

TURKISH PHARMA SECTOR REPORT

Summary



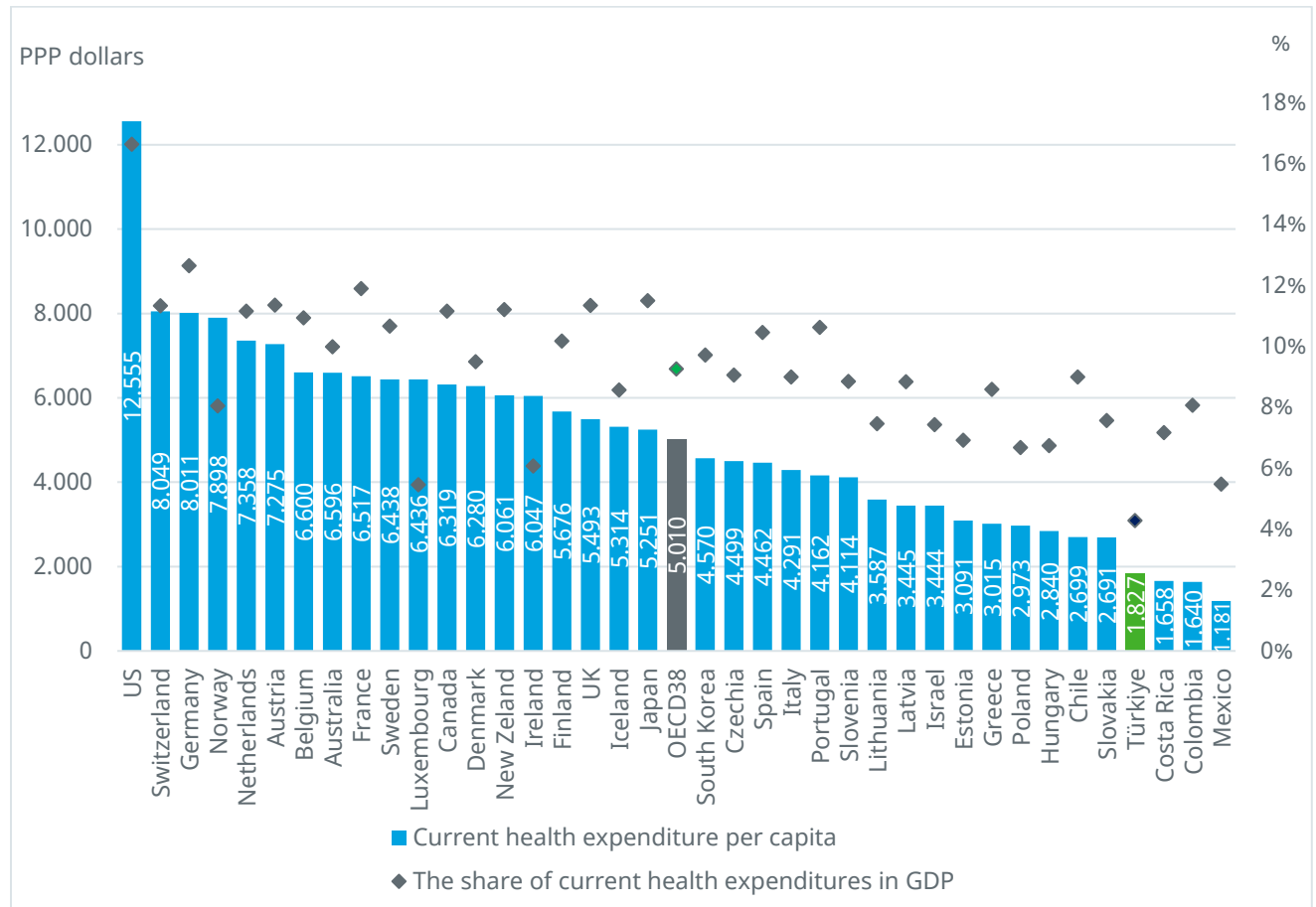
1. HEALTH SECTOR INDICATORS

Health Expenditures

According to the 2022 data, Türkiye is one of the countries with the lowest current health expenditure per capita, among OECD countries, with its 1,827 USD. The share of current health expenditure per capita in GDP in Türkiye is 4.3%, while the OECD average is 9.3%. In 2000, the share of current health expenditure in GDP in Türkiye was 4.6% while the OECD average was 7.1%. It is seen that the difference between Türkiye and the OECD average has increased over the years.

Türkiye has a health system where public health expenditures are predominant. 76.3% of health expenditures in Türkiye were publicly financed in 2022. Türkiye ranks 19th out of 38 countries in terms of the share of public healthcare expenditures, which is above the OECD average (75.7%). (2)

Current Health Expenditure per Capita and share in GDP in OECD Countries (2022)



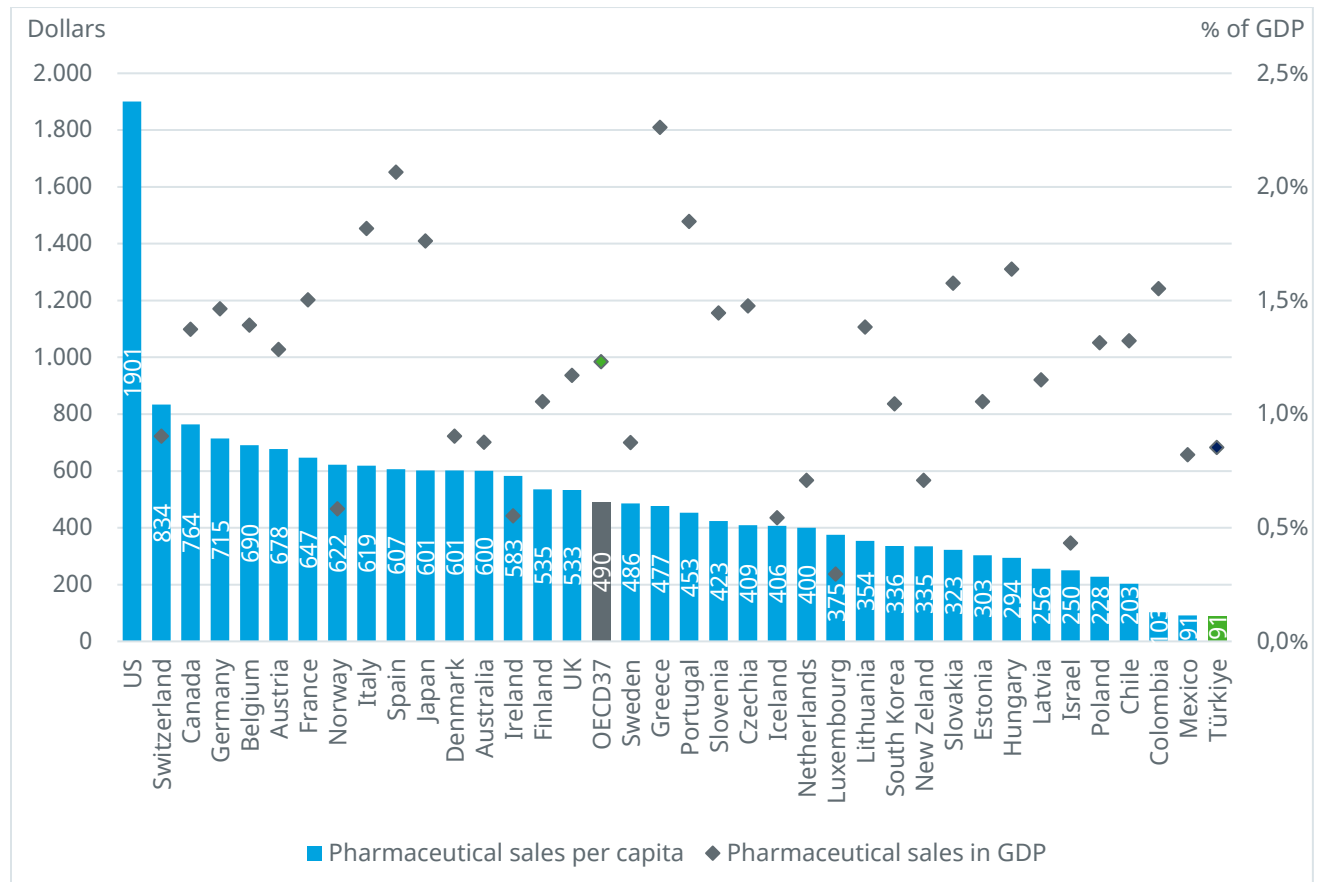
Source: OECD

Note: Data for 2022 are OECD estimates and provisional data

Pharmaceutical Expenditures

Türkiye became the OECD country with the lowest pharmaceutical sales per capita in 2022, at 91 USD. The countries with the highest pharmaceutical sales per capita were the US, Switzerland, Canada, and Germany. The ratio of pharmaceutical sales to GDP was 1.2% on average in OECD countries. In Türkiye, the share of pharmaceutical sales in GDP was at 1.1% in the years 2019-2020, and in the subsequent years, this ratio decreased, reaching 0.9% in 2022. With this ratio, Türkiye ranks 29th among OECD countries. The countries with the highest shares of pharmaceutical sales in GDP are the US, Greece, Spain, and Portugal.

