Increasing Transparency and Good Governance in the Pharmaceutical Sector: Lebanon a Country Case Study

A successful joint Lebanon WHO Good Governance in Medicines Programme

Background

Lebanon is a small country on the eastern coast of the Mediterranean sea with a total land area of 10,452 km$^2$ and a population of 4,194,000 in 2008, where 87% lives in the urban areas and the remaining 13% lives in rural areas. It is a country that has experienced one of the most serious and destructive civil wars in the region from 1975-1989, political instability since 2005, heavy Israeli aggressions in 2006, various assassinations and economic deficit in 2009 and has a national debt of approximately 50 billion dollars. The effects of all these tumultuous events are still seen decades later as it has severely affected all aspects of life, including the health sector. As a result Lebanon has been faced with a weakened primary health care system, an unrestricted growth of a high technology private health sector and high cost pharmaceuticals.

The country is witnessing a demographic transition with 27.3% of the population under 15 years of age and 7.4% over 65. The remaining 75% is between 15 to 64 years of age. Life expectancy at birth is estimated at 72 years. Adult male literacy rate is 93% and adult female literacy is 84%.

While being in the midst of demographic transition, Lebanon is facing a double disease burden. The acute respiratory infections, brucellosis and other zoonoses, are still significantly present. Concurrently, chronic ailments are becoming more prevalent, such as diabetes, hypertension, depression and cancer. Health related environmental problems and risky lifestyles are widespread.

There is an oversupply of doctors and nurses, the Health Information System (HIS) is fragmented and data are collected through household surveys such as the PAPFAM and MICS or through a hospital based epidemiological surveillance. An effort towards the expansion of the surveillance system to generate data from the public health network and the private sector, through the creation of regional observatories and reinforcing the districts surveillance units, has

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1 Department of Statistics, MOPH 2007
2 Department of Statistics, MOPH 2007
3 PAPFAM Lebanon 2004
4 World Health Organization 2008  http://www.who.int/countries/
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Health financing in Lebanon is very diverse. There are two employment-based social insurance schemes, four different schemes to cover the security forces, the Ministry of Health financing, which is the insurer of uninsured, the private insurance sector, in addition to out-of/pocket expenditures. All public schemes involve some cost sharing. The high burden of out-of-pocket expenditure remains the largest source of health expenditure in Lebanon, reaching as high as 70% of total expenditures. Of this, 25% is the pharmaceutical expenditure alone. The pharmaceutical sector in Lebanon is complex and the high medicines bill could be due to many overlapping elements, amongst them, that 80% of all the market drugs are imported and patent branded. Other elements are the increased number of pharmacists and physicians that work in the private sector, the absence of an independent national regulatory authority for medicines, and the lack of transparency at one or more levels of the pharmaceutical chain.

The government allocated 10.2% of the GDP to the health sector. In 2003, the medicine budget was Lebanese pounds (L.L) 29 billion while in 2007 the medicine budget was L.L. 52 billion. (1$=1500L.L). It is estimated that more than 25% of Lebanon’s health expenditure is on pharmaceuticals. For example, in 2007, the MOPH spent about US$ 34 millions on medicines: 4% on essential drugs, 5% on vaccines and 90% on chronic illnesses medicines (cancer treatment expenditure is the highest). The majority of registered medicines in Lebanon are imported, mostly from Europe and the USA. They account for more than 80% share (value) of the pharmaceutical market and are imported by 85 importers. The 8 local manufacturers have only the remaining 6% of the market and operate only to a quarter of their capacity. Lebanon has 1923 pharmacies and 4673 pharmacists distributed over the 10425km² of Lebanese territory. This large number has a direct impact on the availability of medicines, but not necessarily on accessibility and affordability. The pharmaceutical sector in Lebanon is complex and the high medicines 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 medicine costs. There is an obvious surfacing political interest in the pharmaceutical sector for reform but not enough will and commitment. In addition, Lebanon does not have a modern medicine regulatory authority structure in place or a national medicine policy or 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. The mismanagement of the system and the resources due to lack of effective laws and regulations or some sort of corruption or lack of transparency at one or more levels of the pharmaceutical system could be the underlying causes of the high medicines bill and the lack of efficiency in providing affordable and accessible medicines to all.

