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

# SYRIAN ARAB REPUBLIC

World Health Organization
Regional Office for the Eastern Mediterranean

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**WHO Library Cataloguing in Publication Data**

Measuring transparency to improve good governance in the public pharmaceutical sector: Syrian Arab Republic / World Health Organization. Regional Office for the Eastern Mediterranean

p.

ISBN: 978-92-9021-652-0

ISBN: 978-92-9021-681-0 Online

1. Pharmaceutical Services - organization and administration - Syria 2. Public Sector - Syria 3. Drug Approval 4. Drug Evaluation I. Title II. Regional Office for the Eastern Mediterranean

(NLM Classification: QV 737)



Printed by WHO Regional Office for the Eastern Mediterranean Region

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# Foreword

Over the last few decades the entire world has made great progress and achieved tremendous accomplishments in the field of science and technology. This has had massive impact on the growth of the pharmaceutical sector. However, in spite of this growth, there are still huge segments of the world suffering from the poor delivery of good medicines. Although in many cases this is due to poverty, wars or the accelerating growth of the population, it is a fact that the prevalence of corruption in the pharmaceutical sector hinders the efficiency of medicines regulation and supply.

In recognition of this fact, and in light of the detrimental effects that corruption in the pharmaceutical sector can have on the health of the population, the Syrian government considers the pharmaceutical sector as a crucial part of the health system and is fully committed to continuously assessing and identifying areas for improvement in its structure and function. Based on this, the Ministry of Health, in collaboration with the World Health Organization conducted this transparency study using a standard tool developed by WHO, "Measuring transparency to improve good governance in the public pharmaceutical sector", in July 2008. The aim was to provide a comprehensive picture of the level of transparency and vulnerability to corruption in eight essential functions of the public pharmaceutical system, i.e. registration, licensing, promotion, inspection, clinical trials, selection, procurement and distribution of medicines.

The results of this study represent the views of a wide range of knowledgeable professionals who are well aware of the pharmaceutical situation in the Syrian Arab Republic. Acknowledging this, the Ministry of Health has taken the results into serious consideration. In March 2009, two national workshops for disseminating and discussing the results were conducted in Damascus and Aleppo. The stakeholders and ministry of health officials present committed to addressing the gaps identified in this important assessment. This commitment extends beyond improving the specific areas identified in this assessment. Transparency and accountability are important pillars of good governance and it is our firm commitment to institutionalize these concepts in every sphere of medicine policy and management practice.

Our association with the World Health Organization is longstanding and it is also our partner in this important programme. I welcome this new publication and I am confident it will provide an important roadmap for promoting good governance in our pharmaceutical sector so that it can effectively deliver public goods to the public and achieve its other development objectives.

Dr Rida Said
Minister of Health
Syrian Arab Republic

# Preface

The goal of the WHO Good Governance for Medicines programme is to improve the situation of medicines regulation and supply. Guided by the WHO Medicines Strategy and launched in late 2004, the programme is raising awareness of potential abuse in the public pharmaceutical sector and promoting good governance. Its ultimate aim is to ensure that essential medicines reach the people who need them, not the black market.

The World Bank has identified corruption as the single greatest obstacle to economic and social development. As the Good Governance project increases in momentum, more and more public health ministers and national medicines regulatory authorities are taking up the challenge to address it.

The Good Governance for Medicines programme offers a three-step technical support package which involves: national transparency assessment; development of a national framework on good governance for medicines; and implementation of a national programme. The global programme is being successfully implemented in some 30 countries around the world.

This report presents the findings of the first phase of the national Good Governance for Medicines programme in the Syrian Arab Republic. The assessment aims to obtain a picture of the level of transparency and potential vulnerability to corruption in the public pharmaceutical sector using WHO's assessment instrument. In the Syrian Arab Republic, the assessment looked at eight functions: medicines registration, licensing of pharmaceutical establishments, inspection of pharmaceutical establishments, promotion, selection, clinical trials, procurement and distribution.

The national assessment represents a baseline from which to monitor the country's progress over time in terms of transparency. However, by dealing with unethical practices, concepts of transparency and accountability, the assessment raises sensitive issues and it is imperative that it should be conducted in a constructive manner. The goal of the project is not to measure corruption but to examine how resistant or vulnerable the system is towards unethical practices.

The assessment is an entry point for the development and promotion of a national programme on good governance for medicines and should not be seen as an end in itself. It is the beginning of a process aimed at bringing about desirable and sustainable changes in the governance of the pharmaceutical sector. This exciting challenge has already been accepted by an increasing number of countries.

Assessment findings will help a country to identify vulnerable aspects that could lead to corruption and unethical practices. They will also determine what can be done to increase system transparency and accountability with the goal of improving access to medicines for peoples, especially vulnerable and marginalized groups.

# Acknowledgements

This report was prepared by Professor Amer Al-Mardini, Vice President of Damascus University and Dr Souheila Al Hakeem, Pharmaceutical Affairs Expert. Rawa Akasha and Aalae Alkhalil, Masters students at the Faculty of Pharmacy were coassessors for the study and they assisted in collecting and analysing the data. The views in this document were collected through interviews with a wide range of key informants whose experience and knowledge within the pharmaceutical sector in the Syrian Arab Republic provided the basis for this assessment and its recommendations. WHO acknowledges the input of all contributors with thanks.

WHO also acknowledges with appreciation the support of H.E. Dr Maher Al-Housami, the Minister of Health and H.E. Dr Maysoon Nasry, Deputy Minister of Health for Pharmaceutical affairs. HE Dr Reda Said was appointed as Minister of Health after conclusion of this study and is supporting the continuation of the good governance for medicines efforts. Dr Habib Abboud, Director of Ministry of Health Quality Control Laboratories and Dr Hend Elsebaii, Director of Pharmaceutical Affairs were WHO's government counterparts for the study. The commitment and sincere efforts of the Ministry to improve access to medicines in the Syrian Arab Republic is indispensable to the initiation and continuation of efforts to curb corruption and increase transparency and accountability in the regulation and supply of medicines. The Ministry of Health provided information and support during the assessment process.

WHO is grateful to the Federal Ministry for Economic Cooperation and Development (BMZ), Germany for its generous contribution to this work. The studies would not have been possible without this source of financial support.

Guitelle Baghdadi-Sabeti and Fatima Serhan, of WHO headquarters, Zafar Mirza and Mohamed Ramzy, of WHO Regional Office for the Eastern Mediterranean, provided support to initiate the Good Governance for Medicines programme in the Syrian Arab Republic and provided technical support throughout the assessment process.

# Executive summary

This report presents the results of transparency assessments carried out in the Syrian Arab Republic. It gives a comprehensive assessment of the level of transparency and the level of vulnerability to corruption within the eight primary functions of the pharmaceutical sector – registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution of medicines. The results were validated through consultation with a wide range of stakeholders at two national workshops held in Damascus and Aleppo in March 2009.

The methodology provides both qualitative and quantitative information. Two national investigators selected by the Ministry of Health carefully chose 70 key informants from various sectors and backgrounds relating to pharmaceuticals, according to WHO recommendations. They conducted a series of interviews with the key informants and in some cases conducted more than one interview with each key informant due to the fact that many key informants were experienced and well informed in different aspects of pharmaceutical affairs. In fact, managers and personnel are involved in numerous tasks and participate in more than one function of the sector. As a result they possess deep insight and understanding of many functions in the pharmaceutical sector. In total the national assessors conducted 118 interviews.

The information collected was then converted using a rough quantification method into a zero to 10 scale, to provide a score for each function in terms of vulnerability to corruption (minimal to extreme). The scoring indicates vulnerability in terms of the policy, the regulatory and administrative structures and the procedures at the time of the survey.

The quantitative data show that the areas of medicine licensing, procurement and distribution received the highest scores and are marginally vulnerable to corruption; medicines registration, inspection, selection and promotion are moderately vulnerable to corruption; while the clinical trials function had the lowest score and is very vulnerable to corruption.

It was also shown that although there is a great deal of legislation and many regulatory decrees in existence relating to the pharmaceutical sector many of the key informants are not well acquainted with them and many lack the interest to investigate them. The emphasis is placed on gaining the appropriate medicines at reasonable prices. Therefore, one of the main challenges facing the Ministry of Health is not that its staff are corrupt but rather that they lack the understanding of the transparency concept. A lack of awareness of the importance of transparency can often provide a basis for corrupt practices to take place.

The study also showed that the Ministry of Health has its own unique system for dealing with medicines but that many of the regulatory decrees and much of the legislation relating to the pharmaceutical sector are not up-to-date and some guidelines are not stringently applied. Other important observations were that there are some weaknesses in the publishing and advertising of items related to the pharmaceutical sector; there are no standard operating procedures for some functions; and there are no good practice guidelines for some pharmaceutical functions and the existing ones are not regularly updated. The public are poorly informed of medical laws and processes, due to ineffective advertising and lack of accessibility to information. There are also no job descriptions, or requirements for the declaration of conflicts of interest, either for employees or committee members and although there are written documents describing committees' composition and terms of reference there are no written criteria for the selection of members or documentation on their individual roles and responsibilities. It was discovered that there is a lack of highly qualified pharmacists and technicians working in the public sector because of the low wages offered in comparison to the private sector. The results show that there are apparent weaknesses in communication between medical officers and applicants and that there is no formal appeals process in place. In addition, appeals that are made are not dealt with independently.

In summary, the diagnostic framework and methodology that this study introduces aims to provide health specialists and government decision-makers with the necessary information to prioritize those areas in the pharmaceutical system that need the highest investment and regulation. In turn, this will help to ensure that investments in the pharmaceutical system are maximized and that access to essential medicines is improved.

# 1. Introduction

Access to medicines continues to be one of the biggest challenges for the Syrian Arab Republic. With total government health expenditure on medicines of around 45% in 2006, the pharmaceuticals sector is an attractive target for corruption.

Corruption manifests itself in different ways and works at different levels. For example, corrupt behaviour can emanate from information imbalances between the various stakeholders such as manufacturers, regulators, health care providers and consumers. When information is not shared equally and not all players have access to necessary information in order to be able to make independent assessments of medicines, or else processes are not clearly defined; vulnerability of the pharmaceutical sector to corruption increases. Corruption can have a significant impact on public health, the national economy and the credibility of institutions within public health sector.

The World Health Organization (WHO) initiated the Good Governance for Medicines programme in an attempt to curb corruption in this sector. The Syrian government agreed to participate in the programme because it believes in the necessity of increasing transparency and accountability and promoting ethical practices.

Corrupt practices in this sector can have a threefold impact. First, they can have a health impact; the government's capacity to provide good quality essential medicines is reduced due to the wastage of public resources and this causes the influx of unsafe and ineffective medical products onto the market. Such low quality medicines will affect patients negatively. Second, corruption can have an economic impact; the Ministry of Health allocates around 50% of its budget to medicines, so any loss in this expenditure affects the whole financial balance of the Ministry. Finally, corrupt practices affect the government's image and credibility. Board members and management teams in public and private health organizations occupy positions of trust. Any lack of transparency could cause the public to doubt the ethical conduct of such institutions, in turn reflecting on the credibility of the Ministry of Health. This could potentially impede useful relations between international donor agencies (such as the European Union, European Investment Bank, WHO, UNICEF, Aga Khan Foundation) and the government.

The Good Governance for Medicines programme is divided into three phases. In phase I the national assessment of transparency and potential vulnerability to corruption is carried out using the WHO standardized assessment instrument which focuses on the eight central functions of the pharmaceutical sector, namely: registration of medicines, licensing of pharmaceutical establishments, inspection of

establishments, medicine promotion, clinical trials, selection of essential medicines, procurement of medicines and distribution of medicines.

Phase II launches the development of a national programme on Good Governance for Medicines. This involves a wide consultation process encompassing the basic components of the programme, including regulations and administrative procedures, collaboration mechanisms with other good governance, anti-corruption initiatives including sanctions for irresponsible behaviour.

Phase III involves the implementation of the National Good Governance for Medicines programme. In order to achieve the goal of greater transparency/accountability in the pharmaceutical sector, WHO recommends that organizations focus on concerned stakeholders, and that stakeholders develop a common understanding of transparency and leadership capabilities. These aims can be accomplished by conducting fully integrated institutional courses for training on the new administrative procedures of Good Governance for Medicines.

The Syrian Arab Republic has embarked on phase II of the programme. The aim of the Ministry of Health in implementing the WHO three-phase approach is to curb corruption in the pharmaceutical sector by applying transparent and administrative procedures and promoting ethical practices among health professionals. Transparency is seen as an essential lever for the promotion of accountability. In order to increase stakeholder engagement in the process, the Ministry of Health will: increase the awareness of all stakeholders of the potential for corruption in the pharmaceutical sector and its detrimental impact on health systems; promote the development of procedures to minimize the possibility of unethical behaviour and remove the gaps in the system that can lead to corruption; and reinforce national capacity for governance in medicines, reliable health care and supplying systems. This report summarizes the major findings of the transparency assessment of the pharmaceutical sector. The aim of the study was to assess the vulnerability to corruption of the eight decision points in the pharmaceutical sector, namely: medicines registration, licensing of pharmaceutical establishments, inspection of pharmaceutical establishments, promotion, selection, clinical trials, procurement and distribution.

# 2. Overview of the pharmaceutical sector

## 2.1 Health care services

The Syrian Arab Republic is a middle-income developing country. However, compared to developing countries within the same region, it provides fairly good living conditions. In 2006 the population was 18 717 million and the total land area is 185 180 square kilometres.

The health expenditure per capita rose from US$ 60 in 2003 to US$ 82 in 2006. Formal health care services are generally classified into two categories: public and private. The public health sector comprises the Ministry of Health and its Directorates as well as other government institutions, including the Ministry of Higher Education, Ministry of Defence, Ministry of Interior and the Ministry of Economy. Health directorates in 14 governorates provide hospital care, primary health care, disease prevention and health promotion through their public hospitals and health centres. According to a 2006 survey the Ministry of Health provides hospital care through its 78 hospitals, while the Ministry of Higher Education provides health care in 13 teaching hospitals in Damascus, Aleppo and Leticia.

The Ministry of Health is considered to be the main body concerned with primary health care, especially preventative services. This is carried out through the networks of health centres. Public funds for health care are channelled from the government via the Ministry of Finance to various ministries and public institutions. According to 2006 statistics, the government spent 7.82% of its entire budget on health. The Ministry of Health provides the health sector with about 65.8% of the total government health expenditure, while the Ministry of Higher Education contributes 18.6% of government health spending (Annex 1). The Ministry of Health is therefore the prime contributor of health care delivery services through the majority of hospitals, clinics, dispensaries and health posts. It is estimated that between 60% and 70% of government health expenditure is on hospitals and primary care centres, while the rest is allocated to providing potable water and a healthy living environment for the population.

Another source of public expenditure is Ministry of Health investments. The central health administration spends 30% of its funds on investments and the returns on these investments are deployed throughout the health sector.

The private health care providers (see Annex 2) include private hospitals, clinics and pharmacies. According to a 2002 survey, close to 60% of private health expenditure goes to private physicians and according to the 2003-2004 survey, 55% is spent on medicines in private pharmacies.

Contributions are also made by donors. These include the European Union, European Investment Bank, WHO, UNICEF, Aga Khan Foundation among others. International donors contributed 29 million Euro (1.8 billion Syrian Pounds) to the health sector. All of these were grants in the form of long-term loans provided by the European Investment Bank.

Total health expenditure (see Annex 3) comprises government health expenditure, government investments, private health expenditure, and donor's health expenditure.

## 2.2 Background to the pharmaceutical sector

The National Medicines Policy of 2007 provides a framework for the pharmaceutical sector in the Syrian Arab Republic. It specifies those high authorities concerned with medicine affairs as follows:

- The higher committee for medicine affairs is named the Drug Technical Committee and is headed by the Minister of Health.
- The Deputy Minister for Pharmacy Affairs and Medicines supervises the Directorate of Pharmaceutical Affairs, the Directorate of Medicine Affairs, the Directorate of Drug Quality Control and the Directorate of Drug Quality Control and Laboratory Research
- The Deputy Minister for Pharmacy Affairs and Medicines is responsible for all administrative and executive applications to the Minister of Health as well as Drug Technical Committee decisions.

The organizational structure of the pharmaceutical sector is as depicted in Annex 4. The framework of the national medicines policy aims to:

- Adapt the national essential medicines list (NEML) to represent consensus on the essential medicines for meeting the requirements of high quality care.
- Ensure that patients receive the treatment of choice.
- Provide guidance for the local manufacture of pharmaceuticals and the importation of pharmaceuticals from international providers.
- Provide continual support for the local production of pharmaceutical products until such a time that self-sufficiency is reached.
- Increase export volume and lower importation by only allowing the importation of what is not available on the national pharmaceutical market.
- Encourage the rational use of medicines in manufacturing and prescribing, to protect the population from the misuse of medicines.

- Provide safe, effective and affordable medicines of the required high quality at a reasonable price.
- Ensure all medicines are equally dispensed and sufficiently supplied to all citizens.

The principle duties of the four directorates covered by the national medicines policy are to:

- Issue legislative decrees and regulatory decisions that comply with the latest scientific and economic developments in medicines by the Drug Technical Committee which is the control authority concerned with medicines affairs.
- Select the EML, licensing pharmaceutical establishments and registering pharmaceutical preparations, pricing of medicines, medicine supply, storage and distribution.
- Set a precise national system to ensure the high quality of medicines by setting specifications and criteria for good practices, conducting regular inspections and clinical control.
- Increase the awareness of the population with regard to medicines, using medical publications, training and directive guidelines and by controlling the medicine promotion process according to the principle of rational use of medicines.
- Conduct medicinal research.
- Study economic policies of medicines.
- Support human resource and technical cooperation with other countries.
- Evaluate and monitor the application of all regulations and requirements.

## 2.3 The pharmaceutical sector

The government provides virtually free or inexpensive medical care to its citizens. In most cases services at governmental clinics and health centres are free to all citizens. It also imposes a ceiling on charges by private hospitals. The public health programme is administered by the Ministry of Health and is augmented by programmes arranged by other related ministries.

The government policy seems to encourage local manufacturers or suppliers to provide good medicines to the government. It reinforces investment in the medicine industrial sectors to increase coverage of local needs and encourages production of medications not locally made. According to a survey performed in 2007, the number of local manufacturing industries was 60 with 5709 pharmaceutical preparations exported to 43 countries. Some of pharmaceutical preparations from 44 Syrian pharmaceutical industries are manufactured under license from foreign companies.

A closer look at the medicine market reveals that 90% of medicine consumption is locally manufactured medicine while 10% is from imported medicines.

## 2.4 Challenges facing the sector

The growth in the population presents a key challenge for the country's economic development which will result in added pressure on the labour market and lead to a rise in poverty. The current shift to a market oriented economy is considered vitally important and steps towards this are under way. However, this shift could also threaten the general well-being of the population, considering its often high associated social costs. This situation has made the modernization of public welfare structures and the upgrading of social legislation a necessity

Within the pharmaceutical sector there are some specific obstacles. They are related to procedures and laws that are not made publicly accessible and are not always accepted or adhered to, and to the fact that there is also no mandatory declaration of conflict of interest for most governmental employees.

The main challenges can be summarized as follows:

- growing needs and the increasing demand on health services;
- increased gap between the revenue and health services cost;
- health sector's structural and functional weakness;
- absence of mechanisms for the declaration of conflict of interest and lack of guidelines in this regard in the pharmaceutical sector.

# 3. Methodology

## 3.1 Prior to assessment

The Deputy Minister for Pharmacy Affairs and Medicines issued a clearance letter, officially approving the assessment exercise and circulated to all directorates and relevant institutions. This official letter was an essential step that facilitated the launch of the interview process and provided support and encouragement to the national assessors during the process.

## 3.2 National assessors

Two national assessors were selected by the Ministry of Health and according to WHO recommendations. National assessors were selected from different institutions and from two different professional backgrounds. One was selected from the Ministry of Higher Education and Damascus University and the other from a nongovernmental organization, and was formerly employed by the Ministry of Health.

Certain steps needed to be taken before embarking on the first phase of the Good Governance for Medicines programme. They included:

- Studying WHO's transparency assessment instrument and the government website.
- Checking the availability of decrees, regulatory decisions, laws, statistics, health reports and various guidelines related to the pharmaceutical sector by contacting some individuals who provided insight and access to this evidence.
- Making preliminary visits to governmental and private pharmaceutical offices and centres to prepare for this programme.
- Making an organizational chart of the structure of the pharmaceutical sector of the Ministry of Health (Annex 4) and selecting key informants from this sector.
- Studying the health system in order to identify and select key informants.

## 3.3 Selection of key informants

In order to gain accurate scores from the questionnaires in all eight functions, it was necessary to choose key informants (KIs) from all areas of the pharmaceutical sector

including those who were involved either directly or indirectly in such functions. Interviews were held with senior and junior professionals from both the public and private sectors, nongovernmental organizations and from the media. The national assessors selected 70 KIs from various backgrounds. Due to the fact that the health sector suffers from a lack of experienced professionals, some KIs were interviewed for more than one function, which reflected more correctly the nature of their positions. Annex 5 illustrates the number of KIs and the distribution of KIs across the pharmaceutical sector.

## 3.4 Data analysis and scoring

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

**Method 1**: Each indicator in this method was formulated to require a binary answer, either yes or no, with no option of a 'don't know' (D.K.) answer. A 'yes' was given a value of 1 and a 'no' was given a value of 0, where a value of 1 represents low vulnerability to corruption and a value of 0 represents high vulnerability to corruption. Where a KI responded with a 'yes' but no evidence was found, a score of 0 was given.

**Method 2**: Questions for this method consisted of sub-questions, each sub-question also had a binary answer of yes or no. Each 'yes' answer was given a score of 1 and each 'no' was given a score of 0. If the KI did not know the answer, there was an option of assigning a 'don't know' (D.K.) answer. The final rating for method 2 indicators was obtained by dividing all yes answers by the total number of valid answers. Answers of D.K were considered invalid and were subtracted from the total number of sub-questions in calculating the score. In this method, each indicator was rated between 1 and 0 and as in method 1: a value of 1 represents low vulnerability to corruption and a rating of 0 represents high vulnerability to corruption. Degree of vulnerability to corruption for each function is measured according to a scale of 1-10 points. These 10 points are divided to 5 categories starting from extremely vulnerable and ending in minimally vulnerable. Table 1 shows the scale for vulnerability to corruption.

**Table 1. The scale for degrees of vulnerability to corruption**

| Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|
| 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 –1.0 |

**Method 3**: Questions in this method were crucial, as they provided deeper insights into the perceptions and understanding of KIs and enabled cross interpretations to be made between this set of questions and related questions in method 1 and 2. The questions began with a statement and KIs were asked to answer whether they strongly disagreed, disagreed, were undecided, agreed, strongly agreed, didn't know (D.K.) or if they felt the statement was not applicable (N.A.) (Table 2).

**Table 2. Possible responses to indicators from Method 3**

| Answers | Strongly disagree | Disagree | Undecided | Agree | Strongly agree | N.A. | D.K. |
|---|---|---|---|---|---|---|---|
| Total | | | | | | | |

We have presented this information by using bar charts showing the range of perceptions of KIs for each indicator.

**Method 4:** Questions in method 4 were open-ended questions and provided an opportunity to gain information in the form of recommendations.

## 3.5 Special considerations and difficulties

Some KIs were interviewed for more than one function due to their experience, qualifications and the nature of their positions Personnel from the governmental sector are involved in many duties and participate in more than one committee so most of them have experience and can provide deep insights across many functions.

While there are rules, decrees and regulatory decisions, many related stakeholders are not aware of them; only those who carry out or are subject to such rules are familiar with them.

# 4. Results

## 4.1 Registration

*Introduction*

Registration of medicinal products in the Syrian Arab Republic is a legal requirement according to article 3 of decree No 489 and article 20 of decree 40[1]. There is a system of administration to ensure that all pharmaceutical products are registered. This system is supervised by the Pharmaceutical Affairs Directorate, of Medicine Studies in cooperation with other committees while registration approval is given by a decision from the Drug Technical Committee, which is the national Medicine Regulatory Authority.