Pharmaceutical Sales Per Capita and Share in GDP in OECD Countries (2022)



Source: IQVIA analysis; IQVIA Market Prognosis 2023-2027, OECD, UN World Population Projections 2022

Note: 2022 GDP data is used from OECD in current prices and current exchange rates. Costa Rica pharmaceutical market data is not available.

The OECD database does not contain financing breakdown data for total pharmaceutical expenditures of Türkiye. According to the Health Expenditure Statistics shared by Turkish Statistical Institute (TurkStat), 75.6% of health expenditures defined under "Retail sales and providers of other medical supplies" were covered by the public in 2021.

Number of Physicians and Nurses

According to the 2022 data, the number of physicians per 1000 people in European countries typically ranges between 3 and 5, whereas Türkiye falls behind with 2.2 physicians per 1000 people, below the OECD average of 3.7. Looking at the number of nurses by country, Türkiye has 2.8 nurses per 1000 people, while OECD countries have an average of 9.8 nurses per 1000 people. (2)

Number of Hospitals and Hospital Beds

When the number of active hospitals and bed capacities in countries is compared, South Korea ranks top with the highest ratio of hospitals and hospital beds per unit population. In Türkiye, the number of hospital beds per 1000 people increased by 12% to 3% between 2015-20. Türkiye has similarity with the countries such as Spain, Netherlands and Italy in terms of the number of hospital beds per population but the country lags behind in terms of the number of healthcare personnel.

Life Expectancy

When looking at one of the significant indicators of the health status in countries, which is the average life expectancy, Japan has the highest average life expectancy with 84.5 years. While the average life expectancy in OECD countries is 80.3 years, it is 78.6 years in Türkiye. Türkiye had an average life expectancy of 58.1 years in 1980, has been one of the countries with the most significant increases in average life expectancy in the last 40 years. (2)

Mortality Rates

Looking at the total mortality rate per unit population, the top 3 countries with the lowest total mortality rates are Japan, South Korea, and Australia, respectively. Türkiye has the 18th lowest death rate with 969 deaths per 100,000 population among 34 OECD countries. Looking at the causes of death, in Türkiye, 154 out of 100,000 people die each year due to cancer, while 384 die due to stroke. It is observed that the number of cancer-related deaths per unit population is lower in Türkiye compared to other countries.

In European countries with low infant mortality rates, the annual death rate recorded among 1,000 infants is generally between 1 and 3. However, Türkiye, with an infant mortality rate of 9.1, has a higher infant mortality rate than many European countries and the OECD average. (2)

2. GLOBAL PHARMACEUTICAL MARKET INDICATORS

Global Pharmaceutical Market Size

The global pharmaceutical market, which has grown at a compound annual growth rate of 6.9% in the last 5 years, reached a sales volume of 1,448 billion USD in 2022, with a growth of 7.8% compared to the previous year. When looking at the pharmaceutical market sizes of countries in 2022, the United States is the largest pharmaceutical market with 643.1 billion USD. China follows with 162.6 billion USD, and Japan with 74.6 billion USD.

Türkiye ranks 22nd with an approximate pharmaceutical market size of 7.7 billion USD, and its share in global pharmaceutical sales is 0.52%. Although the Turkish pharmaceutical market showed growth of 78.1% in local currency in 2022, when viewed in terms of US dollars, it is observed that the market deflated by 4.8% compared to the previous year. (3)

Market Share of the Top 50 Companies in the Global Pharmaceutical Market by Country

The companies that ranked in the top 50 in global pharmaceutical market sales have been identified, and their market shares in countries have been examined. It is observed that most of these companies are primarily innovative companies that develop innovative pharmaceuticals. In 2022, these identified companies constituted 87% of pharmaceutical market sales in the United States. Looking at Türkiye, the market share for these top 50 companies accounts for 47% of Türkiye pharmaceutical market. Türkiye has similar ratios with developing countries such as Brazil (51%) and Thailand (46%). (3)

Patent Protected Pharmaceutical Market

Patents protect the property rights of pharmaceutical companies over their newly developed treatments and provides a competitive advantage to researcher companies. The share of patent-protected products in the total pharmaceutical market is higher in developed countries, particularly in the US, where drug development activities are intensively carried out, compared to other countries. In 2022, the share of patent-protected products in the pharmaceutical market was highest in the US with 64%. In Türkiye, patent-protected products accounted for approximately 15% of the pharmaceutical market value in 2022. Türkiye had a lower patent-protected market share than Poland and Greece besides developed countries. (3)

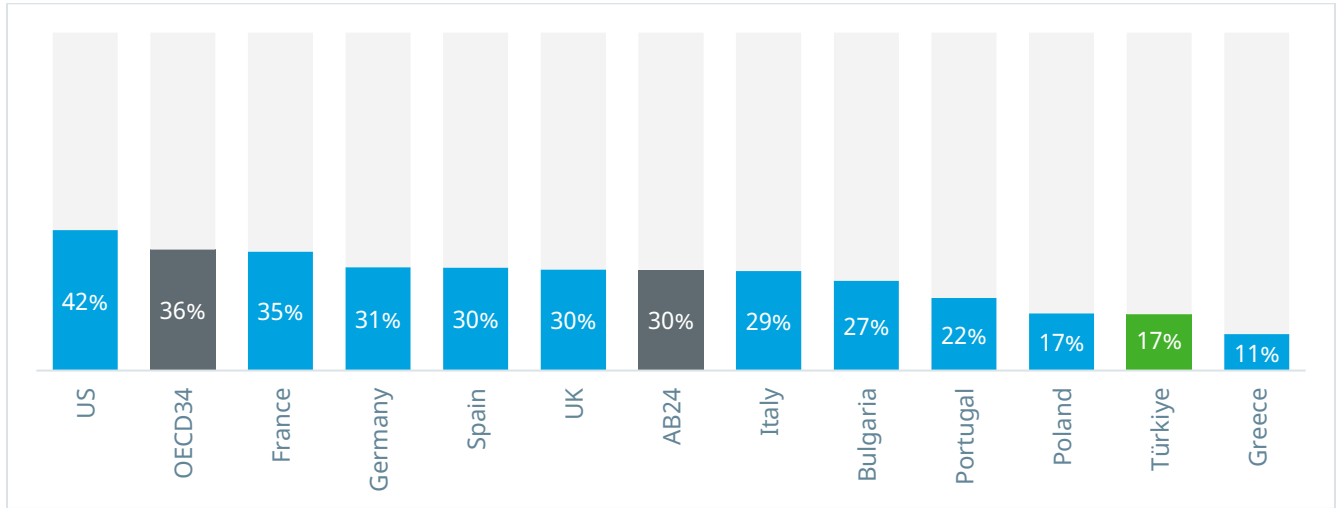
When examining the distribution of products with ongoing patent protection in Türkiye as of 2022, approximately 57% of the sales value comes from treatments in the field of oncology, while 20% comes from treatments related to the digestive system and metabolism area.

Biotechnological Pharmaceuticals Market

According to the biotechnological pharmaceutical market definition developed for this report, there are 124 reference biotechnological drugs and 28 biosimilar drugs available in the Turkish pharmaceutical market in 2022. In 2022, approximately 1.1 billion USD (18.9 billion TRY) sales of reference biotechnological drugs and 64.3 million USD (2.6 billion TRY) sales of biosimilar products were recorded in the Turkish pharmaceutical market.

While biotechnological drugs make up 16.6% of the Turkish pharmaceutical market, this ratio is 35.8% on average in OECD countries and 29.9% on average in EU member countries.

Share of Total Biotechnological Market in Pharmaceuticals Market in Türkiye and Selected Countries (2022)



Source: IQVIA analysis, IQVIA MIDAS

Note: Total biotech market includes reference biotech and biosimilar products

Mergers and Acquisitions in the Pharmaceutical Industry

Pharmaceutical companies often engage in mergers and acquisitions to expand their portfolios, strengthen their R&D activities, or enter new markets. In recent deals, large pharmaceutical companies that dominate the market have strengthened their portfolios and R&D capabilities by acquiring small biotechnology companies that focus on innovative drug development.