Currently the government has decreased the price of drugs by 20% and created incentive schemes which are supposed to decrease the pharmaceutical bill pronouncedly. In addition, the new policy which is supposed to promote the use of generic drugs will help further in strengthening the cost containment strategy in the pharmaceutical sector.

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5 World Health Organization 2008 http://www.who.int/countries/
6 EMRO country profile page http://www.emro.who.int/emrinfo/index.asp_Ctry=leb
7 Ammar, W. Health Beyond Politics. 2009.
8 EMRO country profile page http://www.emro.who.int/emrinfo/index.asp_Ctry=leb

WHO GGM Lebanon Case Study 2010
The following is the current Ministry of Health structure:

The department of pharmacy at the Ministry of Health has 3 sub-units: inspection; importation and exports; and narcotics. It handles all medicine regulatory control matters, including licensing of premises and pharmacists. Currently, the national medicine quality control laboratory is not functioning.

There is no regulator of medical practice in Lebanon, or checks over doctors’ fees or control over doctor’s prescriptions. Consequently physicians have freedom to market/promote any specific brand without restriction; and the heavy promotion of brands to the 8000 doctors in Lebanon (more than 2 doctors per 1000) has created trade name affinity and loyalty. As a result, knowledge and use of generic names hardly exists. In addition incentives for pharmacists to dispense cheaper medicines are non-existent, as by law the pharmacist is not allowed to substitute a generic for a prescribed medicine and their profit is a fixed percent of the price of the medicine. Pharmacists can sell most medicines without prescription (exceptions are psychoactive medicines for which prescription is required). The current number of registered pharmacists at the order of pharmacists is 4667 of whom 3562 are in practice.

For all the reasons mentioned and since the end of the civil war, the Government of Lebanon embarked on a health sector rehabilitation and reconstruction program primarily for strengthening the Ministry of Health. Restructuring of medicine policy emerged as a main concern for the Ministry of Health. The pharmaceutical sector reform aims to reduce the national medicine bill and make medicines in Lebanon more affordable and accessible to those in need of them. Within the pharmaceutical sector the political will to bring about change is apparent though not yet focused and refined. Resistance to change is usually expressed by the sector’s stakeholders. As a result, many initiatives and projects have been initiated to tackle these challenges, but there is still much to be done to achieve the desired objectives.
Corruption is a recurrent issue brought to public debate frequently in Lebanon. Several attempts to establish laws and regulations to limit corruption have succeeded, such as, the law for unexplained sudden wealth. In 2001, a newly established NGO conducted a public campaign to promote anticorruption awareness, essentially targeting the public at large, but there was no follow up. Anticorruption interventions, if initiated, are generally poorly sustained. Currently the new government set 14 priorities to be addressed in the coming 4 years; priority number 3 focuses on modernization of the administration and fighting corruption. Under which it is stated that the government is committed to implement the UN convention for fighting corruption.

The main reasons why Lebanon became involved and was determined to implement the Good Governance for Medicines (GGM) Program was: to aid the significant efforts that were being made to regulate the pharmaceutical sector, to fulfill the commitment of the MOPH in improving good governance and transparency as part of regaining its stewardship in health and, to maintain the credibility and the availability of funds through WHO.

The case study will describe the process of implementation of phase I & II of the GGM program, the main results, successes and challenges that were faced.

**Good Governance for Medicines Programme in Lebanon**

The Lebanese GGM programme follows the WHO model, seen below, and it was launched with the goal of reducing corruption in the pharmaceutical sector by applying transparent and accountable administrative procedures while promoting ethical practices among civil servants involved in the public pharmaceutical sector. As a Government commitment to strengthening health policy, it adopted GGM as part of its commitment and the MOPH assigned a team from the ministry to coordinate the efforts, giving the necessary permission to access all available documentation. The MOPH has also allocated a special budget for 2010-2011 to carry on phase 3 of the GGM program.

