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**THE ROLE OF PHARMACISTS AND PHARMACIES IN THE
PROVISION OF HEALTH CARE
IN SIX NEAR EAST COUNTRIES:**

Literature Review

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INTRODUCTION

This literature review of documents relating to the role of pharmacies, pharmacists and other commercial drug sources in the provision of health care services in the Near East is part of a larger study undertaken by The Futures Group for a health sector assessment by the Near East Technical Office of the Agency for International Development.

The report examines the marketing and distribution of drugs; the nature and cost of pharmacy products and services; the recruitment, training, licensing, supervision and associations of pharmacists; and the role of pharmacies and pharmacists as deliverers of health care in the six Near East countries of Egypt, Tunisia, Jordan, Lebanon, Morocco, and Yemen. The seventh country proposed for study, Oman, is not covered in this report as an extensive literature search, and inquiries to embassies and other organizations proved unsuccessful in gathering any information on the pharmacy sector of this country.

While the absence of documentation on the pharmacy/pharmaceutical situation in Oman is understandable, the author of this report was initially surprised to learn that very little printed information was available on Lebanon, a country which had one of the first pharmacist education programs in the region and was responsible until recently for the training of many Near East pharmacists. It was soon discovered that the lack of information regarding Lebanon is due primarily to the situation of political and economic chaos which has plagued the country since the middle 1970s. The information printed in the report on Lebanon is therefore methodologically different from the other five country reports; it is the result of extensive interviews with expatriate Lebanese who are or until recently were involved in pharmacy/pharmaceutical enterprises in Lebanon.

EGYPT

Pharmacists and Pharmacies

The United Arab Republic of Egypt is not only the most populous Arab country with 40 million persons, but has one of the most sophisticated health systems in the region in terms of numbers of physicians and pharmacists. The number of pharmacists has practically doubled in the last decade from a reported 8,368 in 1973 to 16,070 in 1980.

	<u>1973</u>	<u>1974</u>	<u>1975</u>	<u>1976</u>	<u>1977</u>	<u>1978</u>	<u>1979</u>	<u>1980</u>
Pharmacists	8368	9298	10228	11256	12314	13367	14729	16070
Per 10,000 Population	2.4	2.6	2.7	2.9	3.2	3.4	3.6	3.8
Pharmacist/ Population Ratio	4255	3899	3646	3396	3176	2917	2682	2489
Physicians	23725	25797	28837	31969	35489	**	**	**

Sources: "Basic Statistical Information of Health Services," Ministry of Health, July, 1981; and Sixth Report on the World Health Situation, Part 2, WHO, 1980.

According to Egyptian law, the participation of pharmacists is required at several key junctures in the provision of health care. Pharmacy ownership and management, pharmaceutical manufacturing, factory directorship, and factory laboratory analysis require trained licensed pharmacists. According to the Ministry of Health, fewer than 20 percent of the licensed pharmacists are

** Data not available.

employed by the Ministry; the remainder work in private sector retailing or pharmaceutical manufacturing. Many of those pharmacists employed by the MOH also work in the private sector after hours.

Licensed pharmacies in Egypt numbered 5378 in January 1982. Over one-third of all the pharmacies (1914) are located in the Greater Cairo area, 13 percent are located in the districts surrounding Alexandria, another 30 percent are located in the remaining Lower (Northern) Egypt region, and 20 percent of the pharmacies are located in Upper (Southern) Egypt.

Pharmacies must be owned and managed by a licensed pharmacist and pass an initial inspection and licensing procedure under the Ministry of Health. Pharmacists may not own more than two pharmacies. Egyptian law states that new pharmacies cannot be established within 100 meters of an existing pharmacy and must conform to several safety, sanitary and health regulations including safe water, electricity and sewage systems, locked cabinets for narcotics, and a minimal floor size of 25 square meters. Pharmacies are inspected twice annually by MOH inspectors who will check stock expiration dates and select sample drugs for laboratory testing at the National Organization for Drug Control and Research. Hours of operation are prescribed by law although "night service" pharmacies-open from 6 p.m. until 7 a.m. - are permissible with special MOH licensing. Such "after hours" pharmacies must have a licensed pharmacist present at all times and should maintain a stock of emergency drugs.

Pharmacies are regularly serviced by pharmaceutical distributors whose sales agents function as "order takers" rather than detail persons. Purchase from EGYDRUG, the public sector distribution firm which supplies the majority of pharmaceuticals, must be placed in person by the pharmacist at the regional office for delivery to the pharmacy in one to three weeks.

Pharmacist Education and Training

Six of Egypt's 12 Universities offer degree programs leading to the A.B.S. in Pharmacy: Cairo, Alexandria, Assyut, Tania, Zagazig and Mansoura. The five year programs provide a strong emphasis on chemistry and pharmaceutical compounding, with a very few courses on pharmacy management.

Over 1,300 pharmacists graduate annually from these institutions. Recent legislation mandates that newly graduating pharmacists are required to complete two years of compulsory government service (frequently in rural areas) before being allowed to enter the private sector market. All pharmacists must be licensed by the Ministry of Health. Pharmacists who were not trained in Egypt must pass a MOH examination to be licensed.

Pharmaceutical Production, Importation, and Registration

Approximately 80 percent of all pharmaceuticals consumed in Egypt are produced or at least packaged locally, primarily through the public sector. Over 2000 pharmaceuticals are manufactured in Egypt; 600 are imported. According to a USAID/Cairo report entitled "Industrial Outlook Report Pharmaceuticals-Egypt", the pharmaceutical industry in Egypt is comprised of several public sector companies including an importer of raw materials, an importer of finished products (which also distributes the locally produced pharmaceuticals to pharmacies), a manufacturer of chemicals for drug production, a packaging firm and seven pharmaceutical manufacturers. Additionally, the GOE has undertaken joint ventures with three foreign pharmaceutical manufacturing firms (Pfizer, SwissPharma, and Hoescht). The private sector pharmaceutical industry consists of one American firm, a wholly-owned subsidiary of Squibb, which manufactures pharmaceuticals in Egypt, and 45 importers of finished products. The private importers combined account for less than 10 percent of the imported drug

products, or approximately 1-2 percent of all drug consumption in the country. While private importers, through sales agreements with foreign pharmaceutical firms, continue to expand their product line and distribution channels, it is unlikely that such efforts will be more than moderately successful given the tighter import restrictions recently imposed by the Egyptian government.

The recent import restrictions were designed as a "counter offensive" to the flood of pharmaceuticals, primarily penicillin, tetracycline, and other antibiotics, which entered the market following the liberalization of import requirements in 1976. At that time, an oversupply of these drugs entered the market at prices even below the price-controlled locally manufactured products, resulting not only in the abrupt curtailment of local production but also wastage of between US\$5-10 million worth of pharmaceuticals as production sat in government warehouses.

Additionally, it is the aim of the GOE to strengthen its local manufacturing industry with a view towards not only meeting local consumption needs but also increasing exports of locally produced public sector pharmaceuticals to neighboring African and Arab states. Approximately 50 percent of the public sector pharmaceutical capital equipment was installed before the mid 1960's and thus is quickly becoming outmoded. The GOE Five Year Plan (1978-82) has allocated over US\$50 million for capital improvements and plant renovation. Expansion of several public sector companies is already in progress or has been completed at many sites around Cairo and in Alexandria.

Pharmaceutical production in Egypt is monitored and regulated by the Higher Council for Pharmaceuticals, Chemicals and Medical Equipment. This office is comprised of representatives of the Ministry of Health, the Chairmen of the Boards of the public sector pharmaceutical companies and professors of Egyptian university faculties of medicine. The Higher Council is empowered

with broad regulatory authority, including directing the mix of locally produced and imported pharmaceuticals, determining distribution channels, and setting prices.

The Higher Council for Pharmaceuticals is assisted in its mission by three sub-committees: the Supreme Committee for Importation of Finished Products, the Supreme Committee for Registration, and the Tariffication Committee.

The Supreme Committee for Importation of Finished Products is primarily responsible for determining the type and amount of imported products to be allowed into the country given the capabilities of local production to meet the needs for pharmaceutical products. While the Supreme Committee will not permit the import of products which can be and are being produced through local manufacture, it will permit importation of competing brands of the same foreign drugs to promote competitive pricing of these pharmaceuticals.

The Supreme Committee for Registration, as its name implies, is responsible for determining the efficacy and safety of drugs proposed for sale in the Egyptian market. All imported and locally produced drugs must be tested in GOE laboratories before product registration will be granted and sales to the public may commence. In addition to local laboratory testing, laboratory test results from foreign government health offices, independent laboratories and pharmaceutical firms will be considered. Registration applications must include the proposed public price, samples of the product, container and printed packaging materials, and draft packaging and package leaflet text. Imported products must also have a certificate of authorization for sale in the country of export, public sales prices in all countries where currently marketed, and the import (FOB) price into Egypt. Registration and testing of most pharmaceuticals, particularly those which are locally produced, requires between three and nine months; other preparations, including tranquilizers and imported products,

may require up to five years. Registration may be refused for a number of reasons including the proposed price. Product registrations are valid for a period of 10 years.