The acquisition of Celgene, which develops innovative treatments in the fields of oncology and immunology, by the US-based pharmaceutical company Bristol-Myers Squibb in 2019 for 80.3 billion USD is recorded as the highest-value deal in the last 20 years globally. (5)

The largest mergers and acquisitions in the Turkish pharmaceutical sector in the last 20 years are shown. In 2012, the acquisition of Mustafa Nevzat Pharmaceuticals by the US-based pharmaceutical company Amgen for 669 million USD was the highest value deal in the history of the Turkish pharmaceutical industry. Later renamed Gensenta İlaç, Mustafa Nevzat İlaç became part of the Eczacıbaşı Group in 2022 with an acquisition worth 135 million USD. (6)

The Top M&A Deals in the Turkish Pharmaceutical Industry in the Last 20 Years

Year	Target Company	Investor Company	Share (%)	Deal Value (Million Dollars)
2012	Mustafa Nevzat İlaç	Amgen	95.6	669.2
2007	Eczacıbaşı Jenerik İlaç	Zentiva	75	606.5
2009	Eczacıbaşı-Zentiva Sağlık Ürünleri		25	193.1
2020	OM Pharma	Abdi İbrahim	28.5	549.0
2019	Sanovel İlaç	MCP - Morgan Stanley&Co LLC	30	200.0
2006	Biofarma İlaç	PiLS - CVCI	100	200.0
2022	Gensenta (Previously Mustafa Nevzat)	Eczacıbaşı İlaç	100	135.0
2011	Frik İlaç	Recordati	100	130.0
2015	Neutec Toplam Kalite	Takeda	100	121.4
2003	Fako İlaç	Actavis Grubu (Previously Pharmaco)	89	60.0
2006			11	20.4
2008	Yeni İlaç	Recordati	100	60.0
2008	Monrol Nükleer Ürünler	Eczacıbaşı İlaç	50	43.4
2008	Frik İlaç	İş Girişim Sermayesi	17	15.3

Source: EMIS

Note: Deals with a disclosed deal value of more than 10 million USD in the last 20 years are shown.

MCP: Metric Capital Partners, PiLS: Partners in Life Sciences, CVCI: Citigroup Venture Capital International

3. TURKISH PHARMACEUTICAL MARKET INDICATORS

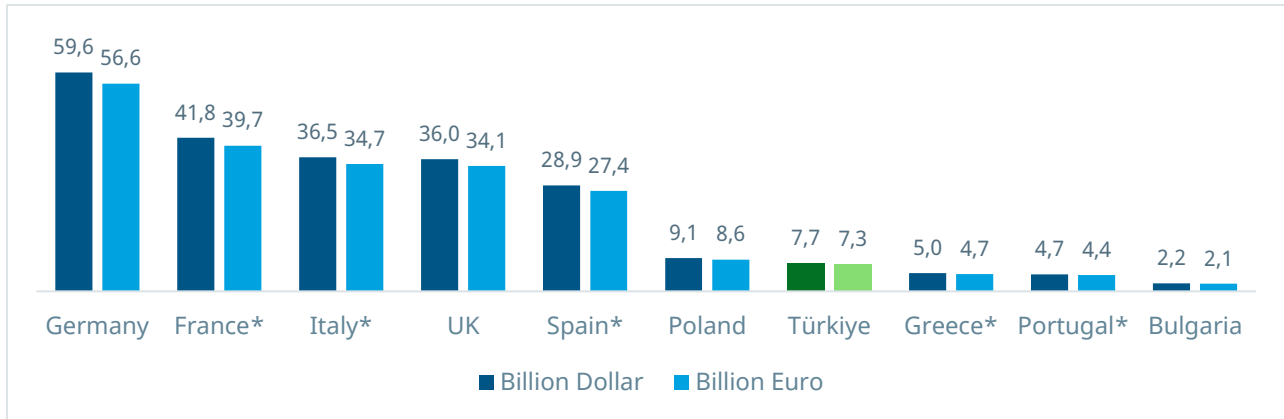
Türkiye is one of the most important emerging markets for the pharmaceutical industry due to factors such as the country's advanced healthcare infrastructure, improvements in diagnostic and treatment facilities, increasing health awareness, migration, and rapid population growth.

Comparison of the Turkish Pharmaceutical Market with Other Countries

In addition to the reference countries in the pricing legislation, Germany, UK, Poland, and Bulgaria are selected to benchmark Türkiye's pharma market performance against other countries, considering market size and population parameters. The pharmaceutical market size in Türkiye reached 7.7 billion USD (7.3 billion EUR) in 2022. Accordingly, while Türkiye ranks ahead of countries such as Greece and Portugal in terms of pharmaceutical market size, it lags behind countries such as Germany and France, with which it is more similar demographically.

Turkish pharmaceutical market had 7.9% growth in unit sales between 2020 and 2022. Despite being the country with the highest growth in terms of units sold among selected countries, Türkiye was the only country where the pharmaceutical market has shrunk in terms of dollars. The main reasons for decrease of the pharmaceutical market in dollar terms, despite the high growth rate in local currency terms, are the rapid depreciation of the Turkish Lira and the fact that the fixed drug exchange rate used in drug pricing remains very low compared to the real exchange rate. (7)

Pharmaceutical Market Size by Country (2022)



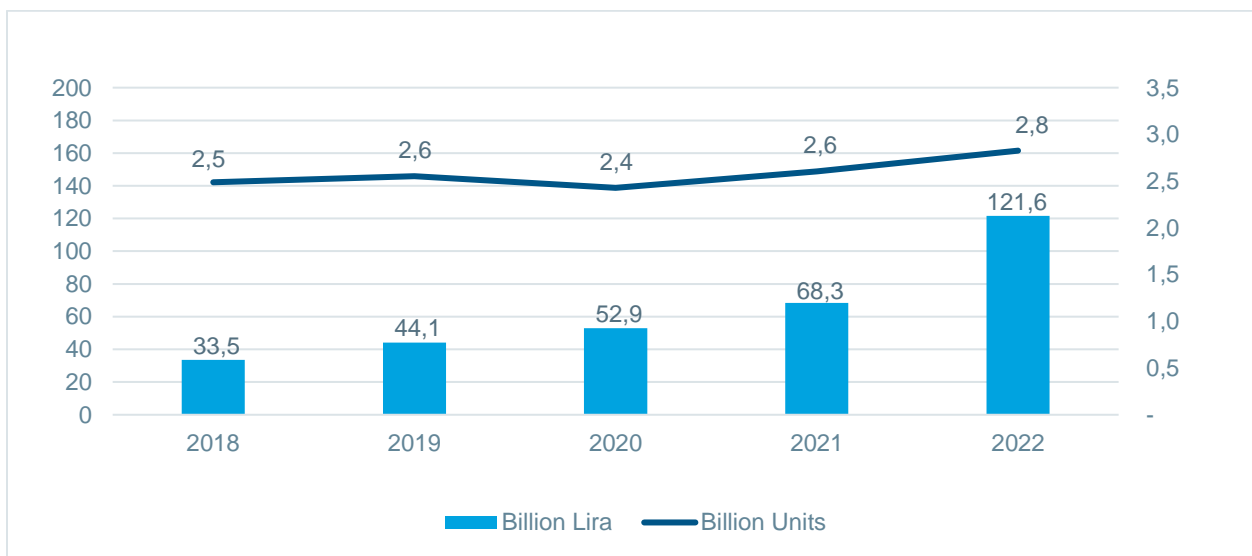
Source: IQVIA Market Prognosis 2023-2027

*Reference countries included in Türkiye's drug pricing legislation

Turkish Pharmaceutical Market Development

Turkish pharmaceutical market reached 121.6 billion TRY in 2022 by growing 78% compared to the previous year. On volume basis, 2.8 billion units are sold in 2022, with an 8.5% increase. (3)

Turkish Pharmaceutical Market Size (2018-2022)



Source: IQVIA MIDAS Database

Factors Affecting Turkish Pharmaceutical Market Growth

Analyzing the factors that contributed to observed growth of 53.3 billion TRY in the Turkish pharmaceuticals market in 2022, the price increase had a contribution of 86.5%, the increase in unit sales of existing products contributed by 17.7%, while the contribution of newly introduced products and packages to the growth remained low. Therefore, it can be said that the primary driver of the growth in the Turkish pharmaceutical market in 2022 was price increases.

