

3. INSTITUTIONAL FRAMEWORK OF THE LEBANESE PHARMACEUTICAL SECTOR

3.1 The Government through the Ministry of Public Health regulates the pharmaceutical market through a set of policies and regulations. The Ministry impacts drug production and quality control, licensing, import, registration, pricing, and inspection.

Establishment, Production, & Quality Control

3.2 With regards to drug manufacturing, the Government intervenes in setting the norms and standards regarding the establishment, setting, construction, and operation of pharmaceutical companies (Decree No. 106, 09/16/1983). In order to ensure that pharmaceutical products are consistently produced according to quality standards, the Government, through Decision No. 35, 2/20/1985, formulates its own requirements for Good Manufacturing Practice (GMP) based on WHO guidelines. Emphasizing that good quality must be built into the manufacturing process, GMP law covers all aspects of the production process including materials, premises, equipment, training of personnel, and hygiene of staff, etc. It is concerned with sampling, testing, documentation and release procedures that ensure that the necessary and relevant tests are properly carried out throughout the production process.

Registration and Pricing

3.3 Whether being produced locally or imported, all pharmaceutical products must be registered at the MOPH. Any importation or distribution of drugs that is not submitted to the control of the MOPH is considered illegal and therefore subject to seizure.

3.4 The drug registration process follows a chain of links that are all submitted to the control of a Drug Registration Technical Committee (DRTC) at the MOPH. Registration includes two distinct but equally important parts, (1) registration of the manufacturer as a company (entity), and (2) registration of each individual drug. The DRTC is expected to study the drug's files within a maximum period of three months. Once the drug meets MOPH requirements, the DRTC sends the drug's samples to the Central Laboratory for testing. If approved, the file is then forwarded to the Pricing Committee to price it within one month.

3.5 Several factors such as technical, administrative, and economic considerations come into play while fixing the price of the drug to consumers. The price of the imported drug is based on the cost price or the sale price in the country of origin according to duly authenticated documents. To this price 7.5% is added as freight expenses and 12.5% for clearance duties and other expenses if the price is FOB. In case the price is CIF then only 12.5% for clearance duties and other expenses is added. Both prices FOB⁹ or CIF¹⁰ are converted to public prices in Lebanese pounds according to an index related to the movement of exchange rates. The importer's profit is set at 10% and the pharmacist's at 23 percent of the drug's price. It is worth noting that drug importers pay a fee of 0.75 percent

⁹ FOB: Free on Board.

¹⁰ CIF: Cost, Insurance, and Freight.

of the import bill to the Lebanese Order of Pharmacists, of which 0.25 percent is deducted from the pharmacist's profit. An additional fee of 0.25 percent of the import bill is also paid to the Lebanese Order of Physicians.

3.6 Factors that come into play while fixing the price of the locally manufactured drug include cost of production, public price of similar products marketed in Lebanon, cost and profit index, and classification of pharmaceutical manufacturing companies. It is worth noting that manufacturers pay a fee of 0.25% of their export bill to the Lebanese Order of Pharmacists.

3.7 In case the DRTC and the Pricing Committee could not decide upon the approval or rejection and price of the drug respectively, the Minister of Public Health has the right to give the approval to import the product and sell it at the price set in the presented file until the Committees decide about its status.

3.8 Parallel importation is legal in Lebanon. Decision No. 539 dated 08/25/1998, allows companies other than official agents to bring medicines into Lebanon on a condition that the invoice is lower than the export registered price by 25 percent.

3.9 Within the system of registration, the MOPH drug inspection unit has the responsibility to inspect the manufacturing establishments, inspect the drugs at Customs, inspect retailers, hospitals, Government institutions that provide health services, dispensaries, and NGOs.

3.10 The pharmaceutical cycle is best described in Chart "3".

Bilateral Trade Agreements

3.11 Through the years, Lebanon built good trade relations with the Arab States, Europe, Asia, South America, and other regions of the World. Many bilateral agreements were initiated, some signed, ratified, and enforced and others are still draft agreements awaiting signatures of both parties to promote trade and economic development.

3.12 Arab States are the main importers of Lebanese pharmaceutical products. Lebanon signed bilateral trade agreements with Egypt, Jordan, Iraq, Kuwait, Saudi Arabia, and Syria. These agreements include lists of tariff exempt and partially exempt trade products. Table "8" specifies in particular the state of trade of pharmaceutical products between Lebanon and these nations as per their signed agreement.

