

# PHARMACEUTICAL INDUSTRY

Prepared by  
Songül BEKTAŐOĐLU  
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Export Promotion Center of Turkey

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Production of pharmaceutical preparations done in pharmaceuticals laboratories between years 1928-1950 had been increased with the establishment of local and foreign invested plants starting from year 1952, which is the start for the “fabrication period” of the Turkish pharmaceuticals industry.

Within the period after year 1984 to date, investments of foreign capital companies have been increased and especially after year 1990, 19 foreign capital firms have been entered into Turkish pharmaceuticals market. 134 companies are operating in Turkey. Two of these companies, Social Securities Institution Pharmaceuticals Plant and Ministry of Defence Army Pharmaceuticals Plant, are publicly owned, others are private enterprises.

Today, there are approximately 300 entities operating in Turkey. Among 42 manufacturing facilities, 14 of them are multinational firms.

The following international pharmaceutical companies have subsidiary manufacturing operations in Turkey: Bayer (Germany), GlaxoSmithKline (UK), Aventis Pharmaceuticals, Inc (US), Pfizer (US), Roche (Switzerland), Sanofi (France), Novartis (Switzerland) and Baxter (US).

The leading Turkish manufacturers are EIS Eczacıbaşı, Abdi İbrahim, Fako, İlsan İltaş, Mustafa Nevzat, İbrahim Ethem and Bilim.

Pharmaceutical industry has a production structure which has high level of technology and automation. Approximately 25.000 people is employed in the sector. Pharmaceuticals industry due to its nature is one of the industries which has the high proportion of personnel (50%) with university education. The distribution of highly educated employees is: pharmacists 4,5%, doctors 3%, chemical engineers 7,5%, chemists 7%, biologists 9,5%.

Pharmaceutical industry is mainly located in the Marmara Region especially in provinces of İstanbul, Kocaeli and Tekirdağ. Better infrastructure, easy supply of packaging materials and technical personnel, telecommunication and transportation facilities and the existence of a high number of health institutions in the region are main reasons.

The Turkish pharmaceutical industry has a well-organized structure. Most of manufacturers and exporters have been organized under the roof of an association.

### Capacity and Production

Pharmaceutical production trends are closely related to domestic and foreign demand. The capacity utilization and the pharmaceutical production were respectively 70 % and 1.4 million units in 2006. Domestic industry meets 90 % of the pharmaceutical demand but the new pharmaceutical products like the ones, for cancers, vaccines and hormones are imported.

In 2006 there were 1.205 hospitals in Turkey with a total bed capacity of 192.685. Average capacity utilization was 60 %. An important new trend is towards receiving incoming patients from European (mainly United Kingdom) or Middle East countries for treatment in Turkish private hospitals.

Domestic pharmaceutical production is dominated by non-innovative preparations including anti-rheumatoid, antibiotics and analgesics. As of the year 2006, the number of pharmaceuticals on the market is 3100. Including alternative posologies, the number is 7200. These figures include non-prescription products which are known as OTC (Over The Counter) products in European Union. Nevertheless İlsan İlaş has a sound worldwide know-how and technology in pellet development and production. İlsan İlaş has got process patents for omeprazol pellet production in Europe, Canada and South Korea, and has also been granted FDA approval for finished product.

Mustafa Nevzat plants have been approved for the API and finished dosage forms by FDA. This is also a “first” for the Turkish Pharmaceutical Industry. Mustafa Nevzat signed strategic partnership agreements with several leading US generic companies for marketing and sales of its products

Although a local high-tech or biotechnology and research-based manufacturing segment has not yet significantly developed, basic production techniques has reached internationally acceptable standards.

Leading products in Turkey, by consumption, include antibiotics, analgesics, anti-rheumatics, cough and cold products, vitamins and minerals, cardiovascular preparations, antiacids and antiseptics.

#### *Production of Pharmaceutical Products in Turkey*

Years	Quantity (million units)	Value (US \$ million)
2001	952	1.932
2002	969	2.262
2003	1.130	3.100
2004	1.321	3.378
2005	1.366	4.410
2006	1.433	3.947

*Source: Pharmaceutical Manufacturers' Association*

The production and marketing of all pharmaceuticals must be authorized by the Ministry of Health, and pharmaceutical products and firms must be registered in the Ministry.

The production of raw materials in Turkey concentrates on the active ingredients of antibiotics and analgesics, by using the methods of fermentation, extraction and synthesis.

In Turkish pharmaceutical raw materials sector, 11 plants of private sector and 1 plant of public sector are in operation. The major characteristics of pharmaceutical raw materials industry are that the investments are made at a great proportion by privately owned companies and the existing production capacity can be easily shifted to various production possibilities.

Raw material inputs for certain drugs such as morphine and its derivatives and paracetamol are produced in volumes large enough to achieve self-sufficiency as well as to satisfy export demands. It is worth to mention that Afyon Alkaloids Factory produces 20 % of the morphine consumption of the pharmaceutical industries all over the world.

