

6. Main Issues and Recommendations

6.1 Based on all information presented earlier in the report and available confidential data³⁴, we have analyzed the main issues and classified them into five main categories.

6.2 These issues were subject to discussions the Workshop with the seven manufacturers who responded to the survey prepared by Tomorrow's Advice and other concerned parties from Public and Private Sectors.

I. Limited Quality Control Measures (Public and Private Sectors)

- Insufficient drug testing of imports and manufactured products
- Insufficient independent data for registration
- Insufficient technical, financial, and human resources for proper monitoring of drug imports and of manufacturing processes
- Lack of internal controls reduces effectiveness of inspection measures
- Increased potential for counterfeiting
- Industry Image and credibility at risk

II. Lack of Modernization of Laws and Procedures: Drug Registration, Customs, Intellectual Property Rights (MOPH, Customs, MET)

- Delays in reviews causing unregistered drugs to enter the market
- Lack of consumer protection measures
- Increased competition without regard to quality
- Lack of implementation of a prescription drug policy
- Unmonitored self-medication practices
- Unclear definitions: medicaments versus food additives (duties 6% versus 15%)
- Delays in customs processing impacting production schedules
- Lack of foreign investment interests
- Limited transfer of know-how (no licensing)

III. Low Consumer Confidence

- Lack of confidence in authorities' Quality Control measures and testing
- Absence of certified and trusted testing facilities (Private sector or Private Hospitals)
- No Bio-equivalency tests on manufactured drugs
- Lack of awareness campaigns and Industry building image

IV. Outdated Essential Drug List (MOPH)

- Burdening monitoring systems

³⁴ Findings extracted from "Lebanese Manufacturers Questionnaire, 1999-2000" are illustrated in Appendix E.

- Increasing health costs to consumers and public institutions

V. Inaccessible Data (Public and Private Sectors)

- Lack of organized data and transparency
- Delays in reacting to Industry Developments
- Dissemination of biased data
- Lack of consumer awareness

6.3 Related recommendations were summarized and identified as a starting point for Industry to pursue reform and development. As to Public Sector, we recommend that major weaknesses in infrastructure be remedied to assure Industry of the proper growth environment. Other Private Sector was invited to share and participate in the required restructuring of the Pharmaceutical Sector.

I. RECOMMENDATIONS – INDUSTRY

Invest

- Higher Technical Expertise for Quality Control
- Adopt and produce according to GMP rules and regulations
- Bio-Equivalency drug tests or similar tests
- Promotion to improve image and heighten consumers' awareness on Quality Control measures used

Diversify

- Shift productivity to better match demand
- Network with original manufacturers of drugs
- Explore new prospect markets

Communicate

- Share information
- Propose amendments to laws, regulations, and procedures resulting in high quality standards and cost cutting impact to Public Institutions
- Activate Consumer Protection efforts against low quality foreign drugs
- Coordinate and support targeted efforts of professional organizations such as Order of Pharmacists, Physicians etc...
- Strengthen relations with educational institutions and universities

II. RECOMMENDATIONS – PUBLIC SECTOR

Regulate

- Create a comprehensive centralized database with sharing ability for concerned parties
- Streamline registration, testing, monitoring, and enforcement process to increase effectiveness and efficiency
- Update GMP regulations to correspond to International Standards
- Develop International Trade Agreements
- Develop Intellectual Property Rights Law
- Improve licensing standards in coordination with Professional Organizations
- Increase transparency and accountability among Public Officials, Manufacturers, Traders, Physicians, and Pharmacists
- Adopt an update Essential Drug List

Monitor

- Higher technical expertise for Quality Control
- Enforce inspection and testing procedures and ramifications
- Identify Performers and Quality Control complying parties
- Intensify Consumer Protection efforts and heighten Consumer awareness on drug related health risks
- Coordinate and support targeted efforts with professional organizations such as Order of Pharmacists, Physicians, etc...
- Develop drug cost containment measures
- Improve coordination with International Organizations such as WHO
- Improve attitude towards Industry
- Develop educational programs that fit Industry needs

Facilitate

- Share information
- Simplify trade procedures impacting manufacturers
- Encourage Private sector initiatives to support Public sector monitoring and testing services
- Publish guides for related Laws, regulations, and streamlined processes
- Participate and share in training activities with Professional Organizations, Manufacturers, and Traders