Pharmaceutical Prices and Consumption

The Tariffication Committee is responsible for setting prices of imported and locally produced drugs. Imported drug prices are generally set at approximately 186 percent of the FOB price, which includes a 20 percent importer/distributor mark-up and a 10 percent retailer mark-up. The profit margin (mark-ups) allowed on locally produced drugs is generally higher.

Prices are set at the time of product introduction in the market and have only been increased once in the recent past: a 30 percent increase in 1977 which affected all but approximately 300 of the 2200 drugs produced in Egypt. The price increase was effected not only to reduce the government's subsidy of the cost of pharmaceuticals for the public, which was running about LE 40 million annually before the increase, but also to discourage smuggling. It is estimated by the Ministry of Health that up to 20 percent of local production (or LE 30 million of the LE 136 million value of total production) is siphoned off for smuggling into neighboring countries.

Despite the price increase, Dr. Ibrahim Badran, Minister of Health, reports that 85 percent of all drugs are available for under 50 piastres (US\$ 0.70). Additionally, it is estimated that approximately 60 percent of all drugs consumed in Egypt are distributed free through government hospitals, clinics, and public sector firms. Free distribution of pharmaceuticals has encouraged medicine consumption, which is reported to be increasing at a rate of 20-25 percent annually. The majority of pharmaceuticals consumed and the greatest increase in consumption are found in the major urban areas of Cairo and Alexandria.

These two metropolitan areas, accounting for approximately half of the total population, consume approximately 60 percent of all pharmaceuticals, although consumption in the rural areas is also increasing at a near equal pace as health care is further extended into these areas.

The low control prices for drugs as well as the great access to free government distribution outlets has also resulted in a penchant for self- and over-medication.

Advertising/Promotion

Pharmaceutical advertising to the general public is strictly forbidden in Egypt, although promotion and advertising directed to pharmacists, physicians and auxiliary health personnel is permitted. Pharmaceutical manufacturing factories may establish scientific offices or "Scientific Departments" (SD's) for the purpose of promoting medicinal products through special licenses granted by the Ministry of Supply. The director of the SD must hold Egyptian citizenship. Once approved, these promotional offices may distribute literature, detail, and provide product samples to members of the medical profession. Additionally, product advertisements can be placed in pharmaceutical or medical journals.

Association of Pharmacists

The Egyptian Pharmacist Association was established with Law No. 47 on July 14, 1969. All pharmacists - whether currently practicing their profession or not - must be registered with this Association. Expatriate physicians from other Arab states who are licensed to practice in Egypt are also required to be registered with the Association.

MOROCCO

Number of Pharmacists and Pharmacies

The World Health Organization estimated that there were approximately 365 pharmacists in Morocco in 1974. This number increased to 535 in 1978. The 1980 WHO Sixth Report on the World Health Situation reports that 64 of these pharmacists are employed in the public health sector, leaving a majority of pharmacists to operate in the private sector. By 1978, public sector pharmacists had increased to 136. With a population of approximately 19 million, the pharmacist:population ratio in Morocco stands at 1:35,513. This average statistic belies the actual distribution of health services which is heavily weighted in favor of urban inhabitants. For example, according to a 1977 USAID/Morocco paper entitled "Survey of Private Sector (Pharmacies) Sales of Condoms and Oral Contraceptives in Morocco," 219 of the nation's then 437 pharmacies, or 50 percent, were located in the Prefectures of Rabat-Sale and Casablanca. The population in these two prefectures represents about 16 percent of the nation's total.

Additionally, it would be incorrect to assume that all pharmacists are in the profession of dispensing drugs. Dahir No. 1-59-367 of 19 February 1960 (partially amended in 1978) which embodies regulations governing the practice of the profession of the pharmacist, reports that the professional skills of the pharmacist are required at all levels of drug activity. In addition to retail sales of pharmaceuticals, the pharmacist may choose a more strictly managerial career. Specifically, according to Dahir 1-59-367, "any establishment, depot, or warehouse used for the manufacture, storage, or wholesale distribution to retail chemist's shops of products, compounds and preparations -- whether specialties or not -- intended for pharmaceutical use and packaged in medicinal doses by weight to be sold for use in human or veterinary medicine" is required "to be

owned by a pharmacist." The manufacture, compounding, preparation and packaging for sale of pharmaceutical products is to be performed under the direct supervision of a pharmacist.

Licensing of Pharmacists

According to Dahir No. 1-59-367, all practicing pharmacists must be licensed from the Secretary-General of the Government in consultation with and with the approval of the Minister of Public Health. Pharmacists intending to practice in the retail sector must also register, whether they will be taking possession of an operating pharmacy or plan to open a new facility. Pharmacists are not allowed to operate more than one pharmaceutical establishment, must be both sole owner and personal manager of the pharmacy, and must reside in the locality where the business is established.

The pharmacist may only employ the services of trained pharmaceutical dispensers or assistant dispensers in his establishment and are proscribed by law from selling any other items except "medicaments, articles dealing with the healing arts and hygiene, and dietetic, hygiene, and chemical products."

Dahir 1-59-367 of Moroccan law dictates that the sale of any "medicine, drug, substance, compound or preparation to which medicinal, curative or preventive properties are attributed" is restricted to sale by licensed pharmacists only. However, under certain conditions, practicing physicians may also sell pharmaceuticals. The sale of medicines by a physician is permitted in localities where no pharmacy exists within a radius of 25 kilometers. In such cases, the physician must receive prior authorization from the Secretary-General of the Government after consultation with the Minister of Public Health, the National Pharmacy Council, and the Medical Council.

Under such conditions, the physician may dispense medicaments but must submit to strictly defined legal boundaries. For example, the physician may stock such necessary drugs in his private office facilities, but this shall not be construed to be a dispensing facility for public sales. He may not supply pharmaceuticals except as personally prescribed for treatment of the patient, nor can he employ anyone to manage the depot of these medicines. Finally, the authorization to sell drugs shall be withdrawn in the event that a licensed pharmacist opens an establishment in the locality or within 25 kilometers of the locality. It is worth noting that this situation is the only exception to the law which would legally allow a person to, in effect, practice both pharmacology and medicine at the same time. Moroccan law dictates that a person may not practice in more than one medical or health auxiliary field concurrently even if he is qualified and licensed in more than one field. In practice, of course, the pharmacist does play a role in diagnosis, administration of injections, and the provision of medical advice.

According to a May 1980 Pharmacy International article, "International Survey into Emergency Pharmaceutical Services," "after hour" services are arranged for on a local basis, and the type of service differs in different regions of the country. However, after hour services are restricted to the emergency supply of medicines as prescribed by a physician.

Pharmacist Training

Dahir No. 2-73-528 of 23 November 1973 provides for the establishment of training schools for members of the allied health professions under the Ministry of Public Health. Three levels of diplomas are awarded from these training schools. Persons who have completed three years of secondary education or are officials of the Ministry of Public Health with at least four years of public

service may apply to study in a two-year program leading to the Diploma of Licensed Health Auxiliary (DLHA). Persons who have passed the baccalaureat after completing seven years of secondary education or its equivalent and LHA's with three years of experience may apply for two-year studies leading to the State Diploma of Health Auxiliary (SDHA) in any number of technical health professions including "pharmaceutical dispenser." Pharmacists holding a SDHA desiring to (1) own or manage establishments which manufacture, store or wholesale pharmaceuticals, or (2) serve as pharmaceutical analysts, must undertake a further two years of training leading to the State Diploma of Specialized Health Auxiliary (SDSHA) in the field of Pharmacology. Only holders of the SDHA may compete for entrance into the training school for the SDSHA. According to the WHO Sixth Report on the World Health Situation, in 1977 the Ministry of Public Health managed 26 schools providing the LHA, 12 technicians' training schools leading the SDHA, and one school for senior personnel training in addition to the two university medical faculties at Rabat and Casablanca.

Certificates or diplomas from foreign institutions which entitle the bearer to practice pharmacy are honored in Morocco subject to verification in the process of licensing.

Pharmacist Association

Moroccan Law No. 1-75-453 of 17 December 1976 is the authorizing legislation establishing the Association of Pharmacists. The Association is comprised of all pharmacists authorized to undertake private practice including: "dispensing pharmacists; pharmacists owning or managing establishments in which products, compounds, or preparations for use in human or veterinary medicine are manufactured, held or sold by wholesale to retail dispensaries; or

acting as technical or commercial directors of such establishments or as pharmacy assistants; or as pharmaceutical analysts "pharmaciens biologistes."

