

Analysis of the pharmaceuticals market and its technological development in Turkey

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Objectives: The objectives of this study were to analyze the current structure of the Turkish pharmaceuticals market to explain the latest developments and to offer some insight into the likely policy issues that this sector will face.

Methods: Systematic searches of the relevant Turkish and English research literature were made, using electronic databases in addition to written reports.

Results: The pharmaceutical industry in Turkey currently has eighty-seven manufacturing firms, eleven raw material manufacturers and thirty-eight importing firms. These add up to a total of 136 firms, 35 of which are driven by foreign capital, with 8 of these foreign-run firms having their own plants in Turkey. The industry employs approximately 19,000 personnel. In terms of growth, the value of pharmaceutical products in Turkey recently has exceeded that in Europe. In addition, per capita drug consumption levels are quite low compared with the Organisation for Economic Co-operation and Development and European Union countries. Major international players in the medical equipment and pharmaceutical products sector have also been opening offices in Turkey to reap the benefits of this rapidly evolving market.

Conclusions: The pharmaceutical industry in Turkey is quite advanced and diverse, with high quality, generic pharmaceutical products being manufactured as well as poor quality copies that have not been appropriately tested in terms of bioequivalence and bioavailability. The country faces a low level of drug consumption due to economic and cultural constraints compared with Western countries. Governmental control and regulations are key issues because the majority of drug purchases (70–80 percent) throughout the country are currently reimbursable through public sector agencies such as the Pension Fund and the Social Insurance Organization.

Keywords: Pharmaceutical sector, Turkish health system, Health status

In many countries, the publicly funded share of drug expenditures has increasingly become the focus of health policy. There has been worldwide concern over the high prices of drugs, not only in terms of healthcare costs but also in the context of equitable distribution. The pharmaceutical industry, being at least as multinational as other high-tech industries, therefore, offers an interesting measure of how emerging markets assimilate developments, both in using new technology and in paying for it. Thus, it is worthwhile to examine the pharmaceutical industry and its components within the health system of a given country. As one of the wealthier developing countries, Turkey is an example of some common themes that guide the assimilation of technology and interactions with other countries in general. Lately, Turkey is struggling to recover from the effects of an eco-

nomical crisis and government officials are trying to impose budget cuts in the health and education sectors. The purpose of this study is to analyze the current structure of the Turkish pharmaceuticals market to explain the latest developments and to offer some insight into the likely policy issues that this sector will face.

The pharmaceutical industry in Turkey, with its roughly 19,000 employees in 2001, grew at an average rate of 14 percent per year from 1995 to 2000, far exceeding the 7.2 percent growth in Europe during this same period (1;2). In dollar terms, the value of pharmaceutical products in the Turkish market reached \$2.7 billion in terms of producer prices. Yet Turkey has the lowest pharmaceutical consumption rate among all European countries (7;8). Based on ex-factory prices, Turkey's per capita pharmaceutical

Table 1. Health Expenditures and Health Status of Selected Countries^a

Country	Per Capita GDP using current PPPs 2004	Total health expenditure as a % of GDP 2003	Health expenditure per capita USD PPP 2003	Pharmaceutical expenditures as % of total expenditure on health 2003	Infant mortality rate, deaths per 1,000 live births 2003	Life expectancy at birth-Total (years) 2003	Age structure, percentage of total population 65 and over 2004	Overweight or obese population percentage total population, BMI >25 kg/m ² 2003
Turkey	7,700	6.6	452	24.8	29.0	68.7	5.7	43.4
USA	39,700	15	5,635	12.9	7.0	77.2	12.4	65.7
France	29,600	10.1	2,903	20.9	3.9	79.4	16.3	37.5
Switzerland	33,600	11.5	3,781	10.5	4.3	80.4	16.1	37.1
UK	31,400	7.7	2,231	15.8	5.3	78.5	15.6	62.0
Germany	28,500	11.1	2,996	14.6	4.2	78.4	19.3	49.2
Spain	25,600	7.7	1,835	21.8	4.1	80.5	16.8	48.4
Greece	21,500	9.9	2,011	16	4.8	78.1	16.8	57.1
Netherlands	31,100	9.8	2,976	11.4	4.8	78.6	13.8	45.0
Poland	12,600	6	677	–	7	74.7	13.0	43.1
Hungary	15,900	7.8	1,115	27.6	7.3	72.8	15.6	52.8

^a Source: Organisation for Economic Co-operation and Development Health Data 2005.

