Chapter Four

PHARMACEUTICALS

Pharmaceuticals being the major item of health spending, far ahead of hospitals and physicians' fees, stand on the top of policy makers' priority list. On the other hand, quality arose as a public concern with the divulgation of seizures of counterfeit and smuggled drugs, sometimes blown up out of proportion by the media.

The number of currently registered drugs slightly exceeds 5000, of which almost one thousand are manufactured locally, and the others are imported by 101 agents and distributers from 580 manufacturers spread over the world, especially in Europe.

The distribution of prescribed pharmaceuticals by therapeutic class shows that cardiovascular drugs are on the top of the list with almost 20% of market share, including 11% antihypertensive medications. Antibiotics lie in the second position (12%) followed by anti-inflammatory and analgesic drugs (9%). Psychotropic medications represent 5.5% of the market, including 3.5% anti-depressive and 1% tranquilizers and sedatives. It is worth mentioning that vitamins, mineral supplements and "tonics" amounted to 26.8 billion LBP in 2007. Needless to say that most of the time, these additives bring no significant benefit to the patients' health and obviously constitute a waste of resources.

Finally, anti-diabetic drugs represent 3.5% of the market and medications for asthma and COPD 2.3%.

1- THE PHARMACEUTICAL MARKET

Pharmaceuticals account for an important share of the Lebanese market with a sales volume exceeding 900 million USD in 2007. Households annual OOP spending on drugs was estimated at 100 USD per capita in 2005.

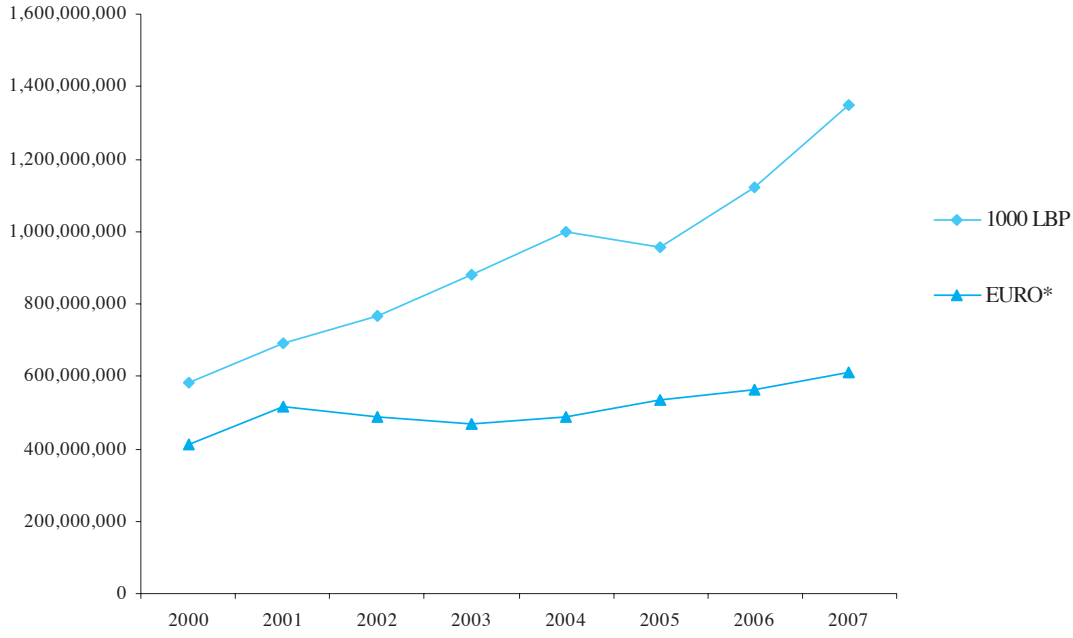
Pharmaceutical prices are set in application of a Ministerial Decision. This decision is issued following a relatively complicated procedure that involves all stakeholders and concerned ministries as well as the State Council. It sets a price structure that defines freight and mark-ups on landed costs of the imported drugs, including profit margins for importers and drugs handlers. It provides also for an updating mechanism, whereby a price index is issued regularly to take into account currency exchange rates. In addition, the MOPH watches over price decreases in the exporting country, and compares prices with neighboring importing countries in order to lower the market price accordingly. The MOPH Pharmaceutical Inspection Department controls drug prices in the market, and sanctions are taken against pharmacies practicing over-pricing.