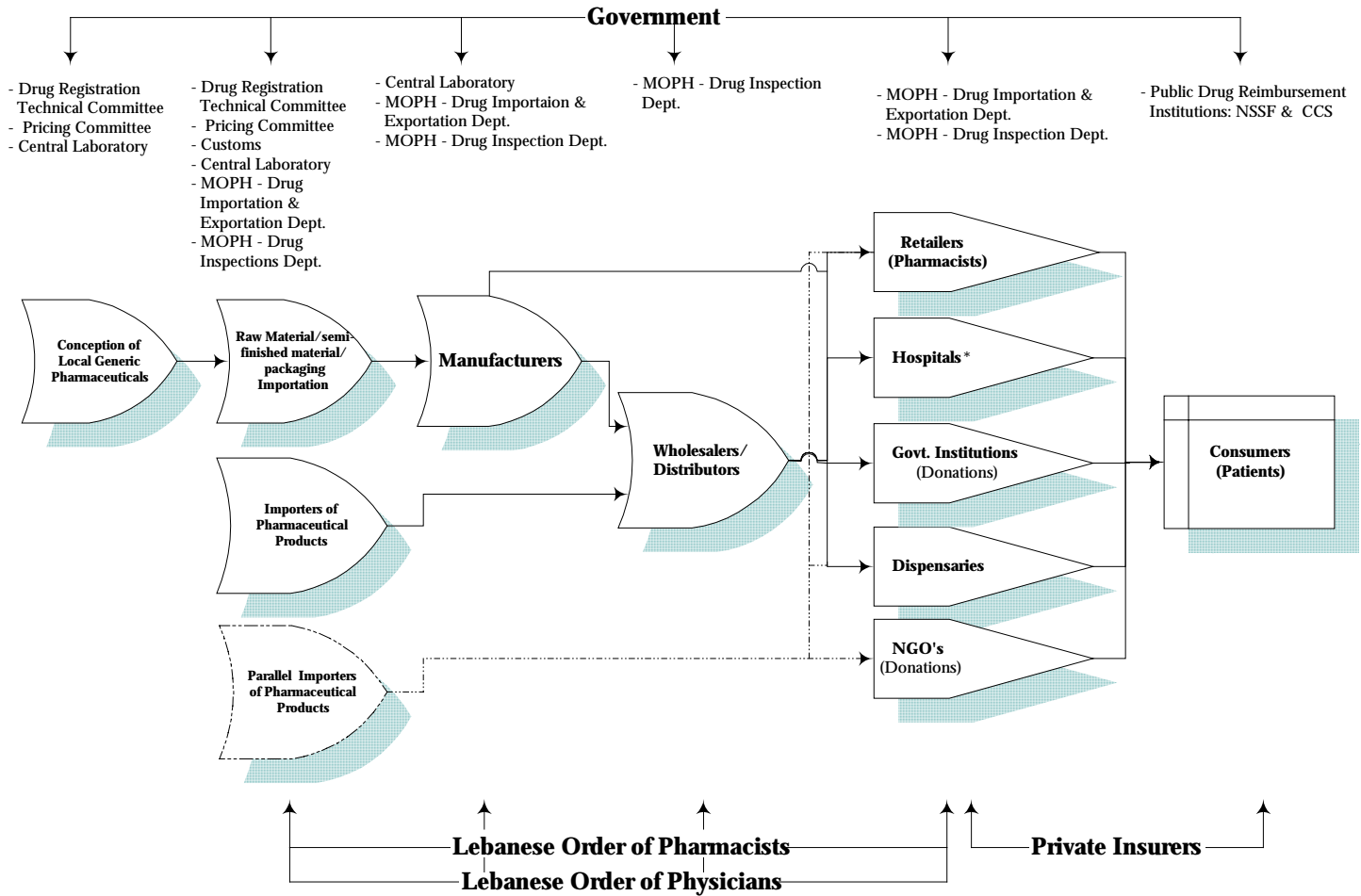
3.13 In 1994, Lebanon and Syria signed an agreement of Brotherhood and Coordination. Unlike other trade agreements, this agreement (Law No. 298) is comprised of several sections regarding mutual cooperation on several issues, one of which is related to Health. Within the field of Drugs, several articles were agreed upon:

- To cooperate and coordinate in all health related issues (Article 1).
- To establish one common list of Essential Drugs between the two countries revised according to a special arrangement (Article 2).
- To establish common standards for the issuance of certificate of origin and certificate of manufacturing and quality control (Article 3).