The functions of the Association include "(1) encouraging and coordinating the participation of its members in the development of the pharmaceutical sciences; (2) ensuring that its members comply with the legislation governing their profession and fulfill their professional and ethical duties; (3) safeguarding the traditions of honor and integrity of the profession; (4) expressing its views on draft legislation concerning pharmacy and the pharmaceutical profession, where consulted by the Government."

Section 4 of the legislation provides for the establishment of two regional councils of dispensing pharmacists (for North and South Morocco respectively), a Council of Manufacturing and Distributing Pharmacists, a Council of Pharmaceutical Analysts, and a National Council of the Association.

Sale of Pharmaceuticals

All drugs are classified by the Ministry of Health in one of three categories: classes A, B, or C. Class A drugs, which include toxics and barbiturates, may not be sold without prescription. Class B drugs, including "dangerous" drugs such as sulfas, corticoids, antibiotics, etc., are also restricted to sale by prescription only and are not repeatable. In practice the prescription requirements are not strictly enforced, however. Class C drugs consist primarily of proprietary pharmaceuticals such as analgesics, vitamins, cough/cold remedies, etc., and may be sold without prescription. Although both prescription and non-prescription drugs are by law restricted to sale in pharmacies, in practice simple proprietary medicines such as aspirins are also available from neighborhood stores.

According to IMS World Publications, total sales of pharmaceuticals through all outlets in 1978 was estimated to be US\$106 million. The following table provides IMS estimates of sales since 1976:

Total Pharmaceutical Sales Through All Outlets (millions)

	<u>Dirhams</u>	<u>U.S. Dollars</u>
1976	373	84
1977	392	89
1978	426	106
1979	454	113

Source: IMS

Private retail pharmacies accounted for approximately 80 percent of total sales, or US\$85 million. The remainder can be attributed to distribution through hospital, clinic, and other government health service institutions. Per capita consumption of pharmaceuticals equalled nearly US\$6 in 1978, although much of this cost was assumed by the government, which reimburses consumers for drug expenditures according to the level of income through its program of universal medical insurance (Caisse Nationale de Securite Nationale). Private insurance policies are also available through a number of companies. Pharmaceutical prices are controlled by the Central Department of Pharmacy in the Ministry of Health. The retail price of a pharmaceutical generally includes 10 percent wholesale and 30 percent retail margins, although the retailer's margin for dietetic products is generally reduced by 10 percent.

According to IMS statistics, ten product groups accounted for over 40 percent of the total 1978 retail pharmaceutical market in Morocco. Systemic antibiotics, including tetracyclines, ampicillins and penicillins accounted for 21

percent of the total market, or US\$6 million. (Nestle and its subsidiary Guigoz accounted for 64 percent of the infant foods market.) Six percent of the total market, or US\$5 million in sales, was attributed to analgesics, cough and cold products. Approximately US\$4 million was spent on antidiarrheals and vitamins for 5 percent of the market; and 4 percent, or US\$3 million, was expended on sex hormones, tonics, antirheumatics, antacids, and ulcer treatments.

Advertising/Promotion

Section 18 of Decree No. 2-76-266 of 6 May, 1977 declares that pharmaceutical specialties may only be advertised subject to an advertising license which must be issued by the Central Department of Pharmacy of the Ministry of Public Health. Copies of advertising texts and documentation must be submitted in advance to the Central Department of Pharmacy. Section 21 prohibits the use of articles intended as gifts or bonuses for advertising purposes.

Under the provisions of Section 22, specialized medicaments prepared in pharmacies are not permitted to be advertised in any way.

Section 24 of the law prohibits dispensing pharmacists, distributing wholesalers, stockists, and manufacturers of pharmaceutical products from offering or promising bonus articles, direct or indirect material benefit, etc., to physicians, veterinarians, dentists, other health professionals and auxiliaries, or others authorized to prescribe or administer medicaments. Gifts intended for research or education purposes are permissible, but must be approved by the Ministry of Public Health in advance of the giving. Clinical laboratories are prohibited from carrying out advertising other than the dissemination of scientific information to physicians or pharmacists.

Medical samples may be provided to pharmacists subject to the provisions regarding importation, trade, and possession of poisons, and provided such

samples are: (1) expressly solicited by the recipient; (2) clearly and indelibly marked with the words "Free medical sample, not for sale;" and (3) licensed or being licensed in Morocco.

Production, Registration, and Drug Distribution

It is estimated that approximately 70 percent of the demand for pharmaceuticals is met through local production. Nearly 95 percent of domestic production of medicines is manufactured under license to the foreign originators.

Moroccan law No. 1-76-432 of 15 February, 1977 (which amends specific sections of 1-59-367 regarding control of pharmaceutical products) states that "all imported or domestically manufactured pharmaceutical specialties must be licensed in advance by the Minister of Public Health through its Central Department of Pharmacy. Registration procedures are very clearly elucidated in the registration law.

Section I states that applications must include: (1) the name, address, etc., of the manufacturer or importer; (2) the number and date of the license of practice issued to the manufacturing or importing pharmacist; (3) the "special name" of the pharmaceutical, (the nonproprietary name as listed in the pharmacopoeia currently in force and the WHO recommended international non-proprietary name must be used in addition to the brand name); (4) the pharmaceutical form and the contents or number of therapeutic units in the various presentations; (5) the formula of the specialty and its composition including excipients, coloring matters, etc; (6) details of harmful constituents; (7) modes of administration, therapeutic indications, precautions, and normal dosages; (8) contraindications and side effects; (9) the presumed period of stability, including the expiration date, coded and uncoded as prescribed by the Minister of Public Health; (10) whether the application is for the purpose of

importation or local manufacture; (11) details of the places of manufacture, inspection, packaging and distribution; (12) the conditions of the contract with the manufacturer, where the applicant is not the manufacturer, and in particular guarantees of compliance of the medicament; (13) in the case of a specialty already approved in a foreign country, the certificate from the competent authority in that country attesting that the manufacturer is authorized to produce pharmaceutical specialties in that country, and that the specialty proposed is authorized and used in that country; (14) proposed prices; (15) the nature or composition of the container and the text of the proposed label and package insert; and (16) five samples. Brand names must be chosen so as to avoid confusion with other medicaments and must not be misleading as to the quality or properties of the specialty.

Section 3 of the law states that "where the application is for a product whose preparations details are contained in the pharmacopoeia currently in force in Morocco, the manufacturer is not required to carry out pharmacological or toxicological tests or clinical tests."

This application must be supported with a description of the method and conditions of manufacture and techniques used for the control of raw materials and the finished product; and reports on clinical trials and physio-chemical, toxicological, and biological tests. Applications will be reviewed by the Technical Commission of the Ministry of Health, which may recommend that applications be rejected if any of the above information is found to be untrue. An application may also be rejected on the basis of proposed price of the product. Licenses are valid for a period of five years and may be revoked if the product is later found to be ineffective, results in unnamed side effects, or if the licensee fails to market the product within a period of six months following the issuance of the

license. The license may be renewed every five years upon application by the manufacturer or importer.

According to the legal provisions, the registration process should require no more than 90 days, with a possible 60 day extension, however, in practice it is reported that registration may take from six months to one year.

Local manufacture of pharmaceuticals requires a separate manufacturing license. IMS reports that while there are no "Good Manufacturing Practice" requirements, the Ministry of Health is required to conduct periodic plant inspections.

Importers, agents, or distributors usually purchase drugs directly from the manufacturer and sell them to a wholesaler for distribution to pharmacies. Private hospitals generally purchase directly from the agent or distributor. However, pharmacies themselves may serve as "quasi-wholesalers" of drugs as when, according to local custom, neighborhood stores purchase simple proprietaries such as aspirin from pharmacies for resale.

Law No. 1-75-286 of 17 December 1976 establishes the National Office of Pharmaceutical Products and Medical Equipment which is empowered to acquire a holding in all companies engaging in the manufacture, import and export, packaging, and sale of pharmaceutical products and medical equipment.

Pharmaceutical Inspections

In addition to Ministry inspections of pharmaceutical manufacturing plants, the law also provides for inspections of pharmacies, herbalists' shops, pharmaceutical depots and industrial/commercial establishments engaged in the manufacture, packing, holding, warehousing, or wholesale sale of pharmaceutical products.

Inspectors must hold diploma in pharmacy and are appointed by the Ministry of Health. In certain instances, private practice Moroccan pharmacists may be required to perform inspections, although such appointed pharmacists may not inspect establishments within the prefecture in which they perform their profession.

Pharmaceutical inspectors are responsible for enquiring into, detecting, and reporting contraventions of the law and regulations of the practice of pharmacy relating to poisons, professional ethics, and rules, and may be instructed by the Minister of Public Health to initiate special investigations.

