**PHARMACEUTICAL INDUSTRY**

**Development of Turkish Pharmaceutical Industry**

The development of the Turkish pharmaceutical industry, which has undergone parallel stages to the pharmaceutical industry in the world and has reached an international level today, can be divided into three cycles:

1. The pharmacy period before the Republic,
2. The lab period and from the Republic to the end of World War II.
3. Factory period after World War II.

In the pre-Republic period; the preparation of medicines started in community pharmacies. In 1915, the number of medicines which are made in community pharmacies had reached 30, but the variety of these remained limited like some codex ampoules, force medicines and drops. The other medicines needed were imported, and they were sold without quality and price control and without licensing.

After the declaration of the Republic, with the law numbered 1262 issued in 1928, the state control in the import and production of medicines was provided. The pharmaceutical industry started to develop when the chance was given to domestic preparations to compete with the imported drugs.

During the Second World War, the pharmaceutical industry continued to suffer from impossibilities, in addition, domestic medicinal production reached a level that could be considered as better than underdeveloped countries and major services were provided to the country's health situation during the distressful war years.

In the years following the Second World War, drug-manufacturing laboratories had the opportunity to improve their activities and became pioneers of the modern Turkish pharmaceutical industry. In the period of rapid industrialization between 1952 and 1957, 60 percent of the country's needs were met.

**What is equivalent medicine?**

Equivalent drugs are products that have the same properties as reference drugs, so they are proven by scientific studies that provide the same treatment on the patient, and are offered for sale after the reference medicines have expired. The four key features of equivalent medicine are being effective, quality, reliable and economical.

An equivalent drug has the same efficiency, quality and reliability with the reference. But their prices are lower because equivalent products do not have to repeat laboratory and clinical research done for the reference.

**What is the reference drug?**

The reference drug is the first product developed by the innovator company and given to the market under patent protection. After the shelf life is over, equivalent products are produced with reference to these products.

**What is bioequivalence?**

Bioequivalence is considered to be the guarantee of the equivalent product and the reference product that provides the same treatment. Two drugs with the same active substance, in the same amount, in the same or similar pharmaceutical form and with the same rate and extent of passage to the blood through the applied body region, are considered as bioequivalents.

**Patent protection**

The patent is the right of the inventor to manufacture, use or sell the invention subject to competition for a certain period of time. Patents period is 20 years in our country as well as in the whole world that protect new inventions within the scope of intellectual property rights for a certain period. In our country, the patent law entered into force in 1995, and patent protection in medicine has been implemented since 1 January 1999.

**Data Exclusivity**

Data exclusivity is an additional market protection in the patent, which prevents the health authorities from accepting equivalent license applications for a certain period of time, as stated in the Association Council Decision 2/97, and the duration varies from country to country.

In our country, the Regulation on Licensing of Medicinal Products for Human Use, published on January 19, 2005, has been applied for 6 years data exclusivity for reference products. The new EU drug legislation (Directive 2004/27), which entered into force in November 2005 and amended Directive 2001/83, has been for 8 + 2 + (1) years for data access for EU Member States.

The new data exclusivity period shall apply only to the reference products which have been applied for in the registry after the date on which the new directive enters into force. Hence, the first equivalent drug registration applications to be made within the data exclusivity period of 8 + 2 + (1) years will not be realized before 2013.

**Data Protection**

Protecting data against unfair commercial use of unexplained tests (pharmacological, toxicological and clinical efficacy tests) or other data that are mandatory for the relevant national authority to market a drug containing a new chemical substance; It is the obligation to not disclose this information.

The confidentiality of information presented for the purpose of obtaining a license under the provisions of the Decree Law No. 551 and the Regulation on Licensing of Medicinal Products for Human Use in our country is guaranteed.

**Medical Product Market in Turkey**

Medicinal products market is made up of medical and non-medical products in Turkey. Non-medical products includes;

* Biocidal products licensed from the Ministry of Health, some medical devices in pharmaceutical form, special medical supplies, cosmetics and dermocosmetics;
* Vitamins, food supplements and foods permitted from the Ministry of Food, Agriculture and Livestock.