GDP, gross domestic product; USD, United States dollar; PPP, purchasing power parity unit; BMI, body mass index.

consumption of \$38 in 2001 was among the lowest in Europe. It was reported that per capita consumption increased to \$45 in Turkey in 2002 (per capita health expenditure \$150–170). Europe-wide per capita spending on healthcare goods and services is USD 2,140. Especially in rural areas and small cities, due to financial, transportation, and other constraints, Turkish people are reluctant to see a physician for their illness unless it becomes absolutely necessary (3;4;10). In Europe, the average share of healthcare expenditure in gross domestic product is approximately 8.5 percent, significantly above Turkey's share of 6.6 percent (see Table 1).

This pattern is changing, however, particularly in major cities where sophisticated health services are available and the average income level is higher. Turkey's population of 68 million grows 2 percent annually, and this growth combined with rising incomes, growing public awareness of health care, urbanization, and Turkey's proximity to both Europe and Asia makes this country one of the most dynamic healthcare markets in the world. The social security system in Turkey now covers the health needs of 70–80 percent of the population, but the current government is planning to expand this coverage to all citizens, which in turn will expand the pharmaceutical industry (5;9;10). Other factors indicating further growth are the rising demand for private health insurance, the proliferation of private hospitals and clinics, advances in technology, and expected increases in the prevalence of cancers and cardiovascular diseases as the average age of the population increase (4;6). This is the context in which the present study analyzes the structure of the Turkish pharmaceuticals market and attempts to offer some insight into the likely policy issues that this sector will face.

METHODS

Systematic searches of the relevant Turkish and English research literature were made, using electronic databases in addition to written reports. Official government documents were analyzed as well, as sources of both data and detailed statements of policy. When possible, figures were cross-checked against those provided from another sector; for example, government statistics were checked against figures provided by the pharmaceutical industry itself, and these figures were checked against previous academic studies.

RESULTS

Pharmaceutical Production and Consumption in Turkey

There were around 21,000 pharmacies in Turkey in 2003 (7). This number is generally deemed sufficient, but the fact that not all citizens are covered by an insurance program negatively affects drug sales (9). There is a surplus of pharmacists in the country, with approximately 900 new pharmacists graduating from universities each year.

In the pharmaceutical sector, there are 87 manufacturing firms, 11 raw material manufacturers, and 38 importing firms, totaling 136 firms (9;10). Of these, thirty-five are driven by foreign capital, and eight of these foreign-run firms have their own plants in Turkey. Domestic manufacturing firms specialize mostly in the production of generic products, which constitute 22 percent of total pharmaceutical product sales. The Social Insurance Organization is the major buyer of generic products. The market for generic pharmaceutical products is supported by domestic producers that enhance financing

capabilities, provide logistics for exportation and retail sales to third countries, and provide the competitive advantage of a strong workforce and world standard manufacturing technologies (4).

Currently, pharmaceutical firms in Turkey are capable of producing nearly all kinds of pharmaceutical products, and in terms of infrastructure, Turkey is technologically ready to compete with firms in the European Union. However, Turkey relies on imports predominantly from the United States, Germany, Switzerland, the United Kingdom, and France for the supply of biotechnology products as well as investment intensive pharmaceuticals such as cancer drugs, vaccines, and hormones (7;8). Pharmaceutical imports into Turkey reached USD 1.6 billion in the year 2001 (see Table 3) (14). Imports are made either by local companies who represent foreign suppliers, or by the local branches of foreign companies. The pharmaceuticals sector is among Turkey's most foreign-capital intensive.

On the other hand, the pharmaceutical industry in Turkey has been exporting its products since 1978. Whereas exports were initially to North Africa and the Middle East, in the 1990s, trade became dominated by sales to the Russian Federation, Azerbaijan, Germany, Austria, Belgium, Holland, and Switzerland (8;10).

Pharmaceutical-grade raw materials is another area in which Turkey relies on imports to provide for up to 80 percent of demand (4). Although Turkey began producing raw materials for the manufacture of antibiotics, painkillers, and sulfamides back in the mid-1960s, the sector received few incentives and the companies producing these products faced high costs. In 2002, raw material production reached 3,909 tons, which contained large amounts of Turkey's export products such as paracetamol, acetylsalicylic acid, alkaloids of opium, and their derivatives (7). In the raw material production sector, one plant is state owned and ten plants are privately owned. Diverting investments to promote raw material production would add a variety of new products to the list of choices available to Turkish consumers.

According to reports, the top ten best selling pharmaceutical preparations account for 40 percent of the total market. Antibiotics, analgesics, and antirheumatoid preparations continue to top the pharmaceutical sales charts (7;10). Table 2 shows pharmaceutical consumption by therapeutic class in 2002 and 2005. Table 3 shows the current structure of the Turkish pharmaceutical industry and that projected for 2023.