As the public price of drugs is closely tied to the importation currency, the mix of countries exporting to the Lebanese market impacts most of the national pharmaceutical bill items. Calculated in percent of total number of registered non domestic drugs, those imported from EU countries represent as much as 79.42% compared to 5.75% from the United States, and 9.59% from Arab countries, more than half of which are manufactured in Jordan.

Table IV-1: Distribution of the number of registered drugs by exporting country (2008)

	Euro Zone countries	Other EU countries	Arab countries	USA	Others	Total
Number of registered dugs	2213	1018	390	234	213	4068
%	54.40	25.02	9.59	5.75	5.24	100%

Imported drugs volume, calculated at public price in Lebanese Pounds has been steadily increasing, giving the impression that the volume and cost are increasing at the same speed. Fig IV-1 shows clearly however, that the slope of the curve of importation converted into EURO, is much narrower. This indicates that constant price increase in nominal LBP can be largely attributed to inflation.



* Euro calculation is based on the yearly end of period exchange rate of Banque Du Liban

Fig IV-1: Volume of imported medicines at public price 2000-2007

Total drugs market in 2005, amounted to 677,376,000 USD, with 80% sold in pharmacies, 14% consumed in hospitals and 6% purchased directly by the MOPH, the Army and the Internal Security Forces. For the same year, household out-of-pocket purchasing of medicines amounted to 374.2 million USD, representing more than half of the total market.

It is worth mentioning that, while households total spending on health was significantly lower in 2005 compared to 1998, those related to drugs remained almost the same.

Maintaining almost the same amount in LBP disbursed by households for purchasing drugs, despite significant increasing price, indicates clearly that cheaper sources of supply have become available for at least part of the population. This reflects probably the role of PHC centers and essential drugs programs, as well as the growing free provision of expensive drugs by the MOPH.

Table IV-2: Spending on drugs by households and intermediaries in 1998 and 2005 (1000 LBP)

	1998*	2005*	% increase
Intermediaries	199,093,247	267,099,296	34.2
Households	560,000,000	564,121,023	0.7
Total	759,093,247	831,220,319	9.5
% total households spending**	25.35	31.01	5.7

* Medical supplies, consumables as well as drugs consumed within hospitals are not included.
** Households spending on drugs in % of total households spending on health.

One of the most important characteristics of the pharmaceutical market is the predominant role of medical professionals. This issue is particularly critical in Lebanon because of the absence of any framework for medical prescription accountability. The quasi-absolute freedom in prescribing medicines gives treating physicians a tremendous power over the demand side, and constitutes a major obstacle to cost rationalization. Pharmaceutical firms have a determining influence over all forms of post-university medical education, through financing research and related publications, as well as through sponsoring medical conferences and seminars. Physicians who do not attend scientific events are targeted through marketing campaigns providing each one with selective information and a variety of incentives. The total pharmaceutical bill is sensitive to the marketing of new molecules, particularly when promotion goes beyond the approved indications for the patented drug, without necessarily showing solid evidence of added effectiveness.

In addition to the information asymmetry that gives the prescribers power over demand, unfair competition practiced by pharmaceutical firms contributes also to market failure. That is how, upon patent expiry and registration of a less expensive

generic, the originator company, instead of competing by reducing the price, floods physicians with free samples, and offers generous bonuses to pharmacists reaching sometimes one hundred percent. This practice is against fair competition. It also favors big pharmacies, capable of purchasing bigger quantities with higher bonuses, to the detriment of small ones.

Over prescribing branded drugs becomes a particularly serious issue with the incredibly exorbitant prices of innovative medicines witnessed lately, exceeding easily one thousand dollars for a month treatment. The case of Glivec®, for example, that costs more than four thousand USD for one patient's monthly treatment is revealing. This medicine is effective to stop the disease[1] as long as it is administered, but does not cure it. This leads to an ever increasing number of consumers resulting from additional new cases, without dismissing old ones that are neither healed nor deceased. Simple arithmetics shows that in few years the whole MOPH drugs' budget would barely suffice for purchasing this single medicine. It is only legitimate to ask why this medicine is so unrealistically expensive? It is so, in comparison with other "orphan drugs"[2]. And for how long? The Orphan Drug Act guarantees the developer of an orphan product seven years of market exclusivity[3].In any case, this issue should also be dealt with in light of the Doha Declaration that emphasized the relationship between TRIPS and public health and clarified the meaning of Article 8 of the TRIPS agreement. Particularly in considering that patent protection should not be used as a means for merely extracting high rates of return on pharmaceutical investments, but rather as a means to encourage the development of new medicines[4]. It is noteworthy that the Glivec generic competitor has been duly registered by the MOPH more than a year ago but is still not marketed in Lebanon!

