The Pharmaceutical Industry in Turkey

REPUBLIC OF TURKEY PRIME MINISTRY
INVESTMENT SUPPORT AND
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Glossary of Terms

Acronym	Definition
AIFD	Association of Research-Based Pharmaceutical Companies
BağKur	Former Social Security Organization for Artisans and the Self-Employed (Became SGK)
BMI	Business Monitor International
BRIC	Brazil, Russia, India and China
CAGR	Compound Annual Growth Rate
CBRT	The Central Bank of the Republic of Turkey
CEE	Central and Eastern Europe
CEO	Chief Executive Officer
CIS	Commonwealth of Independent States
CTD	Common Technical Document
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIU	Economist Intelligence Unit
ES	Civil Service Retirement Fund
EU	European Union
EUR	Euro
FDI	Foreign Direct Investment
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GPvP/GVP	Good Pharmacovigilance Practices
İEGM	General Directorate of Pharmaceuticals and Pharmacy
İEİS	Pharmaceutical Manufacturers Association of Turkey

Acronym	Definition
IMF	International Monetary Fund
KOSGEB	Small and Medium Enterprises Development Organization
KPI	Key Performance Indicator
MEA	Middle East and Africa
MNC	Multinational Company
MoH	Turkey's Ministry of Health
MSI	Market Surveillance and Inspection
OECD	Organization for Economic Co-operation and Development
OHSAD	Private Hospitals and Health Institutions Association
OIZ	Organized Industrial Zone
OTC	Over-the-Counter
PMI	Purchasing Managers Index
Prod	Product
PTTS	Pharmaceutical Track and Trace System
Q	Quarter
R&D	Research & Development
Ref	Reference
RRR	Risk/Reward Rating
SADER	The Healthcare Products Manufacturers & Representatives Association
SEİS	Health Industry Employers' Association of Turkey
SGK	Social Security Institution
SME	Small and Medium Enterprises
SPO	State Planning Organization

Glossary of Terms

Acronym	Definition
SPW	Sale Price to Wholesaler
SSI	Social Security Institute
SSK	Former Social Insurance Organization (Became SGK)
TPA	Turkish Pharmacists' Association
TEYDEB	The Scientific and Technological Research Council of Turkey
TİM	Turkish Exporters Assembly
TİTUBB	The Turkish Pharmaceutical and Medical Device National Information Data Bank
TL	Turkish Lira
TRNC	Turkish Republic of Northern Cyprus
TTB	Turkish Medical Association
TÜBİTAK	Scientific and Technological Research Council of Turkey
TÜMDEF	Medical Device Manufacturers and Suppliers Association
TurkStat	Turkish Statistical Institute
TUSİDER	Healthcare Association of Turkey
UK	United Kingdom
USA	United States of America
USD	United States Dollar
VAT	Value Added Tax
WHO	World Health Organization

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Executive Summary

- Turkey has demonstrated robust macroeconomic growth in recent years thanks to the government's ambitious growth program and this growth will be sustained over the next 5 years. According to OECD forecasts, real GDP growth is projected to increase about 4% in 2014 and 2015, while the EIU expects an annual average growth rate in real GDP to be about 5% in the short term.
- In 2012, Turkey's pharmaceutical market was the 6th largest market in Europe and 16th largest in the world in terms of sales. Pharmaceutical sales reached a stunning USD 12.5 billion, which means a CAGR of nearly 10% between 2003 and 2012.
- Domestic and international investors are ramping up their new investments in the pharmaceutical sector to take advantage of Turkey's attractive market, where the healthcare industry and the pharmaceutical sector grew by 5.8% and 8.9%, respectively, from 2012 to 2013. While the growth in real GDP was 3.5% for the same period.
- According to BMI's Risk/Reward Ratings (RRRs) which provides a globally comparative and numerically based assessment of a market's attractiveness, Turkey ranks 5th out of the 20 emerging markets in CIS and CEE with a score of 58.
- Turkey has one of the largest and youngest labor pools in Europe with more than 65% of the population aged between 24 and 54. The strength of Turkey's labor force is reflected in the pharmaceutical sector. Turkey continues to put emphasis on education to improve the quality of the workforce. In 2011-2012 academic year, there were more than 41,000 students that graduated from vocational training schools and universities from fields that were related to the pharmaceutical sector.
- Turkey's newly designed investment incentive program divides Turkey into six separate regions. It supports investors in the industry by providing varying tax reductions of between 15-65% depending on investment region and scale as well as social security support for 2 to 12 years depending on the region the investment is made. The Ministry of Health (MoH) has also launched a strategic action plan for the healthcare industry which details ambitious 2017 and 2023 targets for the industry. Moreover, the Ministry of Science, Technology and Industry also defined six ambitious targets and the related actions to achieve these targets.
- Special focus has been given to Free Healthcare Zones that bring numerous advantages to the public and the companies operating in them. There will be 4 free healthcare zones established by 2017 and 10 by 2023, according to the MoH.

I. General Overview of the Turkish Economy and the Pharmaceutical Sector

A. Macroeconomic Overview of Turkey

B. Global Pharmaceutical Sector

C. History of the Pharmaceutical Sector in Turkey

D. Overview of the Pharmaceutical Sector in Turkey

E. FDI in Turkey

Turkey's fast-growing economy is expected to attract more investment in the future

- Turkey has undergone a profound economic transformation over the last decade and its economy is quite solid. It is the 17th largest economy in the world and the 6th largest economy in Europe with a GDP of approximately USD 786 billion in 2012.
- Having boomed as fast as 9.3% and 8.8% in real terms in 2010 and 2011, the OECD projects a real GDP growth of around 4% in 2014 and 2015, while EIU projects on average 5% growth until 2017
- Monetary policy played a vital role over recent years. Turkish inflation has stayed under 10% since 2004 and year-end inflation was 6.2% in 2012. The government's efforts of taming inflation over the last decade has paid off and the CBRT projects an inflation rate of 5% in 2013 and 2014.

Figure 1: GDP Growth Rate (Constant Prices)

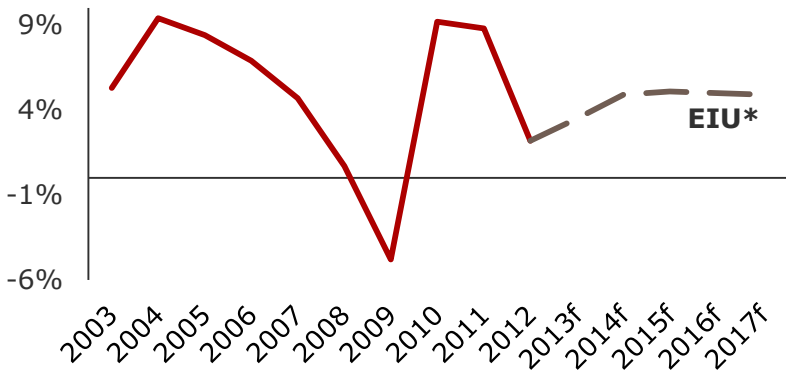

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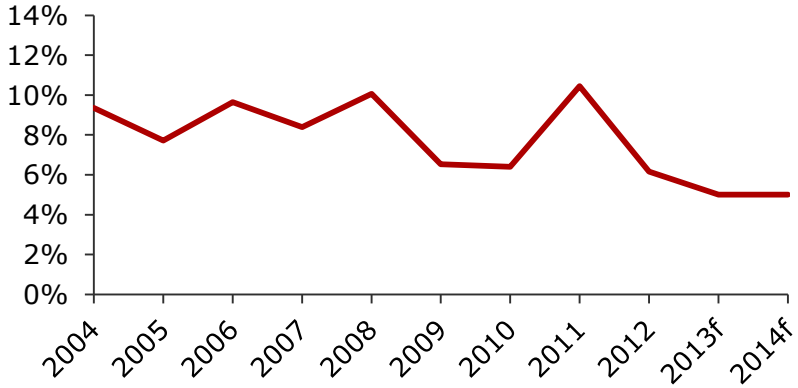
Figure 2: Inflation

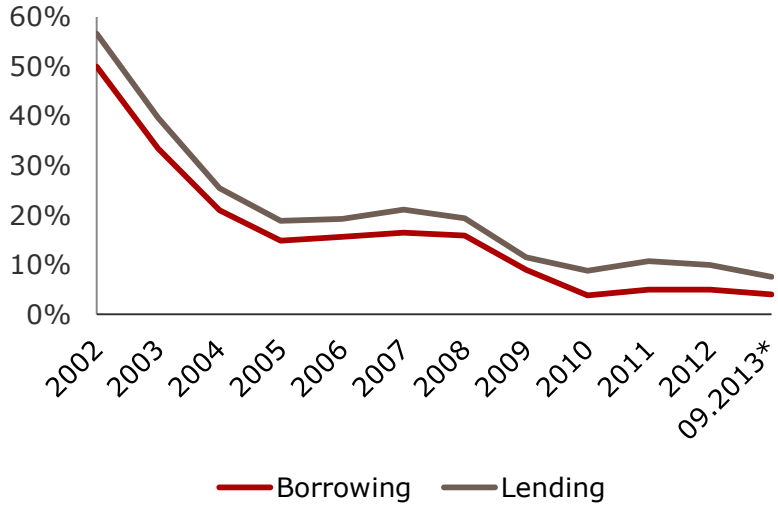


f: forecast of CBRT

Source: Turkstat, EIU, CBRT

Capitalizing on its economic policies, the investment environment in Turkey has become increasingly more welcoming to foreign investors

Figure 3: The Central Bank of the Republic of Turkey O/N Interest Rates



* As of September 2013

- The overnight lending rates have been steadily decreasing over the years and were around 7.5% in September 2013, which was a 500 basis point decrease from 2002.
- Fitch Ratings announced Turkey's investment grade rating as BBB in November 2012 and Standard & Poor's announced a BB+ rating in March 2013. These events signal further upgrades and are expected to boost the inflow of institutional funding.
- Moody's raised Turkish government bond ratings to Baa3 and revised its outlook to stable from positive in May 2013.

Table 1: Turkey's Credit Ratings

	Rating (Local Currency)	Outlook (Local Currency)	Rating (Foreign Currency)	Outlook (Foreign Currency
Standard & Poor's	BBB	Stable	BB+	Negative
Fitch	BBB	Stable	BBB-	Stable
Moody's	Baa3	Stable	Ba1	Positive
JCR	BBB-	Stable	BBB-	Stable

Source: CBRT, Moody's (May 2013), S&P (Febuary 2014), Fitch (December 2013), JCR (May 2013)

The global pharmaceutical market is expected to grow 4% in 2013 from the previous year

- According to EIU forecasts, global healthcare and pharmaceutical spending are expected to increase in 2013 compared to the previous year at a rate of 2.4% and 4.0%, respectively. In Turkey, however, forecasts indicate higher growth rates than global rates. Specifically, the healthcare sector is expected to grow 5.8% and the pharmaceutical sector 8.9% in 2013.

Figure 4: Healthcare and Pharmaceutical Spending Growth by Region, 2013 Forecasts

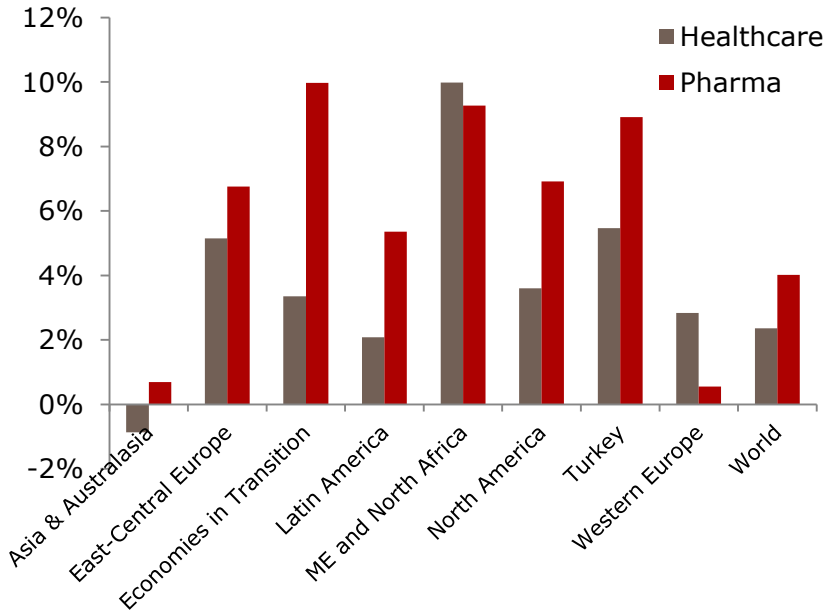


Table 2: Growth Rate of Pharmaceutical Industry in Various Regions

Region	2012-2016f
Asia/Africa/Australia	10-13%
Latin America	10-13%
Tier 3*	**7-10%**
North America	1-4%
Europe	0-3%
Global	**3-6%**

f: forecast

* Pharmerging Tier 3 counties are Argentina, Egypt, Indonesia, Mexico, Pakistan, Poland, Romania, South Africa, Thailand, **Turkey**, Ukraine, Venezuela, Vietnam as indicated in IMS reports.

Source: Economist Intelligence Unit, IMS Health Market Prognosis, May 2012, Deloitte Analysis
Economies in transition: Bulgaria, Czech Republic, Hungary, Poland, Romania, Russia, Slovakia, Ukraine.
* ME: Middle East

Turkey's pharmaceutical sector has a history of significant transformation and improvement

Figure 5: Turkish Health and Pharmaceutical Sector Timeline

1950-1972

- Beginning of the industrial period.
- Raw material manufacturing starts.
- Increase in foreign direct investments.
- 95% of demand is met with local production.