Pricing of Medicinal Products for Human Use

In Turkey, the Ministry of Health sets the maximum retail prices of drugs. This authority is provided for by Law no. 1262 on Pharmaceutical and Medicinal Products and Law no. 3359 on Healthcare Services, which specify that the Min-

Table 2. Pharmaceutical Consumption by Therapeutic Class: 2002, 2005^a

Therapeutic class	% 2002	% 2005
Antibiotics	18.1	17.8
Analgesics, antimigraine prep.	12.3	9.5
Antirheumatic system, muscle relaxants	11.0	12.4
Cough and cold prep.	8.4	8.5
Vitamins, minerals, antianemics	6.4	6.1
Dermatologicals	5.3	4.9
Stomatologicals, antacids, and antiemetics	5.2	5.2
Cardiovascular system prep.	6.1	7.5
Hormones and gynecological prep.	4.5	4.0
Otologicals, eye-ear prep.	4.3	4.3
Antihypertensives and diuretics	1.0	3.4
Others	17.6	16.7

^aSource: Pharmaceutical Manufacturers' Association (2004). *Pharmaceuticals in Turkey, 2002, 2005*. Prep., preparations.

istry will ensure the affordability of medicinal products for human use. The Ministry of Finance is authorized to investigate the suitability of these prices (6;14;15).

The Ministry of Health sets the maximum retail price of original products, excluding value added tax, as follows. From a list of five countries, namely France, Italy, Spain, Portugal, and Greece, the two with the lowest prices for the drug in question are taken as a reference (11–13). The Ministry then sets the maximum retail price of the drug by taking 90 percent of its average ex-factory price in these two countries, then adding the profits of wholesalers and pharmacies. In the case of imported drugs, if the ex-factory price of a drug in its home country is lower than the reference price, then the profit rates of wholesalers and pharmacies are added to that price instead. For generic products, retail sales prices are set by taking not more than 70 percent of the average of the ex-factory sales price of the original versions of these products, then adding the profit rates of wholesalers and pharmacies. This percentage may be increased to 80 percent if locally manufactured raw materials have been used in the production of generic products. Ex-factory prices of products packed for hospitals have to remain at least 10 percent below the unit prices of the original products.

Scientific Advisory Board

Since 2003, the Ministry of Health has maintained a Scientific Advisory Board for the purpose of overseeing the registration and postregistration phases of medicinal products for human use (12). The board is composed of at least fifty people from universities, educational hospitals and other public and private entities, various levels of government, vocational unions, and nongovernmental organizations. The board is selected by the General Directorate with the approval of the Minister. Permanent members of the Board are the

Table 3. Main Indicators of the Pharmaceuticals Market in Turkey for 2001 and 2023^a

	2001	2023 Projections by the pharmaceutical sector representatives
Population (million)	68.1	85
GDP (billion USD)	151.4	850–900
Per capita income (USD)	2207	11,000
Total imports (billion USD)	41.40	160
Total exports (billion USD)	31.34	120
Research Expenditures/GDP	.4%	> 1%
Per capita pharmaceutical consumption (USD)	38	160
Total pharmaceutical market (million USD)(ex facto prices)	2,553	13,600
Finished pharmaceutical products (million USD)	1,862	5,440 (40% of market share)
Imports: finished pharmaceuticals (million USD)	698	8,160 (60% of total market share)
Imports: pharmaceutical raw materials (million USD)	836	3,500
Total drug imports (million USD)	1,534	11,660
Exports: finished drugs (million USD)	77	600
Exports: raw materials (million USD)	72	1,000
Total drug exports (million USD)	149	1,600
Prescribed drug consumption	75–80%	85%
Prescribed drug consumption (brand name)	50%	80%
Prescribed drug consumption (generic)	50%	20%
Biotechnologic product consumption	7.6% (2.6% from pharmacies)	30%
Biotechnologic generic consumption	0%	7%
No. of pharmaceutical companies	136	40–50
No. of pharmaceutical product distribution sources	100 (10 depo + 90 cooperation)	5–6
Pharmacies	20,628	25,000
Share of drug consumption within health expenditure (%)	25	15

^aSource: Vizyon 2023. (2003). *Teknoloji Öngörü Projesi: Sağlık ve İlaç Paneli Ön Raporu*. GDP, gross domestic product; USD, United States dollar.

Undersecretary of the Ministry, the related Deputy Undersecretary, the Pharmaceutical General Director, and the related Deputy General Director. The Board is divided into the following commissions.

Advisory Commission for the Registration of Medicinal Products for Human Use. This commission presents its views on medicinal products for human use that are subject to registration by the Ministry. This responsibility is connected to the Ministry's authority to include or exclude drugs from the list of narcotics, psychotropics, or drugs subject to control. The commission analyzes the medicinal products from a clinical aspect and provides opinions that serve as a basis in registration. The commission has a minimum of six members, including the following: one representative of the Pharmaceutical and Cosmetic Research Directorate at the Refik Saydam Hygiene Center, two clinicians, one pharmaceutical technologist, one pharmacologist, and the representative of the Ministry.