TUNISIA

Pharmacists: Number and Training

According to a July 1978 article "Pharmacy in Tunisia", published in the Bulletin d'Information of the Federation Internationale Pharmaceutique, the number of pharmacists in Tunisia increased threefold in less than a decade, from 94 in 1968 to 387 in 1977. Approximately 100 of these 387 pharmacists are agents of the public health system who work at hospital dispensaries and laboratories. The remainder are registered in the retail sector. The ratio of pharmacists per inhabitant in 1977 was 1:15,697. The number of pharmacists "in the pipeline" suggests that the pool of trained pharmacists may increase another 300 percent in the coming decade. Specifically, the author of the article, who incidentally was then President of the Conseil de l'Ordre des Pharmaciens, reported that there were nearly 1000 pharmacy students in France, the traditional training site for pharmacists, and an additional 630 students enrolled in the recently established Faculty of Pharmacy in Monastir, Tunisia. The first graduating class at Monastir was in June 1979.

Training of pharmacists for retail ("dispensary") positions requires five years of study. Hospital pharmacists require an additional four-year residency. Finally, pharmacy students may continue their studies by preparing a "Diplome d'Etude Approfondies", or doctorate, leading to eligibility for an industrial or university career.

The Practice of the Pharmaceutical Profession and Operation of Pharmacies

Law No. 73-55 of 3 August 1973 is the legal code regarding the profession of pharmacists and the operation of pharmacies. "Pharmaceutical undertakings," are defined under the law as (a) the Central Pharmacy of Tunisia; (b) retail dispensaries and pharmaceutical agencies; (c) wholesale establishments; (d)

laboratories manufacturing pharmaceutical products; and (e) laboratories performing biological analyses, directed by pharmacists. To operate any of these pharmaceutical undertakings requires an operating license and specialized training for the specific activity above. To gain a license, the pharmacist must hold at least five years Tunisian nationality, have a pharmaceutical diploma issued by the State or awarded by a foreign university approved by the Tunisian government, be registered with l'Ordre de Pharmaciens, (the Association of Pharmacists), and have completed military obligations.

A pharmacist holding an operating license for retail dispensaries may not own more than one dispensary, nor may he/she be involved in any other commercial activity by law unless granted exemption by the Minister of Public Health. For example, a dispensing (retail) pharmacist may be authorized to: (1) work part time in hospital establishments, research or teaching departments, or pharmaceutical agencies; or (2) operate a clinical laboratory in localities where none otherwise exists (although the pharmacist will need to close the facility in the event a pharmacist licensed for laboratory work is authorized to establish himself there).

Pharmacists may enter into partnerships to open a pharmacy, but the partnership may own only a single dispensary. According to the law, the pharmacist is held responsible for managing the pharmacy and must practice his profession personally, e.g., medicaments must, under all circumstances, be prepared or supplied by the pharmacist or under the supervision of the pharmacist. According to the Order of 27 July 1974 of the Minister of Public Health, pharmacists may also administer injections on medical prescription, but only on the premises of the retail establishment.

According to a May 1980 Pharmacy International article "International Survey into Emergency Pharmaceutical Services," "after hours" services are

available through any of three means: public health hospital dispensaries, a late-evening pharmacy service wherein one pharmacy in a district remains open late on a rotating schedule, and finally through a "pharmacist on call" arrangement.

Pharmacy Distribution, Medicaments Supply

According to the Bulletin d'Information article, "Pharmacy in Tunisia," Tunisian law stipulates that no more than one pharmacy per 5000 inhabitants shall be established in a given area. A distance of 200 meters must be maintained between pharmacies, and minimum pharmacy size is 50 square meters. Tunisian law further requires that a pharmacy must stay in business for at least two years, beginning on the date of purchase or opening, before it can be sold or closed.

Pharmacies are concentrated in the larger urban areas. For example, by the late 1970s, there were approximately 75 operating pharmacies in Tunis (population 550,000) and another 20 in Sfax (population 180,000). In many locations where no private pharmacy exists (primarily rural areas), the government will establish "pharmaceutical agencies" which may sell patent medicines or, as they are legally referred to, "pharmaceutical specialities." By 1978, 83 such pharmaceutical distribution points were in operation. Pharmaceutical agencies are not allowed to prepare preparations, to mix chemicals or galencial products ("specialized dispensary medicaments"), nor to stock narcotics. Such agencies are designed to provide a provisional solution to the lack of pharmaceutical dispensaries only and are staffed by government pharmacist technicians. A 1976 Bulletin d'Information article on "Pharmacy in Tunisia" reports that "as soon as these agencies become profitable, they are taken over by qualified pharmacists." During the Fourth Plan (1972-1976), WHO reports that 34 pharmaceutical agencies were sold to young pharmacists.

The distribution and supply of medicaments begins at the Pharmacie Centrale de Tunisie (PCT) which is the sole authorized organization for importation of drugs into Tunisia. Approximately 80 percent of the 3500 patent medicines used in Tunisia are imported, primarily from France.

The PCT is responsible for manufacturing nearly all of the remaining 20 percent, employing in the process approximately 25 percent of all government (public health) pharmacists. PCT manufactured pharmaceuticals represent about 15 percent of consumption through the private sector dispensaries and 55 percent of consumption in the hospital sector.

National pharmaceutical production accounts for less than 15 percent of total drug sales, however, primarily due to the price freeze on drugs since 1968. The WHO report suggests that with the relative stagnation in hospital consumption of drugs in recent years, the PCT is concentrating its production activities on better coverage of national needs in the private sector, broadening its range of current products, and manufacturing more drugs under license.

National drug consumption in Tunisia came to almost 15 million dinars (US\$37 million) in 1975. A consumer expenditure survey the same year showed that average annual per capita drug expenditure amounted to 2.205 dinars (US \$5.40) compared with 0.539 dinars (US\$1.30) in 1966. While national production accounted for less than 15 percent of drug sales in terms of value, WHO reports that drug imports rose by 15 percent in 1973, 17 percent in 1974 and 20 percent in 1975. The WHO report suggests that the increase in drug consumption is attributable to four trends in Tunisia; namely, the rise in national income, the increase in number of mutual benefit societies and group insurances, the opening of new medical practices in the cities, and the increase in self-medication.

Distribution of pharmaceuticals is conducted by the PCT directly (whose original purpose for creation was the supply of pharmaceuticals to hospitals) and

seven wholesalers. Four of these wholesalers are pharmacist-cooperatives, i.e., private sector. The three remaining wholesale organizations are subsidiaries of the PCT. According to the 1978 "Pharmacy in Tunisia" report, the cooperatives and the public sector each distribute 50 percent of the pharmaceuticals.

Product Advertising and Sampling

According to Law No. 73-55 Part I, "Medical and pharmaceutical advertising," prior authorization of the Minister of Public Health is required for advertising medicaments, defined under the law to be "any substance or compound presented as having curative or prophylactic properties with human or animal diseases, and any product which may be administered to persons or animals with a view to establishing a medical diagnosis or restoring, correcting, or modifying their organic functions." Legal determinations regarding advertising for dispensaries or the store windows of pharmacies and in places designed to be visible from the outside are somewhat ambiguous, stating only that such advertising may not be carried out by "methods or procedures contrary to the dignity of the pharmaceutical profession."

Under the law, medical samples may not be supplied to pharmacists unless the recipient has specifically requested them in writing, and unless legal criteria regarding prescribing and use of the medicaments are fulfilled. Additionally, it is prohibited for pharmaceutical manufacturing laboratories, wholesale establishments, and dispensing pharmacists to provide physicians, allied health personnel, midwives, or others entitled to prescribe or apply medicaments with any rebates, any articles or products, or any direct or indirect material benefits.

Pharmacy Inspection

As provided for in Law No. 61-51 of 31 May 1961, pharmacist-inspectors of the Secretariat for Public Health and Social Affairs are to carry out inspections of pharmacies and pharmaceutical undertakings, for the purpose of ensuring that pharmacists are observing the legal codes for pharmacies and pharmaceutical undertakings; in particular, that stocks are properly stored, and prescription registers are up to date. The law does not stipulate the timing or regularity of such inspections.

Regulatory/Professional Organizations Involved in Pharmacy Operations

Secretariat for Public Health and Social Affairs

The major government agency with regulatory authority over pharmacies and pharmaceutical undertakings is the Secretariat for Public Health and Social Affairs, particularly the Minister of Public Health under the Secretariat.

