

Measuring transparency to improve good governance in the public pharmaceutical sector

LEBANON



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Lebanon



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Foreword

Over the past 30 years Lebanon has endured recurrent conflicts that have severely impacted its health sector. As a result the country is now faced with a weakened primary health care system, unrestricted growth of the private sector and significant impacts on the pharmaceutical sector. To address these challenges, and to ensure that essential medicines reach the people who need them, at a reasonable cost, it is important now more than ever for Lebanon to tackle the issues of regulation and transparency in medicines regulation and supply.

For this reason the Ministry of Health, in collaboration with WHO conducted this transparency study using a standard tool developed by WHO, “Measuring transparency to improve good governance in the public pharmaceutical sector,” in October-November 2007. The aim was to provide a comprehensive picture of the level of transparency and vulnerability to corruption in six essential functions of the public pharmaceutical system: registration, promotion, inspection, 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 Lebanon. Acknowledging this, the Ministry of Health has taken the results into serious consideration. In December 2008, at the national workshop for disseminating and discussing the results, we 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 WHO is long-standing 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. Mohammad Jawad Khalife
Minister of Health, Lebanon

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 Lebanon. 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 Lebanon, the assessment looked at six functions: medicines registration, inspection of pharmaceutical establishments, promotion, selection, 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 people, especially vulnerable and marginalized groups.

Acknowledgements

This report was prepared by Dr Rasha Hamra, Dr Collette Raidy and Dr Maha Naous, all staff of the Lebanese Ministry of Health using the transparency assessment tool developed by WHO. The authors also collected and analysed the data. The assessment was conducted in Lebanon in October and November 2007. 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 Lebanon 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 the Minister of Health, Dr Mohammad Jawad Khalife, and the Director-General of the Ministry of Health, Dr Walid Ammar. Their commitment to improving access to medicines in Lebanon 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 additional information and support during the assessment process.

Guitelle Baghdadi-Sabeti, of WHO headquarters, Zafar Mirza and Mohamed Ramzy, of WHO Regional Office for the Eastern Mediterranean, and Houssain Abouzaid and Alissar Rady of WHO Lebanon provided support to initiate the Good Governance for Medicines programme in Lebanon as well as technical support throughout the assessment process.

Executive summary

This report presents the results of a transparency assessment carried out in Lebanon. It gives a comprehensive assessment of the level of transparency and the level of vulnerability to corruption within the six primary functions of the pharmaceutical sector – registration, inspection, promotion, selection, procurement and distribution of medicines.

The methodology provides both qualitative and quantitative information. Three national investigators, selected by the Ministry of Health, collected data by conducting a series of interviews with 50 carefully selected key informants. 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 the vulnerability in terms of the policy, the regulatory and administrative structures and the procedures at the time of the survey.

The quantitative data reveal that the area of medicine distribution received the highest score and is minimally vulnerable to corruption; medicines registration, inspection, and procurement are marginally vulnerable to corruption; and the promotion and selection functions had the lowest scores and are moderately vulnerable to corruption.

The results indicate the vulnerabilities of the policy, structures, and procedures in place at the time of the survey. They do not reveal in any way the level of possible existing corruption in the country.

Lebanon has laws controlling the different activities within the domestic pharmaceutical sector. Various decrees, sub-decrees, regulations, and circulars have also been published by the Ministry of Health. A website has been developed in order to disseminate information, which in the future will provide access to all the procedures and the criteria for any decision-making within the Ministry of Health.

Each area of the public pharmaceutical sector has an operational and functional committee responsible for decision-making that is made up of all relevant stakeholders in the country and not only Ministry of Health staff.

Medicine registration

There is a standard application form for applications for registration, which is available for download from the Ministry of Health website and all registered pharmaceutical products are listed according to a defined minimum level of information. A formally established technical committee is responsible for the

registration decisions and the committee comprises sufficiently qualified members and meets regularly. There is also an appeals process for rejected applications and sanctions are applied to staff in violation of the law. The principle weaknesses in the area of medicine registration are that there are no standard operating procedures and members of the registration committee simply use a checklist to evaluate applications; there is no requirement for committee members to declare conflicts of interest; and the process for application for registration is complicated and can take up to two years to complete.

Control of medicine promotion

There is a law in Lebanon that stipulates that all promotional materials should be approved by the Ministry of Health prior to their use by companies. However, advertisement to professionals is not controlled and takes many forms in Lebanon, including sending physicians to international conferences abroad. In addition although there is a law about promotional materials of companies, there is no control of published medical information, and there is no committee for approving or monitoring such provisions on medicine promotion and advertisement. The ethical criteria for medicine promotion are no adequate or sufficient to enhance good prescribing and dispensing practices.

Inspections

In the area of inspection, there is a provision covering the inspection of medicine distributors in the Pharmacy Law of 1994 and the inspection unit is active in terms of the inspection of pharmacies, detection of counterfeit medicines and checking imported medicines at the customs. However, there is a lack of updated Good Manufacturing Practices (GMP) and routine GMP audits for local manufacturers. There is also no provision for the declaration of conflicts of interest by the parties involved in inspection activities.

Selection

Lebanon was the first country in the WHO Eastern Mediterranean Region to create a list of medicines to be adopted by the country, which in 1987 was developed into its first essential medicines list. While the existing essential medicines list is in line with WHO procedures and recommendations and all of the key informants interviewed were aware of it, it is not distributed widely enough and is not available on the Ministry of Health's website. Also, although there is a committee responsible for developing the selection of the national essential medicines list, there are no standard operating procedures guiding the committee's decision-making process and there are no clear selection criteria for the committee's members. Furthermore there are no national standard treatment guidelines to guide the selection of medicines process by and for prescribers and committee members are not required

to declare conflicts of interest. On a positive note, the Lebanese essential medicines list is currently undergoing revision.

Procurement

Procurement of medicines in Lebanon varies depending on the type of pharmaceutical product. There are written procedures for the procurement of medicines through tenders and bids, which are made publicly available through being published in local newspapers. There is a tender committee, which follows written guidelines concerning the process of the bid. There is also a formal appeal process to be followed in case of rejection of bids. However the tender list is not based on the essential medicines list and is not listed by generic name but by brand names. There are also no criteria for the selection of the tender committee and members are not required to declare any conflicts of interest. Although an objective quantification method is used to determine the quantity of pharmaceutical products to be purchased, it is not applied due to budget constraints.

Distribution

Since procurement methods vary, distribution channels vary also. There is systematic and orderly shelving of products in the central medicine warehouse and a computerized system is employed for the inventory and to track the movement of pharmaceuticals from the central medicine warehouse to end beneficiaries. An external audit is carried out annually by an independent central auditors unit and a physical stock take is done annually on all items in the central medicine warehouse by internal staff. Although all free medicines provided by the government are marked with a printed statement to indicate that they are free of charge, this can be easily removed. There is also no security management system at the central medicine warehouse, and no computerized program that links all levels and points of distribution.

Recommendations

In order to increase openness and transparency, Lebanon should develop written procedures for all activities of the six core areas of the pharmaceutical sector. In addition, information like terms of reference of the committees, and roles, responsibilities and professional qualifications of the members could be added to the document describing the composition of the committee.

All law enforcement processes should be clearly defined, as well as the roles and power of officials and committees to enforce the law. All laws and regulations should also be made easily accessible to the public.

Declaration of conflicts of interest should also be required for the members of committees and government officials. An appeal mechanism to manage the concerns and complaints from the private sector should be developed.

This assessment was the first step of the WHO programme on *Good Governance for Medicines*. The next steps will be the implementation of recommendations and the development of a national ethical framework based on core values and ethical principles.

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 helps to ensure that investments in the pharmaceutical system are maximized and that access to essential medicines is improved.

Evidence from this assessment will help policy-makers revise and adjust the existing policies and procedures. Some legislative and administrative reforms are needed to establish a transparent system. A good system with transparent procedures and strong ethical structures is needed to improve good governance.

1. Introduction

This assessment is designed to provide Lebanon with a comprehensive picture of the level of transparency and potential vulnerability to corruption of six functions of the pharmaceutical sector at the public level. The assessed functions include: registration of medicines, control of medicine promotion, inspections, selection of medicines, procurement of medicines, and distribution of medicines.

The World Bank defines corruption as “behaviour on the part of officials in the public and private sectors, in which they improperly and unlawfully enrich themselves and/or those close to them, or induce others to do so, by misusing the position in which they are placed,” in other words it is “the abuse of entrusted power for private gain”. Transparency involves defining policies and procedures in print and publishing the printed documentation, giving reasons for decisions to the parties concerned and giving reasons for rejection of applications. It should be present at all levels of decision-making. Transparency encompasses the development of clear workplans and operating procedures. It should be encouraged through open systems of communication with stakeholders and the provision of easy access to information.

This report summarizes the findings of the national transparency assessment in the pharmaceutical public sector that was carried out in Lebanon between October and November 2007. This assessment marks the first step in an effort to increase the transparency and accountability of the pharmaceutical sector. The results of the assessment will inform the development and implementation of a national officially adopted Good Governance for Medicines (GGM) programme in Lebanon.

2. Overview of the public pharmaceutical sector in Lebanon

2.1 Country information

For the past 30 years Lebanon has endured recurrent conflicts that have severely affected its health sector and resulted in a weakened Ministry of Health, cost escalation, particularly in Ministry of Health expenditures, a weakened primary health care system, unrestricted growth of the private sector and have had significant impact on the pharmaceutical sector. The high level of health expenditure in Lebanon places it at the same level in terms of expenditure as developed countries, where Lebanon spends approximately 10%–11% of its GDP on health. Lebanon's population is estimated at 3.7 million. Pharmaceuticals constitute 25% of the total health care expenditure in Lebanon and the majority of the Lebanese population pay out-of-pocket for pharmaceutical products with an average cost of US\$ 125 per person per year. Even this figure is believed to be an underestimate but there is no documentation of a more accurate up-to-date figure.

2.2 Health system

The Ministry of Health covers hospital inpatient expenditures of all uninsured persons in Lebanon, which amounts to approximately half of the population. In addition, the Ministry of Health provides individual patients with severe, debilitating diseases such as HIV/AIDS, cancer, multiple sclerosis, mental illnesses, kidney dialysis, etc., with medicines free of charge through the Ministry of Health public medicine dispensing system. In 2006, 1741 new cases of cancer were treated at the expense of the Ministry of Health. However, the national statistics report an average of 4000 new cancer cases per year. The cancer treatment options used are known to be very expensive and constitute 53% of the budget allocated for medicines at the Ministry of Health. So in parallel, the Ministry of Health expenditures are also increasing fast, with 5.5% of the government budget allocated to health. In 2003, the medicines budget was Lebanese pounds (LBP) 29 billion while in 2007 the medicines budget was LBP 52 billion.

Furthermore, the Ministry of Health procures essential medicines and vaccines for primary health centres from UNICEF, covering about 50% of children with vaccinations. The remaining 50% are vaccinated by the private sector. The Ministry of Health has a parallel programme for distribution of medicines for chronic diseases (diabetes, hypertension and other diseases), in collaboration with a large nongovernmental organization, through public health dispensaries across the country.

2.3 Pharmaceuticals market

The majority of registered medicines in Lebanon are imported, mostly from Europe and the USA. They account for a 94% share (value) of the pharmaceutical market and are imported by 85 importers. The seven local manufacturers have only 6% of the market and operate only to a quarter of their capacity. Lebanon has 1923 pharmacies and 4673 pharmacists distributed over the 10 425km² of Lebanese territory. This large number has a direct impact on the availability of medicines, but not necessarily on accessibility and affordability.

2.4 Pharmaceuticals regulation

The only law in Lebanon that governs the pharmaceutical sector is the pharmacy law of 1994, which also includes the management of the practice of the profession.

The department of pharmacy at the Ministry of Health has three sub-units: inspection; importation and exports; and narcotics. It handles all medicine regulatory control matters, including licensing of premises and pharmacists. Currently, the national medicine quality control laboratory is not functioning.

There is no regulator of medical practice in Lebanon, nor checks over doctors' fees nor control over doctor's prescriptions. Consequently physicians have the freedom to market/promote any specific brand without restriction; and the heavy promotion of brands to the 8000 doctors in Lebanon (more than 2 doctors per 1000 population) has created trade name affinity and loyalty. As a result knowledge and use of generic names hardly exists. In addition incentives for pharmacists to dispense cheaper medicines are non-existent, as by law the pharmacist is not allowed to substitute a generic for a prescribed medicine and their profit is a fixed percentage of the price of the medicine. Pharmacists can sell most medicines without prescription (the exceptions are psychoactive medicines for which prescription is required).

For all the reasons mentioned and since the end of the civil war, the Government of Lebanon embarked on a health sector rehabilitation and reconstruction programme primarily aimed at strengthening the Ministry of Health. Restructuring of medicine policy emerged as a main concern for the Ministry of Health. The pharmaceutical sector reform aims to reduce the national medicine bill and make medicines in Lebanon more affordable and accessible to those in need of them. Within the pharmaceutical sector the political will to bring about change is apparent though not yet focused and refined. Resistance to change is usually expressed by the sector's stakeholders. As a result, many initiatives and projects have been initiated to tackle these challenges, but there is still much to be done to achieve the desired objectives.

