

4. STATUS OF THE PHARMACEUTICAL INDUSTRY IN LEBANON

4.1 The Lebanese “Practice of the Pharmaceutical Profession” Law¹² defines medicinal drugs as “*any simple or compound substance with therapeutic, preventive, or physiological properties used in human or veterinary medicine and surgery*”. For a product to be classified as medicinal drug, it must belong to one or more of the following categories:

- Pharmaceutical specialties
- Sterilized items of medicinal nature, specially prepared for the dressing of wounds, in particular tissues and bandages which are sterilized or impregnated with antiseptics
- Medicinal mineral water, i.e. water which is not used as normal drinking water in the case of sound health
- Serum, vaccines, and medicinal products of human or animal origin
- Products to be used for medicinal baths or hydrotherapy
- Cosmetics containing medicinal products of a therapeutic nature
- Milk intended for nursing infants aged less than six months in containers not exceeding half a kilogram, and milk modified in accordance with the milk classification regulations

4.2 Pharmaceutical products may be dispensed with or without physician’s prescription. Drugs that are dispensed without a prescription are known as Over-The-Counter (OTC) medicaments while those that need a physician’s prescription to be dispensed are known as Prescriptive medicaments. All prescriptive or OTC medicaments are assimilated to one or more of the following classifications:

- 1- drugs under patent
- 2- brand-name generics with original product still under patent rights
- 3- brand-name generics with expired patent rights of original product
- 4- generic drugs

4.3 The first two categories belong to the Proprietary Name (PN) class of medicaments while categories 3 and 4 belong to the Non-Proprietary Name (NPN) class.

4.4 Irrespective of their classifications, medicaments in Lebanon are almost all dispensed as OTC even though technically a large number of them ought to be exclusively dispensed under physicians’ prescriptions. The only pharmaceutical products requiring a prescription that pharmacists will not dispense as OTC are tranquilizers that have a barbituric (sleepy) effect (Ministerial Decision No. 303, August 8th, 1967).

Patented and Brand-Name Medicaments

4.5 Brand name is the name given to a drug by the manufacturer. The use of this name is reserved exclusively to its conceiver. The brand name is granted patent rights if it satisfies the following definition formulated under the Trade Related Aspect of Intellectual Property

¹² Law no. 367, article no. 36, August 14, 1994 entitled “Practice of the Pharmaceutical Profession”.

Rights (TRIPS) Agreement¹³; “any invention of a pharmaceutical product or process that fulfills the established criteria of novelty, inventiveness and usefulness is granted patent right for a minimum of 20 years”. Afterwards, and in some cases before the end of the patent period, a generic product can be registered marketed and produced.

Generic Medicaments

4.6 Generics are competing versions of off-patent brands that contain the same active substance, usually are bio-equivalent but not necessarily, and offer a price differential to the branded version. It is usually manufactured without a license from the innovator-company and marketed after the expiry of patent or other exclusivity rights. However, not all generics are available off-patent (Appendix “C”), as inventor companies sometimes license a generic version prior to patent expiry.

4.7 Lebanese manufactured¹⁴ pharmaceutical products belong to the following class of drugs:

- 1- off-patent brand name generic
- 2- generic

Product Classes

4.8 This report classifies locally manufactured pharmaceutical products according to the Lebanese Reference for Health Professionals¹⁵, MEDICA. Pharmaceutical products are classified according to 29 therapeutic categories listed in Table “9” of which MEDICA also includes 196 subcategories.

4.9 Each of these therapeutic categories as well as their corresponding sub-categories constitute market segments in which local manufacturers, as well as importers, are positioned. It is important to know that locally manufactured pharmaceuticals are not present in all of these segments.

Table 9. Classification of medicinal products according to the Lebanese drug reference MEDICA

| Therapeutic Categories | Therapeutic Categories | Therapeutic Categories |
|---------------------------|----------------------------|--------------------------|
| 1. Allergology | 11. Gastroenterology | 21. Otolology |
| 2. Analgesics | 12. Gynecology | 22. Parasitology |
| 3. Anesthesiology | 13. Hematology | 23. Pneumology |
| 4. Anti-Infectives | 14. Hemostasis | 24. Rhinology |
| 5. Anti-Inflammatory | 15. Hepatology | 25. Rheumatology |
| 6. Antispasmodics | 16. Immunology | 26. Stomatology |
| 7. Cardiology & Angiology | 17. Metabolism & Nutrition | 27. Toxicology |
| 8. Dermatology | 18. Neurology & Psychiatry | 28. Urology & Nephrology |
| 9. Diagnostic | 19. Oncology | 29. Dietetic Products |
| 10. Endocrinology | 20. Ophthalmology | |

Source MEDICA, “The Lebanese Reference for Health Professionals”, Le Medic s.a.r.l., 1999.

Market Size

¹³ World Health Organization. Globalization and Access to Drugs. Implications of the WTO/TRIPS Agreement. Action Programme on Essential Drugs, Geneva, 1997.