There are requirements and procedures for registering medicines but it is essential to license manufacture sites before registering their medicinal products. The process for registering local medicinal products begins by filling in a form for manufacturing medicine and sending it by email. The form is available on the Ministry of Health website. Once received submitted forms are studied and evaluated according to specific criteria by the Study Committee headed by the Deputy Minister for Pharmacy Affairs and Medicines. Then they are registered in special records at Pharmaceutical Affairs Directorate. A registration file is submitted for medicinal products which is studied by the Application-Sub Committee according to the assessment criteria and priced by the Pricing Committee. The Drug Technical Committee issues initial approval for manufacturing. The manufacturer is then given time to send samples/specimens to Drug Quality Control and Laboratory Research through the Pharmaceutical Affairs Directorate for analysis. The Drug Technical Committee gives registration approval for manufacturing of the first preparation within 1 year depending on the initial approval and the results of analysis. Specimens from the first preparation are sent to the quality control directorates at the Health Directorate for laboratory analyses and stability studies. Finally, the Drug Technical Committee gives permission for releasing and marketing the products upon the satisfactory results of the analyses that ensure safety, efficacy and good quality. The manufacturer then produces a second preparation of the medicine and the concerned quality control directorates make random checks on the following preparations. Annex 6 illustrates the procedure involved in registering local medicines.

[1] Syndicate book for all decrees and regulatory decisions.

**Table 3. Backgrounds of KIs interviewed for registration function**

| Governmental | | Private | | | NGO | Media | Total |
|---|---|---|---|---|---|---|---|
| Ministry of Health | General Foreign Trade Organization | Manufacturer and scientific office | Private store | Scientific advertising office | | | |
| 10 | 1 | 1 | 3 | 2 | 1 | 1 | 19 |

Registering of foreign pharmaceutical products is initiated by submitting a registration form to the General Foreign Trade Organization (GFTO)/Medicine Division with all the required documents, certificates and studies attached. It technically studied by the Directorate of Medicine Studies. The Pharmaceutical Affairs Directorate check the authenticity of certificates of origin. Stability studies of 10 samples are conducted at the laboratory directorate with the consultation of physicians. Clinical studies evaluation is done at the Clinical Control Department. The Drug Technical Committee issues its decision upon the satisfactory results of the analyses and technical information. The applicant is then informed of the decision via the GFTO/Medicine Division. Registration fees are divided into three parts: the first and second parts are paid to the GFTO/Medicine Division while the third portion is given to the Pharmacy Syndicate. Annex 7 illustrates procedure for registering imported medicines.

The objective of registration is to protect patients by ensuring that all circulated medicinal products in the country are safe, efficacious and of good quality. Therefore all medicines must undergo precise procedures for registration. In order to assess the level of transparency and the extent of vulnerability to corruption for the registration function, 19 interviews were conducted. KIs were selected from various sectors and backgrounds (Table 3).

*Comments on each indicator*

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

The Ministry of Health has an official list for all registered medicines and it is updated regularly each year. The Ministry of Health in cooperation with Consulting Scientific Council formulate this list in a book issued under the title of the Syrian Drug Reference. This book/reference includes information about registered pharmaceutical products approved for sale or distribution, such as company name, generic and brand name, pharmaceutical dosage form, approved indication, adverse effects and contradictions. The list of all registered pharmaceutical products is available at Pharmaceutical Affairs Directorate and it contains the same information as was mentioned previously in the Syrian Drug Reference. 89% of the KIs said that there is a list of registered products available at the Ministry of Health.

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

The Ministry of Health has a database of all registered medicines in the country and it provides information on the registration status of medicines on request. The list of pharmaceutical products, provided by the Ministry of Health, contains the following information: company name, generic and brand name, pharmaceutical dosage form, approved indication, adverse effects and contradictions. 81% of KIs stated that this list exists and provides what they describe as the basic level of information about medicines. But it does not provide information about the site of manufacture, date of registration, validity of registration, and conditions for registration

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

There are written procedures for applicants on how to submit an application for the registration of medicinal products and 73% of the KIs were aware of such a procedure. These procedures describe the process to follow in submitting an application, mention the data to be submitted and the criteria for registration but they do not indicate the timeframe for processing or the fees.

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

There are written procedures for assessing/evaluating applications submitted for the registration of medicinal products, available on the Ministry of Health website ,these procedures describe the process to follow in assessing submissions, specify issues to be considered in assessing submission, and provide guidance on report writing. But they do not. mention a time frame for processing. Of the KIs, 63% said that assessing procedures exist, while 23% said that such procedures do not exist and 15% said that they do not know if they exist or not.

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

There is a standard application form publicly available for submission of applications for registration of medicinal products. This form is readily available at Ministry of Health website and requires a description of the product, a brief summary of the method of manufacture, specification of the pharmaceutical ingredients and excipients and a summary of the product characteristics.

92% of the KIs said that there is a standard application form publicly available for submitting applications for registering medicinal products.

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

There are no written guidelines on how and where medicine registration officers meet with applicants. Applications are submitted to the Deputy Minister office and

studied by the Applications Committee and then transferred to the Drug Technical Committee for approval. 10% of KIs said that there are guidelines available at the Ministry of Health, another 10% did not know if such guidelines exist or not and 80% of the KIs believed that no clear guidelines are available.

**Indicator I-7:** Is there a functioning formal committee involved in the assessment of the applications for the registration of pharmaceutical products?

There are many functional and operational committees involved in the registration process. Their members have the responsibility of examining the dossiers according to assessing criteria and making a decision for registration. There was awareness among interviewees of the committees involved in the assessment of applications as 90% of them answered yes and only 10% said that such committees do not exist.

**Indicator I-8:** Are there clear written criteria for selecting the members of the committee?

There are no written criteria for the selection but members should be proficient and must have appropriate professional qualifications and technical skills. 42% of the KIs said that such criteria do not exist, 11% did not know if these criteria exist or not, while 47% said that written criteria for selecting members of the committee do exist in the Ministry of Health.

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

There is an up-to-date internal document that specifies the committee and describes the members' functions and responsibilities but it does not define the accountability of the members, quorum requirement, membership terms/rotation requirements, or the financial benefits given to members. There is also no mention of declaration for conflict of interest for members, such as investment in the pharmaceutical business. 63% of the KIs said that there is a document describing the composition and terms of the committee, 16% had no idea whether this document exists or not and 21% said that such a document is not available.

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

There is no requirement for the declaration of issues of conflict of interest by committee members. All the KIs said that there are no guidelines on conflict of interest issues.

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

36.84% agreed that there is a systematic and objective method used for selecting members of the registration committee based on written criteria specified for this purpose, 26% did not agree with the statement, 10% strongly disagreed, 10.53% were undecided and the rest answered not applicable or that they did not know (Figure 1).

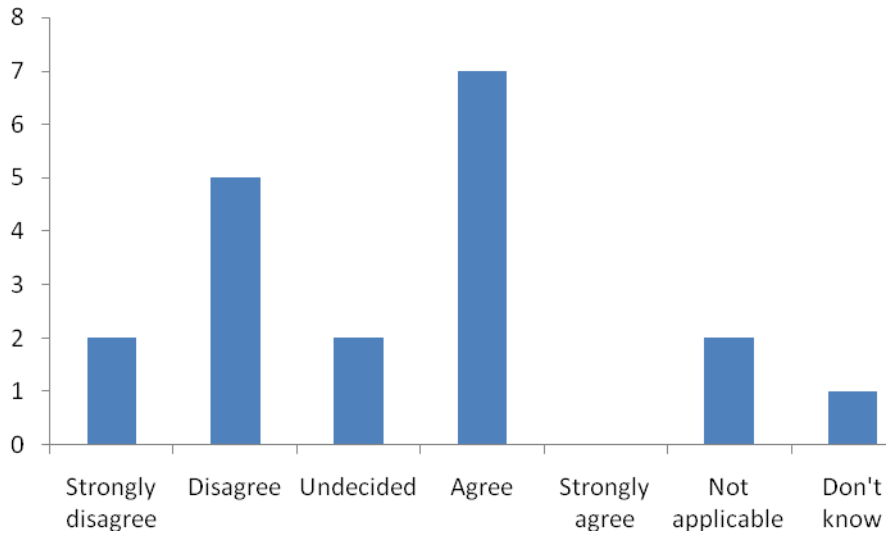



**Figure 1. Perceptions of KIs of the selection process of registration committee members**

This answer should be interpreted in conjunction with responses to indicator I-8. In fact, there are no written criteria for the selection of committee members. Members are selected from the pharmaceutical sector of the Ministry of Health and in general they possess high-levels of experience.

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

The decisions are made by the Drug Technical Committee and there are guidelines for the process but they are not available in written format. The Drug Technical Committee issues its decisions upon receiving the Quality Control directorate results of analyses, that ensure the safety, efficacy and good quality of the medicine and provide the technical information that is supplied by Pharmaceutical Affairs Directorate. These guidelines describe the mandate of the committee, number of meetings it should convene, procedures for decision-making and the reporting structure. However these guidelines and the decisions of meeting are not publicly available

63% of the KIs said that such guidelines do exist while 31% said that these guidelines do not exist and 6% did not know if such a guidelines exist or not.

**Indicator I-13:** Is there a formal appeals system for applicants who have their registration applications rejected?

There is no formal appeal system for applicants whose medicines are rejected. However it was revealed that applicants can appeal if they are not satisfied with the results and there is a committee for reviewing appeals and responding to applicants. 48% of KIs said that there is a process for appealing the decision of the committee when registration of a medicine has been refused, while 52% said such a mechanism does not exist.

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

Of all the KIs, 31.6% disagreed with the statement 42.1% agreed with the statement, while 15.7% strongly agreed and the remaining KIs were divided across responses of not applicable and don't know (Figure 2).

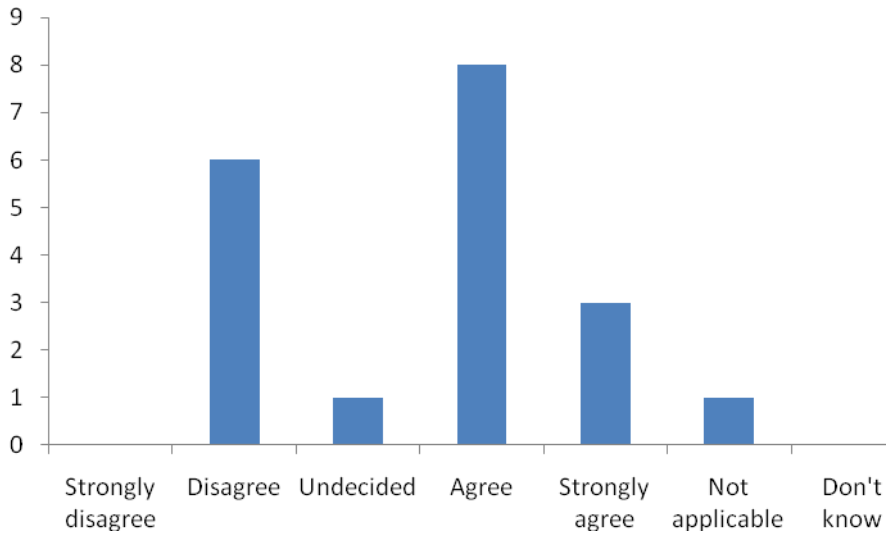



**Figure 2. Perceptions of KIs of the influence on decisions of gifts and benefits given to registration officials**

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

47.36% of the KIs agreed and 31.57% strongly agreed with the statement "The registration committee meets on a regular basis and keeps minutes of its meetings", while 15.79% disagreed and 5.26% did not know (Figure 3).

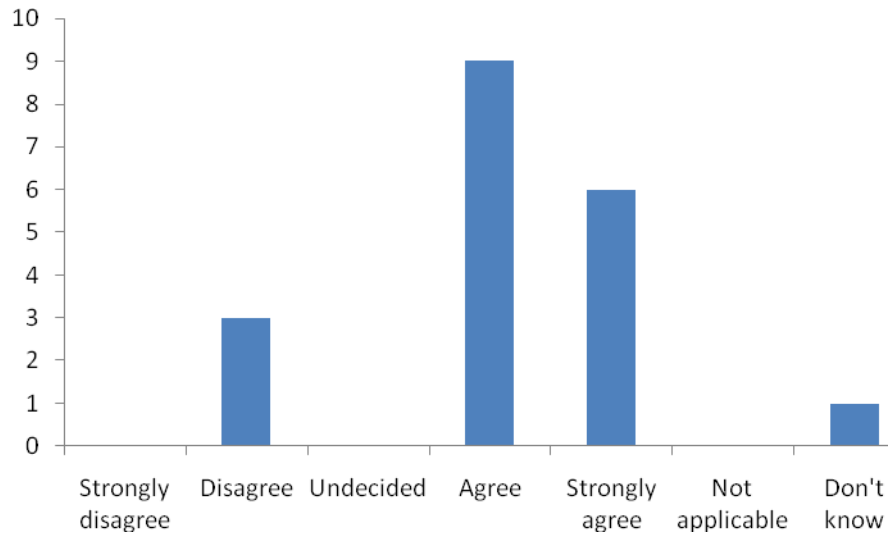



**Figure 3. Perceptions of KIs of the conduct of registration committee meetings**

**Indicator I-16:** In your opinion, what types of unethical behaviour are common in the registration system in your country?

While 32% of the KIs said that there is no unethical behaviour in the registration system, 31% claimed that favouritism and bribery commonly exist and a few KIs described prejudice in this system.

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

The first actions that KIs would take to improve the registration process would be to:

- Select the members of the registration committee according to scientific and ethical criteria.
- Conduct a comprehensive study of all the problems facing the registration process followed by a systematic plan of action to work towards resolving them.

- Speed up the process by which laws and regulatory legislations that contribute to quality control and safety procedures are issued.
- Establish an integrated centre for medicine services, including new premises, equipment and staff; and provide incentives to employees by way of awards and financial remunerations.
- Introduce an electronic automated knowledge management system across all levels to ensure that staff obtain up-to-date information instantly.
- Secure, training and support for a technical group of pharmacists and assistant technicians.
- Create a technical committee at the Ministry of Health to assess medicines activity before attempting to make large scale amendments in the country.
- Introduce the inspection and control of medicines from unknown companies and/or a qualified list of suppliers , specifically from countries like China and Korea, and those that provide vital medications, such as anti-cancer products, blood derivatives and insulin etc.
- Enforce the law of protection of intellectual property on imported medicines.
- Create a system of strict surveillance, involving allocating personnel responsible for studying the effectiveness of imported and registered medicines and others responsible for taking random samples of medicines and measuring them according to Good Manufacturing Practices (GMP).

*Data analysis and interpretation*

The final score for the medicine registration function, calculated for indicators from method 1 and 2, was 5.12. Table 4 shows that this score falls between 4.1 and 6.0, ranking the registration function as moderately vulnerable to corruption.

**Table 4. Final score for the vulnerability to corruption for the registration function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Registration score | | | 5.12 | | |

## 4.2 Licensing of pharmaceutical establishments

*Introduction*

Licensing of pharmaceutical establishments is a mandatory procedure. It is covered by three decrees and their attached regulatory decisions: Decree No 489 in 1952;

Decree No 40 for the year 1949 and their regulatory decisions 24/T, 25/T for local manufacturers and chemical stores; Law No 67 in 2001 for stores; and Decree No 12 in 1970 and its regulatory decisions for pharmacies.

There is a system of administration and enforcement intended to ensure that all pharmaceutical establishments are licensed. This system is supervised by the Drug Quality Control Directorate, established in March 1988, through which all the required information needed for licensing is processed. The Drug Technical Committee is the national higher authority that makes the decisions for licensing.

According to a survey performed in 2007, the number of local manufacturing industries was 60. The total number of pharmacies were 10 400, stores 340 and scientific advertising offices 60. The number of pharmaceutical sites that were licensed was 10 400 pharmacies[2].

Licensing follows a systematic process and there are guidelines for helping manufacturers to license their pharmaceutical establishments. Before applying to get a license, they need to fulfil certain requirements according to regulatory decision 24/T. Following this the manufacturer submits a written letter for initial approval to the office of the Deputy Minister for Medicine Affairs or to the Ministry's e-mail address asking for a license for a pharmaceutical establishment. This written request is transferred to the Quality Control Directorate A credited application containing the information about medicine manufacturers, available on the Ministry of Health website[3] and at the Quality Control Directorate, is filled out by the proprietor of this request. It is then evaluated by the Application Study Committee according to specific criteria and providing all the documentation is attached. These criteria was renewed by the Quality Control Directorate following the committee's decision taken on 20 Feb 2006. The Drug Technical Committee examines the Application Study Committee's evaluation and accordingly gives its decision. The owner of the application is then informed of the Drug Technical Committee's decision. If an applicant is offered an initial approval, a request must be submitted to the office of the Deputy Minister for Medicine Affairs to inspect the establishment to check compliance with the Ministry of Health's standard requirements. This request is transferred to the Quality Control Directorate where the information on the final steps is available to applicants. An application for assessing/inspecting the local establishment is prepared by the Ministry of Health and either the Assessing Committee or the Quality Control Directorate pursues inspection procedures according to the guidelines for inspection. A final report on the evaluation/inspection is prepared and presented to the Drug Technical Committee, which issues its final licensing providing that there are no outstanding issues regarding the establishment. Finally, the issued decision is released to manufacturers and the Registering and Licensing Division.

[2] Source: Ministry of Health, Syrian Arab Republic.

[3] http://www.moh.gov.sy/Pages/DrugAndNutrition/fmain_11.htm (accessed 12 May 2009)

The establishments/areas that need licensing include: local and foreign manufacturers, line product lines, chemical stores, pharmacies, importing and exporting agents and scientific offices for promotion and advertisement. In its simplified form, the licensing system involves the steps shown in Annex 8.

There is in place a mandatory system for the licensing/authorizing of pharmaceutical establishments. All stages of the licensing process are supervised appropriately by specific committees and there is a high authority in the Ministry of Health responsible for medicine related affairs called the Drug Technical Committee. The licensing system is complemented by an efficient system of inspection and access to drug quality control laboratory facilities. There are guidelines and procedures for licensing available on the Ministry website or at the Drug Quality Control Directorate, including information on the necessary procedures for applicants to submit the required documents, guidelines for assessing license applications and procedures for decision-making and for the issuance of licenses. The pre and post-licensing inspection system checks how far pharmaceutical establishments are in compliance with the requirements.

In order to assess the level of transparency and extent of vulnerability to corruption for the licensing function, 17 interviews were conducted with KIs from various backgrounds and sectors (Table 5).

**Table 5. Backgrounds of KIs interviewed for licensing function**

| Ministry of Health | Private | | | NGO | Total |
|---|---|---|---|---|---|
| | Private manufacturer and stores | Private store | Scientific advertising office | | |
| 8 | 2 | 2 | 2 | | 17 |

*Comments on each indicator*

**Indicator II.1:** Is it a legal requirement to have a license in order to operate a pharmaceutical establishment?

All KIs from the government and the private pharmaceutical sector agreed that there are well-defined decrees and regulatory decisions for licensing of pharmaceutical establishments. In reality, these laws indicate the requirements that should be met in terms of qualification of personnel, premises, facilities and procedures etc., in order to obtain a license for a pharmaceutical establishment. The percentage of KIs that answered yes to this indicator was 100%.

**Indicator II.2:** Does the Medicines Regulatory Authority have a unit responsible for issuing pharmaceutical establishment licenses?

KIs from the government and private pharmaceutical sector are aware of the existence of such a unit. The percentage of those who answered yes was 100%. The Drug Technical Committee is the higher authority for medicine affairs. It issues licenses to all pharmaceutical establishments.

**Indicator II.3:** Are there written procedures for the submission of applications for licensing?

The Ministry of Health has publicly available written procedures for submitting applications for licensing of pharmaceutical establishments. These procedures cover all administrative criteria that must be followed for licensing. They describe all technical and salubrious requirements for pharmaceutical sites, needed documents but without including the time-frame for processing of an application or fees except for licensing of foreign sites. 94% of the KIs agreed that there are written procedures for applications for licensing.

**Indicator II.4:** Are there written guidelines for assessing applications for a license?

There are written guidelines for assessing applications but these guidelines are not publicly available. 59% of the KIs said that there are guidelines available at the Ministry of Health while 30% said that there are no clear guidelines and11% did not know if there are guidelines or not. The percentage of yes answers to this indicator was quite low due to the fact that such guidelines are not made easily accessible to the public.

**Indicator II.5:** Is the submission of a pre-licensing inspection report one of the requirements for making decisions on whether to issue a license or not?

One of the main steps in the licensing process is the assessing/inspecting of local establishments by the Assessing Committee to check whether the site for the intended pharmaceutical establishment complies with the requirements described in the written guidelines and procedures. Then the final report of inspection is drawn up and presented to Drug Technical Committee. Sometimes the Quality Control Directorate is delegated to pursue the inspection. The Drug Technical Committee then issues its final licensing so long as there are no comments or defects detected by the Assessing Committee regarding the establishment. 88% of the KIs said that the submission of a pre-licensing inspection report was one of the requirements for decisions on whether to issue a license or not, while 5% answered that they did not know.

**Indicator II.6:** Is there a functioning formal committee that assesses applications for licensing of a pharmaceutical establishment?

There is an effective official committee for assessing and evaluating applications submitted to gain licenses. This committee is called the Application Study Committee. The percentage of KIs that answered yes was 100%.

**Indicator II.7:** Are there clear written criteria for selecting the members of the committee?

There are no criteria for selecting the members of the committee but it is imperative that the committee constitute directors and technicians from the Medicines Regulatory Authority. Sometimes technicians may be called from outside this authority. There is no requirement for members to sign a conflict of interest form or refer to specific codes of conduct. 76% of KIs said that there are written criteria for selecting the members of the committee, while 18% said that such written criteria are not available.

**Indicator II.8:** Is there a written document that describes the composition and terms of reference of the committee?

There is a written document that describes the names and the level of expertise of committee members but it does not include the specific roles, responsibilities, areas of authority or the accountability of each member and does not mention the benefits they receive. It is also not publicly available. 71% of the KIs said that there is a document describing the composition and terms of the committee, while 24% said such a document is not available, 5% did not know whether a document exists or not. There is a lack of transparency in that the document does not specify its members' roles and responsibilities and the guidelines are not open to the public.

**Indicator II.9:** Does the Medicines Regulatory Authority carry out regular (at least every 2 years) post-licensing inspection of all licensed pharmaceutical establishments?

The percentage of KIs that answered yes was 94%. This was due to the KIs' knowledge of the existence of the post-licensing inspection programme. Actually, Medicines Regulatory Authority executes regular post-licensing inspections according to a scheduled timetable, involving at least 2 rounds annually for each pharmaceutical site, but without prior notification to the pharmaceutical establishment (Annex 9**)**.

**Indicator II.10:** Is there an up-to-date list of all licensed pharmaceutical establishments available in the country?

There is a list of all licensed pharmaceutical establishments containing accurate and current information and it is updated annually. This list indicates the following: type of establishment, name and address of premises, name of qualified person/contact person, and the date of the last inspection. However it does not indicate a validity date for the license. All KIs were aware that such a list exists, illustrated by 87% of them answering yes.

**Indicator II.11:** To what extent do you agree with the following statement: "The licensing of pharmaceutical establishments is systematically carried out according to policies and procedures"?

76.47% of all KIs agreed with the statement: "The licensing of pharmaceutical establishments is systematically carried out according to policies and procedures" while 5.88% (1 out 17) strongly agreed, 11.76% strongly disagreed and 5.88% disagreed (Figure 5). Also, according to responses to indicators II.3 and II.4, most of the KIs are aware of these procedures, which include all the administrative criteria that must be followed for licensing.

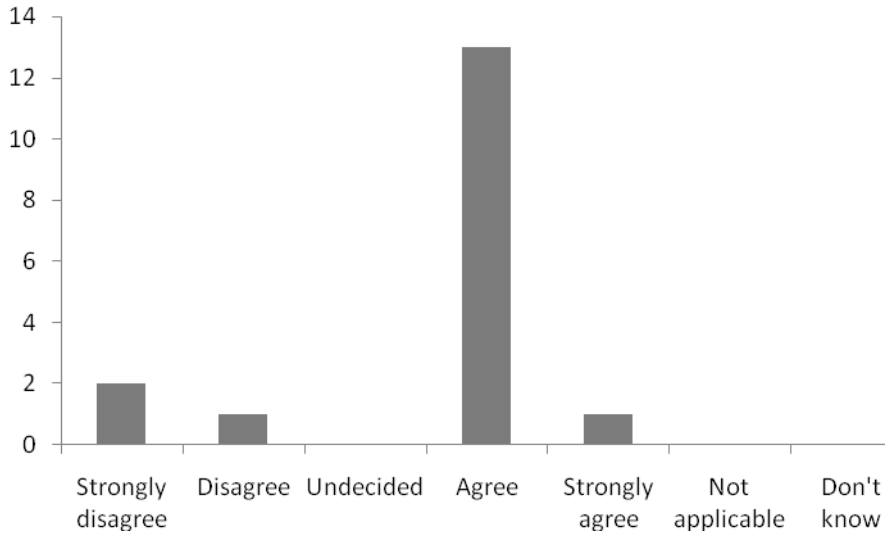



**Figure 5. Perceptions of KIs of the policies and procedures of the licensing process**

**Indicator II.12**: Is there an independent appeals system for applicants who have their applications for licensing rejected?

