

WORLD HEALTH ORGANIZATION

**MEASURING TRANSPARENCY
TO IMPROVE GOOD GOVERNANCE
IN THE PUBLIC PHARMACEUTICAL SECTOR**

LEBANON ASSESSMENT

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Acknowledgments

This assessment is based on interviews conducted in Lebanon from October to December 2007 using the Transparency assessment developed by WHO. The author thanks all concerned officials of the Ministry of Health, especially those from the Department of Import & Export of Medicines, Inspection & other Pharmaceutical Departments at the Ministry of Health. A special thank you also goes to people who accepted to be interviewed from the private sector, academia, and international; organizations, for their participation and their time.

The authors desire to express their best wishes to the Government of Lebanon and the Ministry of Public Health for the next steps of the project on good governance in the pharmaceutical sector.

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LIST OF ABBREVIATIONS

EIPD:	Export & Import of Pharmaceutical Department
EML:	Essential Medicines List
GDP:	Good Distribution Practices
GMP:	Good Manufacturing Practices
GPP:	Good Pharmacy Practices
KI:	Key Interviewee
MIS:	Management Information System
MoH:	Ministry of Health
NA:	National Assessors
NI:	National Investigator
OTC:	Over the counter
PPP:	Public Procurement Procedures
SOPs:	Standard Operating Procedures
WHO:	World Health Organization

DRAFT

EXECUTIVE SUMMARY

This report presents the results of the study *Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector* in Lebanon. The assessment provides a picture of the level of transparency and potential vulnerability to corruption in six essential functions of the public pharmaceutical sector: registration, control of drug promotion, inspection, selection, procurement, and distribution of medicines.

This assessment was essential before launching any intervention aimed at increasing transparency. The data has been collected by a team of three people through standard questionnaires (developed by WHO & was used in 7 countries before) with selected key interviewees. The results indicate the vulnerabilities of the policy, structures, and procedures in place at the time of the survey. It doesn't reveal in any way the level of possible existing corruption in the country.

Findings

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 (MOH). Lebanese MOH developed a website in order to disseminate information. this website can be used in the future to access all the procedures and the criteria for any decision making within the ministry.

Each area of the public pharmaceutical sector has an operational and functional committee responsible for decision making that are made of all relevant stakeholders in the country and not just MOH staff.

Registration

There are written guidance for companies to submit an application including a standard application form to register their products. There is also an up-to-date list of all medicines registered in the country published on the website of the MOH.

Promotion

The actual legislation requires that material for advertisement of non-prescription and prescription drugs should be approved by the Ministry of Health prior to any promotional act.

Inspection

A scheduling system identifies facilities to be inspected. Inspectors use standard checklist for the inspection of pharmacies and companies. There is guidance to write the report which is subject to internal review and audit.

Selection

LEBANON has a national Essential Medicines List (EML) publicly available.

Procurement

LEBANON uses the Public Procurement Procedures (PPP). PPP are general procedures for the procurement of any goods or services by the government that are used in other ministries as well. They include guidance for the type of procurement method to be used.

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 committee, roles, responsibilities, and professional qualifications of the members could be added to the document describing the composition of the committee.

A recommendation would be to clearly define all law enforcement processes as well as roles and power of officials and committees able to enforce the law. All laws and regulations should also be made easily accessible.

Declaration of interest should also be developed for the members of committees and government officials. Another recommendation would be to develop an appeal mechanism to manage concerns and complains of the private sector.

Conclusion

This assessment was the first step of the WHO's project on *Good Governance in 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.

Evidence from this assessment will help the policy makers revise and adjust the actual 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 are needed to improve good governance.

1. INTRODUCTION

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 means: defining policies and procedure in print and publishing the printed documentation, giving reasons for decisions to the party concerned and giving reasons for rejecting applications. Transparency should be present at all levels of decision-making, work plans, operating procedures, communication with the stakeholders and 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 & November 2007.

1.1 Objectives

This assessment is designed to provide Lebanon and other countries all over the world with a comprehensive picture of the level of transparency and potential vulnerability to corruption in the procedures followed and structure of the system of six functions of the pharmaceutical sector at the public level.

The assessed functions include:

- Registration of Medicines
- Control of Medicine Promotion
- Inspection
- Selection
- Procurement of Medicines
- Distribution

This assessment is an initial step that will be followed by the development and implementation of a national officially adopted Good Governance of Medicine (GGM) program in Lebanon based on the results of this assessment in an effort to increase the transparency/accountability of the pharmaceutical sector.

1.2 Methodology

1.2.1 Official clearance

The Lebanese Ministry of Public Health agreed to participate in the WHO's project on Good Governance in Medicines. Clearance from the MPH was obtained before the initiation of the process by the national assessors. The Minister of Health and the General Director were verbally informed about the assessment objectives, methodology and the process to be followed when conducting the assessment. Full support was guaranteed.

1.2.2 National Assessors

Three national assessors were selected and nominated by the Ministry of Public Health. They were appointed by HE the Minister of Public Health due to their expertise in policy, quality and supply in the public pharmaceutical field in Lebanon.

The three national assessors received training on the WHO transparency assessment methodology in Geneva, September 2007. This training provided the basis for conducting the assessment in a manner consistent with other participating countries globally, while maintaining flexibility for national assessors to adapt the assessment instrument should local needs or discrepancies necessitate this.

The three NAs were involved in the following:

- Desk Work: collection of related material (Laws & Regulations) by section.
- Finalize List of KIs to be interviewed for each section
- Prepare Letters to be send to KIs to ask for appointments and confirmation
- Training on Arabic version of the translated questionnaire
- Conduction of Interviews with selected KIs, each NA was expected to conduct 15 interviews each according to distributed work. (Every NA was given the chance to conduct interviews on all different sections to avoid any bias)
- Meeting with WHO Consultant (co-facilitator) who made a visit to Lebanon to assess the progress of the assessment and who were given detailed feedback on the Arabic version of the assessment and the distribution section (since it is the first time to be used). Visit was between 12 & 14 November, 2007
- Data Entry/Data Analysis/Transcription of Results
- Feedback meetings on the results and the findings
- Report Writing
- Planning for the feedback meeting
- Planning for a national workshop

1.2.3 Data Collection Tools

A different questionnaire is designed for each section (function) of the assessment, where four methods are used to determine the level of transparency of the practice. The methodology used in this assessment is intended primarily to collect qualitative information on selected indicators and then quantify the vulnerability to corruption by having a final score (Method 1&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.

- Through semi-structured interviews:

The questionnaire is administered during a formal interview conducted by the national assessor (NA) with a key informant (KI).

- Collection of relevant documents:

To validate the information on structural indicators with existing evidence in the country and compare the evidence found with the replies of the KIs by finding and collecting documents.

1.2.4 Selection of key informants

KIs were selected based on their direct involvement in the pharmaceutical sector representing the public and private sector, non-governmental organizations, international organizations, and media. KIs were selected to include both senior and junior professionals, members of MOH registration committee, regular pharmacist staff at MOH, representative from a local manufactures, representative from big & small pharmaceutical companies, representatives of scientific offices, members of orders of pharmacists & physicians, academia, WHO staff, Unicef staff, representatives of NGOs (big & small), representative from governmental hospitals (big & small), media consultants, staff at central warehouse, staff at procurement office, members of tender committee, staff at inspection department, staff from the financial department, and staff of the primary health program.

All interviews were conducted between 29.10.2007 and 21.11.2007

50 KIs were interviewed as follow:

10KIs for Registration section

5KIs for the Promotion section: could not find enough KIs due to short time.

5KIs for the Inspection section: could not find enough KIs due to short time.

10KIs for the Selection section

10KIs for the Procurement section

10KIs for the Distribution section

1.2.5 Interviews and Data sources

Table 1: Interviews by type of institution

	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

Documents and references were collected from MOH website: www.public-health.gov.lb Provisions of relevant laws, decrees, sub-decrees, regulations and circulars related to the public pharmaceutical sector.

1.2.6 Statistical analysis

Four methods are used to determine the level of transparency by using rough quantification. Each of the four methods was given equal weight.¹

The first and the second methods consisted of a series of questions that require a binary answer (yes/no). A “yes” is given a value of 1 and a “no” is given a value of 0. A value of 1 represents low vulnerability to corruption and a rating of zero represents high vulnerability. The second method involves questions that each includes a series of binary sub-questions or criteria. The final rating of those indicators is the total number of yes answers divided by the total number of valid answers. Questions not answered by the KI are not taken into account in the calculation of the score.

The third method implies subjective questions which probe the perceptions of the KIs. The KI is asked whether he strongly agrees, agrees, is undecided, disagrees or strongly disagrees with the statement. Basic frequencies have been used to present the results. The fourth method used open questions. KIs can also provide additional input on the function in general.