- Foundations were laid in the 1900s by pioneering pharmacists.
- The laboratory period started in the 1930s.

1973-1990

- Stagnancy until 1984.
- Good Manufacturing Practices (GMP) and various related standards began to be applied.
- Advanced technological development occurred because of heavy investments.

1991- 2003

- Annual market growth of 10% on average.
- Unstable pricing and reimbursement policies.
- 20-year patent licensing. (1995)

2004-2007

- Reference pricing system.
- Reduction of VAT from 18% to 8%.
- Data protection & Bolar provision (experimental testing).
- Transfer of SSK hospitals to the Ministry of Health
- The three main social security systems are combined under one single entity.

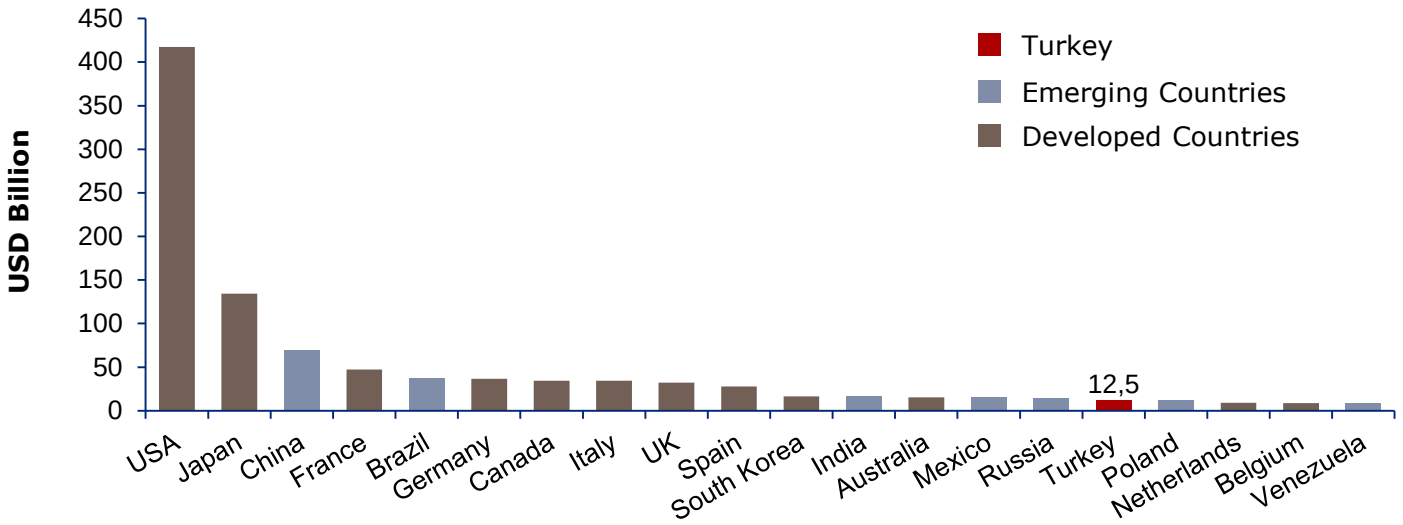
2008-2013

- Introduction of new R&D law.
- Introduction of the Universal Health Insurance System.
- The New Investment Incentive Program launched in 2012 identified pharmaceuticals in its "Priority List" of investments.

Since January 2010 all license holders are obligated to place a track and trace barcode on manufactured goods.

Turkey has the 6th largest pharmaceutical sector in Europe in terms of sales

Figure 6: Top 20 Countries According to Pharmaceutical Sales in 2012

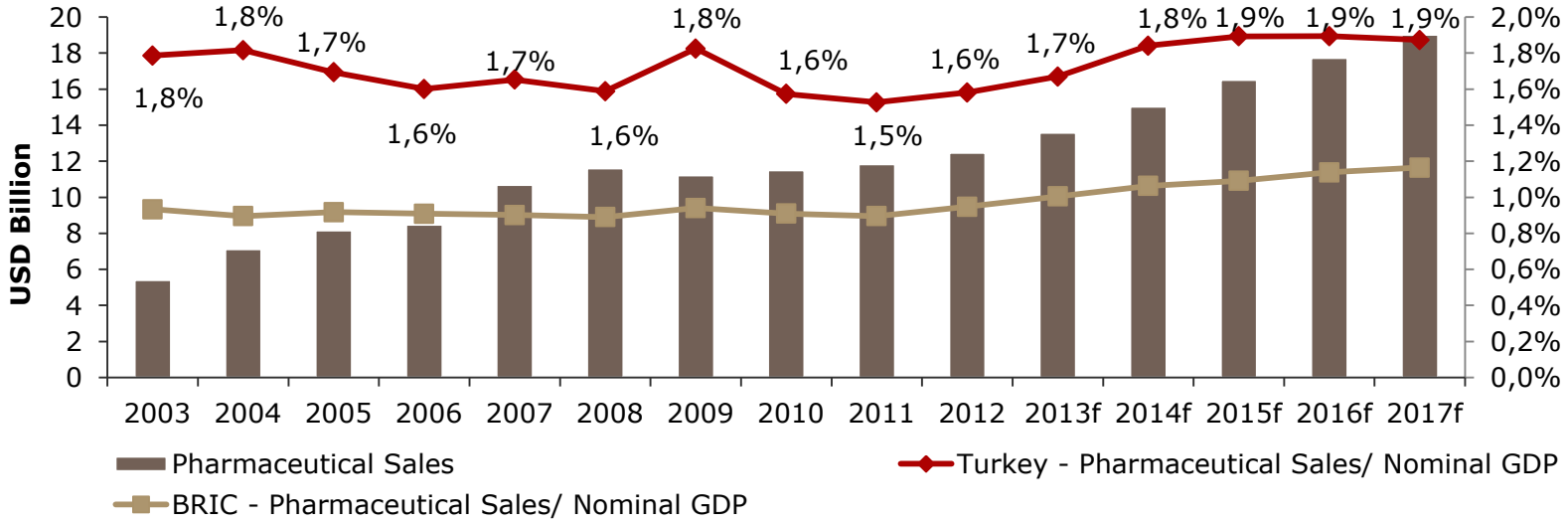


- Turkey was the 6th largest market in Europe and the 16th largest pharmaceutical market in the world in 2012 with USD 12.5 billion in sales, followed by Poland with USD 12 billion and the Netherlands with USD 9 billion. It is expected to grow further by 7%-10% each year until 2015 due to the aging population, increased average life expectancy and increased access to healthcare services.

Source: EIU, AIFD

Turkey has been a rising star with pharmaceutical sales quadrupling over the last decade surpassing the average sales to GDP ratio of BRIC countries

Figure 7: Pharmaceutical Sales of Turkey, 2003-2017



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- Turkey's pharmaceutical sales grew at a CAGR of 9.7% from 2003 to 2012. This is expected to increase at a CAGR of 8.8% from 2012 to 2017 surpassing USD 19 billion, which indicates high local demand for pharmaceuticals.
- As the country's total pharmaceutical sector has grown larger, the major local players have flourished. Turkey's pharmaceutical market is dominated by international companies which accounted for 31.5% of the total market in 2012. However, local manufacturers such as **Abdi İbrahim (7.5%)** and **Bilim İlaç (4.9%)** also held considerable shares in 2012. Above all, the market is heavily fragmented based on the fact that there are approximately 300 pharmaceutical companies in Turkey and they add up to a market share of 44%.

Source: EIU, Espicom, Deloitte Analysis, IMS

The government's healthcare transformation program resulted in an increase in pharmaceutical spending

Figure 8: Pharmaceutical Spending in Turkey per Capita, in PPP USD

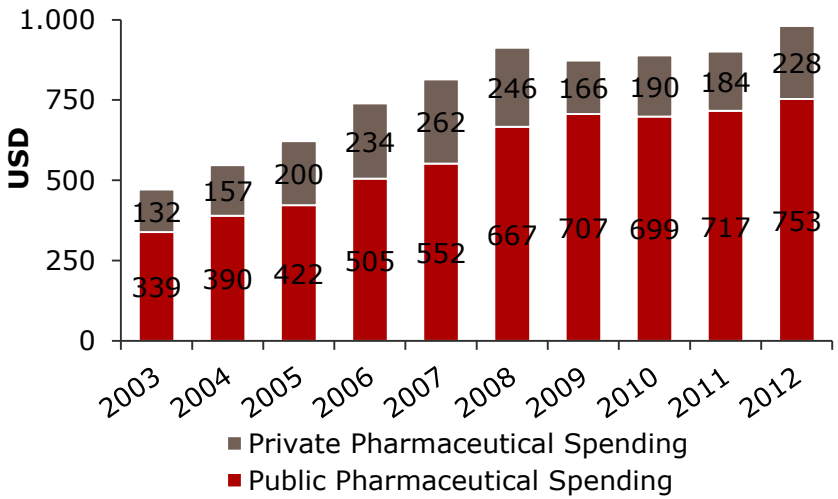
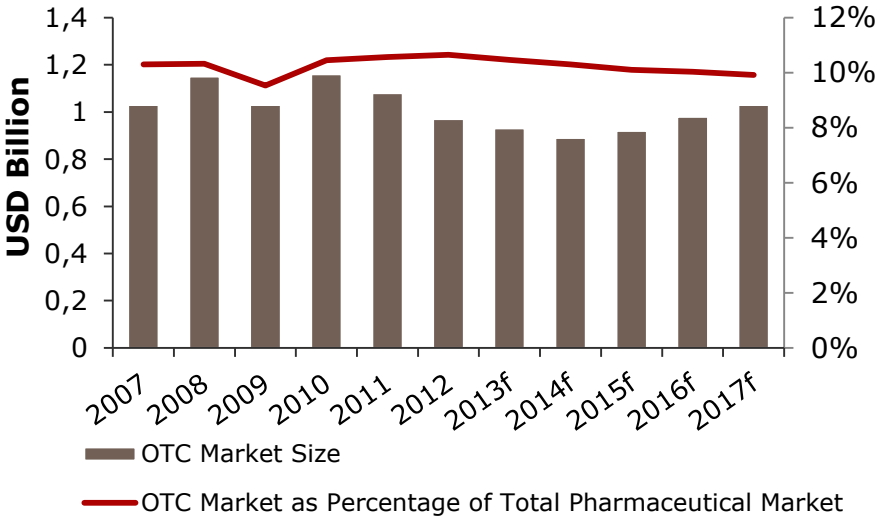


Figure 9: OTC Market in Turkey



PPP: Purchasing power parities

f: forecast e: expected/not announced yet

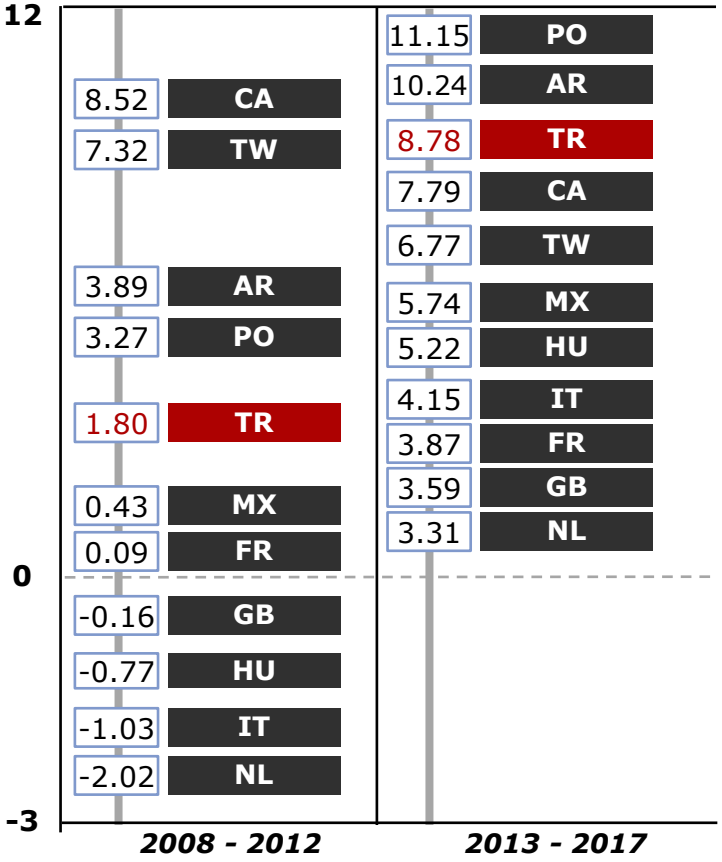
Note: Year-end exchange rates are obtained from Central Bank of Turkey. The TL/USD values are: 1.39 in 2003, 1.34 in 2004, 1.34 in 2005, 1.41 in 2006, 1.16 in 2007, 1.52 in 2008, 1.49 in 2009, 1.54 in 2010, 1.89 in 2011, 1.78 in 2012.

- Pharmaceutical spending in terms of PPP USD increased at a CAGR of 8% from 2003 to 2012 with more than USD 900 in 2012.
- Turkey's spending still lags behind that of OECD average of USD 3,324 but will increase further as the government's budget for pharmaceutical expenditures increase. The government announced a USD 7.4 billion budget on pharmaceutical expenditure, which is a slight decrease of 6% from the previous year's budget of USD 9.3 billion. However, the budget will grow at least by the expected inflation rate over the coming years.
- The total OTC market size decreased slightly from 2007 to 2012 but is further expected to increase to more than USD 1 billion by 2017.

