

TURKISH PHARMACEUTICAL SECTOR REPORT

SUMMARY

2024



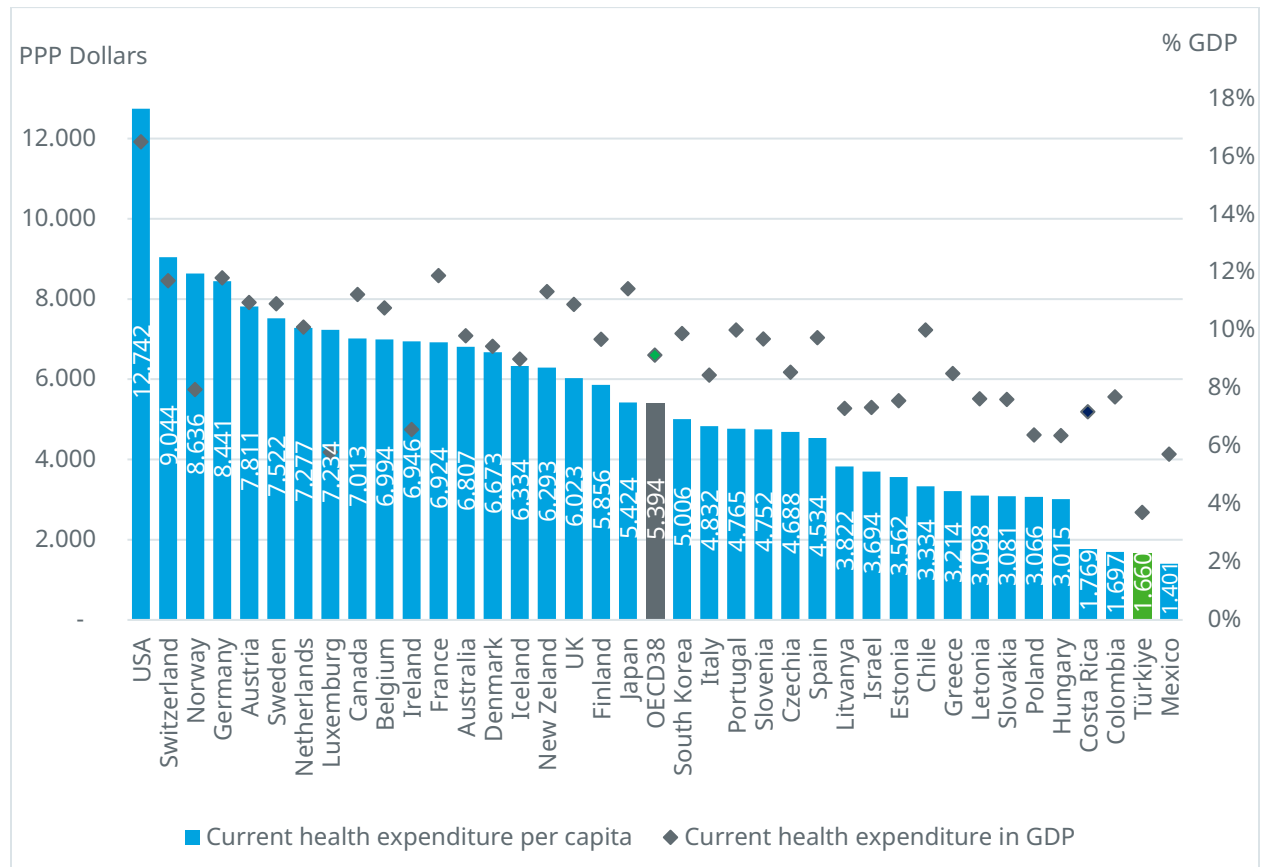
1. HEALTH SECTOR INDICATORS

Healthcare Expenditures

Türkiye has one of the lowest current health expenditure per capita among OECD countries, at \$1,660. While the share of current health expenditures per capita in Türkiye is 3.7% of Gross Domestic Product (GDP), the OECD average is 9.3%. While the share of current health expenditures in GDP was 4.6% in Türkiye in 2000, 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. 75.2% of health expenditures in Türkiye were publicly financed in 2022. Türkiye is close to the OECD average (75.3%) in terms of public health expenditures and ranks 20th among 38 countries.