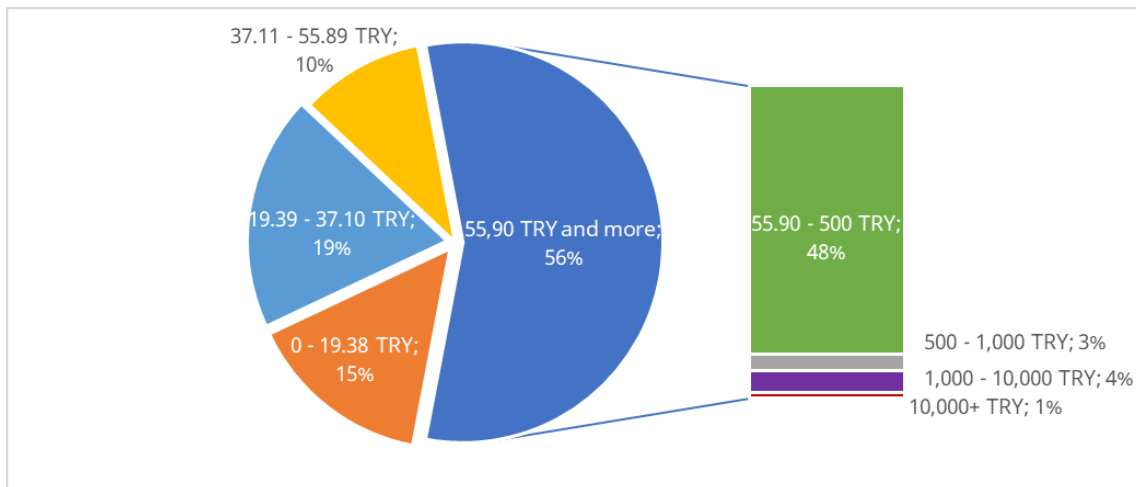
Average Pharmaceutical Unit Prices in Türkiye and Other Countries

Different pricing policies applied in the determination of drug prices lead to varying average drug prices in different countries. In 2022, the average unit price in the pharmaceutical market was 16.9 USD in the United Kingdom, 10.4 USD in Spain, and 10.1 USD in Italy. In Türkiye, where the average unit price is 2.6 USD, drug prices are significantly lower than the price levels in other countries (3). Several factors that result in this are the reference pricing system, the use of a fixed euro exchange rate in drug pricing, mandatory public discounts, and delayed access to high-cost innovative treatments in the market.

Distribution of Pharmaceutical Sales According to Price Levels in Türkiye

In Türkiye, the discount rates used in determining the reimbursed prices of pharmaceuticals are based on the product group and the sales price to the wholesaler as specified in the Health Implementation Communiqué. The group of products priced at 55.90 TRY and above accounts for 56% of total pharmaceutical market sales. Looking at the sub-breakdown of this group where most of the sales are, reveals that products priced above 500 TRY account for approximately 8% of the total pharmaceutical market value, while products priced above 10,000 TRY account for only 1% of the market.

Pharmaceutical Sales by Price Levels (2022)



Source: IQVIA REHO Database

Note: Price levels belong to the SUT announced in December 2022. Price levels are revised in February, July, and December in 2022. Prices are calculated as net TL sales divided by net unit sales.

Pharmaceutical Prices by Patent Status in Türkiye

In 2022, the average unit price of medicines with patent protection in Türkiye is calculated as 539.14 TRY. The average unit price of products without patent protection, which constitute most of the market in terms of volume, was realized as 40.10 TRY and the average unit price of the market was TRY 43.03. (3)

Access to Innovative Treatments Statistics

The W.A.I.T. 2022 report prepared by IQVIA evaluates the accessibility of 168 innovative treatments approved by the European Medicines Agency (EMA) countries between 2018 and 2021. Germany ranked first with an accessibility rate of 88%, followed by developed countries such as Italy, Austria, Denmark, Denmark, Switzerland, France, and UK. In the study, in which the EU average was 45%, Türkiye was one of the countries with low access to the innovative treatments, with access to 10 innovative treatments (6%) as of 2023. (9) When the findings of the previous W.A.I.T. studies conducted between 2018 and 2022 are analyzed, the rate of access to innovative treatments in Türkiye, which was 20% in the 2018 study, decreased over the years to 6% in 2022.

Rare Diseases and Orphan Drugs

Türkiye is taking basis of the EU definition of rare diseases. With more than 5 million individuals estimated to have rare diseases, the prevalence of rare diseases in Türkiye is thought to be higher than in European countries due to the high rate of consanguineous marriages. It is estimated that approximately 30 million people in Europe and approximately 300 million people worldwide are affected by rare diseases. In many countries around the world, treatments that are used for a limited number of patients are defined as "orphan drugs" and their R&D activities and market access processes are supported by various legal regulations. However, Türkiye has not implemented any legal regulations specifically for orphan drugs. (10) In the W.A.I.T. study, the accessibility in countries to 61 treatments with orphan drug status that received regulatory approval by the EMA between 2018 and 2021 was examined. In the study, Türkiye, which has access to 4 orphan drugs, was one of the countries with the lowest access to orphan drugs with an access rate of 7% where the EU average was 39%. (9)

Digital Health and Telemedicine

Digital health and telemedicine applications have started to be utilized more frequently, especially during and after the pandemic period. While examinations in Türkiye previously required the physical presence of the patient, the framework for the provision of remote health services was determined with the regulation published by the Ministry of Health in February 2022.

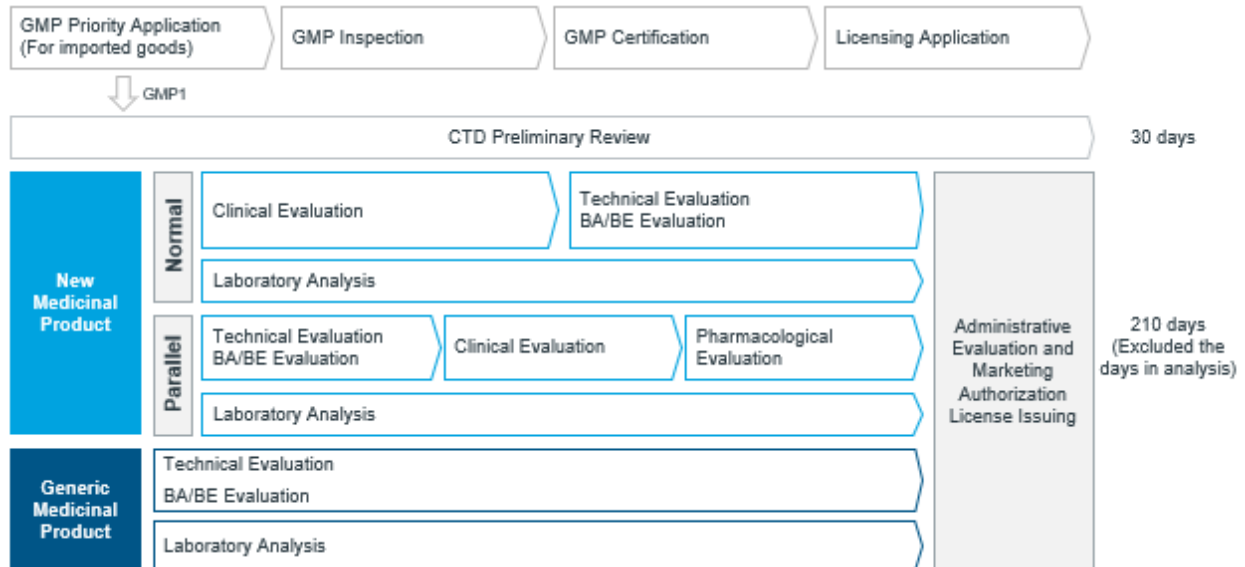
Accordingly, institutions affiliated to the Ministry of Health or private health institutions that have obtained a remote health service activity permit can provide the remote health services specified in the relevant regulation. (14)

APPENDIX

Appendix-1. Marketing Authorization Process in Türkiye

In Türkiye, the medicines licensing process is carried out by Turkish Medicines and Medical Devices Agency (TITCK). This process consists of preliminary evaluation, scientific evaluation, and administrative evaluation. For products to be authorized, production sites need to obtain Good Manufacturing Practices (GMP) certificate by TITCK. Licensing and GMP inspection can be carried out simultaneously for the products with priority status. After the application is submitted, a preliminary review is completed within 30 days. After informing applicant about the application status, missing documents need to be completed within 30 days. The completed documents are evaluated by the TITCK within 30 days. The licensing process of eligible applications can be initiated in certain periods of the year. For original medicinal products, clinical, technical, bioavailability (BA) / bioequivalence (BE) and pharmacological evaluations are performed. For generic medicinal products applications, clinical and pharmacological evaluations are not performed. The list of products licensed by the TITCK is announced on the official website of the TITCK and once a year on the Official Gazette.

Marketing Authorization Process in Türkiye



Source: TITCK

Appendix-2. Drug Pricing System in Türkiye

Reference pricing has been used in the Turkish pharmaceutical market since 2004 as a method used in the pricing of pharmaceuticals. The price of the product in the country with the lowest ex-manufacturer price among 5 reference countries (France, Italy, Spain, Portugal and Greece), import country and batch release country is selected. The reference price is multiplied by the fixed Euro exchange rate used to calculate the price of the products in Turkish Lira. Original medicinal products without generics receive the full reference price, while generics and original products where generics are available take 60% of the reference price. When determining the public reimbursement price of a medicine to be reimbursed by the Social Security Institution (SSI), different public discounts are applied depending on different factors such as whether it is original or generic, presence of generics in the market, price protection status and the ex-manufacturer price of the medicine.