III. RECOMMENDATIONS – PRIVATE SECTOR

Assist

- Develop Quality Control measures for Public sector and Manufacturers

- Enforce codes of Professional Ethics and encourage compliance with Laws and Regulations
- Coordinate and support targeted efforts of Public sector Institutions in regulating and monitoring activities of the Manufacturers and the Traders
- Develop Professional Organizations' activities to meet future challenges
- Develop educational programs that fit Industry needs

Inform

- Share information
- Participate in Consumer Protection related activities
- Heighten consumer awareness on drug related health risks
- Coordinate and support targeted efforts of manufacturing in improving their image and promoting Quality Control measures used
- Improve attitude towards Industry

6.4 Main issues were agreed to by most Workshop participants. Recommendations were considered reasonable and provided a benchmark for strategic development. An Industry vision may soon be developed now that the framework is clearly defined.

6.5 Discussions and findings led to narrower, specific however basic issues requiring immediate actions by parties or responsible officials.

Inaccessible Data

6.6 As in most fields, information specific to product types, costs, quality, prices, competition, markets, funding, investments, regulations, etc. are crucial to the development of the Pharmaceutical sector. Such data is not readily available; nor is it consistent and reliable. It is scattered, piecemealed, and outdated.

6.7 The public sector lacks a computerized database that includes information regarding drug registration files, imports, exports, raw material, quality control standards, inspection procedures, results, and measures taken. Such a deficiency limits the capability of the Ministry of Public Health to plan efficient drug policies. The absence of such data leads to the dissemination of biased data and the absence of consumer awareness regarding imported drugs, locally manufactured drugs, and other health related issues.

6.8 Responsibility and accountability of Public officials, manufacturers, traders, physicians, and pharmacists are not well identified. Relationships and roles are not clarified. Therefore, assessment of the efficiency of the system can not be made. The current system does not report whether all parties are performing their job in the right way, whether reliable data and information are being shared, or whether the Orders of both physicians and pharmacists are performing and enforcing their respective codes of professional ethics. The lack of such transparency limits the Public sector's abilities to efficiently plan, strategize, and regulate. Furthermore, it limits Private citizens' ability to keep Public sector officials accountable for results.

6.9 Cooperation and networking among members of the Industry remain insufficient and therefore hinder development of a common industry vision and strategy, and the lack of organized data causes delays in reacting to Industry needs.

6.10 New trends in pharmaceutical production are not examined and new lines of products are not produced. Local production remains defenseless in front of Traders and foreign manufacturers' innovative ways to compete and market their products.

6.11 Consumers do not have access to data to help prevent harmful effects to themselves and provide themselves with quality products at lower prices. This type of information may lead to better quality products, price competition, and lowering the health care bill without compromising quality.

Recommendation: Establishment of a Centralized Database

6.12 The MOPH is required by law to monitor imported and locally produced drugs. It's objective is to constantly oversee Public Health and therefore guard against harm from drugs consumed in the Country. A centralized database is required to make such monitoring possible considering available technological advancements that reduce the cost of such an endeavor and increase efficiency.

6.13 The Lebanese Order of Pharmacists is experienced on issues facing consumers today. They also have access to professionals with the required skills and commitment to the Profession. They can assist in the design of a database that once established can be shared by the Order and the MOPH to contribute to its quality and its maintenance.

6.14 The Lebanese Order of Physicians is constantly updated by professionals representing local and foreign manufacturers. An independent database with information submitted by MOPH and the Lebanese Order of Pharmacists might improve the efficacy of prescription made by doctors and lower the cost to patients.

6.15 Consumers are the main benefactors. MOPH should be easily identifying drugs that must not be circulating in the Country. Medical information related to the drug may be readily available to consumers and protect them from any drug related dangers. Accurate information may also help consumers alter their habits towards healthier behavior.

6.16 Manufacturers may benefit by sharing information that help them identify market needs and characteristics and capitalize on their strengths and improve on their weaknesses. Such data can be used to communicate drug related health risks to consumers and spread Consumer Protection campaigns with approved data by regulating bodies.

6.17 We can site numerous opportunities that a centralized database can provide to this sector specifically, the consumer, and the Lebanese economy in general. Such efforts are currently being made by the Arab Council on Drugs. They are creating a Drug's database in Egypt to capitalize on the opportunity to create a forum for all relevant information.