Current Health Expenditure Per Capita and Share in GDP In OECD Countries

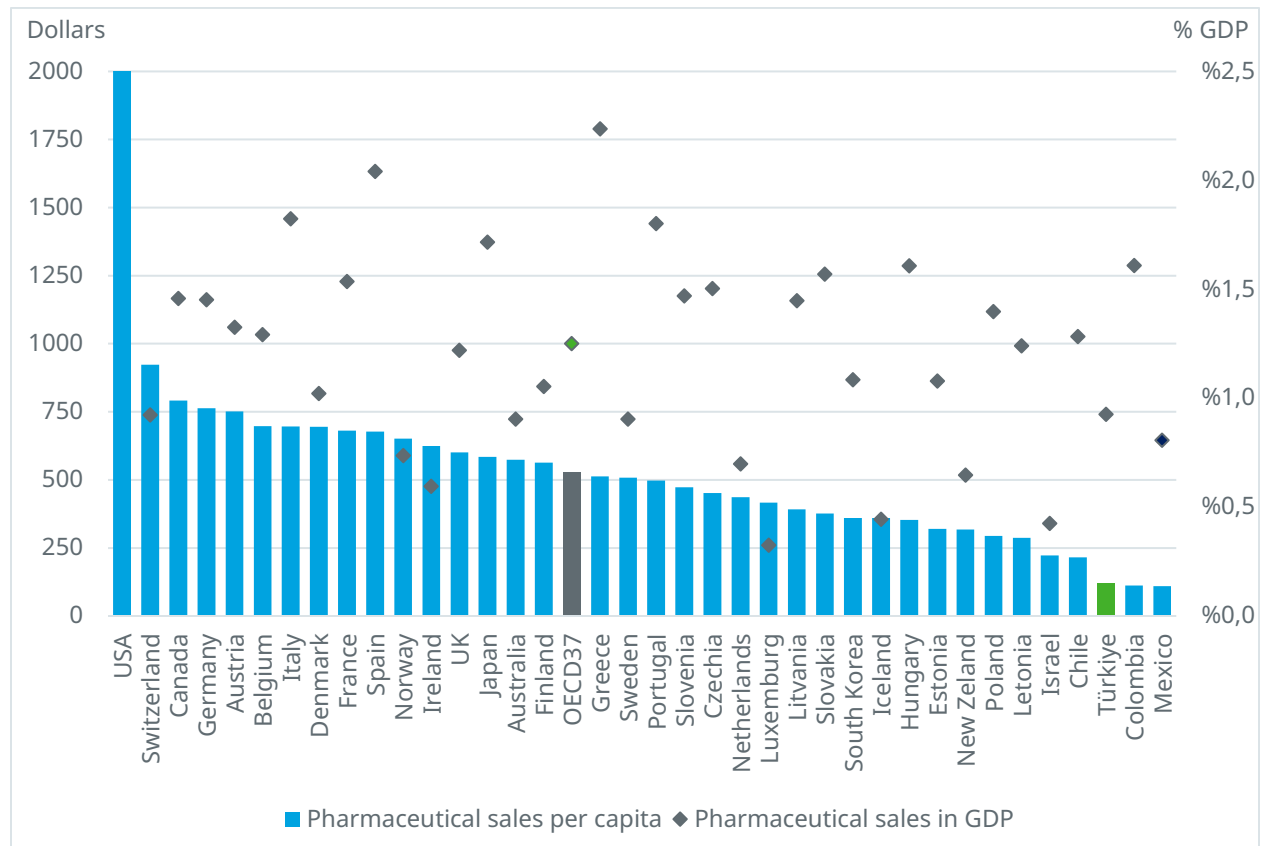


Source: OECD consists of actual or estimated data for 2023 or the nearest year. Germany, Austria, Sweden, Luxembourg, Canada, Ireland, Denmark, Iceland, United Kingdom, South Korea, Italy, Portugal, Czechia, Lithuania, Estonia, Chile, Hungary, Colombia: 2023 OECD forecast. Australia, New Zealand, Japan, Israel: 2022 OECD forecast. Other countries: 2022 actual.

Pharmaceutical Expenditures

Among OECD countries, Türkiye had the third lowest per capita pharmaceutical sales at \$119, after Mexico and Colombia in 2023. The leading countries in per capita pharmaceutical sales are the USA, Switzerland, Canada and Germany. The ratio of pharmaceutical sales to GDP, was at 1.3% on average in OECD countries. The share of pharmaceutical sales in GDP in Türkiye was 1.1% in 2019-2020 and this ratio decreased in the following years, falling to 0.9% in 2023. With this rate, Türkiye ranks 26th among OECD countries.

Pharmaceutical Sales Per Capita and Share in GDP in OECD Countries (2023)



Source: IQVIA analysis; IQVIA Market Prognosis 2024-2028, OECD Population Projections, World Bank
 Note: No pharmaceutical market data available for Costa Rica.

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), 70.5% of health expenditures defined under "Retail sales and providers of other medical supplies" were covered by the public in 2022.

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 2.3 physicians per 1000 people, below the OECD average of 3.8. Looking at the number of nurses by country, Türkiye has 2.9 nurses per 1000 people, while OECD countries have an average of 9.1 nurses per 1000 people.

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 15% to 3.1% between 2015-22. Türkiye is close to European countries such as Spain and Italy in terms of the number of beds per population but lags behind in the number of healthcare personnel.

Life Expectancy

When we look at life expectancy, which is one of the important indicators of health status in countries, life expectancy at birth in Türkiye is 77.5 years, while the average for OECD countries is 81 years. The OECD country with the highest life expectancy was Switzerland at 84.2, and the country with the lowest was Mexico at 75.4. Türkiye has been the country with the highest increase in life expectancy at birth in the last 40 years.

Mortality Rates

The countries with the lowest total death rates are Japan, South Korea and Switzerland. According to the latest data shared by the OECD for Türkiye, the number of deaths recorded per 100 thousand population in Türkiye in 2019 was 969. However, the average for OECD countries is 911.

When looking at the causes of death, 154 out of 100,000 people in Türkiye die from cancer, and 384 out of 100,000 people die from circulatory system diseases. It is observed that cancer-related deaths are 197 out of 100,000 people in OECD countries, and this rate is lower in Türkiye than in other countries.

When looking at the infant mortality rates under one year old, the mortality rate recorded per 1000 babies in European countries is generally between 1 and 4. Türkiye has the 4th highest infant mortality rate among OECD countries, with a rate of 9.1 in 2022, after Colombia, Mexico and Costa Rica. The mortality rate per 1000 babies is an average of 4.1 in OECD countries.

2. GLOBAL PHARMACEUTICAL MARKET INDICATORS

Global Pharmaceutical Market Size

The global pharmaceutical market, which grew at a CAGR of 5.8% between 2018 and 2023, reached 1,607 billion dollars in 2023, growing by 8.2% compared to the previous year. The USA has the largest pharmaceutical market with 727.4 billion dollars and constitutes 45% of the global pharmaceutical market. The USA is followed by China with 160.8 billion dollars. Türkiye ranks 19th with a pharmaceutical market size of 10.3 billion dollars. The Turkish pharmaceutical market grew by 90.4% in local currency in 2023, while the growth recorded in dollar terms was 32.7%. Türkiye was the fastest growing market in 2023 compared to the previous year, followed by Poland with 22.9% growth rate and Mexico with 22.2% growth rate. On the other hand, Russia, the 12th largest pharmaceutical market, shrank by 17.1% in dollar terms last year.

Market Share of 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. The companies identified accounted for 89% of the US pharmaceutical market sales in 2023. Looking at Türkiye, the market share for these top 50 companies accounts for 48% of Türkiye pharmaceutical market. With this rate, Türkiye appeared to be close to countries such as Mexico (44%) and Russia (50%).

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 2023, 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 14% of the pharmaceutical market value in 2023. Türkiye had a lower patent-protected market share than Poland and Greece asides from developed countries.