Only answers of Method 1 & 2 are accounted in the final score. All individual scores for method 1 & 2 were entered on the computer using the consolidation Excel Sheet template that was structured by WHO and used to calculate the final score for each section for the transparency assessment.

The results are interpreted as the degrees of vulnerability to corruption as follows.

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

1.2.7 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 analysis 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 is designed where KIs and other key actors in the pharmaceutical field will have a chance to scrutinize the report findings and comment on sections where needed.

¹ For more details see assessment instrument

2. OVERVIEW OF THE PUBLIC PHARMACEUTICAL SECTOR IN LEBANON

For the past 30 years Lebanon endured recurrent conflicts that severely affected its health sector resulting in a weakened Ministry of Health (MOH), cost escalation, particularly in MOH expenditures, a weakened primary health care (PHC) system, unrestricted growth of the private sector, and definitely had its impact on the pharmaceutical sector. Furthermore, the inflation of health expenditures put Lebanon at the same rank of expenditures of industrialized countries where Lebanon spends approximately 10-11% of its GDP on health.

Pharmaceuticals constitute a high share of the total health expenditure in Lebanon accounting for 25% of the total health care expenditure. The majority of the Lebanese population (the total population estimated to be around 3.7 million) pays out-of-pocket for the pharmaceutical products with an average cost of \$125 per person per year (this figure is believed to be underestimated but there is no documentation of an updated figure). This fact can be related to the characteristics of the medical practice in Lebanon where there is no gatekeeper in medical practice, nor checks over doctors' fees neither control over doctor's prescriptions consequently physicians can market any specific brand. In addition, the heavy promotion to the 8000 doctors in Lebanon (more than 2 doctors per 1000) has created trade name affinity; subsequently knowledge and use of generic names hardly exists. Furthermore, by law the pharmacist is not allowed to substitute a generic for a prescribed drug and has no incentive to dispense the cheaper drugs since their profit is a fixed percent of the price of the drug.

The majority of the registered drugs in Lebanon are imported drugs; mostly from Europe and the USA, accounts for 94% share (value) of the pharmaceutical market; they are imported by 85 importer. The 7 local manufacturers have only 6% of the market and operate only to a fourth of their capacity. Pharmacists can sell most drugs without any prescription (exceptions are psychoactive drugs for which prescription is enforced). Lebanon has 1923 pharmacies and 4673 pharmacists (distributed all over the Lebanese territories 10425km²); this high number has a direct impact on availability of drugs, but not necessarily on accessibility and affordability.

At the Ministry level

In parallel, the Ministry of health expenditures is also increasing fast, where 5.5% of the government budget is allocated to health. In 2003, the drug budget was 29 billion Lebanese pounds (L.L) while now in 2007 the drug budget is 52 billion L.L. The ministry covers hospital inpatient expenditures of all uninsured persons in Lebanon, which amounts to approximately half of the population. In addition, MOH provides individual patients with drugs free of charge for severe (debilitating) diseases (HIV/AIDS, cancer, multiple sclerosis, mental illnesses, kidney dialysis, etc..) through MOH public drug dispensing system. In 2006, 1741 new cases of cancer were treated at the expense of the

MOH mind that the national statistics reports 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 drugs at the MOH.

On the other hand, MOH procures essential drugs and vaccines for primary health centers from UNICEF, covering about 50% of children with vaccination (the remaining 50% are vaccinated in the private sector). The MOH has a parallel program for distribution of drugs for chronic diseases (diabetes, hypertension and other diseases) in collaboration with a big NGO through public health dispensaries all over the country.

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

The department of Pharmacy at the MOH has 3 sub-units; Inspection, Importation & Exports, and Narcotics. It handles all drugs regulatory control matters, including licensing of premises and pharmacists. Currently, the national drug quality control laboratory is not functioning.

For all the reasons mentioned above and since the end of the civil war, the Government of Lebanon embarked on a health sector rehabilitation and reconstruction program in strengthening the MOH institutional capacity among other things. Restructuring of the drug policy emerged and still till date is as a main concern for the MOH. The pharmaceutical sector reform aims to reduce the national drug bill and make drugs in Lebanon more affordable and accessible to those in need of them. At the general scene of the pharmaceutical sector, the political will to bring change is apparent though not yet focused and refined. The usual resistance to change is obviously expressed from the sector's stakeholders. As a result, many initiatives and projects took place and a lot is still to be done to achieve the desired objectives.

The pharmaceutical sector in Lebanon is complex and the high drug bill could be due to many factors overlapping. Different stakeholders are involved in different stages of this sector. These include players from the Public sector, Private sector, and others. Lebanon's very large number of pharmacists and physicians, most of them working in the private sector contribute to escalating drug costs. There is an obvious surfacing political interest in the pharmaceutical sector reform but not enough will and commitment.

In addition, Lebanon does not have a modern drug regulatory authority structure including a National drug Policy-meaning a policy document that lays out a vision for the future of the sector and defines political, technical, economic and health related parameters that form the framework for pharmaceutical legislation. Another reason might be mismanagement of the system and resources due to lack of effective laws and regulations. Or it could be some sort of corruption or lack of transparency at one or more levels of the pharmaceutical system.

3. DATA PRESENTATION

The next section presents qualitative information collected through interviews for each indicator. The scores are presented in attached annex (A). Some indicators were asking the opinion of KIs on the types of unethical behaviour common in the registration system, in the control of drug promotion, in inspection in the selection process, and in procurement system. These answers are not presented in the report but were used to analyze the results and to elaborate the recommendations. KI 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.

3.1 Drug 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 last version is published on the website and updated every year.

Hard copies are available for free at the MOH 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 manufacturer but that information should be provided in the dossier. Actually, there is no specification for drugs 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 EIPD. Procedures are the reflection of various decrees, sub-decrees, and pharmacy law of 1994 on the process and rules for drug registration published by the Ministry of Health (MOH). It describes the process to follow and documents to submit for registration. Distributors and Companies wanting the procedures can come to EIPD at MOH and ask for it or access it from MOH website. Yet, seven KIs over ten were considering 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 that was approved lately by the council of ministers about the registration of pharmaceuticals and control. a national workshop will be held soon 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. The current law do not mention the timeframe for processing. Based on interviews, the duration of the process is not always the same, since 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 EIPD 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 timeframe 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 EPID. Hundred per cent of KIs were aware that it was publicly accessible (companies wanting to get the form can come to EPID and ask for it). The forms are also available at the MOH 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. However, there are no guidelines setting limits between government officers and applicants. But there are official days of the week where 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 representing staff at MOH, academia, and representatives from order of pharmacists and order of physicians.

There are no written criteria for selection but members should be pharmacists or physicians. All members have appropriate professional qualification 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 shall 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 (COI) form that members of the committee and public officials are obliged to complete?

There are no requirements for the declaration 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"?

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	1	4	0	5	0	0	0	10

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

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 the years of practice.

The committee usually signs the registration report and sends it to the Minister for approval. The report fits on one sheet and contains name of the product, the manufacturer, 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.

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

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

A formal appeal for applicants who have their drug rejected can be submitted to the registration committee. Reasons for rejection are explained in writing. Applicants have to come to EIPD 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"?

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	2	4	0	3	1	0	0	10

Six KIs over ten (60%) answer that gifts cannot influence the final decision.

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 of them mention conflict of interest and favoritism.

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 action that the KIs would take to improve the registration process in Lebanon regarding the **quality of services offered by public institutions:**

- Train employees of the public institution on new registration laws
- All files should be on CD especially technical part
- Adopt the international procedures for registration

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

- publish all requirements, process and procedures
- publish SOPs
- increase the services on the MOH website and increase publicity of the website
- increase knowledge of the services how people work by increase the awareness
- clarify the procedures of registration to the public
- submission of the files in the website
- there should be guidelines on COI
- the appeal committee should be different from the registration committee
- Accept the application electronically (especially the changes that occurred to the product.

3.2 Control of drug promotion

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

The pharmaceutical law no. 367 dated 1994, in the articles 41 and 69, stipulates that the 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 that was issued March 10, 1999 has been issued and again in February 15, 2007 as a reminder to companies regarding this issue.

The order of pharmacists is very active in regard of preventing advertisement of drugs to the public and violations are punished.

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

The provisions on promotion of medicines mention only the following areas: advertisement to 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 needed.

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 drugs and non prescription drugs are subjected to the pre-approval process of the MOH.

Any person who advertises pharmaceutical without authorization from the MOH shall be penalized. Based on this law, the MOH has right to immediately suspend the offending advertisement of pharmaceutical 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 we know, MOH has never filed a lawsuit in this area.

There are no rules or legislation concerning the advertisement of drugs directed to health care professionals for prescription drugs. Consequently, there is no enforcement mechanism for that kind of activity.

There is no complaint mechanism to report unethical practices in the promotion of drugs.

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

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

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 drug promotion.

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

There are no written Standard Operating Procedures (SOPs) guiding the services responsible for pre-approving or monitoring drug promotion and advertising.