Source: Ministry of Health , AIIFD, Deloitte analysis

As a result, the pharmaceutical market is expected to grow a CAGR of 8% between 2013 and 2017

Figure 10: Pharmaceutical Market Growth for 2008-2012 and 2013-2017 in Selected Countries



Source: EIU Database, AIFD, Deloitte Analysis

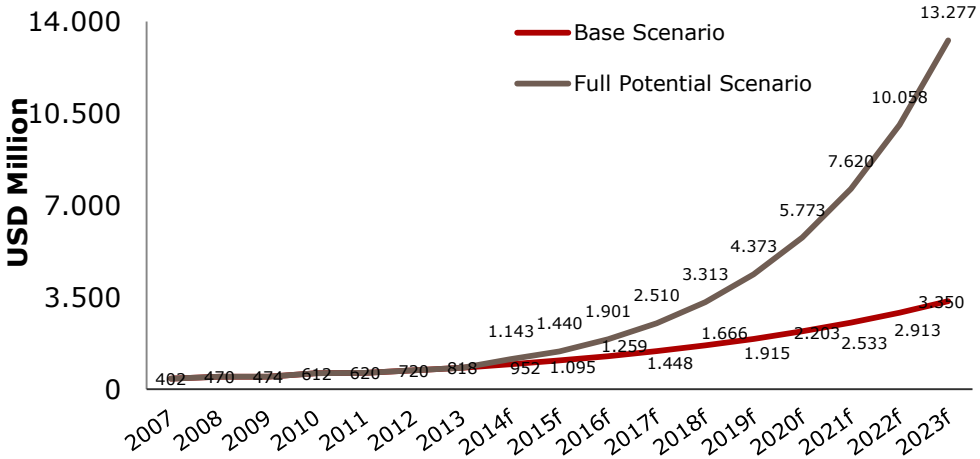
Note: The numbers in the first column refer to 2008-2012 CAGR and the numbers in the second column relate to the expected 2013-2017 CAGR.

Note: Countries in the table are as follows: Argentina (AR), Canada (CA), France (FR), United Kingdom (GB), Hungary (HU), Italy (IT), Mexico (MX), Netherlands (NL), Poland (PO), Turkey (TR) and Taiwan (TW).

- Between 2008 and 2012, the CAGR for Turkey was 1.8%. Most developed countries experienced negative CAGR rates within the same period.
- According to Economist Intelligence Unit, the pharmaceutical sector in Turkey is expected to boom with a CAGR of almost 9% from 2013 to 2017 and will pass the world average CAGR of 7% for that period by 2017.
- The Turkish pharmaceutical sector has extensive facility infrastructure, which is comparable to international standards. 76% of drugs consumed in Turkey are on a box basis and 49% on a value basis and are locally produced.

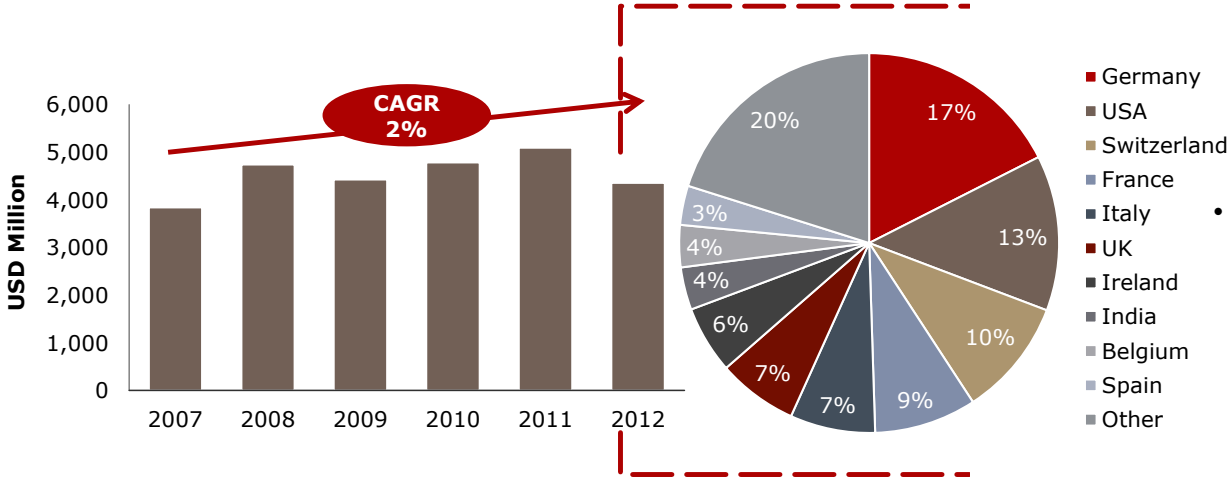
Pharmaceutical exports also experienced a surge at a CAGR of 10% from 2007 to 2012

Figure 11: Turkey's Pharmaceutical Exports



- Turkey's pharmaceutical exports increased at a CAGR of 10% from 2007 to 2012, surpassing USD 720 million.
- Regarding export values, the top ten countries had over 55% of the total export share. Germany leads with 10% in 2012, followed by Iraq with 8%, South Korea, which is Turkey's largest export market in Asia, with 7%.
- Working toward 2023 targets, the Turkish pharmaceutical sector is positioned to deliver over USD 13 billion worth of exports by 2023.

Figure 12: Turkey's Pharmaceutical Imports and Top Ten Countries that Turkey Imported from in 2012



- Turkey's pharmaceutical imports increased by only a CAGR of 2% between 2007 and 2012 as local production increased. The export/import coverage ratio increased from 10% in 2004 to more than 17% in 2012.
- Germany is the leader of the countries that export to Turkey, having a 17% share of Turkey's imports in 2012. The top ten countries that Turkey imports pharmaceuticals comprise approximately 80% of total pharmaceutical import.

Source: TIM 2023 Export Strategy Report, TurkStat, Deloitte Analysis
Note: HS Codes 2936, 2937, 2938, 2939, 2941, 30 were used in the analysis

Turkey ranks 5th out of the 20 CEE and CIS pharmaceutical markets according to BMI's RRR tool

- BMI's Risk/Reward Rating (RRR) tool, which provides global comparison and a numerically based assessment of a market's attractiveness, was established to asses the risks and rewards of given countries in the pharmaceutical sector. Turkey's pharmaceutical Risk/Reward Rating (RRR) score for the 4th quarter of 2013 was 58 points. Consequently, Turkey takes 5th place among 20 markets surveyed in CEE and CIS countries for pharmaceuticals .
- Turkey's large drug market, coupled with the sector's long-term growth potential, enabled the country to score relatively well for rewards.

Table 3: Selected Countries in BMI's Risk/Reward Rating Report

	Ind. Reward	Cou. Reward	Reward	Ind. Risk	Cou. Risk	Risk	RRR*	Rank
Czech Republic	25.2	15.6	40.8	12.4	10.0	22.4	63.2	1
Poland	26.0	13.5	39.5	11.6	10.5	22.1	61.6	2
Russia	30.4	13.0	43.4	9.5	7.6	17.1	60.5	3
Greece	24.8	15.6	40.4	9.5	8.4	17.8	58.2	4
Turkey	26.0	12.6	38.6	10.2	8.9	19.1	57.7	5
Slovakia	22.0	11.9	33.9	12.6	9.9	22.5	56.4	6
Romania	22.8	12.2	35.0	11.9	9.3	21.2	56.2	7
Hungary	19.2	13.8	33.0	11.2	10.0	21.2	54.2	8
Bulgaria	18.8	14.9	33.7	11.2	8.8	20.0	53.7	9
Slovenia	14.8	13.2	28.0	14.7	10.5	25.2	53.2	10
Estonia	12.8	14.6	27.4	13.3	11.4	24.7	52.1	11
Ukraine	22.8	13.0	35.8	8.4	6.1	14.5	50.3	12

*RRR: A market's RRR score is made up of the sum total of the Reward score (Industry Rewards + Country Rewards) and the Risks score (Industry Risks + Country Risks).
Source: BMI

Turkey's FDI for the manufacturing of chemicals and chemical products, which also covers pharmaceuticals, increased at a CAGR of 27% from 2008 to 2012

Figure 13: FDI Inflows to Turkey, 2003-2012

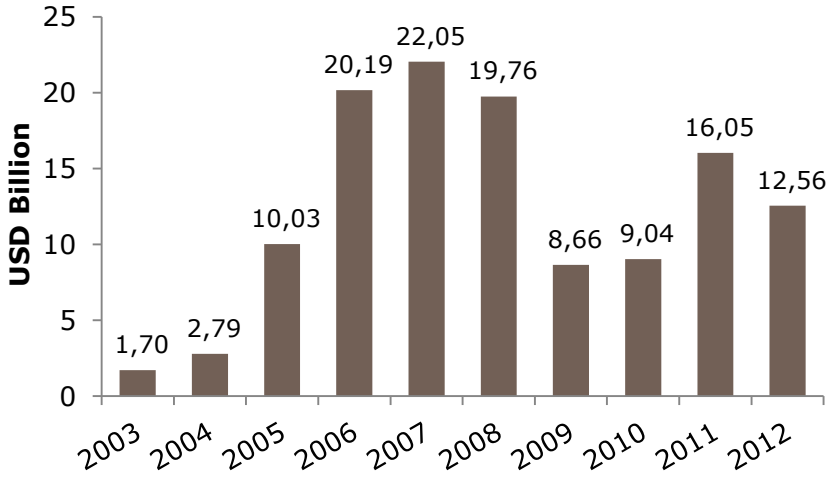
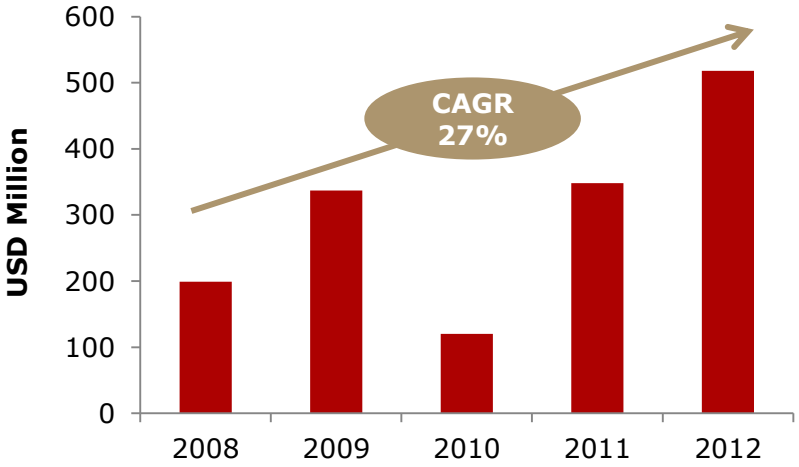


Figure 14: FDI in the Chemical Industry in Turkey*



* Includes the manufacture of chemicals, chemical products and basic pharmaceutical products and materials.

- Turkey has become an attractive destination for FDI. FDI inflows were weak after 2002, but then experienced an incremental increase and reached a record level of USD 22 billion in 2007. The decrease in 2009 can be explained by the global crisis which lowered FDI all around the world, including Turkey. However, according to the 2011 values, Turkey has recovered well from the downturn.

Source: World Development Indicators, World Bank DataBank, CBRT

- The volume of FDI inflows directed to Turkey shows a promising recovery. 2012 FDI inflows rose to **USD 12.5 billion**, compared to USD 8.6 billion in 2009.
- Moreover, Turkey was able to attract an impressive level of FDI to the chemical industry, which includes pharmaceutical manufacturing as well as other chemical manufacturing. FDI inflows to the industry increased at a CAGR of 27% from 2008 to 2012, exceeding the USD 500 million level in 2012.

Turkey is attracting pharma giants from all over the world…

- The R-Pharm Group established a subsidiary in Turkey that will take care of local registering, marketing and sales activities for owned and licensed pharmaceuticals. By entering the Turkish market, the R-Pharm Group wants to expand the distribution market for pharmaceuticals produced in its manufacturing sites in Russia. The company is now opening an office in Istanbul
- The R-Pharm Group sees the Turkish pharmaceutical market as a prospective market that has both attractive policies and regulations for foreign investors and ongoing programs supporting the local pharmaceutical sector.
- The company is also planning to construct a biotech manufacturing site in Turkey similar to existing Russian ones.
- The R-Pharm Group is going to invest EUR 100 million into its Turkish business. These resources will be spent on pharmaceutical registration, R&D and phase 1 construction of the manufacturing site.
- Moreover, global pharmaceutical giant Baxter is set to invest in Turkey. The company has been known to invest in pharmaceuticals geared towards the immune system.

"The rapidly growing Turkish market is a good platform for our geographical expansion. We expect that our Turkish subsidiary will secure the supply of R-Pharm medical products to the Middle East and Africa."

R-Pharm Group, CEO Vasily Ignatiev, May 2013

R-PHARM
Innovative health technologies

"U.S. pharmaceutical firm Baxter has announced plans to make a USD 170-180 million investment in Turkey..."