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[1] Chronic Myelocytic Leukemia with Philadelphia chromosome.

[2] The term "orphan drug" refers to a product that treats a rare disease affecting, fewer than 200,000 Americans in the USA, and less than five persons in 10,000 population in the EU.

[3] The Orphan Drug Act was signed into US law in on January 4, 1983.

[4] TRIPS Agreement, Article 8. The Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 3, 14 Nov. 2001.

2- REGISTRATION AND QUALITY OF DRUGS

The Department of Pharmacy is the MOPH regulatory arm for pharmaceuticals and drugs handlers. Professional associations and universities are actively involved in quality assurance and registration of drugs through a technical committee chaired by the MOPH Director General in accordance with the 1994 Pharmacy Practice Law. Although the law stipulates that decisions are taken by a majority vote and in case of a tie, the Chairman has the casting vote, the Director General has never used this prerogative for the past 15 years. As a matter of fact, it is extremely rare to have a vote, as decisions are almost always reached by consensus.

Box IV-1: Registration Requirements for original drugs (new molecules)

- Manufacturing Plant: Filled questionnaire and GMP certificate.
- Free sale certificate, Certificate of Pharmaceutical Product (CPP).
- Attestation of origin of raw material with GMP certificate for each related manufacturer.
- Certificate of Analysis mentioning the quantity and purity of raw material and methods of analysis.
- Pharmaceutical studies (disintegration, dissolution, pH) and stability data for 3 different batches.
- Complete and detailed bioavailability of active ingredients issued by the source which carried out the study.
- Complete studies on drug efficacy (pharmacodynamic data).
- Complete studies on toxicological effect of the drug (toxicological data) including: teratogenecity and carcinogenicity.
- Pharmacokinetic studies.
- Clinical trials and if available post-marketing study.
- Summaries of toxicological, pharmacological and clinical information from published scientific literature.
- Patent certificate (with the closet expiry date).
- Certificate of analysis issued from a recognized laboratory.
- Six (6) samples of the product.
- Supporting research bibliography.

Registration of drugs, as defined by the 1994 law, became outdated with changes occurring in the pharmaceutical sector at the international level. A large movement of mergers and acquisitions between multinationals took place in the last two decades along with globalization and WTO empowerment. This large scale

structural change in the pharmaceutical industry and trade, resulted in fragmentation of manufacturing and involvement of multiple industrial and commercial parties, in a manner that complicates and disperses responsibilities related to commerce, quality and price. Like health authorities in other Developing Countries, Lebanon was relying on quality control and pricing as done by the "Country of Origin" considered as a reference, and entrusted for certifying all documents required for registration. The "Country of Origin" is a key notion in the 1994 law stipulating, as a prerequisite for registration, that the product conforms to the same specifications as registered and marketed in the country of origin, including the tradename, pack form and size as well as pharmaceutical characteristics. The purpose was to make sure that the manufacturer is not dedicating a production line with lower requirements for export to Developing Countries. The technical committee is challenged by the fact that nowadays, the same drug is sold in different countries with different names, sizes and forms, and the notion of one "country of origin" does not apply anymore, as many countries can be involved in the manufacturing and commercialization processes.

Box IV-2: Registration requirements for generic drugs

- Manufacturing plant: Filled questionnaire and GMP certificate.
- Free sale certificate, certificate of pharmaceutical product (CPP).
- Attestation of origin of raw material with GMP certificate for each related manufacturer.
- Certificate of analysis quantity and purity of raw material and methods of analysis.
- Pharmaceutical studies (disintegration, dissolution, pH) and stability data for 3 different batches.
- Complete and detailed bioequivalence issued by the entity which conducted the study.
- Certificate of analysis issued from a recognized laboratory.
- Six (6) samples of the product.
- Supporting research bibliography.
- Optional: - Letter stating that the drug is marketed in at least 2 countries other than its country of origin.
  - Post-marketing clinical studies
  - Drug approval and recognition of the manufacturing plant by other countries.