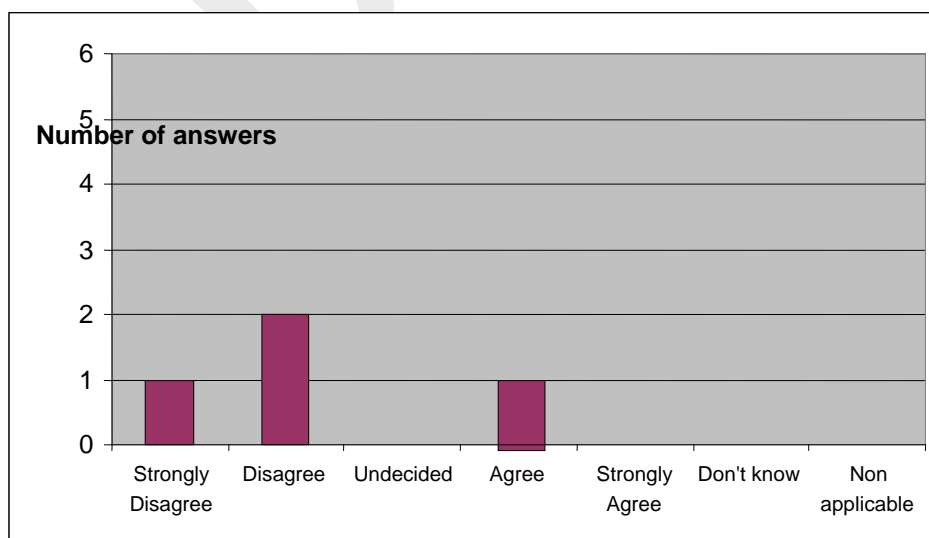
Indicator II.8: Are there written guidelines on conflicts of interest (COI) with regard to control of medicine promotion activities?

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

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

Majority do not agree with the statement.

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	1	2	0	1	0	1	0	5



There is no organization outside the MOH involved in reviewing, assessing and monitoring the promotion of medicines in LEBANON. In addition, there is no mechanism to reporting unethical practices in promotion.

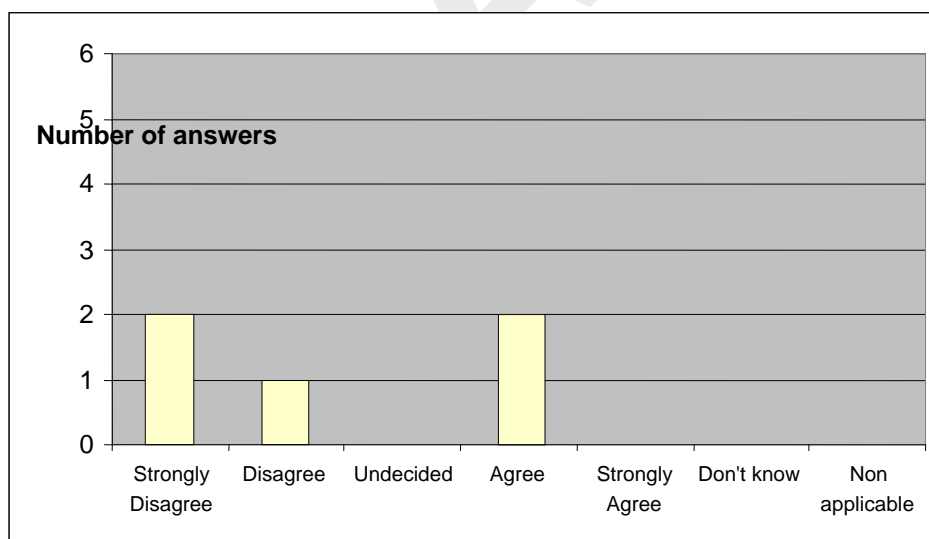
Indicator II.10: To what extent do you agree with the following statement: "Civil society/nongovernmental organizations have a great influence on improving the control of drug promotion in your country"?

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	1	1	0	2	1	0	0	5

60% agree or strongly agreed with the statement: "Civil society / nongovernmental organizations have a great influence on improving the control of drug promotion in Lebanon".

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

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	2	1	0	2	0	0	0	5



60% of KIs disagree or strongly disagree that the provision was not respected because the law was not enforced.

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

a) Involving health professionals and health institutions in general

The types of unethical behaviour those are common in the drug promotion area in Lebanon regarding health professionals and health institutions in general:

- material gifts (5)

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

There are no regulatory office or committee members responsible for drug 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 drug promotion process in your country?

a. The first action that the KIs would take to improve the drug promotion process in Lebanon in terms of the quality of services offered by public institutions:

- To enforce legislation covering drug promotion and advertising.
- establishing committee/ Government service for monitoring and enforcing the provisions on drug promotion
- written and publicly available SOPs guiding the services responsible for pre-approving or monitoring drug promotion
- To monitor the action of the pharmaceutical companies during the process of promotion
- to develop new regulations that would cover all drug promotion related issues
- The government should, in collaboration with medical associations, introduce and enforce policies that establish and monitor ethical standards with respect to pharmaceutical company promotion to prescribers.
- Review and enforcement of the laws and regulations to cover controlling drug promotion completely
- Drug promotion must be only for the registered drug and depending on scientific studies
- Training the health professionals how to adopt a good prescribing practice
- Enforce a law to monitor and punish unethical practice of the drug companies
- Comprehensive practitioner and consumer education program about the impact of unethical drug promotion

b. The first action that the KIs would take to improve the drug promotion process in Lebanon in terms of transparency in the services offered by public institutions:

- To establish a committee responsible for controlling drug promotion, and having a clear term of reference, COI, and SOPs.
- The services offered by public institution must be clear to the public and to the health professionals.
- Publish all available regulations and guidelines concerning controlling drug promotion.

3.3 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 medicines 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 drugs and checking the imported medicines at the customs and assures the quality of drugs available in the market.

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

KIs reported in a large majority that the provisions on inspection provide power to the inspector to enter at any reasonable time in any facility where medicinal products are produced, packaged, stored, distributed or tested in order to carry out an 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; it require inspectors to be provided with special identification document; it requires that a copy of the provision is available to companies being inspected

Law and regulation 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 MRA?

There are a written guidelines on classification of Good Manufacturing Practices (GMP) (last updated 1985) but we don't have a written guidelines on classification of Good Distribution Practices, the GMP guidelines are available in writing and easily accessible to all stakeholders.

Indicator III.4: Are there written procedures/mechanisms to prevent regulatory capture 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 MOH have procedures (not written) which help to prevent regulatory capture between inspectors and manufacturers/distributors inspected like: 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 to visit sites in teams, inspectors 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 inspector from another country.

The only written document available is the schedule of inspection for pharmacies and companies which is prepared on regular basis by the head of the inspection 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 (COI) with regard to inspection activities?

There are no written guidelines for the management of conflict 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. As is it required 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 standard operating procedures (SOPs) for inspectors on how to conduct inspections?

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

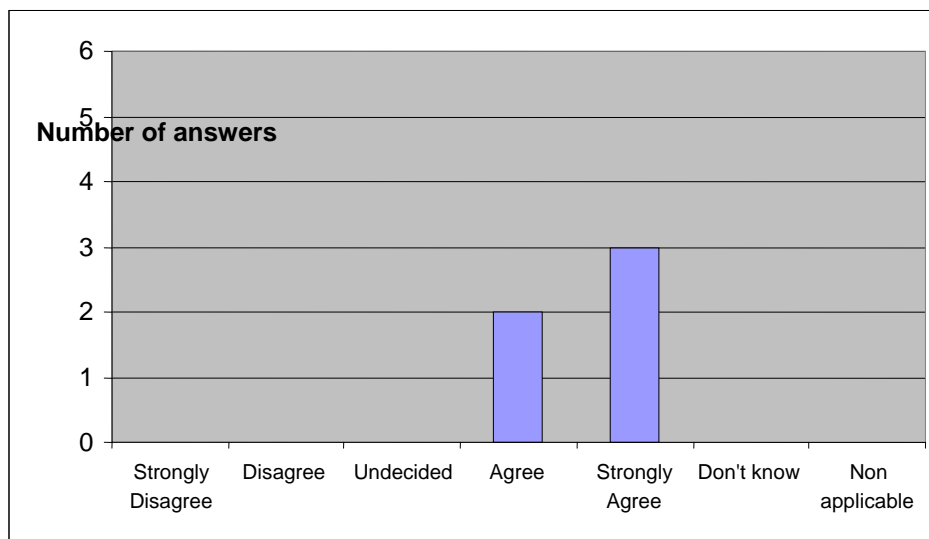
Indicator III.8: Are there written criteria for the selection and recruitment of inspectors?