The pharmaceutical sector in Lebanon is complex and the high medicines bill could be due to many overlapping factors. Different stakeholders are involved in different

stages of the medicines cycle. These include players from the public sector, private sector and civil society. Lebanon's very large number of pharmacists and physicians, most of them working in the private sector, contribute to escalating medicine costs. There is an obvious surfacing political interest in the pharmaceutical sector for reform but insufficient will and commitment. In addition, Lebanon does not have a modern medicine regulatory authority structure in place or a national medicine policy or policy document that lays out a vision for the future of the sector and that defines political, technical, economic and health related parameters that form the framework for pharmaceutical legislation. Mismanagement of the system and resources due to lack of effective laws and regulations, together with some degree of corruption or lack of transparency at one or more levels of the pharmaceutical system may also contribute to the high medicines bill and the lack of efficiency in providing affordable and accessible medicines to all.

3. Methodology

3.1 Study design

A different questionnaire was designed 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 was intended primarily to collect qualitative information on selected indicators and then quantify the vulnerability to corruption by giving a final score (Method 1 and 2) and perceptions of relevant health professionals in the public and private sectors (Method 3). Method 4 is used to capture additional information by using open-ended questions. The instrument for measuring transparency in the public pharmaceutical sector was used.

To implement this study three national assessors were officially nominated by the Ministry of Health. All national assessors were Ministry of Health staff although the main national assessor was not involved in any of the six sections of the pharmaceutical sector. The national assessors managed the whole assessments exercise, receiving training on the assessment methodology and on the Arabic version of the questionnaires; collecting related materials and sources, including laws and regulations for each function, to validate the information on structural indicators with existing evidence in the country and compare the evidence found with the replies of the key informants (KIs); compiling lists of KIs across the different functions and arranging and conducting interviews with the informants; compiling and analysing the results; writing the report summarizing the findings; and planning a national workshop on the assessment results. The questionnaires were administered during formal interviews conducted by the national assessor with a key informant.

The Ministry of Health gave WHO written clearance for permission to conduct the interviews for this assessment through national assessors trained by WHO. The Minister of Health and the Director-General were verbally informed about the assessment objectives, methodology and the process to be followed when conducting the assessment and full support was guaranteed.

3.2 Selection of key informants

Key informants were selected based on their direct involvement in the pharmaceutical sector. KIs were selected to include both senior and junior professionals from the public and private sector, nongovernmental organizations, international organizations and the media. They included government officials such as pharmacy staff at the ministry, the central warehouse, the inspection department, the procurement office, the financial department and from the primary health care

Table 1. Distribution of KIs across government, private sector, nongovernmental organizations, international organizations and the media

	Government Official	Private Sector	NGO	International Organization	Media	Total KI/Section
Registration	4	4	2			10
Promotion	2	2			1	5
Inspection	5					5
Selection	3	3	2	2		10
Procurement	5	3	1	1		10
Distribution	5	2	2	1		10

* Total KIs interviewed 50

programme; members of the Ministry of Health registration committee and the tender committee; and representatives from large and small governmental hospitals and from scientific offices. From the private sector they included representatives from local manufacturers and large and small pharmaceutical companies. Finally, they included large and small nongovernmental organizations, staff from WHO and UNICEF, members of the Orders of Pharmacists and Physicians, academics; and media consultants. Table 1 shows the distribution of KIs across government, private sector, nongovernmental organizations, international organizations and the media.

3.3 Data collection and scoring

During the study period between 29 October 2007 and 21 November 2007 data collection involved utilizing a diagnostic tool for interviewing a total of 50 key KIs: 10 KIs for the registration function, 5 KIs for the promotion function, 5 KIs for the inspection function, 10 KIs for the selection function, 10 KIs for the procurement function and 10 KIs for the distribution function. Only answers under Methods 1 and 2 are counted in the final score. Method 1 requires that each indicator is a binary answer, either “yes” or “no”. A “yes” is given a value of “1” and a “no” is given a value of “0”, depending on the availability of a supporting document. Method 2 involves questions with a series of sub-criteria. Each criteria is answered by “yes” “no” or “don’t know”. Then the total “yes” answers are counted and divided by the total number of valid answers. “Don’t know” answers are not considered valid answers and are subtracted from the total answers to give the total number of valid answers. Each question is scored between “1” and “0”. For each function, an average rating is calculated and the results are converted to a zero to 10 scale. All individual scores for Method 1 and 2 were entered into the consolidation template and used to calculate the final score for each section for the transparency assessment. The results are interpreted according to a scale of degrees of vulnerability to corruption as shown in Table 2.

Table 2. Scale for degrees of vulnerability to corruption

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

Method 3 involved subjective questions that probe the perceptions of the KIs. The KI was asked whether they strongly agree, agree, are undecided, disagree or strongly disagree with each statement. Basic frequencies have been used to present the results. Method 4 used open questions. KIs could also provide additional input on the function in general.

3.4 Ethical considerations

Confidentiality is an important part of the assessment methodology. To ensure the anonymity of key informants and the confidentiality of their answers each KI was designated a code number which was used for all analyses and record keeping. The names and identities of KIs were not recorded in any way that would lead to their identification. To ensure objectivity of researchers, a national validation workshop was designed where KIs and other key actors in the pharmaceutical field had a chance to scrutinize the report findings and comment on sections where needed.

4. Results and data presentations

4.1 Summary

This section of the report presents the results of the questionnaires that were filled in by the national assessors with the 50 key informants.

4.1.1 Scales of vulnerability

The overall scores for each function of the assessment are summarized in Table 3. For a more detailed presentation of these results see Annex 1.

Table 3. Vulnerability scale scores in the six different functions in Lebanon

Indicator	Registration	Promotion	Inspection	Selection	Procurement	Distribution
Indicator 1	1*	1	1	1	0.797	1
Indicator 2	0.7155	0.53	1	–	1	–
Indicator 3	0.7137	0.75	0.585	0.254	1	1
Indicator 4	0.4303	1	0.602	0.601	1	1
Indicator 5	1	0.33	0.028	1	0.668	1
Indicator 6	0	0.4	1	–	0.177	0.2
Indicator 7	1	0.4	0.76	0.268	0.0175	0.876
Indicator 8	0.7482	0	0.85	0.02	–	1
Indicator 9	0.7567	–		0.208	0.730	0.467
Indicator 10	0	–		0.146	0.385	0.932
Indicator 11	–	–		–	0.728	0.65
Indicator 12	0.4597	–		–	0.862	0.455
Indicator 13	1				–	0.626
Total	7.8241	4.41	5.825	3.497	7.367	9.207
Final score**	6.52	4.9	7.28	4.37	6.7	8.37
Degree of vulnerability	Marginally vulnerable	Moderately vulnerable	Marginally vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

* The numbers represent the average per question, which is calculated only based on valid responses and all D.K and N.A answers were discarded.

** Final score: total average/number of indicators x 10

4.1.2 Perceptions of KIs

KIs were asked to give their opinion on a series of statements. The responses are reported in Table 4.

Table 4. Perceptions of KIs on the transparency level of each function

Section	Question	Perception of KIs
Registration	The members of the registration committee are systematically and objectively selected based on the written criteria in force in Lebanon	50% Agree
	Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decision	60% Strongly agree or Agree
Promotion	The legal provisions on medicine promotion have been developed in broad consultation with all interested parties	60% Strongly disagree or Disagree
	Civil society/NGOs have a great influence on improving the control of medicine promotion in Lebanon	60% Strongly agree or Agree
	The provisions on medicine promotion are well respected in Lebanon	60% Strongly disagree or Disagree
Inspection	The integrity of the inspectors is not at all influenced by personal gains, such as bribes, gifts, etc	100% Strongly agree or Agree
Selection	The national EML has been developed in consultation with the opinion of all interested parties and using an evidence-based approach	60% Strongly disagree or Disagree
	The committee responsible for the selection of the national EML is operating free from external influence	40% Strongly agree or Agree
Procurement	The members of the tender committee are systematically selected based on specific criteria	40% Don't know or not applicable
	The procurement system in Lebanon is operating in a totally transparent manner	40% Agree, 40% Disagree
Distribution	The port clearing is done smoothly and there is no need for bribery or gift giving to expedite the process	50% Strongly agree or Agree
	There are very rarely leakages in the medicine distribution system	40% Agree, 40% Disagree

4.2 Data presentation

The following section presents qualitative information collected through interviews for each indicator. The scores are presented in Annex 1. Some indicators asked the opinion of KIs on the types of unethical behaviour common in the registration system, in the control of medicine promotion, in inspection, in the selection process, and in the procurement system. These answers are not presented in the report but were used to analyse the results and to elaborate the recommendations. KIs were also asked for the first action that they would take to improve the quality and the transparency of each service. Again, these answers are not presented in the report but are used in the recommendations.

4.2.1 Medicine registration

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

There is an up-to-date list of products registered in Lebanon. The latest version is published on the website and updated every year.

Hard copies are available free of charge at the Ministry of Health offices.

Indicator I.2: Does it provide a minimum level of information?

The list provides the product description, name and country of manufacturer, date of registration, validity of the registration and conditions for registration.

The list doesn't include the site of the manufacturer but that information should be provided in the dossier. There is no specification for medicines prescription only, pharmacist supply, and over-the-counter. With the exception of narcotics and psychotropic medicines, all medicines can be bought without prescription.

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

Written procedures for applicants on how to submit an application have been produced by the Export and Import of Pharmaceuticals Department. Procedures are the reflection of various decrees, sub-decrees, and the pharmacy law of 1994 on the process and rules for medicine registration published by the Ministry of Health. They describes the process to follow and documents to submit for registration. Distributors and companies can get these procedures directly from the Export and Import of Pharmaceuticals Department at the Ministry of Health or access it from Ministry of Health website. However, 7 KIs out of 10 believed that the document was not publicly available.

Data to be submitted and criteria for registration are presented in the Guidelines for Submission of Pharmaceutical Product. There is the new law of Decree of 530 which was approved recently by the Council of Ministers about the registration of pharmaceuticals and control. A national workshop will be held in the near future to distribute all relevant information about the new law to manufacturers and pharmaceutical companies.

The fees for registration are clearly presented in the Pharmacy Law of 1994. Although the current laws do not mention the timeframe for processing. Based on the interviews, the duration of the process is not always the same, since a queuing system is used.

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

Evaluators at the Export and Import of Pharmaceuticals Department are trained by the registration committee on how to assess applications. A one-page checklist guides them in the assessment of the pharmaceutical dossier. The checklist enumerates items that should be included in the pharmaceutical dossier. There is no mention of the time-frame for processing an application as it depends on the complexity of the application and the queuing list. The new law of registration will provide complete guidance to evaluators on how to assess applications submitted for registration.

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

The application form is available at the Export and Import of Pharmaceuticals Department. 100% of KIs were aware that it was publicly accessible (companies wanting to get the form can come to the Export and Import of Pharmaceuticals Department and ask for it). The forms are also available at the Ministry of Health website. The application form covers all important information.

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

When documents are missing in the pharmaceutical dossier or when clarifications are needed, an applicant can meet with government officials. There are no guidelines setting limits on meetings between government officers and applicants but there are official days of the week when such meetings can take place.

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

There is a functional and operational committee for registration. Members have the responsibility to examine the dossiers and to make a decision for registration.

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

Members of the committees are mentioned by titles in the pharmacy law of 1994 and comprise representatives of staff at the Ministry of Health, academia, and representatives from the Order of Pharmacists and Order of Physicians. There are no written criteria for the selection of members but members should be pharmacists or physicians. All members have appropriate professional qualifications and technical skills.

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

The Minister of Health issues a yearly decree on the composition of the registration committee by names. It is an internal document based on the Pharmacy Law. This decree is publicly available upon request.

The document also specifies that the committee should attend meetings (6 to 8 times per month) and carry out their work at the invitation of the head of the committee. There is a direct financial benefit for the members that is mentioned in the Pharmacy Law of 1994.

Indicator I.10: Is there a conflict of interest form that members of the committee and public officials are obliged to complete?

There are no requirements for the declaration of conflicts of interest by committee members.

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"?

Although there are no written criteria for the selection of committee's members, 50% (5/10) of KIs agreed with the statement based on implicit criteria for professional qualifications and specific expertise (Table 5).

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

The decision-making process is not available in written format. However, interviews revealed that the registration committee follows consistent procedures developed over years of practice.

The committee usually signs the registration report and sends it to the Minister for approval. The report is one sheet long and contains the name of the product, the manufacturer, the strength and dosage form, presentation, clinical data (SPC, conditioning notice, clinical summary), and conclusion. The registration licence is issued at the end of the process and is valid for life. It can take up to two years before the registration committee evaluates a product.