¹⁴ Results presented in this study correspond to seven out of the eight manufacturers that responded to the questionnaire.

¹⁵ MEDICA, “The Lebanese Reference for Health Professionals”, Le Medic s.a.r.l., 1999.

4.10 The size of the Lebanese pharmaceutical market is estimated at approximately \$300 million. It is a demand driven market where imported patented and brand name generics constitute the bulk of market sales followed by imported non-proprietary name generics, and locally manufactured brand name generics (produced under license) and generics¹⁶.

4.11 Traders market some 2,737 different types of drugs while manufacturers have 747 types of marketed drugs. The total number of medicament types available to consumers is 3,484 (Table “10”).

Table 10. Drug types available in the Lebanese market

| | Local Manufacturers | Traders |
|---|---|---|
| Number of firms | 8 | 100 |
| Number of different types of marketed drugs | 747 | 2,737 |
| Categories of marketed drugs | - Prescriptive - OTC | - Prescriptive - OTC |
| Types of marketed drugs | - Brand Name Generics ^(a) - Generics ^(b) | - Patented - Brand Name Generics - Generics |

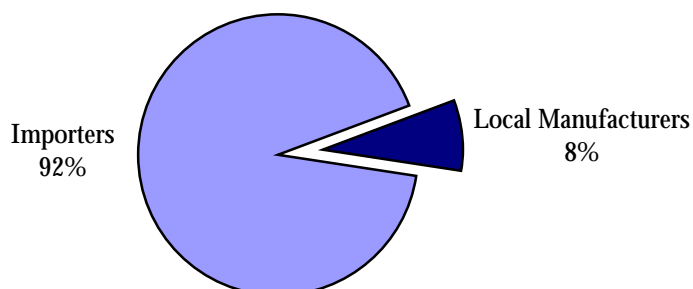
Source Ministry of Public Health, 2000.

(a) Manufactured under license

(b) Local manufacturers produce own generic drugs and/or generics under license

4.12 Traders of pharmaceutical products retain 92 percent of the market share while local manufacturers maintain the remaining 8 percent (Chart “4”). Moreover, 28 percent of traders cover about 90 percent of the import market and play a key role as a link between Lebanon and the international pharmaceuticals market.

Chart 4. Distribution of market shares



4.13 Pharmaceutical products trade balance is largely in deficit. Amounts of imports are more than 65 folds that of exports. Table “11” shows the amounts of pharmaceutical imports from 1996 to 1999 and their share out of total imports. The average annual growth of pharmaceutical imports is a little more than 9 percent. Their average share of total imports is not far from 3.5 percent.

¹⁶ Exact figures of sales by type of marketed drugs (Patented, brand-name generic, and generic drugs) are not made available due to lack of consistent and reliable data.

Table 11. Pharmaceutical imports and their share of total imports (1996 – 1999)

| | 1996 (\$) | 1997 (\$) | 1998 (\$) | 1999 (\$) |
|--|---------------|---------------|---------------|---------------|
| Total Imports | 7,559,126,817 | 7,456,574,175 | 7,055,190,527 | 6,206,533,308 |
| Annual variation (decline) | - | (1.4%) | (5.4%) | (12.0%) |
| Total imports (% of GDP ¹⁷) | 58.2 | 50.2 | 43.5 | - |
| Pharmaceutical imports | 211,188,784 | 214,856,574 | 248,421,155 | 275,266,946 |
| Annual variation (decline) | - | 1.7% | 15.6% | 10.8% |
| Growth (1996=100) | - | 1.7% | 17.6% | 30.3% |
| Share of pharmaceutical imports of total imports | 2.8% | 2.9% | 3.5% | 4.4% |
| Pharmaceutical imports (% of GDP) | 1.6 | 1.4 | 1.5 | N/A |

Source: Lebanese Customs (Ministry of Finance), 2000 – Trade Information Center (Ministry of Economy and Trade), 2000.

4.14 Pharmaceutical products are mainly imported from France, United Kingdom, Germany and Switzerland (Table “12”). In 1999, more than 18 percent of all pharmaceutical imports originated from France and 17 percent from the United Kingdom. Less than 2 percent came from Arab countries such as Syria, Jordan, Saudi Arabia, United Arab Emirates, Egypt, and Kuwait.