The criteria for selection and recruiting inspectors only include the profession qualification required (pharmacist). Recruitment of inspectors does not need minimum number of years of work experience in the area, and does not base on recommendations from former employers. Recruitment is done through an independent official body “Majles El Khedma 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 agrees 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."

Sector	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	0	0	0	2	3	0	0	5



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 there are no common unethical behaviors in the registration system, but one of them mention favoritism.

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 action that the KIs would take to improve the inspection process in Lebanon regarding the **quality of inspection services** offered by public institutions:

- Training the inspectors.
- Increase the number of the inspectors.
- clear guidelines should be followed
- To establish an independent directorate for inspection

- Assurance of Good Manufacturing Practice and Good Distribution Practice should play a more significant role in drug 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 are:

- Written guidelines on conflict of interest with regard to inspection activities and mechanism of monitoring, sanction.
- System for manufacturers' inspection.
- Publishing all guidelines and procedures for inspection.
- Publishing post inspection reports.
- All the regulation covering inspection of medicines, and all the guidelines and procedures regarding inspection activity should be present on website.

3.4 Drug Selection

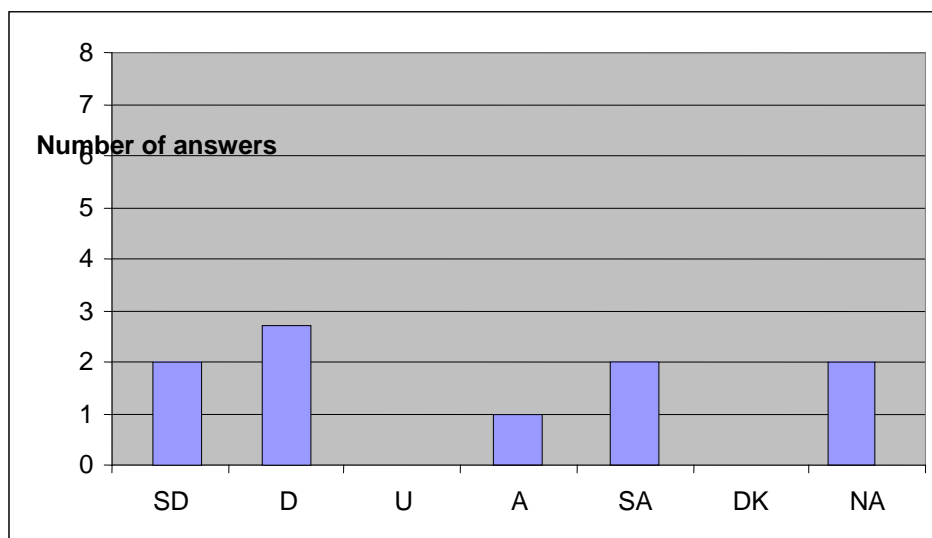
Indicator IV.1: Does the government have an officially adopted national essential medicines list (EML) publicly available?

The last edition of the LEBANON's essential medicine list (EML) was developed and published in 2002. The last updated list was not widely distributed, yet it was available at the ministry whenever someone asked for it (but not 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% disagreed or strongly disagreed with the statement "The Lebanese Rational Drug List has been developed in consultation with, and considering the opinion of, all interested parties and using an evidence-based approach"

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	2	3	0	1	2	2	0	10



The EML was updated every now and by an unofficial committee that included relevant staff from the ministry and WHO.

In addition, although the EML exists but not really used in practice, especially in the private sector due to strong trade name affinity caused by heavy promotion especially for newly marketed drugs. No national guidelines on treatment exists 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 drug selection are generally not used and there seems to be a general misconception on selection, use and concept of essential drugs.

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

The list was prepared by alphabetical pharmacological classification of drugs, by generic name and it included route of administration, dosage forms and strengths and by level of health care. It was developed based on WHO list taking into consideration the Lebanese health context.

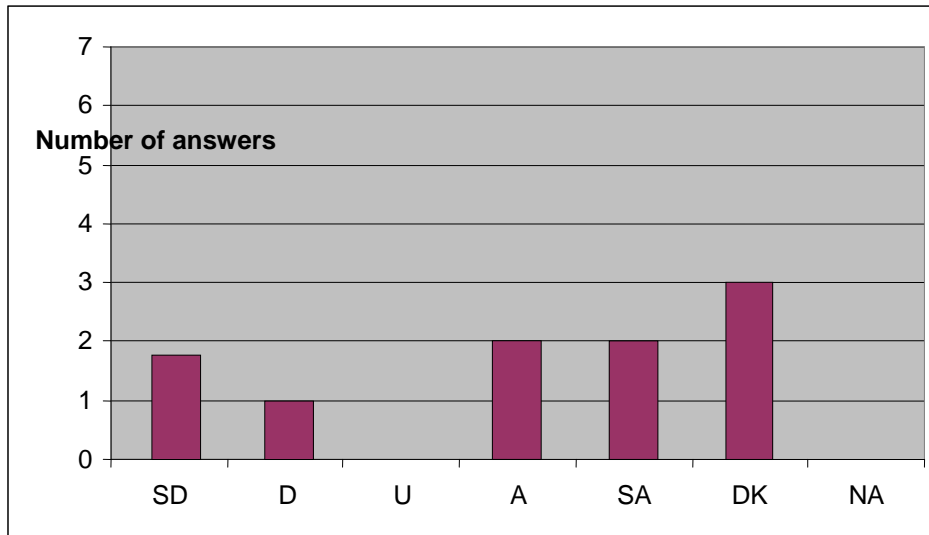
But we do not have national treatment guidelines for all common diseases in Lebanon, so the EML is not linked to national treatment guidelines, and EML is revised every 5-6 years.

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

A National list that was developed in 2002 was developed by an unofficial committee that included relevant staff from the ministry and 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"?

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	2	1	0	2	2	0	3	10



As the picture shows, 40% either agree or strongly agree with the statement. Members of the committee are free from the influence of the pharmaceutical companies.

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 (COI) 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 (SOPs) that describe the role and responsibilities of the selection committee?

There is a relatively clear decision making process but it is not available in a written format. The role 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.

None known to the KIs in this field.

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

a. The first action that the KIs would take to improve drug selection in terms of the **quality** of services offered by public institutions:

- choosing the drug must be depending on cost-effectiveness studies
- The rational drug list must be linked to national standard treatment guidelines
- the drug selection should be on the basis of the scientific (generic) name
- set treatment guidelines for chronic diseases and enforce doctors to stick to it
- a national standard treatment guidelines must be published and must be linked to the rational drug list
- a member from private sector must be in the selection committee

b. The first actions that the KIs would take to improve drug selection in terms of **transparency** in the services offered by public institutions are:

- publish all the scientific information for the reasons of choosing these drugs
- set written guidelines on the COI
- training members to review on cost-efficacy bases
- set laws to force all doctors in public sector to stick to the lis
- The rules for decision-making in the SOPs must be clear & transparent to the public.

3.5 Procurement

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

The government pays for a certain number of drugs for the uninsured of the Lebanese population (50% of the population).

Ministry of Health uses 3 different procurement channels (mechanisms) depending on the type of the drug. The MOH procure vaccines and essential medicines for the use at the primary health care level through UNICEF. MOH pays for a big NGOs that is responsible for the procurement and distribution of chronic medications for more than 450 primary health care centers that provide medications for free for 150,000 patients yearly. 60 different medications are procured to cover for 15 chronic diseases.

The rest of the allocated budget of MOH for drugs is used to procure drugs for sever diseases like cancer, HIV, some psychiatric illnesses through a local tender procedure done by the MOH. The MOH distribute these drugs for free for around 15,000 patients yearly.

So, there are different drug procurement mechanisms that are followed depending on the type of the pharmaceutical product. The only procurement procedure that the ministry is directly involved in is the procurement of expensive drugs for sever diseases. All payments of procurement are done by the directly Ministry of Finance and all procurement procedure 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. There is the direct contracting when value is up to 3million L.L per patient, there is the price comparison when the value is up to 100million L.L and there is the public bidding when the value is more than that.

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

Drug 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 drugs 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 (TC) that is formed yearly by a Ministerial decree and has different responsibilities than the procurement office.

There is written guidelines for the committee to follow concerning the process of the bid. The drug lists are developed based on the most prescribed drugs for the treatment of a certain disease (usually follow FDA guidelines).