The Good Governance for Medicines (GGM) program in Lebanon was introduced by the Ministry of Health in collaboration with WHO in 2007 with the *Measuring Transparency Assessment Tool* for **Phase I**. This assessment was conducted during a 1 month period in 6 functions of the pharmaceutical sector: registration, promotion, inspection, selection, procurement and distribution of medicines. It included interviews with 50 key informants. They included government officials such as pharmacy staff at the ministry, staff from the central warehouse, the inspection department, the procurement office, the financial department and from the primary health program; members of the Ministry of Health registration committee and the tenders committee; and representatives from large and small governmental hospitals and scientific offices. From the private sector they included representatives from local manufacturers, large and small pharmaceutical companies. Finally they included large and small NGOs, staff from the WHO and UNICEF, members of professional associations of pharmacists and physicians, academia and media consultants. The involvement of both the public and the
private sectors was taken into account from the start, despite encountering some fear from the private sector KIs who initially were not willing to open up with the assessors until they understood that their identity would be kept confidential and that the interview was considered a self-evaluation from within the Ministry and that their input was highly necessary and valuable in helping to improve the services provided by the Ministry. All KIs were updated on the progress of the assessment and kept involved in the program.  

The transparency of each of the surveyed functions was rated on the basis of 10 points as recommended by the WHO instrument, where 1 is the most vulnerable to corruption and 10 the least vulnerable to corruption. The registration, inspection procurement and distribution functions showed a marginal vulnerability to corruption with ratings between 6-8. The selection and promotion functions showed a rating between 3.5-4 falling into the “very vulnerable” to corruption category. As a whole, the pharmaceutical system of the country showed a marginal vulnerability to corruption with a 6.3 rating.

Key Strengths:
In the “Medicine Registration” area there is a standard registration application form and an official listing of pharmaceutical products with some information available on the MOH website. A formally established technical committee which meets regularly and is formed by qualified members is responsible for the registration decisions.

In the “Control of Drug Promotion” area, the Lebanese law stipulates that all promotional material should be approved by the Ministry of Health prior to their use by pharmaceutical companies.

In the “Inspections” area there is a provision covering the inspection of all pharmaceutical firms by the pharmacy law issued in 1994 through an inspection unit which is active, works on detecting counterfeit medicines and checking imported medicines at customs and inspecting pharmaceutical firms.

In the “Selection” area the existing Essential Medicines List (EML) is in line with WHO procedures and recommendations and all of the key informants interviewed were aware of it. There is also a committee responsible for developing the selection of the national EML.

In the “Procurement of medicines” area there are written procedures for the procurement of medicines through tenders and bids, which are published in local newspapers. There is a tender committee, which follows written guidelines concerning the process of the bid. There is also a formal appeal process to be followed in case of rejection of bids.

In the “Distribution” area, there is a central distribution warehouse (CDW) where the medicines are systematically and orderly shelved through a computerized system for inventory and tracking operations. An external audit is carried out annually by an independent central auditors unit and a physical stock assessment is done annually on all items in the CDW by internal staff. Free medicines provided by the government are marked with a printed statement to indicate that they are free of charge.

Key Weaknesses:
In the “Medicine Registration” area there are no standard operating procedures and the members of the registration committee simply use a check-list to evaluate applications. There is also no requirement for committee members to declare conflicts of interest (COI) and the process for approving an application can take up to two years in order to be completed.

In the “Control of Drug Promotion” there is no committee to approve and monitor the

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8 WHO Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector: Lebanon. 2009
implementation of the law that requires MOH approval for promotional material. There is also a lack of ethical criteria for medicine promotion which jeopardizes good prescription and dispensing practices.

In the “Inspections” area there is a lack of updated Good Manufacturing Practices (GMP) and routine audits for local manufacturers. There is also no provision for the declaration of COI by the parties involved in inspection.

In the “Selection” area the EML is not distributed widely and is not available on the Ministry of Health’s website. There are no standard operating procedures guiding the selection committee’s decision-making processes and no clear selection criteria for the committee’s members and they are not required to declare COI. Furthermore, there are no national standard treatment guidelines for the selection of medicines processes.

In the “Procurement of Medicines Area” the tender list is not based on the EML and is not listed by generic but by brand names. There are also no criteria for the selection of the tender committee and its’ members are not required to declare any COI. Although an objective quantification method should be used to determine the quantity of pharmaceutical products to be purchased, it is not applied due to budget constraints.

In the “Distribution” area although the free medicines are listed, these can be easily removed, as there is no security management system at the CDW, and the computerized program doesn’t link all levels and points of distribution.