6.18 Coordination among all concerned parties may result in a successful effort towards a well organized database.

Outdated Essential Drug List

6.19 The Essential Drug List in Lebanon has not been updated since 1987. Due to new drugs that were registered and launched ever since, the current List is no longer referred to nor acceptable.

6.20 Syria and Jordan both have adopted an Essential Drug List that specifically include Syrian and Jordanian manufactured products respectively while excluding imported drugs. Both Government policies tend to favor local products and allow foreign products to target unfulfilled market needs and specific consumer types.

6.21 The Essential Drug List update causes the MOPH to reconsider the quality of many drugs that are currently registered in Lebanon. Eliminating such drugs can be a major step towards improving consumer protection.

6.22 In addition, the MOPH can identify those drugs that are bio-equivalent and available at lower prices than others. Public institutions, Orders and other Private Sector, as well as consumers would greatly benefit from an Essential Drug List that identifies what they may need to consume of quality drugs at lowest available cost.

Recommendation: Updating of the Essential Drug List

6.23 Similar to the competition in the region, the MOPH should update the Essential Drug List. For Lebanon however, the List should include for each therapeutic category one or two products of each sub-category. The choices should be made to include required quality at the lowest usual cost for local and foreign essential products. Public Institutions may use this list for Public Reimbursements plans.

6.24 Considering the open trade policy of Lebanon, all other quality products may remain registered and may be imported or manufactured in Lebanon. Not listing a drug does not automatically exclude the drug from being sold in Lebanon.

Low Consumer Confidence

6.25 The consumer, uncertain of the capacity of the authorities' quality control measures and testing to control the medicine market, finds its refuge in the very well known trademarks. Trust and confidence towards manufactured drugs are not granted and are therefore not always prescribed nor consumed. Further, Lebanon is considered a "brand name" country, and thus confidence in the locally manufactured products, whether drugs or others, is not as high as that in original branded products.

6.26 Most physicians are distrustful of most locally manufactured products due to a perceived deficiency in effective and efficient quality control measures. New products are developed with more reliable and efficient formulas due to technological advancements. Physicians prefer to prescribe new products to maximize safety and results.

6.27 Bio-equivalency tests or similar tests are not carried out where applicable to ensure that manufactured drugs have absorption and utilization characteristics at levels similar to

those of the original brand name. The absence of such tests jeopardizes the credibility of the manufactured drug. As its quality is untested, consumer confidence in the drug remains low.

6.28 Promotion efforts on behalf of local manufacturers are not concentrated on image building but rather on sales and revenues for both local and foreign products. Consumers are not made aware of the quality control procedures and standards followed by manufacturers. They are therefore unable to evaluate the safety, efficacy, and quality of the manufactured products.

Recommendation: Rebuilding Consumer Confidence in Local Products

6.29 It is up to the Industry to promote itself. Consumer public awareness campaigns about quality control measures taken and available are important. Opening up factories to the media to promote the Industry should be considered. Safety issues and quality assurance measures should be discussed.

6.30 It is up to the MOPH and the MET to protect consumers from drug related dangers. But their related limited resources and their outdated mechanisms keep them from achieving their objectives. They end up bearing responsibility for all deficiencies since they are unable to hold others accountable where and when appropriate.

6.31 Orders and other concerned parties can lend a hand to the Public sector and Industry in launching public awareness campaigns. They can provide consumers with information needed to help them monitor pharmacists and the quality of dispensed products. Consumers can also help report findings and make the Public sector's job much easier.

Drug Registration Delays and Inefficiencies

6.32 The DRTC at the MOPH is formed of eight members: the Director General of the Ministry of Public Health (President), the Chief of the Directorate of Pharmacy (Member), the Chief of the Pharmaceutical Inspection Directorate (Member), the chief of Imports and Exports Directorate (Member and Decider), two members representing the Lebanese Order of Physicians, and two members representing the Lebanese Order of Pharmacists (Law # 367, "Pharmacy Act", Part 5, article # 54, dated 8/14/1994).

6.33 These members are expected to fulfill their duties in their permanent jobs as well as the duties assigned to the Committee. Practice proved that such double duty is neither efficient nor effective. Delays caused by the Committee inflict severe damage to Industry development as well as Consumer Protection efforts.

6.34 The Pricing Committee is formed of three members (concerning imported products): the Chief of the Directorate of Pharmacy, the Chief of the Pharmaceutical Inspection Directorate, and the chief of Imports and Exports Directorate. A representative from both the Ministry of Economy and Trade and the Ministry of Industry are to be added in the case of pricing locally manufactured products (Decision No. 1/208, dated 4/3/1983). These members also carry their Committee duties in addition to their permanent duties, DRTC duties, or other applicable duties.