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

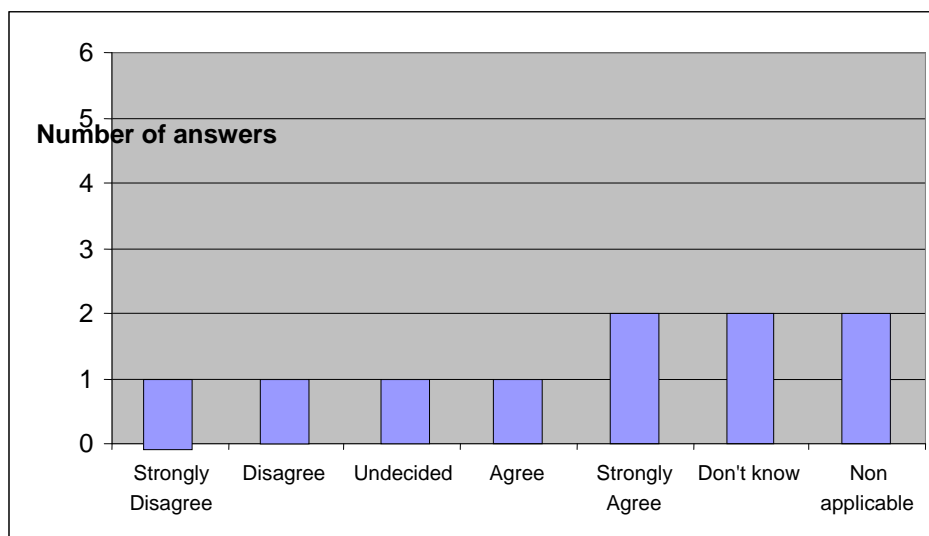
No specific or written criteria are available. But the tender committee include members who are appointed for their professional expertise. The members should have skills that complement each other, including senior government officials in various departments at the MOH and pharmacists, but it does not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

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

There is no declaration of conflict of interest. In the view of 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)"?

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	1	1	1	1	2	2	2	10



In this indicator could not have a clear cut answer.

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 monitor supplier and facility performance. It also record all quality assurance Information for products purchased, and track the status for each order, including the quantities actually purchased compared with the original estimates made.

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

The Inspection department is responsible for the inspection of all drug 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 TC.

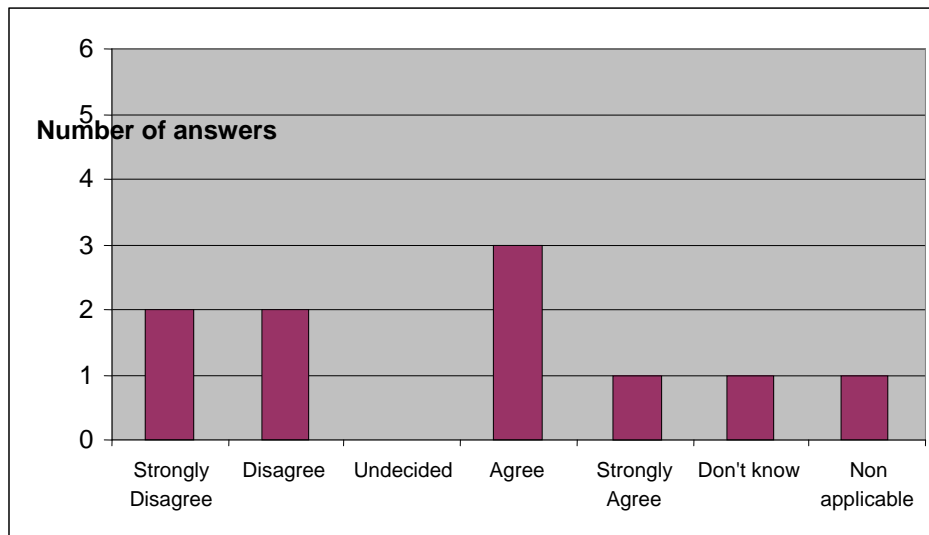
Indicator V.12: Does the procurement office undergo regular audits?

Audit is compulsory as required by the Law on Audit of Lebanon. There is an annual audit of the Procurement Unit of the MOH

There are different types of audit on the procurement office, audit from the ministry of finance to check for the contracts done since they are the paying party and the central audit which is an independent entity by the government to have 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"?

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	N.A.	D.K.	#
Total	2	2	0	3	1	1	1	10



KIs equally agree/strongly agree and disagree/strongly disagree on this statement. Two of the ten KIs did not know. so we cannot have a final conclusion regarding this.

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 Jordan:

- 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:
 - Train employees of the public institution
 - The criteria for selecting tender members committee must require representation from client facilities.

- The structure of procurement department should include the following key functional areas: specification section; accountancy section; quality assurance section; including audit; procurement section; receiving and checking section; and the Information Technology support.
- Public sector tender procurement should be restricted to the Rational Drug List.
- Procurement procedures should be reviewed to ensure that prospective suppliers are pre-qualified, and their performance is monitored for product quality, service reliability, delivery time and financial viability and appropriately recorded in retrievable database.
- Simplifying procurement process which will have a positive impact on the system and improve effectiveness which can be achieved by: requiring a more evidence-based approach to drug selection for procurement and rationalization of drug 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:

- Set written guidelines on COI with regard to procurement process.
- Submission of the tender process and result in the website.
- The members of the tender committee must declare COI.
- The blacklist of non-performing or poor performing suppliers should be regularly updated and a copy of the list be forwarded to the procurement department.

3.6 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% agrees or strongly agree with the statement "Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process".

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

Computerized system is used to control expiry dates of medicines put alphabetically or by manufacturer, etc.

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

There is no effective security management system to oversee storage and distribution, although there is a regulations for monitoring of entry and exit to warehouses; limited access to unauthorized persons. However, there is no alarm system for security breaches and there is no physical search when leaving the warehouse.

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

There are an 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 staffs continuously produce the most recent records of current stock levels reconciled with physical count of selected medicines. General physical count takes place once per year.

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

The warehouses are subjected to external auditing by Central Audit office at regular intervals, and sudden auditing by ministry of health. When asked, the warehouse supervisor should be able to provide the date of the last audit that was conducted and show: report of warehouse audit; audit is 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 provide information on medicines that have left the warehouse to health facilities including: type of medicines that have left the warehouse; quantity of medicines that have left the warehouse; the person who verified the amounts; the intended recipients of these medicines; 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 include; a manual/document exchange system between distribution points at all levels; telephone contact between all levels of the distribution points; and fax contact between some levels of the distribution points; but a computerized system is unavailable currently.

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

There is no programme exist 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: the procedures foreseeing the application of sanctions for corrupt behaviour exist; they include the type of sanctions to be applied depending 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% agrees or strongly agrees with the statement “there are very rarely leakages in the medicine distribution system in Jordan”.

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

a. 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:

- Train employees of the public institution
- More effective security management to oversee storage and distribution
- A computerized system for the communication between distribution points

4. DATA ANALYSIS AND DISCUSSION

4.1 Scales of Vulnerability

The overall scores for each function of the assessment are summarized in Table 1. For a more detailed presentation of these results please refer to Annex A.

Table 1: Vulnerability scale scores in the six different sections for Lebanon.

Function	Registration	Promotion	Inspection	Selection	Procurement	Distribution
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

Table 2: Perception of KI on the transparency level of each function

Section	Question	Perception of KIs
Registration	The Members of the registration committee are systematically & objectively selected based on the written criteria in force in Lebanon	50% Agree
	Gifts & 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 drug 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 drug promotion in Lebanon	60% Strongly Agree or Agree
	The provisions on drug 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 evidence-base 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 member 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 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 information was collected during the interviews and through the analysis of the information supplied by KIs. The information is presented in the areas of registration, promotion, inspection, selection, procurements and distribution of medicines.

4.2.1 Drug Registration

Description of Registration Process in Lebanon:

The registration of pharmaceutical products is the responsibility of a technical committee which is under the Ministry of Health. Imported and locally produced drugs applications for registration are studied by this committee whose members are specified in the 1994 law pertaining to drugs. Specifications are laid down in the decrees. Registration requirements were set in the Ministerial Decision (MD) 233 dated March 9, 2003 then amended by the MD 212/1 dated April 5, 2004. The latest registration check list used includes additional requirements that were added by the Technical committee. In addition, to this check list there is no clear documented and published policy as for the conditions to obtain a drug registration approval. There is no guideline as for the number of applications an applicant is allowed to submit in one shot or during a limited period of time. Number of accepted applications is random, depending on the completeness of the file submitted. As a result, Lebanon is reported to have over 4000 registered drugs. Registration is for life; there is thus no requirement for registration renewal.

Before the application is submitted to the technical committee a regular staff 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 then is granted a number reflecting the technical committee queuing system.

The members of the technical committee are specified in the 1994 law to include members from MOH, order of pharmacist, order of physicians and from academia. The MOH members are mentioned by titles, for example in the committee there are the head of pharmacy department, head of export & import department and head of inspection department, usually these members serve for a long time as long as they are in their position (some remained the same for a decade and more). While the 2 members from each the orders of pharmacists and physicians are replaced every time there are new elections in the orders administrations. The registration committee is allowed to meet 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.