Drug Pricing System in Türkiye

Process	Reference Pricing	Fixed Exchange Rate	Reference Price Factor	Mandatory Public Discount
Reference drugs with no equivalents	Lowest ex-man price among reference countries is considered  Greece France Spain Portugal Italy + Batch-release country + Imported country	Reference price in Euro is multiplied with the latest fixed exchange rate, to get the price in Turkish Lira	100%	41% (72,94 TRY and higher) 31% (48,42 – 72,93 TRY) 10% (25,30 – 48,41 TRY) 0% (25,29 and less)
Reference drugs with generics and generic drugs			60%	28% (72,94 TRY and higher) 18% (48,42 – 72,93 TRY) 10% (25,30 – 48,41 TRY) 0% (25,29 and less)
Price protected drugs*			80%	28%** (72,94 TRY and higher) 10% (48,42 – 72,93 TRY) 0% (25,30 – 48,41 TRY) 0% (25,29 and less)

Source: IQVIA analysis; *Pricing Rules on Medicinal Products for Human Use*

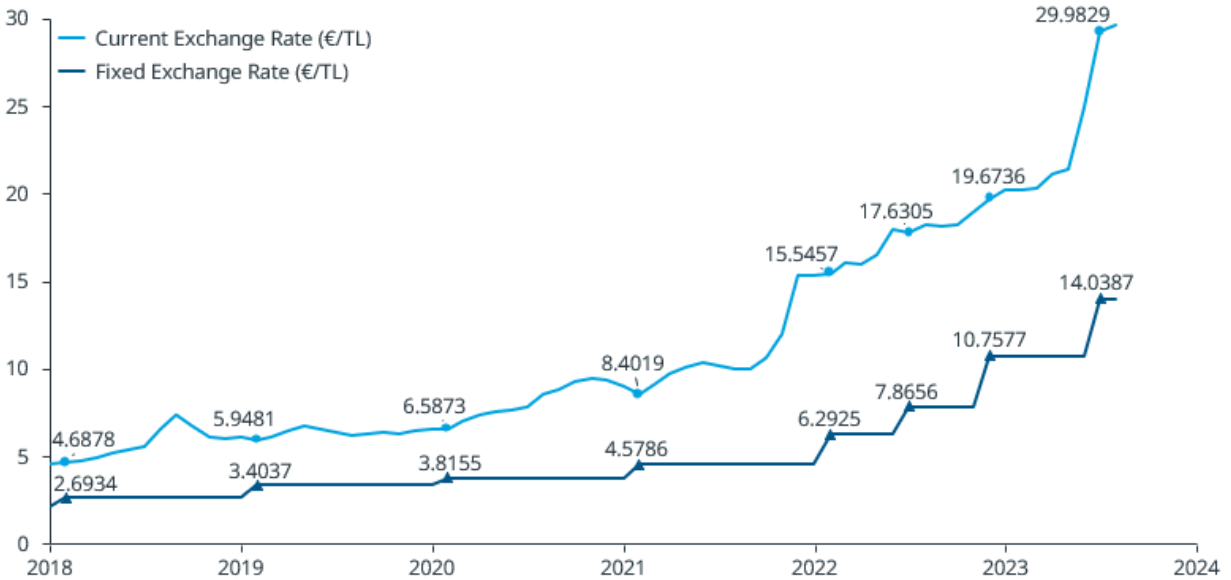
* A product, any pharmaceutical form of which was first marketed in the world before 8/1/1987

**40% discount is applied for price protected products without reference and cost card

Appendix-3. Fixed Exchange Rate Used in Drug Pricing

Drug prices in Türkiye are calculated using a fixed exchange rate. According to the legislation, the fixed Euro value to be used in the pricing of medicines is calculated by taking 60% of the average Euro exchange rate of the previous year (70% until 2018) and updated in February of each year. However, due to the rapid rise of the exchange rate, the fixed exchange rate was updated more than once in a year in 2022 and 2023. At the last update on July 23, 2023, the fixed drug rate was calculated as 47% of the current exchange rate. The fact that the fixed exchange rate is well below the current exchange rate creates problems especially in the procurement of imported medicines. This situation poses a risk to the availability of critical medicines and might have a negative impact on the availability of innovative medicines in Türkiye in the medium and long term. The high difference between the current exchange rate and the fixed drug rate has a negative impact not only on importer companies but also on local pharmaceutical manufacturers due to higher production costs.

Current Exchange Rate and Fixed Drug Rate



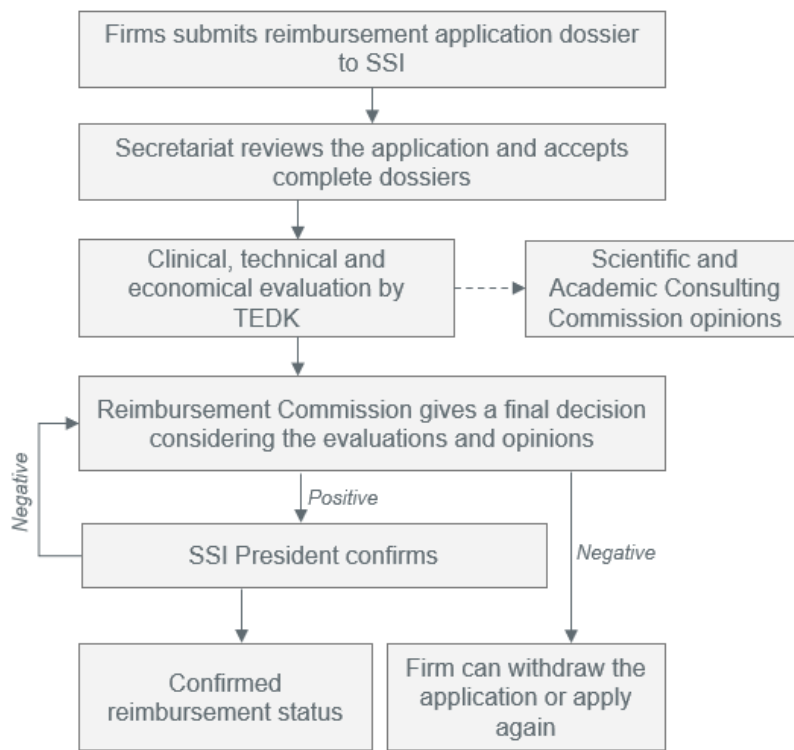
Source: IQVIA analysis; TCMB, TITCK

Fixed Exchange Rate update dates: Feb 2018, Feb 2019, Feb 2020, Feb 2021, Feb 2022, July 2022, Dec 2022, July 2023

Appendix-4. Drug Reimbursement Process in Türkiye

Pharmaceutical companies apply to the SSI to receive public reimbursement after their products receive regulatory approval. Accepted applications go through clinical, technical, and economical evaluations by the Medical and Economic Evaluation Commission (TEDK). If needed, the commission may ask opinion from scientific and academic advisory commissions. The Drug Reimbursement Commission decides on the reimbursement by considering the evaluations and submits to the SSI Presidency. Reimbursement decisions are published in the Official Gazette following the approval from the SSI President. Drugs licensed and reimbursed in Türkiye are published in the Annex 4/A list of the Health Implementation Communiqué (SUT) (17).

Drug Reimbursement Process in Türkiye



Source: IQVIA analysis; SSI Pharmaceutical Reimbursement Regulation

Besides the regular reimbursement process, "Alternative Reimbursement" agreements pave the way for innovative medicines with high treatment costs to be included in the reimbursement system. These agreements have been in place in Türkiye since 2016. There are different types of agreements such as price discounts, cap agreements, price-volume agreements, portfolio agreements and value-based payment agreements. In Türkiye, applications for the alternative reimbursement model are evaluated and decided by the Alternative Reimbursement Commission and submitted to the Health Services Pricing Commission for approval. Agreement details between the SSI and the pharmaceutical company, such as payment terms and price discounts, are kept confidential for alternative reimbursement products. (18)

Products that are not licensed in Türkiye or licensed products that cannot be found for the treatment of the patient can be supplied from abroad. Drugs procured from abroad on prescription basis and reimbursed by the SSI in this way are published in the Annex-4/C list of the SUT. The supply of the relevant medicines is carried out through the Turkish Pharmacists Association and Ibn-i Sina Health Social Security Center.