- To establish common pharmaceutical registration guidelines and consider the drug registered in one of the two countries registered in the other one (Article 4).
- To cooperate with each other in order to provide the other party with the drugs according to its needs, with preference to locally manufactured drugs (Article 5).
- To exchange import and export information regarding pharmaceutical products (Article 6).
- To cooperate in training employees in the manufacturing, registration, pricing and drug control fields (Article 7).
- To cooperate in quality control procedures and quality control tests (Article 8).

To date, no major implementation of the above points has taken place.

Chart 3. Institutional framework of the Lebanese pharmaceutical sector



* Private hospitals can import medicaments directly from foreign suppliers for educational purposes

Table 8. Trade related Agreements between Lebanon and Arab States¹¹

Country	Law Number	Date of Agreement	Terms of the Agreement with respect to the trade of Pharmaceutical Products*
Egypt	147	05/06/1992	Lebanese Exports (30/02 and 30/03) including Serum, vaccination, and medicine for human and veterinary use are exempt from tariff in Egypt. Egyptian pharmaceutical exports are not exempt from tariff in Lebanon
	48	02/23/1999	Agreement signed as a consequence of the Arab League Agreement. All industrial products including pharmaceutical products of Lebanese and Egyptian origin are exempt from tariff in both countries
Jordan	186	01/04/1993	Pharmaceutical products falling under the codes 30/02 and 30/03 (antibiotics, drugs for veterinary use, and drugs used for the treatment of tuberculosis) are exempt from tariff in both countries. Medicine for human use is subject to 1/3 tariff exemption in both countries
Kuwait	574	07/24/1996	To prepare and execute a list of tariff exemption for industrial products
	Meeting Minutes	09/19/1998	All Lebanese pharmaceutical products falling under the codes 30/03 and 30/04 are exempt from tariff. All other industrial products of Kuwait and Lebanese origin are exempt from tariff by 25% each year as of 01/01/1999
Syria	14461	05/13/1970	Lebanese pharmaceutical products falling under the code 30/03 are exempt from tariff in Syria. Tariff on pharmaceutical products falling under the code 30/02 are not tariff exempt in both countries
	298	04/22/1994	Agreement of Brotherhood and Coordination
	12942 (Decree)	08/31/1998	Reducing tariff on Syrian industrial products by 25% each year as of 01/01/1999
	4 (Syria)	08/04/1998	Reducing tariff on Lebanese industrial products by 25% each year as of 01/01/1999
	Meeting Minutes	11/02/1998	Implementation of Decree # 12942, and Law # 4 (Syria). All products of Syrian and Lebanese origin, which are tariff exempt as per Law 14461 remain tariff exempt. All other industrial products are 25% tariff exempt as of 01/01/1999
Iraq	67/46 71/19	06/8/1967 ratified in 02/27/1971	Pharmaceutical products falling under the codes 30/03 and 30/04 (medical cotton) are 50% and 60% exempt from tariff respectively in both countries
Saudi Arabia	71/67	12/20/1971	Pharmaceutical products falling under the codes 30/02, 30/03, and 30/04 (medical cotton) are exempt from tariff in both countries
Sudan	71/20	02/27/1971	Lebanese pharmaceutical products, which fall under the code 30/03 (drugs for human and veterinary use) are exempt from tariff in Sudan. Pharmaceutical products originating from Sudan are not exempt from tariff in Lebanon.

* Classification of the pharmaceutical products according to the Customs is detailed in Appendix "B".

¹¹ Trade Information Center, Ministry of Economy & Trade.

3.14 Negotiations and study to join the EuroMed Agreement and World Trade Organization are underway. In addition, many draft trade agreements that promote and facilitate trade were initiated awaiting approval and signature. Countries concerned include states from the Arab, Asian, European, and South American regions: Bahrain, Libya, Sudan, Tunisia, Yemen, Indonesia, India, Iran, Kasakhsitan, Korea, Pakistan, Thailand, Cyprus, Greece, Letwania, Malta, Russian Federation, Slovekia, Brazil, Mexico, and Venezuella.

* * *