Strengths:

Include the existence of:

- A list of all registered pharmaceutical products that include a defined minimum 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 is placed on the website of the ministry. A drug formulary will soon be printed and distributed to health professionals.
- A standard application form for submission of application, which is publicly accessible and readily available in addition to registration requirements check list available on the website of the ministry as downloadable files along with directions on the department responsible for receiving applications for registration (Department of Drugs Import & Export), fees, and data to be submitted. These documents are available at the Import & Export department at the ministry as well.
- The application form holds the product name (trade & generic); the check list requirements include: GMP certificate, certificate of analysis, bioavailability studies, pharmacodynamic & pharmacokinetic data, clinical trials, price certificate, etc...
- A formally established technical committee responsible for registration for pharmaceutical products composed of professionals from relevant parties with technical skills, which meets on regular basis. The committee reaches its decision by majority, in cases of tie votes; the vote of the head of the committee will make the final decision. There is a quorum requirement for the meetings.
- The result of an application is given in written format to the applicant. With reasons for rejection if the product was rejected by the committee.
- An appeal process for applicants who have their application rejected exists; all appeals are submitted to the same technical committee that made the original decision on the application.

Weaknesses:

- Although, the applicant is asked to submit a CD that contains all relevant information with the hard copy of the application requirements; manual maintenance of the information submitted for registration application is still in use.
- There are no available documented Standard Operating Procedure for registration; the committee use only the registration requirements check list to evaluate the applications. Decision is based on the judgment of the committee members.

- Lack of detailed terms of reference for the committee members; lack of description of duties, lack of description of responsibilities and accountability of the committee members.
- There is no pre-defined registration timeline, a queuing system is used. Time needed to registration can vary from four months for apriority life-saving product, to two years.
- No required conflict of interest form to be completed for the members of the registration committee.
- No official list of OTC drugs issued and published by the MOH.

Conclusion

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

KIs Perception:

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

4.2.2 Control of Drug Promotion

Description of Drug Promotion Process in Lebanon:

The pharmaceutical law no. 367 dated 1994, in the articles 41 and 69, stipulates that the 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 that was issued March 10, 1999 has been issued and again in February 15, 2007 as a reminder to companies regarding this issue.

The order of pharmacists is very active in regard of preventing advertisement of drugs to the public and violations are punished.

The order of pharmacists, the importers and representatives of multinational companies are currently working on a marketing ethics initiatives.

There is a rare advertisement of drugs to the public if ever that takes place in Lebanon. On the other hand, advertisement to the professionals is not controlled. Heavy promotion to physicians takes many forms in Lebanon. Only big multinational companies have restrictions on drug promotion to professionals; they have internal code of ethics that they act accordingly.

Strengths:

- There is a law about prior approval by MOH for promotional material used by companies.
- Strong actions taken by the order of pharmacists to prohibit advertisement of drugs to the public.
- Existence of collaboration between the order of physicians, the order of pharmacists, importers and local industry to control the promotional practice of pharmaceutical companies.

Weaknesses:

- No control of published medical information by the MOH; although law exists, no official committee exists for approving and monitoring and enforcing the provisions on drug promotion and advertisement
- Lack of ethical criteria for drug promotion that enhance good prescribing and dispensing practices and in line with WHO criteria

Conclusion

Thus, Lebanon scored relatively low on the function of Drug Promotion Control; this is mainly due to the lack of applied law and lack of code of ethics. It was found to be moderately vulnerable to corruption in this regard. In practice there is a restriction on drug promotion to the public, but not to the professionals due to lack of control by the MOH, but the order of pharmacists play an active role.

KIs Perception:

60% of the KIs interviewed think that the legal provision on drug promotion was not developed in consultation with all interested parties, thus the provisions are not well respected. Same proportion of people interviewed think that the civil society and NGOs will have an influence on improving the control of drug promotion.

4.2.3 Inspection

Description of Drug Inspection Process in Lebanon:

There is a provision covering inspection of medicines 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 drugs and checking the imported medicines at the customs and assures the quality of drugs available in the market.

There is a lack of updated guidelines and standards for Good Manufacturing Practice (GMP), the latest Lebanese GMP guidelines go back to February 20, 1985. GMP certificates are granted for local manufacturing plants once they are submitted for approval and registration by the responsible committee (where the inspection unit is not included). There is no GMP routine audit for local industry after that. Local manufacturing plants undergo inspection of their active ingredients and their finished products by sampling of such which is sent for analysis. Yet, there local manufacturers have self-imposed standards that are beyond the Lebanese law requirements.

The necessity to export pharmaceutical products to abroad markets or to obtain sub-licensing contracts from international pharmaceutical industry had led to this self-imposed standard. The inspection work is decentralized by areas, each inspector follow the head of the health department in areas outside the capital. No common reporting system between the areas in terms of inspection work done. The inspectors are under-equipped (no transportation facilities in case they wanted to go to distant areas, no computerized work; only manual reports).

Strengths:

- Presence of a comprehensive provision and law covering inspection activities.
- Giving the inspectors all the power needed with detailed description of duties and responsibilities.
- Availability of a SOPs on how to conduct inspections
- Availability of selection and recruitment criteria of inspectors.
- Availability of continuous internal review of all reports of the inspection unit by the head of the inspection unit

Weaknesses:

- Lack of an updated GMP standards
- Lack of routine GMP audits for local manufactures
- Lack of conflict of interest written guidelines with regard to inspection activities.

Conclusion

Lebanon scored relatively high on this section, thus it is marginally vulnerable to corruption; due to the presence of strong law, committed staff although under-equipped.

KIs Perception:

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

4.2.4 Selection

Description of Drug Selection Process in Lebanon:

Lebanon has a history of drug selection that goes back to early 1960s; it was one of the first countries in the region to create a list of limited drugs to be adopted and reimbursed in the country, that 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 drug. Ministry of Health worked on its first essential medicine list (EML) in 1987 that was updated in 1992 after an official committee was formed for this purpose. This committee was formed by the Minister of Health back then based on the WHO recommendation to have an updated EML. This committee involved members from all interested parties (Ministry, WHO, UNICEF, Orders of pharmacists and physicians, representative from all universities of medicine and pharmacy, representatives from NGOs). After the committee finished the selection process of drugs to be included in the list it was sent out to many medical centers for review.

All feedback and recommendations about the content were used to finalize the EML. This list included 200 drugs (in Lebanon there is 4382 registered drug) that were classified into 3 categories depending on the level of health care used in (Essential drugs for Primary Health Care Use, for General Hospital Use, and drugs used for specialized units in hospitals and dispensaries). The list was prepared by alphabetical pharmacological classification of drugs, by generic name and it included route of administration, dosage forms and strengths. It was developed based on 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 drugs, the need for a EML, selection committee, how it was developed and the final list adopted.

The recommendation of the committee was to update the EML yearly. Nevertheless this was not applied.

Since then the EML was 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. The last updated list was not widely distributed, yet it was available at the ministry whenever someone asked for it (but not on the website of the ministry).

The EML exists but not really used in practice, especially in the private sector due to strong trade name affinity caused by heavy promotion especially for newly marketed

drugs. Explicit criteria for drug selection are generally not known in Lebanon and there seems to be a general misconception on selection, use and concept of essential drugs. In addition, medical practice in Lebanon follow different schools of practice; thus no national guidelines on treatment exists which adds to the difficulty of using the EML in practice.

IMPORTANT NOTE: After the conduction of this assessment (drug selection section) with one of the high level authority 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 from ministry, international organizations, medical societies and academia. It was given a duration of 2 months to finish its activities. It is expected to have the new updated EML of Lebanon early 2009. 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 by parts depending on the therapeutic group and was sent out for specialists in each field to get their scientific and professional feedback (for example the part related to antineoplastic drugs was sent to an oncologist and the part that contained HIV drugs was sent to a specialist infectious physician for review)

Strengths:

- There is a national essential medicines list in Lebanon, and all KIs know about its existence.
- The existing EML is in line with WHO procedures and recommendations; drugs are listed by their generic name and classified by level of health care.
- The existence of a committee responsible for the developing and selection of the national EML
- Lebanese EML is in the process of revision, last list was developed in 2002 (revision within 5-6 years).

Weaknesses:

- Although an EML exist, it is not widely distributed and it is not available on the ministry website.
- There are no written criteria for selection process for including or deleting medicines from the national EML, and no selection criteria of the members of the selection committee.
- There are no Standard Operating Procedures (SOPs) for the selection committee. No specified terms of reference for the selection committee.
- Since, there are no national standard treatment guidelines; selection process is not truly based on country needs.

- No conflict of interest form is being signed by the members of the selection committee.

Conclusion

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

This assessment had the power to initiate change; action was taken to form a new committee and the revision of the EML is in process. If a new assessment will be conducted after 2 months from now it will result in higher scores.

KIs Perception:

60% of the KIs believe that the national EML was developed excluding some parties that were supposed to be involved in the selection process. In addition, only 40% believe that the selection process is operating without external influence.

4.2.5 Procurement

Description of Drug Procurement Process in Lebanon at Ministry Level:

The government pays for a certain number of drugs for the uninsured of the Lebanese population (50% of the population).