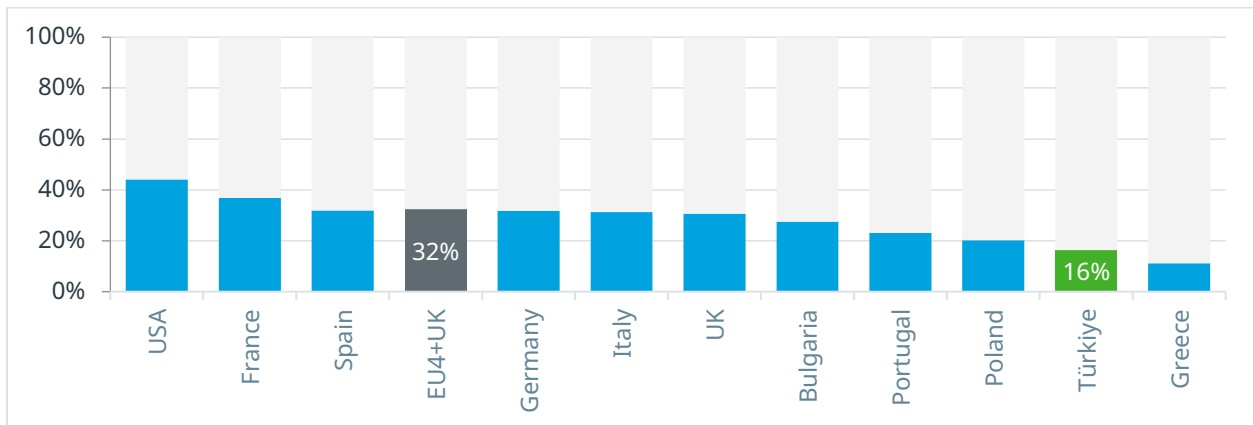
When examining the distribution of products with ongoing patent protection in Türkiye as of 2023, approximately 57% of the sales value comes from treatments in the field of oncology, while 20% comes from treatments related to the digestive system and metabolism area.

Biotechnological Pharmaceuticals Market

Biotechnological drugs are large and complex molecules obtained from living cells using recombinant DNA technology. Some enzymes, hormones, blood products, vaccines, monoclonal antibodies are included in this group. There were 130 reference biotechnological and 25 biosimilars in Türkiye pharmaceutical market in 2023. Total sales of biotechnological products in Türkiye were 1.6 billion dollars in 2023.

While biotechnological drugs make up 16% of the Turkish pharmaceutical market, this ratio is 32% on average in 5 countries including EU4 countries and the United Kingdom.

Share of Total Biotechnological Market in Pharmaceuticals Market in Türkiye and Selected Countries (2023)



Source: IQVIA analysis
EU4: Germany, France, Italy, Spain. UK: United Kingdom

Mergers and Acquisitions in the Pharmaceutical Industry

Strategic partnerships, mergers and acquisitions in the global pharmaceutical sector shape the dynamic structure of the sector. Pharmaceutical companies generally engage in mergers and acquisitions to expand their portfolios, strengthen their R&D activities or enter new markets. When we look at recent agreements in particular, we see that large pharmaceutical companies that dominate the market are strengthening their portfolios and R&D capabilities by purchasing small biotechnology companies that focus on innovative drug development.

The largest mergers and acquisitions in the global pharmaceutical sector in the last 20 years are given. The acquisition of Celgene, which develops innovative treatments in oncology and immunology, by the US-based pharmaceutical company Bristol-Myers Squibb for \$80.3 billion in 2019 was recorded as the highest-value deal in the last 20 years. Pfizer's acquisition of American biotechnology company Seagen, which develops cancer treatments, for \$43.4 billion and Amgen's acquisition of Horizon Therapeutics for \$27.8 billion were the two giant acquisitions in the pharmaceutical sector in 2023.

Top 25 M&A Deals in the Global Pharmaceutical Industry in the Last 20 Years

Year	Target Company	Investor	Deal Value (Billion Dollars)
2019	Celgene	Bristol-Myers Squibb	80.3
2015	Allergan	Actavis	74.8
2009	Wyeth	Pfizer	68.0
2004	Aventis	Sanofi-Synthelabo	66.5
2020	Allergan	AbbVie	64.1
2019	Shire	Takeda	58.2
2009	Schering-Plough	Merck & Co	45.7
2023	Seagen	Pfizer	43.4
2021	Alexion	AstraZeneca	41.1
2016	Actavis Generics	Teva	40.5
2016	Baxalta	Shire	32.0
2017	Actelion Pharmaceuticals	Johnson&Johnson	29.6
2014	Forest Laboratories	Allergan	28.0
2023	Horizon Therapeutics	Amgen	27.8
2006	Bayer Schering Pharma	Bayer CropScience U.S.	21.4
2015	Pharmacyclics	AbbVie	20.8
2020	Cytiva	Danaher	20.7
2020	Immunomedics	Gilead Sciences	20.6
2011	Sanofi Genzyme	Sanofi	20.1
2014	MSD (Consumer Health)	Bayer	17.7
2015	Sigma-Aldrich	Merck	17.0
2006	Pfizer (Consumer Health)	Johnson & Johnson	16.6
2010	Shokando	Mitsui & Company	16.5
2015	GlaxoSmithKline (Oncology)	Novartis	16.0
2007	Organon BioSciences	Schering-Plough	16.0

Source: Pitchbook

Note: The top 25 deals with disclosed deal values from the last 20 years are shown.

The acquisition of Mustafa Nevzat İlaç by the US-based pharmaceutical company Amgen for \$669 million in 2012 was the highest value deal in the history of the Turkish pharmaceutical industry. Later renamed Gensenta İlaç, Mustafa Nevzat İlaç was included in the Eczacıbaşı group with the acquisition worth \$135 million in 2022.

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

Year	Target Company	Investor	Share (%)	Deal Value (Million Dollars)
2012	Mustafa Nevzat	Amgen	95.6	669.2
2007	Eczacıbaşı	Zentiva	75	606.5
2009	Eczacıbaşı-Zentiva		25	193.1
2020	OM Pharma	Abdi Ibrahim	28.5	549.0
2019	Sanovel	MCP - Morgan Stanley & Co. LLC	30	200.0
2006	Biofarma	PiLS-CVCI	100	200.0
2022	Gensenta (Formerly Mustafa Nevzat)	Eczacıbaşı	100	135.0
2011	Frik	Recordati	100	130.0
2015	Neotec	Takeda	100	121.4
2003	Fako	Actavis Group (Formerly Pharmaco)	89	60.0
2006			11	20.4
2008	Yeni İlaç	Recordati	100	60.0
2008	Monrol Nuclear Products	Eczacıbaşı	50	43.4
2008	Frik	İş Private Equity	17	15.3

Source: EMIS

Note: Agreements in the last 20 years and above 10 million dollars.

