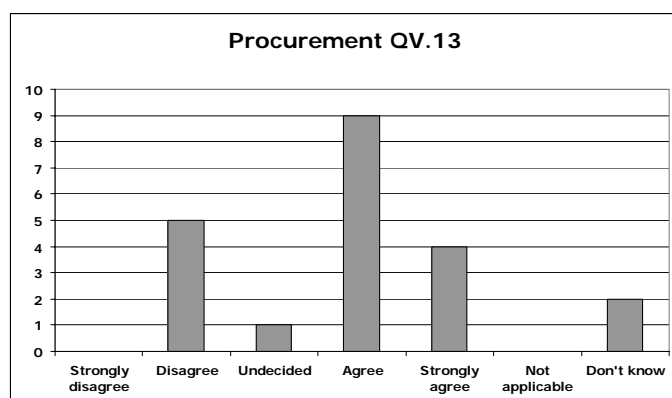
Indicator V.11: The issue of a post-tender system to monitor and report on suppliers' performance to the Tender Committee is covered by the current Desk Instruction 21, Administering a Contract (especially under Guidance Note 1, "selecting a Contract Administrator to monitor the performance of both parties against the contract implementation plan", and 2, Contracting Administration for Goods, which focuses on ensuring that goods are delivered on time and are acceptable to the procuring entity, in terms of quality and supporting documents, and that the procuring entity meets its obligations to pay for the goods delivered. The procurement unit has the overall responsibility for contract administration and reports to the IPC or TC.

However, about 29% of KIs interviewed (or 6 out of 21), said there is a post-tender system in place to monitor and report on suppliers' performance to the TC. About 19% of KIs (or 6 out of 21) said the system does not exist. And about 52% of KIs interviewed (or 11 out of 21), said they do not know of the existence of this system.

The Desk Instructions on this indicator are neither comprehensive enough nor explicit and therefore fall short of meeting the requirements of an ideal post-tender system. Most of the criteria in this indicator are not met, and so the system cannot be qualified as being efficient.

Indicator V.12: The Public Procurement Act 2003: Part VI, Section 39 provides for regular audits of procurement activities. Of the KIs interviewed, on average 33% (or 7 out of 21) said that the procurement office undergoes regular audits, about 10% (or 2 out of 21) said no, they were not. The percentage of respondents who did not know was 57% (or 12 out of 21).

There is no regulation available for the implementation of legislation on auditing. It is not clear as to how audits are conducted. Often, audits are not proactive but rather reactive, usually responding to a tip-off about some irregularities taking place in a particular organization. These kinds of audits are not always welcomed by the public and reports emanating from such audits are not publicly and easily accessible because they are like police reports.



Indicator V.13: When KIs were asked to express their opinion of whether the procurement system in Malawi is operating in a totally transparent manner, 62% (or 13 out of 21), agreed or strongly agreed with the statement; 24% (or 5 out of 21) disagreed with the statement; and 10% (or 2 out of 21) did not know, while 5% (or 1 out of 21) were undecided.

The Office of the Director of Public Procurement (ODPP) has recently embarked on a country-wide sensitization campaign about public procurement. The results of that campaign are being reflected in the responses of the KIs to this indicator. They responded in reference to procurement in Government in general because that is what the ODPP is all about, not pharmaceuticals specifically.

Indicator V.14: Unethical behaviours common in the procurement system in Malawi that scored highly were conflict of interest and favouritism, both at 47%, followed by bribery which scored 33%, material gifts scored 19%, political influence scored 5% and other forms of unethical behaviour scored 14%. However, in comparison to other functional areas, it received the highest rating, probably because most of the respondents selected were those who professionally deal with registration and are closely involved with the legislation and guidelines relating to registration.

4. Data analysis and interpretation

4.1 Registration

The final score for registration was calculated at 4.84. According to the table below, this final score falls between 4.1 and 6.0, implying that registration is moderately vulnerable to 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 2.62	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

4.2 Control of medicine promotion

For indicators II.1 to II.8, and methods 1 and 2, only 5 out of 12 KIs provided responses based on knowledge of facts and with evidence to back their responses. Using the 10-point rating scheme as indicated in the table below, the final score for control over drug promotion was **1.375**, showing that in Malawi, there is very low transparency in control over drug promotion, i.e., it is extremely vulnerable to corrupt practices, as shown in the table below.