Table 5. KI perceptions on membership selection for the registration committee

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
1	4	0	5	0	0	0	10

In fact, many products have not been fully evaluated and are sold under a temporary licence that is permitted by law after 3 months from the date that the registration file is submitted to the committee officially. This kind of licence will be abolished in the future when the new draft law is approved.

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

A formal appeal from applicants who have their medicine rejected can be submitted to the registration committee. Reasons for rejection are explained in writing. Applicants have to go to the Export and Import of Pharmaceuticals Department to get the written detailed explanation. The applicant can make corrections and re-submit the dossier again. No formal written procedure describes the appeal process.

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

60% of KIs (6/10) responded that gifts cannot influence the final decision (Table 6).

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

Although most of the KIs agreed that there are no common unethical behaviors in the registration system, three mentioned conflicts of interest and favouritism as common in the registration system.

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

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

- Train employees of the public institution on new registration laws.
- Record all files electronically on CD, particularly the technical parts.
- Adopt international procedures for registration.

Table 6. KI perceptions of officials in charge of medicines registration

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
2	4	0	3	1	0	0	10

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

- Publish all requirements, process and procedures.
- Publish standard operating procedures.
- Increase the services provided on the Ministry of Health website and increase publicity of the website.
- Increase knowledge of the services offered and the way in which people work in order to increase awareness.
- Clarify the procedures of registration to the public.
- Provide for the submission of the files in the website.
- Issue guidelines on conflicts of interest.
- Ensure that the appeal committee is different than the registration committee.
- Accept applications electronically, particularly changes that occurred to the product.

4.2.2 Control of medicine promotion

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

The Pharmaceutical Law no. 367 dated 1994, in articles 41 and 69, stipulates that promotional materials should be approved by the Ministry of Health prior to use by companies. Thus, it is forbidden to publish or advertise anything related to medications to the public before getting approval from Ministry. A reminder note was issued on March 10, 1999 and again on February 15, 2007 to companies regarding this issue. The Order of Pharmacists is very active with regard to preventing the advertisement of medicines to the public and violations are punished.

Indicator II.2: The provisions on medicine promotion and advertising include explicit mention of the following areas.

The provisions on promotion of medicines mention only the following areas: advertisement to the public, restrictions on and monitoring of free samples, and packaging, labelling and package inserts. However, it does not cover advertisement to professionals, qualification and training of medical representatives, symposia and

scientific meetings, post-marketing scientific studies, speaker's fees and consultancies, and restrictions and limits on gifts and gimmicks.

Indicator II.3: Is pre-approval of promotional and advertising materials officially required?

Pre-approval of promotional and advertising materials for health providers are not officially required, while pre-approval of advertising material to the public is officially required.

Indicator II.4: Do the provisions foresee an enforcement mechanism on promotion and advertisement of medicines?

The Pharmacy Law specifies that authorization from the Ministry of Health is required for the advertisement of pharmaceuticals. In practice, only advertisements directed to consumers for prescription medicines and non-prescription medicines are subjected to the pre-approval process of the Ministry of Health.

It also specifies that any person who advertises pharmaceuticals without authorization from the Ministry of Health shall be penalized. Based on this law, the Ministry of Health has the right to immediately suspend the offending advertisement of pharmaceuticals and then to prepare a file to be forwarded to the court. In practice, the enforcement of the law is weak. The process to bring a case to court is long and as far as is known, the Ministry of Health has never filed a lawsuit in this area.

There are no rules or legislation concerning the advertisement of medicines directed to health care professionals for prescription medicines. Consequently, there is no enforcement mechanism for that kind of activity. There is also no complaint mechanism to report unethical practices in the promotion of medicines.

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

There is no formal complaints procedure to report unethical promotional practices.

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

There is no government service or committee responsible for monitoring and enforcing the provisions on medicine promotion.

Indicator II.7: Are there written and publicly available standard operating procedures (SOPs) guiding the services responsible for pre-approving or monitoring medicine promotion and advertising?

There are no written SOPs guiding the services responsible for pre-approving or monitoring medicine promotion and advertising.

Indicator II.8: Are there written guidelines on conflicts of interest with regard to control of medicine promotion activities?

There are no written guidelines on conflicts of interest with regard to the control of medicine promotion activities.

Indicator II.9: 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"?

The majority of KIs did not agree with the statement.

There is no organization outside the Ministry of Health involved in reviewing, assessing and monitoring the promotion of medicines in Lebanon. In addition, there is no mechanism for reporting unethical practices in the promotion function (Table 7, Figure 1).

Table 7. KI perceptions of the legal provisions on medicine promotion

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
1	2	0	1	0	1	0	5

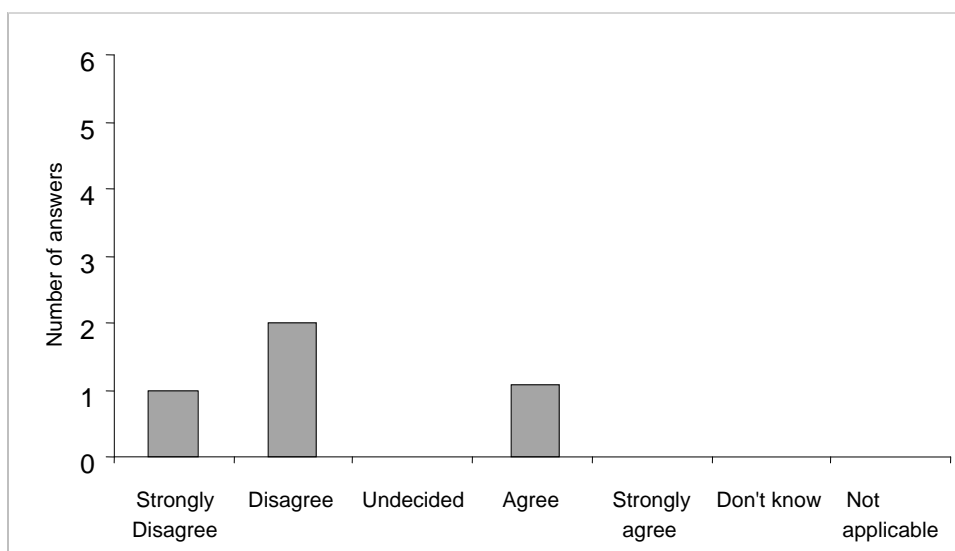


Figure 1. Range of perceptions of KIs

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

60% of respondents agreed or strongly agreed with the statement "Civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in Lebanon" (Table 8).

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

60% of KIs disagreed or strongly disagreed that the provision was not respected because the law was not enforced (Table 9, Figure 2).

Table 8. KI perceptions of the influence of civil society/nongovernmental organizations on medicine promotion

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
1	1	0	2	1	0	0	5

Table 9. KI perceptions of the respect for the provisions on medicine promotion in Lebanon

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
2	1	0	2	0	0	0	5

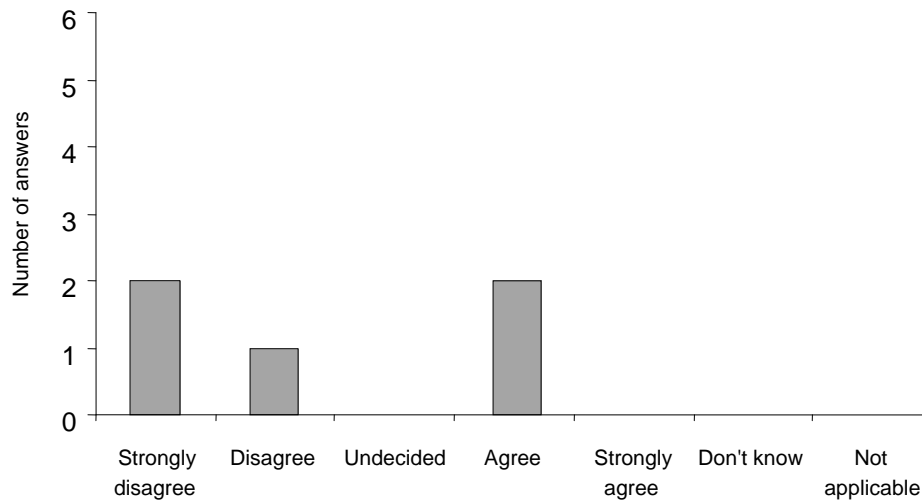


Figure 2. Range of perceptions of KIs

Indicator II.12: In your opinion, what types of unethical behaviour are common in the medicine promotion area in your country?

a) Involving health professionals and health institutions in general.

- The type of unethical behaviour common in the medicine promotion area in Lebanon involving health professionals and health institutions in general concern material gifts (5).

b) Involving regulatory office staff and committee members responsible for controlling medicine promotion.

There are no regulatory office staff or committee members responsible for medicine promotion in Lebanon.

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

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

- Enforce legislation covering medicine promotion and advertising.
- Establish a committee/ government service for monitoring and enforcing the provisions on medicine promotion.
- Write and make publicly available standard operating procedures guiding the services responsible for pre-approving or monitoring medicine promotion.

- Monitor the actions of the pharmaceutical companies during the process of promotion.
- Develop new regulations that would cover all medicine promotion related issues.
- Introduce and enforce policies that establish and monitor ethical standards with respect to pharmaceutical company promotion to prescribers. The government should do this in collaboration with medical associations.
- Review and enforce laws and regulations to cover the complete control of medicine promotion.
- Ensure that medicine promotion is only for registered medicines and dependent on scientific studies.
- Train health professionals on how to adopt good prescribing practices.
- Enforce a law to monitor and punish unethical practices of medicine companies.
- Introduce a comprehensive practitioner and consumer education program about the impact of unethical medicine promotion.

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

- Establish a committee responsible for controlling medicine promotion, with clear terms of reference, conflict of interest policies and standard operating procedures.
- Ensure clarity in the services offered by public institutions to the public and to health professionals.
- Publish all available regulations and guidelines concerning controlling medicine promotion.

4.2.3 Inspections

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

There is a provision covering inspection of medicine distributors (pharmacies, importers, and local distributors) in the Pharmacy Law 1994. The inspection unit is active in terms of inspection on pharmacies, detection of counterfeit medicines and checking the imported medicines at the customs, and assures the quality of medicines available in the market.

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

A large majority of KIs reported that the provisions on inspection provide power to the inspector to enter at any reasonable time any facility where medicinal products are produced, packaged, stored, distributed or tested in order to carry out inspections. It defines the inspectors' duties, responsibilities and powers to take action in case of violations of provisions of the medicines legislation and or regulation, requires that inspectors be provided with a special identification document and that a copy of the provision is made available to companies being inspected.

The law and regulations on inspection are supposed to be distributed widely. In practice, managers of pharmacies, companies and manufacturers are not always aware of the law.

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

There are written guidelines on classification of GMPs, last updated in 1985. The guidelines are available in writing and easily accessible to all stakeholders. However, there are no written guidelines on classification of GDPs.

Indicator III.4: Are there written procedures/mechanisms to prevent regulatory capture¹ between inspectors and the manufacturers or distributors that he/she inspects?

There are no written procedures to prevent regulatory capture between inspectors and the companies inspected, however the inspection department at the Ministry of Health have unwritten procedures which help to prevent regulatory capture between inspectors and manufacturers/distributors inspected. These procedures include the rotation of inspectors based on a scheduling system; a rotation mechanism requiring inspectors from one geographical area to inspect companies/pharmacies in other areas; inspectors are required to visit sites in teams; and inspectors are required to inspect under the observation of another inspector who will report on what he/she observed. There is no external auditing of the inspection done by an inspector from another country.

The only written document available is the schedule of inspection for pharmacies and companies, which is prepared on a regular basis by the head of the inspection

¹ Definition of "capture" Reference is in the glossary of the assessment instrument:
<http://www.who.int/entity/medicines/areas/policy/goodgovernance/AssessmentinstrumentENG.pdf>

department. A scheduling system is functioning to assure that every pharmacy is covered by inspection.

Indicator III.5: Are there written guidelines on conflicts of interest with regard to inspection activities?

There are no written guidelines for the management of conflicts of interest.

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

There is a standard report format that should be signed by the inspector, the responsible pharmacist and the shareholder/manager of the establishment at the end of the inspection. It is also required that each inspection report should be reviewed by the Head of the Inspection department. A summary report is produced for the Director of the Pharmacy Department, General Director and the Minister of Health.

Indicator III.7: Are there written SOPs for inspectors on how to conduct inspections?

Inspectors have written SOPs to guide them in performing their duties. These procedures are available to the inspectors in writing and comprise a checklist and information on the format and content of the inspection report. However, there are no details of the requirements for pre- and post-inspection activities.

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

The criteria for selection and recruiting inspectors only include the professional qualifications required (pharmacist). Recruitment of inspectors does not need minimum number of years of work experience in the area, and is not based on recommendations from former employers. Recruitment is done through an independent official body, *majlis el khidma el madanya*.