The key recommendations provided by national assessors were:

1. Develop written procedures for all the activities of the six core areas of pharmaceutical sector
2. Documents with terms of reference, requirements, roles, responsibilities, professional qualifications, functions, composition of committees and its' members
3. Develop Declaration of Conflict of Interest forms for members of committees and government officials
4. Develop an appeal mechanism to manage concerns and complaints of the private sector
5. Update National GMP (last GMP standards in Lebanon were established in 1983)
6. Form a new committee for the revision of the Essential Medicine List (last committee was formed in 2002)
7. Draft a Code of Ethics for Medicine Promotions

During **Phase II** of the GGM Programme, the **WHO Model Framework for Good Governance in the Pharmaceutical Sector** was used as a main instruction manual. The first National GGM workshop took place in December 2008 and was attended by 50 stakeholders and high level officials involved in the pharmaceutical sector. During this conference the results and recommendations of the National Transparency Assessment were shared, discussions followed and the national GGM framework, phase II of GGM program, was introduced.
Next, the GGM National Steering Committee was officially nominated by a ministerial decree no. 812/1, headed by the Minister of Public Health and the Director General of the Ministry of Health. The Committee also included representatives from the Order of Physicians, the Order of Pharmacists, the Syndicate of drug importers, the Syndicate of drugs manufacturers, the Central Inspection, the Council of Civil Service - Department of Research and Guidance, the World Health Organization, the Ministry of Administrative Development Affairs, the Consumer Protection Association and a Media Consultant, who ensured media coverage of GGM progress by writing articles that were published in the local newspapers.

The main task of the steering committee was the formal adoption of the GGM program through the establishment of an implementation plan. At the same time, a task force (working team of the GGM) was nominated to develop and finalize the framework document in consultation with the steering committee.

The task force consisted of staff from the Ministry of Public Health and experts in the field of pharmacy and academics. The Task force was given only 4 months to carry out their duties which included: meeting at least twice per month, developing the GGM framework draft for Lebanon, based on the WHO model, review all relevant documents and Lebanese laws on the subject provided by the national committee, and provide feedback to the national committee about the progress of their work.

The working team studied the 10 components of the WHO GGM framework guide and divided the work amongst the 6 members. Each one was asked to do a literature search for each component as related to good governance within the Lebanese laws and Ministry policies and procedures.

The focus of the work was on the discipline based approach since the team agreed that these are practical concepts that can be identified and applied. Thus, the framework components were rearranged according to the priorities discussed and were developed based on existing laws and regulations applicable to the public pharmaceutical sector. The results included laws and administrative procedures related to good governance, sanctions, and mechanisms to promote transparency that are now currently enforced in Lebanon.

Also, it was agreed to move the code of conduct of the WHO model (which is separate) to the discipline based part since, the team found a comprehensive list targeting all civil servants that is obligatory by law. This code of conduct covered all practices permissible and prohibited for public sector employees, in addition to the rights, duties and responsibilities of civil servants. In general these are applicable to employees working in the public pharmaceutical sector as well.

The Lebanese GGM framework defined corruption, categorized its relevant forms and the possibility of its occurrence in public administration, its impact and implications on the
pharmaceutical sector with a view on how to diagnose and prevent and/or sanction its different forms from taking place.

Moreover, the document covering the mechanisms of reporting any the breaches, suggested cooperation with other initiatives of good governance, and encouraged collaboration with institutions that fight corruption via administrative, judicial, social, and media means.

As for the values based approach and the Ethical framework, the team adopted the different components of the WHO model with some adjustments to fit the Lebanese culture.

This component was considered as important as the discipline based one, since it is believed that there is a need for boosting ethical conduct and moral behaviour in the administrative work and commitment of employees in the public sector during the performance of their public duties, which can help prevent unethical practices and decrease corruption.

Thus, the WHO GGM framework was a useful tool that Lebanon followed and implemented to guide its work while tailoring the different components to the Lebanese context.

This document was officially adopted and cleared by the national steering committee, adding their final comments on the document developed by the task force. The final version of the document was distributed during a national conference that took place in June 2009. This conference again attended by all relevant stakeholders where the process and the different components of the Lebanese GGM framework were presented and discussed.

It should be noted that this document may be adopted as a guide during the implementation of the third phase, since it raised many issues that thoroughly covered a wide range of concepts on behavioural and legal norms.