There is no independent appeals system in the licensing process for those whose applications are rejected, but each applicant is allowed to lodge a complaint to the committee that rejected their application. This complaint is then studied thoroughly by the same committee and then a decision is taken and the protester is informed with the result. The percentage of KIs that answered yes to this indicator was 35.7% while 7.6% of KIs were unable to give a decision and answered that they didn't know. 29.4% said that there is a system for appeal and 52.9% said there was no appeal system. This signifies a lack in transparency as there should be an official system for accountable appeals openly available to all applicants.

**Indicator II.13:** To what extent do you agree with the following statement: "The formal committee that assesses applications for licensing of pharmaceutical establishment is fully operational and meets on a regular basis"?

76.47% of the KIs agreed with the statement "The formal committee that assesses applications for licensing of pharmaceutical establishment is fully operational and meets on a regular basis" while 11.76% were undecided and 11.76% disagreed (Figure 6). If we consider the response to indicator II.6, the differences in the KIs opinions appears to be related to their understanding of the application studying committee's role and main responsibilities. KIs who had direct contact with the committee acknowledged the committee's operational functionality and regularity in meeting.

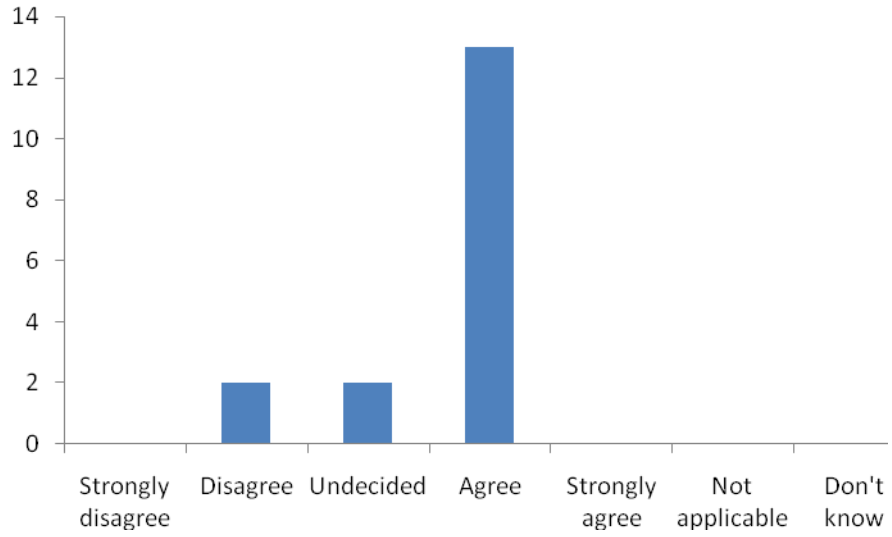



**Figure 6. Perceptions of KIs of the functioning of the licensing committee**

**Indicator II.14:** In your opinion, what types of unethical practices commonly occur in the process of licensing pharmaceutical establishments in your country, if any?

58% of the KIs answered that there are unethical practices taking place within the licensing process. 24% said that favouritism is the most common unethical behaviour and 11% answered that bribery was most common.

**Indicator II.15:** If you were in a position of highest authority, what would be the first action that you would take to improve the licensing process for pharmaceutical establishments in your country?

The fist actions that KIs would take to improve the licensing process of pharmaceutical establishments would be to:

- Speed up the licensing process.
- Automate the licensing process within an "e-government" model.

- Issue clear criteria for the selection of committee members.
- Allocate a clear time frame for processing of licenses in order to deal with the demand of applications.
- Create the position of Warrant Officer within the Ministry of Health to improve the level of control over pharmaceutical products at various institutions.
- Eliminate the red tape and bureaucracy that cause delays and make the process complicated and unclear.
- Enforce the application of the same standards for all, that is, no favouritism and genuine equal opportunities.
- Apply a policy of retribution and punishment on the licensing staff.
- Rotate the group of administrative staff responsible and ensure they serve a maximum period of 5 years.
- State carefully detailed criteria for each action to be taken, to guide the licensing committees.
- Establish an independent committee for medicine affairs such as the Syrian FDA.

*Data analysis and interpretation*

There were 15 indicators related to the licensing of pharmaceutical establishments, 11 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 licensing.

The result of the questionnaire on the licensing function was 7.42. Table 6 shows that this final score falls in the range of 6.1 – 8.0, ranking the licensing function as marginally vulnerable to corruption.

**Table 6. Final score of the vulnerability to corruption of the licensing function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Licensing score | | | | 7.42 | |

## 4.3 Inspection of establishments

*Introduction*

The purpose of inspection is to ensure that pharmaceutical operations, such as production, import and export, warehousing, distribution and promotion, are carried out in accordance with clear standards and guidelines as well with the national legislation and related regulations.

The Ministry of Health established the Drug Quality Control Directorate in 1988 and supplied it with expert pharmacists, doctors and assistant technicians. This directorate is involved in inspecting manufacturers, storage and distribution

activities in warehouses, controlling local and imported pharmaceutical products, conducting clinical control for pharmaceutical products, executing the Drug Technical Committee's decisions related to medicine control and evaluating appeals about local and imported medicines. The Directorate developed the national Good Manufacturing Practice (GMP) guidelines in cooperation with WHO in 1995 and renewed it in 2004.

The Drug Quality Control Directorate began applying the rules of the Good Manufacturing Practice in 1994 for all National pharmaceutical manufacturers. In 1998 the first guidelines for inspection were issued under the name of the Drug Quality Control System of the Syrian Arab Republic. They define the systematic inspection for pharmaceutical establishments, internal inspection and external auditing by related supervised systems of the Ministry of Health. These guidelines comprise inspection lists, according to the Good Manufacturing Practice and special requirements for the manufacturing departments, warehouses and Quality Control Laboratories. These lists are renewed regularly according to Good Manufacturing Practice requirements.

The Drug Technical Committee has recently standardized the process for inspection, which involved providing guidelines for the Assessing Committee at the Drug Quality Control Directorate and its related divisions in governorates. These guidelines state the terms needed for good manufacturing, guidelines for writing the final report, and the necessary amending procedures as well as a time-frame.

The Directorate of Drug Quality Control and Laboratory Research is responsible for applying the Quality Lab System and this system acts as a framework for directorate performance. The Directorate shares responsibilities with the Drug Quality Control Directorate in terms of observation, inspection and pharmaceutical control activities, in applying Good Manufacturing Practices, Good Distribution Practices (GDP), Good Laboratory Practices (GLP), Good Pharmaceutical Practices (GPP) and Good Clinical Practices (GCP). This directorate also seeks for certification from the International Standardization Organization (ISO.) It analyses specimens from medicines in the licensing process, including: special medicines for cardiac, respiratory, psychotic and hormonal diseases; preparations for injections such as vials, ampoules and serums; preparations intended for export; eye drops; medicines which are the subject of complaints in the random inspection process; and clinical and bioavailability studies.

In fact, all Syrian pharmaceutical manufacturers have been granted the Good Manufacturing Practice certificate according to the specific procedures for granting the Good Manufacturing Practice certificate to pharmaceutical establishments in the Syrian Arab Republic (see Annex 10). Also pharmaceutical stores are eligible for the Good Storage Practice (GSP) certificate, granted by the Syrian Ministry of Health/Drug Quality Control directorate, if they meet the standard requirements for good practice. The inspection process is illustrated in Annex 9.

In order to assess the level of transparency and the extent of vulnerability to corruption for the inspection function in the Syrian Arab Republic, 11 Interviews were conducted. KIs were representative of various backgrounds and sectors (Table 7).

**Table 7. Background of KIs interviewed for the inspection function**

| Ministry of Health | Private | | | NGO | Total |
|---|---|---|---|---|---|
| | Manufacturer and scientific office | Private store | Scientific office and store | Pharmacy syndicate | |
| 5 | 3 | 1 | 1 | 1 | 11 |

*Comments on each indicator*

**Indicator III.1:** Is there a provision in the medicines legislation/regulation covering the inspection of pharmaceutical establishments?

90 % of KIs were aware of the existence of regulations that cover the inspection of pharmaceutical establishments, while 10% of KIs said that no that such regulations exist.

**Indicator III.2:** Is the provision on inspection comprehensive enough?

There is provision for the inspection of pharmaceutical establishments in the legislation. It gives inspectors the powers to inspect premises and activities including power to enter, at any reasonable time, any place where medicinal products are produced, packaged, stored, distributed or tested in order to carry out an inspection. It defines the inspectors' duties, responsibilities and powers to take action in case of any violation of the medicines legislation and/or regulations. This provision if available to companies. However it does not provide inspectors with a special identification document/card but in fact, pharmaceutical sites' managers know inspectors. 100% of the KIs agreed with the provisions mentioned above.

**Indicator III.3:** Are there written guidelines on classifying non-compliance with Good Manufacturing Practices that describe the types of deficiencies and the corresponding measures to be taken by the Medicine Regulatory Authority?

There are written guidelines on Good Manufacturing Practices available at the Drug Quality Control Directorate and on the Ministry of Health website. These guidelines describe various types of deficiencies and the corresponding procedures that must be taken to rectify them. The guidelines are written and publicly available to all stakeholders but one of the defects in these guidelines is that the Medicine Regulatory Authority is responsible for the appeal system. There is no appeal system involving an independent body who were not involved in the original decision. 100% of the KIs said that such guidelines exist.

**Indicator III.4:** Are there written guidelines on classifying non-compliance with Good Distribution Practices that describe the types of deficiencies and the corresponding measures to be taken by the Medicine Regulatory Authority?

There are no written and clear guidelines on Good Distribution Practices but there are guidance documents for the distributors and manufacturers. 54.54% of the KIs said that there are clear guidelines for that purpose while 27.27% did not know if such guidelines exist and 18.18% stated that such guidelines do not exist.

**Indicator III.5:** Are there written procedures/mechanisms to prevent regulatory capture between inspectors and the manufacturers or distributors that he/she inspects?

The procedures are documented and they include that the inspectors have to visit site in teams with a team leader and the rotation of inspectors is based on a scheduling system. However they do not include specifications about the requirement of inspectors to inspect under the supervision of another inspector who will report on what he/she witnesses (peer review). Neither do they specify rotation of inspectors from one geographical area to another, or provide for independent auditing for the inspections, as auditors are affiliated to the Drug Quality Control Directorate. The percentage of KIs who answered yes was 26% while 36.36% of KIs did not know about such procedures and 18.18% said that such procedures do not exist.

In accordance with this steps must be taken to issue more obvious, clear and publicly available procedures to prevent regulatory capture between inspectors and the inspected manufacturers or distributors.

**Indicator III.6:** Are there written guidelines on conflict of interest with regard to inspection activities?

There are no written guidelines on conflict of interest, with regard to inspections activities. 0% of KIs answered yes to this question.

**Indicator III.7:** Are inspection findings and conclusions subject to an internal review?

Inspection findings and conclusions undergo internal review and auditing. Following this, the reports are presented to the Drug Technical Committee which takes the appropriate decision. 72.72% of the KIs agreed that inspection findings undergo internal review procedures, while 18.18% do not know of such a procedures and 9% said that such a review process does not exist.

**Indicator III.8:** Are there written standard operating procedures (SOPs) for inspectors on how to conduct inspections?

There are written SOPs for conducting inspection. There are also supplementary documents and a check list to help inspectors to conduct inspections. It includes the procedures detailing requirements for pre/post-inspection activities. Also there is a scheduling system for identifying companies due for inspections within a set timeframe, and format for inspection reports.

54.54% of the KIs said there are SOPs for inspection while 36.36% did not know about the procedures and 9% said that such SOPs do not exist. These numbers may show a certain lack of awareness or insufficient utilization regarding the SOPs.

**Indicator III.9:** Are there written criteria for the selection and recruitment of inspectors?

There are no written criteria for the selection and recruitment of inspectors but most inspectors are chosen due to their professional experience and qualifications in the medicine control field. The Ministry of Health has a limited number of professionals to conduct the inspection process due to reluctance of pharmacists to enrol in governmental employment. 36.36% of the KIs said that there are written criteria available, while 54.54% did not know if such criteria exist and 9% said that such criteria do not exist. The majority of the KIs believe that such criteria should exist as an essential requirement for inspection process

**Indicator III.10:** To what extent do you agree with the following statement: "The integrity of inspectors is in no way influenced by personal gain, such as bribes, gifts, or any other benefits, etc"?

36.36% of KIs disagreed and 45.45% agreed with the statement "The integrity of inspectors is in no way influenced by personal gain, such as bribes, gifts, or any other benefits, etc". A further 9.09% strongly agreed, while 9.09% did not know (Figure 7).

As the shown in the responses above (III.5, III.6) there are no criteria that regulate the relationship between inspectors and pharmaceutical businesses. Although the answers are distributed between agree and disagree, consensus was that the absence of such guidelines mentioned in III.5, III.6 create conditions where inspectors may be influenced by financial or other gifts.

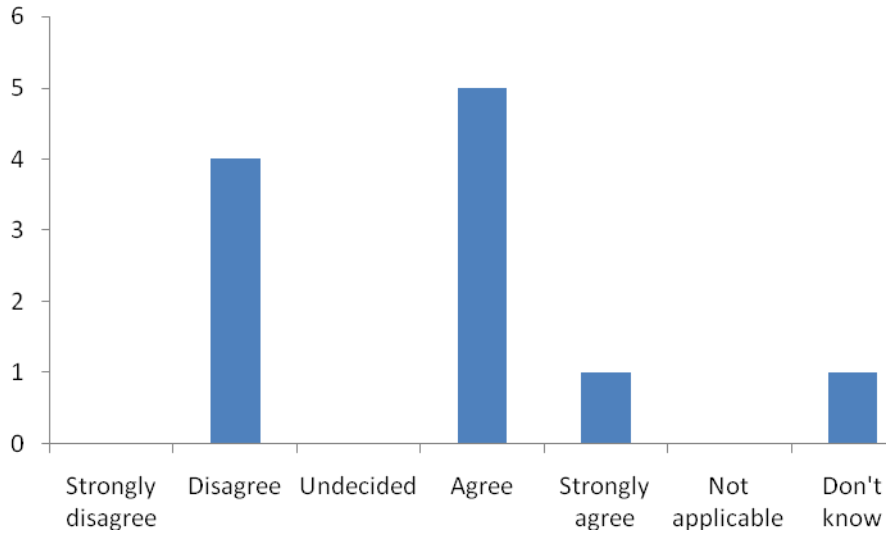



**Figure 7. Perceptions of KIs of the integrity of inspectors**

**Indicator III.11:** To what extent do you agree with the following statement: "Inspection activities are systematically carried out in accordance with the guidelines and procedures to prevent biases (e.g. peer review, rotation)"?

Of the KIs, 72.72% agreed with the statement "Inspection activities are systematically carried out in accordance with the guidelines and procedures to prevent biases (e.g. peer review, rotation)". 18.18% were undecided and 9.09% disagreed (Figure 8).

The responses to this indicator are largely related to the responses to indicator III.3, III.7 and III.8, which highlighted the lack of GMP guidelines, an appeal system that is not independent of the body making the original decision and absence of any policies on conflict of interest. All of these can cause biases and influence the level of transparency because the guidelines mentioned in indicator III.3 help inspectors to be objective in their decision-making, and make the inspection process more transparent. In several sections of this document, the KIs respond to similar sections based on their view on the well-functioning and/or integrity of the individuals responsible for a certain duty. In the discussions, KIs would consistently mention that it is better to have a preventative system rather than rely solely on the good will of individuals.

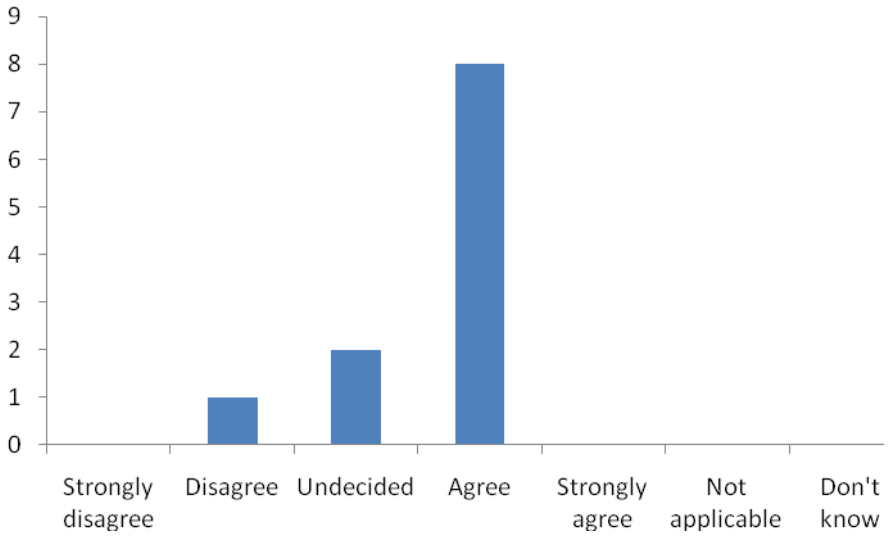



**Figure 8. Perceptions of KIs of the inspection procedures**

**Indicator III.12:** 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), conflicts of interest (e.g. investments in pharmaceutical companies), etc.

72.72% of the KIs said that there is no unethical behaviour in the inspection area while 9% spoke of issues of conflict of interest. Others stated that sometimes when errors take place in some of the advanced laboratories, they are dealt with in a lenient manner.

**Indicator III.13:** 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?

The first actions that the KIs would take to improve the inspection process would be to:

- Increase the number of senior specialists in the field of inspection.
- Make recruitment based on successful completion of training.
- Increase the number of inspectors and training them in a systematic way for the long term.
- Require that members of committees attend regular, intensive training courses.
- Develop a clear set of criteria for the selection of inspectors.
- Rotate the roles of committee members at all levels based on a defined scheduling system.
- Appoint inspectors with high qualifications and extensive professional experience.

- Amend the laws, decrees and legislation currently in force to make it in line with laws implemented in other Arab countries such as Jordan and Saudi Arabia namely, the Pharmaceutical Inspection Convention Scheme.
- Provide continual assessment and training of inspectors especially on GMP and involve specialists from the private sector in these activities.

*Data analysis and interpretation*

The final score for inspection was 5.88 after assessing the level of transparency and extent of vulnerability to corruption for the inspection function calculated from indicators of methods 1 and 2. Table 8 shows that this score falls between 4.1 and 6.0, indicating that the inspection function is moderately vulnerable to corruption.

**Table 8. Final scores of vulnerability to corruption for the inspection function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Inspection score | | | 5.88 | | |

## 4.4 Control of medicine promotion

*Introduction*

Medicine promotion, according to WHO criteria, includes all informational and influential activities by medicine manufacturers and distributors to induce the prescription supply, purchase and/or use of medicines across all media including the internet.

It is imperative to have in place regulatory laws and establish directorates/bodies for controlling medicine promotion activities as the publishing of biased and misleading information can affect the usage and consumption of medicines, which in turn could harm the health of citizens.

The medicine promotion system was controlled by decree No. 161 and its related executive decisions issued in 1965 up until the passing of law No. 7 2005. This includes a provision governing the work of scientific offices in medical advertising. It is concerned with the distribution of free medical samples; advertising products, including leaflets, books, journals, articles, medical publications and bulletins and product labelling; licensing with fees for establishing scientific offices; inspection over these offices; and the liabilities of companies and manufacturers in case of any breach of the law. Law No. 7 defines a framework for the legal functioning of scientific offices and managers within the field of medicine promotion.

The Pharmaceutical Affairs Directorate is the public body that supervises the medicines promotion process to prevent inaccurate information reaching patients

and health professionals by controlling medical advertising offices and by monitoring promotional materials and medical bulletin boards.

In order to assess the level of transparency and the extent of vulnerability to corruption for the promotion function, 15 KIs were interviewed. They were selected from different backgrounds and sectors (Table 9).

**Table 9. Backgrounds of KIs interviewed for medicine promotion function**

| Ministry of Health | Private | | | | Media | Total |
|---|---|---|---|---|---|---|
| | Manufacturer and scientific office | Private store | Scientific office and store | Manufacturer and store | | |
| 5 | 3 | 2 | 3 | 1 | 1 | 15 |

*Comments on each indicator*

**Indicator IV.1**: Is there a provision in the medicines legislation/regulations covering medicine promotion?

The law (No. 7 2005) on the management of pharmaceuticals sets the basis for the control of medicine promotion and it specifies that further regulations of the Ministry of Health will determine the formalities and conditions for the advertising of pharmaceuticals. 86.66% of the KIs said that such legislation exists, while 13.33% said that there is no clear legislation regarding medicine promotion.

**Indicator IV.2**: Do the provisions on medicine promotion include explicit mention of the following forms of promotion?

The provisions on medicine promotion include explicit mention of advertisement to professionals and the public, the qualifications and training of medical representatives, the scientific meetings and promotion of exported medicines. However it does not include restrictions on giving out free samples, paying of speakers fees and consultancies, restrictions and limits on giving gifts, gimmicks or packaging inserts or on post marketing scientific studies .

93.33% of the KI s answered that the national regulations on promotion of medicines cover all types of promotional activities. Only 6.67% said that such provisions do not exist.

**Indicator IV.3**: Is pre-approval of promotional materials officially required?

Out of 15 KIs, 12 were aware of regulations that provide restrictions on the advertising of medicinal products or pre-approval of promotional and advertising materials. These regulations require information about the name of active ingredients, brand name, company name, major indication for use, adverse effects, contraindications, medicine interactions and the cost.

**Indicator IV.4**: Do the provisions foresee an enforcement mechanism on promotion of medicines stating the sanctions in case of violation?

There are no rules and is no legislation concerning the advertisement of medicines directed towards health care professionals for prescription medicines. Consequently, there is no enforcement mechanism for that kind of activity. Of the KIs, 9 out of 15, or 54.54% were knowledgeable about the enforcement mechanisms on promotion and advertising of medicines.

**Indicator IV.5:** Is there a formal complaints procedure to report unethical promotional practices?

There are no mechanisms for complaints or reports of unethical practices within the area of promotion of medicines. Health professionals can address their complaints by way of a letter to the Ministry of Health on their own initiative but there is no official process for how it will be dealt with. 73.33%, or 11 out of 15, of the KIs said that such procedures are non-existent. 26.66%, or 4 out of 5 of those from the private sector, said that such procedures do exist.

**Indicator IV.6:** Is there a service or committee responsible for monitoring and enforcing the provisions on medicine promotion?

There is committee responsible for monitoring the provision of medicine promotion. A member of the committee monitors and reports inappropriate advertising violations. 50% of the KIs said that there is no committee for monitoring medicine promotion and they came from both the public and the private sector.

**Indicator IV.7**: Are there clear criteria for selecting the members of the service/committee?

There are no clear written criteria for selecting the members of the service/committee other than that they must have sufficient experience. All the KIs said that there are clear criteria for selection of the members of the service committee. This perception seems to be due to KIs approval of the selection of members and thus leading the assumption that clear application criteria is applied in their selection. This study has investigated the availability of clear criteria, in writing or reports, but they do not exist.

**Indicator IV.8:** Is there a written document that describes the composition and terms of reference of the service/committee?

There is a written document describing the formation of the committee that is responsible for the promotion of a medicine and this document contains the names of members and their level of experience as well as their duties. However, it does not include the roles and responsibilities of members, the material benefits they receive or the frequency of meetings. The document is not available to the public. 46.66% of

the KIs said that such a document does not exist, implying a lack of awareness of such a document, while 40% of the KIs said that such a document does exist.

**Indicator IV.9:** Are there written, publicly available SOPs guiding the services responsible for pre-approving or monitoring medicine promotion and advertising?

The committee checks that information complies with the indications that were approved for marketing. But there is no written guidance for the system of evaluation. 60% of the KIs said that there are no SOPs available, while 40% responded that such SOPs do exist.

**Indicator IV.10:** Are there written guidelines on conflict of interest with regard to the control of medicine promotion activities?

All the KIs said that there are no written guidelines on conflict of interest with regard to inspection activities.

**Indicator IV.11:** To what extent do you agree with the following statement:

"The legal provisions on medicine promotion have been developed in broad consultation with all interested parties"?

40% of KIs agreed and 6.67% strongly agreed (1 out 15) with the statement "The legal provisions on medicine promotion have been developed in broad consultation with all interested parties". A further 26.67% disagreed, 6.76% strongly disagreed, 6.67% were undecided (1 KI) and 13.33% did not know (Figure 9). If this question is interpreted in conjunction with the responses to indicator IV.1 it can be determined that there is no clear criteria for who should be consulted on the legal provisions of promotion activities.