Table 12. Countries of origin of pharmaceutical imports¹⁸ (1996 - 1999)

| Exporting Country | 1996 (%) | 1997 (%) | 1998 (%) | 1999 (%) |
|-------------------|---------------|---------------|---------------|---------------|
| United Kingdom | 17.08 | 22.76 | 20.89 | 17.71 |
| France | 16.92 | 19.36 | 17.80 | 18.13 |
| Switzerland | 15.44 | 12.46 | 11.96 | 11.65 |
| Germany | 12.18 | 12.75 | 12.44 | 14.38 |
| Belgium | 8.42 | 6.42 | 7.38 | 7.38 |
| United States | 5.68 | 5.16 | 6.41 | 6.19 |
| Holland | 3.78 | 4.22 | 4.67 | 4.60 |
| Italy | 3.21 | 3.39 | 4.38 | 4.20 |
| Austria | 3.03 | 2.23 | 2.11 | 2.34 |
| Denmark | 1.95 | 2.06 | 2.07 | 2.09 |
| Spain | 1.37 | 1.56 | 2.08 | 2.33 |
| Ireland | 1.36 | 0.85 | 1.67 | 2.97 |
| Canada | 1.20 | 1.45 | 0.80 | 0.67 |
| Jordan | 0.54 | 1.19 | 0.80 | 1.26 |
| Other | 7.84 | 4.14 | 4.54 | 4.10 |
| TOTAL | 100.00 | 100.00 | 100.00 | 100.00 |

Source: - Lebanese Customs (Ministry of Finance), 2000.

- Trade Information Center (Ministry of Economy and Trade), 2000.

¹⁷ The Nominal GDP (Mn\$) is 12,993; 14,868; and 16,235 for the years 1996, 1997, and 1998 respectively. GDP for 1999 is not available. Economic Indicators for Lebanese Economy, MET (1990 – 1998).

¹⁸ Information is sorted in a descending order based on 1996 imports.

4.15 Pharmaceutical exports slightly exceeded 4 million US dollars in 1999. This figure includes drug re-exportation activities. The share of re-exported pharmaceutical products cannot be determined because classification used by the Lebanese Customs does not allow this type of differentiation.

Table 13. Pharmaceutical exports and their share of total exports (1996 – 1999)

| | 1996 (\$) | 1997 (\$) | 1998 (\$) | 1999 (\$) |
|--|-------------|-------------|-------------|-------------|
| Total Exports | 733,123,690 | 642,281,813 | 660,949,470 | 676,776,673 |
| Annual variation (decline) | - | (12.40%) | 2.90% | 2.40% |
| Total exports (% of GDP) | 5.60 | 4.30 | 4.10 | - |
| Pharmaceutical exports | 1,367,535 | 2,205,006 | 3,121,272 | 4,115,883 |
| Annual variation (decline) | - | 61.20% | 41.60% | 31.80% |
| Growth (1996=100) | - | 61.20% | 128.20% | 200.90% |
| Share of pharmaceutical exports of total exports | 0.19% | 0.34% | 0.47% | 0.61% |
| Pharmaceutical exports (% of GDP) | 0.01 | 0.01 | 0.01 | N/A |

Source: Lebanese Customs (Ministry of Finance), 2000 - Trade Information Center (Ministry of Economy and Trade), 2000.

4.16 Table “13” above shows that the average annual variation of pharmaceutical exports between 1996 and 1999 reached about 45 percent (Chart “5”) while their average share in total exports remained less than 0.5 percent. However, if we consider 1996 as base year, we find that pharmaceutical exports have tripled in a period of four years (from 1996 to 1999) while imports grew by one third during that same period (Chart “6”).

Chart 5. Annual variation of pharmaceutical exports and imports (1996-1999)

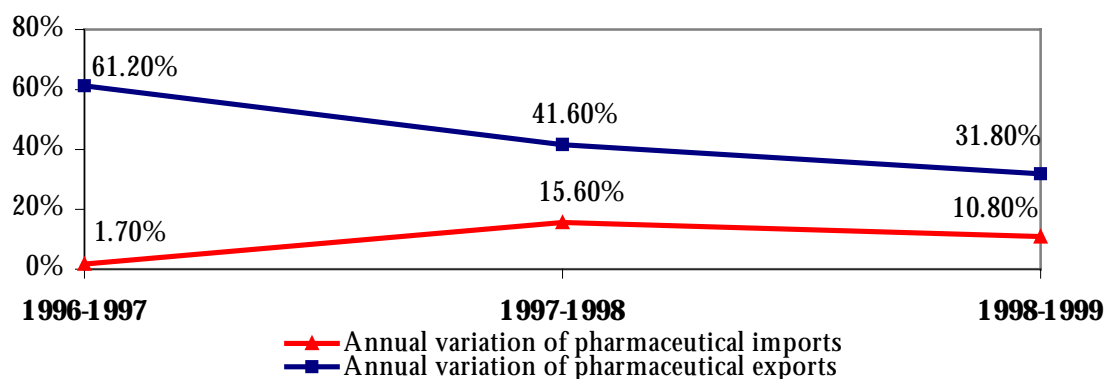
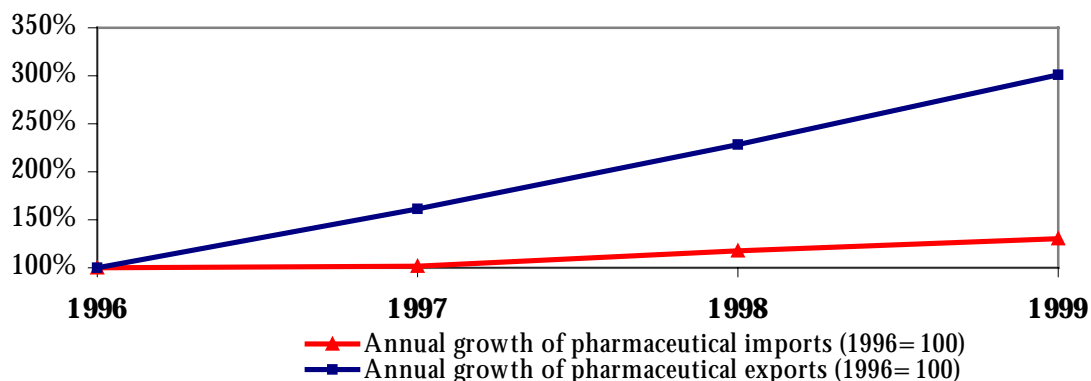