Minister of Science, Industry and Technology, Nihat Ergün, June 2012

Baxter

…which has manifested in M&As worth USD 1.7 billion since 2006

Acquirer	Target	Date	Deal Value USD Millions	Stake
Citibank Venture Capital Ltd; Partners in Life Sciences (PiLS)	Biofarma Pharmaceuticals Co. Ltd.	2006	200	100%
White Swan Corporation B.V.	Taymed Sağlık Urunleri Ticaret Ltd. Şti.	2006	N/A	100%
Partners in Life Sciences (PiLS)	Munir Sahin İlaç Sanayi ve Ticaret A.Ş.	2006	22	100%
International Pharma Ltd.	Deva Holding A.Ş.	2006	50.2	18%
Actavis Group hf (formerly Pharmaco hf)	Fako İlaçlari A.Ş.	2006	20.4	10%
Eastpharma Holding	Saba İlaç Sanayii ve Ticaret A.Ş.	2007	10	96%
Zentiva NV	Eczacıbaşı-Zentiva Kim. Ur. San. ve Tic. A.Ş. Eczacıbaşı-Zentiva Sag. Urun. San. ve Tic. A.Ş.	2007	602	75%-75%
Sandoz International GmbH	Roche Holding AG (Gebze production plant)	2007	N/A	100%
Eczacıbaşı İlaç	Monrol Nükleer Ürünler	2008	43.1	50%
İş Girişim Sermayesi	Dr. F. Frik İlaç Sanayi	2008	13.4	17%
Partners in Life Sciences	Betasan Pharmaceuticals	2008	N/A	100%
Recordati SpA	Yeni İlaç	2008	60	100%
Ebewe Pharma	EBV Limited	2008	N/A	99.5%
Zentiva NV	Eczacıbaşı-Zentiva Kim. Ur. San. ve Tic. A.Ş. Eczacıbaşı-Zentiva Sag. Urun. San. ve Tic. A.Ş.	2009	N/A	25%-25%
Alliance Boots	Hedef Alliance Holding	2010	N/A	10%
Polpharma	Cenovapharma	2011	N/A	77%
Recordati SpA	İş Girişim Sermayesi (shares in Dr. F. Frik)	2011	30.5	100%
NBK	Dem İlaç	2012	N/A	N/A
Amgen	Mustafa Nevzat İlaç	2012	669	96%

Source: Deloitte, Annual Turkish M&A Reports

II. A Detailed Look at the Turkish Pharmaceutical Sector

A. Overview of the Pharmaceutical Value Chain

B. Policy and Regulatory Landscape

C. Discovery and R&D, Raw Material Production, Pharmaceutical Manufacturing, Wholesale and Retail

D. Major Stakeholders in the Pharmaceutical Sector

E. Special Focus: Biological Products, Oncological Drugs and Blood Products

The Ministry of Health is the regulatory body of the pharmaceutical sector

- The Ministry of Health oversees the industry and has several different institutions under its auspices. These institutions include the General Directorate of Pharmaceuticals and Pharmacy (İEGM), the Public Healthcare Institute, the Public Hospitals Institute, the Directorate General of Health for Border and Coastal Areas. IEGM oversees all activities in the pharmaceutical sector.
- The SSI oversees the price and reimbursement mechanism for pharmaceuticals.

The Ministry of Health, Social Security Institute

Discovery and R&D

- Currently, Turkey's pharmaceutical sector is not focused on discovering new molecules to produce new drugs. Instead of concentrating on discovery, which needs large amounts of capital, Turkey is concentrating on modifying existing molecules and adjusting dosage.

Raw Material Production

- There are 10 different companies and 12 different raw material producing facilities that are involved in production.
- Raw materials are used to manufacture pharmaceutical goods or are exported to other countries.

Pharmaceutical Manufacturing

- More than 300 international and domestic pharmaceutical companies operate in Turkey.
- 70 firms have pharmaceutical end-product manufacturing in Turkey. More than half of the production facilities are located in Istanbul, which is the business center of Turkey.

Wholesale

- There are more than 500 wholesale companies, but only about 200 of these firms are active.
- Wholesalers mainly sell pharmaceuticals to pharmacies but can also sell some cosmetics and other FMCG (fast-moving consumer goods) products to pharmacies.

Retail

- There are more than 24,000 pharmacies in Turkey as of 2012. Pharmacies are distributed according to population density across the country.
- Pharmacies also sell some cosmetic and FMCG (fast-moving consumer goods) products.

The Turkish healthcare sector has been transforming and evolving since the early 90s

The Healthcare System

- Turkey's Ministry of Health (MoH) was founded in 1920. It is the largest healthcare provider and is still the country's only preventative healthcare services provider. The MoH is also the main provider of primary and secondary care. The MoH is responsible for the nation's health policies and its health services. At the provincial level, health services provided by the MoH are administered by provincial health directorates, which are accountable to provincial governors.

Source: Ministry of Health, IEGM

- The Turkish Drug and Medical Device Institute, a part of the MoH, is in charge of the control and regulation of pharmaceutical prices. Manufacturers and importers are obliged to apply for the MoH's authorization for new product prices, as well as for price increases and decreases.
- Turkey complies with international treaties in the field of intellectual property and complies with European Union standards. By adopting patent protection into national legislation for pharmaceuticals, the transformation period right allowed by the WTO's TRIPS Agreement* was waived and as of January 1, 1999, all applications that had been accepted since 1995 were given patent protection.
- The data protection liability under TRIPS entered into effect in Turkey in March of 1995. In this context, all of the confidential information submitted for the purpose of obtaining a license is protected.
- With this development, laws that are related to data protection in Turkey got closer to European standards.

*WTO's TRIPS Agreement: The Agreement on Trade Related Aspects of Intellectual Property Rights in the World Trade Organization

Pricing System:
In Turkey, the reference pricing system began in 2004.

- Prices are regulated by the Turkish Drug and Medical Device Institute, which is a part of the Ministry of Health. Turkey operates a reference pricing system, implemented in 2004 and amended extensively in 2009, 2010 and 2011.
- To determine the price of pharmaceuticals sold in the market, Turkey operates an external reference pricing system: the lowest ex-factory price of the products among five EU members (France, Spain, Italy, Portugal and Greece) and the country of origin, from which the drug is procured, is then reduced by 11%. The reference price level can mean the price is reduced to 60% of the comparable product in the EU states. In addition, a public discount of 28% (for generics) and 41% (for innovative products without generic equivalents) is then applied to the prices. Final retail prices have predetermined wholesale and pharmacy margins, plus a VAT of 8%.
- However, if the countries in which the relevant pharmaceuticals are being manufactured and imported are outside of the mentioned reference countries and have warehouse sales prices that are lower than the reference country price, the price in the country with the lowest warehouse sales price is accepted as reference price.

Table 4: Pharmaceutical Prices in Turkey

Reference Pharmaceuticals that Do Not Have Generic Competition	Reference Pharmaceuticals that Have Generic Competition	20 Year Pharmaceuticals (over TL 6.79)
Reference Price + Wholesaler and Pharmacist Profit Margin + 8% VAT	60% of the Reference Price + Wholesaler and Pharmacist Profit Margin + 8% VAT	80% of the Reference Price + Wholesaler and Pharmacist Profit Margin + 8% VAT

Source: Pharmaceutical Manufacturers Association of Turkey, İEİS, İEGM

Pricing System:

The VAT rate applied to medicines in Turkey is lower than that of European countries.

Table 5: VAT Rates Applied to Medicines in Selected European Countries

Country	Standard VAT Rate (%)	VAT Rates Applied to Medicine		Country	Standard VAT Rate (%)	VAT Rates Applied to Medicine	
		Prescription (%)	OTC (%)			Prescription (%)	OTC (%)
Austria	20	10	10	Poland	23	8	8
Bulgaria	20	20	20	Iceland	25.5	25.5	25.5
Czech Republic	21	15	15	Italy	21	10	10
Denmark	25	25	25	Norway	25	25	25
Estonia	20	9	9	Romania	24	9	9
Finland	24	10	10	Slovakia	20	10	10
Germany	19	19	19	Turkey	18	8	8

Source: EFPİA, Figures Key Data 2013

Social Security Institute:

SSI is the single entity made up of the three former social security institutes.

The History of Health Insurance in Turkey

Former Social Insurance Organization - SSK

- The plan covered almost all privately employed workers and blue-collar public sector workers, retirees and their dependents. The SSK was mainly financed through mandatory contributions from employers and employees. Additional income was obtained from fees paid by non-members using SSK services (e.g. members of BağKur) and from co-payments.

Former Social Security Organization for Civil Servants – Emekli Sandıgı

- The plan provided healthcare benefits to currently employed and retired white-collar public sector employees and their dependents (active civil servants are separately insured by the Ministry of Finance). Insurance premiums are collected from income and the plan is subsidized from the government budget for pension and healthcare benefits.

Former Social Security Organization for Artisans and the Self-Employed – BağKur

- The scheme provided insurance for independent traders and the self-employed. A reimbursement system was established and fees are determined independently by the institution. Co-payments of 20% from active members and 10% from retired members are required for the purchase of drugs, as is the case of SSK.

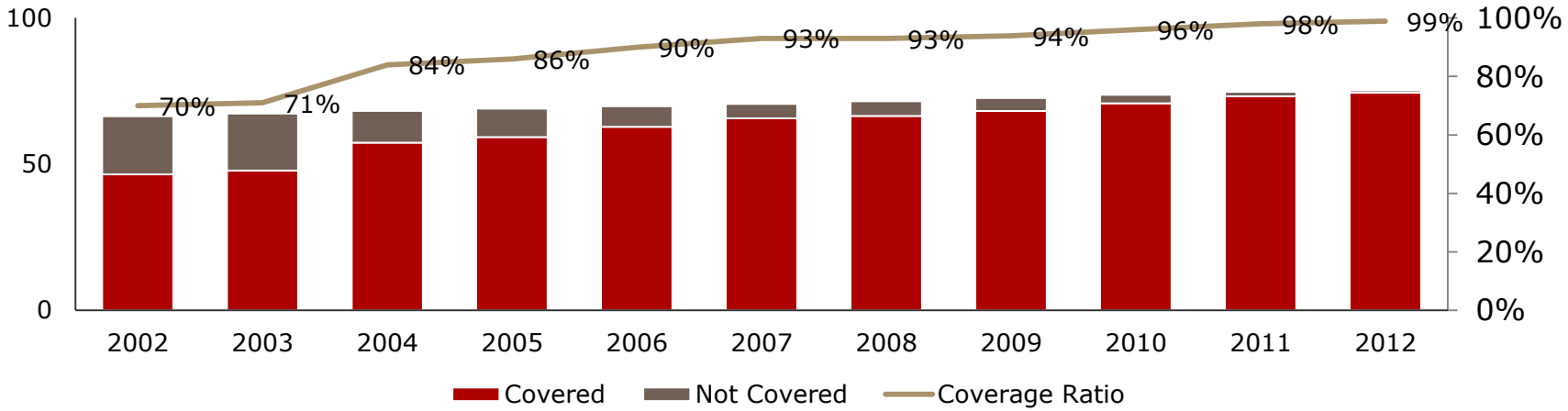
Social Security Institution (SSI)

- In 2006, the three main social security systems, namely SSK, BağKur and Emekli Sandığı, were combined under one single entity, the Social Security Institute. The population covered with the Green Card health plan is also covered by the new social security institution in order to make sure that all citizens are supported. There will also be only one payment agency for healthcare, the Universal Health Fund, making the system more efficient and effective. This new system is a part of Turkey's ongoing healthcare reforms and aims to solve many problems of the Turkish health system over the years, including low population coverage, reliance on out-of-pocket payments and an uneven distribution of facilities and personnel.

Social Security Institute:

Social Security coverage expanded rapidly in Turkey, which in 2012 covered 99% of the population.

Figure 15: Social Security Coverage



- The social security system in Turkey went through a major transformation, resulting in a faster and more efficient system because it centralized control of different social security funds into a single institution.
- Within the scope of the program, the three insurance funds, namely SSK, Emekli Sandığı and BağKur, were merged into a sole body called the Social Security Institute (SSI).
- The social security system now covers approximately 99% of the total population with 75.2 million people covered, which is an increase of 29% from 2002.

Source: SSI

Social Security Institute:

Drug reimbursement is governed by the inter-ministerial Reimbursement Commission, led by the Social Security Institute.

	Reference		Generics	20 Year		
SPW ≤ 3.55	4% -> 0%		4% -> 0%	4% -> 0%		
3.56 ≤ SPW ≤ 6.78	**Without Generics**	**With Generics**	28% -> 20%	11% -> 7%		
	41% -> 20%	28% -> 20%				
6.79 ≤ SPW ≤ 10.21	41%	28%	28%	**Production**	**With Ref.**	**Without Ref.**
				28% -> 20%	28% -> 20%	40% -> 20%
10.22 ≤ SPW	41%	28%	28%	28%	28%	40%

SPW: Sales Price to Wholesaler

- Pharmaceutical companies have to apply to the Ministry of Health and SSI in order to include their drugs in the reimbursement program. Reimbursement procedures for different pharmaceutical products and medical devices may differ and are explained in detail in the SSI Health Application Legislation.
- Reimbursement is made for pharmaceuticals that are at most 10% above the determined price of the related pharmaceutical in the generic group.
- Discounts are applied by pharmaceutical companies and pharmacists to the public for pharmaceutical purchases.

Source: Medical Enforcement Ddeclaration dated 12.11.2013, Pharmacutical Manufacturers Association of Turkey, İEİS

Social Security Institution

Reimbursement amount was more than USD 7 billion in 2012.