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

All KIs agreed or strongly agreed with the statement "The integrity of inspectors is not at all influenced by personal gains, such as bribes, gifts, material or other benefits, etc" (Table 10, Figure 3).

Table 10. KI perceptions of the integrity of inspectors

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
0	0	0	2	3	0	0	5

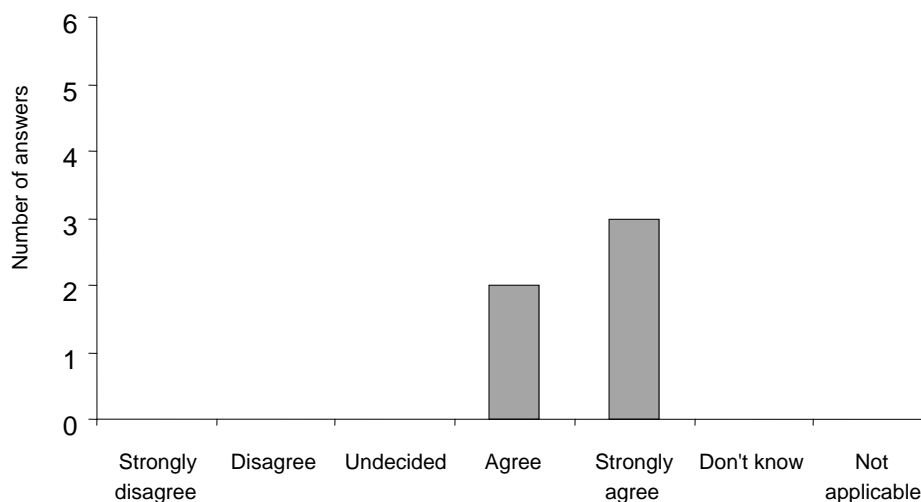


Figure 3. Range of perceptions of KIs

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

Although most of the KIs agreed that no types of unethical behaviours are common in the registration system, one KI mentioned favouritism.

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

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

- Train the inspectors.
- Increase the number of inspectors.
- Ensure that clear guidelines are followed.
- Establish an independent directorate for inspection.
- Ensure that good manufacturing practices and good distribution practices play a more significant role in medicine regulation.

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

- Provide written guidelines on conflicts of interest with regard to inspection activities and introduce a mechanism for monitoring this and applying sanctions if it is abused.
- Introduce a system for manufacturers' inspection.
- Publish all guidelines and procedures for inspection.
- Publish post inspection reports.
- Ensure that all the regulations covering inspection of medicines, and all the guidelines and procedures regarding inspection activity are present on the website.

5.2.4 Medicine selection

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

The last edition of Lebanon's EML was developed and published in 2002. The last updated list was not widely distributed. It was available at the Ministry whenever someone asked for it but was not available on the website of the Ministry.

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

50% of KIs disagreed or strongly disagreed with the statement "The Lebanese Rational Medicine List has been developed in consultation with, and considering the opinion of, all interested parties and using an evidence-based approach" (Table 11, Figure 4).

Table 11. KI perceptions of the development of the Lebanese essential medicines list

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
2	3	0	1	2	2	0	10

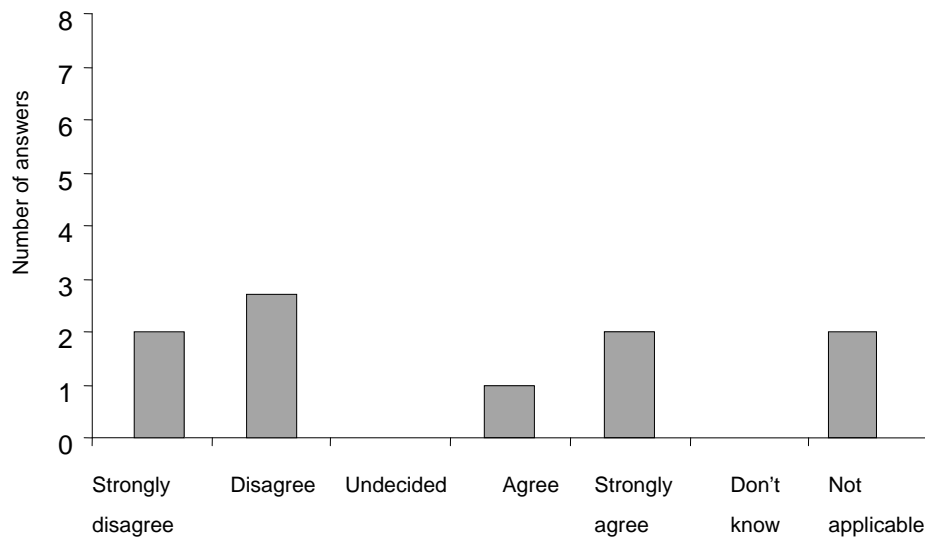


Figure 4. Range of KI perceptions

The EML was updated periodically by an unofficial committee that included relevant staff from the Ministry of Health and the WHO.

In addition, although the EML exists it is not really used in practice, especially in the private sector, due to strong trade name affinity caused by heavy promotion particularly for newly marketed medicines. No national guidelines on treatment exist, which adds to the difficulty of using the EML in practice.

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

Explicit criteria for medicine selection are generally not used and there seems to be a general misconception on selection, use and concept of essential medicines.

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

The list was prepared by alphabetical pharmacological classification of medicines, and by generic name, and included route of administration, dosage forms and strengths and level of health care. It was developed based on the WHO list taking into consideration the Lebanese health context. However, there are no national treatment guidelines for all common diseases in Lebanon, so the EML is not linked to national treatment guidelines. The EML is revised every 5-6 years.

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

A national list was developed in 2002 by an unofficial committee that included relevant staff from the Ministry of Health and the WHO.

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

40% of KIs either agreed or strongly agreed with the statement "The committee responsible for the selection of the national EML is operating free from external influence" (Table 12, Figure 5). Members of the committee are free from the influence of the pharmaceutical companies.

Table 12. KI perceptions of the selection of medicines committee

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
2	1	0	2	2	0	3	10

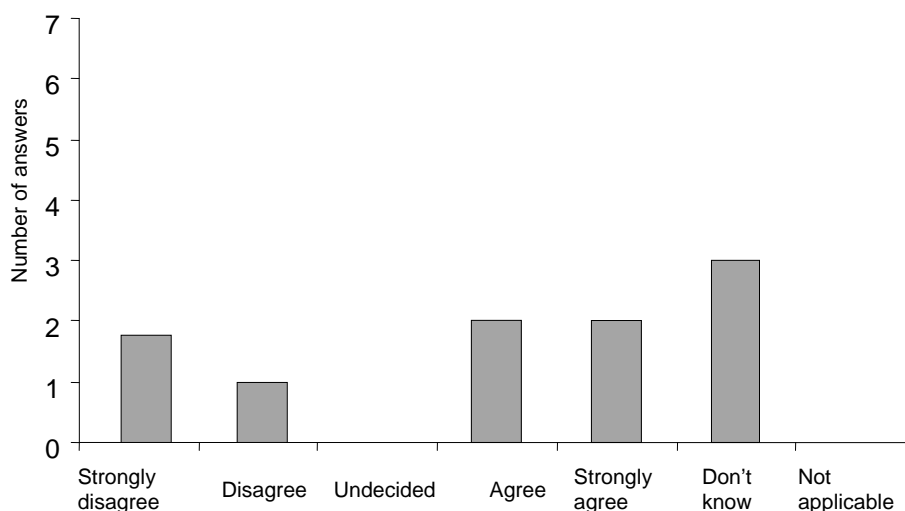


Figure 5. Range of perceptions of KIs

Indicator IV.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. Members are selected based on their knowledge of pharmacy and medicine as well as their clinical and field experience.

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

There is no conflict of interest policy.

Indicator IV.9: Are there clear and publicly available standard operating procedures that describe the roles and responsibilities of the selection committee?

There is a relatively clear decision making process by which the committee operates but it is not available in a written format. The roles and responsibilities of the selection committee are also not in written format.

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

There are no SOPs available in a written format.

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

There is no common unethical behaviour known to the KIs in this area.

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

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

- Ensure that the selection of medicines is based on cost-effectiveness studies.
- Ensure that the rational medicine list is linked to national standard treatment guidelines.
- Ensure that medicine selection is on the basis of the scientific (generic) name.
- Set treatment guidelines for chronic diseases and enforce doctors to stick to it.
- Publish national standard treatment guidelines ensure that this is linked to the rational medicine list.

- Ensure that a member of the private sector is on the selection committee.
- b) The first actions that the KIs would take to improve medicine selection in terms of transparency in the services offered by public institutions would be to:
- Publish all the scientific information that forms the rationale behind the selection of these medicines.
 - Introduce written guidelines on the declaration of conflicts of interest.
 - Train members to review on a cost-efficacy basis.
 - Introduce laws to ensure that all doctors in public sector abide by the list.
 - Ensure that the rules for decision-making in the standard operating procedures are clear and transparent to the public.

4.2.5 Procurement

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

The government uses transparent and explicit procedures for procurement of pharmaceutical products. The government pays for a certain number of medicines for the uninsured of the Lebanese population (50% of the population). The Ministry of Health uses three different procurement channels/mechanisms depending on the type of medicine. Firstly, the Ministry of Health procures vaccines and essential medicines for use at the primary health care level through UNICEF. Secondly, the Ministry of Health funds a large nongovernmental organizations that is responsible for the procurement and distribution of chronic medications for more than 450 primary health care centres that provide medications for free for 150 000 patients annually. Sixty (60) different medications are procured to cover 15 chronic diseases. Finally, the rest of the allocated budget for medicines of the Ministry of Health is used to procure medicines for severe diseases such as cancer, HIV and some psychiatric illnesses through a local tender procedure done by the Ministry of Health. The Ministry distributes these medicines for free to approximately 15 000 patients annually.

So, there are different medicine procurement mechanisms that are followed depending on the type of pharmaceutical product. The only procurement procedure that the Ministry is directly involved in is the procurement of expensive medicines for severe diseases. All payments of procurement are carried out directly by the Ministry of Finance and all procurement procedures are audited by the Central Audit Office.

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

There are different types of procurement methods to be followed depending on the purchasing value. Direct contracting is used when the value is up to LBP 3 million per patient, price comparison is used when the value is up to LBP 100 million and public bidding is the method used when the value is above LBP 100 million .

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

Medicine quantification is done using the patient files at the central warehouse from previous years adding a 20% expected increase in number of cases. The determination of the quantity of medicines required is based on historical consumption data.

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

There is a formal appeal process to be followed in case of rejection of bids.

Indicator V.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 that is formed annually by a Ministerial decree and has different responsibilities than the procurement office. There are written guidelines for the committee to follow concerning the process of bids. The medicine lists are developed based on the most prescribed medicines for the treatment of a certain disease (usually following US Federal Drug Administration guidelines).

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

There are no specific or written criteria available for tender committee membership. However, the tender committee includes members who are appointed for their professional expertise. The members should have skills that complement each other, including senior government officials in various departments at the Ministry of Health and pharmacists, but it does not include representation from client facilities.

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

There is no requirement for the declaration of conflicts of interest. In the view of the KIs, there is no need for this because the criteria for any tender award are sufficiently clear (quality of medicines and price).

Indicator V.8: To what extent do you agree with the following statement: "The members of the tender committee are systematically selected based on specific criteria (see question V.6)"?

The answers to this indicator were mixed and did not provide a clear cut answer (Table 13, Figure 6).

Table 13. KI perceptions of the selection of tender committee members

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
1	1	1	1	2	2	2	10

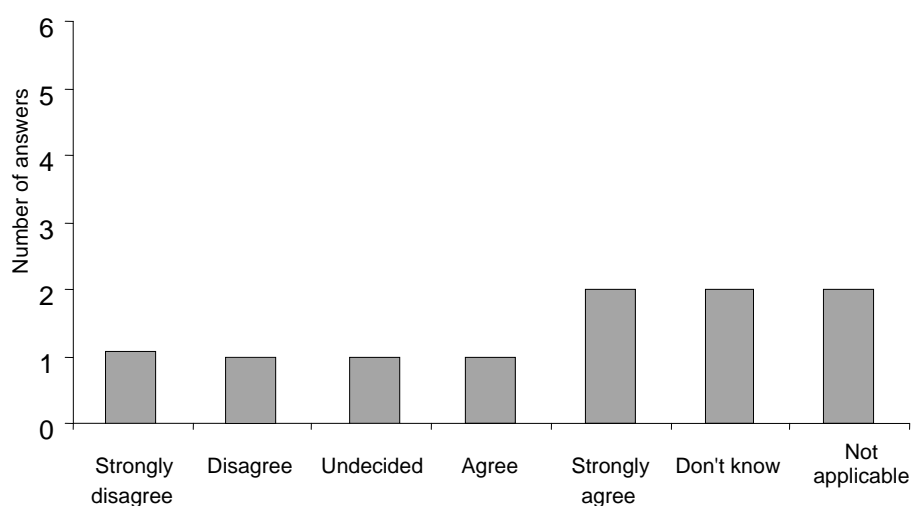


Figure 6. Range of perceptions of KIs

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

The management information system is computerized and it includes product records and monitors supplier and facility performance. It also records all quality assurance information for products purchased and tracks the status for each order, including the quantities actually purchased compared with the original estimates made.