Appendix-5. Important Developments in Turkish Pharmaceutical Industry

- ❖ Fixed Euro exchange rate updates used in the drug pricing
- ❖ Amendment to the Reimbursement Regulation
- ❖ Amendment to the Alternative Reimbursement Regulation
- ❖ Covid-19 normalization
- ❖ Increasing number of immigrants
- ❖ Drug shortages
- ❖ Earthquake disaster (Feb 6, 2023)
- ❖ Presidential and parliamentary elections (May 14, 2023)
- ❖ Change in VAT regulation (July 10, 2023)
- ❖ Increasing activity in health tourism
- ❖ Increasing physician migration abroad
- ❖ Health infrastructure developments and completed city hospitals
- ❖ New opening "Centers for Healthy Aging" (YAŞAM)

4. PRODUCTION

In addition to the production of reference and generic drugs, there is limited production of active ingredients in Türkiye. In pharmaceutical production, there are drugs that cannot be produced in Türkiye for reasons such as requiring advanced technology or demand in small quantities in the country. (34) (35) Looking at the production performance of the Turkish pharmaceutical sector, according to TurkStat data, the production value of the "Manufacturing of Basic Pharmaceutical Products and Pharmaceutical Materials" sector was realized as 99 billion TRY in 2022. (36)

An analysis of the distribution of local and imported pharmaceuticals reveals that 86% of the Turkish pharmaceutical market in 2022 is composed of locally produced products in unit terms, while this ratio is 47% in value terms. In 2022, 34% (0.8 billion units) of the 2.4 billion units of locally produced products sold in the Turkish pharmaceutical market come from reference medicines, while 90% (TRY 51.5 billion) of the TRY 57.1 billion worth of locally produced pharmaceutical sales come from reference medicines. (37) In addition, 63% of Türkiye's biosimilar market, worth 1.6 billion TRY, is produced locally. Enoxaparin sodium, epoetin alfa, filgrastim, infliximab, insulin glargine and trastuzumab are biosimilar molecules produced in Türkiye. (37)

According to TurkStat Annual Industry and Service Statistics, in 2022, the number of enterprises in the Manufacturing of Basic Pharmaceutical Products and Pharmaceutical Materials group is 717 and the number of employees is 47,511. (36) As of September 2023, there are 109 pharmaceutical and radiopharmaceutical production facilities, 12 raw material production facilities and 6 herbal supplements and dietary food production facilities approved by the TITCK in Türkiye. (38)

5. FOREIGN TRADE

HS codes 2936, 2937, 2938, 2939, 2941, 3001, 3002, 3003, 3003, 3004, 3006, 2936, 2937, 2938, 2939, 2941, 3001, 3002, 3003, 3004, 3006 under the Harmonized System were included in the analysis to identify pharmaceutical and pharmaceutical products.

In 2022, global pharmaceutical exports reached 820 billion USD, with the top 10 exporting countries accounting for 79% of total exports. Germany (126 billion USD), Switzerland (102 billion USD) and the US (87 billion USD) were the top three exporters of pharmaceuticals globally, while Türkiye ranked 26th with 1.9 billion USD in pharmaceutical exports.

The top 3 global importers of pharmaceuticals are the USA (174 billion USD), Germany (81 billion USD) and Belgium (57 billion USD). Developed countries generally import pharmaceuticals from each other, while their imports from developing countries are limited. Türkiye, on the other hand, imported 5 billion USD of pharmaceutical products in 2022.

The volume of pharmaceutical exports in Türkiye increased at a compound annual growth rate of 11.9% between 2018 and 2022 and reached 76.1 million kilograms in 2022, which represented a 9.1% growth compared to the previous year. The growth in the value of pharmaceutical exports lags behind the volume-scale growth performance. The pharmaceutical export price per kilogram in Türkiye declined after 2020, reaching 24.9 USD in 2022. An analysis of pharmaceutical export prices per kilogram by country shows that Türkiye, with a price per kilogram of 24.9 USD, has a lower export price level than many European countries. (41)

In 2022, Türkiye exported pharmaceuticals to 182 countries, mainly in the Middle East, Asia, and Europe regions. South Korea ranked first, accounting 22.8% of Türkiye's pharmaceutical exports with 433.5 million USD. South Korea is followed by Iraq, Kazakhstan, Uzbekistan, and Iran.

Türkiye imported approximately 5 billion USD worth of pharmaceuticals from 110 countries in 2022. The US and European countries, where R&D and innovation are strong, have a significant share in Türkiye's pharmaceutical imports. Germany ranked first, accounting for 19.8% of Türkiye's pharmaceutical imports with 982.4 million USD. Germany is followed by the US, South Korea, China and Switzerland.

6. INVESTMENT

Looking at the countries with available investment data for the pharmaceutical sector in the OECD, the US is the top country that invests in the pharmaceutical industries of other countries with FDI outflows of 19.1 billion USD in 2021. Ireland, France, and Sweden were the other leading countries in FDI outflows in 2021. Companies in Türkiye realized FDI outflows of 69 million USD in 2020 and 12 million USD in 2021 in the pharmaceutical sector. (43)

Looking at FDI inflows, the US, which is the leader in the global pharmaceutical industry and home to the headquarters of many multinational pharmaceutical companies, was the top country of foreign investment in the pharmaceutical industry in 2021 with 60.6 billion USD in FDI inflows. The US was followed by Ireland with FDI inflows of 7.4 billion USD. In Türkiye, FDI in the pharmaceutical industry was 111 million USD in 2019 and 277 million USD in 2020, but 37 million USD of foreign investment left the country in 2021. (43)

Today, many countries offer incentives to increase foreign capital inflows, but it should be considered that incentive programs alone are not sufficient for FDI inflows. Macroeconomic growth, qualified labor force, predictability, stability, and transparency of the country of investment, practices regarding intellectual property rights, legal framework, policies and regulations in the country, strategic objectives of the country in the sector are among the factors affecting FDI inflow. (44)

Intellectual property rights are important for supporting innovation and investment in the pharmaceutical industry. (51) Strong protection of these rights has been an important factor affecting trade and investment decisions in the pharmaceutical industry. Therefore, a positive relationship between intellectual property rights and investments in the sector is expected. (52) Depending on the different regulations for the protection of intellectual property rights in countries, the relationship between R&D investments can be expected to vary across countries or regions. When comparing the share of pharmaceutical research and development (R&D) expenditures by businesses and patent-protected pharmaceutical sales within the pharmaceutical market in countries, it is observed that in many countries leading in pharmaceutical R&D expenditures, the shares of patent-protected drugs are generally high.

Strong intellectual property protection, along with factors such as a predictable and stable political climate, a qualified workforce, sustainable policies for market access, and capabilities in production and logistics, play crucial roles in a country's ability to attract high-tech and high-value investments. (53) Türkiye's ability to become competitive with other countries in the biopharmaceutical sector, both in terms of investment amount and added value, can be achieved by increasing investments and creating a more attractive investment environment through improvements in these relevant factors.

7. R&D ACTIVITIES

R&D Value Chain and Processes

R&D activities for innovative medicines cover a long and complex process. The process starts with basic research and continues with drug discovery and preclinical studies. Following the successful completion of preclinical studies, clinical trials are conducted to verify the safety and efficacy of the target treatment on humans. After receiving regulatory approval from authorities, monitoring of products continues after they are launched on the market. In summary, the development of a single new drug involves a long R&D process that starts with 5,000-10,000 candidate molecules and takes up to 15 years to complete. The average cost of developing a new drug is estimated at approximately 2.6 billion USD. Drug development costs have increased exponentially over the last 20 years. The main reason for that is targeting more complex diseases with advances in science and technology and the development of innovative therapies that reshape the field, such as gene therapies. (54)

Trends in R&D in the pharmaceutical industry have changed over time, driven by scientific and technological developments. In addition to the efforts of big pharmaceutical companies, startups and small-size biotechnology companies have started to play an active role in pharmaceutical R&D processes. According to the Global R&D Trends 2023 report prepared by IQVIA, 67% of new drugs coming to the US market in 2022 are developed by emerging biopharma companies. Emerging biopharma companies are involved in two-thirds of new treatments developed today. Considering that this ratio was 51% in 2017 and 33% in 2002, it is seen that biopharma companies have taken an important role in pharmaceutical R&D activities by increasing their influence over time. (55)

In line with this trend, there has been an increase in the number of biotech startups acquired by big pharmaceutical companies. (56) The most high-profile acquisition of 2022 was the 27.8 billion USD acquisition of rare disease startup Horizon by Amgen. The total value of the 10 largest biopharma M&A deals in 2022 was approximately 69 billion USD. (57)

R&D Expenditures in the Pharmaceutical Industry

OECD provides a breakdown of R&D expenditures by industry for financial and non-financial companies. A country-by-country comparison of the share of the pharmaceutical R&D expenditures across all industries shows that 33.4% of total R&D expenditures spent by companies in Switzerland is allocated to the pharmaceutical industry. Other countries with a high share of pharma in R&D expenditures are Belgium and Denmark. In 2020, the US, whose pharmaceutical R&D activities accounted for 16.8% of total R&D expenditures, was the country with the highest value of R&D investment in the pharmaceutical industry (92 billion USD). In Türkiye, the share of pharmaceutical investments in total R&D investment is 1.6%, which is lower than many OECD countries. (2)

Clinical Trials

In the Turkish pharmaceutical industry, there are 42 R&D centers approved by the Ministry of Industry and Technology and 15 phase 1 clinical research centers approved by the Ministry of Health.