For the MOPH to face these challenges, a legislation amendment was deemed necessary. Law number 530, issued in

2003 to amend the 1994 law introduced new concepts, aside of the "country of origin", to be considered as a responsible party. These include the "manufacturer", "marketing authorization holder" and "applicant for certificate"; whereby the responsible country would be the country of residence of the responsible party. It is worth mentioning that five years of consultations with stakeholders were needed to reach a seeming agreement on an application decree for Law 530. The emphasis was put on the manufacturer of the pharmaceutical form (MPh.F), the responsible party for batch release and quality control, if different from MPh.F, and their related country (ies).

On the other hand, the MOPH has adopted a clear policy focusing on quality and cost of pharmaceutical products. In the absence of an operational public laboratory for drug analysis, the technical committee decided to impose a certificate of analysis from an internationally recognized laboratory as a prerequisite for registration. Local industry was required to conduct a bioequivalence study similar to imported generics. Prior to marketing, imported drugs are subject to direct inspection, and batch analysis' certificates are required. Biopharmaceuticals and biosimilar products are subjected to strict requirements and more scrutiny.

Box IV-3: Additional requirements for biopharmaceuticals and biosimilar products.

- Registration certificate of the manufacturing plant, GMP certificate, and official statement indicating the Inspecting Authority.
- Detailed information on the ability of the plant to manufacture biological material, including Genetic Chemistry, Animal Cell Culture, Protein Chemistry (Extraction, Purification, Analysis, Fixation, Dose Determination, and source of material used in production (Cells. Fixation material…) with GMP for this source.
- Product Studies: Chemical Analysis, Clinical Studies, Comparative studies with the originator drug. Stability studies, Studies confirming compliance of different batches to unique standards, Study of side effects among which is secretion of antibodies after use.
- Post-marketing study on therapeutic and side effects, comparative post-marketing clinical studies with the brand drug including efficacy and side effects.
- Six (6) samples of the product.
- Supporting research bibliography.

Twenty five additional pharmacists were recruited in 2007 to strengthen the MOPH inspection body in Beirut and provinces. Regular inspection of pharmacies and drugstores was scaled-up and led to a significant number of confiscations of counterfeit and smuggled drugs, in addition to disciplinary measures and referral to court. During the first 6 months of 2008, 65 ministerial decisions were issued for withdrawal of illicit drugs; of which 51 were smuggled including 3 narcotics, and 14 counterfeit including one narcotic.

Despite the closing of the Central Laboratory, the strict regulation of drug registration guarantees to some extent the quality of imported and domestic pharmaceuticals. Exceptions are related to parallel import and relatively small quantities of drugs donated to NGOs that bypass the system and reach dispensaries after obtaining a special permit from the Minister of Public Health.

Box IV-4: Requirements for parallel import

- Importation of registered medical and pharmaceutical products is not restricted to any importer or agent, and is allowed any duly licensed entity.
- Importation from countries other than the registered exporting country (country of origin) is conditioned by the presentation of a certificate stating that, the product is registered and sold in the concerned country (Free Sale Certificate) as it is registered and is sold in the manufacturing country, without restrictions.
- Both the manufacturer and the manufacturing country must be registered in Lebanon [(1)].
- Drugs imported through parallel channels are subject to:
  1) The same inspection and control mechanisms as regularly imported drugs.
  2) Their public price is based on the invoice price and would follow the price index variations[(2)]
- Narcotics and other restricted drugs and those with similar locally produced products cannot be imported through this process.

(1) This condition was not provided for by the original decision # 90/1 of 13 March 1992, it was introduced by Decision # 539/1 of 25 Aug. 1998.
(2) Originally, Decision # 539/1 of 25 Aug. 1998 imposed at least 25% discount on the original product price. This condition was removed by Decision # 96/1 of 13 Feb. 2002.

3- COST CONTAINMENT

Facing the high cost incurred in satisfying an ever increasing demand, mostly induced by suppliers and innovative

medicines, and considering the information asymmetry and the failure of market mechanisms to adjust, the MOPH had to adopt a multidirectional cost containment policy.

3.1- Modifying the price structure

Until recently, pricing was based on decision 208/1 issued in 1983. The price-dependent profits, in fixed percent for all categories, encouraged importation and dispensing of expensive drugs. The margin allocated in the price structure for clearance and commission was exaggerated considering variable custom exemptions on imported drugs. Shipping and insurance expenses were uniformly calculated for both far and close countries. The freight percentage set as an average for USA, Canada, Australia, European and other countries, led obviously to over-pricing, as most of pharmaceuticals are imported from nearby European countries. Moreover, the freight was calculated as a percentage of the price, not in relation to shipment fees which are based on volume. This means that expensive drugs, with small volume and high price, generate more profit than less expensive ones. This phenomenon was further magnified by the cumulative margins of the price structure (Box 5).