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

The inspection department is responsible for the inspection of all medicine consignments.

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

No post-tender system is used to report on suppliers' performance to the tender committee.

Indicator V.12: Does the procurement office undergo regular audits?

Auditing is compulsory as required by the Lebanese Law on Auditing. There is an annual audit of the Procurement Unit of the Ministry of Health. There are different types of audit on the procurement office including an audit from the Ministry of Finance to check on the contracts completed since they are the paying party and the central audit, which is an independent entity that conducts audits on all types of governmental organizations and ministries.

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

40% of KIs agreed or strongly agreed with the statement "The procurement system in your country is operating in a totally transparent manner", while a further 40% disagreed or strongly disagreed with this statement. Two of the 10 KIs answered that they did not know and not applicable.

Table 14. KI perceptions of the transparency of the procurement system

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
2	2	0	3	1	1	1	10

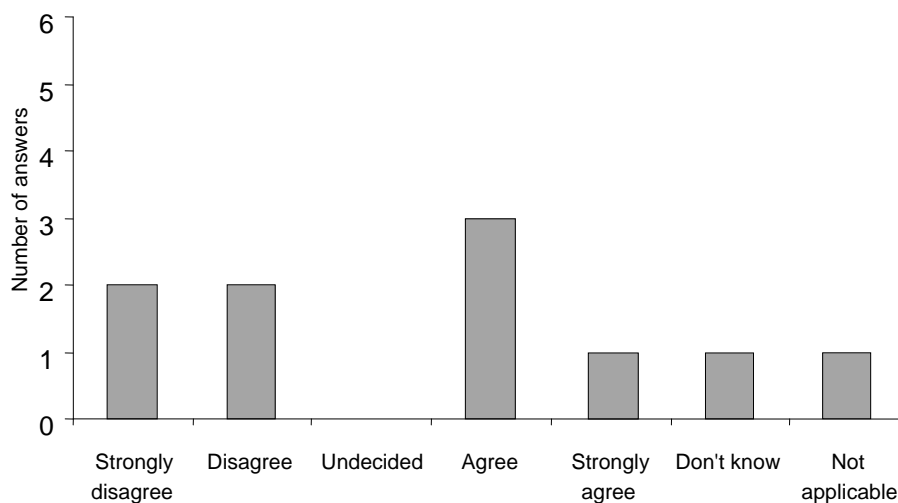


Figure 7. Range of perceptions of KIs

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

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

- a) material gifts (6)
- b) travelling (2)
- c) favouritism (2)

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

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

- Train employees of the public institution.
- Ensure that the criteria for selecting members of the tender committee requires representation from client facilities.
- Structure the procurement department so as to include the following key functional areas: specification section; accountancy section; quality assurance section, including audit; procurement section; receiving and checking section; and information technology support.

- Ensure that public sector tender procurement be restricted to the Essential Medicine List.
- Review procurement procedures to ensure that prospective suppliers are pre-qualified, that their performance is monitored for product quality, service reliability, delivery time and financial viability and that this is all appropriately recorded in a retrievable database.
- Simplify the procurement processes to have a positive impact on the system and improve effectiveness. This could be achieved by requiring a more evidence-based approach to medicine selection for procurement and rationalization of medicine requirements.

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

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

4.2.6 Distribution

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

The inspection department is responsible for port clearing.

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

50% of KIs agreed or strongly agreed with the statement "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process" (Table 15).

Table 15. KI perceptions of the the port clearing process

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
0	2	0	3	2	0	3	10

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

There is a designated staff member responsible for checking receipts against the packing list when supplies arrive at the warehouse. The responsible person should prepare documentation through a receiving report on the basis of the invoice specifying the types, quantities and condition of the supplies received.

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

Government medicines can be identified by imprints on containers and external packaging.

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

Products in warehouses are organized systemically by dosage forms: tablets and capsules, injections, syrups and suspensions, creams and ointments, etc. and these dosage forms are arranged according to therapeutic action. A computerized system is used to control expiry dates of medicines listed alphabetically or by manufacturer.

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

There is no effective security management system to oversee storage and distribution, although there are regulations for monitoring entry and exit to warehouses, thereby limiting access to unauthorized persons. However, there is no alarm system for security breaches and there is no physical search conducted upon exit from the warehouse.

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

There are inventory records and procedures in the warehouses at the various levels of the distribution system. The inventory control system provides information on the following elements: the average working stock; the frequency of reordering; the quantity of reordering; the average inventory; the expiry dates.

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

The warehouse staff continuously produce the most recent records of current stock levels reconciled with physical count of selected medicines. General physical count takes place once a year.

Indicator VI.9: Are there independent audits of warehouses by external inspectors or auditors?

The warehouses are subjected to external auditing by the Central Audit office at regular intervals and random auditing by the Ministry of Health. When asked, the warehouse supervisor should be able to provide the date that the last audit was conducted and show a report of the warehouse audit. The audits are carried out at least once a year.

Indicator VI.10: Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health facility?

A computerized system provides information on medicines that have left the warehouse to health facilities including: the type of medicines that have left the warehouse; the quantity of medicines that have left the warehouse; the person who verified the amounts; the intended recipients of these medicines; and the date that the medicines arrived at the designated health facility.

Indicator VI.11: Is there a well-functioning communication system between distribution points?

The communication system between distribution points includes: a manual/document exchange system between distribution points at all levels; telephone contact between all levels of the distribution points; and fax contact between some levels of the distribution points. However, a computerized system is unavailable currently.

Indicator VI.12: Does a programme exist for monitoring and evaluating the performance of the medicine distribution system?

No programme exists for monitoring and evaluating the performance of the medicine distribution system.

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

Sanctions are imposed on individuals for theft or corrupt practices. There are procedures for the application of sanctions for corrupt behaviour. The type of sanctions applied depends on the nature and gravity of the act of corruption.

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

40% of KIs agreed or strongly agreed with the statement “There are very rarely leakages in the medicine distribution system in Jordan”(Table 16)

Table 16. KI perceptions of the medicine distribution system

Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know	Total
3	1	0	2	2	0	2	10

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

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

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

5. Data analysis and discussion

The following sections provide an area-specific analysis of the results obtained during the interviews with the key informants. It is important to stress that this data was collected during the interviews and compiled through the analysis of the information supplied by KIs. The information is presented for the areas of registration, promotion, inspection, selection, procurements and distribution of medicines.

5.1 Medicine registration

5.1.1 Background

The registration of pharmaceutical products is the responsibility of a technical committee, which works under the Ministry of Health. Imported and locally produced medicine applications for registration are studied by this committee whose members are specified in the 1994 law pertaining to medicines. Specifications are laid down in decrees. Registration requirements were set in the Ministerial Decision 233 dated 9 March 2003 and then amended by the Ministerial Decision 212/1 dated 5 April 2004. The latest registration checklist used includes additional requirements that were added by the technical committee. In addition, to this checklist there is no clearly documented and published policy on the necessary requirements and conditions for obtaining medicine registration approval. There are no guidelines on the number of applications an applicant is allowed to submit at one time or during a limited period of time. The number of accepted applications is random, depending on the completeness of the files submitted. As a result, Lebanon is reported to have over 4000 registered medicines. Registration, once granted, is for life as there is no requirement for registration renewal.

Before the application is submitted to the technical committee a regular staff member at the pharmacy department checks the completeness of the file with all the requirements for registration. A new requirement is to provide all information in a hard copy and on CD. The application is then granted a number that defines its place in a queuing system for review by the technical committee.

The members of the technical committee are specified in the 1994 law to include members from Ministry of Health, Order of Pharmacists, Order of Physicians and representatives from academia. The members are mentioned by titles, for example in the committee there is the head of the pharmacy department, head of the export and import department and head of the inspection department. Usually these members serve for the duration of their post. Some have remained the same for a decade or more.

The two members from each of the Orders of Pharmacists and Physicians are replaced every time there are new elections in the Orders' administrations. The technical committee meets four to six times a month. Registration fees are paid at the Ministry of Finance. The technical committee members are granted financial incentives for each meeting.

5.1.2 Strengths of the registration function

The strengths of the registration function are as follows:

- A list of all registered pharmaceutical products is available on the website of the Ministry of Health. The list contains a minimum defined level of information, such as the name of the product (brand and INN), the name of manufacturer, country of origin, dosage form, strength, presentation and registration number. A medicine formulary will soon be printed and distributed to health professionals.
- There is a standard application form for the submission of applications, which is publicly accessible, readily available and downloadable.
- There is a registration requirements checklist available on the website of the Ministry as a downloadable file. It provides directions on the department responsible for receiving applications for registration, (the Department of Medicines Import and Export) fees and the data to be submitted. These documents are also available at the import and export department of the Ministry of Health.
- The registration application form requires the product name, that is, both the trade name and the generic name.
- The checklist requirements include the GMP certificate, certificate of analysis, bioavailability studies, pharmacodynamic and pharmacokinetic data, clinical trials and price certificate etc.
- A formally established technical committee is responsible for the registration of pharmaceutical products.
- The registration committee comprises professionals representing relevant parties with the required technical skills and they meet on a regular basis. The committee reaches its decision by majority vote and in the case of a tie vote the head of the committee makes the final decision. There is a quorum requirement for the meetings.
- The result of an application is given in a written format to the applicant with the reasons for rejection if the product was rejected by the committee.

- There is an appeal process for rejected applications and all appeals are submitted to the same technical committee that made the original decision on the application.
- In the case of violations on the part of the parties involved in registration, the violation is registered and actions are taken. For example, the head of the Import/Export unit has been dismissed from the position twice in five years for violation of the law.

5.1.3 Weaknesses of the registration function

The weaknesses of the registration function are as follows:

- Although, the applicant is asked to submit a CD that contains all the relevant information with the hard copy of the application manual maintenance of the information submitted for the registration application is still in use.
- There are no documented standard operating procedures available for the registration function.
- The committee only use the registration requirements checklist to evaluate the applications and the decision is based on the judgment of the committee members.
- There are no detailed terms of reference for the committee members.
- There is no detailed description of the duties or responsibilities of committee members and consequently a lack of accountability of committee members.
- There is no pre-defined registration time line, a simple queuing system is used. Consequently the time needed to complete registration can vary from 4 months for a priority life-saving product to 2 years. To submit a medicine registration application you need to make an appointment at two different departments at the Ministry before the file can be accepted and studied by the technical committee. Getting such an appointment can take months.
- The level of contact between the staff working in the medicine regulation and applicants is not formalized and communication between both parties is not recorded.
- There is no required conflict of interest form completed by the members of the registration committee.
- There is no official list of over-the-counter medicines issued and published by the Ministry of Health.

5.1.4 Vulnerability to corruption score

Lebanon scored relatively high in the registration function and was found to be marginally vulnerable to corruption in this regard.

5.1.5 Perceptions of KIs

50% of KIs interviewed believe that members are systematically and objectively selected for the technical committee. 60% believe that gifts and other benefits will not affect the decisions of the committee members.

5.2 Control of medicine promotion

5.2.1 Background

The Pharmaceutical Law no. 367 of 1994, in the articles 41 and 69, stipulates that the medicine promotional materials should be approved by the Ministry of Health prior to use by companies. Thus, it is forbidden to publish or advertise anything related to medications to the public before receiving approval from the Ministry. A note was issued on 10 March 1999 and again on 15 February 2007 as a reminder to companies regarding this issue. The Order of Pharmacists is very active with regards to preventing the advertisement of medicines to the public and all violations of this are subject to punishment. The Order of Pharmacists, the importers and representatives of multinational companies are currently working on a marketing ethics initiative.

The advertisement of medicines to the public is extremely rare in Lebanon. Contrary to this advertisement to professionals is not controlled. Heavy promotion to physicians takes many forms in Lebanon, most commonly sending physicians on trips to attend conferences outside of Lebanon. Only large multinational companies have restrictions on medicine promotion to professionals as they have their own internal code of ethics that they act according to.

5.2.2 Strengths of the promotion function

The strengths of the promotion function are as follows:

- There is a law regarding the prior approval of the Ministry of Health for the use of promotional material by companies.
- The strong stance taken by the order of pharmacists to prohibit the advertisement of medicines to the public.
- There is collaboration between the society of physicians, the society of pharmacists, importers and local industry regarding the control of the promotional practices of pharmaceutical companies.

5.2.3 Weaknesses of the promotion function

The weaknesses of the promotion function are as follows:

- There is a lack of control of published medical information by the Ministry of Health.
- Although a law exists, no official committee exists for approving, monitoring and enforcing the provisions on medicine promotion and advertisement.
- There is a lack of ethical criteria in line with WHO criteria for medicine promotion that could enhance good prescribing and dispensing practices.