Figure 16: Reimbursements in the Turkish Pharmaceutical Market

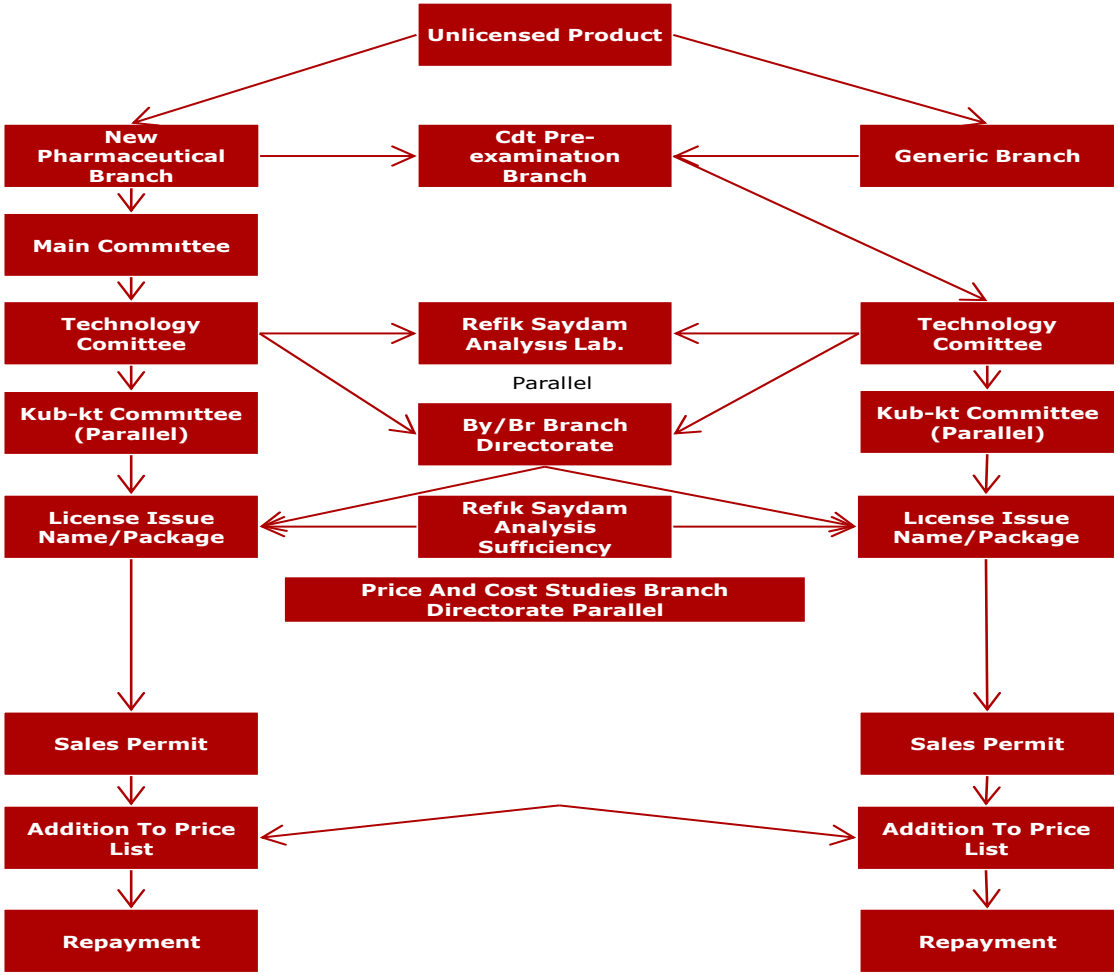
Note: Year-end exchange rates are obtained from the Central Bank of Turkey. The TL/USD values are 1.49 in 2009, 1.54 in 2010, 1.89 in 2011, 1.78 in 2012 and 2.13 in 2013.

- Turkey's total reimbursement within the pharmaceutical market in terms of value decreased to USD 7.28 billion in 2012, which accounts for a decrease of 7.3% CAGR from 2009 to 2012.
- Moreover, the number of reimbursed drugs unit sales decreased at a CAGR of 2.1% during the same time frame.
- Therefore, companies are trying to expand into the OTC market with different product offerings.

Source: AIFD

Licensing Regulation:
Per licensing regulation, the whole process takes 240 days.

Figure 17: Licensing Process

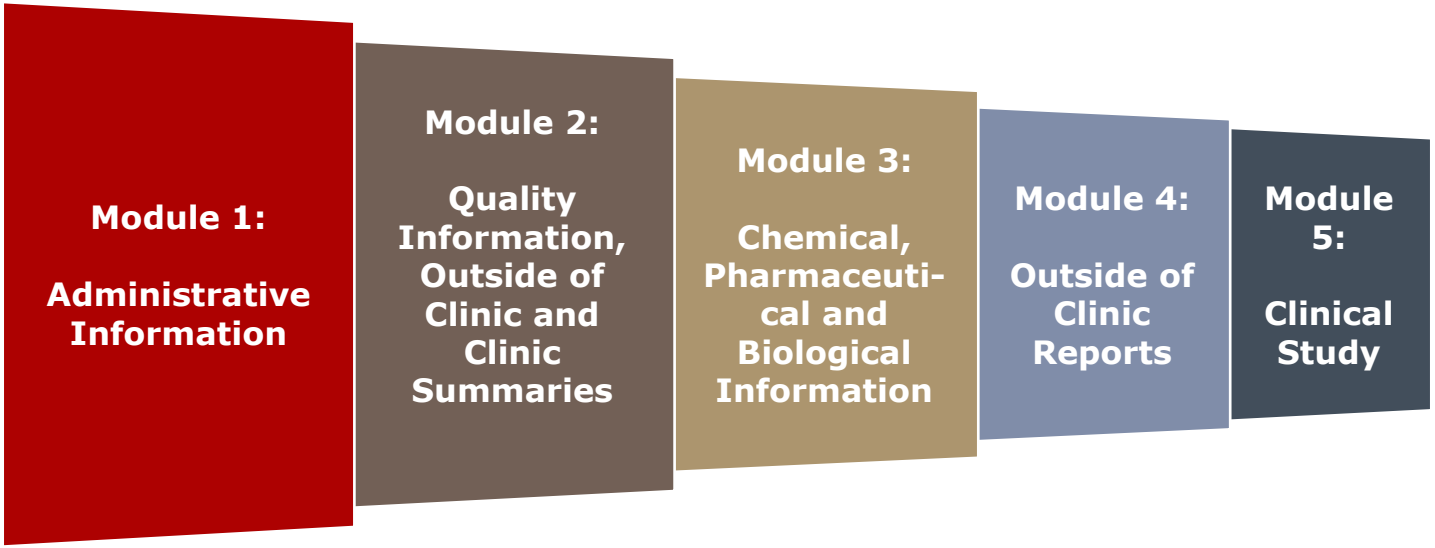


Source: Pharmacutical Manufacturers Association of Turkey, İEİS

- In Turkey, real persons and legal entities are required to present an application to the Ministry in order to receive a license for their products.
- To make procedures more efficient and less time consuming, different committees operate simultaneously. The related Committees are as follows:
  - **Advisory Committee for the Licensing of Pharmaceuticals:** Issues an opinion for the product that will be licensed.
  - **Pharmaeconomic Advisory Committee:** Reviews the pharmaceutical in terms of effectiveness and cost-benefit as well as performing a cost minimization analysis.
  - **Technology-Pharmacology Advisory Committee:** Examines the product pharmacologically.

Licensing Regulation:
Applications should be presented in a CTD format.

- The licensing process in Turkey is carried out according to the provisions of the Human Medical Products Licensing Regulation, which was prepared under the scope of Law No. 1262 named the Pharmaceutical and Medical Preparations Act and in compliance with European Union legislation. The Human Medical Products Licensing Regulation came in to effect on January 19, 2005
- The application files are prepared and presented in CTD format in accordance with regulations. CTD format, which is an international standard, was established to present applications in an organized manner and standardized with the procedures of pharmaceutical licensing authorities in Europe, the USA and Japan.
- CTD format comprises these five modules:



Source: Pharmaceutical Manufacturers Association of Turkey, İE İS

Licensing Regulation:
Different requirements are necessary for generic and reference licensing.

Table 6: Requirements for Licensing in Generic and Reference Drugs

Licensing Requirements	Generic	Reference
General Information of Company	✓	✓
Product Properties	✓	✓
Expert Report	✓	✓
Pharmaceutical Compound	✓	✓
Good Manufacturing Practices	✓	✓
Primary Materials Inspection	✓	✓
Finished Product Inspection	✓	✓
Stability Test (Active Content and Finished Product)	✓	✓
Comparison of Generic Product with Reference Product	✓	
Pre-Clinical Studies		✓
Clinical Studies		✓
Bio-Equivalence	✓	

Source: Pharmaceutical Manufacturers Association of Turkey, İEİS

- A reference pharmaceutical is a product that has been developed by an innovating company and offered to the market under patent protection. After the patent period has expired, these products are used as reference products in order to produce generic pharmaceuticals.
- Generic pharmaceuticals are medications that have been scientifically proven to have the same properties as the reference pharmaceutical and therefore, provide the same therapeutic results in the patient. They are presented for sale after the patent period for the reference pharmaceuticals have expired. A generic pharmaceutical must have the same effectiveness, quality and reliability as its reference pharmaceutical.
- All of the phases that generic pharmaceuticals go through from production until it is put on shelf for sale, are the same ones that reference pharmaceuticals go through as seen in the table on the left. Only the clinical studies that are performed on living organisms by reference pharmaceutical producers are not done. Therefore, the R&D costs are significantly reduced.

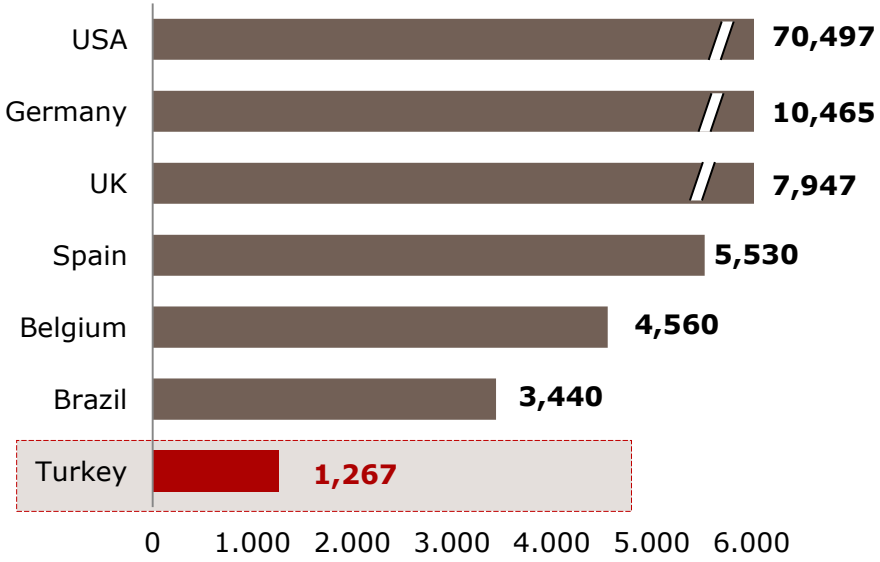
With the Pharmaceutical Track and Trace System, the fingerprint of a pharmaceutical will always be monitored

- The Pharmaceutical Track and Trace System monitors pharmaceuticals at every stage and was created in order to prevent fraud and maintain patient security.
- Under this system, all pharmaceuticals produced in Turkey are defined with a two dimensional barcode system which contains a variety of information. The barcode is the pharmaceutical's fingerprint. The barcode number, serial number, expiration date and party number are included in the barcode.
- As of January 1, 2010 all license holders are required to place a barcode on all products that they produce.
- Hospitals, health centers, family physician centers, pharmacies, pharmacy warehouses, manufacturers, importers and reimbursement institutions are all stakeholders under the scope of the Pharmaceutical Tracking System.

Products Under the Scope of the System	Products Outside the Scope of the System
• **Drugs:** These are the prescription drugs which can be obtained only from pharmacies with a valid prescription. • **Medical Nutrition Products:** The products on the market known as "food supplements" and those used for medical purposes called "medical nutrition products". As with drugs, medical nutrition products require monitoring and they fall under the scope of the system.	• Serums, radiopharmaceuticals and drugs manufactured for private use with the exception of medical food and enteral nutrition products lie outside the scope of system until 01/01/2014.

Turkey is ranked 35th in the world in terms of clinical research conducted

Figure 18: Total Number of Clinical Research Conducted in the World, 2013

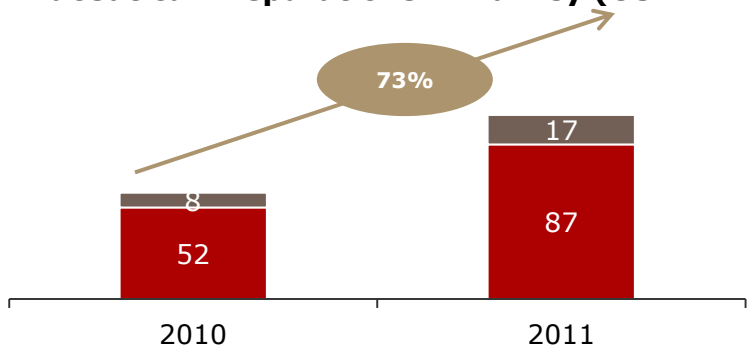


- The Turkish Drug and Medical Device Institute is the regulatory authority for drug discovery and R&D. It also monitors clinical research and R&D activities in Turkey. The institute has prepared the legislation related to clinical research in August 2011, which is compatible with the European Union directives.
- Companies that want to conduct research in the following areas must apply for permission from the Ministry of Health for:
  - Pharmaceuticals, medical products and herbal medicinal products that will be tested on human subjects.
  - Pharmaceutical studies
  - Bioavailability and bioequivalence studies
  - Studies of medical devices and medical device clinical research
  - Stem cell transplantation research
  - Organ and tissue transplantation
  - New surgical methods research
- Turkey is ranked 35th in number of clinical research conducted in the world and 19th in Europe. Turkey conducted over 1,200 clinical trials in 2013 and took a share of 0.6% of total clinical research conducted in the world.

Source: clinicaltrials.gov, Ministry of Science, Industry and Technology

In order to develop research, Turkey has increased its R&D expenditure by a massive 73% from 2010 to 2011

Figure 19: Business Expenditure on R&D in Manufacturing of Basic Pharmaceutical Products and Pharmaceutical Preparations in Turkey (USD Million)



Note: Year-end exchange rates were obtained from the Central Bank of Turkey. The TL/USD values are 1.54 in 2010 and 1.89 in 2011.