In order to reverse incentives, a degressive scale for profit margins had to be considered. Two ministerial decisions issued in June 2005 had a direct impact on drugs' prices. The first, decision # 301/1 imposes adjustment of prices based on a price comparison with Jordan and KSA. Among 1102 drugs common with KSA and 1006 with Jordan, 872 drugs were priced in Lebanon based on an ex-factory price higher than the other two countries. Re-pricing led to variable decreases reaching for some drugs 40%.

The second, decision # 306/1 provides for a new pricing structure that lowers the mark-ups set in 1983 in a degressive way i.e profit margins decrease as ex-factory prices increase. The new scheme features four classes of products, where pharmacy mark-ups range from 24 to 30 and importer/ wholesale mark-ups from 8 to 10 percent. This decision introduced for the first time a mechanism for periodic price revision. It widened the country basket for ex-factory price comparison to 14 countries besides the

country of origin. Two other radical measures were also introduced: the first stated that public price in Lebanon must never be above the pharmacy retail price in any one of the reference countries, and the second stated that if any company abstains from delivering on time the requested documents for periodic re-pricing, the concerned drug would be subject to automatic price reduction with variable percentages depending on whether the drug is a patent, off-patent brand or generic, and on how long it has been put on the market.

Box IV-5: Comparison of pricing structures

Pricing structure according to Decision # 208/1 - 1983

		Shipping & Insurance		Customs Clearing comm.		Importer profit	Pharmac. profit
	FOB	x 7.5%	= 107,5	x 11,5%	= 119.8	x 10% = 131,8	x 30% = 171,4

Pricing structure according to Decision 306/1 - 2005

A	0-10$	x 6%	= 106	x 10%	= 116,6	x 10% = 128,26	x 30%= 166,73
B	10-50$	x 4.5%	= 104,5	x 8,5%	= 113,38	x 10% = 124,72	x 30%= 162,13
C	50-100$	x 3.5%	= 103,5	x 7,5%	= 111,26	x 9% = 121,27	x 27%= 154,02
D	> 100$	x 2.5%	= 102,5	x 6,5%	= 109,16	x 8% = 117,89	x 24%= 146,19

Unfortunately, under pressure exercised by multinationals and importers, the decision # 306/1 was amended a few months later[5] to increase the freight and customs mark-ups, which nevertheless remained inferior to those of 1983. Most importantly the amendment decision, replaced the comparison with each European country by a comparison with the median price of European countries, which practically excludes extreme prices such as those of Portugal. This comparison is only applicable for drugs imported from Europe. The amendment decision canceled also the above mentioned “radical measures” of public price ceiling and automatic price decrease.

[5] Decision #51/1 dated 24 January 2006.

Box IV-6: Drug pricing according to decision 51/1

The public price is set by the application of rules of conversion of the registered exfactory price (table b).

- Price conversion indexes are calculated based on foreign currencies exchange rates as issued by the Banque Du Liban. Exchange rates are re-considered when a change of the average rate for 2 consecutive weeks of at least 3% occurs upward or downward.
- The registered price is split into segments according to table a. if the registered price is in a currency other than US Dollars, the amount thereof is converted into Dollars.
- Public price calculated according to the segment to which the product is assigned, pursuant to table 1 in the following manner:

- The amount of freight and insurance expenses (column 2) and the amount for clearing, customs duties and other expenses (column 3) is added to the registered FOB price. Clearing, customs duties and other expenses are added to the registered CIF price (column 3).
- The entire sum is multiplied by the base mentioned in column 6 and resulting from the profit margin of the distributor (column 4) and the profit margin of the pharmacist (column 5).