5.2.4 Vulnerability to corruption score

Lebanon scored low on the function of medicine promotion control. It was found to be moderately vulnerable to corruption in this regard. This is mainly due to the lack of applied laws and the lack of a code of ethics. In practice there are restrictions over medicine promotion to the public, but not to the professionals. There is a lack of control by the Ministry of Health, but the Order of Pharmacists do play an active role.

5.2.5 Perceptions of KIs

60% of the KIs interviewed stated that the legal provision on medicine promotion was not developed in consultation with all interested parties, thus the provisions are not well respected. The same percentage of KIs think that civil society and nongovernmental organizations will have influence on improving the control of medicine promotion.

5.3 Inspections

5.3.1 Background

There is a provision covering the inspection of medicine distributors including pharmacies, importers and local distributors in the Pharmacy Law of 1994. The inspection unit is active in terms of inspection of pharmacies, detection of counterfeit medicines, checking the imported medicines at the customs and assuring the quality of medicines available on the market. There is, however, a lack of updated guidelines and standards for GMP, the latest Lebanese GMP guidelines date back to 20 February 1985. GMP certificates are granted for local manufacturing plants once they are submitted for approval and registration by the responsible committee. The inspection unit is not involved in this. There is no GMP routine audit for local industry following the issuance of certificates. Local manufacturing plants undergo inspection of their active ingredients and their finished products by sending samples

for analysis. Yet local manufacturers have self-imposed standards that are beyond the Lebanese law requirements. The necessity to export pharmaceutical products to markets abroad or to obtain sub-licensing contracts from the international pharmaceutical industry is what led to these self-imposed standards. The inspection work is decentralized and undertaken according to geographical areas. Each inspector follows the head of the health department in areas outside the capital. There is no common reporting system across the areas for the inspection work done. The inspectors are under-equipped in that no transportation facilities are provided for them when they travel to distant areas, none of the work is computerized it is all manual and only manual reports are produced.

5.3.2 Strengths of the inspections function

The strengths of the inspections function are as follows:

- There is a comprehensive provision and law covering inspection activities.
- Inspectors are given the power they require to do their job with a detailed description of duties and responsibilities.
- There are standard operating procedures on how to conduct inspections.
- There are selection and recruitment criteria of inspectors.
- There is continuous internal review of all reports of the inspection unit by the head of the inspection unit.

5.3.3 Weaknesses of the inspection function

The weaknesses of the inspection function are as follows:

- Updated GMP standards are not consistently available.
- GMP audits for local manufactures are not conducted routinely.
- There are no written guidelines on conflict of interest with regard to inspection activities.
- There is a lack of incentives for inspectors.

5.3.4 Vulnerability to corruption score

Lebanon scored relatively high in the inspection function, which ranked it as marginally vulnerable to corruption. This is likely due to the presence of a strong law governing the function and the presence of committed staff, even if they are under-equipped.

5.3.5 Perceptions of KIs

All KIs interviewed agreed that the integrity of the inspectors is not influenced by personal gain or bribes.

5.4 Selection of medicines

5.4.1 Background

Lebanon was the first country in the region to develop a limited list of medicines to be adopted and reimbursed in the country in the early 1960s. It was developed by the National Social Security Fund, while the first reference of WHO regarding this topic was in mid 1970s. This first list contained 1300 medicines. The Ministry of Health worked on its first essential medicine list (EML) in 1987 and it was subsequently updated in 1992 after an official committee was formed for this purpose. This committee was formed by the Minister of Health based on the WHO recommendation of developing an updated EML. The committee comprises members from all interested parties such as the Ministry, WHO, UNICEF, pharmacists and physicians, representatives from all universities in medicine and pharmacy and representatives from NGOs. After the committee finished the selection process of the medicines to be included on the list it was sent out to many medical centres for review. All feedback and recommendations about the content were used to finalize the EML.

This list included 200 medicines, even though in Lebanon there are 4382 registered medicines, that were classified into three categories depending on the level of health care they are used in, i.e. essential medicines for primary health care use, for general hospital use and medicines used for specialized units in hospitals and dispensaries. The list was prepared according to alphabetical pharmacological classification of medicines, by generic name and it included the route of administration, dosage forms and strengths. It was developed based on the WHO list taking into consideration the Lebanese health context.

The EML list was widely distributed to relevant health professionals in 1995 as a booklet explaining the definition and concept of essential medicines, the reasoning behind the need for an EML, information about the selection committee, how the list was developed and the final list adopted. The recommendation of the committee was to update the EML annually. However this was not applied and since then the EML has been updated every now and then by an unofficial committee that included relevant staff from the Ministry and WHO. The last updated version was developed in 2002 and it was not widely distributed. It was available at the Ministry whenever someone asked for it but was not made available on the website of the Ministry. The EML exists but it is not really used in practice. This is particularly the case in the private sector due to strong trade name affinity caused by heavy promotion especially for newly marketed medicines. Explicit criteria for medicine selection are generally not known in Lebanon and there seems to be some general misconception about the selection, use and the concept of essential medicines. In addition, medical practice in Lebanon follows different schools of practice, thus no national guidelines on treatment exists, which adds to the difficulty of using the EML in practice.

It is important to note here that after this assessment was conducted on the medicine selection function, which involved interviewing a high level official at the Ministry, an official selection committee was formed one week later to review and update the existing list. The new committee was formed including all relevant parties of the Ministry, international organizations, medical societies and academia. It has initiated its activities and the newly updated EML of Lebanon is expected to be ready in the near future. To prepare for its activities, the head of the new selection committee sent the existing list for comparison with the latest WHO list, which was issued in March 2007. In addition, the existing list was divided into sections depending on the therapeutic group and was sent out to specialists in each field to get their scientific and professional feedback. For example the section related to antineoplastic medicines were sent to an oncologist. This section contained 35 medicines versus only 19 in the most updated WHO list. The section that contained HIV medicines was sent to a specialist infection physician for review, this section contained 10 medicines versus 20 in the WHO list.

5.4.2 Strengths of the selection of medicines function

The strengths of the selection of medicines function are as follows:

- There is a national essential medicines list in Lebanon and all KIs are aware of its existence. (The score of Indicator 1 on this issue was 1 for all 10 KIs.)
- The existing EML is inline with WHO procedures and recommendations, i.e. the medicines are listed by their generic name and classified by the level of health care.
- There is a committee responsible for the development and selection of the national EML. The Lebanese EML is under a process of revision as the last list was developed in 2002, which means a revision within 5 years.

5.4.3 Weaknesses of the selection of medicines function

The weaknesses of the selection of medicines function are as follows

- Although an EML exist, it is not widely distributed and it is not available on the Ministry of Health website.
- There are no written criteria for the selection process or for including or deleting medicines from the national EML and there are no selection criteria for the members of the selection committee.
- There are no standard operating procedures for the selection committee, thus the decision-making process is not clear. There are also no specified terms of reference for the selection committee.
- Since there are no national standard treatment guidelines the selection process is not necessarily based on the country's needs.

- There is no conflict of interest form signed by the members of the selection committee.

5.4.4 Vulnerability to corruption score

Lebanon scored low on this function and rated as moderately vulnerable to corruption, since the activities of the selection committee were not re-activated for many years. In addition, there are no clear written criteria for the selection of medicines to be included in the EML list. Lebanon has a wide range of medicines for selection not based on the treatment guidelines but based on the availability of so many medicines in the market.

However, this assessment had the power to initiate change. Following this assessment action was taken to form a new committee for the revision of the EML and that is now underway. Therefore if a new assessment were to be conducted now it would result in higher scores. Yet a drawback of the assessment itself is that it focused only on the selection of essential medicines while the Ministry of Health is involved in the selection, procurement and distribution of other more advanced types of medicines (for example medicines for the treatment of cancer, multiple sclerosis, etc.).

5.4.5 Perception of KIs

60% of the KIs interviewed believe that the national EML was developed excluding some parties that should have been involved in the selection process. In addition, only 40% believe that the selection process is operating without external influence.

5.5 Procurement of medicines

5.5.1 Background

The government pays for certain medicines for the uninsured of the Lebanese population (approximately 50% of the population). The Ministry of Health uses three different procurement channels or mechanisms depending on the type of the medicine. The Ministry of Health procure vaccines and essential medicines for the use at the primary health care level through UNICEF. The Ministry pays LBP 3 billion (US\$ 2 million) for UNICEF to procure all the needed vaccines for almost 335 000 Lebanese children and to provide essential medicines (but not chronic medicines) used in primary health care centres around the country which serve around 750 000 people annually. UNICEF uses an international bidding system that the Ministry is not involved in. Estimation for the amounts needed are based on the annual consumption, adding a certain percentage increase each year. The Ministry of Health pays LBP 4 billion (US\$ 2.7 million) to a large nongovernmental organization

that is responsible for the procurement and distribution of chronic medications for more than 450 primary health care centres that provide free medication for 150 000 patients annually. In total 40 different medications are procured to cover 15 chronic diseases. The remaining of the allocated budget of the Ministry of Health for medicines, which is around LBP 45 billion, is used to procure medicines for severe diseases like cancer, HIV and some psychiatric illnesses, through a local tender procedure done by the Ministry. The Ministry distributes these medicines without charge through a modern, computerized central warehouse that was established in 1996. This centre serves around 15 000 patients yearly.

So there are different medicine procurement mechanisms followed depending on the type of pharmaceutical product and the only procurement procedure that the Ministry is directly involved in is the procurement of expensive medicines for severe diseases. There are different types of procurement methods to be followed depending on the purchasing value. There is direct contracting when value is up to LBP 3 million per patient, there is price comparison when the value is up to LBP 100 million and there is public bidding when the value is greater than LBP 100 million. All payments are processed by the Ministry of Finance. For the latter method, there is a tender committee that is formed yearly by a ministerial decree which has different responsibilities than the procurement office. There are written guidelines available for the committee to follow concerning the process of the bid. The medicine lists are developed based on the most prescribed medicines for the treatment of a certain disease, usually following US FDA guidelines, and not based on the EML of Lebanon. The selection process of the medicines on this list could not be evaluated with the current assessment. Medicine quantification is done using the patient files at the central warehouse from previous years.

When the medicine list is set, the tender is advertised in three different newspapers. The medicine list is set by brand name not by generic name but it is allowed for any similar product to apply for the tender. The procedure to be followed by the tender committee and the deadlines for applications are also published. There are no specific criteria for the committee and there is no conflict of interest form signed by committee members (procurement office staff need to sign a similar form in case it exists). There is a formal appeal process to be followed in case of the rejection of bids. No post-tender system is used to report on suppliers' performance to the tender committee. There are different types of audit on the procurement office including an audit from the Ministry of Finance to check for the contracts completed since they are the paying party and the central audit which is conducted by an independent entity of the government for audits on all types of governmental organizations and ministries.

Despite the standard guidelines and procedures for the procurement of medicines, shortage in the supply of some medicines is common and remains a problem due to many factors. These include the unpredictable timing of public procurement procedures and limited medicine budgets.

5.5.2 Strengths of the procurement of medicines function

The strengths of the procurement of medicines function are as follows:

- There are written procedures for the procurement of medicines through tenders and bidding that are publicly available. They are published in the local newspapers at the time of the tender.
- An objective quantification method is used to determine the quantity of pharmaceutical products to be purchased. It is based on yearly consumption plus a 20% predicted increase in consumption.
- Formal appeals do exist.
- An external audit is conducted regularly by the Ministry of Finance and another is conducted by an independent central audit unit.
- An advanced management information system or logistic support system is in place at the central warehouse thanks to the support of the WHO.

5.5.3 Weaknesses of the procurement of medicines function

The weaknesses of the procurement of medicines function are as follows:

- There are no specific criteria for the selection of tender committee membership and there is no requirement for the signing of a conflicts of interest form.
- Although, there is an objective quantification method to determine the quantity of medicines needed, it is not applied due to budgetary constraints.
- No quality control is conducted on the purchased medicines, since the central quality laboratory is currently not functioning.
- There is no formal post-tender system in place to report on the performance of the suppliers to the tender committee or procurement office.

5.5.4 Vulnerability to corruption score

Lebanon scored relatively high on this section, ranking it as marginally vulnerable to corruption.

5.5.5 Perception of KIs

Concerning the perception of the KIs about the selection process of the tender committee; most of them (40%) did not give a clear answer and the rest were divided between agree and disagree. So it was difficult to reach a clear conclusion regarding this question.

As for the transparency of the procurement system in Lebanon, peoples opinions were divided between agree and disagree (40% agreed vs. 40% disagreed). So once

again it was difficult to get an overwhelming indication of the perception of transparency of the procurement system.