The Rating for Drug Promotion in a 10-Point Rating Scheme

Extremely Vulnerable	Very Vulnerable	Moderately Vulnerable	Marginally Vulnerable	Minimally Vulnerable
0.0 – 2.0	2.10 – 4.00	4.10 – 6.00	6.10 – 8.00	8.10 – 10.00
1.375				

4.3 Inspection of establishments

Using the 10- point rating scheme for rating the degrees of vulnerability to corruption, it can be seen that inspection is moderately vulnerable to corruption as indicted in the table below.

The Rating for Inspection on a 10-Point Rating Scheme

0.00 – 02.00	2.1 -4.0	4.1-6.0	6.1-8.0	8.1 – 10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable 4.34	Marginally vulnerable	Minimally vulnerable

4.4 Drug selection

The overall score for of **1.59** falls in the bracket 00.00 – 2.00 which indicates that drug selection is extremely vulnerable to corrupt practices and unethical behaviour which includes an extremely non-transparent tendency. This overall score for drug selection is indicative of how far the pharmaceutical sector is from putting into place mechanisms for making drug selection as effective as desired.

0.0 -2.0	2.1 -4.0	4.1-6.0	6.1-8.0	8.1 – 10.0
Extremely vulnerable <u>1.59</u>	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

4.5 Procurement

The final score was 3.0. According to the 10-point rating system, 3.0 falls in the 2.1-4.0 range on the scale and clearly indicates how Malawi's procurement function is vulnerable to 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 3.5	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

5. Recommendations

While there are recommendations specific to each functional area, the NAs found that there are some general recommendations that concern all the functional areas in the pharmaceutical sector.

These include that:

- There should be increased information-sharing on drugs through training and motivation of those involved with drugs;
- Government should provide SOPs and guidelines on COI, in writing, with clear and simple forms for completion by those involved and written procedures to be followed in the process of declaring COIs. These prerequisites should be publicly available and easily accessible.
- Government should ensure the promotion of proper, publicly available and speedy public tendering procedures
- In order to avoid delays in distribution of medicines, the Government should also ensure improved communication with all those involved in drug registration, promotion, inspection, selection, procurement and distribution.

Specific recommendations

Registration - Government should ensure the following:

- Up-to-date list of registered medicines in Malawi should be made publicly available and easily accessible.
- Deliberate effort should be made by the PMPB to ensure that Government institutions such as the Malawi Revenue Authority have up-dated lists of registered medicinal products.
- Written procedures for assessors, guidelines on composition and selection procedure for members of the various registration committees, COI forms and the like are in place to guide those involved with drug registration.

- Guidelines on how to handle medicinal products at port of entry should be developed to help the handling of registered as well as unregistered medicinal products.
- Civic education on the importance of registering medicinal products.

Control of Medicine Promotion - Government and all stakeholders should stamp out corruption through a number of interventions, including:

- Development of regulation on drug promotion to support the act.
- Dissemination of the act to stakeholders involved in drug promotion.

Inspection of Establishments – A number of critical issues that were raised require that Government undertake the following important activities:

- The mechanisms for declaring COI by inspectors, and the consequences of not abiding by the guidelines, should be developed and their implementation expedited.
- The use of part-time inspectors should be reviewed and mechanisms for ensuring transparency and absence of favouritism or bias through peer reviews by inspectors from the region explored.
- Guidelines on the qualifications required for inspectors and should be clearly spelt out in the regulations, to ensure proper recruitment.
- Results of inspections should be publicized to stakeholders in the pharmaceutical sector.

Selection of Essential Medicines - The National Drug Policy (NDP) is not being fully implemented and shortfalls in drug selection are a direct consequence of this weakness. In terms of drug selection the following is recommended:

- The Government should reconstitute the National Drug Committee (NDC), which should revise the EML as matter of urgency and also ensure that relevant stakeholders are widely consulted during the revision process.
- The Government should ensure that rules/criteria for EML selection process are publicly available.

Procurement of Medicines - Pharmaceuticals are not ordinary commodities; they are goods of a special type. However, the GoM procurement guidelines, although comprehensive, are general in nature, and do not provide for procurement of pharmaceuticals as special items or commodities. It is therefore recommended that:

- The procurement laws should be amended to incorporate World Bank Guidelines for the procurement of pharmaceuticals.
- The international and bilateral agencies should assist the GoM to boost its printing capacity so as to meet the demand for the public procurement documents/guidelines.
- The GoM should hire staff technically trained in the procurement of medicines, in addition to building the capacity of existing staff.
- An enforcement mechanism should be put in place so as to ensure compliance.
- The GoM should undertake a gradual introduction of Computer Management Information Systems for monitoring and reporting on the pharmaceutical procurement processes.