Chart 6. Growth of pharmaceutical exports and imports (1996-1999)



4.17 Lebanese pharmaceutical exports are mainly destined to Arab countries. However, some Western European countries import specific types of medicaments that are manufactured locally. In 1999, more than 33 percent of all pharmaceutical exports were destined to the Jordanian market and around 16 percent to Iraq (Table “14”). Surprisingly, 10 percent of the pharmaceutical exports went to the United Kingdom. Among the countries that regularly (1996-1999) import Lebanese manufactured pharmaceutical products are Syria, Jordan, Kuwait, Bahrain, Oman, United Arab Emirates, United Kingdom, and Cyprus.

Table 14. Destination of pharmaceutical exports¹⁹ (1996 - 1999)

| Importing Country | 1996 (%) | 1997 (%) | 1998 (%) | 1999 (%) |
|----------------------|---------------|---------------|---------------|---------------|
| Jordan | 23.29 | 43.84 | 3.85 | 33.34 |
| Cyprus | 20.38 | 11.22 | 9.37 | 6.58 |
| Oman | 11.27 | 2.52 | 1.83 | 1.29 |
| United Arab Emirates | 10.99 | 7.90 | 11.69 | 9.33 |
| Sudan | 10.67 | 12.79 | 6.68 | 8.09 |
| Kuwait | 4.68 | 7.77 | 2.36 | 5.85 |
| Yemen | 3.79 | 2.46 | 1.90 | - |
| Saudi Arabia | 2.23 | 0.12 | 3.19 | 2.11 |
| Romania | 1.82 | - | - | - |
| Qatar | 1.48 | - | 0.26 | 0.31 |
| Bahrain | 1.29 | 2.25 | 0.46 | 2.11 |
| Syria | 1.18 | 1.86 | 1.45 | 1.46 |
| United Kingdom | 1.04 | 0.06 | 0.96 | 9.90 |
| France | 0.42 | 0.07 | - | - |
| Iran | - | - | 0.06 | 1.38 |
| Switzerland | - | - | - | 1.35 |
| Armenia | - | - | 2.64 | - |
| Belgium | - | 5.93 | - | 0.02 |
| Bulgaria | - | - | - | - |
| Czech Republic | - | - | 1.69 | - |
| Iraq | - | - | 38.24 | 16.18 |
| Libya | - | - | - | - |
| United States | - | 0.90 | 11.06 | - |
| Other | 5.47 | 0.31 | 2.31 | 0.70 |
| TOTAL | 100.00 | 100.00 | 100.00 | 100.00 |

Source - Lebanese Customs (Ministry of Finance), 2000.

- Trade Information Center (Ministry of Economy and Trade), 2000.

Production Capacities

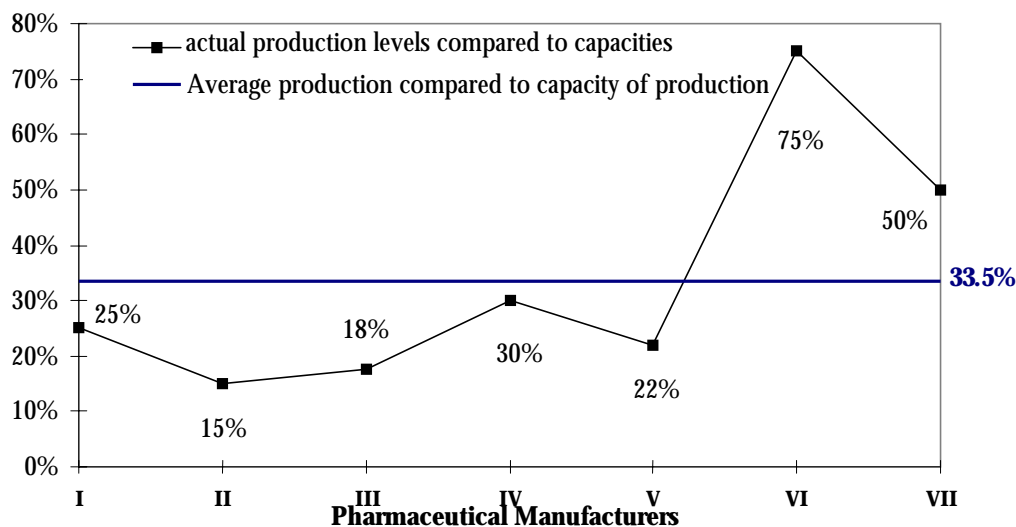
4.18 Local pharmaceutical manufacturers are operating at low levels of their production capacities except for the serum-producing firms. The industry’s average operating capacity of production is as low as 33.5 percent (Chart “7”). If we only consider manufacturers producing traditional brand name generics and generic medicaments while excluding serum manufacturers this average falls to 22 percent.