According to the number of industry-sponsored clinical trials started in 2022, the US is the undisputed leader globally. Among the other leading countries in clinical trials, you'll find China, the EU5 countries (France, Germany, Italy, Spain, and the United Kingdom), Australia, and Canada. Türkiye, with 143 industry-sponsored clinical trials initiated in 2022, ranked 20th. When it comes to the number of new trials initiated, Türkiye lags countries like Taiwan, Hungary, Brazil, and Argentina. (60)

Similar to the global trend, there was no major change in the number of clinical trials initiating in Türkiye every year until 2021. Due to Covid-19 studies, the number of new clinical trials started in 2021 was higher than the level seen in previous years. In 2022, 143 new clinical trials were initiated in Türkiye, which is below the number of clinical trials that were initiated in the pre-pandemic period. Phase 3 studies had the highest share among all clinical trials. In Türkiye, 96 of the 143 studies started in 2022 were phase 3 and 36 were phase 2. Phase 1 and Phase 4 trials are conducted in smaller numbers. (60)

According to the AIFD Economic Value Survey, the investment in clinical research in Türkiye by research-based pharmaceutical companies in 2022 was realized as 239 million USD (40) The contributions of clinical research to the Turkish economy, healthcare system and patients are highly valuable. According to a study conducted by IQVIA in 2020, it was estimated that clinical research conduct in Türkiye creates an annual economic value of 327.7 million USD per year. The 11th Development Plan also emphasizes the critical role of clinical research and sets policy objectives for this area (54).

Looking at the sponsor companies of clinical trials started in Türkiye in the last 5 years, MSD ranked first with 93 studies, while other leading multinational pharmaceutical companies were Novartis (75 studies), Roche (73 studies) and AstraZeneca (71 studies) (60).

Startup Ecosystem and Innovation

According to the "Global Startup Ecosystem Index 2023" report, Türkiye ranks 45th among the 100 countries with the best startup ecosystems. According to this assessment, Türkiye's startup ecosystem performed close to countries such as Croatia, Greece, and Argentina, but lagged behind most EU and OECD countries. (61)

According to the EU Innovation Scoreboard data published annually by the EU Commission, which measures the innovation and research performances of EU members and other European countries, Türkiye's innovation score in 2022 was determined as 50.92. In the study, where the EU average was measured as 107.92, Türkiye performed similarly to Balkan countries such as North Macedonia, Albania, and Bulgaria in the field of innovation and research.

Startups with a valuation exceeding 1 billion USD are defined as 'unicorns'. According to July 2023 data shared by CBInsights, there are 1221 'unicorns' in the world. Of these, the number of startups operating in the health and life sciences sector is 122. While the US and China host the most unicorn startups in the healthcare sector, there are no unicorn startups in Türkiye. (63)

Innovation and Startup Ecosystem in Healthcare and Pharma in Türkiye

Various policy documents include goals to increase Türkiye's competitiveness in the global area by developing new pharmaceuticals and health technologies. The pharmaceuticals and medical devices sector is identified as one of the six priority sectors in the 11th Development Plan.

On the other hand, pharmaceutical companies have also established various programs to support entrepreneurship activities in Türkiye and provide support to promising startups in the health and pharmaceutical sector.

In 2022, startups operating in Türkiye reached a total investment value of more than 1.8 billion USD through 277 investment agreements. The top three leading sectors in terms of investment value were delivery-logistics, gaming, and software. The total investment value of 21 startups in the health and biotechnology sectors amounted to 7.5 million USD. (77)

Number of Patents in Biotechnology in the World and Türkiye

According to the World Intellectual Property Organization (WIPO) data, a total of 9336 patents were obtained in biotechnology globally in 2022. In Türkiye, a total of 148 patents have been obtained in biotechnology in the last 12 years and 58% of these patents were obtained between 2020 and 2022. It is seen that Türkiye has a small share in the world in biotechnology patent applications but has shown a significant increase in the number of patents in recent years. (78)

Initiatives Conducting Biotechnological Activities in Türkiye

In 2020, the number of enterprises engaged in biotechnology activities in Türkiye was 499. Among these, 36 enterprises have foreign partnerships. (79) When the enterprises are analyzed according to their field of activity, the highest number of enterprises are in DNA/RNA studies. Synthetic biotechnology and process biotechnology are the fastest growing areas compared to 2019. (79) In 2020, approximately 74% of the startups engaged in biotechnology activities in Türkiye consisted of small businesses with 1 to 9 employees. (79)

REFERENCES

1. WORLD HEALTH ORGANIZATION (2018), *Global reference list of 100 core health indicators (plus health-related SDGs)*.
2. OECD.Stat (2022), Accessed: August 2023,. <https://stats.oecd.org/>. [Online]
3. IQVIA MIDAS Database. [Online]
4. *[Biyoteknolojik İlaçlar (2020), https://biyoteknolojikilaclar.net]* [Demir-Dora D. (2017). *Biyofarmasötik ürünlerin geliştirilmesinde biyobelirteçler. Türkiye Klinikleri J Pharmacol-Special Topics; 5(2):sf. 75-83*].
5. Pitchbook (2022), M&A Deals, Accessed: August 2023. [Online]
6. EMIS (2022), M&A Deals, Accessed, August 2023. [Online]
7. IQVIA, Market Prognosis Global (2023). [Online]
8. *IQVIA (2023), Market Prognosis Greece Q2 2023*.
9. EFPIA (2023), Patients W.A.I.T. Indicator Survey 2022. [Online]
10. *IQVIA (2020), Türkiye İçin Klinik Araştırma Stratejisinin Faydaları*.
11. WHO (2019), *Recommendations on Digital Interventions for Health System Strengthening. Geneva: World Health Organization; 1, Introduction, Url: https://www.ncbi.nlm.nih.gov/books/NBK541905/*.
12. *IQVIA (2021), Digital Health Trends 2021*.
13. OECD (2023), *The COVID-19 Pandemic and the Future of Telemedicine, OECD Health Policy Studies, OECD Publishing, Paris, https://doi.org/10.1787/ac8b0a27-en*. [Online]
14. *T.C. Sağlık Bakanlığı (February 2022), Uzaktan Sağlık Hizmetinin Sunulmasına Dair Yönetmelik*.
15. TITCK, İlaç Ruhsatlandırma, <https://www.titck.gov.tr/faaliyetalanlari/ilac/ilac-ruhsatlandirma>. [Online]
16. *Resmi Gazete (September 2017), Beşeri Tıbbi Ürünlerin Fiyatlandırılması Hakkında Tebliğ, https://www.resmigazete.gov.tr/eskiler/2017/09/20170929-11.htm*.
17. *Resmi Gazete (August 2022), Sosyal Güvenlik Kurumu İlaç Geri Ödeme Yönetmeliği, https://www.resmigazete.gov.tr/eskiler/2022/08/20220825M1-1.htm*.
18. *Resmi Gazete, (May 2023), Alternatif Geri Ödeme Yönetmeliği, https://www.resmigazete.gov.tr/eskiler/2023/05/20230512-32.htm*.
19. Gün + Partners (2022), *Yeni Sosyal Güvenlik Kurumu İlaç Geri Ödeme Yönetmeliği Yayınlandı, (https://gun.av.tr/tr/goruslerimiz/makaleler/yeni-sosyal-guvenlik-kurumu-ilac-geri-odeme-yonetmeligi-yayinlandi*. [Online]
20. Gün + Partners (2023), *Sosyal Güvenlik Kurumu Alternatif Geri Ödeme Yönetmeliği Yayınlandı, (https://gun.av.tr/tr/goruslerimiz/makaleler/sosyal-guvenlik-kurumu-alternatif-geri-odeme-yonetmeligi-yayinlandi)*. [Online]
21. *T.C. İçişleri Bakanlığı (2022), 81 İl Valiliğine PCR Testi ve HES Koduna İlişkin Genelge Gönderildi, https://www.icisleri.gov.tr/81-il-valiligine-pcr-testi-ve-hes-koduna-iliskin-genelge-gonderildi*.