6.35 It is clear that burdened members of the DRTC and the Pricing Committee are unable to fulfill the duties of these Committees. It may in fact be that their membership impacts their performance in the permanent jobs also due to the overload. Delays caused by the Committee may also attribute to the rise of the drug bill.

6.36 The requirements of Economic Reform call for efficient and effective measures that do not hinder Industry development while promoting the best interest of the Public and therefore the Consumer.

Recommendation: Improving Drug Registration

6.37 The needs of the Country for the next few years call for immediate attention to the Quality Control measures needed to protect the Consumer and improve the Quality of Life. The current members are committed to several duties at the same time. In addition, technological advancements require a major update in their qualifications. They are also paid for their efforts as members, and the Committees' activities are budgeted.

6.38 Newly appointed members with higher qualifications and more time to dedicate to the Registration and Pricing Committees may eliminate many of the hurdles facing the Industry and allowing unapproved drugs from entering the market. A specific internal control process may be then designed to fit the new trends in drug registration. The Committees may also benefit from the Essential Drug List update and the suggested centralized database.

Customs

6.39 As most sectors, the Pharmaceutical Industry in Lebanon is suffering from the outdated and inefficient processing at Customs. Delays at Customs impact production schedules and cost the manufacturers possible revenues and profits. It also impacts manufacturers cash flows and cause them to incur additional financing charges.

6.40 Unclear definitions of product classifications cause delays as well as additional custom duties to both manufacturers and traders. Duties on raw material could range from 19% to 24% based on the definitions attributed to the items at Customs.

Recommendation: Streamline Custom Processes

6.41 Several studies have been made regarding customs. Most of them indicate the need for Trade facilitation and process streamlining at Customs. Some of them suggested ways of doing so. Jordan modernized its customs processes as well as many other countries in the Region.

6.42 It is crucial for the development of the Industry and the cost containment of the price of drugs that we modernize the process and beat the traditional customs' image. A trade facilitator and not a police force is required to monitor trade activities without compromising compliance with the security and public interest of the Nation.

6.43 Technological advancements are available to identify products, account for them, value them and compute duties in a timely manner. Such processes should be made available to the Industry and to the Country.

Intellectual Property Rights (IPR)

6.44 Lebanon grants protection to the process not the end product (Paris Convention). The end product is considered legal as long as the process followed in manufacturing such products is retailored. Such a law facilitated the registration of unauthorized copies of internationally patented pharmaceuticals.

6.45 The absence of an IPR law led to the registration of pirate copies of questionable quality and to the refrain of the international research-based companies from various forms of investment, technology, transfer of know-how, training, and other value-added activities.

Recommendation : Pharmaceutical IPR

6.46 While IPR Law can help reduce the number of imported registered drugs, it also impacts some manufacturers currently producing without a license. However, this practice is not apparently prevailing in the Lebanese Industry. It is therefore in the best interest of local manufacturers that IPR Law regarding pharmaceuticals is proposed and passed, as long as it is imposed and enforced on both imported and locally manufactured products.

Prescription drug policy

6.47 The Consumer is able to buy prescription drugs over the counter, a practice which led to misuse and overuse. The lack of implementation of enforcement of a prescription drug policy leads to unmonitored self-medication practices, endangering thus the health of the consumer.

Recommendation: Enforcement of Prescription Drug Policy

6.48 It is crucial to differentiate between OTC drugs and prescription drugs. Enforcement of such policy can only secure the safety of the Consumer and raise the burden of direct responsibility to the level of the Public sector monitoring bodies and to the pharmacists. Proper networking and coordination between the MOPH, the MET, the Lebanese Orders of Physicians and pharmacists can only insure success of this move towards improving the consumer's quality of Life.

Reciprocity in Trade Agreements

6.49 In most Trade Agreements signed between Lebanon and other countries, there is an article concerning reciprocity. This article is to ensure that Lebanon receives the same treatment that it provides to that country.

6.50 Registration of Lebanese drugs in foreign countries faces major difficulties regardless of the reciprocity article in Trade Agreements. Imported drugs can easily gain access to the Lebanese market. Lebanese manufactured products face many trade barriers and lack of

access to export markets. Those export markets give priority to their local production and foreign brand-name products.