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

3. TURKISH PHARMACEUTICAL MARKET INDICATORS

Türkiye is one of the important countries among the emerging markets for the pharmaceutical sector due to factors such as the country's developed 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. Among the selected countries, the largest pharmaceutical market, Germany, had a pharmaceutical market size of \$64.7 billion in 2023. In Türkiye, the pharmaceutical market size was \$10.3 billion in 2023. While Türkiye is ahead of countries such as Greece and Portugal in the pharmaceutical market size ranking, it lags behind countries such as Germany and France, with which it is more similar in terms of population.

The Turkish pharmaceutical market had recorded a 4.8% decrease in dollar terms in 2022 due to the rapid depreciation of the Turkish lira against the foreign exchange rate and the fact that the fixed drug exchange rate used in drug pricing remained very low compared to the real exchange rate. Although the increase in the exchange rate continued, the rate of increase in the exchange rate slowed down in 2023 compared to the previous year. In addition, due to the effect of the drug exchange rate increases implemented in December 2022 and July 2023, it was observed that the gap between the real exchange rate and the fixed drug exchange rate throughout 2023 was smaller compared to 2022. As a result of this situation, the average unit price increased by 30% in dollar terms in 2023 compared to the previous year. The Turkish pharmaceutical market, which grew by 32.7% in dollar terms, was the highest growing country in 2023. Double-digit growth rates were achieved in the pharmaceutical market in most European countries in the last year. Another country that showed high growth in 2023 was Poland with 22.9%.

Pharmaceutical Market Size and Growth Performance in Selected Countries

Country	2023 (Billion Dollars)	2022-23 Value Growth %	2022-23 Unit Growth %
Germany	64.7	8.6	2.1
France*	46.5	11.2	1.7
Italy*	41.1	11.6	-0.4
United Kingdom	40.8	11.7	3.7
Spain*	32.3	11.3	1.6
Poland	11.3	22.9	-0.8
Türkiye	10.3	32.7	3.5
Greece*	5.3	6.5	0.7
Portugal*	5.2	11.1	1.1
Bulgaria	2.6	17.8	0.5

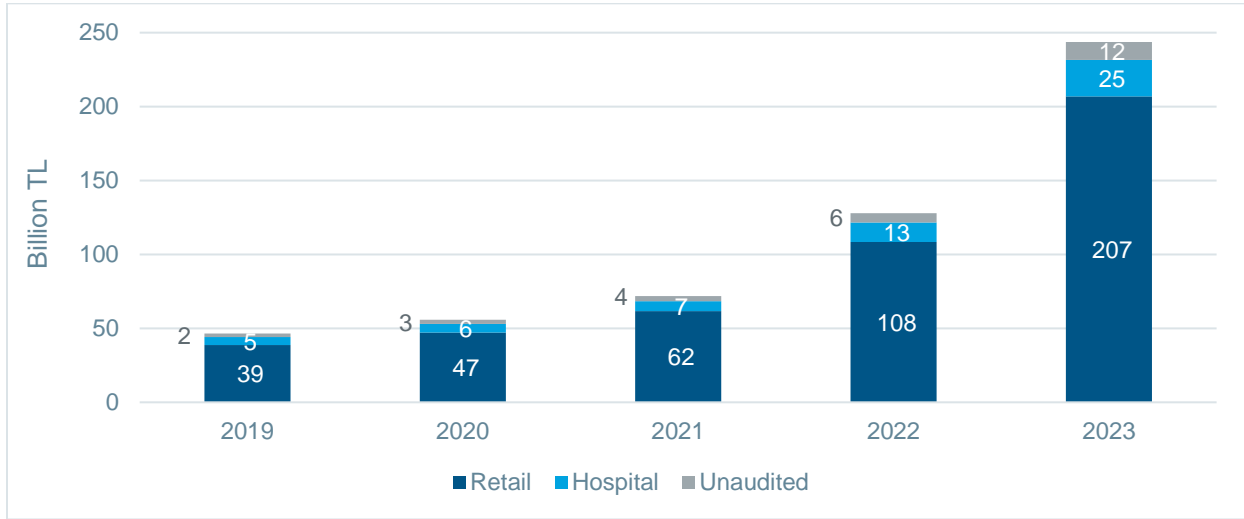
Source: IQVIA Market Prognosis 2024-2028, Note: Box growth rates are calculated based on audited market sales.

*Reference countries included in Turkish drug pricing legislation

Turkish Pharmaceutical Market Development

The Turkish pharmaceutical market reached a sales value of 207 billion TL in the retail channel and 25 billion TL in the hospital channel in 2023. When unaudited sales estimates are included, the total pharmaceutical market in Türkiye reached approximately 244 billion TL in local currency in 2023, an increase of 90% compared to the previous year. Price increases have a significant impact on the high growth.

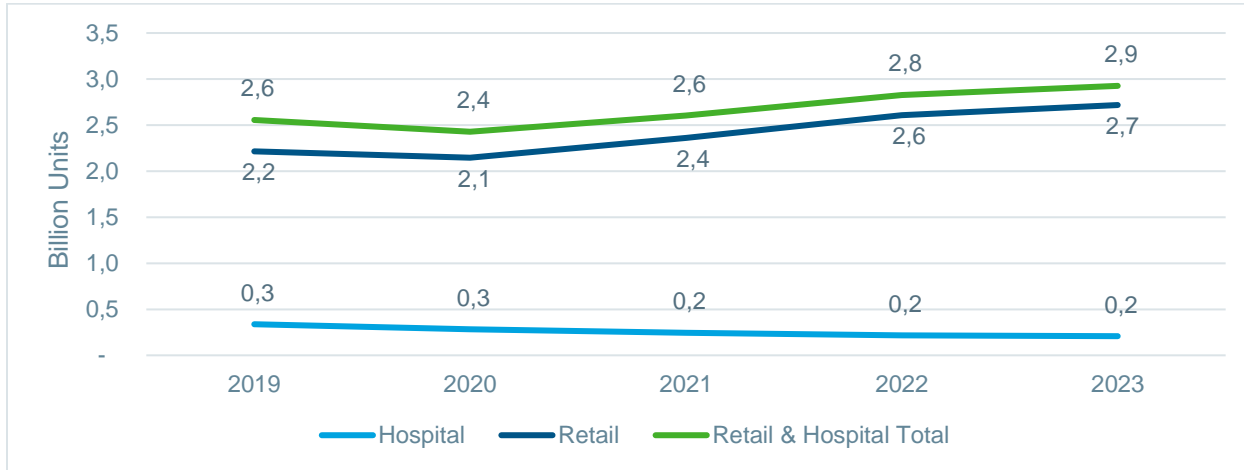
Türkiye Pharmaceutical Market Sales Value (2019-2023)



Source: IQVIA Market Prognosis 2024-2028

The audited market, including the pharmacy and hospital channels, grew by 3.5% in terms of volume in 2023 compared to the previous year, reaching 2.9 billion units.