Table a: Registered Price Segments

Segment	Registered FOB price		Registered CIF price	
A	0$	10$	0.00$	10.70$
B	10$	50$	10.70$	52.50$
C	50$	100$	52.50$	104.00$
D	100$	and above	104.00$	and above

Table b: Basis of Conversion of the Registered Price to a Public Price

1	2	3	4	5	6
Section	**Freight and insurance expenses (only for FOB price)**	**Clearing, customs duties and other expenses**	**Profit margin of the importer**	**Profit margin of the pharmacist**	**Base**
A	7.00%	11.00%	10.00%	30.00%	143.00
B	5.00%	10.00%	10.00%	30.00%	143.00
C	4.00%	9.00%	9.00%	27.00%	138.43
D	3.00%	8.00%	8.00%	24.00%	133.92

The implementation of decision 301/1 led to price reductions on 872 drugs by an average of 20%, with an expected total saving reaching 24 million USD per year. The application of the revised decision 51/1 on the other hand, led to a price decrease per drug ranging from 3 to 15%, and cumulating to an approximate total of 27 million USD yearly. However, a long term impact of this decision is expected to result from the price revision mechanism. In application of this decision, price revision of drugs registered between 2001 and 2006 was achieved as provided for,

targeting 1109 drugs in 2007, and resulting in lowering the public price of 360 drugs with a yearly saving exceeding 10 million USD.

It is worth mentioning that throughout the lengthy procedure of regulations amendment led by Minister Khalifeh, an unremitting fierce campaign was orchestrated through the media, blaming the Ministry for "high cost" and "bad quality" of drugs and accusing the public administration of corruption. It is really a strange coincidence that such campaigns always accompany reform attempts. The campaign has started by over emphasizing the power of the "pharmaceuticals mafia" that is capable of dismissing a health minister! In allusion to the resignation of Minister Emile Bitar in 1971. Not yielding to intimidation, Minister M.J.Khalifeh issued the amending decisions. Then the attacks turned against civil servants accusing them of not being capable nor willing to implement any reform. In a press conference held to announce the impact of regulation amendments on the pharmaceutical bill, the minister of health emphasized: "once the political decision is made, the administration has proved its ability to execute"[6].

3.2- Promoting generic drugs

The MOPH succeeded in imposing exclusively generic drugs in PHC facilities and in making essential medicines widely available in health centers and dispensaries. This could not have a better result than maintaining the 2005 households' related spending at almost the same level as 1998. However, total spending on pharmaceuticals kept increasing as the Ministry failed in changing physicians' prescribing habits or creating accountability mechanisms that could have increased substantially the generics market share.

Physicians are not used to prescribe generic drugs mainly because of their university and post university education and hype promotion campaigns that constitute the main source of information on pharmaceuticals for many of them. Manufacturers

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[6] Minister Mohamad Jawad Khalifeh Press release # 9478/2005, MOPH 22 Sept. 2005

"scientific bureaus" are very active and adopt persuasive marketing techniques that are sometimes ill-founded scientifically, and may even be unethical.

In addition to the influence of pharmaceutical firms, other factors are contributing to the avoidance of generics by the physician as well as the patient. The confiscation of the Central Laboratory building, neighboring the residential palace of the Speaker of the Parliament, without relocation of the Chemistry Branch that is responsible for drug analysis, had a negative impact on professionals and public confidence in generic drugs. In addition, slanderous episodic and probably premeditated media campaigns, damaged the image of the MOPH by affecting public confidence in the whole registration process, and thus reorienting the demand towards branded drugs manufactured by "entrusted" multinational companies. Ironically, one constant allegation of the repetitive campaigns has been the civil servants' "conspiracy" with the "international drugs mafia" against generics and national products. Interestingly, the Order of Pharmacists, and sometimes the Order of Physicians, have been participating in the propaganda, despite the fact that they have a determinant role in drug registration! The two Orders are represented in the committee by four members out of seven, and the Chairman has never used his tipping voting prerogative.

Nevertheless, the MOPH has produced a National Drug Formulary indicating generic alternatives for each brand, that was largely distributed and published on the MOPH website. This would help physicians who are willing to make the effort of looking for cheaper alternative treatments for their patients. It would undoubtedly be most useful for pharmacists, once the legislation allowing them for substitution of prescribed drugs is passed.

3.3- Reforming legislations to enhance competitiveness

Article 80 of the 1994 Pharmacy Practice Law requires pharmacists to adhere to prices set by the Ministry of Public Health. An amendment of this article was issued in Dec 2002 by Law 480 considering the price set by the MOPH as a ceiling not to

be exceeded, but that could be lowered. This amendment had probably a meaningful impact on households' spending on drugs, especially when considering its added effect with other measures taken by the MOPH. However, allowing the pharmacists to substitute a prescribed drug by a less expensive generic would have an even more significant impact. While a Bill supported by the MOPH is now under discussion in Parliament to bring this change, another one was submitted by the Order of Pharmacists' lobby proposing to revoke the above mentioned amendment brought by Law 480.