6.51 Imported drugs are registered in Lebanon within a maximum period of three months or have access to the market afterwards if the drug was not rejected by the Committee on time. Lebanese drugs take up to two years to be registered in some of the Arab Countries.

Recommendation: Enforcement of Reciprocity in Drug Registration

6.52 For the Trade Agreement to be fair and insure similar treatment, the issue of drug registration needs to be resolved. Trade Agreements are managed by committees who are authorized to review issues resulting from the Agreements. The Reciprocity in Drug Registration should be reviewed and raised to the Committees to identify the best mechanism for each agreement and each country for enforcement.

Limited Quality Control Measures

6.53 The Central Laboratory limited resources renders the Laboratory inadequate to meet all test requests and the proper quality control functions. Technical, human and financial resources have not been upgraded to meet the challenges facing the pharmaceutical sector.

6.54 With three individuals in drug quality control as part of a team of ten people in the Chemistry department, the Laboratory is overloaded. Delays caused by the Laboratory impacts the registration process and therefore the quality of imported and local drugs allowed into the market.

6.55 Due to the limited technical capabilities of the Laboratory, only the physicochemical and microbiological tests are performed. Other tests such as Potentiometric situations, infrared identification, assays by HPLC, assays by GC, disintegration tests, and atomic absorption are not carried out. These tests require special instruments not available at the Laboratory.

6.56 The Inspection Department at the MOPH is equally inadequate. Technical skills and technological advancements are not available to efficiently attend to the required issues in a timely manner. Coordination with appropriate professional Orders is also lacking.

6.57 Inspections of manufacturers, importers, wholesalers, retailers, and dispensaries are not performed on a regular basis. Enforcement of Good Manufacturing Practice in all production facilities and the sale of safe and quality drugs are not assured. The presence of counterfeited and illegal drugs in some of the pharmacies, dispensaries, and NGOs is not controlled. The importance of the pharmacist's presence in the pharmacy, the presence of doctors and pharmacists in public dispensaries and NGOs is not monitored.

6.58 With the absence of inspection and monitoring procedures, legalizing parallel importation poses a threat to public health as some drugs of inferior quality gain access to the market. Such drugs bypass the DRTC and therefore no quality control measures are performed on these products, leading to dumping of drugs of questionable quality.

6.59 The technical expertise and scientific knowledge of the DRTC's members are not up-to-date. They lack reliable and scientific data upon which their decisions are to be based. Registration decision is based on the drugs' scientific reports submitted by importers and manufacturers.

6.60 Most manufacturers could improve on their quality control processes. Weaknesses include (1) insufficiency of highly qualified human resources in generic drug development units, quality control and quality assurance departments, etc.; (2) weak infrastructure of regulatory compliance to GMP regulations; (3) quasi absence of internal and external benchmarking and statistical analyses to monitor and track performances. Due to these weaknesses, Industry image and credibility remains at risk.

6.61 GMP compliance levels are low in some local pharmaceutical product manufacturing plants for several reasons: (1) low investment levels in compliance infrastructure (capital and human investment); (2) current compliance efforts are running at minimum cost requisites; (3) absence of prohibitive sanctions of non-compliance on behalf of authorities (such as interruption of production or consequential non-compliance fines); and in some cases (4) an unfavorable cost to benefit analysis for a given operating level of compliance.

Recommendation: Coordinate Efforts and Use Technology for Quality Control

6.62 As industry and the pharmaceutical sector grows, required Quality Control activities will increase rapidly. Manual processing of data, of test results, documentation, and reporting are no longer adequate to meet required levels of activities.

6.63 New advanced methods using latest technology should be introduced to the inspection department. The required level of skills and education is crucial to the success of the Industry and to Consumer Protection. Individuals must not continue to shy away from technology in the performance of their work. They need however, to balance the level of technology needed with the level of benefit acquired.

6.64 Use of professional resources can be made available through proper coordinated efforts with the Lebanese Order of Physicians and the Lebanese Order of Pharmacists.

6.65 The Centralized database can help them improve on processing data.

6.66 Updating the Essential Drug List can alleviate the burden of monitoring, once low quality products are out of pharmacists' and consumers' hands.

6.67 Management at MOPH will have more time to dedicate to their functions once the workload resulting from the Committees is removed from their list of duties. An update of laws and regulations such GMP rules and IPR should foster a better environment for quality respect.

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