

2. STAKEHOLDERS OF THE LEBANESE PHARMACEUTICAL SECTOR

2.1 A complex combination of agencies, institutions, organizations, companies, and individuals impact the pharmaceutical market. Within the pharmaceutical supply system, a number of subsystems exist such as those related to drug development, regulation, production, distribution, prescribing, dispensing, reimbursement, procurement, and consumption. Different stakeholders are involved in different stages of this process. These include players from the Public sector, Private sector, and others. All interact with one another to provide drug treatment as part of society's commitment to health care.

Public Sector

2.2 The pharmaceutical market differs from markets for most other goods and services in that it necessitates very strict rules and regulations in all its aspects starting from the conception of the product to its channels of distribution and finally to the manner in which they are administered to the end user. Therefore, Government intervention is necessary for this market to operate efficiently.

2.3 Players of the Public sector include: Ministry of Economy and Trade (MET) with its Trade Information Center (TIC), Ministry of Industry (MOI), Ministry of Public Health (MOPH), National Bureau of Medicine, Customs under the Ministry of Finance (MOF), National Social Security Fund (NSSF), and Cooperative of Civil Servants (CCS).

2.4 While the MET, MOI, and MOF deal with trade, industry, and customs related issues respectively, the MOPH represents the direct responsible body that regulates the pharmaceutical sector. The drug regulatory authorities at the MOPH include the "Service of Pharmacy" and the "Directorate of the Central Laboratory".

2.5 The "Service of Pharmacy" comprises two units: the Drug Inspection Unit and the Drug Importation and Exportation Unit. The Service of Pharmacy is responsible for:

- Registration of drugs based on quality, safety, and efficacy
- Licensing and inspection of importers, wholesalers, and retailers
- Licensing and inspection of local manufacturers
- Licensing of pharmacists

2.6 The Central Laboratory's main duties reside in testing the drugs' safety and efficacy and in transmitting the outcome of their results to the Drug Registration Technical Committee (DRTC) for final approval. Drug testing requests received by the Central Laboratory are instigated either by the MOPH's Drug Inspection Department or by the DRTC. Tests that are carried out at the Laboratory on drugs include those designated in the pharmacopoeial references (according to individual monographs). However, out of all the designated tests in the pharmacopoeial references, only those that fall within the technical capabilities of the Laboratory are carried out. These include microbiological as well as physicochemical tests:

- 1- Microbiological tests:
 - Sterility test
 - Pyrogen test
 - Assay for potency of autit test

- 2- Physicochemical tests:
 - Loss on drying test
 - Alkalinity or acidity test
 - Identification test
 - Dissolution test for capsules and tablets
 - Assay for contents

2.7 During 1999, the Central Laboratory received a total of 1,396 requests for pharmaceutical testing from various sources. Table “1” below details the number of test requests received in 1999.

Table 1 . Number of pharmaceutical related test requests received by the Central Laboratory in 1999

ITEMS TO BE TESTED	NUMBER
Narcotic drugs	556
Injections and serum	422
Capsules and labels	170
Raw material	79
Creams and lotions	75
Syrups and suspensions	39
Baby milk	19
Suppositories (rectal and vaginal)	14
Eye and/or ear drops	11
Cosmetics	8
Detergents	2
Nasal drops	1
Total	1,396

Source: Central Laboratory, 2000.

2.8 The total number of personnel that carry out drug testing is ten. Seven individuals are assigned to the Chemistry department and three to the Drugs Quality Control laboratory at the Central Laboratory.

2.9 Two public reimbursement institutions, the NSSF and the CCS, cover private sector and public sector employees respectively. They do not use effective cost containment measures for pharmaceutical expenditures. Reimbursements are carried out according to the list of registered drugs (referred to as “Registered Drugs List”) prepared by the MOPH.

2.10 The NSSF covers (1) all types of employees working for a private company and registered as such at the NSSF, (2) maritime employees, (3) instructors in private schools, (4) university students, (5) taxi drivers or owners, (6) public employees of municipalities, and (7) bakeries. Subscribers’ family members are also entitled to coverage provided by the

Fund. The number of subscribers and related beneficiaries from 1996 to 1999 is shown in Table “2” below:

Table 2. Main NSSF’s number of subscribers and related beneficiaries (1996 - 1999)

	Number of subscribers	Annual Variation	Growth (1996=100)	Number of beneficiaries	Annual Variation	Growth (1996=100)
1996	301,000	-	-	873,000	-	-
1997	347,000	15.3%	15.3%	1,025,000	17.4%	17.4%
1998	382,000	10.1%	26.9%	1,127,000	10.0%	29.1%
1999	404,000	5.8%	34.2%	1,140,000	1.2%	30.6%

Source: National Social Security Fund, 1999.