Türkiye Pharmaceutical Market Volume Sales (2019-2023)



Source: IQVIA Retail & Hospital Database

Factors Affecting Turkish Pharmaceutical Market Growth

Analyzing the factors that contributed to observed growth of 110 billion TL in the Turkish pharmaceuticals market in 2022, the contribution of price increases to growth was 91.4% (100.4 billion TL). Another important factor, the increase in unit sales of existing products, contributed to 5.8% (6.4 billion TL) of the market growth, while the contribution of new products to growth was limited. Accordingly, price increases were the main effect of the growth observed in the Turkish pharmaceutical market in 2023.

Average Pharmaceutical Unit Prices in Türkiye and Other Countries

The average unit price in local currency in Türkiye has increased over the years due to the effect of drug exchange rate increases. The average unit price in the Turkish pharmaceutical market reached 79.1 TL in 2023, increasing by 84% compared to the previous year.

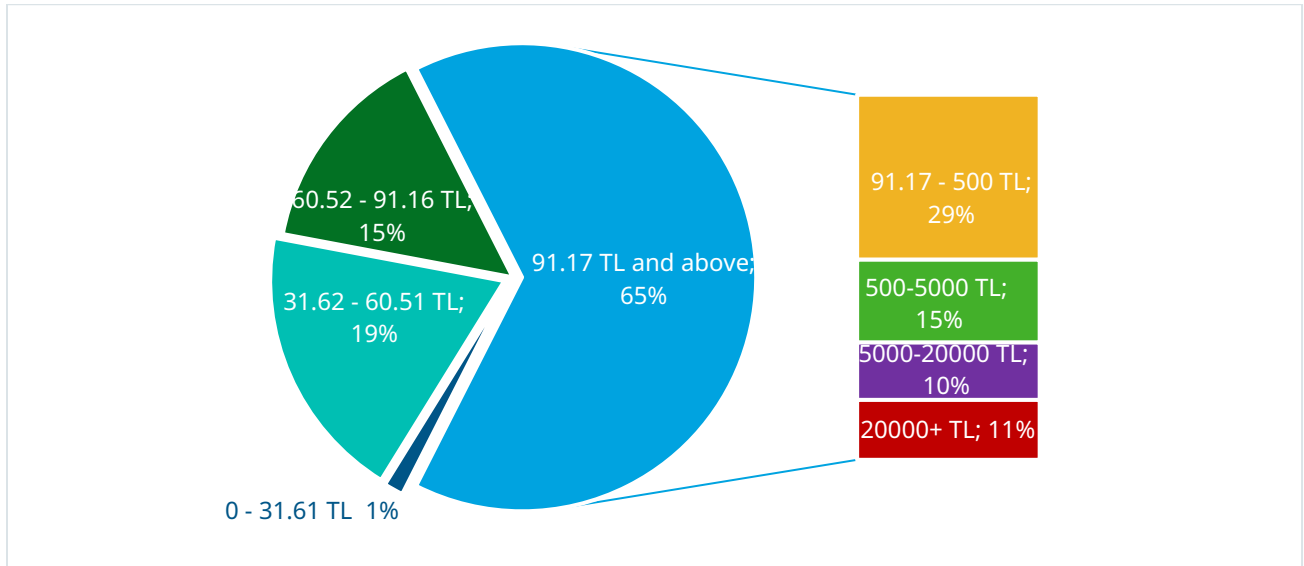
When examined on a dollar basis, the average unit price decreased by 14% in 2022 to \$2.6, but increased by 30% in 2023 to \$3.3. The reason for the decrease in 2022 can be shown as the rapid increase in the dollar exchange rate that started at the end of 2021 and the failure of the drug exchange rate updates implemented in the relevant period to keep up with the sudden increase in foreign exchange. While the average dollar exchange rate increased by 87% in 2022 compared to the previous year, the increase in 2023 was recorded as 44%.

Different policies applied in determining drug prices cause average drug prices in countries to be at different levels. Among the selected countries, the country with the highest average price level in the pharmaceutical market is the United Kingdom. In Türkiye, where the average unit price was \$3.3 in 2023, drug prices remain significantly below the price levels in other countries. 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. In the pharmaceutical market, where four groups are formed according to price scales, the products in the fourth discount scale (Ex-man price 91.17 TL and above) constituted 65% of the total pharmaceutical market in 2023. When the sub-division of this group, where the majority of sales are located, is examined, it is seen that products with a price over 5,000 TL constitute approximately 21% of the total pharmaceutical market sales, and products with a price over 20,000 TL constitute 11% of the sales in the market.

Pharmaceutical Sales by Price Brackets (2023)



Source: IQVIA analysis; IQVIA Retail & Hospital Database

Note: Price brackets are revised in July and December 2023. Price brackets used in the analysis belong to the SUT announced in December 2023.

Pharmaceutical Prices by Patent Status in Türkiye

The average unit price of medicines with ongoing patent protection in Türkiye in 2023 was calculated as 1544 TL. The average unit price of products without patent protection, which constitute the majority of the market in terms of volume, was 69 TL and the average unit price of the total market was 79 TL.

Access to Innovative Treatments Statistics

The W.A.I.T. 2022 report prepared by IQVIA evaluates the accessibility of innovative treatments approved by the European Medicines Agency (EMA) between 2019 and 2022. Access rates for different countries as of January 2023 were examined. When determining the accessibility status of a treatment, public reimbursement in the country is taken as a basis. Alternative reimbursement agreements, treatment lines or other reimbursement conditions are evaluated within an accessible scope.