- R&D expenditure in manufacturing of basic pharmaceutical products and pharmaceutical preparations have increased at a staggering rate of 73% from 2010 to 2011 surpassing USD 100 million in 2011.
- The Center for Basic Drug Research, known as ITAM, was established to increase the global competitiveness of Turkey by focusing on improving R&D investments for the pharmaceutical sector. Moreover, the center will establish a facility that transfers advanced technology in order to manufacture sustainable and value added pharmaceutical products.

Source: Turkstat

- Even though Turkey does not conduct new molecule research, which takes large amounts of capital investment and long research periods, it does conduct research on molecule that have already been discovered and produces other formulas at different dosage levels.
- Moreover, Law No. 5746 supports and encourages the development of technology in Turkish companies so they can become globally competitive through R&D and innovation. This will also increase the quality of product as well as standards. Along with these important attributes it will also fuel innovation in products and manufacturing, decrease production costs, increase productivity, commercialize technical knowledge, develop pre-competitive R&D cooperation between rival companies, intensify technology production and promote entrepreneurship, increase the amount of FDI directed to R&D and innovation funding and finally, increase employment for R&D personnel.
- Pharmaceutical companies constitute 3.5% of the total number of R&D centers in Turkey and they are prominently located in the Marmara region.

There are various incentive programs for the pharmaceutical sector

- In addition to the Investment Incentive System that went in to effect in 2012, pharmaceutical sector investment initiatives are supported through several regulations and incentive plans.

TÜBİTAK-TEYDEB Program

TÜBİTAK Industry R&D Projects Support Program

Law No. 4691 on Technology Development Zones

Law No. 5746 on Supporting R&D Activities

Entrepreneur Support (TÜBİTAK / KOSGEB)

Some Incentives for Investors

- Income tax exemption
- Corporation tax exemption
- Income tax exemption for researchers, developers and R&D personnel
- Social security premium support
- Value added tax exemption

TEYDEB Incentive Programs for Businesses

Figure 20: R&D Business Processes Supported by TEYDEB

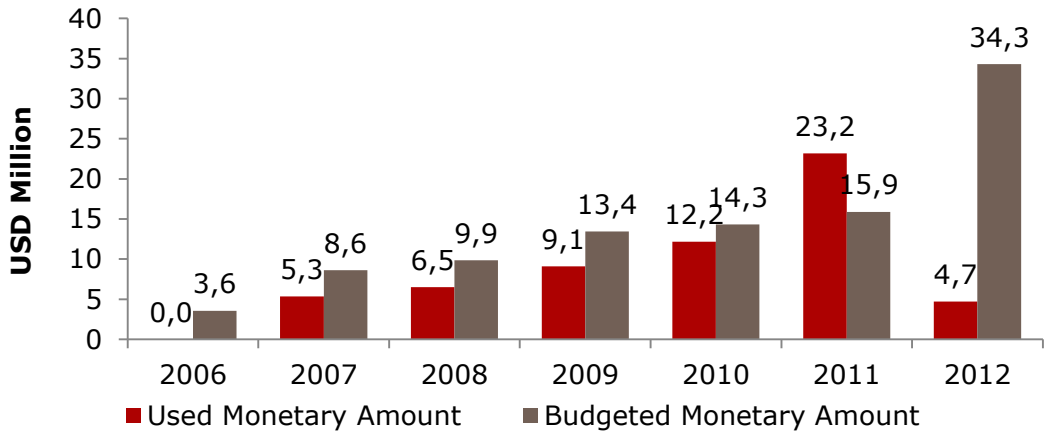
1st Phase: Conceptual Design	2nd Phase: Technology Development
• Understanding of Demand • Ideation of the Product • Idea for Process of Manufacturing	• Design of the Product • Product Prototype • Production System Design • Pilot Production

- **1501: Industry Research and Development** – This program is aimed at supporting companies for their technological R&D activities. Any enterprise located in Turkey which provides added value to the industry can apply to this program. This program supports up to 60% of the proposed project.
- **1502: EUREKA** – The aim of EUREKA is to enhance the collaboration between R&D centers, companies and universities in Turkey and Europe. Support totalling up to 50% is achievable through this program.
- **1503: Project Market Support Program –** The aim of this program is to create collaboration between the private sector/industry and universities to make ideas into real projects using combined expertise. As of 2013, the budget for Program 1503 is defined as TL 25,000 (about USD 12,000) for local projects, TL 30,000 (about USD 14,000) if international players are included in the project.
- **1507: Small and Medium Size Enterprises R&D Support Program –** 1507 is designed for small and medium size enterprises and their role in R&D activities so they can develop available goods, increase standards and decrease costs. Incentive support for Program 1507 is 75% of the total budget.
- **1508: Support Program for Technological and Innovation Focused Ventures –** This program is aimed at young professionals who have innovative projects. Projects that have budget of TL 100,000 (about USD 47,000) will be supported by TEYDEB up to 75% of that sum.
- **1509: International Industry R&D Projects Support Program –** Program 1509 supports international projects that are announced under EUREKA, ERA-NET and the European Union Framework Programs. For big enterprises support up to 60% is available, whereas for small and medium enterprises support up to 75% can be granted by TEYDEB.

SAN-TEZ: University-Industry Cooperation that is supported by the government

- Direct financial support is available for the adaptation of new technology, process development, the improvement of quality and environmental modification projects via university partnerships:
  - Up to 75% of the project budget can be supported by direct grants.
  - The project term is 3 years, with a possible extension of 6 months.
  - Laboratory analysis, test materials and equipment are funded.
  - The application file should be approved within 4 months.
  - The project supervision committee is independent
- The grant program is supported by the Ministry of Science, Industry and Technology. The target of the program is a high level of competitiveness in the market, where the importance of innovation and R&D is understood and Turkey produces and sells its own technology.

Figure 21: Grants for Pharmaceutical R&D Projects by TÜBİTAK (as of 1 June 2012)



Source: TÜBİTAK, Ministry of Science, Industry and Technology

Note: Year-end exchange rates are obtained from the Central Bank of Turkey. The TL/USD values are 1.41 in 2006, 1.16 in 2007, 1.52 in 2008, 1.49 in 2009, 1.54 in 2010, 1.89 in 2011, and 1.78 in 2012.

TEYDEB also supports other company expenditures

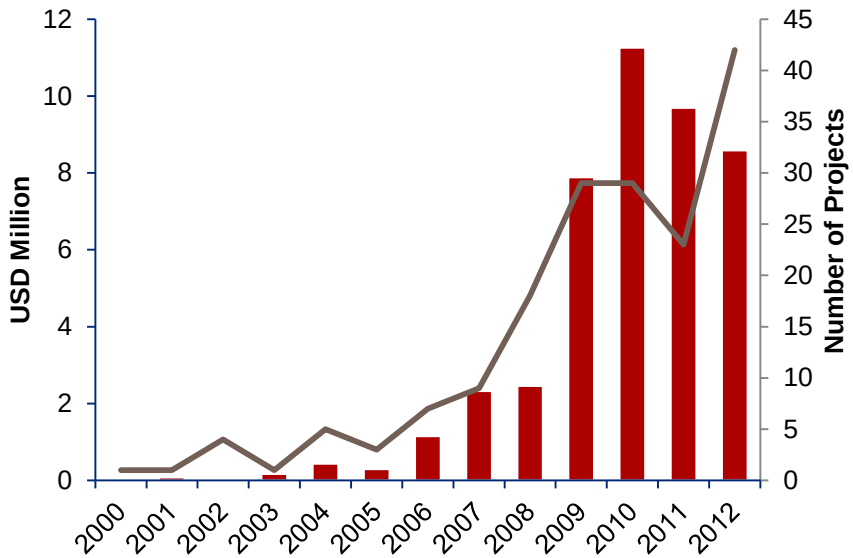
Expenditures Supported by TEYDEB
• Personnel expenses • Equipment, hardware, software and purchases of publications • Consulting services locally and internationally as well other services • R&D expenditures incurred by universities within the country, R&D centers associated with TÜBİTAK and similar associations • Material and other related expenses • Travel expenses of project personnel and – if applicable – of consultants, • Project preparation expenditures (only for Support Program No. 1507), • Certified Public Accountant expenditures (only for Support Program No. 1507), • Expenditures regarding patent registration from the Turkish Patent Institute

TEYDEB Application and Evaluation Process
Interested parties can apply to TEYDEB at any time, however, it is important to note that expenditures up to 3 months before the application date are eligible to benefit from the incentive program.

Application to TÜBİTAK-TEYDEB
↓
TEYDEB Pre-Assessment
↓
Evaluation of the Judge
↓
Decision Making Process
↓
Signing of the Contract upon Project Approval

TEYDEB granted pharmaceutical R&D projects USD 45 million between 2000 and 2012

Figure 22: TÜBİTAK Grants for Pharmaceutical R&D Projects

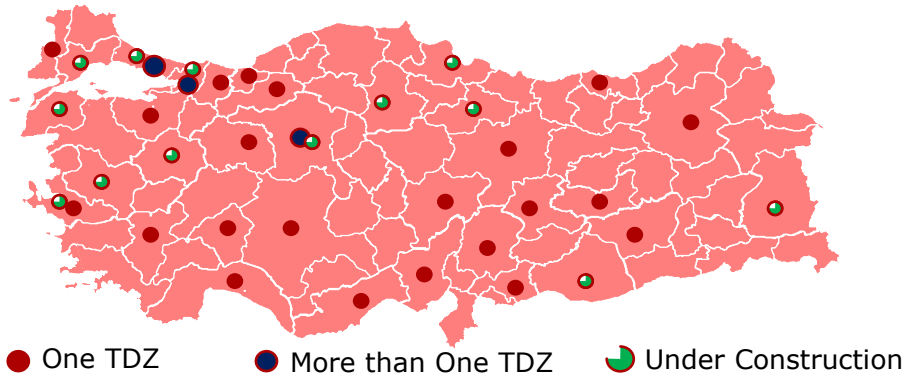


Note: Year-end exchange rates were obtained from the Central Bank of Turkey. The TL/USD values were 1.39 in 2003, 1.34 in 2004, 1.34 in 2005, 1.41 in 2006, 1.16 in 2007, 1.52 in 2008, 1.49 in 2009, 1.54 in 2010, 1.89 in 2011 and 1.78 in 2012.

- The Technology and Innovation Funding Programs Directorate (TEYDEB) supports the R&D activities of private sector organizations.
- In the pharmaceutical sector, a total of USD 45 million was granted to 172 unique pharmaceutical projects between 2000 and 2012. It constitutes a 3.3% share of total grants within that period.

Source: TÜBİTAK, TEYDEB

Technology Development Zones contribute significantly to R&D of pharmaceutical manufacturing industry



The Minister of Science, Industry and Technology, Nihat Ergün: "The 2023 goals for TDZs are 5,500 companies, 65,000 employed, and 10 billion dollars of exports."

- TDZs are organized research and business centers where academic, economic and social structures are integrated. Universities, research institutions, and industrial foundations work together for innovation, information and technology transfer; increasing productivity and reducing production costs; increasing product quality and standards; enabling product development; commercializing know-how; supporting technological investments and entrepreneurship; and creating jobs for researchers.
- TDZs are governed by Law No. 4691, named the Law for Technology Development Areas.
- The support and exemptions for TDZs provided by the law can be categorized under 3 headings: companies, entrepreneurs and faculty members.

✓ The Ministry of Science, Industry and Technology will meet the fixed costs of companies that cannot afford their respective costs. Companies do not have to pay income tax until 2023. They can obtain free access to state-owned intangibles for 5 years, but later have to pay 0.2% of the property tax.

✓ Entrepreneurs operating in this region are exempt from income tax until 2023 from income made through R&D operations and software. Taxes on wages of R&D personnel are exempt until 2023.

✓ Law No. 5746, the R&D Operations Support, will finance 50% of social security premiums for 5 years for R&D personnel.