The application decrees to Law 530 will remain controversial for many years to come. In addition to setting quality requirements for registration, these decrees would also deal with the commercial aspect that would have a determinant effect on the market. What is considered undisclosed information in the application file? What would be the responsibility of the MOPH in data protection, and how would it be assumed? These are questions that the application decrees have to provide with clear answers. Regardless of whether data exclusivity are considered, as additional requirements to TRIPS binding agreements and therefore may be rejected; bilateral negotiations will still be depending most of all on the balance of power. Tremendous pressures are put to extend the data exclusivity period, and at the same time to expand the notion of undisclosed information to include even published (i.e. made public) information in scientific journals or on Internet! In addition, while elaborating the implementing regulations of Law 530, attempts were made to include provisions whereby Lebanon would waive its right to do its own scrutiny and accept certificates of registration issued by foreign authorities such as FDA and EMEA. In this case, Lebanon shall be asked by the USA and the EU to protect data that were submitted to foreign authorities, which overlooks the principle of territoriality of intellectual property.

On the other hand, one has to wonder why Europe is still the main source of drugs for Lebanon, while almost all pharmaceutical mother companies own factories in other countries including the United States that produce the same drugs with cheaper ex-factory prices in US Dollars? Drug importers claim that

they are not allowed to choose the importation country, such a decision is taken by the concerned pharmaceutical firm. In this case, how legitimate is the fact of imposing one particular production site, in light of the basic trade agreements' principle of free movement of goods and money? This concern even extends to products with exhausted patent.

With regard to patented products, an amendment to the Lebanese Patent Law may be required. Under the "national exhaustion of rights" adopted in that law, the rights of the owner of the patent would be exhausted only in respect to goods that have been put on the market in the country with its consent[7]. The World Intellectual Property Organization (WIPO) suggested in this regard that Lebanon may adopt a mechanism of "controlled international exhaustion", under which the authorities would have the competence to decide when it is convenient or not to allow the introduction of goods protected by (exhausted) intellectual property rights abroad through parallel channels of commerce. The Doha Declaration reaffirmed the right of members to adopt an international principle of exhaustion of rights with respect to parallel importation under Article 6 of TRIPS[8]. Regarding off-patent products however, imposing territorial restrictions on licenses as regards the origin of supplies should be dealt with in the framework of competition and antirust legislations.

In all cases, parallel import as currently regulated and practiced in Lebanon, could not be expected to have a meaningful competitive position on the market. As a result of largely mediatised criticisms, the famous parallel import ministerial Decision 90/1 of 13 March 1992 was amended by Decision 539/1 of 25 August 1998, to add strict quality requirements, while

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[7] TRIPS Agreement, Article 28 (Rights Conferred): 1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing* for these purposes that products;

*[footnote]: This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provision of Article 6".

[8] Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5.a. Nov. 2001.

maintaining the imposition of a price reduction by at least 25% compared to the registered original product. These requirements that include the submission of a free sale certificate and an original certificate of analysis, have contributed to narrowing significantly the range of parallel import products. However, the strike that hit badly the competitive effect of parallel import came from Decision 96/1 of 13 February 2002 that kept "a discount" requirement but removed the threshold of 25%. This decision was also issued under mediatised pressure on the ground that the 25% threshold excludes many drugs that could be sold with 20 or 15% reduction and that any discount would be beneficial for the "poor Lebanese". Those "compassionate" for the people do not cease to impress us by their struggle for the public well-being. We are also enchanted by politicians who immediately respond to these compassionate cries. No wonder these compassionates are always reelected with vast majority.

As a result of the "well-intended" militancy, parallel imported drugs ended up being sold at a barely lower price than the original registered product! We cannot wrap up this section without recognizing the "constructive patriotic role" of the media in reaching this end-result.

4- THE NEED FOR A MULTIDIMENSIONAL APPROACH

The registration of drugs is based mainly on the examination of filed documents. MOPH's Technical Committee relies on site inspections performed by the drug regulation authority of the exporting country, as well as drug analysis done in a reference laboratory. Imported drugs do not clear Customs unless the MOPH Inspection Department verifies for each batch, the existence of an analysis certificate duly legalized. There is an obvious and urgent need for a national reference laboratory for drug analysis, an issue that is currently subject to political wrangling. Recruiting the necessary qualified staff remains an important issue in light of existing low public administration salaries. Institutional strengthening is critical for the MOPH to regulate the pharmaceutical market, especially if this requires performing new tasks such as assessing physicians prescribing patterns.