167 innovative treatments that received regulatory approval from the EMA between 2019 and 2022 were evaluated. Germany, where 147 drugs were accessible, ranked first with an access rate of 88%, followed by developed countries such as Italy, Austria and Switzerland, where the access rate to innovative drugs was over 70%. Türkiye, where access to 6 of the innovative treatments observed within the scope of the study, was the country with the lowest access rate among the countries examined, together with Malta, with an access rate of 4%.

Rare Diseases and Orphan Medicines

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. In the W.A.I.T. study, the accessibility in countries to 63 treatments with orphan drug status that received regulatory approval by the EMA between 2019 and 2022 were examined. Among the relevant treatments, there is 1 drug that can be reimbursed in Türkiye in 2023, and limited access to the drug can be provided through the Foreign Medicines List.

Digital Health and Telemedicine

While the use of telemedicine was limited in most OECD countries before the Covid-19, it began to be encouraged by governments after the pandemic largely disrupted face-to-face healthcare services in early 2020. While previous examinations in Türkiye required the physical presence of the patient, the framework for the provision of remote healthcare services was determined by the regulation published by the Ministry of Health in February 2022.

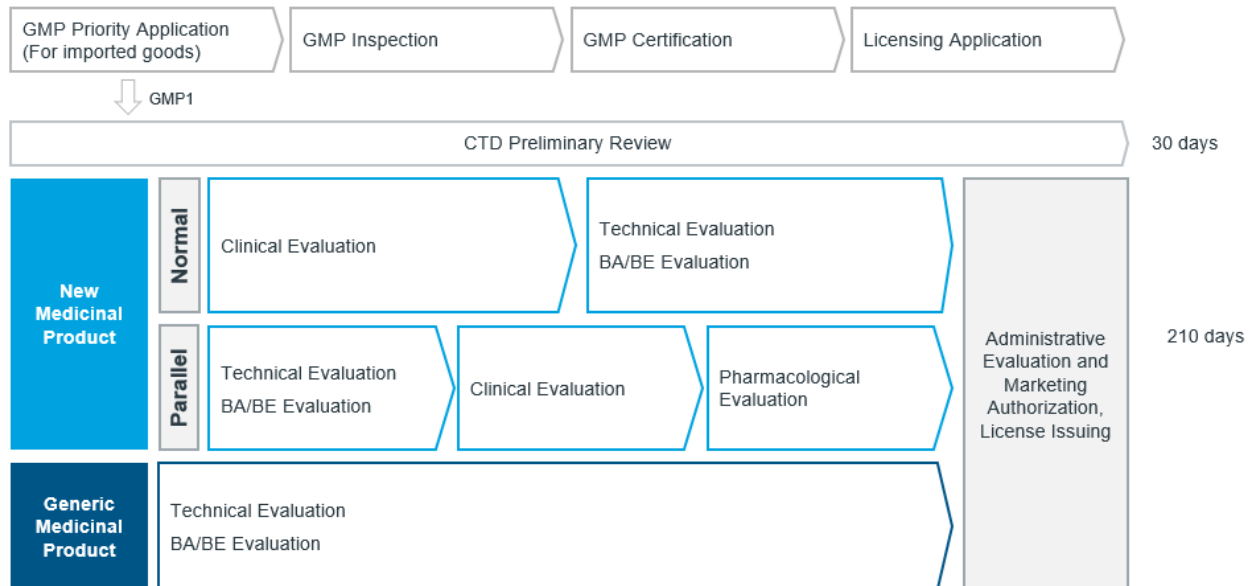
Also, in accordance with the amendment made to the Health Implementation Communiqué on April 21, 2024, remote health services were included in the General Health Insurance reimbursement list. Accordingly, health services provided by specialist physicians in secondary and tertiary health institutions affiliated to the Ministry of Health and during working hours were included in the reimbursement scope. In the process that started with the legislative updates made in the field of remote health services in Türkiye, it is expected that the use of remote treatment services will gradually become widespread.

APPENDIX

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. If the licensing process of reference drugs has been initiated by an authority abroad, applications can be made to TITCK in parallel. However, in order for the licensing process to be completed, the international approval process must be completed. 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

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 generics	Lowest ex-man price among reference countries is considered  Greece France Spain Portugal Italy + Batch-release country + Import country	Reference price in Euro is multiplied with the latest fixed exchange rate, to get the price in Turkish lira	%100	%41 (91,17 TL and higher) %31 (60,52 – 91,16 TL) %10 (31,62 – 60,51 TL) %0 (31,61 and less)
Reference drugs with generics and generic drugs			%60	%28 (91,17 TL and higher) %18 (60,52 – 91,16 TL) %10 (31,62 – 60,51 TL) %0 (31,61 and less)
Price protected drugs*			%80	%28** (91,17 TL and higher) %10 (60,52 – 91,16 TL) %0 (31,62 – 60,51 TL) %0 (31,61 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

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 December 2023, the fixed drug rate was calculated as 55% 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



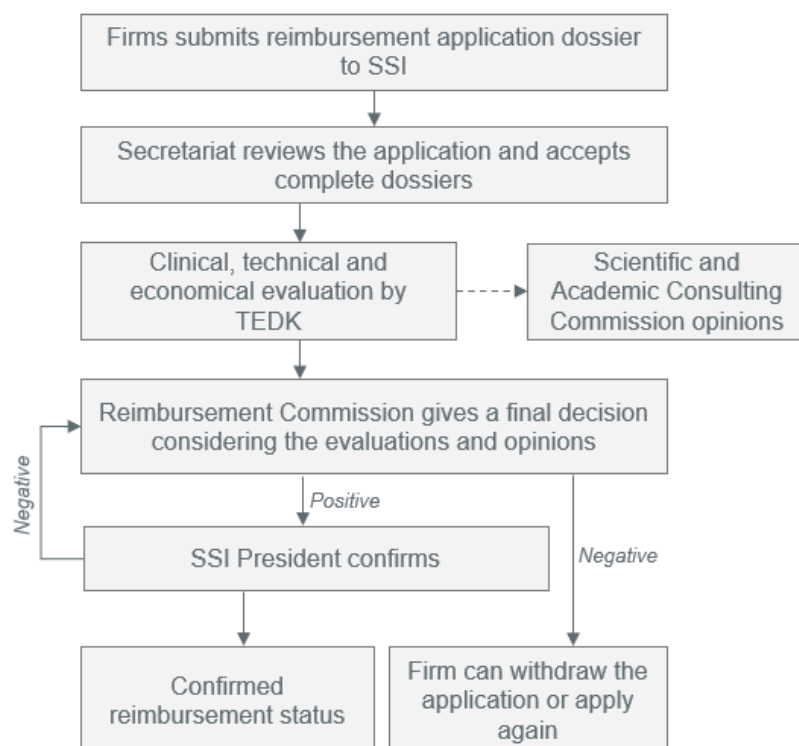
Source: IQVIA analysis; TCMB, TITCK

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

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).