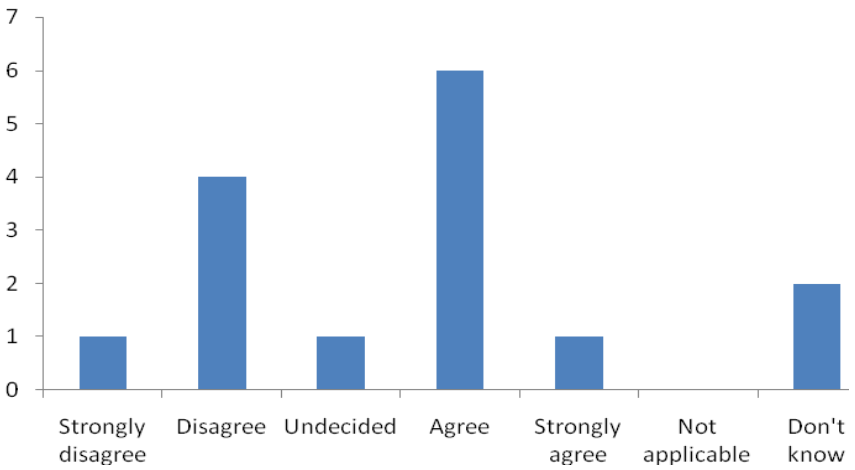



**Figure 9. Perceptions of KIs of the legal provisions on medicine promotion**

**Indicator IV.12:** To what extent do you agree with the following statement:

"Pre-approval of promotional and advertising materials is systematically being obtained before they are made public"?

Of the KIs, 53.33% agreed and 20% strongly agreed with the statement "Pre-approval of promotional and advertising materials is systematically being obtained before they are made public", while 13.33% strongly disagreed, 6.67% disagreed and 6.67% did not know (Figure 10).

In fact, and according to the responses to indicator IV.3 there are regulations that provide restrictions on advertising of medicinal products and on the pre-approval of promotional and advertising materials but they are not applied systematically.

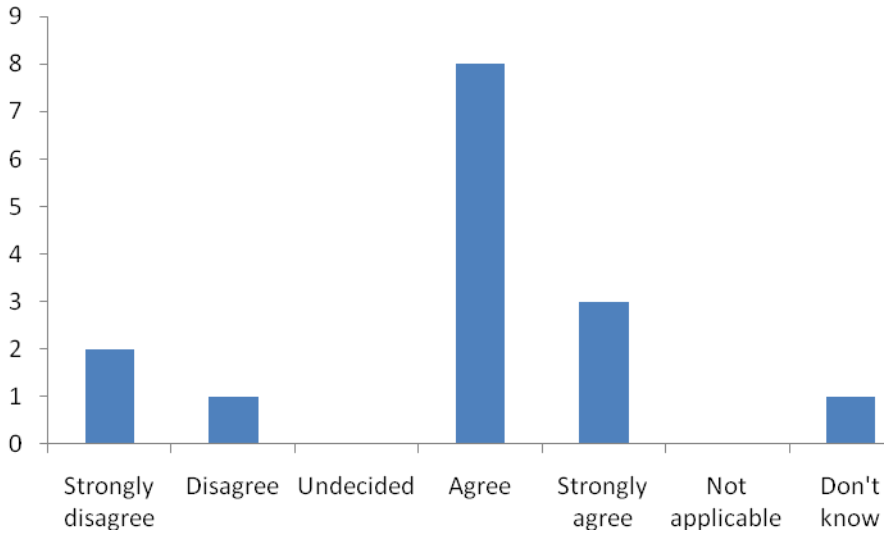



**Figure 10. Perceptions of KIs of the pre-approval of promotional activities**

**Indicator IV.13:** To what extent do you agree with the following statement?

"Civil society/nongovernmental organizations (NGOs) have a great influence on improving the control of medicine promotion in your country"?

33.33% of the KIs disagreed and 20% strongly disagreed with the statement "Civil society/nongovernmental organizations (NGOs) have a great influence on improving the control of medicine promotion in your country". A further 26.67% (4 out 15) agreed and 6.67% strongly agreed that civil society/NGOs have influence on improving the control of medicine promotion, while 6.67% (1 out 15) were undecided (Figure 11).

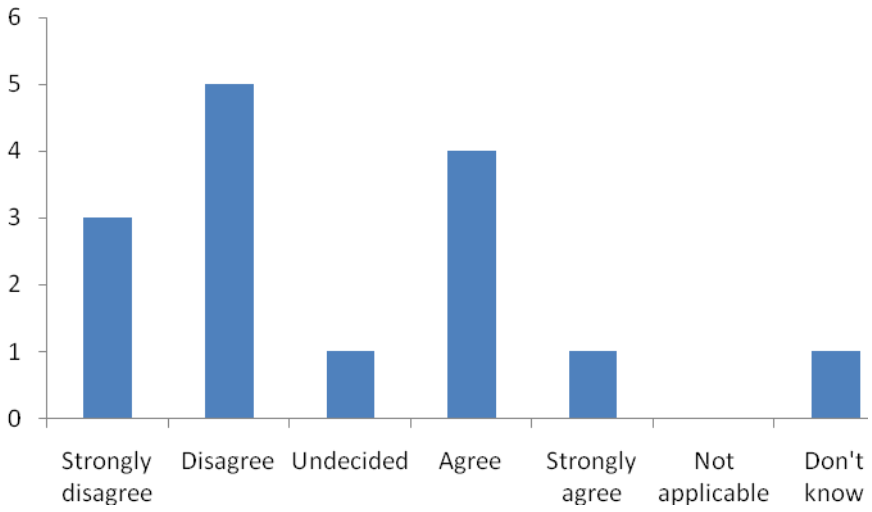



**Figure 11. Perceptions of KIs of the influence of civil society/NGOS on medicine promotion control**

**Indicator IV.14**: To what extent do you agree with the following statement:

"Sanctions foreseen in the provisions on medicine promotion are systematically applied when there is a breach"?

40% (6 out of 15 KIs) agreed and 20% (3 out of 15) KIs disagreed with the statement "Sanctions foreseen in the provisions on medicine promotion are systematically applied when there is a breach". A further 13.33% (2 out of 15) strongly disagreed with the statement (Figure 12). According to the responses to indicator IV.4 there is no enforcement mechanism for that kind of activity.

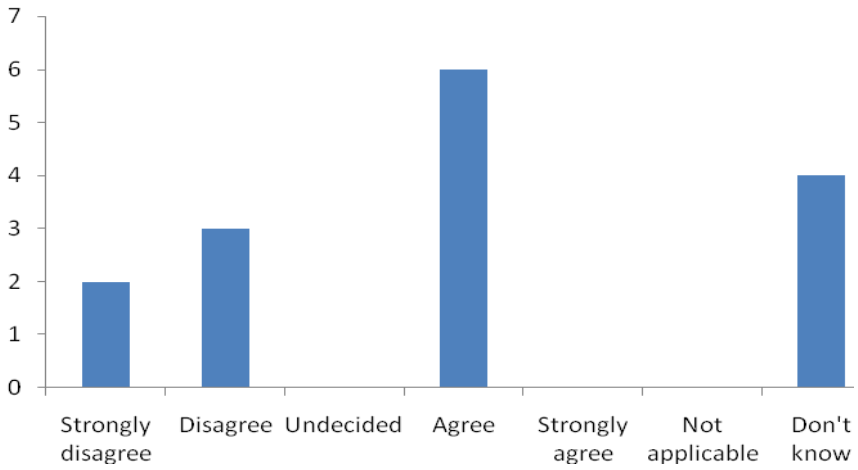



**Figure 12. Perceptions of KIs of the sanctions applied when there is a breach of rules for medicine promotion**

**Indicator IV.15:** In your opinion, what types of unethical behaviour are common in the medicine promotion area in your country?

66.7% of the KIs answered that most unethical practices take place within the promotion process and involve both the regulatory services and health professionals while 33.3% said that there is no unethical behaviour to be seen in the promotion function (Table 10).

**Table 10. Types of common unethical behaviour in the medicine promotion function**

| Unethical behaviour | Involving health professionals and institutions | Involving regulatory services |
|---|---|---|
| Bribery | 28.5% | 20% |
| Favouritism | 14.28% | 10% |
| Conflict of interest | | |
| Material gifts | 28.5% | 10% |
| Others | 20% | 33.3% |

**Indicator IV.16:** If you were in a position of highest authority, what would be the first action that you would take to improve the promotion process in your country?

The first actions the KIs would take to improve the promotion process would be to:

- Introduce rewards for workers.
- Develop ethical standards for the advertisement, promotion and dissemination of medical products.
- Develop clear guidelines and ensure their application.
- Expand and train the technical group.
- Clarify in greater detail the requirements for promotion of each pharmaceutical product according to written instructions.
- Increase the income of workers in the field of promotion.
- Control the promotional bonus.to retail pharmacies
- Increase the income from promotional activities to provide opportunities for the public sector to promote its products in a proper scientific manner.4
- Increase transparency in the functioning of scientific office committees, by applying a well documented scientific approach and not allowing gift giving to doctors and others working in the medical profession.
- Control the work of the promotion committees.
- Introduce a committee with the capacity and authority, through cooperation with the Ministry of Health and the syndicate to register incidents noted by doctors

[4] Currently, low salaries affect the quality of medical representatives in private and public pharmaceutical companies. In the Syrian Arab Republic, this leads to promotion being conducted on a commercial basis with little scientific capacity.

regarding counterfeit medicines and consequently take legal action against these companies.
- Allow the import of medicines, including those that are locally manufactured. This will improve both the quality of medicines by introducing competition and the quality of promotion by encouraging better promotional practices which would lead to advantages for patients.
- Introduce clear guidelines and regulations on the importation of active pharmaceutical ingredients and the selection of suppliers. Currently, promotional activities do not differentiate between the quality of suppliers of active pharmaceutical substances.

*Data analysis and interpretation*

There were 16 indicators related to the promotion of medicines, 10 of which were analysed using methods 1 and 2 and directly contributed to the final rating of the level of vulnerability to corruption for the promotion of medicines.

The results of questionnaires on the control of the promotion function was 4.47. As shown in Table 11, this score falls between 4.1 and 6.0, ranking the function of medicines promotion as moderately vulnerable to corruption.

**Table 11. Final score for the vulnerability to corruption of the medicines promotion function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Promotion score | | | 4.47 | | |

## 4.5 Clinical trials of medicines

*Introduction*

Most clinical studies in Syria are carried out on pharmaceutical products after they are marketed, in the fourth stage of post marketing surveillance. These studies involve: clinical trials for registering imported preparations; regular clinical studies for some groups of specific medicines, such as cardiovascular medicines, antibiotics, hormones, insulin, eye drops and serums etc.; and finally, processing clinical studies according to Drug Technical Committee decisions before releasing some important and expensive specific medicines.

Clinical studies are conducted according to the Declaration of Helsinki guidelines for good clinical practice, approved by the Drug Technical Committee, using the Science of Clinical Pharmacology published in 1993 as an academic reference.

The objective of these studies is to:

- verify or evaluate the efficacy and safety of local and imported medicines;
- verify or evaluate the efficacy of medical and hygienic products;
- identify adverse reactions and decrease the frequency of known adverse effects;
- perform early detection of unknown reaction and interaction;
- decrease errors in medication and promote rational and safe medicine use; and
- detect quality problems of medicines and inform patients and health professionals about them.

It is important to mention here that the programme of Monitoring Adverse Drug Reactions was approved to start on 16th September 2002 and the WHO was notified of this on 3rd October 2002.

Clinical studies in the Syrian Arab Republic are conducted at the Clinical Trial Unit, established at Damascus Hospital in 1991, under the supervision of the Clinical Drug Control Department, which was established in 1990. The Ministry of Health also established a second unit for Clinical trials at Al-Bassel Hospital in 1999.

The Clinical Drug Control Department comprises four units: the Clinical Trial Unit; the Research and Drug information Unit; the Monitoring of Adverse Drug Reactions and Medication Errors Unit; and the Clinics. This department comprises eight specialists in clinical pharmacology, two resident doctors, four technicians and one chemist. Up until now about 200 products have been studied and their results confirmed the effectiveness and safety of local products and their compatibility with standard products.

Finally, on July 20th 2008, the President issued a legislative decree for regulating pharmaceutical studies. The legislative Decree number 37 for 2008 stipulates the organization of pharmaceutical studies and provides legal, technical, moral and religious regulations for this. It also stipulates that a committee for pharmaceutical studies, a scientific ethics committee and a settlement and compensation committee should be founded.

In order to assess the level of transparency and extent of vulnerability to corruption for the clinical trials function, 13 interviews were conducted. KIs were selected from the various backgrounds and sectors (Table 12).

**Table 12. Backgrounds of KIs interviewed for the clinical trials function**

| Ministry of Health | Private | | NGO | Total |
|---|---|---|---|---|
| | Manufacturer and stores | Private store and scientific office | | |
| 7 | 2 | 3 | 1 | 13 |

*Comments on each indicator*

**Indicator V.1**: Is there a legal provision requiring the regulation of clinical trials?

There was no legislation or decree for regulating clinical trials studies; clinical studies were conducted under internal regulatory decisions from the Ministry of Health and the guidelines for good clinical practice, the declaration of Helsinki. Of the KIs, 61.53% answered that there is legal provision requiring the regulation of clinical trials and it is dependant on internal regulatory decisions, while 30.76% said that such provisions are non-existent. 7.71% answered that they did not know.

**Indicator V.2**: Are there written national guidelines on principles of Good Clinical Practice?

There are no written national guidelines for good clinical practices. These practices are taken from the declaration of Helsinki guidelines for good clinical practice and they were approved by the Drug Technical Committee. The Clinical Trial Research and Drug Information Unit was established in the hope that it would be able to provide medicine information and prepare clinical guidelines but unfortunately it did not manage to fulfil this role. 76.92% of the KIs said that there are no written guidelines on the principles of good clinical practice and 7.7% did not know of such procedures, while 15.38% said that such guidelines are available.

**Indicator V.3**: Are there written and publicly available guidelines on the submission of applications to Medicine Regulatory Authority to conduct clinical trials?

There are no written and publicly available guidelines for submitting applications to Medicine Regulatory Authority to conduct clinical trials. 61.53% of the KIs answered that there are no such guidelines and 7.71% did not know if they exist or not, while according to 30.76% of KIs such guidelines exist and are publicly available.

**Indicator V.4**: Is there a documented policy or procedure for the submission of clinical trials applications to an independent ethics committee?

There is no independent ethics committee, so clinical trials applications are submitted to the Drug Technical Committee, but without any documented policies or procedures for the submission of clinical trials applications. 84.61% of the KIs answered that there are no documented policies or procedures available for submitting clinical trials applications, 7.69% did not know of such procedures, while according to 7.69% of KIs, such policies and procedures do exist.

**Indicator V.5**: Are there requirements for the manufacture, importation, exportation and use of investigational products?

Requirements for manufacturing, importing, exporting and use of medicinal products in clinical studies are the same official ways followed by the Ministry of

Health. 46.15% of the KIs said that these requirements exist while 30.76% said that such requirements do not exist and 23.09% did not know if they exist or not.

**Indicator V.6:** Is there a formal review committee in the Medicine Regulatory Authority responsible for reviewing applications and clinical trials results?

In fact, there is no special committee for reviewing clinical trials results. The Drug Technical Committee is the Medicine Regulatory Authority itself and it is the official committee for revising applications and results of clinical trials studies. 53.84% of KIs said that a formal review committee exists, while 38.46% said that there is no committee for reviewing applications and results and 7.7% did not know.

**Indicator V.7:** Are there mechanisms in place to ensure that those involved in the review of applications and clinical trials results have sufficient and current expertise in all required areas?

There is a committee responsible for all clinical studies affairs, studying applications and clinical trials results but there are no mechanisms to ensure members' level of expertise. And in fact, members of this committee do not have sufficient experience in the required areas. 38.46% of the KIs said that such mechanisms are available, while 38.46% of them said that such mechanisms do not exist and 23% did not know. The results imply a lack of awareness from respondents with regards to this.

**Indicator V.8:** Is there a clinical trials inspection system established and operational?

There is no system for clinical trials inspection. 53.84% of the KIs said that such a system does exist and these answers are most likely dependent on the fact that Drug Technical Committee is responsible for clinical trials inspection through the Clinical Drug Control Department. However, 38.46% of KIs said that there is no system for the clinical trials inspection and 7.7% did not know.

**Indicator V.9:** Do the national guidelines require the establishment of an independent ethics committee?

Decree 37 for organizing clinical studies stipulates that a scientific ethics committee should be formed and it provides legal, technical, moral and religious regulations for the functioning of this committee. However, this committee does not yet exist as this decree was newly issued. 69.29% of the KIs said that there is no requirement for the establishment of the independent ethics committee and 23% did not know. 7.6% of the KIs said that the national guidelines require the establishment of an independent ethics committee. The KIs' responses illustrate the need for such a committee to be activated.

**Indicator V.10:** Does the review committee have a time-frame for assessing clinical trials?

There is no time-frame for assessing clinical trials. 61.59% of the KIs said that there is no time-frame specified for assessing clinical trials, 15.38% did not know and 23% said that such a time-frame does exist.

**Indicator V.11:** Are there written guidelines on conflict of interest with regard to clinical trial activities?

All the KIs said that there are no written guidelines on conflict of interest.

**Indicator V.12:** Is there a list/database of all approved and rejected clinical trials applications?

There is a list of all approved and rejected clinical trials applications. The list indicates all clinical trials approved, amended or rejected but it is not publicly available. 38.46% of the KIs said that such a list does exist, while 38.46% said that such a list is not available and 23% did not know. This variance was noted by type of KI as the list is available only for concerned people.

**Indicator V.13:** To what extent do you agree with the following statement:

"The independent ethics committee members are systematically selected based on written selection criteria"?

Of the KIs, 23.08% said that the statement "The independent ethics committee members are systematically selected based on written selection criteria" was not applicable, 7.69% (one KI) disagreed with the statement, 7.69% were undecided, 7.69% strongly agreed and 53.84% answered that they did not know (Figure 13).

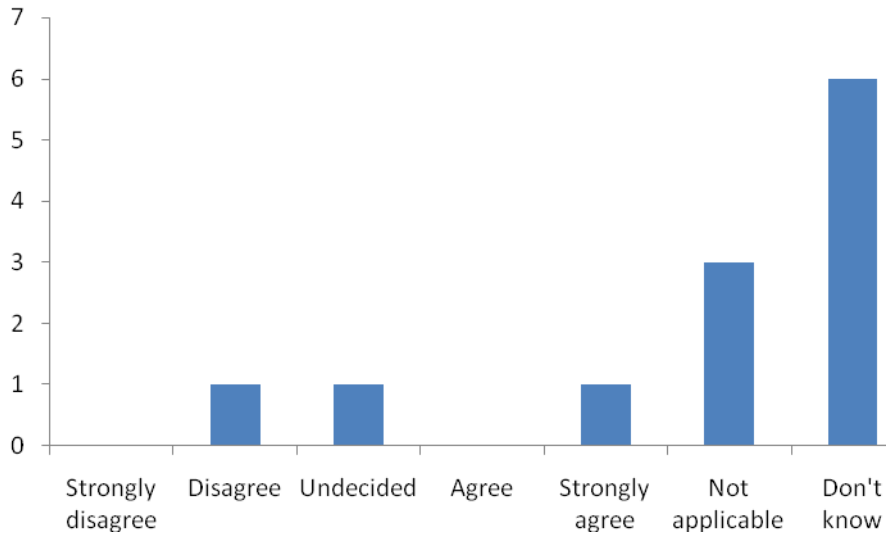



**Figure 13. Perceptions of KIs of selection criteria for independent ethics committee members**

Most probably because the decree mentioned in response to indicator V.9 is newly issued, many of the KIs did not know about it or said that the statement was not applicable.

**Indicator V.14:** To what extent do you agree with the following statement:

"The Medicine Regulatory Authority review committee members are selected systematically based on the written selection criteria"?

Of the KIs, 23.08% said that the statement "The Medicine Regulatory Authority review committee members are selected systematically based on the written selection criteria" was not applicable. 7.69% were undecided and 7.69% disagreed, while 7.69% strongly agreed, 15.38% agreed and 38.46% did not know (Figure 14).

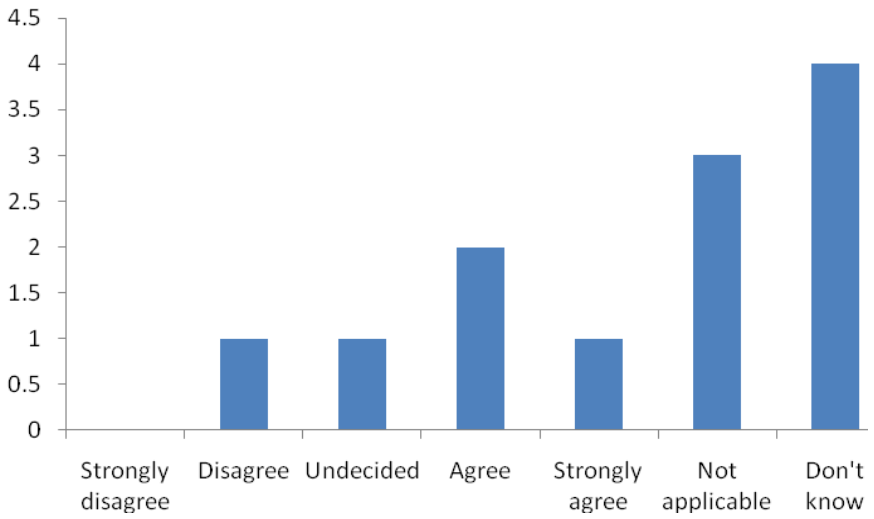



**Figure 14. Perceptions of KIs of the selection of Medicine Regulatory Authority review committee members**

In fact, there is no special committee. Interestingly, the KIs who agreed with this statement were from the private sector and they know that the Drug Technical Committee is responsible for clinical trials inspection through the Clinical Drug Control Department (see indicator V.6).

**Indicator V.15:** To what extent do you agree with the following statement:

"The Medicine Regulatory Authority is ensuring that clinical trials conducted in the country are done in accordance with the regulations and Good Clinical Practice principles"?

23.08% of the KIs agreed and 15.38% (2 out of 13) strongly agreed with the statement: "The Medicine Regulatory Authority is ensuring that clinical trials conducted in the country are done in accordance with the regulations and Good Clinical Practice principles", while 7.69% disagreed, 7.69% were undecided and 15.38% said that the statement is not applicable. The remaining 30.76% did not know (Figure 15). So because of the unclear information regarding clinical trials (see indicators V.1 and V.2) there are many different responses.

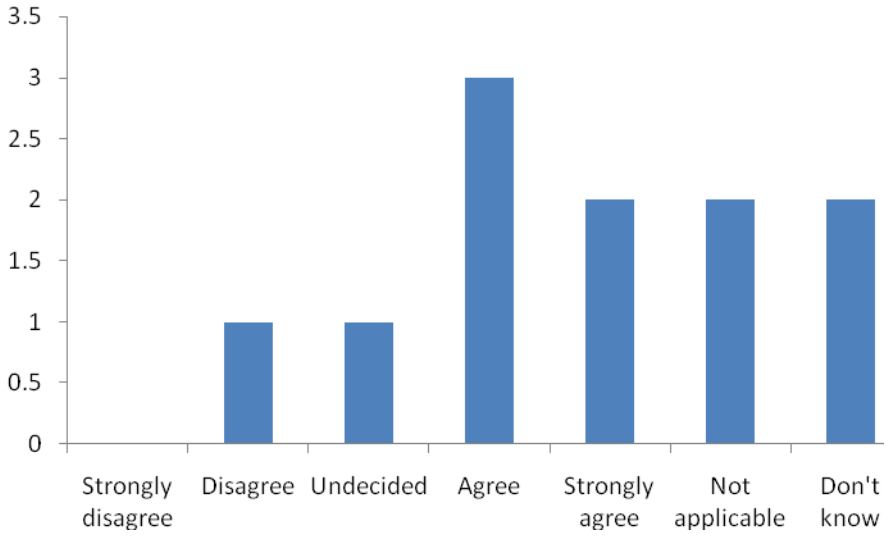



**Figure 15. Perceptions of KIs of how far clinical trials are conducted in line with regulations and Good Clinical Practice principles**

**Indicator V.16:** In your opinion, what types of unethical behaviour are common in the clinical trials area in your country?

46.15% of KIs said that there is no unethical behaviour in the clinical trials area, 7.6% did not know and the rest said that there is some unethical behaviour such as some biased opinions and decisions that lack any reference to scientific studies or established facts.