In the first six months of 2016, medicinal product market value increased to 9.69 billion TL with a growth rate of 16.6% and reached to 1.05 billion boxes with a growth rate of 5.6%.

**Prescription Drug Market (Billion Box)**

**Market Shares at Box Size of Equivalent-Reference Drugs**

The reference drug market, which is at 9.63 billion TL in 2014, has grown by 15.3% in line with the growth of the pharmaceutical market in 2015 and reached 11.11 billion TL. On the other hand, the equivalent drug market has grown with a growth rate 16.4% in the market in 2015, reaching 4.76 billion TL.

**Import-domestic drug distribution**

Imported drugs grew by 16% in value to 9.02 billion TL in 2015 and the box scale increased by 8% to 0.47 billion volume. On the other hand, domestic drugs increased by 15% in 2015 and reached 6.85 billion TL. The box grew by 6% in the same period, reaching 1.40 billion volumes.

**PRODUCTION**

The Turkish pharmaceutical industry has 67 facilities producing at international standards, about 300 enterprises and 31 thousand employees and more than 11 products are being offered to our people.

While Turkey's drug expenditures constitute about one-third of total health expenditures, per capita drug spending;

Turkey 140 $

England $ 257

Germany 301 $

France $ 378

US $ 680

When the figures for the first six months of 2016 are examined, production in the manufacturing industry has increased by 4% compared to the previous year, while production in the chemistry sector in the medium technology category has grown by 7%, and production in the high technology level pharmaceutical sector has increased by 16%.

**Drugs by therapeutic groups**

Antibiotics and antirheumatic products tend to decrease when oncology and blood products tend to increase in 2015. The group with the largest share in the market with 11.1% became oncology product group in 2015. On a box-by-case basis, antibiotics continued to decline in 2015, becoming the second most commonly consumed treatment group with a share of 10.5%. The antirheumatic product group continues to increase its market share and maintain its first place.

**Consumption Rates by Therapeutic Groups**

**World Drug Market**

Turkey's pharmaceutical market reached double-digit growth in the first 6 months of 2016, rising by 16.2% to TL 8.96 billion. Box scale sales grew by 5.9% to 1 billion boxes.

As of the first 6 months of 2016, sales of reference drugs reached 477 million boxes with an increase of 13.4% in value and 6.1% in volume and 3.7% in volume. The market for generic drugs has grown by 22.6%, reaching 2.9 billion TL. Box scale of 7.9% and volume of 528 million.

**Imported-manufactured drugs**

Imported drugs increased by 12.5% and 5.5% in value and volume, respectively. By the first six months of 2016, these products have realized value of TL 4.9 billion and volume of 251 million cubic meters. The products produced domestically showed a growth (21%) above the market and realized 4.1 billion TL and 754 million volume.

**Biotechnological Drugs**

There are 183 reference biotechnology and 38 bioenergy drugs in Turkish pharmaceutical market and 13 of the bioenergy drugs are produced in our country. Biotechnological drugs have grown by 5.6% and 6.5% respectively in value and volume in the first 6 months of 2016. Biodegradable drugs are increasing in value and in the box more than biotechnological drugs, increasing their market share.

**Drugs Newly Entered to Market**

In the first six months of 2016, 193 licensed medicines were introduced into the drug market, 2 of them without a prescription and 191 with a prescription. Drugs newly entered to have been nervous system and oncology drugs. 19 nervous system (10%), 18 oncology (9%), 17 cardiovascular (9%), 15 genitourinary (8%), 14 antibiotics (7%) and 12 digestive systems medication entered into the market. 49% of the newly entering drugs constitute these treatment groups. From January to June 2016, 39 pesticides were introduced into the market, 37 of which were chemicals and 2 were reference biotechnology. Only 1 of these 39 reference products have equivalent competitors and only 6 of these products are produced in Turkey. The average price of these 39 products is 73 TL. Newly entered generic drugs are the number of 154, only 12 of which are in the imported product category. Therefore, there is tendency towards equivalent manufactured products in newly entering medicines. The average price of generic drugs is 10 TL.