¹⁹ Information is sorted in a descending order based on 1996 exports.

4.19 Factors directly impacting the current production levels compared to available production capacities are:

- 1- Aggressive competition from traders
- 2- Low consumer confidence levels in locally manufactured medicaments
- 3- Restricted access to capital for investments
- 4- Weak penetration of locally manufactured drugs in foreign markets; low volumes of exports

Chart 7. Production of the pharmaceutical industry compared to capacities



Source: Lebanese Manufacturers' Questionnaire, 1999-2000.

Market Segmentation

4.20 Segmentation of the Lebanese pharmaceutical market is based on two different levels, the macro and the micro-level. Macro-segmentation of the market consists of a general classification of pharmaceuticals following the type and form of product registration (Patented, brand name or generic). Segmentation at the micro-level involves classification of medicaments according to their therapeutic categories.

4.21 Six out of the eight Lebanese pharmaceutical manufacturers are positioned at the brand name generics macro-segment of the market but their share of the market is negligible compared to that of traders. All eight manufacturers are anchored in the non-proprietary name or generic macro-segment of the market.

4.22 The micro-segmentation of the market is a classification of pharmaceuticals according to 29 therapeutic categories and 196 sub-categories. Lebanese pharmaceutical manufacturers occupy 27 of the 29 therapeutic categories and 74 sub-categories out of the 196 existing ones (Appendix "D"). Positions of locally manufactured pharmaceuticals on the various therapeutic categories and the number of manufacturing firms competing in the same micro-segments of the market are listed in Table "15".

Table 15. Lebanese market segments based on therapeutic categories²⁰

| Therapeutic Categories | Products | Manufacturers | Therapeutic Categories | Products | Manufacturers |
|---------------------------|----------|---------------|----------------------------|----------|---------------|
| 1. Allergology | 11 | 4 | 16. Immunology | 0 | 0 |
| 2. Analgesics | 26 | 4 | 17. Metabolism & Nutrition | 13 | 3 |
| 3. Anesthesiology | 1 | 1 | 18. Neurology & Psychiatry | 54 | 5 |
| 4. Anti-Infectives | 80 | 5 | 19. Oncology | 7 | 3 |
| 5. Anti-Inflammatory | 33 | 6 | 20. Ophthalmology | 4 | 3 |
| 6. Antispasmodics | 5 | 1 | 21. Otology | 2 | 2 |
| 7. Cardiology & Angiology | 52 | 5 | 22. Parasitology | 17 | 5 |
| 8. Dermatology | 81 | 5 | 23. Pneumology | 50 | 6 |
| 9. Diagnostic | 1 | 1 | 24. Rheumatology | 11 | 3 |
| 10. Endocrinology | 15 | 1 | 25. Rhinology | 10 | 3 |
| 11. Gastroenterology | 45 | 6 | 26. Stomatology | 6 | 4 |
| 12. Gynecology | 6 | 2 | 27. Toxicology | 1 | 1 |
| 13. Hematology | 4 | 3 | 28. Urology & Nephrology | 3 | 2 |
| 14. Hemostasis | 2 | 2 | 29. Dietetic Products | 0 | 0 |
| 15. Hepatology | 1 | 1 | | | |

Source: Lebanese Manufacturers Questionnaire, 1999-2000 – Ministry of Public Health, 2000.

Quality Control

4.23 Quality Control/Quality Assurance (QC/QA) practices and procedures that are pursued by the Lebanese pharmaceutical manufacturers are influenced by internal and external factors.

4.24 The key external factor is the Good Manufacturing Practices regulations. The key internal factor is the personal and professional commitment of each manufacturer to ensuring the safety, quality, and therapeutic efficacy of pharmaceutical products. QC/QA professionals use the internal factor as a tool to help achieve GMP quality assurance goals but through methods and procedures set by each manufacturer according to its own standards. This creates non-standardized and non-homogenized and, therefore, differing levels of product quality between locally manufactured medicaments. As a result, bad quality pharmaceuticals undermine the success of good quality ones by means of diverting consumer demand towards high-price and high-quality imported Patented and brand name products.

4.25 Quality control divisions or departments are present in seven local pharmaceutical manufacturing firms. These departments perform the classical QC functions of testing and assessing operations from receipt of raw materials through the production process, packaging and distribution.