6. Conclusions

In summary, the results from this quantitative data show that in Malawi, the weaknesses outweigh the strengths by far. The drug promotion function is very vulnerable to corruption (i.e., a 1.375 rating in a scale of 1.00 to 10.00 is extremely low). This shows that the level of transparency is also extremely low and therefore indicates that drug promotion is highly susceptible to corruption and unethical practices. The only areas where there appears to be slight transparency and knowledge about the provisions relating to drug promotion requirements are among the private sector operators or entrepreneurs (maybe because they are expected to proactively educate themselves about the law on promotion), and in the Government or public sector, as they are the obvious repository and custodians of the laws and regulations. Otherwise, among the media there is absolutely no knowledge about drug promotion legal requirements or provisions.

In this study, it has been observed that on average for all the key functions, Malawi appears to exhibit a level of vulnerability of around **3.36** on the 01.00 to 10.00 rating scale. This means that the pharmaceutical sector in Malawi is very vulnerable to corruption, mainly because of the impact of a number of lapses in the good governance for medicines mechanisms in the sector. The legislation or acts are public documents, which should be publicly available. However, this study has shown that access to these documents is limited by the fact that they are not disseminated widely and, where they are available for public consumption, they are being sold to stakeholders. As such, drug promotion is one of the most neglected in the pharmaceutical sector in Malawi, followed by drug selection, procurement, and drug registration, all of which are very vulnerable. Only drug inspection is moderately vulnerable in the sector.

The final rating of 2.62 for the registration function shows that registration activities in Malawi are very vulnerable to corruption and unethical practices. Issues of absence of guidelines on where registration officers meet with applicants and issues around the need to declare COI contributed to lowering the rating heavily. Many of the procedures in the registration process are not written, which and therefore lead to lack of transparency in these procedures.

The act providing for control over promotion of medicinal products and advertising is enforced through the Minister making appropriate regulations, but it has no provision covering pre-approval and advertising of medicinal materials or products. There is no provision for formal complaints procedures, through which to report unethical promotional practices. The Medicines Committee exists, but is very inactive in respect to control over drug promotion. Most of the respondents answered through guess work and their responses were not validated by knowledge of facts or evidence. This is why only 41% of KIs gave valid responses with evidence. The final rating of 1.3875 on a rating scale of 01.00 to 10.00 is evidence that even among the stakeholders who were expected to be knowledgeable and directly involved in proper drug promotion, there is very little awareness or knowledge of what is needed to properly conduct drug promotional services. Drug promotion was therefore seen as extremely vulnerable, requiring urgent attention by Government and other stakeholders. .

Inspection activities for medicinal products in Malawi are moderately vulnerable to corruption at 4.34. Most procedures and guidelines are in place, but the absence of guidelines on conflict of interest is adversely affecting the transparency of inspection activities. The use of part-time inspectors is also undermining the transparency of these activities. The Pharmacy Act has adequate provisions for the inspection function, but the regulations should be amended to cover some of the gaps identified through this assessment. However, in comparison to other functional areas, it received the highest rating – most likely because most of the respondents selected have been exposed to an inspection by the PMPB.

For drug selection, a rating of 1.59 falls in the bracket 00.00 – 2.00, indicates that, as in drug promotion, it is extremely vulnerable to corrupt practices and therefore susceptible to unethical behaviour. This also means it is exposed to extremely nontransparent tendencies. Being extremely vulnerable, drug selection is open to unethical practices, which are exacerbated by issues having to do with the nonexistence of the selection committee and the fact that the EML has not been revised in more than eight years.

There is hardly any adequate transparency in the procurement function in Malawi, and as such it is very vulnerable to corruption, with a rating of 3.2 on the 10-point rating scale. The procurement laws are comprehensive enough although general in nature, but they are not easily accessible. The reinforcement mechanisms for the act and regulations to ensure compliance are inadequate. Government itself lacks the printing capacity to satisfy stakeholder demands for the act and its accompanying regulations, which have to be purchased from the Government printer. This renders their accessibility limited and dependent on individual initiatives and wishes.