Source: The Ministry of Science, Industry and Technology, Association of Turkish Technology Parks

The number of TDZs has doubled and number of companies active in TDZs has quadrupled in the last 7 years

Figure 23: Total Number of Firms in TDZs, Foreign and Domestic

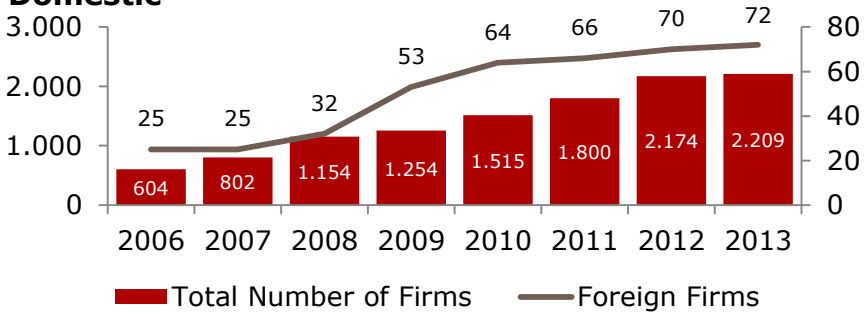


Figure 24: Firms by Sector in TDZs

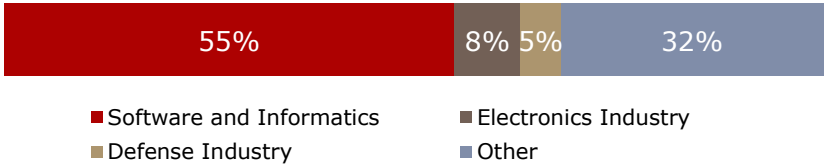
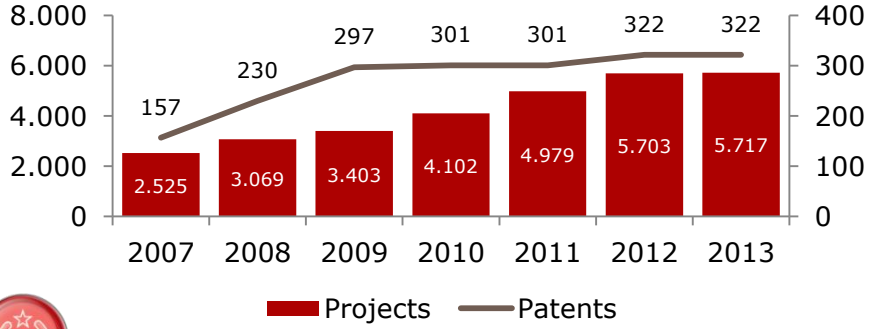


Figure 25: Total Projects and Patents in TDZs



- Every year on average, 4 new TDZs are opened in Turkey. The increasing number of TDZs is expected to continue as Turkey proceeds towards its goals for the year 2023.
- 55% of the firms in TDZs are engaged in the software and informatics business. Other areas of focus are electronics and the defense industry.
- There are **72 foreign investors among the 2,209 firms** in TDZs and their investments are valued at approximately USD 683 million.
- As of April 2013, the number of projects was 5,717 and the total export value reached at the end of 2012 was USD 893 million.
- A total of **322 patent applications** were made by firms in TDZs.
- The employment breakdown in TDZs are as follows: **15,960 in R&D and 3,536 for support personnel**, totaling **19,496 employees**.

Source: Ministry of Science, Industry and Technology

5 firms have been granted R&D licenses by the Ministry of Science, Industry and Technology to conduct research

Table 7: List of Companies Operating Active R&D Centers

Company Name	Location	Description
Abdi İbrahim İlaç Sanayi ve Ticaret A.Ş.	Istanbul	The R&D center was founded in 2008 with an investment of USD 40 million. The company dedicates 5% of its annual turnover to R&D. The center has more than 140 employees and recently developed the world's first ODT (orally disintegrating tablet). The firm has the highest number of TÜBİTAK R&D projects and focuses on know-how transfer.
Bilim İlaç Sanayi ve Ticaret A.Ş.	Kocaeli	Bilim İlaç has a R&D center founded with a USD 15 million investment. The center has 220 high-tech devices and 110 employees. More than 150 of its products of solid, semi-solid and liquid medicines are developed in its own laboratories.
Deva Holding A.Ş.	Istanbul	Deva Holding's R&D center DeArge has 133 trained and specialized personnel working in their facilities. In 2012, they completed 48 product development projects in their laboratories along with 5 ongoing projects with TÜBİTAK, of which 2 was successfully completed in 2012.
Mustafa Nevzat İlaç Sanayi A.Ş.	Istanbul	MN Pharmaceuticals has R&D projects that receives funding from TÜBİTAK's support program.
Zentiva Sağlık Ürünleri Sanayi ve Ticaret A.Ş.	Kırklareli	Sanofi (Zentiva) conducts about 25% of the ongoing R&D projects in Turkey. Since 2010, it works cooperatively with Ege University in their R&D center that employs 70 experts.

Source: ISPAT, Ministry of Science, Industry and Technology

Case Study: Research Centers

FABAL Ege University Pharmaceutical Sciences Research Center

- The center was founded in 2011. It has scientific partnership with various organizations to develop projects. FABAL (Pharmaceutical Sciences Research Centre) focuses on developing a multidisciplinary approach to research and offers consulting, analysis, research collaboration, product development and training activities.
- The total project cost of the center is USD 7 million. The center is involved in multiple projects with ERAD and TÜBİTAK.
- FABAL's main purpose is to support researchers by providing them with facilities and the necessary equipment to test and analyze their data. It also helps with the creation of projects via research collaboration and organizes professional training programs, seminars, and workshops.

ARGEFAR Drug Development Research & Pharmokinetics Application Center

- ARGEFAR is a public institution founded in 1993 within the Ege University Hospital campus in Bornova, Izmir.
- ARGEFAR carries out clinical drug trials, the detection of the bioequivalence of drugs, food analysis, the analysis for the purity of honey, analysis of biocidal products and other types of product development. These projects are funded with TL 8 million and are conducted by 46 researchers.
- ARGEFAR aims to contribute to the development of the sector and continues to integrate with EU programs by developing the physical and technical infrastructure to enable it to work within the EU framework.

Case Study: GlaxoSmithKline, Pfizer

GlaxoSmithKline

- British pharmaceutical giant GlaxoSmithKline will establish a clinical research facility to manufacture vaccines in Turkey with Turkish company İDOL.
- The world's largest maker of vaccines plans to produce five vaccines including those for hepatitis and influenza, while employing 80 scientists and researchers in Turkey.
- In the first stage of production, 17 million doses of vaccines per year will be manufactured. The capacity is expected to be increased to 30 million doses per year the following year.
- The facility will improve vaccine know-how in Turkey, increase R&D spending in the sector and develop co-operation between Turkish and foreign scientists.

Pfizer

- Pfizer, active in Turkey since 1957, produces 77% of the pharmaceutical products marketed in Turkey.
- Pfizer strives to contribute to Turkey becoming a global center of excellence in R&D through activities aimed at improving the R&D environment in the country.
- In May 2011, five projects were awarded in the field of "Pfizer Health Sciences and Technologies" in an innovation project competition held in Hacettepe Technopark. The goal of the competition was to contribute to science, technology and humanity by producing industrial products and technology for both Turkey and the world.
- In November 2012, Pfizer established its third global vaccine facility in Turkey, after having done so in the USA and Ireland. The facility produces pneumococcal conjugate vaccine, which is one of the most significant biotechnological products in the world. State-of-the-art technology is used in the facility to produce the vaccine.
- Having invested over TL 8 million in education and health-oriented social responsibility projects over the last decade, Pfizer Turkey continues to meet the needs and contribute to the welfare of Turkish society

Source: Dünya Gazetesi, invest.org.tr, medical tribune, Pfizer

Many of the raw material and pharmaceutical production facilities in Turkey are close to ports, a factor that eases transportation and logistics

Source: Deloitte Analysis

There are 10 different companies and 12 different facilities that produce raw materials (1/2)

- Turkey imports a large quantity of pharmaceutical raw materials. There are 12 pharmaceutical raw material producing facilities and 10 different pharmaceutical raw material producing companies in Turkey, of which 4 are international companies.

Company	Major Products
Afyon Alkaloitleri Fabrikası	Morphine, recrystallized morphine, morphine hydrochloride, morphine sulfate, codeine base, codeine phosphate, codeine hydrochloride
Med-Mar Tuz	Medical salt production
Deva Holding*	Cefuroxim axetil amorphous, potassium clavulanate and mixtures (avecel, syloid and amoxicillin blends), Amlodipine besylate, bupropion hydrochloride, ezetimibe, ibandronate sodium, lincomycin hydrochloride, netimicin sulfate, pioglitazone hydrochloride, monohydrate piperacillin, pregabalin, risedronic acid, sildenafil citrate, sodium trihydrate alendronate, risedronate sodium, sultamicillin base, sultamicillin tosylate, telmisartan, topiramate, valacyclovir hydrochloride, zolmitriptan, amlodipine mesylate, potassium clavulanate and amoxicillin trihydrate bulk blends with silica microcrystalline celulose and double and triple blends in various proportions.
Mustafa Nevzat	6 APA, 7 sage, alendronate pamidronate (lyophilized), amlodipine besylate, amoxicillin trihydrate, ampicillin anhydrous, ampicillin trihydrate, aripiprazole, acetyl-methoxytryptamine (melatonın), atorvastatin, azithromycin, befloksaton, sodium indanyl carbenicillin, cefazolin sodium, cefaperazon sodium, sodium cefotaxim, ceftriaxon sodium, cephalexin H2O, ciprofloxacin, cloxacillin sodium, doxazosin, donepezil hydrochloride, Etodolac, famotidine, famciclovir, finasteride, fluconazole, fluvastatin, ganciclovir, gemfibrozil, gliclazide, granisetron hydrochloride, indinavir, imatinib mesylate, ketorolac, Clarithromycin, clodronate, fluvoxamine, lamivudine, latamoksef, lomefloxazin, loratadine, medifoksamin, meropenem, mezlocillin sodium, milnacipran, mirtazapine, monosodium
Koçak Farma	Pemetrexed disodium, zoledronic acid monohydrate, methotrexate disodıum, enoxaparin sodium, ibandronate sodium monohydrate, production of raw materials

Source: IEGM
*has 2 facilities

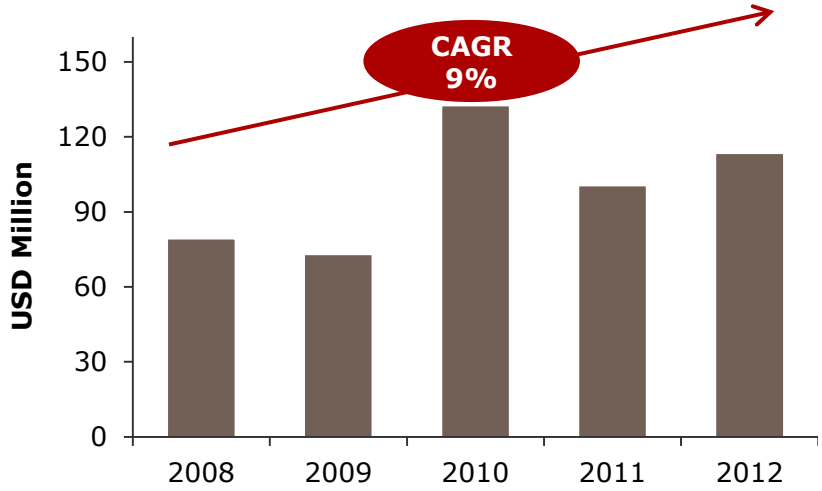
There are 10 different companies and 12 different facilities that produce raw materials (2/2)

Company	Major Products
Sandoz	Pregabalin, pantoprozol sodium, pantoprazole sodium effective alternative production of application under artıcle valnemulin hydrochlorid active actıve substance and intermediate product rosuvastatin ohl, Paracetamol, Paracetamol DC 90%, Paracetamol DC 96%, potassium alendronate, rabeprazole sodium, sertraline HCl, Synthon C, simvastatin, Sulfamethaxozole, trimethoprim, amlodipine maleate, atorvastatin ATV-44, benzalkonium Chloride, ketoconazole, metformin hydrochloride, Mephenoxalone, Mile 2000, naproxen sodium, omeprazole, omeprazole magnesium, inhaled Citrate, Tadalafil adsorbate, Naftifin hydrochlorıd
Ulkar Kimya	methyL hydroxy benzothiazide, lansoprazole micropellets, salbutamol micropellets, dimethylglıcıne, etamsylate, enalapril maleate, astemizole, lansoprazole, colosantel, theophylline pellet, Etodolac, ketoconazole, nifuroxazide, acyclovir, famotidine, indomethacin micropellets, Ciprofloxacin hcl, difluoromethyl benzimidazole, 4 - (4 - methyl sulphonyl phenyl) -2 (5H)-furanone, risperidone, micropellets fenofibrate, itraconazole micropellets, mephenamic Acid, ranitidine HCL, butyl chloro imidazole, budesonide, omeprazole pellets, omeprazole, Valacyclovir, atorvastatin calcium, irbesartan, zolendonik acid monohydrate, candesartan cilexetil, aripiprazole 5 difluromethoxy - 2 (3-4 dimetoxy benzimidazole-2-prydilmetyl sulphonyl, olmesartan Medoxomil, duloxetine micropellets
Yeni Recordati İlaç ve Hammaddeleri	Helmitol (methenamine anhidrometilencitrat)
Atabay Kimya	Crystal paracetamol, oseltamivir, acetylcysteine, aripiprazole
Konya Şeker	Medicinal products for human use and sugar manufacturıng for use in the productıon of liquid and inert

Source: IEGM

Although Turkey is lagging behind in terms of raw materials produced, its exports have been on the rise

Figure 26: Foreign Trade Statistics of Raw Materials in Turkey

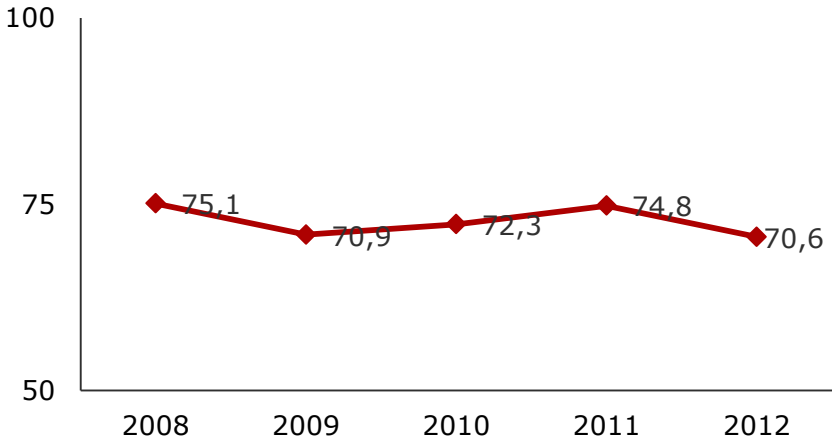


- Total raw materials exports were more than CAGR 9% from 2008 to 2012 surpassing USD 113 million, while imports increased CAGR 3% during the same period with more than USD 1.6 billion.
- Turkey's geographical location allows cultivation of many different plants that can be used as raw materials in the pharmaceutical sector.