4.26 However, personnel occupying QC functions are insufficient in terms of number of individuals and in terms of qualifications. The average size of the personnel responsible for QC in the industry is five individuals. Only two manufacturers employ QC personnel with high qualifications (Ph.D. Pharmacists and Pharmacists) (Table “16” and Chart “8”).

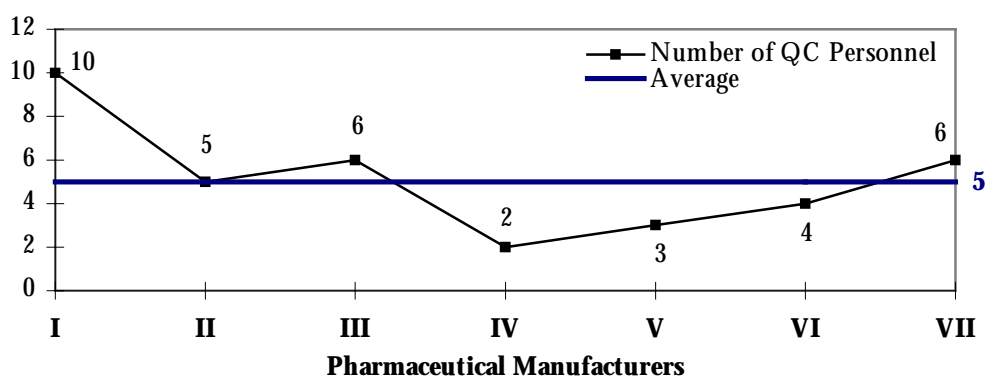
²⁰ These statistics take into consideration all eight manufacturers. The list of registered manufactured products was gathered from the Ministry of Public Health and includes all eight manufacturers.

Table 16. Qualifications and number of Quality Control personnel employed by pharmaceutical Manufacturers in 1999

| | Personnel | Manufacturers |
|-------------------|-----------|---------------|
| Ph.D. Pharmacists | 3 | 2 |
| Pharmacists | 7 | 4 |
| Food Engineer | 1 | 1 |
| MS Biology | 1 | 1 |
| BS Chemists | 6 | 2 |
| BS in Medical Lab | 3 | 2 |
| Biologist | 3 | 2 |
| Baccalaureat-II | 2 | 1 |

Source: Lebanese Manufacturers Questionnaire, 1999-2000.

Chart 8. Number of Quality Control personnel employed by pharmaceutical Manufacturers in 1999



Source: Lebanese Manufacturers Questionnaire, 1999-2000.

Raw Material

4.27 Since Lebanon lacks the raw material needed to produce the different pharmaceutical products, manufacturers import mainly their raw material from Switzerland, Italy, France, EEC, Holland, USA, Germany, England, and Spain. Out of the seven manufacturers who answered the Questionnaire, only one imports its raw material from countries such as India, and China.

4.28 Raw materials imported for the purpose of manufacturing pharmaceutical products whether active raw materials, active nutritional supplements, excipients or packaging components are not exempt from duties or taxes. In fact, most raw material custom duties range from 6 to 14 percent with some accounting for 19 and 24 percent especially on non pre-printed pharmaceutical packaging material.

Local Demand

4.29 The nation's consumers are faced with the task of choosing medicines for themselves and their families in a marketplace where foreign imported medicaments and locally manufactured medicaments compete but not over the same grounds. Consumers in Lebanon are of three types: (1) high-income consumers, (2) middle-income consumers, and (3) low-income or poor consumers. Pharmaceutical companies usually target one or several

of these categories through prices. Even though, prices of medicaments follow a strict and pre-established procedure nevertheless distributors maintain a certain level of flexibility. This flexibility is achieved through either discounts obtained in the country of origin of the imported medicament or through cost containment methods managed by local manufacturers.

4.30 Lebanese consumers are remarkably self-reliant when faced with treating most common health problems, choosing to call a doctor only for the most serious or specialized health care needs. In treating themselves, they rely heavily on a variety of OTC products, viewing these medications as generally safe but not entirely risk free. Many recognize the possibility that their use of OTCs may mask a more serious health problem, and many also admit using more than the recommended amount of an OTC because they felt it necessary to effectively relieve their symptoms. Consequently, consumers rely heavily on their pharmacists' recommendations and on labeling information when selecting and using these medications.

4.31 The pharmacist plays an important role in the way Lebanese consumers treat minor illnesses. They look to the pharmacist to provide both general and product specific information as well as guidance when they are selecting and using medicaments. The information provided by the pharmacist is considered to be very valuable by most consumers. In fact, many consumers have a "personal" pharmacist in the same way they might have a "family" physician. The benefits of this relationship extend to both the consumer and the pharmacy, and include better communication between the pharmacist and the consumer.

4.32 Pharmacists' recommendations not only carry a lot of weight in consumers' selection of medicaments, they also influence consumers to change their existing purchasing behaviors. More than half of all adults say they have started using an OTC or prescriptive medicament specifically because a pharmacist recommended it. Somewhat fewer, but still more than one-third of adults decide not to purchase a product specifically because of a pharmacist's recommendations.