Ministry of Health uses 3 different procurement channels (mechanisms) depending on the type of the drug. The MOH procure vaccines and essential medicines for the use at the primary health care level through UNICEF. MOH pays 3 billion L.L (2 million \$) for UNICEF to procure all the needed vaccines for almost 335,000 Lebanese children, and to provide essential drugs (but not chronic drugs) that are used in the primary health care centers around the country which serve around 750,000 yearly. UNICEF use an international bidding system that the ministry is not involved in. estimation for the amounts needed are based on the yearly consumption adding a certain percentage increase.

MOH pays 4 billion L.L around (2.7 million \$) for a big NGOs that is responsible for the procurement and distribution of chronic medications for more than 450 primary health care centers that provide medications for free for 150,000 patients yearly. 40 different medications are procured to cover for 15 chronic diseases.

The rest of the allocated budget of MOH for drugs which is around 45 billion L.L is used to procure drugs for sever diseases like cancer, HIV, some psychiatric illnesses through a

local tender procedure done by the MOH. The MOH distribute these drugs for free through a modern, computerized central warehouse that was established in 1996. This center serves around 15,000 patients yearly.

So, there are different drug procurement mechanisms that are followed depending on the type of the pharmaceutical product. The only procurement procedure that the ministry is directly involved in is the procurement of expensive drugs for severe diseases. There are different types of procurement methods to be followed depending on the purchasing value. There is the direct contracting when value is up to 3million L.L per patient, there is the price comparison when the value is up to 100million L.L and there is the public bidding when the value is more than that. All payments are done by the Ministry of Finance.

For the latter method, there is a tender committee (TC) that is formed yearly by a Ministerial decree and has different responsibilities than the procurement office.

There is written guidelines for the committee to follow concerning the process of the bid. The drug lists are developed based on the most prescribed drugs for the treatment of a certain disease (usually follow FDA guidelines) and not on the EML of Lebanon (selection process of drugs in this list could not be evaluated with the current assessment used). Drug quantification is done using the patient files at the central warehouse from previous years.

When the drug list is set, the tender is advertised in 3 different newspapers. The drug list is set by brand name not by generic, but it is allowed for any similar product to apply for the tender. The procedure to be followed by the TC and the deadline to apply are also published. There are no specific criteria for the TC and there is no conflict of interest form signed by TC members (procurement office staff needs to sign a similar form in case it exists). There is a formal appeal process to be followed in case of rejection of bids. No post-tender system is used to report on suppliers' performance to the TC. There are different types of audit on the procurement office, audit from the ministry of finance to check for the contracts done since they are the paying party and the central audit which is an independent entity by the government to have audits on all types of governmental organizations and ministries.

Although procurement of drugs, follow standard guidelines and procedures, yet, shortage in the supply of some drugs is common and remain to be a problem due to many factors. Among which unpredictable timing of public procurement procedures and limited drug budgets.

Strengths:

- There is a written procedure for procurement of drugs through tenders and bidding that is publicly available by being published in the local newspapers at the time of the tender.
- The use of an objective quantification method to determine the quantity of pharmaceutical products to be purchased. It is based on yearly consumption plus 20% predicted increase in consumption.
- Formal appeals do exist.
- An external audit is being conducted regularly by the Ministry of Finance and another independent central audit unit.
- The existence of an advanced management information system; Logistic Support System (LSS) placed at the central warehouse with the support of WHO.

Weaknesses:

- No specific criteria for the selection for tender committee membership and no conflict of interest form is signed.
- Although, there is an objective quantification method to determine the quantity of drugs needed, it is not applied due to budgetary constrains.
- No quality control is being conducted on the purchased drugs, 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 TC or procurement office.

Conclusion

Lebanon scored relatively high on this section, thus it is marginally vulnerable to corruption.

KIs Perception:

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, could not reach a conclusion regarding this question.

As for the transparency of the procurement system in Lebanon, people opinions were divided between agree and disagree (40% agree vs. 40% disagree) and again we could not have an overweighing answer.

4.2.6 Distribution

Description of Drug Distribution Process in Lebanon by the Ministry:

The ultimate objective of the MOH of a successful pharmaceutical management system relies on good management and control of pharmaceutical distribution. An equitable system for drug inventory and distribution is in place to support the objectives set by the MOH in this regard to improve monitoring and management of pharmaceutical usage and expenditure as well as securing accessibility to the most deprived slices of the Lebanese population.

Regarding public drug supply, since we have different methods for procurement of drugs, we have different distribution channels. In 1999-2000 period, some of the public hospitals gained managerial anatomy and no longer receive their drugs from the MOH central drug warehouse (CDW). The remaining small public hospitals and the primary health care centers and facilities are still dependent on the CDW as the sole source of essential drugs, vaccines and other medical supplies. The CDW was established in 1996; in 2001 it was upgraded with computer hardware and software packages with the help of WHO.

MOH chronic distribution program is done through a big NGO that is responsible for procurement and distribution of drugs for chronic disease patients at several primary health care centers. This party is acting as the managing body of the project; MOH only role is to provide the needed budget for this project.

Another MOH public drug dispensing system through which the MOH distribute for free medications for chronic catastrophic conditions such as cancer for individual patients. This center is part of the CDW, is situated in the capital (Beirut), where patients come from all over Lebanon. Patients who benefit from this drug dispensing office/center are those with no private health insurance or not covered by any other health scheme. A list of eligibility criteria are set by the ministry. Applications of patients are studied by a scientific committee. Then the dispensing center will issue patient cards, monitor treatment and provides medications on monthly basis. Cancer drugs make the bulk of this operation both financially (52% of the budget) and in patient numbers (30% of the patients). A new project is currently implemented to decentralize the distribution of cancer drugs and other drugs in different areas in Lebanon for more efficiency and increase satisfaction of the patients.

The CDW has a computerized inventory system; it produces automated reports and statistics on consumption needs, and movement of drugs (in and out). And currently the logistic support system LSS was introduced by WHO support.

Strengths:

- There is a systematic and orderly shelving of products in CDW by type of drug (for example: vaccines are stored separately from other drugs). Syrups and vials are stored separately from other dosage forms.
- There is a computerized management system for inventory that is used in the CDW and provides the information needed on average working stock and inventory for each product, frequency and quantity of reordering.
- A physical inventory is done annually on all items in the CDW by internal staff to double check stock records, and randomly on selected items especially expensive drugs.
- External audit is carried once a year by an independent central auditors unit, and any time when there is a official complain or suspect of deviation from practice.
- There is a computerized system to track movement of pharmaceuticals from CDW to end beneficiaries (Hospital, PHC, Patients). It keeps record of the type and quantity of medicines that have left the warehouse, date and 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 regular basis by continuous feedback from recipients and by self-evaluation that is done yearly.

Weaknesses:

- Although all drugs provided by the government is stamped with a sentence saying “Distributed for free by the MOH”, yet the stamp can easily be removed.
- The CDW has no security management system in place; no monitoring on entry and exit, no alarm system and no searching security system is used. .
- No computerized program that connects all levels and points of distribution to each other, delay in feedback and ordering process.

Conclusion

Lebanon scored high in this section, and was found to be minimally vulnerable to corruption. MOH is receiving support from WHO in this regard, i.e. providing the CDW with a new information system, computers and other equipments, and the installation of the new LSS computerized program to better manage the distribution process.

KIs Perception:

50% only agreed that the port clearing process is done smoothly. Opinions were divided equally (40% vs. 40%) that there is or there isn't 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.

5. RECOMMENDATIONS

The pharmaceutical sector in Lebanon is complex due to many factors.

The first step in dealing with this complexity is to have a transparent process along all levels of the 'medicines chain' at the public level at least starting from the registration of medicines; inspection of manufactures and distributors; selection of medicines; their procurement and distribution ending with the control of drug promotion to the public and professionals. Having an explicit and clear policy/regulatory procedure in place is an important requirement for good governance of medicines practices.

The assessment used is a tool to evaluate the level of transparency of the government in conducting its operational work and identify weaknesses in the system which might act as an entry point for corrupted behaviour. Thus, based on the results of this assessment, Lebanon can initiate an action to adjust/amend or change some of its laws, administrative structures and procedures at the pharmaceutical sector. The scoring of this assessment does not imply in any way that any of the sections of the pharmaceutical sector in Lebanon is corrupt or any section is more corrupt than the other.

The results of this assessment need to be discussed in a national workshop involving all relevant stakeholders from private and public sectors to come up with consensus on what is the action plan that need to be followed to start the implementation of the GGM in the public sector.

The results show that the drug promotion and the drug selection process in Lebanon need more laws and regulations to regulate and enforce the practice. Other functions of the pharmaceutical sector need to be more transparent by making the procedures followed and decisions taken publicly available to all.