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.

Key Developments affecting Turkish Pharmaceutical Industry

- ❖ Fixed Euro exchange rate updates used in the drug pricing
- ❖ Earthquake disaster (February 6, 2023)
- ❖ Circular on the establishment of “Centers for Healthy Aging” (YAŞAM) (March 30, 2023)
- ❖ Amendment on the Alternative Reimbursement Regulation (May 12, 2023)
- ❖ Presidential and parliamentary elections (May 14, 2023)
- ❖ Change in VAT regulation (July 10, 2023)
- ❖ TİTCK reaching World Health Organization (WHO) maturity level 3 (September 21, 2023)
- ❖ Amendments on the drug legislation (March 1, 2024)
- ❖ Establishment of Health Valley (May 25, 2024)
- ❖ Change of minister of health (July 2 2024)
- ❖ Health tourism
- ❖ Health infrastructure developments and completed city hospitals

4. PRODUCTION

In addition to reference and generic drug production in Türkiye, there is also limited active ingredient production. There are drugs that cannot be produced in Türkiye due to reasons such as requiring advanced technology or being consumed in small quantities in the country. According to TÜİK data, the production value of the “Manufacture of Basic Pharmaceutical Products and Pharmaceutical Materials” sector was 181 billion TL in 2023.

In 2023, locally manufactured drugs constituted 88% of the Turkish pharmaceutical market in terms of units and 57% in terms of value. It is observed that local drugs increased their market share in terms of both units and value, especially as of 2022. Local products unit sales increased by 7% in 2023 compared to the previous year, reaching 2.6 billion units. When considered in terms of value, local market grew by 104% in the last year, reaching a sales value of 131.5 billion TL. In 2023, approximately 36% (~47.8 billion TL) of local drug sales in the Turkish pharmaceutical market were made up of reference drugs, while local reference drug sales grew by 98% in value compared to the previous year.

On the other hand, biosimilar drugs produced locally (Epoetin alfa, filgrastim, infliximab, insulin glargine, trastuzumab) generated sales of 1.2 billion TL in 2023. In Türkiye, where biosimilar products reached 3.3 billion TL and the total biotechnological market reached 37.8 billion TL, it is seen that local production in the biotechnological drug market remains limited.

According to TurkStat Annual Industry and Service Statistics, in 2023, the number of enterprises in the Manufacturing of Basic Pharmaceutical Products and Pharmaceutical Materials group is 782 and the number of employees is 49806. As of July 2024, there are 99 pharmaceutical production facilities, 10 radiopharmaceutical production facilities, 13 raw material production facilities, 3 herbal supplements and 4 special medical purpose dietary food production facilities are operating approved by the TİTCK in Türkiye.

5. FOREIGN TRADE

HS codes 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 2023, global pharmaceutical export reached \$876 billion, with the top 10 exporting countries accounting for 76% of total exports. Germany, Switzerland, and the US are the top 3 pharmaceutical exporting countries worldwide, while Türkiye ranks 28th.

The top 3 countries in global pharmaceutical imports in 2023 are the USA, Germany and Belgium. Developed countries generally import pharmaceuticals from each other, while their imports from developing countries are limited.

In Türkiye pharmaceutical sector imports increased by 9% annually to approximately 5.4 billion dollars in 2023. The product groups that stand out in Türkiye's pharmaceutical sector imports are vaccines, insulins, blood products, oncology products and reference biotechnological products.

The pharmaceutical exports in Türkiye increased with a compound annual growth rate of 12.6% between 2019 and 2023 and reached 77.6 million kilograms in 2023, with an increase of 6.1% compared to the previous year. The pharmaceutical export price per kilogram, which has been on a downward trend in Türkiye since 2020, increased by 9.4% in 2023 to \$28.4. Looking at the kilogram prices in pharmaceutical sector exports by country, Türkiye has a lower export price level than many European countries with a kilogram price of \$28.

Türkiye exported a total of \$2.2 billion worth of medicines to 179 countries, mainly Middle Eastern, Asian and European countries, in 2023. South Korea ranked first among the countries to which Türkiye exported medicines, with \$458 million, while other leading countries were Hungary, Georgia, Iraq, Poland, Iran, Azerbaijan, Cyprus, Kazakhstan and Uzbekistan. The top 10 countries to which Türkiye exported medicines accounted for 58% of its medicine exports, while the share of the top 20 countries was 72%.

Türkiye received \$5.4 billion pharmaceutical import from 92 countries in 2023. The USA and developed European countries, where R&D and innovation are strong, are key import countries of the Turkish pharmaceutical sector. Germany, constitute 18% of Turkish pharmaceutical markets imports with 962 million dollars, followed by the USA, Ireland and China. The share of the first 10 import countries was 80%, while the share of the top 20 countries was 96%.

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 \$17 billion in 2022. Other countries with over \$1 billion in FDI outflow in the pharmaceutical industry in 2022 are Sweden, Italy and France. Companies in Türkiye made \$34 million in FDI outflow in the pharmaceutical sector in 2022.

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 2022 with 19 billion dollars in FDI inflows. Other leading markets that attracted investment in the pharmaceutical sector in 2022 were Ireland and Italy. Ireland attracts the attention of foreign investors in many areas, including the pharmaceutical industry, thanks to the incentives and long-term policies it implements to attract foreign capital to the country. FDI in the pharmaceutical industry in Türkiye was 209 million dollars in 2020 and 74 million dollars in 2021, but it is seen that 152 million dollars of foreign investment left the country in 2022.

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.

Intellectual property rights are important for supporting innovation and investment in the pharmaceutical industry. 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. 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 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. 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.