References

1. IBRD Loans and IDA Credits, World Bank Guidelines-Technical Note, World Bank, May 2004.
2. Malawi Government, Pre-registration Training Programme, PMP&B.
3. Malawi Government, Pharmacy, Medicines and Poisons Act, PMP&B, No. 15 of 1988.
4. Malawi Government, Pharmacy, Medicines and Poisons Regulations, PMP&B, No. 40A of 1988.
5. Malawi Government, National drug Policy, MoH, July 1991.
6. Malawi Government, Public Procurement Act, ODPP, No. 8 of 2003.
7. Malawi Government, Public Procurement Regulations, ODPP, 2004.
8. Malawi Government, ODPP, Desk Instructions for Public Procurement.
9. Malawi Government, Procurement Manual, MoH, February 2007.
10. Malawi Government, Drug Leakage Study Report, MoH, 2006.
11. Malawi Government, Assessment of Regulatory Authority Report, MoH.
12. Pharmacy, Medicines and Poisons Board, Guide to GMP Inspector.
13. Pharmacy, Medicines and Poisons Board, A Guide to Registration, Licensing and Scheduling of Medicinal Products in Malawi, PMP&B, August 1999.
14. World Health Organization, Operational Principles for Pharmaceutical Procurement, WHO, 1999.
15. World Health Organization, guidelines for Drug Donations, WHO, 1999.
16. World Health Organization and Health Action International, Drug Promotion, WHO, 2005.

Annexes

Annex I: Questionnaires

SECTION I: DRUG REGISTRATION

I.1 Is there an up-to-date list of all registered pharmaceutical products available in the country? DK = Do not know

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 (brand name & INN), dosage form, strength, primary packaging, any identifying mark	0	1	
2. Name of manufacturer	0	1	
3. Country of manufacture	0	1	
4. Site of manufacture	0	1	
5. Date of registration	0	1	
6. Validity of registration	0	1	
7. Conditions for registration	0	1	
8. Prescription only or OTC	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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 recipients	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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?

	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. Require research experience in the area of expertise	0	1	
7. Specify organization to be considered when selecting members	0	1	
8. Give a timeframe to serve as a committee member	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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?

	No	Yes	D.K.
1. Describe clearly the mandate of the committee	0	1	
2. Available publicly and in writing	0	1	
3. Describe the number of meetings it should convene	0	1	
4. Describe procedures for decision-making	0	1	
5. Include clear time limits for decision-making process for the committee	0	1	
6. Describe the reporting structure	0	1	
7. 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 drug 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 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.**
- I.16 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 in terms of:**
- a. The quality of services offered by public institutions
 - b. Transparency in the services offered by public institutions

SECTION II: DRUG PROMOTION CONTROL

II.1 Is there a provision in the medicines legislation/regulations covering drug promotion and advertising?

No	Yes	D.K.
0	1	

II.2 Do the provisions on drug promotion and advertising include explicit mention of the following areas?

	No	Yes	D.K.
1. Advertisement to professionals	0	1	
2. Advertisement to the public	0	1	
3. Qualification and training of medical representatives	0	1	
4. Restrictions on and monitoring of free samples	0	1	
5. Symposia and scientific meetings	0	1	
6. Post-marketing scientific studies	0	1	
7. Speakers' fees and consultancies	0	1	
8. Packaging, labelling and package inserts	0	1	
9. Promotion of exported drugs	0	1	
10. Restrictions and limits on gifts and gimmicks	0	1	
Total			

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

II.3 Is pre-approval of promotional and advertising materials officially required? - should contain as a minimum the information listed below?

	No	Yes	D.K.
1. Pre-approval of materials required?	0	1	
2. Name of active ingredient (INN or generic name)	0	1	
3. Brand name			
4. Major indication(s) for use	0	1	
5. Adverse effects	0	1	
6. Contraindications	0	1	
7. Drug interactions	0	1	
8. Cost	0	1	
Total			

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

II.4 Do the provisions foresee an enforcement mechanism on promotion and advertisement of medicines, stating the sanctions in cases of violation?

No	Yes	D.K.
0	1	

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

II.5 Is there a formal complaints procedure to report unethical promotional practices?

	No	Yes	D.K.
1. Written procedures for placing complaints	0	1	
2. Procedures publicly available	0	1	
3. Evidence that complaints procedure is used	0	1	
4. Results of complaints are published	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

II.6 Is there a service or committee responsible for monitoring and enforcing the provisions on drug promotion?

	No	Yes	D.K.
1. Service or committee formally established	0	1	
2. Terms of reference publicly available	0	1	
3. Composed of professionals with technical skills	0	1	
4. Meets regularly	0	1	
5. Decisions of meetings publicly available	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

II.7 Are there written and publicly available Standard Operating Procedures (SOPs) guiding the services responsible for pre-approving or monitoring drug promotion and advertising?

	No	Yes	D.K.
1. SOPs are written and publicly available	0	1	
2. A standard form or checklist (for pre-approval or monitoring) exists	0	1	
3. Standard form checks that information complies with information approved for drug registration	0	1	
Total			

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

II.8 Are there written guidelines on conflicts of interest (COI) with regard to control of medicine promotion activities?