5.6 Distribution of medicines

5.6.1 Background

The ultimate objective of the Ministry of Health is a successful pharmaceutical management system. This objective relies on good management and control of pharmaceutical distribution. An equitable system for medicine inventory and distribution is in place to support the objectives set by the Ministry in this regard and to improve monitoring and management of pharmaceutical usage and expenditure as well as securing accessibility to medicines for the most deprived sections of the Lebanese population. Regarding public medicine supply, since there are different methods for procurement of medicines, there are different distribution channels. In the period 1999–2000 some of the public hospitals gained managerial autonomy and consequently no longer receive their medicines from the Ministry of Health central medicines warehouse. The remaining small public hospitals and the primary health care centres and facilities are still dependent on the central medicines warehouse as the sole source of essential medicines, vaccines and other medical supplies. The central medicine warehouse was established in 1996 and in 2001 it was upgraded with computer hardware and software packages thanks to the help of WHO.

The Ministry of Health chronic distribution program is done through a large nongovernmental organization that is responsible for procurement and distribution of medicines for chronic disease patients at several primary health care centres. This party acts as the managing body of the project and the Ministry's only role is to provide the needed budget for this project.

Another Ministry of Health public medicine dispensing system is the way in which the Ministry distributes without charge medications for chronic severe conditions such as cancer to individual patients. This centre is part of the central drug warehouse situated in Beirut, where patients come from all over Lebanon. Patients who benefit from this medicine dispensing centre are those with no private health insurance or who are not covered by any other health scheme. A list of eligibility criteria is set by the Ministry. Applications of patients are studied by a scientific committee. Then the dispensing centre issues patient cards, monitors treatment and provides medications on a monthly basis. Cancer medicines make up the bulk of this operation both financially, taking 52% of the budget and in terms of numbers of patients (30% of the patients). A new project is currently being implemented to decentralize the distribution of cancer medicines and other medicines to different areas in Lebanon for greater efficiency and to increase the satisfaction of patients.

The central medicines warehouse has a computerized inventory system. It produces automated reports and statistics on consumption needs and the movement of medicines in and out. Recently the logistic support system was introduced with WHO support.

5.6.2 Strengths of the distribution function

The strengths of the distribution function are as follows:

- There is systematic and orderly shelving of products in central medicines warehouse according to type of medicine. For example vaccines are stored separately from other medicines and syrups and vials are stored separately from other dosage forms.
- There is a computerized management system for the inventory that is used in the central medicines warehouse and provides the information needed on the average working stock and inventory for each product, the frequency and the quantity for reordering.
- A physical inventory is done annually on all items in the central medicines warehouse by internal staff to double check stock records and it is also conducted randomly on selected items, particularly expensive medicines.
- An external audit is carried out once a year by an independent central auditors unit and any time that there is an official complaint or suspicion of deviation from practice.
- There is a computerized system to track the movement of pharmaceuticals from the central medicines warehouse to end beneficiaries such as hospitals, primary health centres and patients. It keeps record of the type and quantity of medicines that have left the warehouse, the date and the end recipient of the medications.
- There is a well-established communication system between all distribution points using manual documentation and telephone communication. The performance of the distribution system is monitored and evaluated on a regular basis by continuous feedback from recipients and by self-evaluation that is conducted annually.

5.6.3 Weaknesses of the distribution function

The weaknesses of the distribution function are as follows:

- Although all medicines provided by the government are stamped with the printed statement "Distributed for free by the Ministry of Health", the stamp can be easily removed.

- The central medicines warehouse has no security management system in place, no monitoring on entry and exit, no alarm system and no searching security system is used.
- There is no computerized program that connects all levels and points of distribution to each other. There is a delay in the feedback and ordering process.

5.6.4 Vulnerability to corruption score

Lebanon scored high on this function, and was found to be minimally vulnerable to corruption. The Ministry of Health is receiving support from the WHO in this regard in order to provide the central medicines warehouse with a new information system, computers and other equipment and the installation of the new logistic support system computerized program to better manage the distribution process.

5.6.5 Perception of KIs

50% of KIs agreed that the port clearing process is done smoothly. Opinions were divided equally (40% vs. 40%) on whether or not there is a leakage in the medicine distribution system. This could be due to the fact that there is more than one distribution system in place and each is operating in different manner.

6. Recommendations

6.1 General recommendations

The pharmaceutical sector in Lebanon is complex due to many factors. The first step in dealing with these complexities is to have a transparent process across all levels of the 'medicines chain' at the public level covering the decision points of the registration of medicines, inspection of manufacturers and distributors, selection of medicines, the procurement of medicines, the distribution of medicines and the control of medicine promotion to the public and to professionals. Having an explicit and clear policy/regulatory procedure in place is an important requirement for good governance of medicines practices.

This assessment can be used as a tool to evaluate the level of transparency of the government in conducting its operational work in the six functional areas under investigation, in order to identify weaknesses in the system, which could provide an easy entry point for corrupt behaviour. Based on the results of this assessment, Lebanon can initiate an action plan to adjust or amend some of its laws, administrative structures and procedures within the pharmaceutical sector. The scoring of this assessment does not imply in any way that any of the functions of the pharmaceutical sector in Lebanon is corrupt or any function is more corrupt than the other, rather it presents the vulnerability to corruption.

The results of this assessment will be discussed in a national workshop involving all relevant stakeholders from private and public sectors to reach a consensus on the type of action plan needed to start the implementation of the GGM in the public sector.

The results show that the medicine promotion and the medicine selection process in Lebanon require more legislation and regulations to regulate and enforce transparent and efficient practices. Other functions of the pharmaceutical sector need to achieve greater levels of transparency by making the procedures followed and decisions taken publicly accessible to all. Although there are laws and regulations in place that are applied most of the time without violation, many need updating to take into account the continuous developments made in the pharmaceutical sector at all levels. A code of ethics is also needed and the concept of conflict of interest needs to be introduced by law to be applied in practice where applicable.

The primary objective of this assessment was to measure transparency in the six core areas of the pharmaceutical sector in Lebanon. The following recommendations are intended to increase openness and transparency within the sectors and are not intended to address inefficiencies of the system.

6.2 Registration

The following are recommendations to improve the transparency of the registration function in Lebanon:

- Specify a time-frame for an application to be studied by the committee. There is a need for faster registration processing.
- Develop a clearly written document for the public explaining how registration decisions are taken by the committee.
- Develop written guidelines to be followed by the registration committee in the registration process.
- Ensure that formal appeals are submitted to a different regulatory body.
- Widely announce to the public that all the registration forms and requirements are already available on the website; most of the KIs from the private sector did not know that they exist on the website.
- Enforce a re-registration process of medicines every 3 to 5 years. In Lebanon, medicines are registered for life.
- Develop a conflict of interests form to be signed by the members of the registration committee.
- Provide technical support in terms of access to international information and access to data in order to check the data provided by medicine importers.

6.3 Control of medicine promotion

The following are recommendations to improve the transparency of the control of the medicine promotion function in Lebanon:

- Develop a more detailed law for medicine promotion. The existing law is explained in five lines.
- Write standard operating procedures for the control of medicine promotion based on the newly developed law.
- Develop a code of ethics for all medicine promotion activities to the public and to professionals to be enforced by the Ministry and the orders of pharmacists and physicians.
- Form an official committee inside the Ministry of Health and involve other relevant parties such as medical societies and academia to approve promotional material and take action against unethical promotional practices by pharmaceutical companies and individuals.

6.4 Inspections

The following are recommendations to improve the transparency of the medicine inspection function in Lebanon:

- Centralize the process and introduce a reporting system which is the responsibility of one party to ensure better coordination.
- Introduce capacity building activities for the inspectors.
- Better equip the inspector teams with cars and computers.
- Provide legal protection to inspectors as some inspection operations can be dangerous.
- Follow-up on the inspection results through the courts and enforce severe sanctions in cases of violation, particularly in cases of medicine smuggling and counterfeiting.
- Introduce new standards for GMP for local manufacturers and inspection activities that target manufacturers in the country.

6.5 Selection of medicines

The following are recommendations to improve the transparency of the medicine selection function in Lebanon:

- Re-activate the selection committee (already done before the end of the assessment).
- Update the essential medicines list and make it widely available to all by nationwide distribution of hard copies and placing it on the Ministry of Health website. It should also include explanatory notes on the definition and concept of the essential medicines list and the reasoning behind the selection of all medicines on the list.
- Introduce written criteria for the selection of the committee members.
- Develop written criteria for the selection of medicines to be added to or removed from the essential medicines list. Include the use of evidence-based and cost-effectiveness information in the selection process.
- Publicize the essential medicines list widely within the private sector to encourage its use among practitioners. The gap between the public and the private sector needs to be bridged in order to coordinate this.

6.6 Procurement of medicines

The following are recommendations to improve the transparency of the medicine procurement function in Lebanon:

- Consider the impact of external influences on the procurement process.
- Develop standards for the medicines needed and quantities required based on real needs bearing in mind quality.
- Introduce a computerized system for all the steps involved in procurement, starting from announcing the tender or the bid up till procurement is complete.
- Include generics with established quality in the process.
- Announce the tender in all newspapers and on the website of the Ministry of Health with the tender list of medicines. Give enough time between the announcement and the deadline for application.
- Announce the results to the public with justifications.

6.7 Distribution of medicines

The following are recommendations to improve the transparency of the distribution of medicines function in Lebanon:

- Develop a better coding system for marking medications that are distributed by the Ministry of Health to ensure that it cannot be tampered with.
- Introduce security management and install an alarm system and cameras inside the central medicines warehouse.
- Link all points of distribution to each other for easy traceability of medicine stock and a faster ordering system between all levels of distribution and the central medicines warehouse.
- Post the list of medicines available without charge from the Ministry of Health on the Ministry of Health website.
- Ensure the supply of medicines in a practical manner and put a system in place to ensure continuous medicine supply. This can only be guaranteed with proper policy-based budget planning, revision of the current time-consumption, procurement practices and enforcement of Ministry of Health therapeutic guidelines in medicine dispensing.
- Involve the media in order to announce the processes of selection, procurement and distribution to the public, since these are sensitive issues that directly affect patients.

7. Conclusions

The study has shed light on some of the important steps taken by the Ministry of Public Health in Lebanon to maintain transparency and accountability in the public pharmaceutical system. It has also highlighted some areas in need of further efforts. Despite the prevailing political situation at the time of the assessment, strong political will has been shown to protect the system from its vulnerabilities to corruption and unethical practices. Some aspects of the relevant structures, policies and procedures have already been updated and improved in the time between when the study commenced and this report was published.

In this respect, a follow-up assessment following the commencement of Phase III of the project should be scheduled to measure the progress that the country has made and to highlight further areas that are particularly challenging. This would capture the possibly changing perceptions of those involved as well as the structural modifications introduced to the system.

8. Resource documents

- Law no. 367, article no. 36 of 14 August 1994, *Practice of the Pharmaceutical Profession*.
- Seiter A. *Lebanon health sector development project*, Technical discussion paper, Pharmaceutical Reform. Washington DC, World Bank, 2005.
- Helling Borda M, Ibrahim H, and Pogany J. *Comprehensive analysis of the pharmaceutical sector in Lebanon*, 1999.
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- Lebanon essential medicines used at the primary health centre, 1995.
- *Measuring transparency in medicines registration, selection and procurement: four country assessment studies*. Geneva, World Health Organization, 2006.
- *Situation analysis on national drug policies based on essential drugs in Lebanon*, 2002.
- *Good Governance for Medicines Program, Measuring transparency to improve good governance in the public pharmaceutical sector: assessment instrument*. Geneva, World Health Organization, 2007.
- Statistics from Order of Pharmacists, 2006.
- Statistics from Order of Physicians, 2006.
- Statistics from the central drug warehouse, 2007.