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 2024 report prepared by IQVIA, 56% of new molecules launched in the US in 2023 were developed by emerging biopharma companies. When we look at the change in this rate over the years, it is seen that 57% of new molecule launches in the last 5 years in the US were carried out by emerging biopharma companies, while the rate for the previous 5 years was 48%. This shows that the innovation brought to the market by emerging biopharma companies has increased over the years.

In line with this trend, many large pharmaceutical companies continue to strengthen their portfolios by acquiring smaller biotech companies. The highest-value deal of 2023 was the \$43 billion acquisition of Seagen by Pfizer. The total value of the top 10 biopharma mergers and acquisitions deals in 2023 is approximately \$116 billion.

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 37.2% 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 Slovenia, Hungary, Denmark and Belgium. In 2021, the US, whose pharmaceutical R&D activities accounted for 16% of total R&D expenditures, was the country with the highest value of R&D investment in the pharmaceutical industry (104 billion USD). In Türkiye, the share of pharmaceutical investments in total R&D investment is 1.8%, which is lower than many OECD countries.

Clinical Trials

In Türkiye, there are 13 phase 1 clinical research centers approved by the Ministry of Health. According to the number of industry-sponsored clinical trials started in 2023, the US is the undisputed leader globally. Other leading countries in clinical trials include China, Spain, and Canada. Türkiye, which started 168 industry-sponsored clinical trials in 2023, ranked 21st. Türkiye is seen to be behind countries such as the Czechia, Hungary, Brazil, and Argentina in this ranking.

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. 168 industry-supported clinical trials were initiated in all phases in Türkiye in 2023 and the number of phase 3 studies with the highest share was 120.

Looking at the therapy area distribution of newly started clinical trials in 2023, it is seen that 37% of the trials are oncology studies.

The number of newly started clinical trials in countries in 2023, the number of active clinical trials, the number of active clinical trials compared to the population, the number of active clinical trials compared to GDP, and the number of active clinical trials compared to pharmaceutical market size are analyzed. USA ranks first in terms of the number of newly started trials and active studies as of August 2024, while countries with developed economies and healthcare systems such as EU4 countries, UK, China, Canada, Australia, and South Korea are in the top 10. Türkiye ranked 20th in the world in terms of the number of active clinical trials as of August 2024. When different indicators such as the ratio of the number of clinical trials to the population, GDP, and pharmaceutical market size are examined, it is seen that medium-sized Central and Eastern European countries such as Bulgaria, Hungary, and Estonia also stand out. In these proportional rankings, Türkiye ranks lower compared to its position in terms of the total number of active trials. Türkiye ranks 48th in the number of active clinical trials relative to the total population, 44th in the number of active clinical trials relative to the GDP, and 42nd in the number of active clinical trials relative to the pharmaceutical market size.

In the Benefits of a Clinical Research Strategy for Türkiye report published by IQVIA in 2020, the number of industry-sponsored clinical trials in Türkiye was analyzed by year and forecasts were developed for three different growth scenarios. According to the moderate growth scenario indicating medium growth in the report, it was estimated that the number of clinical trials in Türkiye, which was expected to grow with a CAGR of 10.3% between 2019-27, will reach 865 in 2024. In light of the current data as of August 2024, it is seen that the number of active clinical trials in Türkiye has reached 850, converging with the medium growth scenario in the relevant report.

According to the 5-year estimate of the number of clinical trials in Türkiye, in the medium growth scenario where current dynamics continue, it is estimated that the number of clinical trials in Türkiye will exceed 1200 in 2029 with a CAGR of 7.2%. In the scenario where the number of clinical trials increases faster than expected, it is estimated that the number of clinical trials conducted in Türkiye will exceed 1500 in 2029.

According to the AIFD Economic Value Survey, investment in clinical research by research-based pharmaceutical companies in Türkiye in 2023 was 425 million dollars.

When we look at the sponsor companies of industry-sponsored clinical trials initiated in Türkiye between 2019 and 2023, MSD ranked first with 86 studies, while other leading multinational pharmaceutical companies were Novartis, AstraZeneca and Roche.

Startup Ecosystem and Innovation

According to the "Global Enterprise Ecosystem Index 2024" report, Türkiye rose 5 ranks compared to the previous year and became the 40th country with the best enterprise ecosystem. The study analyzed criteria for many different categories such as the number of enterprises, investors and accelerators, private sector enterprise investments, number of employees, working conditions, internet freedom, ease of doing business, and access to technology services. According to this assessment, the enterprise ecosystem in Türkiye was scored similarly to countries such as Bulgaria, Colombia, Chile, and Mexico, but fell behind most European countries.

According to the European Innovation Scoreboard data published annually by the EU Commission, which measures innovation and research performance in EU and other European countries, Türkiye's innovation score in 2023 was calculated as 51.58. In the study where the EU average was 108.47, Türkiye showed similar performance to Balkan countries such as Montenegro, Bulgaria and Macedonia in the field of innovation and research. When the subheadings that make up Türkiye's total innovation score are examined, it is seen that the workforce working in innovative activities, intellectual property and the use of information technologies are the areas where it lags the most compared to the EU average.

Startups with a valuation exceeding \$1 billion are defined as 'unicorns'. According to July 2024 data shared by CBInsights, there are a total of 1,244 'unicorns' in the world. Of these, 118 are in the healthcare and life sciences sector. While the countries that host the most unicorn startups in the healthcare sector are the USA and China, there are no unicorn startups in this field in Türkiye.

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 seven priority sectors in the 12th 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 2023, startups operating in Türkiye reached a total investment value of more than 497 million dollars through 297 investment agreements. While the sector with the highest number of investment deals in 2023 was gaming, software as a service (SaaS) was the sector that received the highest investment value with 128 million dollars. The total investment value of 13 startups that received investments in the health and biotechnology sectors was over 8.4 million dollars.

Number of Patents in Biotechnology in the World and Türkiye

According to the World Intellectual Property Organization data, a total of 9694 patents were obtained in biotechnology globally in 2023. In Türkiye, a total of 183 patents have been obtained in biotechnology in the last 13 years and 66% of these patents were obtained between 2020 and 2023. 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. When looking at other health fields, it is seen that 152 patents were issued in medical technology and 154 in medicine in Türkiye in 2023.

CONTACT US

Maslak Office The building

Maslak District Sumer

Street No:4 Floor:4

Sariyer Istanbul

Türkiye

+90 212 401 9500

iqvia.com