**Indicator V.17:** If you were in a position of highest authority, what would be the first actions that you would take to improve the way clinical trials are carried out in your country?

The first actions that KIs would take to improve the way that clinical trials are carried out would be to:

- Adopt a law for clinical trials.
- Apply the law of pharmaceutical clinical studies as quickly as is possible.
- Create suitable premises equipped with all the required equipments.

- Rehabilitate and train staff working in clinical trials.
- Speed up the establishment of laboratories for equivalence studies that are approved by supreme bodies responsible for ensuring the quality and safety of the medicines used.
- Pass a new law to regulate the relationship between the researcher and the beneficiary of research to ensure the rights of both parties as well as the rights of patients or healthy volunteers.
- Adopt a legal system for dealing with patients who have taken part in clinical studies and establish a special section in hospitals for conducting these studies.
- Officially document reports of the results of laboratory studies.

*Data analysis and interpretation*

To assess the level of transparency and extent of vulnerability to corruption for the clinical trials function, the final score, calculated for indicators from method 1 and 2, was 3.36. Table 13 shows that the final score falls between 2.1 and 4.0, ranking the clinical trials function as very vulnerable to corruption.

**Table 13. Final score for the vulnerability to corruption for the clinical trials function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Clinical trials | | 3.36 | | | |

## 4.6 Selection of medicines

*Introduction*

The National Drug Policy is concerned with the adoption of the NEML to save lives, improve health and meet a high standards of care; as well as ensuring that patients receive their treatment of choice. The NEML provides substantial guidance for the selection of medicines, both locally manufactured and imported from international and national providers.

The EML, adopted by the Ministry of Health, is developed by consulting experts from the WHO together with related medical associations and is used as a reference for the NEML. The EML was first issued in 1988.

The basis of medicine selection is to choose national essential medicines that define and reflect both the government's priorities for medicine supplies in the public sector and the commercial, social and health needs of the country.

In 2006 the Ministry of Health used the NEML sixth edition. This edition is classified according to medical indications. It includes 33 groups, 1000 medicines and has an

index according to alphabetic order. The NEML is wider and more inclusive than the EML and it is publicly available in a printed format that is easily accessible to all.

In order to assess the level of transparency and extent of vulnerability to corruption in the selection of medicines function, 12 KIs were interviewed. They were selected from a variety of sectors and backgrounds (Table 14).

**Table 14. Backgrounds of KIs interviewed for the selection of medicines function**

| Ministry of Health | Private | | | NGO | Total |
|---|---|---|---|---|---|
| | Manufacturer and scientific advertising office | Private store | Scientific advertising office and store | | |
| 6 | 1 | 2 | 2 | 1 | 12 |

*Comments on each indicator*

**Indicator VI.1:** Does the government have an officially adopted national EML publicly available?

There is an official NEML adopted by the Ministry of Health and it is publicly available on the Ministry of Health website. 91.66% of KIs said that this list is available, while 8.33 % ( 1 out 12) said that no such list exists.

**Indicator VI.2:** To what extent do you agree with the following statement:

"The national EML has been developed in consultation with all interested parties and using an evidence-based approach"?

The majority of KIs (75%) agreed or 16.67% strongly agreed with the statement "The national EML has been developed in consultation with all interested parties and using an evidence-based approach". The remaining 8.33% (1 out 12) were undecided (Figure 16).

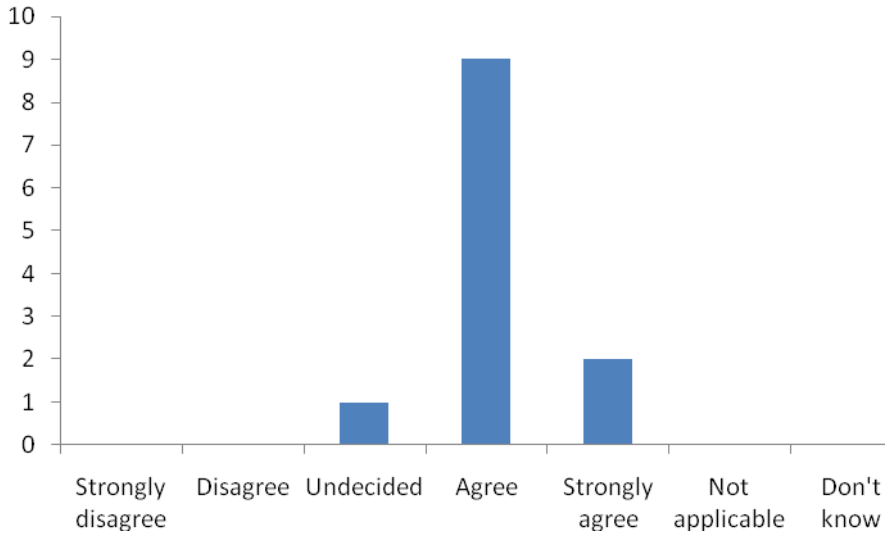



**Figure 16. Perceptions of KIs of the development of the EML**

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

There is a committee composed of professional experts, which adds to and renews the NEML according to WHO recommendations and national needs. Experts use guidelines that are clearly written for including or deleting medicines from the NEML. These guidelines specify medicines that should be included on the basis of efficacy and safety, with regard to the priority health needs of the country, and the cost-effectiveness but these guidelines are not available to public. Of the KIs, 83.33% said that there are clearly written guidelines and the percentage of the valid answers was 60.5%, while 16.66% said that such procedures do not exist.

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

The EML was established after consulting with experts from the WHO and other related medical associations. The first edition was issued in 1988 and it is continuously renewed. This list is published and easily accessible on the Ministry of Health website. The products are listed by generic name and by level of health care and it is linked to the national treatment guidelines. The last edition was issued in January 2006 (sixth edition). All of the KIs said that the list was widely disseminated to all relevant health professional and is in line with WHO procedures.

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

The percentage of answers was 100% as there is a committee of experts responsible for including or deleting medicines from the NEML in the selection process.

**Indicator VI.6:** To what extent do you agree with the following statement:

"The committee responsible for the selection of the national EML is operating free from external influence"?

50% of KIs agreed and 8.33% strongly agreed with the statement "The committee responsible for the selection of the national EML is operating free from external influence". 25% of KIs disagreed with the statement and 16.67% (2 out 14) were undecided (Figure 17).

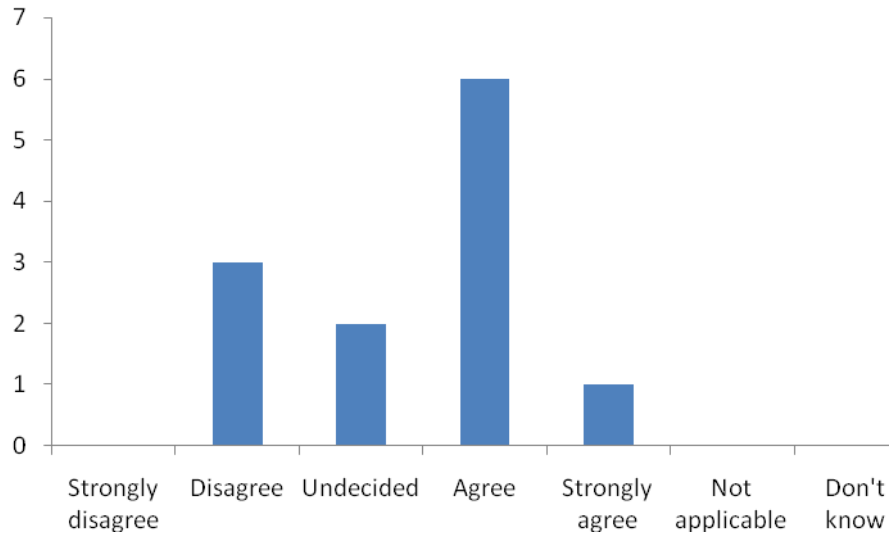



**Figure 17. Perceptions of KIs of the selection of the national EML**

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

There are no written criteria for the selection of the committee members, but members are selected based on their knowledge of pharmacology and medicine as well as their clinical and field experience. They are approved by the Minister of Health and the membership of the committee is not time–limited. 50% of the KIs said such criteria exist while 50% said that there are no clear criteria for the selection of members of the selection committee.

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

All the KIs confirmed that there are no written guidelines on conflict of interest, with regard to the selection of essential medicines.

**Indicator VI.9:** Are there clear terms of reference that describe the role and responsibilities of the selection committee?

The selection committee is selected according to an official decision made by the Minster of Health. This decision is based on names, qualifications and duties of committee's members but this decision is not known by the public. The committee operates according to written terms of reference. 50% of the KIs agreed that there clear terms of reference and the other 50% said that none exist.

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

There are no written SOPs for committee members to help them make their decisions but decision must be unanimous with wide consultation with interested parties to ensure that the committee is operating free from external influence (see indicators VI.6 and VI8). The final decision on the selection of medicines is publicly available and it is disseminated widely.

The percentage of KIs that answered yes was 75% because there is a formal document describing members' duties. It seems most KIs relied on this fact when giving their answers to this question.

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

Of the KIs 54.54% said that there is no unethical behaviour in the selection process and 18.18% said that favouritism is the most common unethical behaviour in the selection process. Others mentioned the occurrence of obtaining false purchase orders to pass a specific purchase request in order to facilitate the process of accepting a specific article on the list; intervention activities that influence the committee; and the insistence of doctors on a particular product regardless of its price or source.

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

The first actions that KIs would take to improve the medicine selection function would be to:

- Demand commitment from all parties to use this list as the basis for the selection of necessary medicines in government.
- Insist on the renewal of such a list annually either by adding substances or having materials withdrawn in accordance with the guidelines of the WHO.
- Conduct training courses for workers on how to abide by these regulations.
- Establish standards for the selection of a specialized committee with clear roles and responsibilities.

- Improve communication by way of increased usage of the internet and the latest information and communication technology.
- Ensure that decisions on the selection of medicines (for the newly developed medicines), are not rushed through before safe usage is approved from worldwide references
- Remain in touch with the latest developments in medicine in the world.

*Data analysis and interpretation*

There were 12 indicators related to the selection of medicines function, 8 of which were analysed using methods 1 and 2 and directly contributed to the final rating of the level of vulnerability to corruption for the selection of medicines.

The final score from the questionnaires for the selection of medicines function is 5.67. Table 15 shows that the result rates the selection of medicines function as moderately vulnerable to corruption, since it is between the ranges 4.1 – 6.0.

**Table 15. Final score of the vulnerability to corruption of the selection of medicines function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Selection of medicines | | | 5.67 | | |

## 4.7 Procurement of medical products

*Introduction*

The strategic objectives of pharmaceutical procurement are to: procure the most effective medicines in the right quantities; select reliable suppliers of high-quality products; ensure timely delivery; and achieve the lowest possible total cost. For these reasons it is essential to have governmental supervision over such an activity.

The system for the procurement of medical products is organized by Law no. 51 of the Contracts System issued on 24th November 2004[5]. Law no. 51 regulates the procuring process for all of the public bodies in government and considers medicines along with all other commodities by executive instructions issued on 20th December 2004 for procurement of imported medicines.

[5] The GFTO medicine division, which is now affiliated to the Ministry of Economy and named 'Sedalia' was the only division that was concerned with importing pharmaceutical products that were not made locally. It solely distributed the imported medicines to the Ministry of Health institutions through GFTO stores. However, now this role is shared with private agents.

Public and private health sectors have different mechanisms for procuring medical products:

1. **Public health centres** obtain their medicines through the following channels:

- Local medicines are procured from national manufacturers by way of invitations, offers or tenders.
- Imported medicines are procured by 'Sedalia' or granted to the Ministry of Health health centres from donating organizations.

2. **Private health sector, i.e.** hospitals and pharmacies, obtain their medicines through the following channels:

- Local products are procured from local pharmaceutical manufacturers through private stores.
- Imported medicines are procured from 'Sedalia' or from exclusive agents of the foreign manufacturers. Exclusive agents are allowed to procure what is not locally available and not related to general health such as vaccines, serums, blood derivatives, antidotes and antitoxins.

In order to assess the level of transparency and extent of vulnerability to corruption of the procurement function, 17 KIs were interviewed. They were selected from different backgrounds and sectors (Table 16).

**Table 16. Background of KIs interviewed for the procurement function**

| Government | | | Private | | | | | Media | Total |
|---|---|---|---|---|---|---|---|---|---|
| Ministry of Health | GFTO | Hospitals | Private manufacture | Private store | Private hospitals | Scientific office and store | Scientific office | | |
| **1** | **4** | **5** | **1** | **1** | **1** | **1** | **2** | **1** | **17** |

*Comments on each indicator*

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

The government follows clear and transparent written procedures for procuring pharmaceutical products. These procedures are controlled by Law no. 51 issued in 2004. These procedures describe the internal process to be followed by staff to process the bids. They require the use of generic names, that procurement is be based on the national essential medicines list, and that the criteria for the adjudication of tenders must be included as part of the tender package. The advertisement of tenders publicly available and the information on tender process and results are made public.

All of the KIs agree that such procedures exist and that government follows these transparent procedures.

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

There are written guidelines for officers on the different methods of purchasing pharmaceutical products. Law no. 51 includes rules for governing purchases such as: direct procurement, tenders, call for bids, contests, and a contract by mutual consent and the execution of work by trust. 82.35% of the KIs said that there are clear guidelines for procurement office staff, while 17.64% said that such guidelines do not exist.

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

There is an objective quantification method for estimating the needed quantities of pharmaceutical products for procurement. It is stipulated in law no. 51, article 8. 88.23 % of the KIs agreed that procurement is done with an objective quantification method, while 5.8% said that no such method is used and 5.8% did not know.

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

There is no formal appeals process for rejected applicants but applicants are permitted to protest and submit an appeal form to the concerned authority. 52.93% of the KIs said that such a process does exist while 47.05% said that no appeals process exists.

**Indicator VII.5**: Is there a tender committee? If so are the key functions of the procurement office and those of the tender committee clearly separated?

There is a tender committee and it is clearly separated from the procurement office, which takes decisions according to Law no. 51, chapter three, article 12. The tender committee, a public entity comprises three members, at least one of whom should be the accountant or financial director of this entity or a subordinate to either of them as the case requires. All of the KIs said that there is an active tender committee and it is responsible for supplier selection for restricted tenders and for contract decisions. The percentage of the valid answers was 70%.

**Indicator VII.6**: To what extent do you agree with the following statement:

"Decisions of the tender committee are always taken into account in the procurement process"?

47.06% of the KIs agreed, 17.65% strongly agreed and 17.65% disagreed with the statement "Decisions of the tender committee are always taken into account in the procurement process". A further 11.76% were undecided and 5.88% (1 out of 17) said that this case is not applicable (Figure 18).

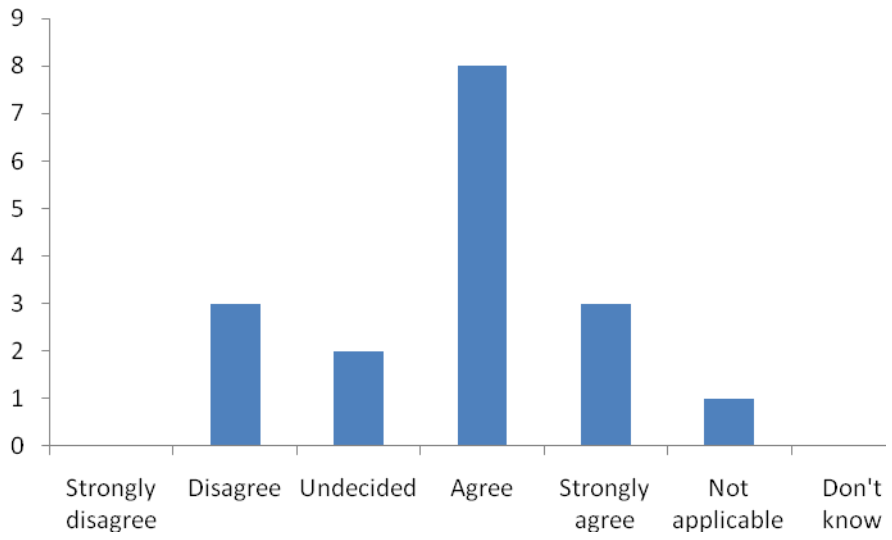



**Figure 18. Perceptions of KIs on the decisions of the tender committee**

**Indicator VII.7**: Are there specific criteria for tender committee membership?

Although there are criteria for selecting members of the tender committee and they are written in the law of offers and tenders (see indicator VII.5), not all public bodies adhere to this law. In fact, the tender committee consists of technicians from specific occupations and with good experience. All of the KIs agreed that there are criteria for selecting members of the tender committee. The members should be selected from senior government officials, end-user facilities, and the membership changes periodically, but there is no requirement for declaration of conflict of interest. The percentage of valid answers was 54.94%.

**Indicator VII.8:** Are there written guidelines on conflict of interest with regard to the procurement process?

All the KIs said that there are no written guidelines on conflict of interest in the procurement function.

**Indicator VII.9:** To what extent do you agree with the following statement:

"The members of the tender committee are systematically selected based on specific criteria (see question V.6)"?

47.06% of KIs agreed and 5.88% (1 out 17) strongly agreed with the statement: "the members of the tender committee are systematically selected based on specific criteria", while 35.29% disagreed and 11.76% strongly disagreed (Figure 19).

As with indicator VII.7 there is a law that specifies the members of the committee but it is not systematically applied, hence there is a range of different answers.

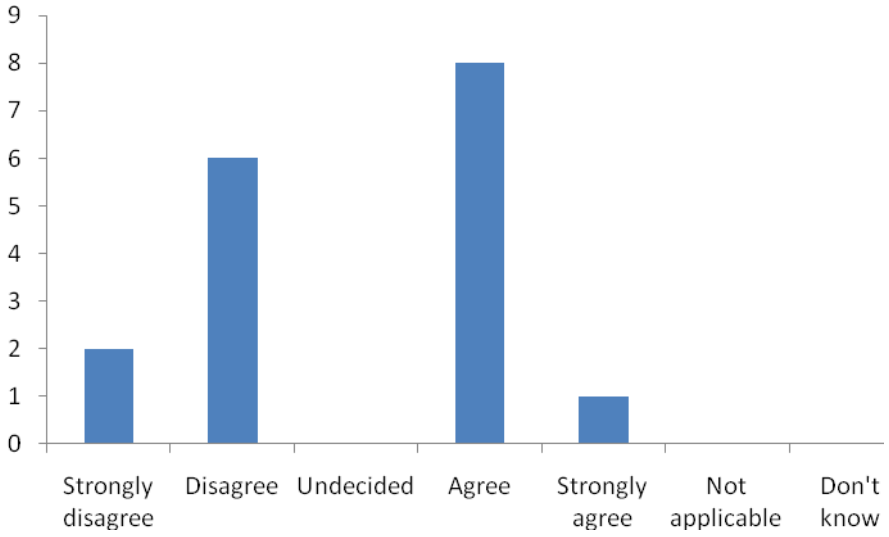



**Figure 19. Perceptions of KIs of the selection of the members of the tender committee**

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

There is diversity across the departments that purchase pharmaceutical products Some of them have computerized information systems for indicating problems while others have an archiving system. The information systems include product records and they monitor supplier and facility performance. They also record all quality assurance information for products purchased and track the status for each order, including the quantities actually purchased compared with the original estimates made. 82.35% of the KIs said that the there is a computerized system, while 17.63% said that such a system is non existent. The percentage of the valid answers is 56.76%.

**Indicator VII.11:** Are there SOPs for routine inspection of consignments?

There are SOPs for inspection but they are not applicable to all kinds of products. Pharmaceutical products are received by a Receiving Committee and the procedures to inspect products differ from type to another. Some products, such as milk and

blood derivative products undergo special inspection. Random samples from milk products are taken and sent to the quality control laboratory and for blood derivatives it is necessary to screen for AIDS and hepatitis.

Other products follow routine inspection involving quantitative and qualitative physical inspection. The batch samples are sent to the quality control laboratories, and all documents are archived in the procurement office. 70.58% (13 out 17) of interviewed KIs said that SOPs for routine inspection of consignments do exist while 29.42% (4 out 17) said that SOPs do not exist.

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

There is an efficient post-tender system to monitor and report on suppliers' performance to the tender committee. It tracks suppliers' lead time, delivery status, shelf-life, and packaging of products. Product quality is also tracked and suppliers with poor performance are blacklisted. 88.23% (15 out 17) of KIs interviewed said that there is a post tender system in place to monitor and report on suppliers' performance to the tender committee, while about 11.76% (2 out 17) of KIs (2 out 17) said that the system does not exist.

**Indicator VII.13:** Does the procurement office undergo regular audits?

The procurement office undergoes regular auditing according to laws and regulatory decisions. The audit reports on pharmaceutical products tendered, quantities of the products procured, and the contracts awarded. However, its results are not publicly available and it does not report on the operating costs of the procurement office. Of the KIs interviewed, 94.11% (15 out 17) said that the procurement office undergoes regular audits, while about 5.88% (1 out 17) said that the procurement office was not subject to such auditing and the percentage of KIs who did not know was 5.88%.

**Indicator VII.14:** To what extent do you agree with the following statement:

"The procurement system in your country is operating in a totally transparent manner"?

52.94% of KIs agreed, 17.65% strongly disagreed and 17.65% disagreed with the statement "The procurement system in your country is operating in a totally transparent manner". A further 11.67% were undecided (Figure 20). This is because of the lack of legislation regulations and many issues of conflict of interest in all procurement processes (see indicators VII.1, VII.8).

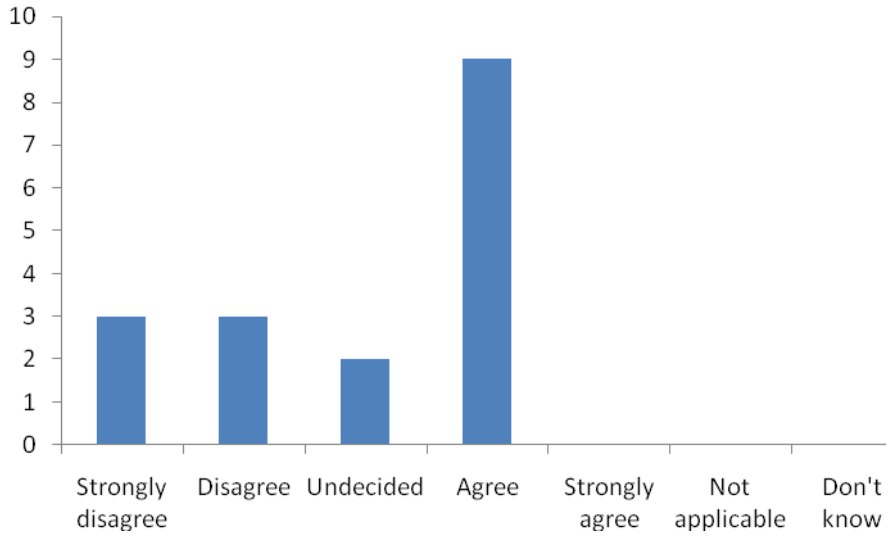



**Figure 20. Perceptions of KIs of the transparency of the procurement system**

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

Unethical behaviour is common in the procurement system. Favouritism and bribery appear to be the most common as 41.17% of KIs considered them to be common behaviour in procurement, while 17.64% said that the giving of material gifts is widely practised. The rest highlighted issues of unfair competition between companies.

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

The first actions that KIs would take to improve the procurement system would be to:

- Make the pharmaceuticals sector independent from the procurement of other products.
- Speed up the pace at which routine work is completed.
- Ensure that tender committee's decisions and the process itself are conducted with greater levels of discretion.
- Monitor and regulate the procurement committee activities and ensure the selection of qualified members to sit on the committee.
- Increase levels of cooperation between various governmental sectors to avoid time wasting bureaucratic procedures and duplication of efforts.

- Improve the General Foreign Trade Organization function, by reducing periods of medicine shortage, by standardizing the procedures and providing medicines at suitable times because these periods of delay affect the dissemination of emergency medicines and force governmental hospitals to wait for long periods to receive these medicines.
- Recruit staff in the pharmaceutical sector with scientific degrees and ensure that vendors and suppliers have at the least a scientific educational background.
- Develop job descriptions and terms of reference for the committee and its members and conduct continual training programmes.
- Develop a process of medicines purchasing according to two criteria. The first one is the quality – the most important – and the second is the price, excluding cardiac medicines and anaesthesia, which should be purchased on the basis of their quality only.
- Ensure that medicine procurement is done according to specific laws dedicated to medical products.
- Eliminate nepotism or favouritism as a factor of influence in the selection of members for the procurement committee. Selection must be based on scientific reasoning and merit.