	No	Yes	D.K.
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for members of 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)	

II.9 To what extent do you agree with the following statement: "The legal provisions on drug promotion have been developed in broad consultation with all interested parties"?

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

II.10 To what extent do you agree with the following statement: "Civil society/nongovernmental organizations have a great influence on improving the control of drug promotion in your country"?

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

II.11 To what extent do you agree with the following statement: "The provisions on drug promotion are well respected in your country"?

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

II.12 In your opinion, what types of unethical behaviour are common in the drug promotion area in your country? These can include bribery, material gifts, favouritism (family, friends), conflict of interest (e.g. investments in pharmaceutical companies), etc.

- a. Involving health professionals and health institutions in general
- b. Involving regulatory office staff and committee members responsible for controlling drug promotion

II.13 If you were in a position of highest authority, what would be the first action that you would take to improve the drug promotion process in your country in terms of:

- a. The quality of services offered by public institutions
- b. Transparency in the services offered by public institutions

SECTION III: INSPECTIONS

III.1 Is there a provision in the medicines legislation/regulation covering inspection of medicines manufacturers and distributors?

No	Yes	D.K.
0	1	

III.2 Is the provision comprehensive enough?

	No	Yes	D.K.
1. Provides power to inspectors to enter at any reasonable time any place where medicinal products are produced, packaged, stored, distributed or tested	0	1	
2. Defines the inspector's duties and responsibilities	0	1	
3. Provides special identification document to the inspectors	0	1	
4. Provision is available to companies being inspected	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

III.3 Are there written guidelines on classification of Good Manufacturing Practices (GMP) or Good Distribution Practices (GDP) non-compliance that describe the types of deficiencies and the corresponding measures to be taken by the Medicine Regulatory Authority (MRA)?

	No	Yes	D.K.
1. Guidelines available in writing	0	1	
2. Guidelines provide classification of GMP/GDP deficiencies	0	1	
3. Define corresponding measures to be taken in case of non-compliance	0	1	
4. Guidelines easily accessible to all stakeholders	0	1	
5. Provide appeals mechanism for companies	0	1	
6. Appeals system independent of the body making the original decision	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

III.4 Are there written procedures/mechanisms to prevent regulatory capture between inspectors and the manufacturers or distributors that he/she inspects?

	No	Yes	D.K.
1. Procedures available in writing	0	1	
2. Require rotation of inspectors based on a scheduling system	0	1	
3. Require inspectors to visit sites in teams with a team leader	0	1	
4. Require inspectors to inspect under the observation of another inspector who will report on what he/she has observed (peer review)	0	1	
5. Rotation mechanism requires inspectors from one geographical area to inspect companies in other areas	0	1	
6. Require external audit of the inspections (from another country)	0	1	
Total			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

III.5 Are there written guidelines on conflict of interest (COI) with regard to inspection activities?

	No	Yes	D.K.
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for inspectors 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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

III.6 Are inspection findings and conclusions subject to an internal review?

No	Yes	D.K.
0	1	

III.7 Are there written standard operating procedures (SOPs) for inspectors on how to conduct inspections?

	No	Yes	D.K.
1. An inspection checklist/aide-mémoire	0	1	
2. Procedures detailing requirements for pre-inspection activities	0	1	
3. Procedures detailing requirements for post-inspection activities	0	1	
4. Scheduling system identifying companies due for inspections within a set time frame	0	1	
5. Format and content of inspection reports	0	1	
Total			

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

III.8 Are there written criteria for the selection and recruitment of inspectors?

If yes do they include the following?

	No	Yes	D.K.
1. Available in writing and publicly	0	1	
2. Qualification required (pharmacist, chemist, etc)	0	1	
3. Minimum years of work experience in the area	0	1	
4. Recommendation from (past work place, association)	0	1	
Total			

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

III.9 To what extent do you agree with the following statement: "The integrity of inspectors is not at all influenced by personal gains, such as bribes, gifts, material or other benefits, etc."?

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

III.10 In your opinion, what types of unethical behaviour are common in the inspection area in your country? These can include bribery, material gifts, favouritism (family, friends), conflict of interest (e.g. investments in pharmaceutical companies), etc.

III.11 If you were in a position of highest authority, what would be the first action that you would take to improve the inspection process in your country in terms of:

- a. The quality of inspection services offered by public institutions
- b. Transparency in the inspection services offered by public institutions

SECTION IV: DRUG SELECTION

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

No	Yes	D.K.
0	1	

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"?

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

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

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

IV.4 Is the EML in line with WHO procedures?

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

No	Yes	D.K.
0	1	

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"?