Pharmacoeconomic Advisory Commission. This commission evaluates medicinal products for human use in terms of pharmacoeconomic data such as cost-

efficiency, cost-benefit, cost-minimization, and cost-usage. The commission has a minimum of six members: one clinical pharmacologist, one general pharmacologist, one clinician, one statistician, one representative of the Ministry of Finance, and one representative of the Ministry of Health.

Advising Commission for Technology/Pharmacology. This commission evaluates each drug from a pharmacological aspect and controls the content of product information leaflets. The commission has a minimum of five members, including the following: two pharmacologists, two pharmaceutical technologists, and one representative of the Ministry.

Bioefficiency–Bioequivalence Evaluation Commission. This commission evaluates the bioefficiency and bioequivalence studies of the medicinal products for human use. The commission has a minimum of five members, including the following: one pharmaceutical technologist, two pharmacologists, one statistician, and one representative of the Ministry.

Radiopharmaceutical Advising Commission.

This commission evaluates the radiopharmaceutical products that are imported or manufactured in Turkey. The commission has a minimum of six members, including the following: one radiopharmacy expert, one nuclear medicine expert, one pharmaceutical technologist, one pharmacologist, one radiation protection expert to be entrusted by the Turkish Atomic Energy Institute, and one representative of the Ministry.

Major Challenges in the Pharmaceutical Sector

A problem that the sector faces in the production of generic pharmaceutical products is the time period involved in acquiring a license, which can be up to 2.5 years (6). Another problem concerning the entire pharmaceutical sector is the state pricing system, which determines the prices of pharmaceuticals instead of the market forces of supply and demand. The state, which is the buyer of 70–80 percent of all pharmaceutical products, determines prices not only according to its own economic benefit but also with a populist tendency, acting on behalf of people adversely affected by high drug prices. Within the major reforms to be launched by the Ministry of Health, many state-owned hospitals will be privatized, which will lead to the liberalization of pricing pressures exerted by the government (14;15).

On the other hand, imported drugs are generally consumed by university hospitals, which receive most of their patients through the Social Insurance Organization, which in turn has a massive debt to the university hospitals. Although problems of funding lead the university hospitals to purchase the cheapest products, private hospitals are also not known for using high quality/expensive products. However, mid-price hospitals tend to use a range of products, from cheap to high quality. As for military hospitals, their annual demand for medical supplies is met through the Ministry of Defense (10;16).

Local pharmaceutical consumption trends indicate that public civil servants, insured by the government, account for 80 percent of all drug purchases. On February 24, 2003, the Turkish Government's Pension Fund published a circular stating that, beginning on March 1, 2003, reimbursement of prescribed pharmaceuticals consumed by its members will be based on a "reference price." This price will be the arithmetic average of the prices of all equivalent drugs in the same group. The Pension Fund covers all employees of the Turkish government and their legal heirs. Drug contribution fees for patients are calculated in line with the existing practice (that is, on total price) for drugs priced below the reference price, and on the basis of the reference price for drugs priced above the reference price. Contribution fees are deducted from salaries.

An example of how a patient will be required to pay for a drug is as follows. Suppose that the average price of six antibiotics in the same group (for example, Amoksilav,

Klavupen, Klamoks, Amoklavin, Bioment-bld, and Augmentin) is Turkish Lira (TL) 26,000,000. If a patient is prescribed Augmentin 1,000 mg, which actually costs TL 30,000,000, the pharmacy will be reimbursed TL 24,000,000 by the Pension Fund, and the remaining TL 6,000,000 will be paid by the purchasing patient. This new development somewhat negatively affects foreign drug manufacturers who have higher costs of production and whose products are priced higher than their domestic equivalents.

CONCLUSIONS

The Turkish healthcare system is undergoing significant change, and the changes are driven by a strengthened national commitment to deliver health care in a fair and equitable manner to all citizens, and a policy of moving toward greater local hospital autonomy through privatization (3;10). Because of the country's unbalanced social structure and the profound gaps in its income distribution, the needs of urban and rural areas are vastly different in Turkey. Drug utilization reflects this finding and varies greatly between urban and rural areas.

The pharmaceutical industry in Turkey is quite advanced and diverse, with high quality, generic pharmaceutical products being manufactured as well as poor quality copies that have not been appropriately tested in terms of bioequivalence and bioavailability. The country faces a low level of drug consumption due to economic and cultural constraints compared with Western countries. This low consumption is a divergence from what in many countries is considered a rational use of resources, with the result that life-saving but expensive drugs are often difficult to access for patients in Turkey. It can be suggested that government control and regulations are necessary because the majority (approximately 70–80 percent) of drug purchases throughout the country are reimbursable through public sector agencies such as the Pension Fund and the Social Insurance Organization.

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