2.11 The NSSF reimburses 80 percent of the drug healthcare bill. Amounts reimbursed by the NSSF on drug bills account on average 11 percent of the in-patient bill, and 51 percent of the outpatient bill. The health care bill reimbursed by the NSSF from 1996 to 1999 is provided below in Table “3”.

Table 3. Total reimbursements carried out by the NSSF (1996 – 1999) (millions L.L.)

	1996	1997	1998	1999
In-Patient	70,000	99,805	107,708	118,000
Out-patient	58,000	80,490	89,669	110,000
Total	128,000	180,295	197,377	228,000
Variation of in-patient reimbursements	-	42.6%	7.9%	9.6%
Growth of in-patient reimbursements (1996=100)	-	42.6%	53.9%	68.6%
Variation of out-patient reimbursements	-	38.8%	11.4%	22.7%
Growth of out-patient reimbursements (1996=100)	-	38.8%	54.6%	89.7%
Variation of total reimbursements	-	40.9%	9.5%	15.5%
Growth of total reimbursements (1996=100)	-	40.9%	54.2%	78.1%

Source: National Social Security Fund, 2000.

2.12 The CCS covers 60,000 public employees, 35,000 of which belong to the educational sector, 9,000 to the different public administrations, and retired employees. The Cooperative covers also family members of subscribers (“beneficiaries”) who are around 290,000 individuals². The Cooperative’s fund is nourished from government contributions and subscription fees of members. The subscription fee amounts to 1 percent of the subscribers gross salary deducted directly. The Cooperative reimburses 75 percent of the drug bill for the subscriber and his family (wife and children). It also reimburses 50 percent of the drug bill of other family members part of the Household of the subscriber.

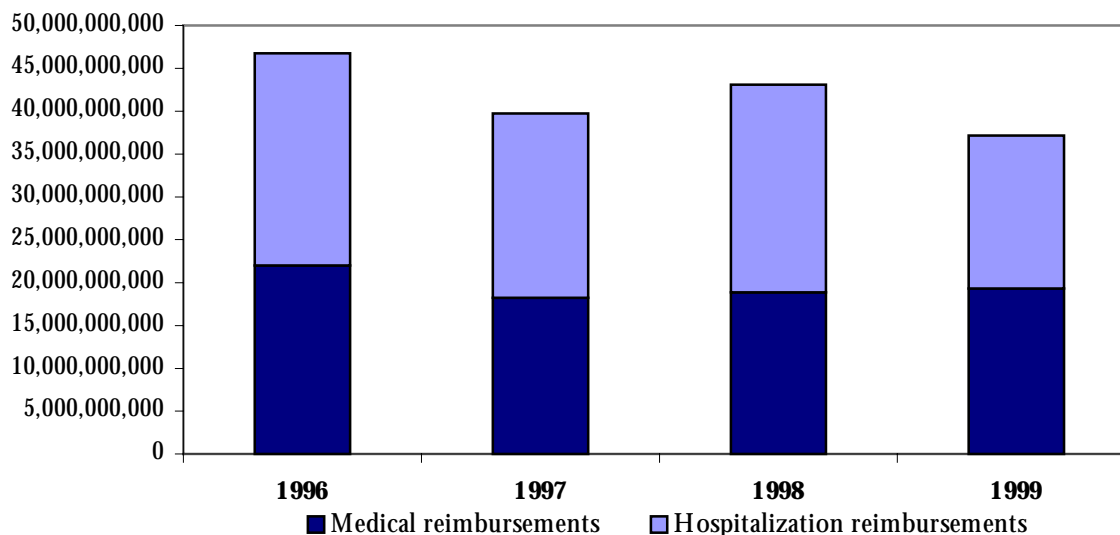
2.13 Disbursements for medical consultations are not accounted for separately from disbursements related to drug purchases, therefore the amount reimbursed for the drug bill by the CCS cannot be determined. Total health care disbursements from 1996 to 1999 are shown in Table “4” and Chart “1” below.