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

IV.7 Are there clear criteria for the selection of members of the selection committee?

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

IV.9 Are there clear and publicly available Standard Operating Procedures (SOPs) that describe the role and responsibilities of the selection committee?

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

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

IV.10 Are the rules for decision-making in the SOPs clear and transparent?

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring (total yes/total valid answers)</i>	

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

IV.12 If you were in a position of highest authority, what would be the first action that you would take to improve drug selection in terms of:

- a. The quality of the services offered by public institutions
- b. Transparency in the services offered by the public institutions

SECTION V: PROCUREMENT OF PHARMACEUTICALS

V.1 Does the government use transparent and explicit procedures for procurement of pharmaceutical products?

	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 made by the Tender Committee	0	1	
9. Require that information on tender process and results are made public (to the extent permitted by law)	0	1	
Total			

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

V.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	

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

No	Yes	D.K.
0	1	

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

No	Yes	D.K.
0	1	

V.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)	

V.6 Are there specific criteria for Tender Committee membership?

	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 client 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)	

V.7 Are there written guidelines on conflicts of interest (COI) with regard to the procurement process?

	No	Yes	D.K.
1. Guidelines on COI exist in writing	0	1	
2. Form for declaration of COI for members of Tender 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. Includes 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)	

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 (see question V.6)"?

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

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

	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)	

V.10 Are there Standard Operating Procedures (SOPs) for routine inspection of consignments?

	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)	

V.11 Is there an efficient post-tender system in place to monitor and report on suppliers' performance to the Tender Committee?

	No	Yes	D.K.
1. Supplier's performance monitored at least annually	0	1	
2. Monitoring system tracks suppliers 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)	

V.12 Does the procurement office undergo regular audits?

	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			

<i>Total yes</i>	
<i>Total valid answers</i>	
<i>Scoring</i> <i>(total yes/total valid answers)</i>	

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"?

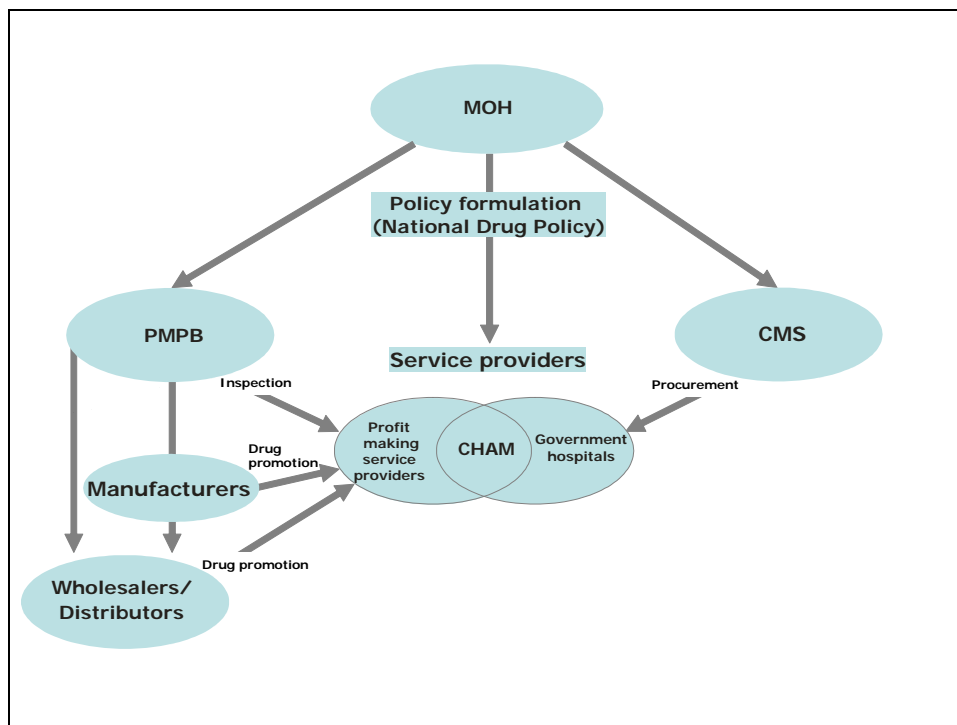
Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.