Specifically, the MPH has the following responsibilities:

- o Directs the Pharmacie Centrale de Tunisie (see below).
- o Sets educational requirements for pharmacists and approves for certification foreign university degree programs in pharmacy.
- o Grants licenses for pharmacists, in consultation with l'Order de Pharmaciens (see below).
- o May provide exemptions from the "single activity" restrictions of pharmacists.
- o Authorizes and establishes "pharmaceutical agencies" where no retail pharmacy or dispensary exists.
- o Approves the opening of all new pharmacies, in consultation with l'Ordre des Pharmaciens.
- o Directs pharmacy inspections
- o Approves all advertising for medicaments.

Central Pharmacy of Tunisia

The Pharmacie Centrale de Tunisie (PCT), as noted above, is under the supervision of the Secretariat of Public Health and Social Affairs. In addition to its monopoly on importing all foreign pharmaceutical specialties, manufacturing locally produced pharmaceuticals, and conducting 50 percent of pharmaceutical distribution, the PCT according to Law No. 51-2 of Dec. 16, 1961 has the following additional responsibilities:

- o Stocking all medicaments, pharmaceutical products, dressings, instruments, accessories and other supplies for use in Tunisia and for other countries where sanitary agreements have been made.
- o Packaging all medicaments, whether specialties or otherwise, and all other products and supplies.
- o Directing the activities of rural pharmaceutical agencies as authorized by the Minister of Public Health.

Higher Council of Public Health

As outlined in Decree No. 69-436 of 13 December 1969, the Higher Council of Public Health is responsible for giving technical advice on all health matters referred to it by the Ministry of Public Health. The Council is composed of a chairman (elected for a two year term by the nine permanent members of the Council) and permanent representatives from the Council of the Association of Physicians, the Council of the Faculty of Medicine, the Council of the Association of Pharmacists, the Council of the Association of Dentists, and non-permanent members. The advisory areas of the council are:

- o The practice of medical, dental, pharmaceutical, and paramedical professions and careers.
- o Applied medical research scientific research.
- o Training of senior personnel.

The Order of Pharmacists

L'Ordre des Pharmaciens is the official Pharmacist Association of Tunisia. By law, all pharmacists are required to belong to the association. The body is governed by a Code of Medical Ethics and is a participating member of the Federation Internationale Pharmaceutique.

The organization is managed by an elected representative body, the Conseil de l'Ordre des Pharmaciens de Tunisie, which is composed of nine members including at least one dispensary pharmacist, one hospital pharmacist and one wholesale or industrial pharmacist. The Council works directly with the Minister of Public Health in approving licenses for pharmacists and approving creation of new pharmacies.

LEBANON

The role of the pharmacist in the provision of health care services in Lebanon is similar to that played in other Middle Eastern countries with two major distinctions. First, while the government legally plays a part in the registration of pharmaceuticals, the licensing of pharmacists, and the approval and inspection of pharmacies, it plays a much less active role in the production and dispensation of drugs than any other country in this study. This is both a tribute to and characteristic of the historical enterprising nature of this traditional trading nation.

The second major distinction which sets Lebanon apart from the other countries in this study is the seeming paralysis of government activities in Lebanon today due to the present political circumstances in the Middle East. This became particularly evident during efforts to gather information on pharmacists for this country profile. Even the World Health Organization has been unable to continue its reporting on Lebanon due to the unavailability of data from the country in the past several years. The information gathered and presented in this profile, therefore, is of a strictly qualitative nature, acquired through conversations with persons knowledgeable about the Lebanese pharmacy and pharmaceutical market by virtue of current or former Lebanese citizenship and professional interests.

The picture which emerged from these discussions and as reported in this country profile is one of a strict and formal legal structure developed over the years alongside the practical application of this industry as it is played out in the present political milieu with very limited government interference or involvement.

Number of Pharmacists and Pharmacies

A 1979 estimate of the number of pharmacists was approximately 1000, however it is impossible to estimate the number working in the private versus the public sectors and the number working in Lebanon versus expatriates abroad.

Pharmacists are actively required in a number of pursuits including pharmacy ownership, pharmaceutical manufacturing, and importation. In this latter effort, pharmacists are used most often as detailers for large pharmaceutical houses, although by law both producing and importing companies must be owned and managed by licensed Lebanese pharmacists.

Although exact figures are unavailable, it is estimated that approximately 40 percent of the country's pharmacies are located in Beirut, a city which accounts for an equal percentage of the 3.1 million total population. The licensing of new pharmacies is the responsibility of the Ministry of Public Health. In addition to ownership requirements, by law pharmacies may not be located within 200 meters of each other. This latter requirement has effectively prevented the legal opening of new pharmacies in Beirut, although during recent years of civil strife in Lebanon it is reported that a number of illegal (i.e., non-licensed) pharmacies have opened. While some may be closed down in MPH pharmacy inspections, inspections are understandably occurring at less frequent intervals than in the past. A Lebanese pharmacist who owned a pharmacy in Beirut from 1967 to 1979 reported that initially his pharmacy was inspected twice annually by the MPH. It was not visited by an inspector once after 1975.

According to the law, pharmacies must be owned and personally managed by licensed pharmacists, although they may be supplementarily staffed by pharmacy dispensers and non-pharmacist sales agents as well. Pharmacy sales are limited to health and hygiene products only. A pharmacist may not by law

own more than one pharmacy nor be involved in any other pharmaceutical undertaking.

As in many other Middle East countries, the pharmacist is very often the first stop for diagnosis of illness, particularly by the lower economic classes. Although pharmacists are not legally permitted to do so, it is customary for pharmacists to perform diagnoses and prescribe remedies. While most drugs are bound by prescription requirements, particularly habit-forming preparations, drugs which by law are only available on prescription are, in practice, widely available without the required prescription. Oral contraceptives, which technically are still illegal in Lebanon, and even amphetamines and barbituates, are freely available without prescriptions today. Retail pharmacists in Lebanon still compound certain medicaments on their premises, although this is generally limited to topically applied and similar simple compounds. Most pharmaceutical preparations are pre-packaged or at least pre-compounded.

Pharmaceutical Production, Registration, and Importation

Domestic pharmaceutical production is undertaken solely through the private sector in Lebanon. There are between 5 and 10 pharmaceutical manufacturing plants in Lebanon although the exact figure is unavailable as plants may open or close frequently due to the current situation. Three of the companies - Libanpharm, Hyka, and Medico - are private ventures wholly owned by Lebanese pharmacists. While some foreign-owned pharmaceutical manufacturing enterprises have withdrawn from Lebanon due to the war, it is reported that Abbott, Warner-Lambert, and Merck, Sharpe, and Dome are still operating in some capacity there. Additionally, a Lebanese company known as Seirlabs packages bulk pharmaceuticals.

Nearly all of the pharmaceuticals listed in the Lebanese pharmacopeia are produced or are capable of being produced in some quantity in Lebanon, excluding some of the more sophisticated steroid pharmaceuticals.

Locally produced manufacturing is also exported to other Middle East countries including Saudi Arabia and Jordan. Lebanon at one time exported its pharmaceuticals to Syria and Iraq but does so no longer. Additionally, exportation continues to limited African countries, primarily Liberia.

Local manufacture consists of both production from imported raw materials and bulk packaging. Manufacturing is regulated by the Ministry of Public Health and is consonant with World Health Organization Good Manufacturing Practices. Local production, whether Lebanese or foreign-owned, accounts for only approximately 10 to 20 percent of the pharmaceutical consumption in Lebanon. The remaining 80 to 90 percent is provided through imports. Most antibiotics and all oral contraceptives are imported from Eastern and Western Europe and the United States, although antibiotics are also imported in bulk and packaged in Lebanon. There are at least 25 major and dozens of minor importing companies in Lebanon today, representing all of the major international pharmaceutical houses.

All pharmaceuticals, whether locally produced or imported must by law be registered with the MPH for sale in Lebanon. Registration applications conform to the WHO standard regulations requiring laboratory testing, certificates of sale in the country of origin for imported products, proposed price, etc. A government testing laboratory opened in 1974 has reportedly been closed down.

The pharmaceutical registration process, which formerly required 6 to 12 months to complete has also been undermined by the political situation. One Middle East pharmaceutical expert reported that "today you lodge your registration papers with the government and if you don't hear any answer in three

months, you start selling. Of course theoretically your product could be recalled at some point, but this never happens. The pharmaceutical industry is running itself with minimal government involvement."

It was also suggested by several information sources that a significant amount of pharmaceuticals are being smuggled into Lebanon. The smuggling, according to these sources, is said to be coming primarily from Syrian government pharmaceutical manufacturing facilities. Government produced drugs in Syria are price controlled to ensure low cost to the consumer and thus can provide a lucrative business to smugglers. (It was even suggested that the Syrian Peacekeeping Forces in Lebanon provided a major source of entry of pharmaceuticals into Lebanon although, of course, this cannot be verified.) It is assumed that the black market pharmaceutical trade contributes heavily to the alarming increase in non-licensed pharmacies in Lebanon.