² The Lebanese “Centre National de la Statistique” estimated the average size of a typical Lebanese family at 4.8 individuals (1997).

Table 4. Total health care disbursements by the CCS (1996 – 1999)

	1996 (L.L.)	1997 (L.L.)	1998 (L.L.)	1999 (L.L.)
Medical ^(a)	21,979,799,000	18,266,805,000	18,896,678,000	19,350,177,000
Hospitalization ^(b)	24,761,768,000	21,500,673,000	24,204,639,000	17,808,047,000
Total	46,741,567,000	39,767,478,000	43,101,317,000	37,158,224,000

Source: Cooperative of Civil Servants, 1999. (a) Includes physician's consultation fees plus medicament purchases (b) Includes hospital fees plus medicaments dispensed by the hospital pharmacy.

Chart 1. Health care disbursements by the CCS (1996 – 1999)

2.14 The Defense Ministry covers approximately 400,000 individuals who are entitled to benefits offered by the Military. Members of the Lebanese Armed Forces and beneficiaries, i.e. wife and children in addition to parents if unemployed, are covered. Career employees are fully covered while contractual employees are reimbursed at 80 percent. Amounts allocated for drug procurement from 1996 to 1999 are shown in Table “5”.

Table 5. Allocated amounts for drug procurement at the Ministry of Defense (1996-1999)

	1996 (L.L.)	1997 (L.L.)	1998 (L.L.)	1999 (L.L.)
Allocated Amounts	4,950,000,000	9,946,729,920	10,109,997,000	10,786,000,000
Variation of Allocated Amounts	-	101.0%	1.6%	6.7%

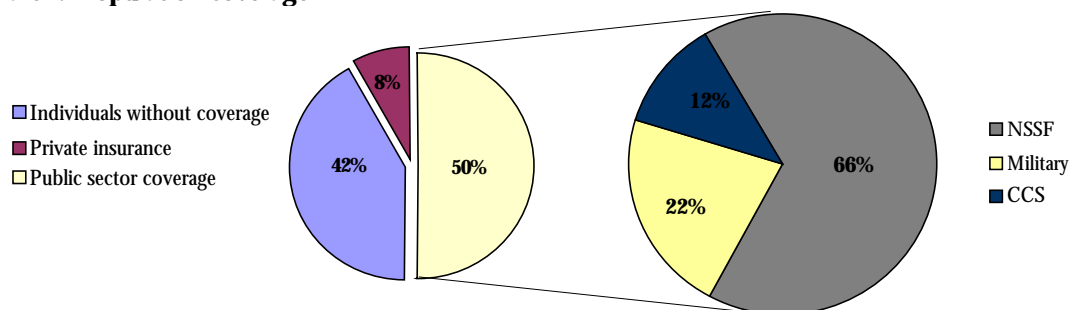
Source: Ministry of Finance, 2000.

2.15 Around 50 percent of Lebanese citizens are covered by public insurance funds³. The NSSF has the largest coverage with over 33 percent, the military benefits covering 11 percent, and CCS covering 6 percent. Private insurance coverage is around 8 percent of the population. The remainder of the population (42 percent) is entitled to MOPH coverage for

³ “Health Financing and Provision in Lebanon: Mission Report”, The University of York, International Programme, Centre for Health Economics, March 2000.

primary hospital care. Chart “2” illustrates the proportions of population covered by different insurance plans.

Chart 2. Population coverage mix



2.16 The National Bureau of Medicine is not active yet. Created in 1983, the Bureau’s main mission intended to reduce the cost of medicine for public institutions by directly importing and providing drugs of good quality at the lowest cost possible.

2.17 The Private sector includes manufacturers, traders, health professionals, health institutions, orders and associations, universities, and private insurers.

Private Sector

2.18 Manufacturers are members of the Association of Lebanese Pharmaceutical Manufacturers (ALPM). There are eight small to medium size manufacturers. Six of them produce brand-generic (under license) and generic drugs, while two others produce serum products.

2.19 There are around 100 pharmaceutical traders importing brand-name patented, brand-name generic, and generic non-proprietary pharmaceutical products from many different foreign laboratories. Only 28 of these importers are members of the Lebanese Pharmaceutical Importers Association.