*Data analysis and interpretation*

There were 16 indicators related to the procurement of medicines, 11 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 procurement of medicines.

The final score from the questionnaire on the procurement of medicines function is 6.3**.** Table 17 shows that the result is positive and it ranks the procurement function as marginally vulnerable to corruption, since it is between the ranges (6.1 - 8.0).

**Table 17. Final score for the vulnerability to corruption of the procurement function**

| | **Extremely vulnerable** | **Very vulnerable** | **Moderately vulnerable** | **Marginally vulnerable** | **Minimally vulnerable** |
|---|---|---|---|---|---|
| | **0.0 – 2.0** | **2.1 – 4.0** | **4.1 – 6.0** | **6.1 – 8.0** | **8.1 – 10.0** |
| Procurement score | | | | 6.3 | |

## 4.8 Distribution of medicines

*Introduction*

The Ministry of Health recognizes the importance of the distribution activity in the management of pharmaceutical products, and the long process and numerous steps it entails, from port clearing, receiving and inspection, inventory control, storage, delivery and disposition, during which it could be subjected to theft, fraud or any other type of unethical behaviour. Therefore, it was essential to issue laws and establish entities the responsible for controlling the distribution process.

The Ministry of Health has issued legislation relating to the distribution process:

- Decree No. 40 on 1st Aug 1949 and its amendments, law No 67 in 2001, for regulating trade of medical/chemical products.
- An executive decision in 1988 for article 21 from decree No 40 stating the requirements for chemical warehouses.
- A regulatory decision, No 8/T on 8th March 1990, pertaining to the requirements of domestic chemical stores.,
- A regulatory decision, No 5/T in 2004 for supplying imported medicines.

There is also a written document including all the required procedures necessary for establishing a medical store, available at the Ministry of Health[6].

The distribution of pharmaceutical products is supervised by the Drug Quality Control Directorate. The Drug Quality Control Directorate is responsible for inspecting storehouses that store and distribute medicines and to check their compliance to General System of Preferences. Stores in the Syrian Arab Republic are offered the General System of Preferences certificate through procedures specified particularly for this purpose, but unfortunately the Drug Quality Control Directorate is unable to present a GDP certificate despite its plans of applying the GMP, GSP, GDP, GPP, GLP and GCP across the whole pharmaceutical sector. This directorate also has guidelines for evaluating and inspecting stores according to the GMP and the specified requirements of the Ministry of Health.

The GFTO Medicine division/Sedalia, is concerned with importing/procuring and distributing pharmaceutical products not locally made through its stores in Ein Tarm. It also deposits locally manufactured medicines at its stores on consignment.

In the past, Sedalia was the only department that imported/distributed foreign medicines but nowadays it is shared with private agencies according to a decision

[6] See the book of acts, decrees, regulating decisions of pharmacy profession issued by the Syrian pharmacy syndicate.

taken by the economic committee and approved by Head of Ministry Council on 9th May 2004. This decision was issued to allow private agents to import medicines that are not related to general health or locally produced and distribute them to the private sector only. Procuring medications that are related to general hygiene such as vaccines, immunoglobulin/sera, blood derivatives and antitoxins and antidotes, is exclusively limited to Sedalia. There is a database of medications that are allowed to be procured by private agencies, including the pharmaceutical dosage, composition, price, name of manufacturers and warehouses and it is available at the Ministry of Health.

There are four parties involved in the distribution process.

1. Sedalia procures, stores and distributes imported medicines to public health centres through its stores. It only stores local medicines that have been purchased from local pharmaceutical manufacturers, purchased through offers or tenders, for public health centres. It also procures, stores and distributes medications that are related to general health for both public and private health centres.

2. Local pharmaceutical manufacturers store and distribute their medicines to the private health sector, hospitals and pharmacies, from stores of manufacturers through private stores.

3. Exclusive agents of foreign companies import medicines that are not related to general health or locally produced and distribute them to the private sector only.

4. Donors supply the Ministry of Health with foreign medicines at no cost. Foreign medicines can be donated free of charge by international donors and distributed through the Ministry of Health care centre.

There is a cascade chart from central source to lower levels in Annex 11 illustrating the steps of medicine distribution.

In order to assess the level of transparency and extent of vulnerability to corruption for the distribution function, 14 KIs were interviewed. They were selected from different sectors and backgrounds (Table 18).

**Table 18. Backgrounds of KIs interviewed for the distribution function**

| Governmental | | | Private | | | | Total |
|---|---|---|---|---|---|---|---|
| Ministry of Health | GFTO | Manufacturer and scientific office | Private store | Scientific advertising office and store | Manufacturer and store | Manufacturer | |
| 2 | 4 | 2 | 3 | 1 | 1 | 1 | 14 |

*Comments on each indicator*

**Indicator VIII.1:** Is there a system in place that can expedite port clearing?

42.85% of the KIs said that such a system exists while 35.71% said that such a system does not exist and the remaining 21.44% did not know. The percentage of the valid answers is 54.54%.

**Indicator VIII.2:** To what extent do you agree with the following statement:

"Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process"?

Of the KIs, 42.86% disagreed and 28.57% strongly disagreed with the statement "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process". A further 14. 29% (2 out 14) agreed and the remaining 14.29% (2 out 14) did not know (Figure 21).

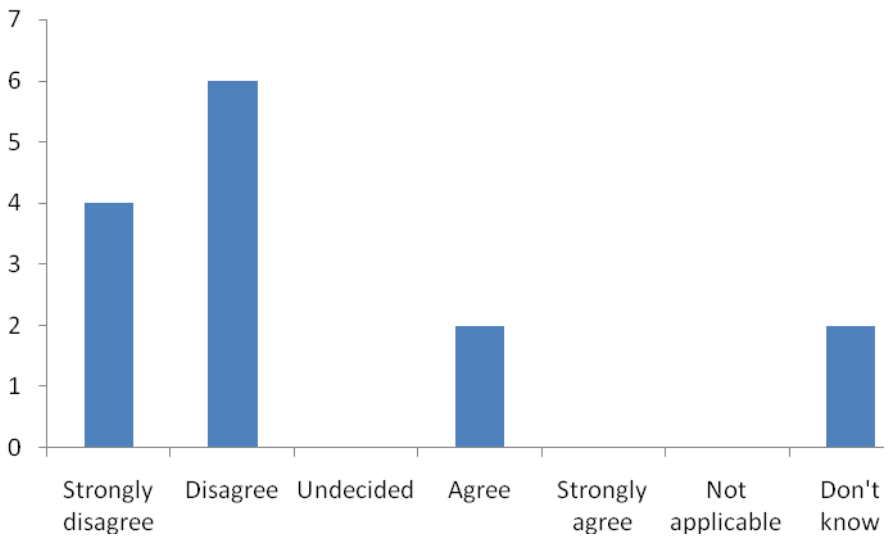



**Figure 21. Perceptions of KIs of port clearing**

As is clear from indicators VIII.1 andVIII.2, a port clearing system does exist but it needs developing and improving. This is why most of the KIs disagreed or strongly disagreed that port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process.

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

There is an inspection system. The system involves a separate space allocated for checking goods on arrival. A person is responsible for checking receipts against the packing list when supplies arrive at the warehouse and then preparing documentation through a receiving report. Of the KIs, 64.28 % said that such a system exists, while 28.57 % said that such a system does not exist.

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

There is a coding system used to identify government medicines and that system differs from one place to another. Of the KIs, 42.85% answered that there is a coding system, while the other 42.85% said that there is no coding system and 14.28% did not know.

**Indicator VIII.5:** Is there systematic and orderly shelving of products in warehouses or storerooms?

There is systematic warehousing at medicine stores but it differs from one store to another according to the departments to which these stores are affiliated. All the warehouses are organized systematically and medicines are shelved by expiry date. However, there is no master map of the warehouses. All KIs said that systematic warehousing does exist

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

Some warehouses have security management systems for storage and distribution while others do not have such security. This may be attributed to the diverse set of departments to which these stores are affiliated. This security system includes monitoring of entry and exit to warehouse, locks with controlled key distribution, and an alarm system. Personnel are subject to a physical search when leaving the warehouse. Finally the controlled substances are separated and secured. Of the KIs, 78.57% said that there is a security management system and the percentage of the responses was 51%, while the other 21.42% said that such a system does not exist.

**Indicator VIII.7:** Are there SOPs for stock management at each level of the distribution system?

There are no SOPs for stock management at each level of the distribution system but staff does work in a proper way according to a chain of command for distribution. 57.14% of KIs said that such SOPs do exist and 42.85% said that such procedures do not exist.

**Indicator VIII.8:** Is there an inventory management system at each level of the distribution system that provides minimum information?

There is a system for directing the stocktaking process and it is used at every level of distribution system and in all departments. This system provides: the average stock,

the amount of safety stock, the frequency of reordering, the quantity of reordering, the average inventory, the lead time and the expiry date. 92.85% said such a system exists, while only 7.14% (1 out 14) said that there is no inventory management system.

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

There is a process of reconciliation between records and the actual numbers of products in warehouses. The frequency of this activity varies between departments; some do it daily, others weekly, monthly or every 3 months. 78.57% of the KI said such a process of reconciliation between records and actual numbers does take place, while 14.28% said that such a process does not take place.

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

There are external independent auditors, who inspect warehouses, and provide evidence/report by way of a warehouse audit but this auditing is not performed regularly. 78.57% of KIs agreed that external audits are conducted on warehouses, while 21.43% (2 out of 14) said that such audits do not take place, and 7.43% did not know.

**Indicator VIII.11:** Is there a system, computerized or manual, historical or current, in place to track the movement of pharmaceuticals from a warehouse to a health facility?

There is either a computerized or manual system at all distributing centres for recording pharmaceuticals movements from warehouses to health centres. These systems provide information including the type and quantity of medicines that have left the warehouse, the intended recipient of these medicines, lead time and date that the medicines arrived at the designated health facility, documentation of problems with supplies received and personnel who verify the amounts received. All the KIs said that such a system exists.

**Indicator VIII.12:** Does the health facility have an appropriate procedure for requesting medicines?

There are appropriate procedures at all health centres for requesting medicines. The request form states the medicine to be supplied, the dosage form, strength and quantity. These requests are checked by a responsible person and dated and signed. Most of the KIs 92.87% said that such a procedure exists.

**Indicator VIII.13:** Are there appropriate written guidelines on the transportation and delivery of medicines to and from warehouses?

There are proper instructions taken into consideration while transporting/delivering medicines to and from warehouses but they are not written guidelines. These instructions on transportation cover the problems of adverse transportation conditions, problems of theft during transportation, mechanisms to prevent swapping of consignments during transportation and require that the person responsible for transportation sign a receipt. 64.28% of KIs said that such guidelines exist, while 28.7% (4 out of 14) said that such guidelines do not exist and 7.15% did not know.

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

There is communication system between suppliers and final users resulting in the smooth coordination of the distribution system. 71.42% of the KIs said that such a system does exist, while 28.57% said the system does not exist. The percentage of responses was 71.4%.

**Indicator VIII.15:** Does a programme exist for monitoring and evaluating the performance of the medicine distribution system?

Medicines are distributed according to a specific system and each pharmaceutical establishment has its own system for monitoring and evaluating the performance of medicine distribution system that is not controlled or regulated by related directorates and committees. 42.85% of the KIs said that such a programme does exist, while 50% said that such a programme does not exist and 7.15% did not know.

As each warehouse has its own system for evaluating the distribution process there are differences in the KIs responses regarding the programme of monitoring and evaluation of the system. Across the warehouses there appear to be differences in the regularity, how systematic, and how well documented the monitoring is. There are also no reports identifying weakness and no evidence that weaknesses, if they are identified, are addressed. The final reports are not publicly available.

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

There are policies and procedures for penalizing individuals or agencies/companies for unethical behaviour. They specify kinds of punishment that should be applied depending on the nature and magnitude of the act of corruption There is also evidence that individuals are sanctioned for corrupt behavior. 57.14% of KIs said that there are sanctions imposed on individuals or agencies for theft or other corrupt practices, 35.71% said that such a sanction does not exist while 7.15% did not know.

**Indicator VIII.17:** Does the medical store/health facility have appropriate procedures for the disposal of expired and/or spoiled medicines?

There are appropriate procedures for disposing of expired or spoiled medicines and they are applied in all medical warehouses. These procedures include a mechanism to notify the responsible committee about expired medicines and a list of disposed medicines. There are also committees that are responsible for supervision of the disposal of medicines and provide reports on the disposal. 85.71% of KIs said that there are procedures for disposal of medicines while 7.14% said that such procedures do not exist.

**Indicator VIII.18:** To what extent do you agree with the following statement:

"There are very rarely leakages in the medicine distribution system in your country"?

21.4% of the KIs strongly disagreed and 35.71% agreed with the statement "There are very rarely leakages in the medicine distribution system in your country", while 35.71% disagreed and 7.14% (1 out of 14) did not know (Figure 22).

In fact not all the warehouses have the desired systems (see indicators VIII.6, VIII.8, VIII.11 and VIII.16), so leakages in the medicine distribution system are possible.

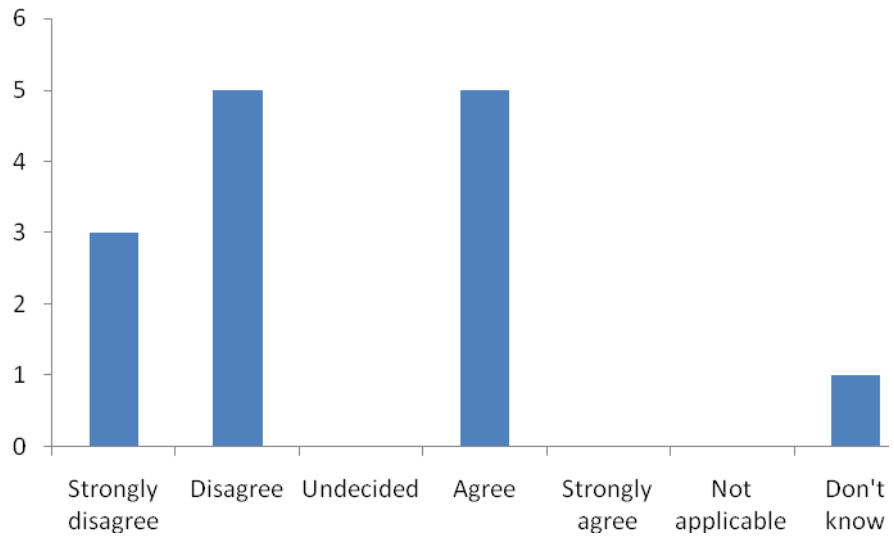



**Figure 22. Perceptions of KIs to leakages in the medicine distribution system**

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

The first actions that KIs would take to improve the systems and processes of public sector medicine distribution would be to:

- Establish a trained group to carry out the distribution process.

- Ensure better enforcement of laws regarding the distribution process.
- Prevent smuggling.
- Provide medicines that are manufactured by the State.
- Provide public hospitals with medicines without packaging.
- Introduce a coding system for identifying governmental medicines.
- Develop an information system that can track the movement of pharmaceuticals that includes the time and date that the medicines arrived at the designated health facilities.
- Implement standard procedures for the transportation and distribution of medicines to take in consideration health requirements of medicines and to avoid exposure to damage, such as refrigerated transportation.
- Install standard mechanisms to maintain the correct conditions for storage of medicines.
- Develop a clearly written manual explaining in detail the requirements of the distribution system.
- Review the organizational work of the GFTO.
- Establish automated systems and global procedures to secure the storage of medicines.

**Indicator VIII.20:** In your opinion, what types of unethical behaviour are common in the distribution in your country?

33.3 % of the KIs said that there is no unethical behaviour in the distribution process, while 41.6% said that all kinds of unethical behaviour exist including bribery and favouritism, which was mentioned by 8.3% of them.

*Data analysis and interpretation*

There were 19 indicators related to the distribution of medicines, 16 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 distribution of medicines.

The final score of the questionnaire for the distribution of medicines function is 6.61. Table 19 shows that this result falls between the ranges (6.1 - 8.0) rating the distribution of medicines function as marginally vulnerable to corruption.

**Table 19. Final score for the vulnerability to corruption of the distribution of medicines function**

| | Extremely vulnerable | Very vulnerable | Moderately vulnerable | Marginally vulnerable | Minimally vulnerable |
|---|---|---|---|---|---|
| | 0.0 – 2.0 | 2.1 – 4.0 | 4.1 – 6.0 | 6.1 – 8.0 | 8.1 – 10.0 |
| Distribution score | | | | 6.61 | |

# 5. Recommendations

## General

1. Develop specific criteria for committee membership selection. These criteria must specify the professional qualifications, technical skills and work experience required and should be written down and made publicly available.
2. Provide standard operating procedures and guidelines and ensure their application.
3. Establish good practices guidelines for the different pharmaceutical operations, such as good storage practice, good distribution practice, good dispensing practice, good pharmacy practice, good quality control laboratory practice; as well as renewing the existing guidelines to make them compatible with international standards such as the International Conference on Harmonization, US Food and Drug Administration, etc.
4. Write guidelines on conflict of interest. A conflict of interest declaration form should be used in all areas of health services and for all functions, specifying the definition of what constitutes a conflict of interest and the actions to be taken in case of any misdeclaration or breach of the conflict of interest guidelines.
5. Provide a balance between improved legislation across all pharmaceutical sectors. Development of improved legislations should be at the same level for all areas.
6. Allow other sectors such as the Women's Association and nongovernmental organizations to participate, in collaboration with the Ministry of Health, in the development process.
7. Improve the Ministry of Health website to make it a suitable channel for publishing and advertising all public information and procedures.
8. Provide criteria for processing applications in certain pharmaceutical functions.
9. Make the recruitment of personnel dependent on successful completion of training. These courses must be advertised on the Ministry of Health website.
10. Provide training and development for all technicians and providing them with clear and suitable responsibilities.
11. Encourage employment in the Ministry of Health and attracting senior experts from a wide range of specializations.
12. Support technicians and providing encouragement for high work standards by providing financial incentives and awards.

13. Automate and computerize all health directorates to ensure accuracy and credibility and to facilitate the overall performance of the Ministry of Health work.
14. Define and prepare clear job descriptions for all workers in the health sector.
15. Provide administrative and judicial appeals systems that are independent from the body that makes the initial decision.
16. Specify a time-frame and fees for submitting files and applications.

**Specific**

*Drug registration*

17. Review registration procedures and their amendments, based on international standards.
18. Expand committees to attract expertise from outside the Ministry of Health.
19. Select imported medicines based on careful scientific studies that require more than certificates of origin in accordance with international practice.
20. Form committees to follow up on medicines in the market particularly imported ones.

*Licensing*

21. Define standards and conditions to be met in terms of premises, facilities, processes, personnel, equipment, materials, etc., in order to get a licence.
22. Speed up the licensing process.
23. Define weaknesses in the system and enforce corrective measures to reduce unethical behaviour, such as applying double standards and favouritism.
24. Define and apply a policy of retribution and punishment.
25. Rotate the administrative staff, at specified time periods, the maximum period to serve should be 5 years.

*Inspection*

26. Increase the number of inspectors and train them to be qualified and proficient in their role.
27. Provide regular training that is in accordance with the internationally accepted guidelines to enhance the level of experience of inspectors. Also, recruitment should be based on merit and expertise in the area.
28. Perform regular and periodic inspections, at least every 2 years, of all pharmaceutical companies.
29. Conduct regular rotation of inspectors.
30. Conduct inspection of all pharmaceutical establishments (pharmacies, stores etc.).

31. Conduct various types of inspection of pharmaceutical establishments including comprehensive or routine inspection, concise inspection, follow-up inspection, special inspection and investigative inspection.
32. Subject the inspection system to external auditing.

*Control of promotion*

33. Develop a set of comprehensive ethical criteria that conforms to the WHO Ethical Criteria for Medicinal Drug Promotion and advertisement.
34. Acknowledge the potential for corruption in promotional practices and introduce measures to prevent this.
35. Direct supervision from the Ministry of Health over the work of medical associations.
36. Coordinate with the Pharmacists and Physicians Association on the subject of promotion.
37. Conduct clinical surveillance on all medicine that is locally manufactured and protected at the country of origin.
38. Control the development and application of laws.
39. Allow nongovernmental organizations to participate in the control and regulation of the promotion process.

*Clinical trials*

40. Insist on passing the new decree on clinical trials as quickly as possible and make sure that this law is appropriately enforced and clinical trials are performed in accordance with it.
41. Develop a public database listing the protocols and results of all clinical drug trials.

*Selection of medicines*

42. Create an independent therapeutics committee composed of health professionals with appropriate scientific and medical knowledge, experience and skills.
43. Make all decisions for including a medicine on the list based on clear criteria and ensure they are carried out in a transparent and open manner.
44. Improve the guidelines for the selection of medicines process, particularly for adding or removing medicine from the essential medicine list.

*Procurement*

45. Introduce an internal and external auditing system to assess the financial and technical performance of the procurement office.
46. Develop clear criteria for selecting the procurement committee members.
47. Computerize the procurement system, including product records and the monitoring of supplier performance.

*Distribution*

48. Improve the coding system to make it specifically identify government supplies and differentiate them from those circulated in the private sector.
49. Develop standard operating procedures for stock management at each level of the distribution system.
50. Introduce a computerized system to track the movement of pharmaceuticals that leave warehouses to go to health centres.
51. Provide appropriate written guidelines on the transportation and delivery of the medicines from/to the stores.
52. Establish a programme for monitoring and evaluating the performance of the medicine distribution system.
53. Establish a national registry for patients and diseases that are existent in the country and refer to this registry in regulating the distribution process.

# 6. Conclusion

Difficult challenges face the pharmaceutical sector in the Syrian Arab Republic such as the increasing demand on health services and the increased gap between health revenue and services costs. Despite this the sector has made several constructive developments over the past few decades. The results of this study draw attention to the importance of developing structures, regulations and procedures to increase transparency and accountability in the public pharmaceutical system, thus decreasing the sector's vulnerability to corruption and/or unethical practices.

The study showed both strengths and gaps in existing regulations and administrative procedures. In general, the majority of key informants were appreciative of the efforts undertaken by the Ministry of Health to improve the pharmaceutical sector through the different functions outlined in this report.

The study revealed that the areas of medicines licensing, procurement and distribution are marginally vulnerable to corruption, medicine registration, inspection, promotion and selection are moderately vulnerable to corruption, while control of clinical trials is very vulnerable to corruption (Table 20). The full scores for each area are given in Annex 12.

**Table 20. Interpretation of results by area**

| Function | Score | Interpretation |
|---|---|---|
| Registration | 5.12 | moderately vulnerable |
| Licensing | 7.42 | marginally vulnerable |
| Inspection | 5.88 | moderately vulnerable |
| Promotion | 4.47 | moderately vulnerable |
| Clinical trials | 3.36 | very vulnerable |
| Selection | 5.67 | moderately vulnerable |
| Procurement | 6.30 | marginally vulnerable |
| Distribution | 6.61 | marginally vulnerable |

In conclusion, efforts need to be intensified to introduce a conflict of interest policy, with clear guidelines and sanctions for reprehensible acts. A mechanism for whistle-blowing, which protects whistle-blowers from repercussion and public officials from false claims needs to be introduced. All operating procedures need to be standardized and produced in a clear publicly accessible form, and all criteria and guidelines for the selection and operation of committees need to be documented and made publicly available, perhaps through active advocacy and marketing of the Ministry's efforts.

The study also showed that improvements are most needed in the fields of control of medicines promotion and clinical trials. Actions to be taken include strengthening the legislative structures, improving regulations and increasing the level of mandatory information available to the public. Further, the development of an ethical infrastructure and codes of conduct and guidelines for employees are equally important. These would aim at improving the awareness and keenness of employees of the sector to enable them to perform according to acknowledged moral values and ethical principles.

This national assessment is the first component of the national good governance for medicines programme and it will be defined through a nationwide consultation process with stakeholders. It will provide a platform for discussion at the national level to develop a national framework. In summary, it is hoped that this work will be fruitful and contribute to the effective development of and provide support for the pharmaceutical sector, which in turn will benefit society.

# 7. Resource documents

Publications of the Ministry of Health

Measuring transparency in the public pharmaceutical sector (Assessment Instrument working document for field testing and revision March 2008)

Measuring transparency in medicines registration, selection and procurement (Four country assessment studies). Geneva, World Health Organization, 2006. http://www.who.int/medicines/areas/policy/goodgovernance/WHO_PSM_PAR_2006.7.pdf. Accessed 13 July 2009.