22. T.C. İçişleri Bakanlığı Göç İdaresi Başkanlığı (2023), Faaliyet Raporu 2022, <https://www.goc.gov.tr/kurumlar/goc.gov.tr/Kurumsal/Strateji/2023-Mayis-/2022-Yili-Faaliyet-Raporu.pdf>. [Online]
23. Anadolu Ajansı (2022), Sağlık Bakanı Koca: İlaç tedarikinin 3-4 hafta içinde normale döneceğini bekliyoruz, <https://www.aa.com.tr/tr/gundem/saglik-bakani-koca-ilac-tedarikinin-3-4-hafta-icinde-normale-donecegini-bekliyoruz/2773564>. [Online]
24. Türk Tabipleri Birliği (2023), 6 Şubat 2023 Kahramanmaraş ve 20 Şubat 2023 Hatay Depremleri Birinci Ay Raporu, (<https://www.ttb.org.tr/userfiles/files/1ayraporu.pdf>). [Online]
25. *Resmi Gazete (July 2023), Mal ve Hizmetlere Uygulanacak Katme Değer Vergisi Oranının Tespiti, Sayı: 32241.*
26. USHAŞ (2023), Sağlık Turizmi Verileri, (<https://www.ushas.com.tr/saglik-turizmi-verileri/>). [Online]
27. Türk Tabipleri Birliği (2023), TTB'ye "İyi Hal Belgesi" başvuru sayısı, <https://twitter.com/ttborgtr/status/1609828230948683782>. [Online]
28. Anadolu Ajansı (2022), Türkiye'nin 20'nci şehir hastanesi hizmete açılıyor, <https://www.aa.com.tr/tr/gundem/turkiyenin-20nci-sehir-hastanesi-hizmete-aciliyor-/2694597>. [Online]
29. Anadolu Ajansı (2023), Ordu Şehir Hastanesi'nin 2024'te hizmete girmesi hedefleniyor, <https://www.aa.com.tr/tr/pg/foto-galeri/ordu-sehir-hastanesinin-2024te-hizmete-girmesi-hedefleniyor/5>. [Online]
30. İHA (2023), Samsun Şehir Hastanesi 2024'ün ilk aylarında açılacak, <https://www.ih.com.tr/samsun-haberleri/samsun-sehir-hastanesi-2024un-ilk-aylarinda-acilacak-33019468>. [Online]
31. Kamu Hastaneleri Genel Müdürlüğü (2023), Sağlıklı Yaş Alma Merkezlerinin Kurulmasına Dair Genelge Yayınlandı, <https://khgmsaglikhizmetleridb.saglik.gov.tr/TR-96308/saglikli-yas-alma-merkezlerinin-kurulmasina-dair-genelge-yayimlandi.html>. [Online]
32. Anadolu Ajansı (2023), Hastanelerde 80 yaş ve üstü için "YAŞAM" devreye giriyor, <https://www.aa.com.tr/tr/saglik/hastanelerde-80-yas-ve-ustu-icin-yasam-devreye-giriyor/2866148>. [Online]
33. Kimyagerler Derneği (2018), İlaç Etken Maddelerinde Yerelleşme, <https://www.kimyager.org/yayinlar/kitaplar/ilac-etken-maddelerinde-yerellesme>. [Online]
34. *T.C. Sanayi ve Teknoloji Bakanlığı (2021), İlaç Sektörü Raporu 2021.*
35. *T.C. Kalkınma Bakanlığı (2018), On Birinci Kalkınma Planı (2019-2023).*
36. TÜİK (2022), Yıllık Sanayi ve Hizmet İstatistikleri, Accessed: August 2023. [Online]
37. *IQVIA Flexview.*
38. TİTCK (2023), TİTCK Denetimine Tabi Yurtiçi Tesisler, Accessed: Eylül 2023. [Online]

39. İstanbul Sanayi Odası (2022), ISO500: Türkiye'nin En Büyük 500 Sanayi Kuruluşu, Accessed: August 2023, <https://www.iso500.org.tr/>.
40. AIFD (2023), Ekonomik Değer Anketi Eylül 2023.
41. UN Comtrade, Accessed: August 2023.
42. TİM (2023), İlk 1000 İhracatçı Araştırması 2022, Accessed: August 2023.
43. OECD.Stat (2021), Finansal DYY Akışları, Accessed: August 2023. [Online]
44. Bryan M., Daria K. (2015), *Foreign Direct Investment in the Pharmaceutical Industry: Why Singapore and not Hong Kong*, *Asian Journal of Comparative Law*. Bryan M., Daria K.
45. [Online] <https://www.hurriyet.com.tr/ekonomi/goz-damlasini-artik-turkiyede-uretecek-42270752>.
46. [Online] <https://www.bloomberght.com/ilac-devinden-turkiye-ye-60-milyon-dolarlik-yatirim-2308442>.
47. GSK (2022) GSK Türkiye ve Abdi İbrahim'den Solunum İlaçlarının Yerli Üretimi için Dev Yatırım, <https://tr.gsk.com/tr-tr/medya/basin-bultenleri/gsk-turkiye-ve-abdi-ibrahimden-solunum-ilaclarinin-yerli-uretimi-icin-dev-yatirim/>. [Online]
48. [Online] <https://www.aa.com.tr/tr/sirkethaberleri/saglik/sanofi-turkiye-uroloji-alanindaki-yeni-teknoloji-transferini-tanitti/680789>.
49. [Online] <https://www.dunya.com/sirketler/danonedan-luleburgaza-yeni-fabrika-yatirimi-haberi-706040>.
50. [Online] <https://www.nestle.com.tr/nestle-turkiye-deki-fabrika-sayisini-5-e-cikardi>.
51. Saha, C. N., & Bhattacharya, S. (2011). *Intellectual property rights: An overview and implications in pharmaceutical industry*. *Journal of advanced pharmaceutical technology & research*, 2(2), 88–93. <https://doi.org/10.4103/2231-4040.82952>.
52. Lippoldt, D. (2006). *Intellectual property rights, pharmaceuticals and foreign direct investment*. *Group d'Economie Mondale de Sciences Po*, 1-10.
53. *Scientific American* (2022), *Worldview, A Global Biotechnology Perspective*, 4. Seri, <https://www.pugatch-consilium.com/reports/SAWorldView2012.pdf>.
54. IQVIA (2020), Türkiye İçin Klinik Araştırma Stratejisinin Faydaları. [Online]
55. IQVIA (2023), Global R&D Trends 2023. [Online]
56. TEPAV (2015), *İlaç Ar-Ge Ekosistemi Raporu*, https://www.tepav.org.tr/upload/files/1430228364-4.Ilac_ARGE_Ekosistemi_Raporu.pdf.
57. Pharmacompass (2023), Top 100 pharma & biotech deals in 2022, <https://www.pharmacompass.com/radio-compass-blog/top-100-pharma-biotech-deals-in-2022>. [Online]
58. T.C. Sanayi ve Teknoloji Bakanlığı (2023), Ar-Ge Merkezleri İstatistikleri, Accessed: August 2023. [Online]

59. TITCK (2023), TITCK Tarafından Onaylanan Faz 1 Klinik Araştırma Merkezleri, Accessed: Ekim 2023. [Online]
60. clinicaltrials.gov, Accessed: August 2023. [Online]
61. *StartupBlink (2023), Global Startup Ecosystem Index 2023*, <https://www.startupblink.com/>.
62. EU, EIS 2023 - RIS 2023, <https://ec.europa.eu/research-and-innovation/en/statistics/performance-indicators/european-innovation-scoreboard/eis>. [Online]
63. CBInsights (2023), The Complete List Of Unicorn Companies, <https://www.cbinsights.com/research-unicorn-companies>, Accessed: July 2023. [Online]
64. *T.C. Sanayi ve Teknoloji Bakanlığı (2022), Ulusal Teknoloji Girişimciliği Stratejisi*.
65. *T.C. Sanayi Bakanlığı (2023), Akıllı Yaşam ve Sağlık Ürün ve Teknolojileri Yol Haritası*.
66. TÜBİTAK, BİGG. [Online]
67. *TÜSEB (2019), İlaçta Biyoteknoloji Ekosistemi*.
68. KOSGEB, Destekler. [Online]
69. AIFD (2022), BIO Startup Program 2022 Bio-entrepreneurship Camp has started, <https://www.aifd.org.tr/en/haberler/bio-startup-program-2022-bio-entrepreneurship-camp-has-started/>. [Online]
70. Abdi İbrahim, Sağlıkta Sosyal İnovasyon Programı: Doz, <https://www.abdiibrahim.com.tr/doz>. [Online]
71. BAYER, G4A Girişim Hızlandırma Programı, <https://www.bayer.com.tr/tr/inovasyon/g4a-girisim-hizlandirma-programi>. [Online]
72. Gilead. Gilead ile Hayat Bulan Fikirler Programı. [Online] <http://www.hayatbulanfikirler.com/anasayfa.html>.
73. Pfizer, Pfizer Türkiye'den sağlık girişimcilerine yönelik Patika Startup Challenge, <https://www.pfizer.com.tr/amacimiz/medyada-pfizer/basin-bultenleri/pfizer-t%C3%BCrkiyeden-sa%C4%9Fl%C4%B1k-giri%C5%9Fimcilerine-y%C3%B6nelik-patika-startup-challenge>. [Online]
74. Anadolu Ajansı (2022), Sağlık hizmetlerinde dijitalleşmeye yön verecek girişimler açıklandı, <https://www.aa.com.tr/tr/sirkethaberleri/saglik/saglik-hizmetlerinde-dijitallesmeye-yon-verecek-girisimler-aciklandi/672364>. [Online]
75. Sanofi, Pharmup, <https://www.sanofi.com.tr/tr/pharmup>. [Online]
76. Sanofi, Oncosprint, <https://www.sanofi.com.tr/tr/pharmup/oncosprint>. [Online]
77. KPMG (2023), Turkish Startup Investments Review 2022. [Online]
78. WIPO, <https://patentscope.wipo.int/search/en/search.jsf>. [Online]
79. TÜİK (2021), Biyoteknoloji İstatistikleri 2020. [Online]

CONTACT US

Maslak Ofis Building
Maslak Mahallesi Sümer
Sokak No:4 Kat:4
Sarıyer İstanbul
Türkiye
+90 212 401 9500

iqvia.com