2.20 Traders in Lebanon are of three types: (1) Agent/Distributor, (2) Wholesaler, or (3) Agent/Wholesaler/Distributor. Their distribution is shown in Table “6” below.

Table 6. Types and number of pharmaceutical traders

	Traders
Agent/Distributor	45
Wholesaler	20
Agent/Wholesaler/Distributor	20
Owning a License but non-active	15
Total	100

Source: Lebanese Pharmaceutical Importers Association, 1999.

2.21 Health professionals include physicians, pharmacists, and nurses. In Lebanon, there are 8,700 doctors⁴, 3,800 pharmacists⁵, and around 4,000 nurses⁶.

2.22 There are around 1,383 pharmacies distributed all across the Lebanese territories with one pharmacy for every 2,892 citizens. Table “7” details the distribution and concentration of pharmacies across the Lebanese regions.

Table 7. Distribution and concentration of pharmacies across the Lebanese regions

Mohafazat	Distribution	Concentration (%)
Beirut	187	13.5
Mount Lebanon	668	48.3
North Lebanon	209	15.1
South Lebanon	131	9.5
Bekaa	135	9.8
Nabatiyeh	53	3.8
Total	1,383	100.0

Source: Lebanese Order of Pharmacists, 1999.

2.23 Physicians should be licensed to practice by the MOPH and be members of the Lebanese Order of Physicians. The characteristics of the medical exercise in Lebanon include liberty of prescription, liberty of the patient to choose the doctor, and direct agreement concerning the fees. The physician is free to prescribe any drug, and therefore can market any specific brand.

2.24 Pharmacists should be licensed to practice by the MOPH and be members of the Lebanese Order of Pharmacists. By law, the pharmacist should be present in his/her pharmacy, is not authorized to change the dosage of the prescription or to substitute the prescribed drug.

2.25 Health institutions comprise hospitals, dispensaries, and health centers. There are 160 private hospitals accounting for 14,350 beds⁷, 15 public hospitals with total bed capacity of 810, 545 public dispensaries, 196 Non-Governmental dispensaries, and 35 public health centers, and 74 Non-Governmental health centers⁸.

2.26 Four universities provide a Major in Pharmacy in Lebanon. The Lebanese University, the Beirut Arab University (BAU), Université Saint Joseph (USJ), and the Lebanese American University (LAU). The main courses undertaken in these universities focus on biochemistry, pharmacology, pharmacokinetics, biopharmaceutics, physiology, therapeutics, pharmaceuticals, pharmacy management, communication between pharmacists and patients, etc. The educational programs in these universities do not emphasize industrial pharmacy and quality control.

⁴ “Health: Reality & Solutions”, Dr. Bahij Arbid, 1998.

⁵ Lebanese Order of Pharmacists.

⁶ “Health: Reality & Solutions”, Dr. Bahij Arbid, 1998.

⁷ Order of Hospitals, 1999.

⁸ “Health: Reality & Solutions”, Dr. Bahij Arbid, 1998.

2.27 Private insurance companies reimburse drugs as part of the health care bill. The type of reimbursement differs from one company to another and as agreed to with the subscriber.

Other Important Players

2.28 Consumers are the main players in the pharmaceutical sector. It is them that all stakeholders of the entire pharmaceutical sector endeavor to cure, protect, guide and satisfy. The difference between drugs and other consumer goods is that consumers have limited knowledge of medicines and therefore rely on advice, authorization, guidance, and protection from physicians, authorities, and other related health parties.

2.29 Non-Governmental Organizations (NGOs) play an important role in supporting the Government in delivering health services to the poor. These include medical consultations and providing drugs to the poor. Some Non-Governmental Organizations receive drug donations part of International Organizations' support.

2.30 International Organizations within the health care system include the World Health Organization, United Nations Development Programme, UNICEF, Red Cross, etc. Having as common belief that good Health is an essential determinant of social development and economic growth, these organizations provide support to the Government in strengthening health services, ensuring equitable access to health services, promoting and establishing international standards concerning pharmaceuticals, protecting health, promoting rational drug use, and providing drug and vaccine donations.

2.31 Duties and obligations of all stakeholders of the pharmaceutical sector are summarized in Appendix "A".

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