This brings us to the issue of reforming professional Orders by removing the unionist function from the concerned legislation. As a matter of fact, unionism of both physicians and pharmacists Orders, is not only getting ahead, but also hindering disciplinary action and professional promotion, that are essential functions from an Order perspective.

On the other hand, developing national capacity for bilateral and international agreement negotiations is becoming increasingly important with globalization and the accession of Lebanon to WTO.

Finally, the ethical dimension of drugs marketing was never given the importance it deserves, save for mediatised moral preaching. Evidence shows that drug promotion influences prescribing and is associated with increased medicines sales; that samples stimulate prescribing; and that doctors rarely acknowledge these facts[9]. Doctors who receive drug company funds tend to request additions to hospital formularies. Drug company sponsorship influences the choice of topics for continuing medical education, the choice of research topics and the outcome of research[10]. A draft code of honor setting ethical standards for marketing practices was developed by the MOPH in 2004 for voluntary adherence of interested parties. This code was inspired from pharmaceuticals associations' codes of ethics. It proposed a regulation mechanism based on self-assessment of the pharmaceutical industry. Evidence suggests that such a code has failed to deter promotional excesses and that self regulation seems to be a service to pharmaceutical associations rather than to the public[11]. A revised version of the code of ethics was recently proposed[12] and published on the web for debate. New ethical

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[9] Norris, P; Herxheimer, A; Lexchin, J; Mansfield, P. "Drug Promotion what we know, what we have yet to learn". World Health Organization and Health Action International. 2005.

[10] Idem

[11] Herxheiner, A; Collier, J. Promotion by the British Pharmaceutical Industry, 1983-8: a critical analysis of self regulation. BMJ 1990; 300:307-311

[12] Ammar, W. The code of ethical standards for drug promotion in Lebanon, and the surveillance and appeal mechanisms. Letter to the Minister of Public Health # 14546/4/08 October 7, 2008.

standards were introduced in response to particular promotion and prescribing practices in Lebanon. Most importantly, the proposed code provides for surveillance of promotional and prescribing patterns and for appeal mechanisms that involve professional orders and the MOPH. It also calls for disclosure of complaints and non-compliance files, in case the violating party abstains from taking convincing corrective measures. This is meant to foster public accountability of pharmaceutical firms and health professionals.

Box IV-7: Highlights from the proposed code of ethical standards for drug promotion.

- *Information* provided should be clear, accurate and limited to what is published in the leaflet upon which the registration was based. No allegations on drug safety or efficiency should be made without scientific evidence. Health care professionals should be provided with complete information on contra-indications and side effects, in order to allow them to make an informed choice of drugs and be able to warn the patient for his best interest. Providers are also requested to report on adverse events that are rare or not mentioned by the producer.
- *Promotional items* should not have an important money value, should be related to professional practice and of benefit to patient care. Cash money or equivalent payments are strictly forbidden.
- *Samples* should be packaged and cleared as such by the pharmaceutical inspection, should be supplied in moderate quantities to prescribers to familiarize them with the products. Drugs packaged for marketing purposes cannot be subject to any kind of donation or bonuses for private clinics or pharmacies.
- Support of drugs companies to *congress, symposia and medical education* is also scrutinized. In kind support such as travel tickets, and accommodation should be restricted to the health care professional in person. Such activities should be planned and communicated in advance, and the concerned professional order should be notified of the event, the organizers, and the list of its participating members. In addition, ethical standards are also set for the information provided, as well as for the selection and reimbursement of consultants.
- No *grants, scholarships, subsidies, support, consulting contracts* should be offered to a health care professional in exchange for prescribing products. Any transaction between pharmaceutical firms and care givers should be transparent and explicit.
- The system of remuneration of medical representatives should not influence adversely the proper prescribing or dispensing of drugs, or be in anyway related to prescribing or dispensing patterns.
- Pharmacists are forbidden from divulgating information on physician's prescribing patterns, and are held responsible if such disclosure occurs.
- The code makes provision for *enforcement mechanisms* including monitoring, investigation, and a three level appeal procedure, involving concerned professional orders, pharmaceutical firms, drug importers and the Ministry of Public Health.