Distribution

It is estimated that approximately 25 percent of all drugs consumed in Lebanon are dispensed free of charge through a system of health clinics. In addition to government operated health clinics; private voluntary organizations, political parties, and religious groups also maintain free health clinics in Lebanon.

Distribution through the retail sector is accomplished by private pharmaceutical distribution companies. Before the war in Lebanon, there were approximately 800 wholesale distributors, although for a number of reasons the number has significantly decreased in recent years. In 1974 the MPH, concerned about the profits on drug sales, initiated passage of Order No. 324/1 which instituted price controls for pharmaceuticals including profit margins of 5-7 percent for wholesalers and 23.5 percent for retailers. The law had the effect of

reducing the number of wholesalers by approximately 50 percent, some of whom later re-emerged as drug importers. According to the sources contacted for this profile, the price controls are summarily ignored in the pharmaceutical market today.

Advertising

There are no restrictions on advertising in Lebanon although very little mass media is used, except for limited OTC products. Medical journals are major sources of pharmaceutical advertising, and it is common for pharmacists to work in promotional offices of the major drug importers. Most of the promotion and sampling are targeted towards physicians, although there are no regulations against detailing pharmacists.

Health Insurance

Government law dictates a reimbursement of pharmaceutical costs up to 70 percent for employees through the Caisse Nationale Securite Sociale. This insurance is only available to regular employees, whether government or private sector.

Pharmacist Training

The American University of Beirut was one of the first institutions in the Middle East to offer special training for pharmacists. The five year program focused heavily on drug compounding, although it was common for students to work at retail outlets over holidays to gain practical management and sales experience. AUB graduated approximately 40 students per year, 50 percent of whom were Lebanese nationals. The Faculty of Pharmacy was dissolved in 1978, however, for financial reasons. Pharmacists training is still offered in a private

institution of higher education operated by French Jesuits in Beirut. Today a number of Lebanese pharmacists practice their profession throughout the Middle East, primarily in the Arab Gulf States.

To qualify for a license to practice pharmacy in Lebanon, the candidate must have completed studies in Lebanon or at another recognized program with equivalent status, must hold Lebanese citizenship, and must pass an examination offered through the Ministry of Public Health. Additionally, it is required that all pharmacists be members of the Pharmacist Association of Lebanon.

JORDAN

Pharmacists and Pharmacies

Of all the countries under examination in this literature review, Jordan is in the unique position of facing a potential overabundance of pharmacists and pharmacies.

The number of pharmacists has steadily increased since the first pharmacy laws were incorporated in Jordan in 1927, just six years following the establishment of the Emirate of Trans-Jordan. According to a 1977 World Health Organization report by W. Hewitt, by 1977 there were a total of 910 Jordanian pharmacists: 67 of whom served in the government public health sector, 283 of whom were employed in the private sector, and 560 of whom were working overseas and in other surrounding Arab countries. By 1980 the number of pharmacists had increased to 1,042, as reported by Amin Shocair, former President of the Jordanian Pharmacy Association in an article, "Pharmacy in Jordan," for the Bulletin of the Federation Internationale Pharmaceutique. Assuming a population of 2.4 million in 1977 and 350 in-country pharmacists, Jordan had one pharmacist per 7,300 persons. It was estimated that in 1980 the ratio has been further reduced to 1:5,500. WHO estimates that 100 new pharmacists are licensed each year. Furthermore the Hewitt WHO report states that if all licensed Jordanian pharmacists were to return to Jordan, the pharmacist/population ratio would be less than 1:2,700, as compared to 1:2,000 in Western Europe. With an estimated 1,450 physicians, Jordan's pharmacist/physician ratio is 1:4.9.

Additionally, Jordan has trained approximately 600 assistant pharmacists, of whom 440 are resident in Jordan.

Pharmacists in Jordan may play any of several roles in the provision of health care. All private sector pharmacies (retail outlets), drug stores (whole-

sale outlets), and the domestic pharmaceutical industries must be owned and managed by pharmacists. In addition, Jordanian law requires that all government hospitals and private hospitals with twenty beds or more employ at least one pharmacist. Pharmacists are also employed in other services of the Ministry of Health, e.g., pharmaceutical licensing, and pharmacy inspections.

According to the Hewitt WHO report, there were 225 pharmacies in 1977. Of the 225 retail pharmaceutical outlets, 106 were located in Amman (population: 600,000). By 1979, the total number of pharmacies had increased to 225, 125 of which were located in Amman, 36 in Zerka, 27 in Irbid, and the remainder in smaller towns and villages. At the 1979 distribution, the ratio of pharmacies to population was 1:4,800 in Amman and 1:13,850 for the rest of the country. Even at these levels the number of pharmacies, particularly in Amman, is considered sufficient to meet the needs of the Jordanian population. Indeed, the pharmacy licensing procedures of the Ministry of Health are viewed by many as a means of limiting the number of new pharmacy openings. In each city there is a waiting list of pharmacists wishing to establish new pharmacies. The Syndicate of Pharmacists, at the request of the Ministry of Health's Pharmacy and Supply Department, annually proposes the number of additional pharmacies needed in various areas of the country. The Pharmacy and Supply Department evaluates the Syndicate's proposal, then forwards its own recommendations to the Minister.

Pharmaceutical Sales

Most pharmaceuticals sold in pharmacies require prescriptions, with the exception of a list of 25 OTC preparations and other household medicines. The government's list of 25 products which do not require prescriptions includes analgesics, cough syrups, anti-diarrhoeals, as well as such products as penicillin and semi-synthetic penicillins, antibiotic ointments, and sulphadiazine. Total

consumption of drugs in 1977 equalled US\$32.5 million, with private sales accounting for 80 percent, or US\$26 million. The remaining US\$6.5 million was assumed by the government through its national health insurance policy. Per capita consumption equalled US\$13.

Pharmacies in Jordan are not restricted to the sale of pharmaceutical or medical products only, and it is reported by former pharmacist association president Amin Shocair that in an effort to increase the income of pharmacists (both prices and profit margins are set by the government) many pharmacies have introduced a growing variety of merchandise, including toiletries, perfumes, and cosmetics. Pharmacies are required by law to be closed one day per week. The provision of access to pharmaceuticals after normal pharmacy hours is coordinated by a central authority, according to the J.C. Bloomfield study, "International survey into emergency pharmaceutical services" (Pharmacy International). Specifically, one or more pharmacies will remain open in each district on a rotation basis. Additionally, a pharmacist may be part of an "on call" arrangement whereby he or she will return to the pharmacy to dispense medicines if needed.

Very little compounding is done on the premises of Jordanian pharmacies today. Retail pharmacists, according to Shocair, see their role as directing clients in the proper use of medication and its storage, and even taking an active role in promoting health education regarding child health care, nutrition, immunization, etc.

The Pharmacy Division of the Ministry of Health employs two pharmacists to carry out periodic inspections of pharmacy facilities, drug stores, and manufacturing plants.

Training and Licensing of Pharmacists

It is worth noting that, despite the abundance of pharmacists, until recently no facilities existed in Jordan for the training and education of pharmacists. Most Jordanian pharmacists have been trained in other Middle East countries, most notably Egypt, Syria, Lebanon, and Iraq, as well as at European universities in Great Britain, Italy, Spain, and Yugoslavia. Jordanian pharmacists have also been trained in the United States. The University of Jordan has had a faculty of pharmacology only since 1973. Pharmacy studies have recently been established at Yarmouk University, however, the focus is primarily on graduate clinical and industrial aspects of the pharmacy practice.

Pharmacists who have completed graduate training are eligible for Ministry of Health licensing upon submission of evidence of completed studies and passage of an examination comprised of written, practical, and oral testing.

The training of pharmacist assistants was undertaken from 1964 through 1977 by the Syndicate of Pharmacists, Jordan's professional pharmacist association. The training school was terminated in 1977 as it was determined the supply of technicians was exceeding the needs of the country. Two-year technical training has been resumed by the Ministry of Health on a limited scale. Only 12 students are accepted annually and successful students are required to provide two years of service to the Ministry of Health upon completion of the training.

Pharmaceutical Registration and Manufacture

Applications for registration of drugs must be submitted to the Ministry of Health. Such applications require information on the manufacturer, proposed price, composition, sources of active constituents, quality control data, containers/packaging, stability, labelling and inserts, clinical use, experimental and

biological studies, and clinical trials and studies. The required information is consonant with WHO drug registration recommendations, including the waiver of experimental, biological, and clinical studies and trials where the pharmaceutical under application is a well-established drug.

Applications must be accompanied by a certificate of analysis from a governmental or other recognized independent laboratory, a certificate of the Ministry of Health of the country of origin showing the product is licensed for sale and being sold in the country of origin, and ten samples of the product.