Although there are some laws and regulations in place and applied most of the time without violation; yet they need to be updated to take into account the continuous development done in the pharmaceutical sector at all levels.

A code of ethics is needed and concept of conflict of interest needs to be introduced by law to be applied in practice when applicable.

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

5.1 Drug registration

- Need to specify a time line for an application to be studied at the committee. Need a faster process for the registration process.
- Need to develop a well elaborated written document for the public explaining how registration decision is taken by the committee.
- Need to develop written guidelines to be followed by the committee in the registration process.
- Formal appeals need to be submitted to a different regulatory body.
- Need to widely announce to the public that all the registration forms and requirements are already placed on the web; most of the KIs from the private sector did not know that they exist on the web.
- Need a re-registration process of drugs every 3 to 5 years. In Lebanon, drugs are registered for life.
- Need to develop a COI form to be signed by the members of the registration committee.
- Need to computerize the whole process of the registration for easy accessibility.
- Need technical support in terms of access to international information and access to double check for data provided by drug importers.

5.2 Control of Drug Promotion

- Need to develop a more elaborated detailed law on this issue. The existing law is explained in 5 lines. Work is needed to write a SOP for monitoring of drug promotion based on the developed law.
- Need to develop a code of ethics for all drug promotion activities to the public and to the professionals.
- Need to form an official committee inside the ministry of health that involve other relevant parties (medical societies, order of physicians & pharmacists, academia, etc) to give approval for promotional material, and take actions against unethical promotional practice by pharmaceutical companies and individuals.

5.3 Inspection

- The process need to be centralized and enforce a reporting system to one party for better coordination.
- Need capacity building of the inspectors.
- Need to well equip the inspector team with cars, and computers.
- Need to have legal protection; some inspection operations might be dangerous.
- The results of the inspection need to be followed in the court and placement of sever sanctions in cases of violation especially in cases of medication smuggling and counter-fitting.
- Need new standards for GMP for local manufacturers; and inspection activities targeting manufacturers in the country.

5.4 Selection

- Re-activate the selection committee (already done before the end of the assessment).
- The EML need to be updated and to be widely available to all by nationwide distribution of hard copies and placing it on the ministry website. Need to have explanatory notes on the definition and concept of EML and reasons for selecting a drug and not another.
- Place written criteria for the selection of the committee members.
- Need to have written criteria on the selection process of drugs to be placed or removed from the EML list. Implement use of evidence-base and cost-effectiveness information in the selection process.
- The EML need to be widely spread in the private sector and encourage its use among practitioners. Need to bridge the gap between the public and the private sector and the need for coordination in this aspect.

5.5 Procurement

- Need standards for drugs needed and quantities based on real needs keeping in mind the quality.
- Use a computerized system for all the steps starting from announcing the tender /bidding till procurement is done.
- Include generics with established quality in the process.
- Announce the tender in all newspapers and on the website of the MOH with the tender list of drugs. Give enough time between announcement and deadline for application.
- Announce the results to the public with justifications.

5.6 Distribution

- Need a better coding system that can not be removed to mark medications that are distributed by the MOH.
- Need security management and alarm system and cameras inside the CDW.
- Need to connect all points of distribution to each other for easy traceability of drug stock and faster ordering system between all levels of distribution and the CDW.
- Place the list of available drugs at the MOH for distribution for free at the MOH website.
- Need to supply drugs in a realistic manner and have a system in place to insure continuous drug supply, which would only be assured with proper policy-based budget planning, revision of the current time-consumption, procurement practices, and enforcement of MOH therapeutic guidelines in drug dispensing.
- For the selection, procurement and distribution sections there is a need to work with Media to announce the process to the public, since these are sensitive issues that affect directly patients.

6. CONCLUSIONS

The study has shed light on some of the efforts which have been undergone 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 of 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 since the study commenced to the date of publishing this report.

In this respect, a follow-up assessment should be scheduled to measure the progress the country has made and to further highlight areas which are particularly difficult in handling. This would most suitable be after phase III of the project has been commenced

to capture the perceptions of those involved as well as the structural modifications introduced to the system.

As demonstrated in the recommendations, Lebanon's priorities regarding good governance for medicines in the coming period should focus on the following areas:

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ANNEX A: SCORE SHEETS

Scores for method 1 and 2 questions:

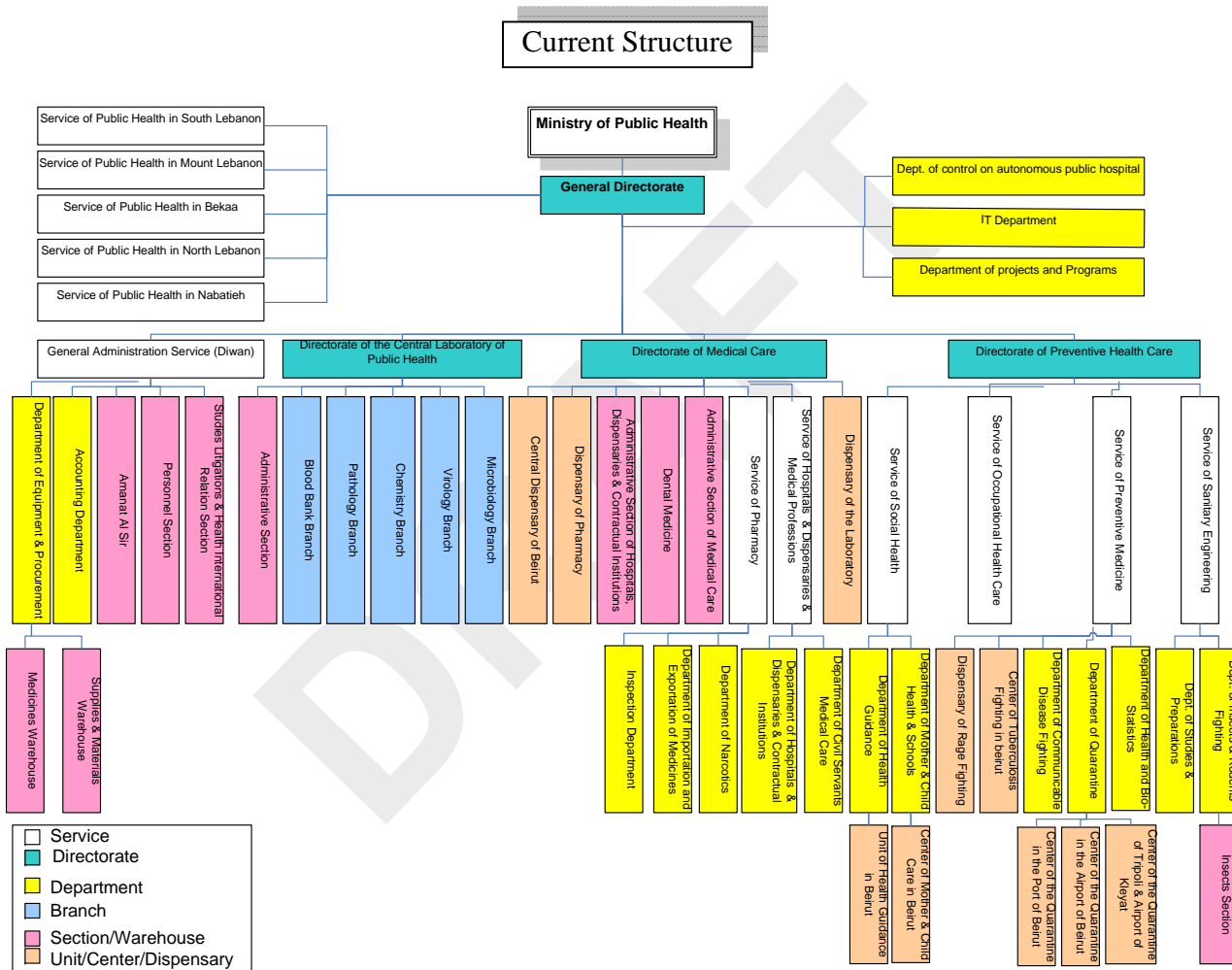
- Registration
- Promotion
- Inspection
- Selection
- Procurement
- Distribution

Method 3

KI perception

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ANNEX B: ORGANIZATIONAL CHART OF CENTRAL LEVEL MINISTRY OF HEALTH



ANNEX C: LIST OF EVIDENCE OBTAINED

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**
- **Check List of Registration Requirements**
- **Ministerial Decision on forming a Technical Committee for Registration**
- **Regulations on Submission of application process**
- **Fees to be paid**
- **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 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 Drugs: Historical Background, Responsible Committee, List of 1992**
- **Ministerial Decree to form a new committee of selection of essential drugs, 2007**

Procurement:

- **Ministerial Decree to form an official Tender Committee (TC)**
- **Summary of activities of TC**
- **Conditions for Bidding Process**
- **Example of contract between Ministry and Supplier**

For Distribution:

- **Distribution Process Description**