*Good governance for medicines*. Geneva, World Health Organization, 2008. (www.who.int/medicines/ggm). Accessed 13 July 2009

Book of Acts, Decrees, and regulating decisions of the pharmacy profession issued by the Syrian Arab Republic pharmacy syndicate.

The national medicines list of the Syrian Arab Republic

Tranaparency International, *The Global Corruption Report 2006: Corruption and Health,* London, Pluto Press, 2006. www.moh.gov.sy

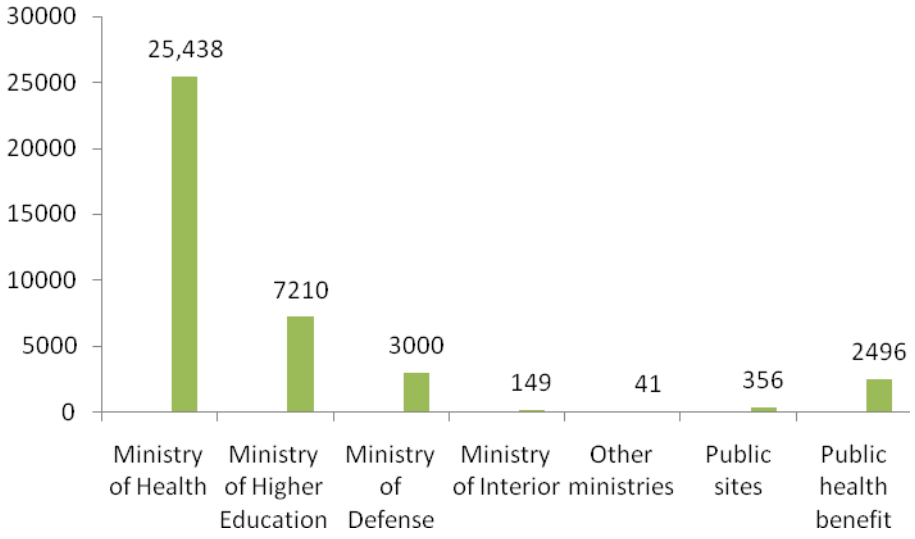
Essential medicines (Bashar Jamal)

*WHO Model List of Essential Medicines* 15th list, Geneva, World Health Organization, 2007.

Contracts System in the Syrian Arab Republic (24th November 2004)

# Annex 1. Government health expenditure

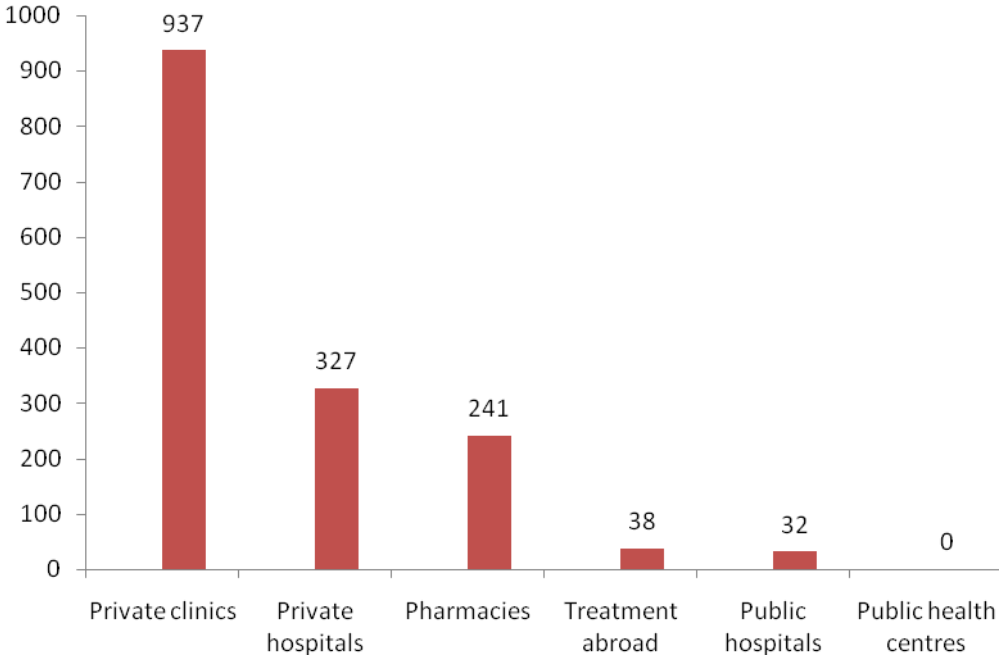
**Government health expenditure 2006**




Expenditure in million Syrian pounds

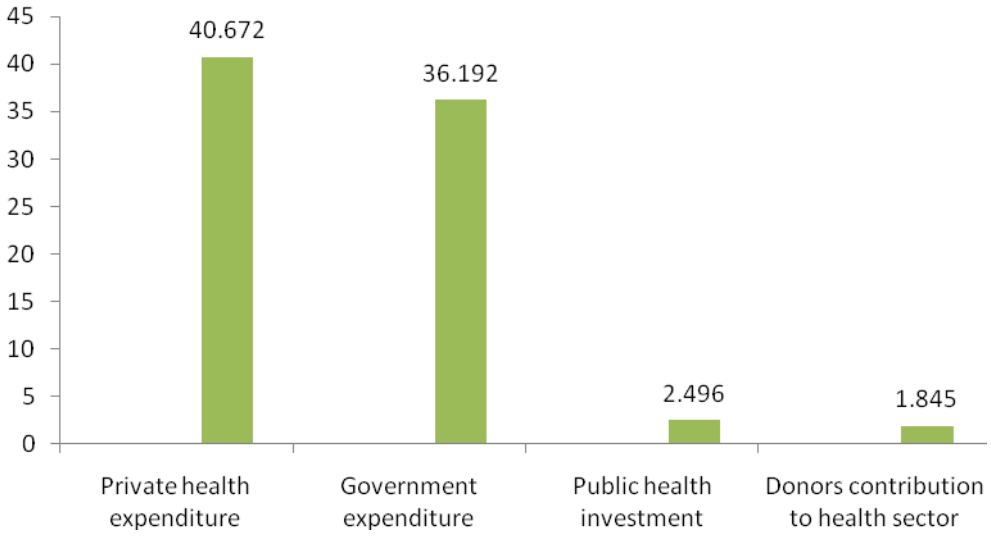
# Annex 2. Private health expenditure

**Private health expenditure per person per year, 2002**




Expenditure in million Syrian pounds

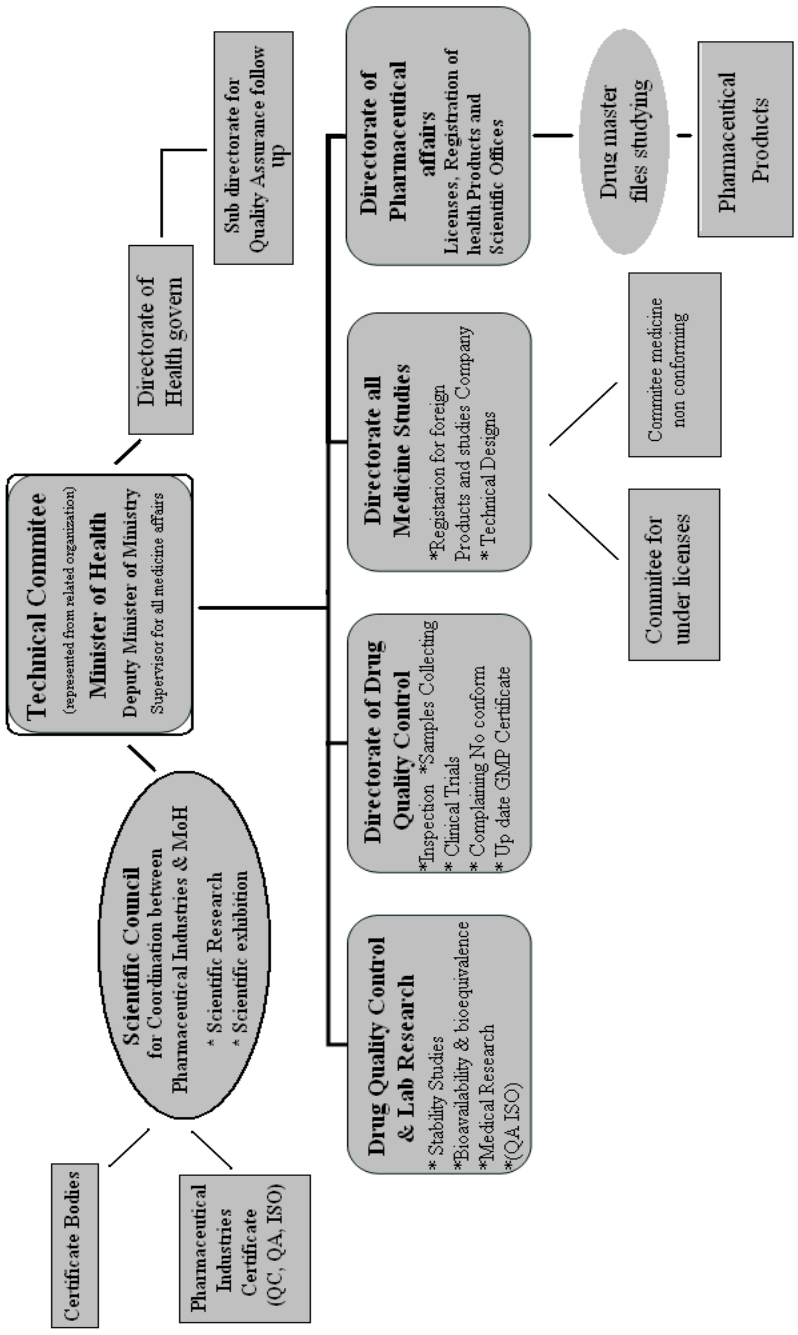
# Annex 3. Total health expenditure, 2006




Expenditure in million Syrian pounds

# Annex 4. Organizational structure of the pharmaceutical sector

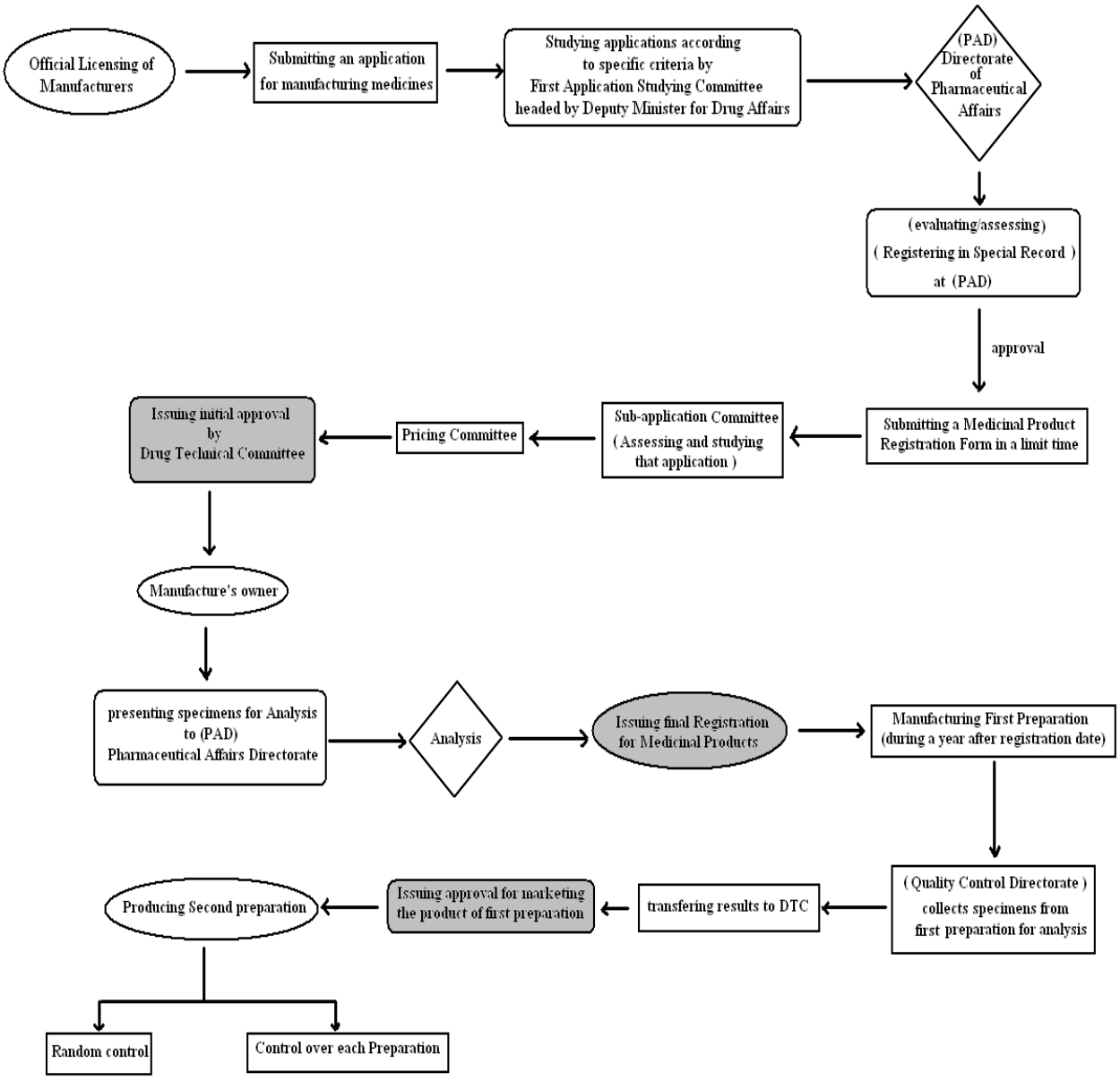
**Organization chart for quality system for medicines in the Syrian Arab Republic**



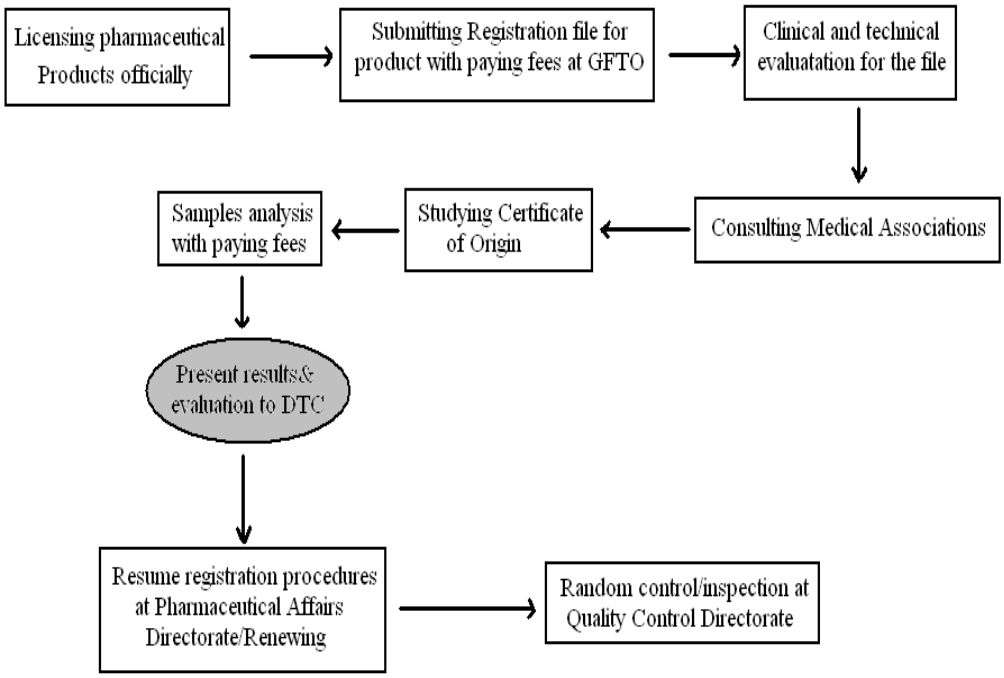
# Annex 5. Number and distribution of key informants

| Type of KIs | Number of KIs | Number of interviews |
|---|---|---|
| **Governmental sector** | | |
| MoH | 18 | 39 |
| GFTO | 5 | 7 |
| Stores | 2 | 4 |
| University | 4 | 4 |
| Hospital University | 3 | 3 |
| | Total number of KIs **32** | Total number of interviews **58** |
| **Private sector** | | |
| Manufacturer | 1 | 1 |
| Manufacturer and Scientific office | 3 | 13 |
| Scientific Advertising office | 5 | 8 |
| Private Store and Scientific Advertising office | 2 | 7 |
| Private Store | 18 | 18 |
| Manufacturer and Private Store | 1 | 2 |
| Private Hospitals | 1 | 1 |
| | Total number of KIs **31** | Total number of interviews **50** |
| **Nongovernmental organization** | | |
| Pharmacy syndicate | 3 | 7 |
| **Media** | | |
| | 3 | 3 |
| **Total** | **70** | **118** |

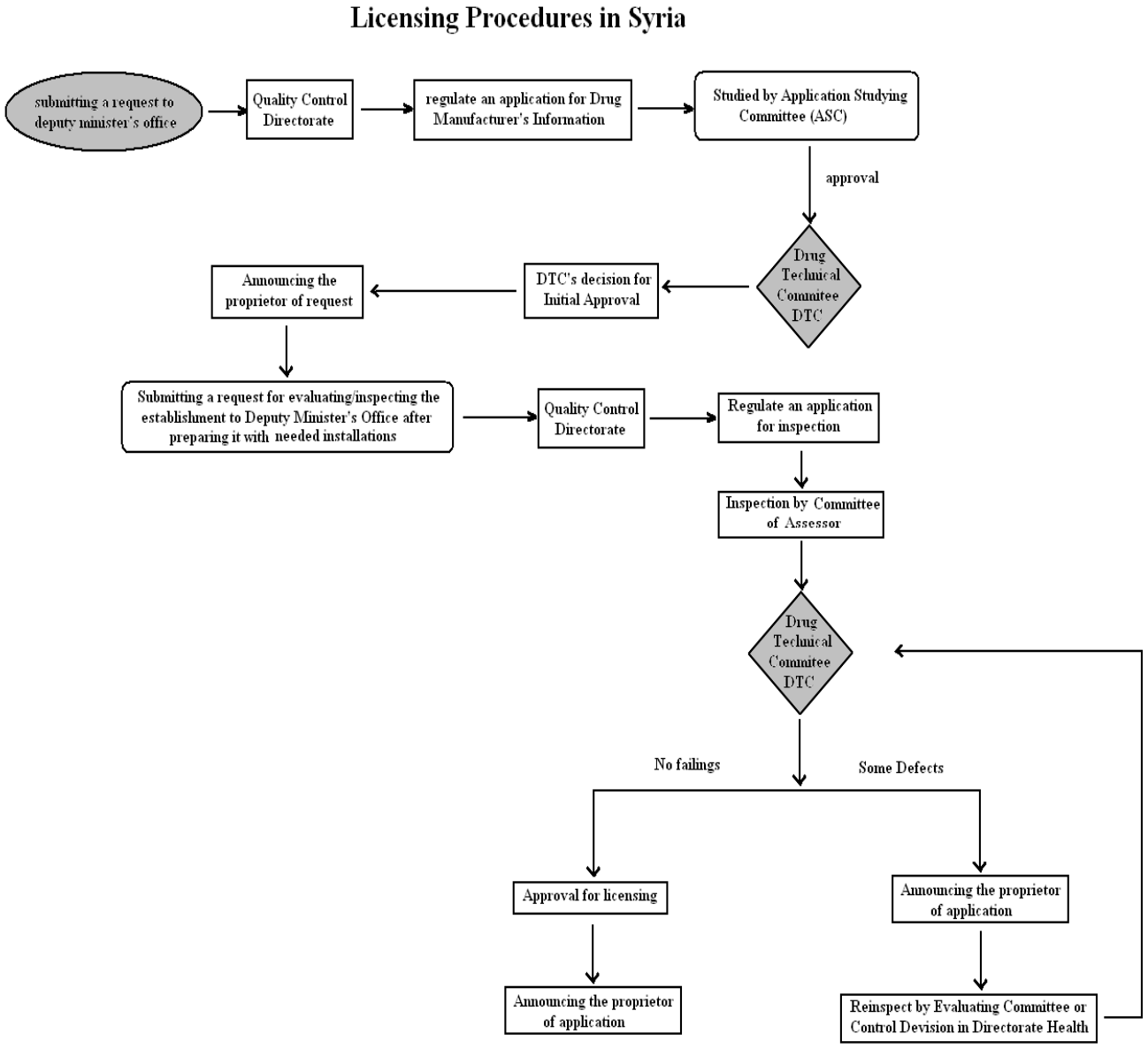
# Annex 6. Procedure for registering local medicines



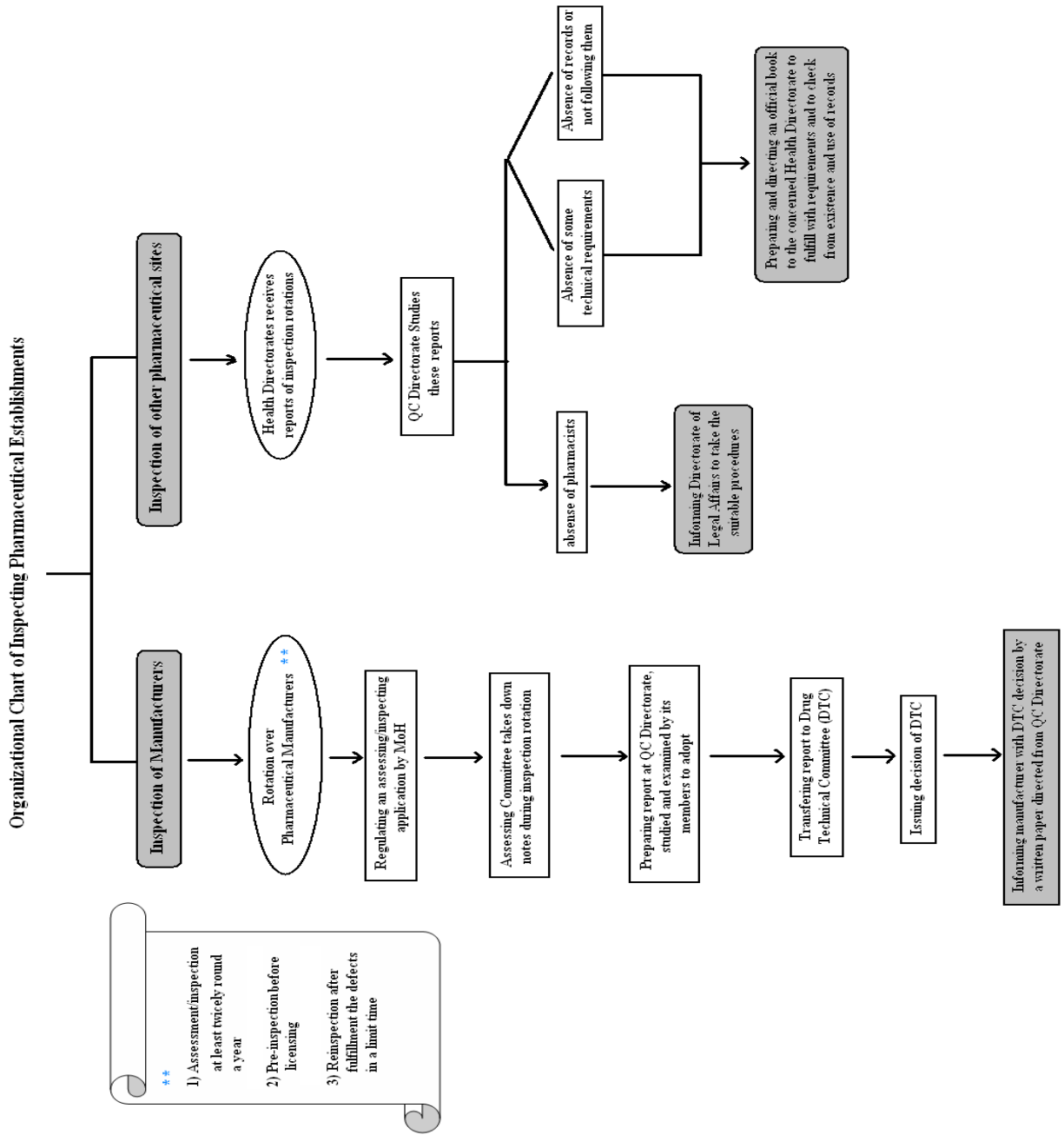
# Annex 7. Procedures for registering foreign pharmaceutical products