Applications are evaluated by three pharmacists under the Pharmacy and Supplies Department and forwarded to the Technical Committee for the Control of Drugs under the Ministry of Health, which makes the final determination regarding the license approval and fixes the wholesale and retail price.

The evaluation and analysis of proposed pharmaceuticals is the responsibility of the Pharmacy Division, with the exception of laboratory testing of pharmaceuticals. The Division does not maintain a quality control laboratory, although one is presently in the development stages with collaboration from WHO. It is expected that the laboratory will be part of the Government Laboratories of the Ministry of Health rather than directly under the Pharmacy Division.

The reduction of nonessential pharmaceuticals has been a major effort over the past 20 years in the Ministry of Health. For example, in 1978 approximately 3,600 pharmaceuticals were on the registered list of drugs for sale in Jordan (with different presentations of the same drug being counted as separate registrations). The number of pharmaceuticals offered for sale in 1978 was less than 25 percent of the 15,000 preparations available on the Jordanian market in 1965.

The Hewitt WHO report states that domestic pharmaceutical production in 1977 was limited to pharmaceutical processing (no basic compounds were

manufactured) by only one company, the Arab Pharmaceutical Manufacturing Company. Established in 1965, by 1977 APM was processing 80 products and accounted for 18 percent of local pharmaceutical consumption. The 1980 WHO Sixth Report on the World Health Organization reports that the development of a domestic drugs industry has been highly encouraged by the Ministry of Health. By 1979 APM sales stood at approximately US\$10 million, with 65 percent of its production being exported to neighboring Arab and African countries. By 1980 three additional production facilities were opened in Jordan. Production of pharmaceuticals included intravenous fluids, analgesics, antibiotics, cough preparations, diuretics, cardiovasculars, and a wide range of over-the-counter preparations. Shocair reports that local production of pharmaceuticals is not provided any market protection by the government, resulting in a competitive environment for domestic production and imported pharmaceutical preparations. It is expected that within the next few years that local production will account for full 40 percent of domestic consumption.

Whether pharmaceuticals are imported or produced locally, they are distributed through a wholesale network of "drug stores" which are limited to supplying private sector pharmacies. These wholesalers also serve as agents for pharmaceuticals imported from over 300 international companies. Few generic drugs are imported. In 1977, 48 such drug stores, owned and managed by pharmacists, were in operation. By 1980 this number had increased to over 65 outlets.

The Supply Division of the Ministry of Health is responsible for the purchase of drugs, medical supplies, and non-medical supplies to accommodate government needs. The Central Medical Stores of the Ministry of Health are responsible for pharmaceutical and other medical equipment storage.

Pharmacy Association (Syndicate of Pharmacists)

The Jordanian Pharmacy Association, the Syndicate of Pharmacists, was formally established in 1957 and presently includes all 1042 registered Jordanian pharmacists whether working in-country or abroad. The association is run by a ten-member board which is elected for a two-year term. The responsibilities of the association are to promote the pharmacological profession and serve in an advisory capacity to the Ministry of Health on the admission of new pharmacists and establishment of further pharmacy facilities throughout the country.

YEMEN

Pharmacists and Pharmacies

The level of pharmacist manpower in Yemen is very low in regard both to the number of physicians (physician/pharmacist ratio) and, perhaps more importantly, to the overall size of the population. Most, if not all, physicians and pharmacists are employed by the Ministry of Health and supplement their income with "after-hours" practices/position. Additionally, Yemen must rely in large part on supplemental foreign manpower. Consider the following:

Total Medical and Pharmacy Manpower, 1975-1980

Number in () = Yemeni nationals of the total manpower

	<u>1975</u>	<u>1976</u>	<u>1977</u>	<u>1978</u>	<u>1979</u>	<u>1980</u>
Physicians	295 (181)	366 (277)	399 (255)	448 (278)	513 (282)	606 (300)
Pharmacists	35 (20)	41 (24)	44 (25)	56 (23)	72 (28)	79 (33)
Pharmacology Technicians	-	-	-	-	-	4 (4)
Pharmacist Assistants/ Technicians	38 (37)	40 (38)	40 (40)	40 (40)	51 (51)	51 (51)

Source: 1979/80 Statistical Yearbook, Government of Yemen, Central Planning Organization.

Another way of examining the level of health services provided to a public is to analyze the number of physicians and pharmacists per 10,000 population. With an estimated population of 6.4 million Yemenis living in Yemen, (GOY, CPO), there are .95 physicians and 0.12 pharmacists per 10,000 population and a

pharmacist/physician ratio of 1:7.9. The following table provides comparable data for other Middle East countries.

Country	Number per 10,000 Population:		Ratio
	Physicians	Pharmacists	
EGYPT	6.7	1.9	1:3.5
IRAN	3.2	1.1	1:2.9
IRAQ	3.9	1.2	1:3.25
JORDAN	3.9	0.8	1:4.9
KUWAIT	12.2	3.0	1:4.1
LEBANON	7.5	2.2	1:3.4
LIBYAN ARAB REPUBLIC	7.7	1.6	1:4.8
SYRIAN ARAB REPUBLIC	2.9	1.5	1:1.9

Source: WHO "Report on a Visit to the Yemen Arab Republic" 1975.

The World Health Organization recommends a ratio of one pharmacist per 10,000 population as the minimum requirement of effective pharmaceutical supply and control services. According to GOY figures, this ratio is currently 1:109,000 in Yemen. It has been estimated, however, that only between 10 and 30 percent of the population actually have access to health services. While the four most populous governorates (Sana'a, Ta'iz, Al-Hodiedah and Ibb) contain just over two-thirds of the country's total population, these same governorates account for 80 percent of the nation's drug stores (160 of 200) and 35 of the 36

pharmacies. It is reasonable to assume that the majority of these health establishments are located in the urban capitals of these four governorates, whose combined population accounts for only 7 percent of the total population. The WHO study reports that in 1976 Yemen had three government drug stores: one in Sana'a, Ta'iz and Hodiedah.

By law, the 240 private drug dispensing outlets do not have to be owned or even staffed by a trained licensed pharmacist.

Impacts on Health Delivery

Given the number of pharmacies and drug stores (approximately 250, excluding hospital drug dispensing facilities) and the number of pharmacists, it is obvious that most medicaments distributed through the private sector are prepared by laymen. Indeed, the WHO report suggests that about 95 percent of all pharmaceutical preparations are distributed by laymen. Even patients who are diagnosed in government health facilities will often be instructed to take their prescriptions to private drug stores and pharmacies, as stock at hospital and clinic drug facilities will have been depleted. A 1981 Oxfam report suggests that 90 percent of the money spent on drugs in 1979 consisted of private expenditures, while the government health services accounted for only 10 percent of the total monies spent on pharmaceuticals. In 1979 this amounted to 157 million rials versus 14 million rials for private and public respectively, or US\$37.5 million versus US \$3.5 million. Per capita expenditures by the private and public sectors in 1979 equalled US\$6 and US\$0.55 respectively.

Both the Oxfam and WHO reports state that over-prescribing is common in Yemen. Frequently Yemenis will receive handwritten prescriptions for four or five different substances, one or two of which might be vitamin or cough syrups and the rest antibiotics. At the drug store the attendant, if he can decipher the

prescriptions, may find he does not have certain substances in stock and will attempt to find substitutes for the unavailable pharmaceuticals, although, as pointed out, these attendants have not received formal training for such situations. Drug store attendants may also prescribe substances themselves in cases where the client has not visited a health center or has withheld the multi-substance prescription from the attendant in an effort to reduce costs. The WHO report suggests that preparations are also "prescribed" by "off-hour" nurses, laboratory technicians, and X-ray technicians. Drug store attendants have also been known to give intravenous injections to clients.

Pharmaceutical Availability and Registration

Yemen produces no drugs of its own and thus must rely on importing all of its needs. The availability of generic drugs is quite limited, with the result that Yemenis are obliged to pay up to 250 percent more for brand name drugs than they would for generic substances. Yemen has approximately 2,200 approved drugs on the market, most of which are packaged with English, French, Spanish or Chinese instructions. There are no legal provisions regarding language for package inserts, so Yemen's imported drugs are infrequently supplemented with Arabic language instructions.

Despite a 1975 WHO recommendation, Yemen does not presently have an "essential drugs list" or "national drug formulary" although three "standard lists of drugs and other expendable items" are provided to government health centers and sub-centers. Vitamin preparations account for nearly one quarter of the entire drug market and one-third of the entire government drug budget, according to the Oxfam report.

Price controls have been effected for pharmaceuticals and a drug registration system has kept the number of drugs available relatively low as compared

to other developing countries. Yemen currently has approximately 2,200 approved drugs on the market. In 1979, 63 percent (1,483) of the 2,345 drugs submitted to the Supreme Authority for Drugs and Medical Equipment were approved for distribution. In the conduct of pharmaceutical registration, the Supreme Authority is responsible for quality analysis, although according to the WHO report, the Supreme Authority does not have laboratory facilities. Without proper quality analysis facilities, it is impossible to determine whether two preparations of the same drug are indeed identical and thus warrant the same price or whether one drug's claim to greater "bioavailability" (time release action) is true and warrants a higher price.