4.33 Lebanese consumers also rely on prescription medications in their efforts to maintain good health, and they view these medications to be about as safe as OTC products.

Marketing Efforts and Consumer Confidence

4.34 For marketing purposes, manufacturers have a sales force of medical representatives. Information dissemination is mainly done on a person-to-person basis, called direct detailing. Representatives visit health care providers to describe the safety and efficacy of the product they are selling.

4.35 It is well perceived by both doctors and pharmacists that the main differentiating key highlighted by manufacturers in marketing efforts is lower prices compared to similar imported versions.

4.36 Consumers are very keen to learn about the quality of the medications that they consume. However, there is no readily accessible information specifically destined to the public regarding medications in general and locally manufactured ones in particular.

Therefore, consumers adopt distrustful attitudes and rely on the available information to form their own perception of the quality of products at their disposal. Consumers react to incomplete and truncated information. Perceptions are formed as a reaction to information emitted by their direct surrounding, physician, pharmacist or the media. Consumers then categorize medicaments into “bad quality” or “good quality” products.

4.37 In general, consumers perceive Lebanese manufactured pharmaceutical products as “bad quality” products for several reasons:

- 1- Total absence of efforts in the direction of consumer awareness and information dissemination measures.
- 2- Marketing efforts of manufacturers mainly target pharmacists and physicians.
- 3- Traders carry out very aggressive awareness and information dissemination campaigns targeting physicians, pharmacists and consumers.
- 4- Traders have intricate marketing networking with a very developed, qualified and extensive sales force.
- 5- Manufacturers’ budgets for marketing campaigns are limited to less than 12 percent of their total budget (Chart “9”).
- 6- Manufacturers have modest marketing and sales force. On average 12 employees are devoted to product marketing (Chart “10”).

Chart 9. Share of manufacturers’ budget devoted to product marketing in 1999

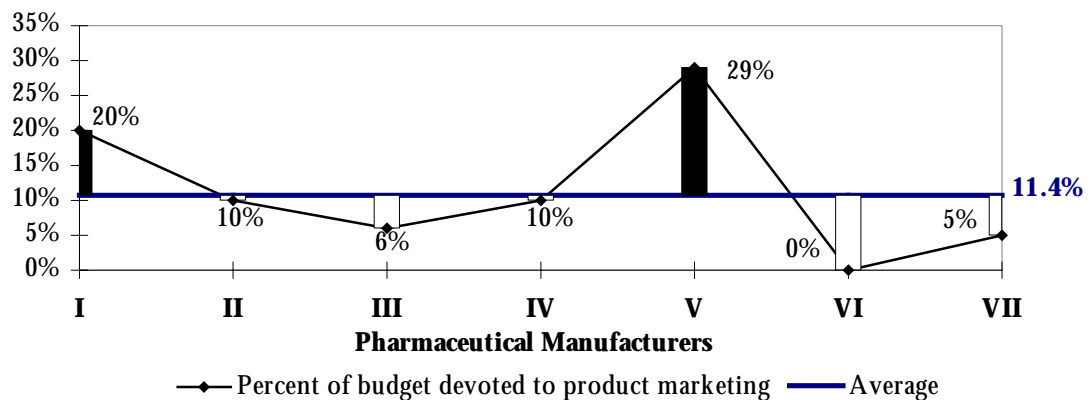
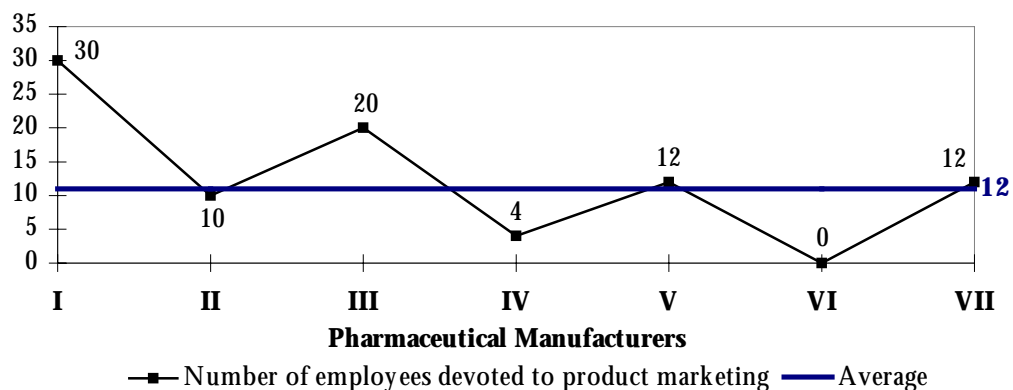


Chart 10. Personnel devoted to product marketing in 1999



Source: Lebanese Manufacturers Questionnaire, 1999-2000.