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

V.15 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 in terms of:

- a. The quality of procurement services
- b. Transparency in procurement services

Annex II: Players in the pharmaceutical sector



Annex III: Stakeholders institutions/ organizations that provided key informants

INSTITUTION	ROLE IN PHARMACEUTICAL SECTOR	NO. OF KEY INFORMANTS
Ministry of Health	Policy formulation	5
	Service provision	6
Pharmacy, Medicines and Poisons Board	Inspection of premises and registration of medicinal products	7
Nurses Council of Malawi	Regulation of Service providers	1
Medical Council of Malawi	Regulation of service providers	1
Central Medical Stores	Procurement	4
Pharmavet	Private whole seller	1
Pharmachemie	Private whole seller	1
Malawi Pharmacies Limited	Manufacturer	1
Pharmanova	Manufacturer	2
Pharmaceutical Society of Malawi	Upholds ethics of pharmacy staff	1
Maula Retail pharmacy	Service provision	
UNICEF	Procurement	1
CHAM Secretariat	Coordination of service providers	2
ODPP	Policy formulation for public procurement	2
Anti corruption Bureau	Promotion of good governance in public sector and investigation of suspected corruption	2
Malawi Revenue Authority	Inspection of goods at all entry points	3
Ministry of Trade	Policy formulation for business operations	1
Ministry of Finance	Provision of funds for public procurement of medicines	1
Red Cross Society	Donations of medicines to public health facilities	2
World Vision International	Donations of medicines to public health facilities	2
Parliamentary Committee on Health	Advocates for health issues in parliament	1
Medical Buying Board	Awards tenders for procurement of medical products	1
SSH Clinic	Service provision	1
St Luke Mission Hospital	Service provision	1
SADM	Manufacturer and whole seller	2
Mwaiwathu Private Hospital	Service provision	2
Michiru Pharmacies Ltd	Service provision	2
Malawi Broadcasting Cooperation	Promotion	1
Television Malawi	“	1
Medical Council of Malawi	Regulation of service providers	1
Central Medical Stores	Procurement	2
Pharmavet	Private whole seller	1
Pharmachemie	Private whole seller	1
Malawi Pharmacies Limited	Manufacturer	1
Pharmanova	Manufacturer	2

Annex IV: Score sheets for functions

Table 1: KI Responses to registration

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	Total	Average per Question
Profession	G	G	G	G	G	G	G	G	G	G		
Indicator I. 1	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 2	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 3	0.9	1	.5	1	0	0.7	1	0	1	0.86	6.96	0.696
Indicator I. 4	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 5	0.75	0.8	.71	1	0	1	0	0	1	1	6.26	0.63
Indicator I. 6	0	0	-	0	-	0	0	0	0	0	0	0
Indicator I. 7	1	1	1	1	-	1	1	1	1	1	9	0.9
Indicator I. 8	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 9	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 10	0	0	0	0	0	0	0	0	0	0	0	0
Indicator I. 11												
Indicator I. 12	0.57	0.29	.57	.83	0	0.4	0	0	0	0.57	3.23	0.32
Indicator I. 13	0	1	1	1	1	0	0	0	1	1	6	0.6
Indicator I. 14												
Indicator I. 15												
Indicator I. 16												
											Total	3.146
											Final Score registration	2.62

Table 2: KI Responses to drug promotion

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	Total	Average per Question
Profession	P	M	M	M	M	P	M	NN	P	P	P	G		
Indicator II.1	0	0	0	1.0	0	0	0	0	1.0	0	1.0	1.0	4.0	0.33
Indicator II.2	0	0	0	0.4	0	0	0	0	0.0	0	0.4	0.1	0.9	0.08
Indicator II.3	0	0	0	0.9	0	0	0	0	0.8	0	0.0	0.0	1.7	0.14
Indicator II.4	0	0	0	1.0	0	0	0	1.0	1.0	0	1.0	0.0	4.0	0.33
Indicator II.5	0	0	0	0.7	0	0	0	0.2	0.0	0	0.0	0.0	0.9	0.08
Indicator II.6	0	0	0	0.0	0	0	0	0.8	0.6	0	0.8	0.0	2.2	0.18
Indicator II.7	0	0	0	1.0	0	0	0	0	0.0	0	0.0	0.0	1.0	0.08
Indicator II.8	0	0	0	0.5	0	0	0	0	0.0	0	0.0	0.0	0.0	0.05
													Total	1.10
													Final score for drug promotion	1.375

Table 3: KI Responses to drug inspection

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	Total	Average per Q.
Profession	P	G	G	P	N	G	P	G	G	G		
Indicator III. 1	1	1	1	1	1	1	1	1	1	1	10	1
Indicator III. 2	1	1	1	0.5	1	1	1	1	1	0.75	9.25	0.93
Indicator III. 3	0	0	0	0	0	0	0	0	0	0	0	0
Indicator III. 4	0	0	0	0	0	0	0	0	0	0	0	0
Indicator III. 5	0	0	0	0	0	0	0	0	0	0	0	0
Indicator III. 6	1	1	0	0	1	-	1	1	1	1	7	0.78
Indicator III. 7	1	1	0.8	0.8	0.6	1	0	0.4	1	1	7.6	0.76
Indicator III. 8	0	0	0	0	0	1	0	1	0	0	0	0
Indicator III. 9												
Indicator III. 10												
Indicator III. 11												
											Total	3.47
											Final Score inspections	4.34