A further, complicating factor is that, due to low government salaries, it is not uncommon for the government drug registration personnel to have afternoon jobs with wholesale establishments or major drug houses.

Pharmacist Training

Yemen does not have any facilities for training pharmacists in-country, thus the government must support the student for five years of study abroad. Government salaries for returning graduate pharmacists are reported to be very low, resulting in the need for pharmacists to take afternoon jobs in private pharmacies, wholesale drug firms or large drug houses. Additionally, Yemen faces the common developing country problem of "brain drain," thus necessitating the overseas training of several candidates to ensure that at least some skilled manpower returns to the country. Additionally, the WHO report suggests that despite WHO's offer of pharmacy fellowships, the government has had difficulty raising qualified candidates.

The training of pharmacist technicians in Sana'a has been under consideration since 1975, although it is not known whether teaching staff, literature,

teaching aids and equipment have been secured for such efforts. WHO estimates that students entering the Health Manpower Institute in Sana'a with practical experience in drug distribution, e.g., after three years experience as a drug store attendant, could be trained for the pharmacist assistant/technicians examination in two years. Students with nine years of schooling but no practical experience would require three years.

BIBLIOGRAPHY

EGYPT

D'Orban, P.T. Assignment Report, Development of the Drug Dependence Programme in Egypt, 28 October to 14 November 1978. World Health Organization, Geneva, January, 1979.

"Egypt: Pharmaceutical Environment." WDMM Update, April/May, 1980.

Graves, Jack L. Foreign Trip Report (AID/RSSA): Egypt, August 12 - September 1, 1981. Department of Health and Human Services, Washington, DC, November 13, 1981.

Hassouna, Mary Taylor. "Assessment of Family Planning Service Delivery in Egypt." Studies in Family Planning, May, 1980, Vol. 11, No. 5. pp. 159-166.

Howell, Betty B. and William B. Novelli. Technical Assistance Report on the "Family of the Future" Contraceptive Sales Program, Cairo, Egypt. American Public Health Association, Washington, DC, November 23 - December 4, 1980.

Industrial Outlook Report: Pharmaceuticals - Egypt. American Embassy Cairo, April 24, 1979.

International Digest of Health Legislation, 1961, Vol. 12, pp. 582-587.

International Digest of Health Legislation, 1972, Vol. 23, pp. 68.

Omran, K. Pharmacist Bulletin SIN 050 and Survey; Current Status. International Fertility Research Program, December 8, 1980.

Omran, K. Report of Pharmacists' Conference, Alexandria, October 25, 1981. International Fertility Research Program, November 30, 1981.

Omran, K. Trip Report, Cairo and Alexandria, Egypt, October 20 - November 4, 1981. International Fertility Research Program, November 30, 1981.

Sallam, Abdon M. "Pharmaceuticals in Africa and the Middle East," Pharmaceuticals in Developing Countries. Conference Proceedings, NAS, 1979. pp. 232-235.

Sixth Report on the World Health Situation, Part 2. World Health Organization, Geneva, 1980, pp. 281-285.

"Supplement on the Pharmaceutical Industry." The Egyptian Gazette. May 1, 1978.

Warner, Timothy N. Draft Logistics Report -- Egypt, August 1981. American Public Health Association, Washington, DC, 3 October 1981.

Zimmerman, Margot L. Trip Report, Egypt, September 28 - October 9, 1980. PIACT, Seattle, WA, October, 1980.

MOROCCO

Household Distribution of Family Planning. Ministry of Public Health, Government of Morocco, U.S. Agency for International Development, International Fertility Research Program, September, 1981.

International Digest of Health Legislation, 1961, Vol. 12. pp. 410-412.

International Digest of Health Legislation, 1966, Vol. 17, p. 918.

International Digest of Health Legislation, 1968, Vol. 19, pp. 210-211.

International Digest of Health Legislation, 1978, Vol. 29, pp. 403-410.

"Morocco: Pharmaceutical Environment." WDMM Update, July, 1980.

Sixth Report on the World Health Situation, Part 2, World Health Organization, Geneva, 1980, pp. 219-221.

Wood, David. Survey of Private Sector (Pharmacies) Sales of Condoms and Oral Contraceptives in Morocco. Population Division, USAID/Morocco, August, 1977.

TUNISIA

CSM Marketing Plan, Syntex Laboratories, 1976.

Household Distribution of Contraceptives in Bir Ali ben Khalifa, Tunisia. International Fertility Research Program, Research Triangle Park, NC, July, 1979.

International Digest of Health Legislation, 1962, Vol. 13, pp. 359-360.

International Digest of Health Legislation, 1970, Vol. 21. pp. 660-664.

International Digest of Health Legislation, 1974, Vol. 25, pp. 180-184.

International Digest of Health Legislation, 1975, Vol. 26, pp. 204-211, 220-221.

International Digest of Health Legislation, 1976, Vol. 27, p. 671.

International Digest of Health Legislation, 1978, Vol. 29, pp. 210-211.

International Digest of Health Legislation, 1979, Vol. 30, pp. 644-647.

Jazi, R. "Pharmacy in Tunisia." Bulletin D'Information, Federation Internationale Pharmaceutique, December, 1976. pp. 15-17.

Maguire, Elizabeth, Ann Way, and Mohamed Ayad. Draft report: Family Planning Service Delivery in Rural Tunisia: A Case Study.

Ouahchi-Bencherifa, A. "Pharmacy in Tunisia." Bulletin D'Information, Federation Internationale Pharmaceutique, July, 1978, No. 2. pp. 10-13.

Sixth Report on the World Health Situation, Part Two. World Health Organization, Geneva, 1980, pp. 309-313.

LEBANON

World Health Statistics Annual, 1978, Volume III, Health Personnel and Hospital Establishments. World Health Organization, Geneva, 1979.

International Digest of Health Legislation, 1956, Vol. 7, pp. 664-665.

International Digest of Health Legislation, 1969, Vol. 20, p. 121.

Interviews with expatriate Lebanese pharmacists, doctors, pharmaceutical specialists.

JORDAN

Hewitt, W. Report on a Visit to Jordan, 3-10 July 1978. World Health Organization, November, 1978.

Jordan Statistical Yearbook, Government of Jordan, 1980.

Shocair, Amin. "Pharmacy in Jordan." Bulletin - Federation International Pharmaceutique. September, 1980.

Sixth Report on the World Health Situation. Part 2. World Health Organization, Geneva, a 1980, pp. 296-299.

YEMEN

Friebel, H.H. Report on a Visit to the Yemen Arab Republic, 19 November - 1 December 1975. World Health Organization, Geneva, April, 1976.

Melrose, Diana. The Great Health Robbery: Baby Milk and Medicines in Yemen. OXFAM, Oxford, 1981.

Statistical Yearbook, Central Planning Office, Government of Yemen, 1980.

GENERAL

Bloomfield, J.C. "International Survey into Emergency Pharmaceutical Services." Pharmacy International, May, 1980, pp. 104-107.

Gish, Oscar and Loretta Lee Feller. Planning Pharmaceuticals for Primary Health Care: The Supply and Utilization of Drugs in the Third World. American Public Health Association International Health Programs Monograph Series, 1978.

Golladay, Frederick and Bernhard Liese. Health Problems and Policies in the Developing Countries. World Bank Staff Working Paper No. 412. The World Bank, Washington, DC, 1980.

Haines, Bernard A. "Worldwide Regulations and Legislation; Their Effects on Pharmaceutical Product Development." Drug Development and Industrial Pharmacy, 1978, Vol. 4, No. 1, pp. 1-30.

Health: Sector Policy Paper. The World Bank, Washington, DC, February, 1980.

Paxman, John M. "Roles for Non-Physicians in Fertility Regulation: An International Overview of Legal Obstacles and Solutions." American Journal of Public Health, January, 1980, Vol. 70, No. 1, pp. 31-39.

Smith, Mickey C. "The Pharmacist and Family Planning: Status and Prospects." Pharmacy International, Vol. 1, No. 10, October, 1980.

Vanderschmidt, Lori, John A. Massey, Jaime Arias, Thieu Duong, Jorge Haddad, Lazare Kaptue Noche, Nabil Kronfol, Eddy K. C. Lo, Shekhar B. Rizyal, Mathura P. Shrestha, and Francisco Yepes. "Competency-Based Training of Health Professions Teachers in Seven Developing Countries." American Journal of Public Health. June, 1979, Vol. 69, No. 6, pp. 585-590.