Phase III activities have not started yet, but the task force for phase II is willing to carry on with the phase III activities after elaborating the action plan and training the 2nd GGM resources in the country.

The GGM programme is currently starting Phase III in Lebanon.

FUNDING

It is worth mentioning that the funding for Phases I and II were provided by WHO, with in kind contributions from the MOPH. For phase III development, the MOPH has allocated partial funding entrusted to WHO for execution under the Joint Program Review and Planning Mission (JPRM) for Lebanon for 2010-2011, with the remaining funds to be pledged. The availability of funds greatly facilitated the implementation of the first two phases. Possible solutions to sustain the activities for phase III are being explored.

LESSONS LEARNED

Key Barriers:

-Political Instability and changes in government: Resulted in delays and loss of time. It was overcome by initiating the process discretely and then readjusting the timing of the activities as frequently as needed.

-Poor understanding of the transparency culture and good governance, the fear of being evaluated and resistance to change: These were handled mainly by deep discussions with
relevant stakeholders, as well as two plenary workshops that took place for all stakeholders to expose the GGM process and philosophy.

**Access to legislation documents:** This issue was overcome by selecting a task force that included MOPH members from different departments and not just from the pharmaceutical related ones, and other members from relevant scientific institutions such as the order of pharmacy and academia

**Maintaining the perseverance of the task force experts:** was overcome by giving minimal incentives and acknowledging their respective contributions in the various phases of the project

**Short time allotted for GGM task force to accomplish the activities requested:** In addition to the fact that they were all full time staff engaged in other activities, which resulted in delays in the execution of the activities. For example, the assessment was completed in December 2007, while the first conference to announce the results of the assessment took place in December 2008, yet the team members were all motivated.

**Bureaucracy:** Made it very difficult to integrate the project within the existing national structure. This issue is still under discussion within the ministry.

**MoH Prioritized Other programmes:** Various programmes and emergency situations, such as the outbreak of H1N1, etc. were constantly prioritized, causing certain difficulties due to the rescheduling of planned activities and others.

**Key successes:**

- Results of the National Transparency Assessment were officially published in 2009
- A national GMP committee was formed by a Ministerial Decree No. 212/1, dated 18 March 2008 to update the national GMP. This committee included members from the private and the public sectors; and private experts represented from academia, pharmaceutical manufacturers, and professional association of pharmacists.
- The final document which was based on GMP WHO guide and adjusted to the Lebanese law of pharmacy was officially adopted by the Government and published in the governmental newspaper, issue no. 24, dated May 28, 2009.
- New committee was formed including all relevant parties of the Ministry, international organizations, medical societies and academia. It was given 6 months to complete its activities and updated EML. The new EML is still under development.
- Declaration of Conflict of Interest forms developed for members of committees and government officials in 2010
- The tender list is currently being listed by generic names and not by brand names as it was done before the assessment.
- Initiating such an intuitive program in a poorly conducive political and administrative environment. This may be due to the fact that Lebanon is a small country and control of public pharmaceuticals is maintained at the central level.
- Involvement of both public and private sectors in this initiative from the beginning of the program.
-Introduction of the theme to stakeholders and their relative commitment to support the transparency and good governance efforts, and

-Creation of dedicated and motivated nucleus of experts with diversity of expertise in the task force that worked on the program. This can be very helpful for the implementation of the initiatives for phase III.

-The GGM project is perceived by the relevant stakeholders and at many levels of the ministry of health as a catalyst for change, and a gradual slow change is already seen in the achieved recommendations that were discussed. The high level political support and commitment from within the ministry is important but not enough. There was and there still is a need to give more attention to the work at the technical level.

**FUTURE DIRECTIONS**

The most important lessons learned mainly are the need for proper planning, time management, human resources and more financial support. Collaboration with key stakeholders is essential and to succeed in the implementation of phase III, more coordination is needed with anti-corruption agencies. Investing in GGM as a strategic opportunity will result in increased public trust. New concepts such as transparency and good governance should be introduced gradually to avoid resistance.

Based on the challenges faced and the lessons learned, the next step will focus on the development of an action plan, after consultation and planning with all stakeholders taking into account the available resources and still focusing on implementing the recommendations that were given during phase I.