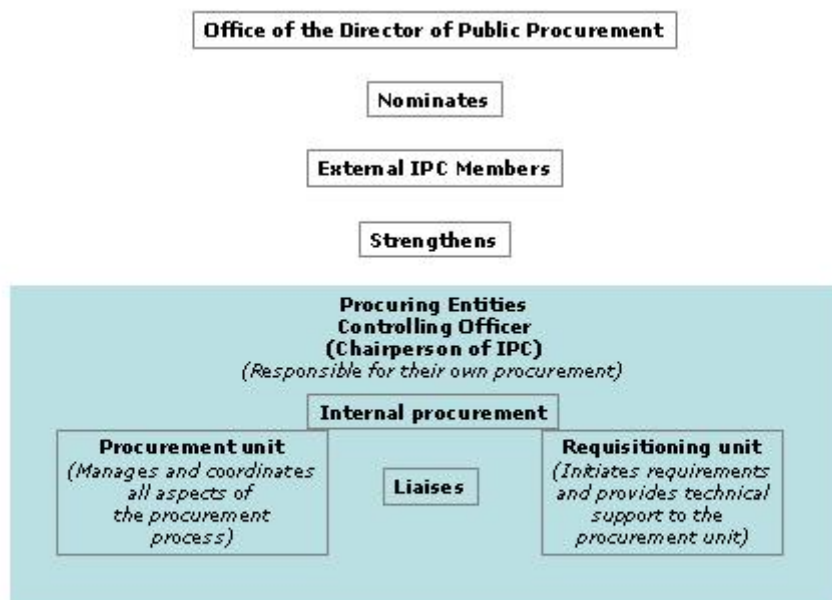
Table 4: KI Responses to selection

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question
Profession	G	P	G	G	G	G	N	N	N	N	N	P	P	G	P		
Indicator IV.1	0	0	0	0	1	1	1	1	1	1	1	0	0	1	1	9	0.6
Indicator IV.2																	
Indicator IV.3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indicator IV.4	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Indicator IV.5	1	0	0	0	1	1	0	1	1	1	1	1	1	0	1	10	0.67
Indicator IV.6																	
Indicator IV.7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indicator IV.8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indicator IV.9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indicator IV.10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Indicator IV.11																	
Indicator IV.12																	
																Total	1.27
																Final Score Selection	1.59

Table 4: KI Responses to procurement

	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	KI 16	KI 17	KI 18	KI 19	KI 20	KI 21	Total	AV. per quest.
Profession*	G	G	G	G	G	G	G	G	P	IO	N	N	N	N	P	P	G	G	G	G	G		
Indicat- V.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	1.0	0.1
Indicat- V.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	1.0	0.1
Indicat-V.3	0.0	1.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0	0.0	1.0	1.0	1.0	12.0	0.6
Indicat- V.4	0.0	1.0	1.0	0.0	1.0	1.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	0.0	0.0	1.0	1.0	0.0	1.0	13.0	0.6
Indicat- V.5	0.0	1.0	0.0	0.7	1.0	1.0	1.0	1.0	0.0	0.0	1.0	1.0	1.0	1.0	0.0	0.0	1.0	1.0	1.0	0.0	1.0	13.7	0.7
Indicat- V.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	0.0	0.0	0.7	0.0
Indicat-V.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.0	0.6	0.0
Indicat- V.8																							
Indicat - V.9	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	3.2	0.2
Indicat-V.10	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.1
Indicat- V.11	0.0	0.0	0.0	0.8	1.0	0.0	1.0	1.0	0.0	0.2	0.0	1.0	0.8	0.0	0.5	0.0	0.0	0.0	0.2	0.0	0.8	7.3	0.4
Indicat- V.12	0.0	0.0	0.0	0.0	1.0	0.9	0.9	0.6	0.0	0.0	0.0	0.9	0.9	0.9	0.6	0.0	0.4	0.0	0.8	0.6	0.8	9.3	0.4
																						Total	3.2
																						Final score	3.0

Annex V: Organizational chart/framework for procurement in public sector



Source: ODPP, *Desk Instructions for Public Procurement* page 4