Annex 1. Score sheets for functions

- Table A1. Medicine registration vulnerability scale points
- Table A2. Medicine promotion control vulnerability scale points
- Table A3. Medicines inspection vulnerability scale points
- Table A4. Medicines selection vulnerability scale points
- Table A5. Medicine procurement vulnerability scale points
- Table A6. Medicine distribution vulnerability scale points
- Table A7. Perceptions of KIs

Table A1. Medicine registration vulnerability scale points

Lebanon		Dates assessment carried out: 29/10/2007–21/11/2007															
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	P	P	N	P	N	P	G	G	G	G							
Indicator I.1	1	1	1	1	1	1	1	1	1	1						10	1
Indicator I.2	0.625	0.5	1	0.75	0.875	0.625	0.625	0.875	0.57	0.71						7.155	0.7155
Indicator I.3	0.857	0.57	0.857	0.857	0.429	0.286	0.857	0.857	0.857	0.71						7.137	0.7137
Indicator I.4	0.8	0.17	0	0.5	0	0	0.833	1	0.5	0.5						4.303	0.4303
Indicator I.5	1	1	1	1	1	1	1	1	1	1						10	1
Indicator I.6	0	0	D.K	0	0	0	0	0	D.K	0						0	0
Indicator I.7	1	1	1	1	1	1	1	1	1	1						10	1
Indicator I.8	0.857	0.75	0.75	0.625	0.625	0.875	0.75	0.875	0.75	0.625						7.482	0.7482
Indicator I.9	1	0.71	0.5	0.857	0.625	0.875	0.75	0.75	0.75	0.75						7.567	0.7567
Indicator I.10	0	0	0	0	0	0	0	0	0	0						0	0
Indicator I.11																	
Indicator I.12	0.67	0.43	0	0.57	0.43	0.429	0.6	0.428	0.71	0.33						4.597	0.4597
Indicator I.13	1	1	1	1	1	1	1	1	1	1						10	1
Indicator I.14																	
Indicator I.15	<i>see text in narrative report</i>																
Indicator I.16	<i>see text in narrative report</i>																
																Total	7.8241
																***Final core registration	6.52083333

*Profession

G = Government or public official

P = Private sector (national or international)

N = Nongovernmental organization (national international)

IO = International governmental organization

M = Media

O = Other

**The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded

***Score = total average/number of indicators x 10

Table A2. Medicine promotion control vulnerability scale points

Lebanon		Dates assessment carried out: 29/10/2007–2111/207															
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	G	M	P	G	P												
Indicator II.1	1	1	1	1	1											5	1
Indicator II.2	0.9	0.83	0.22	0.2	0.5											2.65	0.53
Indicator II.3	1	1	0	0.75	1											3.75	0.75
Indicator II.4	1	1	1	1	1											5	1
Indicator II.5	1	0.67	0	0	0											1.67	0.33
Indicator II.6	1	1	0	0	0											2	0.4
Indicator II.7	1	1	0	0	0											2	0.4
Indicator II.8	D.K	0	0	0	0											0	0
Indicator II.9																	
Indicator II.10																	
Indicator II.11																	
Indicator II.12																	
Indicator II.13	see text in narrative report																
																Total	4.41
																***Final score promotion	4.9

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***Score = total average/number of indicators x 10

Table A3. Medicine inspection vulnerability scale points

Lebanon		Dates assessment carried out: 29/0/2007–21/11/2007															Total	Average per question**
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15			
Profession*	G	G	G	G	G													
Indicator III.1	1	1	1	1	1											5	1	
Indicator III.2	1	1	1	1	1											5	1	
Indicator III.3	0.67	D.K	D.K	D.K	0.5											1.17	0.585	
Indicator III.4	0.5	0.67	0.67	0.67	0.5											3.01	0.602	
Indicator III.5	0.14	0	0	0	0											0.14	0.028	
Indicator III.6	1	1	1	1	1											5	1	
Indicator III.7	1	1	0.6	0.6	0.6											3.8	0.76	
Indicator III.8	0.75	0.5	1	1	1											4.25	0.85	
Indicator III.9																		
Indicator III.10	see text in narrative report																	
Indicator III.11	see text in narrative report																	
																Total	5.825	
																***Final score inspections	7.28125	

*Profession

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**The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded

***Score = total average/number of indicators x 10

Table A4. Medicines selection vulnerability scale points

Lebanon		Dates assessment carried out: 29/10/2007–21/1/2007															
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	P	G	G	P	N	P	IO	IO	N	G							
Indicator IV.1	1	1	1	1	1	1	1	1	1	1						10	1
Indicator IV.2																	
Indicator IV.3	0	0.167	0	0	0	0	0.286	D.K	0.83	1						2.283	0.253666667
Indicator IV.4	0.167	0.67	0.167	0.33	0.83	0.5	0.67	0.67	1	1						6.004	0.6004
Indicator IV.5	1	1	1	1	1	D.K	1	1	1	1						9	1
Indicator IV.6																	
Indicator IV.7	0	0.714	0.14	0	0	0	0	0.33	0.5	1						2.684	0.2684
Indicator IV.8	D.K	0.14	0	0	0	0	0	D.K	0	D.K						0.14	0.02
Indicator IV.9	D.K	1	0.67	0	0	0	0	0	0	D.K						1.67	0.20875
Indicator IV.10	0	0.67	0.5	D.K	0	0	0	0	0	D.K						1.17	0.14625
Indicator IV.11	see text in narrative report																
Indicator IV.12	see text in narrative report																
																Total	3.497466667
																***Final score selecion	4.371833333

*Profession
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***Score = total average/number of indicators x 10

Table A5. Medicines selection vulnerability scale points

Lebanon		Dates assessment carried out: 29/10/2007–21/11/2007															
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	G	P	P	P	G	N	G	G	IO	G							
Indicator V.1	0.714	0.75	0.56	0.75	0.67	0.78	1	0.89	0.857	1						7.971	0.7971
Indicator V.2	1	1	1	1	D.K	1	D.K	1	D.K	1						7	1
Indicator V.3	1	1	1	1	1	1	1	D.K	1	1						9	1
Indicator V.4	1	1	1	1	1	1	D.K	1	D.K	1						8	1
Indicator V.5	0.67	0.67	0.67	0.67	1	0.67	D.K	0.33	D.K	0.67						5.35	0.66875
Indicator V.6	0	0.33	0.33	0.14	0	0	D.K	0.29	D.K	0.33						1.42	0.1775
Indicator V.7	0	0.14	0	0	0	0	D.K	0	D.K	0						0.14	0.0175
Indicator V.8																	
Indicator V.9	0.29	1	0.285	1	0	D.K	1	1	1	1						6.575	0.730555556
Indicator V.10	0.25	0.25	0.25	0.25	D.K	D.K	0.33	1	0.5	0.25						3.08	0.385
Indicator V.11	0.5	0.83	0.5	1	0	D.K	D.K	1	1	1						5.83	0.72875
Indicator V.12	0.67	0.875	0.875	0.875	0.75	D.K	0.857	1	1	0.857						7.759	0.862111111
Indicator V.13																	
Indicator V.14	see text in narrative report																
Indicator V.15	see text in narrative report																
																Total	7.367266667

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M = Media

O = Other

**The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded

***Score = total average/number of indicators x 10

Table A6. Medicine distribution vulnerability scale points

Lebanon		Dates assessment carried out: 29/10/2007–21/11/2007															
	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	N	G	G	G	G	IO	G	P	N	P							
Indicator V.1	1	1	1	1	D.K	D.K.	D.K.	1	D.K.	D.K.						5	1
Indicator V.2																	
Indicator V.3	1	1	1	1	1	1	D.K.	1	1	1						9	1
Indicator V.4	1	1	1	1	1	1	1	1	1	1						10	1
Indicator V.5	1	1	1	1	1	1	1	1	1	1						10	1
Indicator V.6	0.25	0.25	0.5	0	0.25	0	0.25	0.25	0.25	0						2	0.2
Indicator V.7	1	0.5	1	1	0.83	1	1	0.833	0.6	1						8.763	0.8763
Indicator V.8	1	D.K.	1	1	1	1	1	1	1	1						9	1
Indicator V.9	1	0.67	1	0	1	0	0.67	0	0.33	0						4.67	0.467
Indicator V.10	1	1	1	0.83	1	0.83	1	0.83	1	0.83						9.32	0.932
Indicator V.11	0	1	0.75	0.75	1	0.5	0.25	1	0.75	0.5						6.5	0.65
Indicator V.12	0.14	1	0.875	0	0.57	0	0.71	0.14	0.14	1						4.557	0.4557
Indicator V.13	1	1	D.K.	0.67	0.67	D.K.	0	0.67	0	1						5.01	0.62625
Indicator V.14																	
Indicator V.15	see text in narrative report																
																Total	9.20725

*Profession

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**The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded

***Score = total average/number of indicators x 10

Table 7A. Perceptions of KIs

Answers	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Not applicable	Don't know
Total	1	4		5			
Promotion Q14							
Total	2	4		3	1		
Q9							
Total	1	2		1		1	
Q10							
Total	1	1		2	1		
Q11							
Total	2	1		2			
Inspection Q9							
Total	2	3					

Perceptions of KIs

Selection Q2

Total	2	3		1	2	2	
	Q6						
Total	2	1		2	2		3

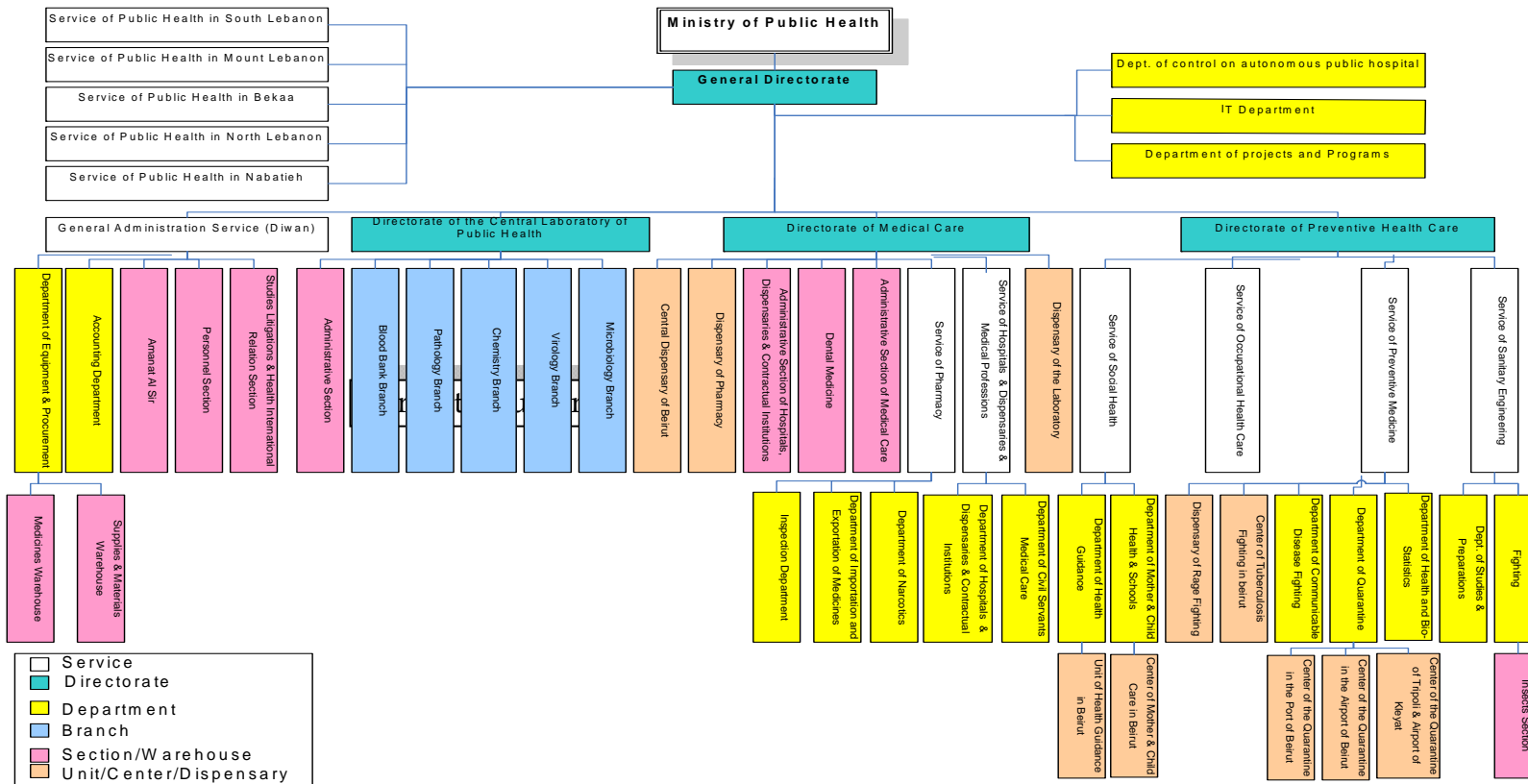
Procurement Q8

Total	1	1	1	1	2	2	2
	Q13						
Total	2	2		3	1	1	1

Distribution Q2

Total		2		3	2		3
	Q14						
Total	3	1		2	2		2

Annex 2. Organizational structure and staffing at the Ministry of Public Health



- Service
- Directorate
- Department
- Branch
- Section/Warehouse
- Unit/Center/Dispensary

Annex 3. List of evidence obtained

The following documents were gathered from various sources including government bodies and organizations and used in the assessment:

Registration:

- Pharmacy law 1994
- Sample of list of pharmaceutical products on website
- Application form for registration placed on website.
- Hard copy application form for registration available at the Ministry of Health.
- Checklist of registration requirements.
- Ministerial decision on forming a technical committee for registration.
- Regulations on submission of application process.
- Sample written format for decision of technical committee.

Promotion:

- Pharmacy law 1994, decree numbers: 36,37, 69.
- Reminder for need of pre-approval of Ministry of Health for promotional material.

Inspection:

- Pharmacy Law 1994, decree numbers: 82-85.
- Instructions placed on website on inspection process.
- Lebanese GMP 1985.

Selection:

- Booklet on Essential Medicines: Historical Background, Responsible Committee, List of 1992.
- Ministerial decree to form a new committee for the selection of essential medicines, 2007.

Procurement:

- Ministerial decree to form an official tender committee.
- Summary of activities of the tender committee.
- Conditions for the bidding process.
- Example of a contract between Ministry and supplier.

Distribution:

- Distribution process description.