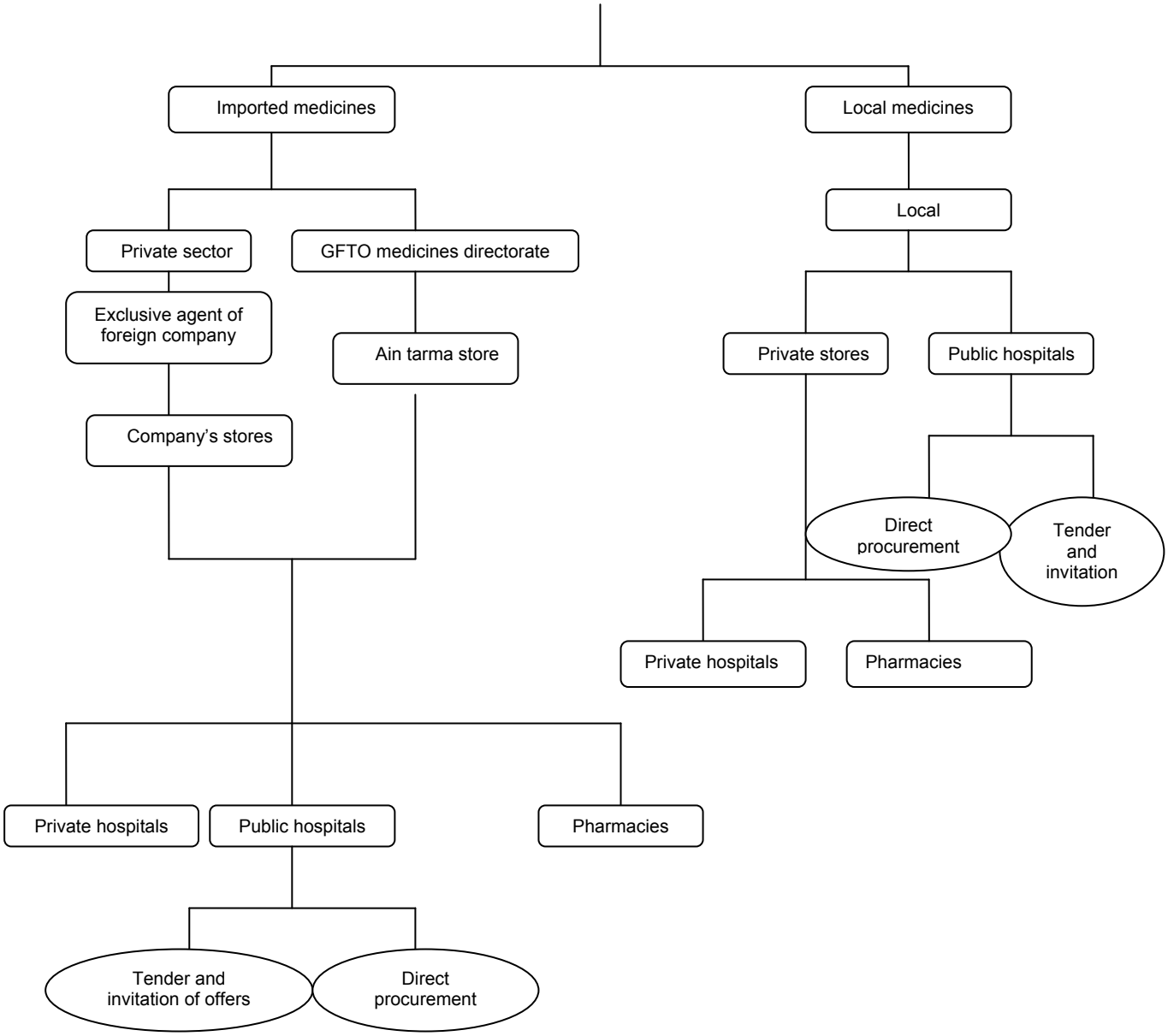
# Annex 8. Licensing procedures in the Syrian Arab Republic



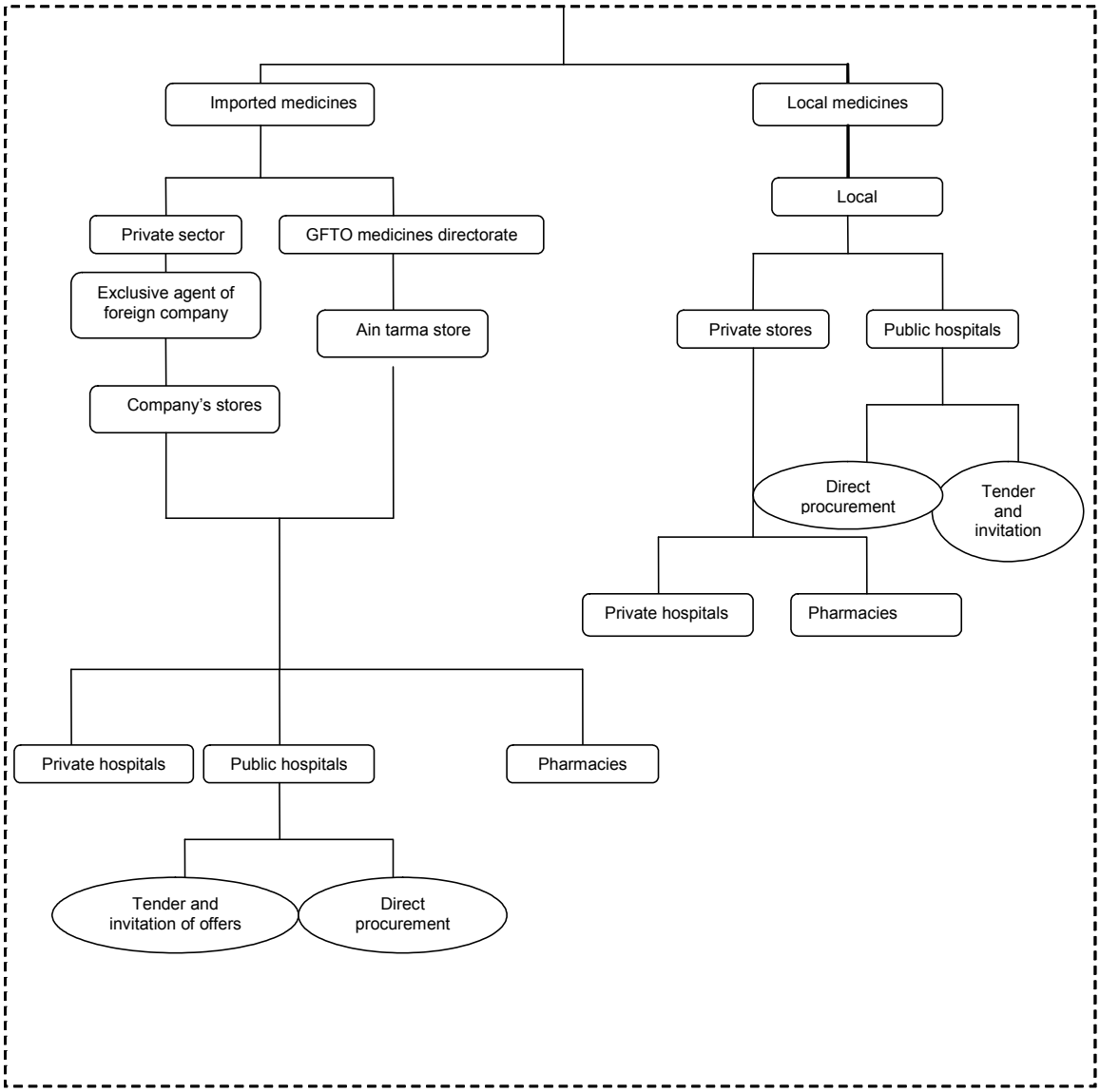
# Annex 9. Organizational chart for inspecting pharmaceutical establishments



# Annex 10. Procedure for offering the GMP certificate to pharmaceutical establishments



# Annex 11. Medicines distribution process



# Annex 12. Score sheets of functions

## 1. Registration

| Registration | K1 | K2 | K3 | K4 | K5 | K6 | K7 | K12 | K17 | K18 | K30 | K35 | K36 | K41 | K44 | K46 | K52 | K60 | K66 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator 1.1** | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 17 | 0.89 |
| **Indicator 1.2** | 0.75 | 1 | 0 | 1 | 0.25 | 1 | 1 | 0.63 | 0.62 | 0.88 | 0.88 | 1 | 1 | 1 | 1 | 0.88 | 0.88 | 1 | 0.57 | 15.3 | 0.81 |
| **Indicator 1.3** | 0.6 | 0.86 | 0.6 | 0.7 | 0.86 | 0 | 0.86 | 0.43 | 0.71 | 0.57 | 0.71 | 1 | 0.86 | 0.86 | 0.86 | 0.86 | 0.75 | 0.83 | 1 | 13.9 | 0.73 |
| **Indicator 1.4** | 0.5 | 0 | 0.8 | 0.5 | 0.5 | 0.5 | 0.6 | | | 0.5 | 0.67 | | 0.83 | 0.83 | 0.83 | 0.2 | 1 | 0 | | 7.43 | 0.44 |
| **Indicator 1.5** | 0.75 | 1 | 1 | 0.9 | 1 | 0.5 | 1 | 1 | 1 | 0.88 | 0.75 | 1 | 0.75 | 1 | 1 | 1 | 1 | 1 | 1 | 17.5 | 0.92 |
| **Indicator 1.6** | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | | 2 | 0.12 |
| **Indicator 1.7** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 17 | 0.89 |
| **Indicator 1.8** | 0 | 0 | 0.5 | 0 | 0.16 | 0 | 0.16 | 0 | 0 | 0 | | 0.33 | 0.33 | 0.33 | 0.66 | 0.5 | 0 | 0.4 | | 3.37 | 0.2 |
| **Indicator 1.9** | 0.63 | 0 | 0.13 | 0.4 | 0.25 | 0.38 | 0.63 | 0 | 0 | 0.25 | | 0.63 | | 0.63 | 0.5 | 0.8 | 0 | 0.33 | | 5.56 | 0.35 |
| **Indicator 1.10** | 0 | 0 | 0 | 0.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.5 | 0.03 |
| **Indicator 1.11** | 0.38 | 0.38 | 0 | 0.1 | 0 | 0.1 | 0.57 | 0 | 0.25 | 0 | 0.13 | 0.75 | 0.6 | 0.75 | 0.88 | 0.88 | 0 | 0.5 | | 6.27 | 0.35 |
| **Indicator 1.12** | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 8 | 0.42 |
| **Total** | | | | | | | | | | | | | | | | | | | | | 6.15 |
| **Final score** | | | | | | | | | | | | | | | | | | | | | 5.12 |

## 2. Licensing

| Licensing | KI1 | KI2 | KI3 | KI4 | KI5 | KI12 | KI13 | KI18 | KI20 | KI23 | KI24 | KI31 | K37 | K41 | K45 | K55 | K62 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator II.1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 17 | 1 |
| **Indicator II.2** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 17 | 1 |
| **Indicator II.3** | 0.5 | 0.66 | 0.66 | 0.5 | 0.83 | 0 | 0.8 | 0.67 | 0.83 | 0.8 | 0.67 | 0.83 | 1 | 0.83 | 0.67 | 1 | 0.83 | 12.08 | 0.71 |
| **Indicator II.4** | 0 | 1 | 1 | 1 | 0 | 0 | 0 |  | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |  | 10 | 0.67 |
| **Indicator II.5** | 0 | 1 | 1 | 1 | 1 | 1 | 1 |  | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 15 | 0.94 |
| **Indicator II.6** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 17 | 1 |
| **Indicator II.7** | 0.3 | 0 | 0.25 | 0.25 | 0.25 | 0 | 0.25 | 0.25 | 0.25 | 0 | 0.5 | 0.5 | 0.67 | 0.75 | 0.33 |  | 0.25 | 4.8 | 0.3 |
| **Indicator II.8** | 0.5 | 0 | 0.5 | 0.25 | 0 | 0 | 0.25 | 0.25 | 0.25 | 0 | 1 | 0.25 | 0.75 | 1 | 0.5 |  | 0.5 | 6 | 0.38 |
| **Indicator II.9** | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 16 | 0.94 |
| **Indicator II.10** | 0.75 | 1 | 0.8 | 0.8 | 1 | 1 | 0.8 | 1 | 0.8 | 0.2 | 1 | 1 | 1 | 1 | 0.8 | 1 | 1 | 14.95 | 0.88 |
| **Indicator II.12** | 0 | 1 | 0 | 1 | 0 | 0 | 1 |  | 0 |  |  | 0 | 1 | 0 | 1 | 0 | 0 | 5 | 0.36 |
| **Total** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | 8.17 |

## 3. Inspection

| Inspection | KI 2 | KI3 | KI4 | KI5 | KI12 | KI15 | KI24 | KI32 | KI57 | KI65 | KI68 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator III.1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 10 | 0.91 |
| **Indicator III.2** | 1 | 0.75 | 0.6 | 0.75 | 0.75 | 1 | 0.75 | 1 | 1 | 1 | 1 | 9.6 | 0.87 |
| **Indicator III.3** | 0.83 | 0.33 | 0.6 | 0.83 | 0.5 | 0.8 | 0.67 | 0.83 | 0.6 | 0.33 | 0.83 | 7.15 | 0.65 |
| **Indicator III.4** |  |  |  | 0.83 | 0 | 0.5 | 0.5 | 0.83 | 0.6 | 0 | 0.83 | 4.09 | 0.51 |
| **Indicator III.5** |  |  | 0.16 |  | 0 |  | 0.2 | 0.8 | 0 | 0.16 | 0.5 | 1.82 | 0.26 |
| **Indicator III6** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Indicator III.7** | 1 | 1 | 1 |  | 0 | 1 | 1 | 1 | 1 |  | 1 | 8 | 0.89 |
| **Indicator III.8** | 1 |  | 1 |  |  |  | 1 | 0.5 | 1 | 0 | 1 | 5.5 | 0.79 |
| **Indicator III.9** |  |  | 0.4 |  | 0 |  |  | 0.25 | 0.6 |  | 0.8 | 2.05 | 0.41 |
| **Total** |  |  |  |  |  |  |  |  |  |  |  |  | 5.29 |
| **Final score inspection** |  |  |  |  |  |  |  |  |  |  |  |  | 5.88 |

## 4. Promotion

| Promotion | KI1 | KI2 | KI3 | KI4 | KI12 | KI19 | KI24 | KI25 | KI31 | KI35 | KI36 | KI43 | KI44 | KI51 | KI1 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator IV.1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 13 | 0.87 |
| **Indicator IV.2** | 0.4 | 0.6 | 0.625 | 0.6 | 0.5 | 0.78 | 0.8 | 0.8 | 0.7 | 0.6 | 0 | 1 | 0.6 | 0.8 | 0.6 | 9.405 | 0.63 |
| **Indicator IV.3** | 0.875 | 0.9 | 1 | 0.875 | 0.9 | 0 | 0.875 | 0.875 | 1 | 1 | 0 | 0.75 | 1 | 0 | 0.875 | 10.925 | 0.73 |
| **Indicator IV.4** | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 0 |  | 1 | 1 | 1 | 9 | 0.64 |
| **Indicator IV.5** | 0 | 0.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 4.5 | 0.3 |
| **Indicator IV.6** | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 1 |  | 1 | 0 | 1 | 1 | 0 | 1 | 7 | 0.5 |
| **Indicator IV.7** | 0.6 | 0 | 0 | 0.6 | 0 | 0 | 0 | 0.4 | 0.75 |  | 0 | 1 | 0.6 | 0 | 0.6 | 4.55 | 0.33 |
| **Indicator IV.8** | 0.4 | 0 | 0 | 0.4 | 0 | 0 | 0.33 | 0.2 | 0 |  | 0 |  | 0.4 | 0 | 0.2 | 1.93 | 0.15 |
| **Indicator IV.9** | 0.6 | 0 | 0 | 0.6 | 0 | 0 | 0.33 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 4.53 | 0.3 |
| **Indicator IV.10** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.5 | 0 | 0 | 0.5 | 0.03 |
| **Total** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **4.47** |
| **Final score** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **4.47** |

## 5. Clinical trials

| Clinical trials | KI2 | KI3 | KI4 | KI9 | KI10 | KI 11 | KI16 | KI24 | KI32 | KI33 | KI41 | KI63 | KI64 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator V.I** | 0 | 0 |  | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 8 | 0.67 |
| **Indicator V.2** | 0 | 0 |  | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0.17 |
| **Indicator V.3** | 0 | 0 |  | 1 | 0 | 0.8 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 3.8 | 0.32 |
| **Indicator V.4** | 0 | 0 |  | 0 | 0 | 0.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.5 | 0.04 |
| **Indicator V.5** | 0 | 0 |  | 1 |  |  | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 6 | 0.60 |
| **Indicator V.6** | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 1 |  | 7 | 0.58 |
| **Indicator V.7** | 0 | 0 |  | 0.5 | 0.5 | 0.5 | 0.25 | 1 | 0 | 0 | 0.5 | 0 |  | 3.25 | 0.3 |
| **Indicator V.8** | 0 | 0 |  | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 7 | 0.58 |
| **Indicator V.9** | 0 | 0 |  | 0 | 0 | 0 |  | 1 | 0 | 0 | 0 | 0 |  | 1 | 0.1 |
| **Indicator V.10** | 0 | 0 |  | 0 | 1 | 0 |  | 0 | 0 | 0 | 1 | 0 | 1 | 3 | 0.27 |
| **Indicator V.11** | 0 | 0 |  | 0 | 0 | 0 | 0 | 0 |  | 0 | 0 | 0 | 0 | 0 | 0 |
| **Indicator V.12** | 0 | 0 |  |  | 0 | 0.75 | 0.75 | 0 |  | 0 | 1 | 0.75 | 0.75 | 4 | 0.40 |
| **Total** |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **4.03** |
| **Final score** |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **3.36** |

## 6. Selection of medicines

| Selection | KI2 | KI3 | KI 4 | KI5 | KI6 | KI16 | KI24 | KI32 | KI33 | KI41 | KI53 | KI58 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator VI.1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 11 | 0.92 |
| **Indicator VI.2** | | | | | | | | | | | | | | |
| **Indicator VI.3** | 0 | 0 | 1 | 0.57 | 0.7 | 0.9 | 0.43 | 0.83 | 1 | 0.86 | 0.14 | 0.83 | 7.26 | 0.61 |
| **Indicator VI.4** | 0.8 | 0.5 | 1 | 1 | 0.8 | 0.8 | 1 | 0.67 | 0.8 | 1 | 1 | 1 | 10.37 | 0.86 |
| **Indicator VI.5** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 12 | 1 |
| **Indicator VI.6** | | | | | | | | | | | | | | |
| **Indicator VI.7** | 0 | 0 | 0.285 | 0.14 | 0.28 | 0 | 0.43 | 0.14 | 0 | 0.71 | 0 | 0.5 | 2.485 | 0.21 |
| **Indicator VI.8** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.25 | 0 | 0 | 0 | 0 | 0.25 | 0.02 |
| **Indicator VI.9** | 0 | 0 | 0.6 | 0.3 | 0 | 0.7 | 1 | 0 | 0 | 1 | 0 | 0.3 | 3.9 | 0.33 |
| **Indicator VI.10** | 0 | 0 | 0.83 | 1 | 0.6 | 0.7 | 0.67 | 0.75 | 0 | 1 | 1 | 0.6 | 7.15 | 0.6 |
| **Total** | | | | | | | | | | | | | | **4.53** |
| **Final score** | | | | | | | | | | | | | | **5.67** |

## 7. Procurement

| Procurement | K8 | K21 | K22 | K24 | K26 | K27 | K28 | K30 | K32 | K34 | K35 | K38 | K40 | K42 | K49 | K50 | K56 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator VII.1** | 0.77 | 0.75 | 1 | 1 | 1 | 1 | 0.75 | 0.87 | 1 | 1 | 0.78 | 0.89 | 0.55 | 0.75 | 1 | 0.77 | 0.77 | 14.65 | 0.86 |
| **Indicator VII.2** | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 14 | 0.82 |
| **Indicator VII3** | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 15 | 0.94 |
| **Indicator VII.4** | 0 | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 9 | 0.53 |
| **IndicatorVII.5** | 0.3 | 1 | 1 | 0.67 | 1 | 0.33 | 1 | 0.67 | 1 | 0.67 | 0.67 | 0.67 | 0.33 | 0.33 | 0.66 | 1 | 0.66 | 11.96 | 0.7 |
| **Indicator VII.6** | | | | | | | | | | | | | | | | | | | |
| **Indicator VII.7** | 0.43 | 0.7 | 0.7 | 0.83 | 0.86 | 0.14 | 0.43 | 0.6 | 0.57 | 0.43 | 0.28 | 0.28 | 0.16 | 0.43 | 0.71 | 0.71 | 0.5 | 9.34 | 0.55 |
| **Indicator VII.8** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.25 | 0 | 0 | 0 | 0 | 0 | 0.5 | 0 | 0 | 0 | 0.75 | 0.04 |
| **Indicator VII.9** | | | | | | | | | | | | | | | | | | | |
| **Indicator VII.10** | 0.57 | 0 | 0 | 0.71 | 0.71 | 0.86 | 0.86 | 0 | 0.16 | 0.86 | 0.71 | 0.5 | 0.86 | 0.57 | 0.57 | 1 | 0.71 | 9.65 | 0.57 |
| **Indicator VII.11** | 1 | 0 | 0 | 0 | 0.5 | 0.5 | 0 | 0 | 1 | 0.67 | 0.25 | 0.67 | 0.75 | 1 | 1 | 0.5 | 1 | 8.84 | 0.52 |
| **Indicator VII.12** | 1 | 1 | 1 | 1 | 1 | 1 | 0.83 | 0 | 0.2 | 1 | 0 | 0.5 | 0.83 | 0.33 | 1 | 1 | 1 | 12.69 | 0.75 |
| **Indicator VII.13** | 0.5 | 1 | 0.88 | 0.5 | 0.75 | 0.75 | 0.5 | 0 | 0.67 | 0.75 | 0 | 0.86 | 0.86 | 0.71 | | 0.75 | 0.88 | 10.36 | 0.65 |
| **Total** | | | | | | | | | | | | | | | | | | | 6.93 |
| **Final score** | | | | | | | | | | | | | | | | | | | 6.3 |

## 8. Distribution

| Distribution | K3 | K8 | K14 | K19 | K24 | K25 | K30 | K32 | K34 | K39 | K47 | K48 | K54 | K61 | Total | Average |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Indicator VIII.1** | | 1 | | 1 | 0 | 1 | 0 | 1 | 1 | | 0 | 0 | 0 | 1 | 6 | 0.55 |
| **Indicator VIII.2** | | | | | | | | | | | | | | | | |
| **Indicator VIII.3** | 0 | 1 | 0 | 0 | 0.5 | 1 | 0.75 | 1 | 1 | 1 | | 1 | 0 | 1 | 8.25 | 0.63 |
| **Indicator VIII.4** | | 0 | | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 6 | 0.5 |
| **Indicator VIII.5** | 1 | 1 | 1 | 0.67 | 0.67 | 1 | 0.3 | 1 | 1 | 1 | 1 | 0.33 | 0.33 | 0.66 | 10.96 | 0.78 |
| **Indicator VIII.6** | 0 | 1 | 1 | 0.33 | 0.83 | 1 | 0.67 | 0.16 | 0.8 | 0.83 | 0 | 0.2 | 0 | 0.33 | 7.15 | 0.51 |
| **Indicator VIII.7** | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 0 | 1 | 0 | 8 | 0.57 |
| **Indicator VIII.8** | 0 | 1 | 1 | 0.86 | 0.71 | 1 | 0.4 | 1 | 1 | 1 | 1 | 0.29 | 1 | 1 | 11.26 | 0.8 |
| **Indicator VIII.9** | 0 | | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 11 | 0.85 |
| **Indicator VIII.10** | 1 | 1 | 1 | 0.3 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0.66 | 1 | 9.96 | 0.71 |
| **Indicator VIII.11** | 1 | 1 | 1 | 0.83 | 1 | 1 | 0.83 | 1 | 1 | 1 | 1 | 0.33 | 1 | 1 | 12.99 | 0.93 |
| **Indicator VIII.12** | | 1 | 1 | 0.67 | 0.83 | 1 | 0.5 | 0.83 | 1 | 1 | 0.83 | 0.5 | 1 | 1 | 11.16 | 0.86 |
| **Indicator VIII.13** | | 1 | 1 | 0 | 0.5 | 0.75 | 0 | 0.2 | 1 | 0.75 | 0 | 0.25 | 0 | 0.66 | 6.11 | 0.47 |
| **Total** | | | | | | | | | | | | | | | | 10.58 |
| **Final score** | | | | | | | | | | | | | | | | 6.61 |