Since 1995, pharmaceutical manufacturers have had to abide by regulations specifying Good Manufacturing Practices(GMP) and Good Laboratory Practices (GLP), necessitating significant investment by local industry companies. The necessary investments for the development of

technology in the industry have been accelerated and today production technology of the Turkish pharmaceutical industry has reached world standards.

The Customs Union with EU has brought about the harmonization of many of the regulations relating to the industry. In this respect, Turkey extended patent protection to pharmaceutical products legally from 1 January 1999. While Turkey started recognizing patents from 1995, given the long development duration for new pharmaceutical products, in practice there are few patent products currently in the market and it is expected that patent protected products will only become more prevalent between 2005 and 2007.

Pharmaceutical manufacturers have to follow the Packaging and Labeling Regulation which is enforced by Health of Ministry and became effective in June 2004. This regulation has been prepared with parallel to EU Pharmaceutical Products Directory (2001/83/EC).

#### Exports

Turkish companies have managed a steady increase in their exports in recent years. In 2007 total value of pharmaceutical industry exports reached US \$ 426 million. About 77 % of the pharmaceutical industry exports is primarily packed ready-for-use pharmaceutical products.

Major export products are the ones containing penicillin, antibiotics and alkaloid medicaments.

Turkey is now exporting various pharmaceutical products to 140 countries including developed countries like Germany, Switzerland, the USA, Austria, Belgium, the Netherlands, the UK, Italy, Canada, Denmark and France.

#### *The Pharmaceutical Industry Exports by Products (Value 1000 US \$)*

HS No.	Products Name	2004	2005	2006	2007	Major Export Markets in 2007
2936	Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvents	744	1.169	1.183	1.541	Uzbekistan, Georgia, Iran, Algeria, Azerbaijan
2937	Hormones, naturel or reproduced by synthesis; derivatives thereof, used primarily as hormones; other steroids used primarily as hormones	998	1.084	559	580	Italy, Belgium, Morocco
2938	Glycoside, natural or reproduced by synthesis, and their salts, ethers, esters and other derivatives	1	0	34	0	
2939	Vegetable alkaloids, natural or reproduced by synthesis, and their salts, ethers, esters and	25.773	20.208	30.692	38.395	USA, England, Iran,

	other derivatives					Switzerland, Hong Kong
2941	Antibiotics	13.463	11.560	9.611	3.876	Belgium, China, Iran, Panama, Tunisia
3001	Glands and other organs for organo-therapeutic uses, dried, whether or not powdered; extracts of glands or other organs or of their secretions for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included	34	92	196	257	Bosnia Herzegovina, Iraq, South Korea, Albania, Algeria
3002	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses: antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms and similar products	4.179	3.938	6.388	5.196	TRNC, Azerbaijan, Iraq, Jordan, South Korea
3003	Medicaments consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packagings for retail sale	58.905	27.536	14.960	12.935	Netherlands, Spain, South Korea, Ireland, Saudi Arabia
3004	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packagings for retail sale	175.246	236.056	273.449	309.892	Germany, Switzerland, TRNC, England, Belgium
3005	Wadding, gauze, bandages and similar articles	9.224	13.218	14.837	15.541	Italy, Russian Fed., Iran, Bulgarian, Iraq
3006	Pharmaceutical preparations and products	1.043	2.186	3.340	13.505	Germany, Hong Kong, Kyrgyzstan, Romania,

						Bulgarian
	TOTAL	289.778	340.746	373.394	426.391	

Source: Undersecretariat of Foreign Trade

*Pharmaceutical Products Exports by Countries (Value: 1000 US \$)*

Countries	2005	2006	2007
Germany	65.961	63.765	82.390
Switzerland	18.139	29.962	31.947
England	14.327	29.339	30.472
USA	22.012	23.321	24.965
TRNC	16.337	19.416	24.580
Belgium	26.494	14.181	17.074
Algeria	17.451	15.012	14.687
Azerbaijan	7.066	7.181	10.417
Spain	19.867	5.201	8.397
Iran	3.441	3.887	7.902
Italy	5.966	7.349	6.626
Kazakhstan	5.329	8.458	6.475
Sudan	191	147	6.314
Denmark	13.537	13.730	5.365
Iraq	2.860	2.325	5.103
Canada	1.403	2.463	5.091
Bosnia Herzegovina	3.303	4.334	4.620
India	3.681	8.019	4.431
Netherlands	8.584	3.535	4.416
Georgia	1.795	2.553	4.230
Bulgaria	1.263	1.741	4.205
France	4.088	4.264	4.205
Australia	913	2.059	4.155
Singapore	2.858	3.351	3.871
Malta	74	1.522	3.783
South Korea	3.664	3.730	3.712
Romania	3.951	3.120	3.431
Poland	701	726	3.394
Portugal	585	2.853	3.339
Russian Federation	2.748	5.649	2.813
Uzbekistan	1.302	1.844	2.671
UAE	2.754	2.064	2.577
Ukraine	991	1.957	2.558
Moldova	1.149	1.210	2.414
Serbia	0	1.987	2.361
Macedonia	1.830	1.427	2.093
Other Countries	54.126	69.707	69.405
Total	340.746	373.394	426.391

*Source: Undersecretariat of Foreign Trade*