Packaging and Transportation of Pharmaceutical Products

4.38 Packaging of pharmaceutical products is carried out on two levels. There is what is known as Primary Pharmaceutical Packaging (PPP) and Secondary Pharmaceutical Packaging (SPP). Primary pharmaceutical packaging involves material in which the finished medicament will be stored and with which it will be in direct contact. These containers can take several different forms, sizes, and volumes with each having different characteristics. Among the PPP we find blister packaging, plastic bottles, pouches and strip packs, tubes, glass bottles, aerosol containers, pre-fillable containers, etc. Secondary pharmaceutical packaging involves the packaging of the PPP. These take the shape of paperboard boxes, shipping containers or other secondary containers.

4.39 Lebanese manufacturers mainly import primary pharmaceutical packaging material from foreign suppliers while rely on local suppliers for secondary pharmaceutical packaging. Local suppliers of PPPs produce limited varieties of forms, sizes and volumes that partially satisfy pharmaceutical manufacturers' needs. Local pharmaceutical manufacturers compensate this local market shortage of a full array of PPP choices by importing them from foreign companies. It incurs additional direct cost on manufacturers, as applied custom duties are consequential especially on non pre-printed packaging material (between 19 and 24 percent).

4.40 Transportation and distribution are (1) integrated within manufacturers operations (own transportation and distribution department), (2) totally subcontracted to a third party, or (3) partially subcontracted (a mix of own and third party transportation and distribution operations).

Demand Outlook

4.41 The growth of the Middle East pharmaceutical market is expected to be faster over the next five years than it was over the past decade (Table "17"). A leading international pharmaceutical markets analysts (IMS) projected a regional pharmaceutical market growth between 1998 and 2002 to be a little less than 10.5 percent representing the second highest market growth expectation after South East Asia and China.

Table 17. Projected growth of world pharmaceutical markets by region 1998-2002

| Regions | Projected market growth (%) |
|----------------------------|-----------------------------|
| North America | 8.6 |
| Europe | 5.3 |
| Japan | -0.2 |
| Latin america | 7.2 |
| South East Asia & China | 11.1 |
| Eastern Europe | 9.4 |
| Middle East ^(a) | 10.4 |
| Africa | 3.2 |
| Indian Sub-Continent | 7.9 |
| Australia | 9.2 |
| CIS | 6.1 |
| Total World Market | 6.6 |

Source: IMS HEALTH, Global Pharma Forecast, 1998.

(a) The projected total value of the pharmaceutical market of the Middle East Region is \$ 10.6 bn

Parallel Imports

4.42 Differences among nations in political, social, economic, legal and regulatory regimes cause differences in prices across countries, which, in turn, create opportunities for arbitrage or *parallel trade*²¹. Typically a parallel trader obtains a product in a low-price country and ships it to a high-price country for resale to compete with products sold through authorized distributors in the high-price country.

4.43 Various existing economic and political pressures tend to foster Pharmaceutical parallel trade in Lebanon²². By its very nature, parallel trade involves exports from low-price countries and promises lower prices in the short run in the high-price countries. Further, the diversion of goods from the authorized distribution channels in a low-price country to the distribution channel in the high-price country offers potentially large profit opportunities to parallel traders. Finally, parallel imports exert competitive discipline in industries predisposed to anti-competitive behavior at the manufacturing or distribution stage.

4.44 Parallel imports of pharmaceutical products across national boundaries operate like violations of local pharmaceutical manufacturers' territorial boundaries by undercutting the incentive to invest in pre- and/or post-sale service. While parallel imports are taking place, purchasers are obtaining pre-sale information from the authorized pharmaceutical distributor but purchase the product at a lower price from the parallel trader. Similarly, the parallel trader is making these sales but disappearing when the purchaser needs post-sale service. Parallel traders of pharmaceuticals who are providing neither pre-sale nor post-sale information are riding free on the information and service provided by the authorized pharmaceutical manufacturers.

4.45 There is a strong tendency for health care providers to select products that their experience suggests are effective, despite the presence in the market of therapeutically equivalent products at different, often lower, prices. In other words, brand loyalty and risk aversion characterize the actual competitive process through which the Lebanese consumer passes. Without an incentive to inform providers about alternatives with similar therapeutic properties, local manufacturers lose sales and consumers fail to achieve the benefits of competition.

4.46 Concerns about maintaining product quality are particularly relevant for local pharmaceutical manufacturers and, ultimately, consumers. Many pharmaceutical products have special handling, labeling and storage requirements. It is difficult for the manufacturer and the consumer of a product sold by a parallel trader to know whether or not the product has been handled and stored properly.

4.47 We do not pretend that this analysis is comprehensive and ends here. The benefits and costs have yet to be quantified; for present purposes we have relied upon our understanding of the relative orders of magnitude of the effects of pharmaceutical parallel trade. The research agenda on this policy issue should include more precise estimation of the effects of parallel trade.

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²¹ The extent to which parallel imports occur has not been measured.

²² In Lebanon, Decree 539 dated 08/25/1998 authorizes parallel imports.