Source: AIFD

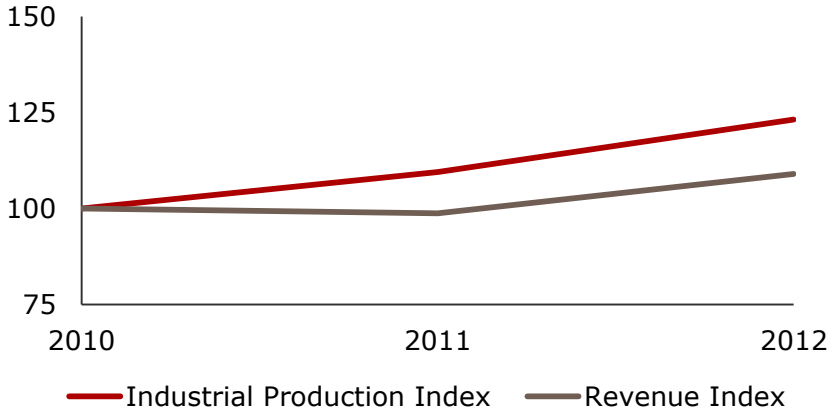
The Pharmaceutical Production Index trajectory has been increasing and new investments are needed to expand capacity

Figure 27: Capacity Utilization Rates in Pharmaceutical Sector Yearly Average



TurkStat NACE Rev.2 Code 21, Manufacture of Basic Pharmaceutical Products and Pharmaceutical Preparations

Figure 28: Industrial Production Index and Revenue Index (2010=100)



TurkStat NACE Rev.2 Code 21
2013 data from Q1 and Q2.

- In the manufacture of basic pharmaceutical products and pharmaceutical preparations, the average capacity utilization rate for the first six months of 2012 was 70.5%, this amount increased to 71.0% during the same period in 2013.

- The production index value for the manufacture of basic pharmaceutical products and pharmaceutical preparations increased steadily through 2012, increasing over 23% and reaching 123.2 points by the end of that year.
- Since 2010, the revenue index for the pharmaceutical sector decreased about 1.2% and fell to 98.8 points in 2011. However, in 2012 the index increased again by 10.3% and reached 109 points.

Source: CBRT, TurkStat, Deloitte Analysis

Turkey's pharmaceutical manufacturing base is expanding as exports grew at a CAGR of 9%

- The manufacturing process is heavily regulated by governmental institutions in the pharmaceutical sector to ensure that the drugs are safe for consumption.

Figure 29: Foreign Trade of Finished Medicine in Turkey

- Turkey's finished medicine exports grew at an impressive CAGR of 9% to more than USD 550 million, while imports decreased by a CAGR of 2% to a little less than USD 2.7 billion.

- A market share of 80% in terms of sales value is held by the top 30 pharmaceutical companies.

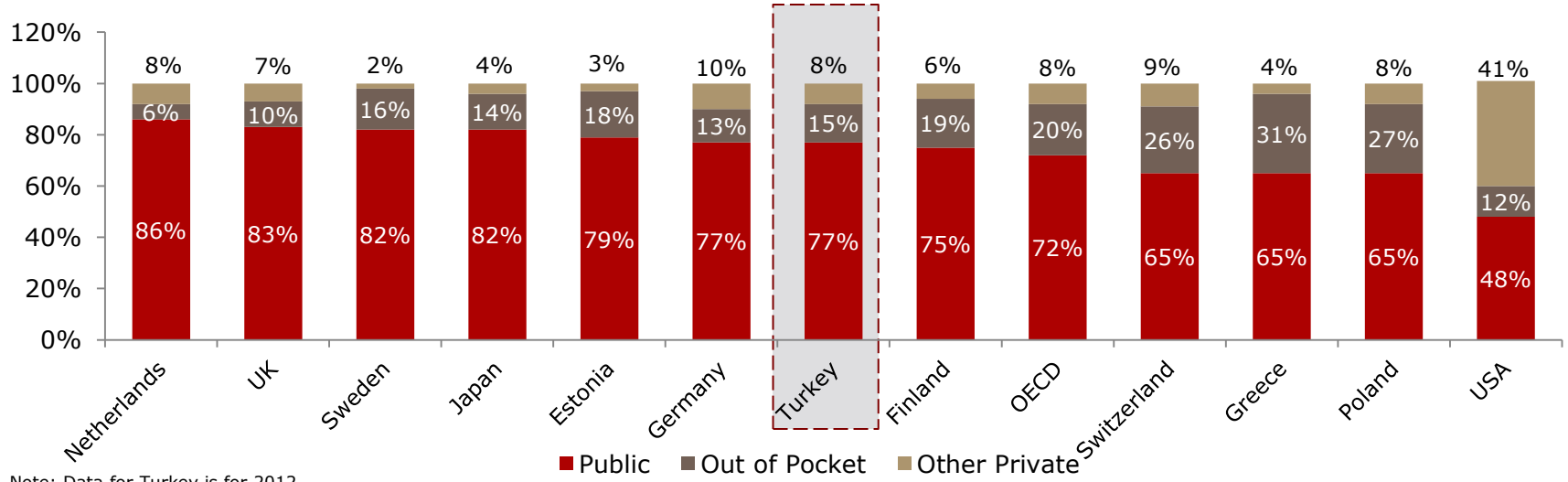
Table 8: Top 10 Pharmaceutical Manufacturing Companies in Turkey

#	Company	Market Share (2012)
1	Abdi İbrahim	7.5%
2	Novartis	7.0%
3	Sanofi	5.8%
4	Bilim	4.9%
5	Pfizer	4.3%
6	Bayer	4.3%
7	Eastpharma	3.8%
8	Glaxo	3.7%
9	Roche	3.4%
10	AstraZeneca	3.0%
Top Ten Total		**47.6%**

Source: AIFD

The publicly financed Social Security System plays a critical role in the provision of healthcare services and the realization of strategic plans and targets

Figure 30: Health Expenditure by Financing Type in Selected OECD Countries, 2011



Note: Data for Turkey is for 2012.

- The publicly financed social security system plays a critical role in the provision of healthcare services in Turkey. As apparent from the OECD comparisons, Turkey has a high share of public healthcare spending at 77%. This is higher than the OECD average of 72%.
- Out of pocket spending is also relatively low in Turkey at only 15%, compared to the OECD average of 20%. Whereas, other private financing is on level with the OECD at 8%.
- As a welfare state, Turkey has strived to make healthcare services more accessible to all of its citizens through equal and fair conditions. In line with this, social security coverage reached 99% in 2012.
- The state also paid health premiums for the low-income portion of the population, which not only leads to an expanding healthcare sector, since the number of visits to healthcare facilities increase, but also allows for the utilization of healthcare services in a more equitable and fair manner.

Source: MoH, OECD

Foreign companies play an important role in the manufacturing phase

- Multinationals with manufacturing facilities operating in Turkey include **Sanofi, Baxter**, **Bayer**, **GSK**, **Novartis**, **Pfizer** and **Roche**, with the recent entry to the market being **EastPharma**. Leading multinationals such as Pfizer, Novartis, Bayer and Roche command market shares of 4-6% each. Baxter runs a 50:50 joint venture (JV) with **Eczacıbaşi** (**Eczacıbaşı-Baxter Hospital Supply Inc.**). Their products and services cover nephrology, haematology, oncology, surgery, anaesthesia and intensive care departments in hospitals, as well as in blood banks and private hemodialysis centers.
- International firms are represented by the Pharmaceutical Manufacturers Association of Turkey (İEİS), which also includes domestic firms. The association's membership stands at 60, with leadership coming from leading domestic player Eczacıbaşı. Pharmaceutical production is the primary activity of İEİS's local and multinational members.

Figure 31: Selected Member Companies, İEİS

Pharmaceutical Manufacturing:
Major Players

GlaxoSmithKline

- GlaxoSmithKline (GSK) is a global pharmaceutical company operating across 40 countries with 102 production facilities and 42,000 employees.
- GSK announced sales of GBP 28.4 billion in 2010.
- GSK has been operating in Turkey for over 50 years and has 10 offices across the country.
- GSK has made Turkey its regional base and Istanbul its headquarters for the MEA region.

2013 Revenue:
USD 44.1 billion

Novartis

- Novartis is a global pharmaceutical company based in Switzerland.
- Novartis Turkey began operating in Turkey in 1997. It bought a production from Roche facility in Gebze in 2007.
- Alexandre Jetzer-Chung, a board member of the company, expressed the company's plan to open a production facility in Turkey so they could sell their products in the Middle East, Central Asia and Africa.

2013 Revenue:
USD 57.9 billion

Pfizer

- Pfizer is a global pharmaceutical company based in the USA.
- Pfizer Turkey began operating in Turkey in 2006. Turkey became the regional leader for the Caucasus and Central Asia region in 2008.
- Pfizer Turkey opened its R&D center in Hacettepe Teknokent in 2010.
- In 2012, Pfizer opened a production facility in Pendik that has a production capacity of 75 million boxes

2013 Revenue:
USD 51.6 billion

Bayer

- Bayer is a German pharmaceutical company based in Germany.
- Bayer Turkey has been operating in Turkey for more than 60 years and employs 1,300 people.
- Bayer Turkey has 18 offices across Turkey with its headquarters located in Ümraniye, Istanbul. Bayer Turkey reached gross sales of EUR 533 million in 2012.
- The company has invested more than EUR 75 million in Turkey since 2000.

2013 Revenue:
USD 25.9 billion

Source: ISO 500

A Success Story: Recordati

"The acquisition of Frik İlaç is an important step forward in our strategy to increase our business in the emerging markets of Central and Eastern Europe, where the pharmaceutical market is growing at rates significantly greater than those of the Western European market. With the acquisition of Frik İlaç, Turkey becomes our third most important market after Italy and France. This market is expected to continue growing at average rates of between 10% and 13% in the next few years and we believe that, thanks to the addition of the new products acquired for our portfolio and the launch of our corporate products, the growth of our Turkish operations will exceed the market trend."

Giovanni Recordati, Chairman and CEO of Recordati, July 2011

RECORDATI

- Dr. F. Frik was founded on November 29, 1968 by Dr. Feridun Frik and is today one of the fastest growing pharmaceutical companies in Turkey. The company has a core portfolio of original prescription products both in primary care and specialist areas and employs 350 personnel, of which around 260 are medical representatives.
- In July 2011, Recordati, a European pharmaceutical group established in 1926, announced the acquisition of 100% of the shares of Dr. F. Frik İlaç A.Ş. The transaction value was of around **USD 130 million**. This was the second acquisition Recordati had made in Turkey, it had previously acquired Yeni İlaç in December 2008.
- Recordati, listed on the Italian Stock Exchange, has a total staff of **over 2,800**, and is dedicated to the research, development, manufacturing and marketing of pharmaceuticals. It has headquarters in Milan, Italy, operations in the main European countries and a growing presence in the new markets of Central and Eastern Europe. Consolidated revenue for 2010 was **EUR 728.1 million**, operating income was **EUR 154.8 million** and net income was **EUR 108.6 million**.

Source: Reuters

The wholesale market is dominated by two major players, namely Selçuk Ecza and Hedef Alliance

- There are more than 500 pharmaceutical warehouses in Turkey but major warehouses such as Selçuk Ecza and Hedef Alliance, both nationwide, account for more than 75% of the total pharmaceutical wholesale market and have over 90% of the market share.

Table 9: Profit Rate of Wholesaler in Turkey

Ex-Factory Price	Profit Rate of Wholesaler
< TL 10	9%
TL 10-50	8%
TL 51-100	7%
TL 101-200	4%
> TL 200	2%

- The rest of the wholesalers composing around 10% of the market are Nevzat Ecza, Dilek Ecza, Galenos Istanbul (Sanovel subs.), Galenos Ankara, YASET (Galenos Ankara subs.), Lokman, Buğra, Prestij, etc.
- Wholesale profit rates are regulated by the Ministry of Health.

Source: AIFD

Pharmaceutical Warehouses

- According to the Pharmaceutical Warehouses and Products that can be Stored in Pharmaceutical Warehouses legislation, pharmaceutical warehouses are not allowed to provide retail sales services in Turkey.
- Warehouses can only conduct wholesale services to:
  - State institution and pharmacies for organizations
  - Private pharmacies
  - Other pharmaceutical warehouses
  - Public hospitals
  - Private hospitals
  - State institutions and organizations that are eligible to procure wholesale pharmaceuticals
  - Healthcare centers
  - Private practices, private diagnosis and treatment facilities*
  - Pharmaceutical manufacturers
- If a pharmaceutical warehouse is established by s real person without a pharmacology diploma, the person establishing the warehouse must hire a pharmacologist as managing director.

* Warehouses can only sell vaccines without any commercial concern

Pharmaceutical Wholesale:
Major Players

Selçuk Ecza

- Selçuk Ecza was founded in 1958 in Konya by the Keleşoğlu family.
- It is one of the largest pharmaceutical distribution companies in Turkey.
- It has 37% of the market share in pharmaceutical distribution.
- Selçuk Ecza has 5,322 employees and a network of 102 pharmaceutical warehouses across the country.

***2012* Revenue:**
USD 2.7 billion

selçuk ecza deposu a.ş

FarmaLojistik

- FarmaLojistik is a joint purchasing and logistics company established with the participations of Edak, Bursa, Istanbul, Guney and Ankara Ecza Koop. under the umbrella of TEKB.
- FarmaLojistik works with 58 pharmaceutical companies.
- It was ranked 101st on the Fortune 500 list in 2011.

***2012* Revenue:**
USD 432 million

FarmaLojistik

Nevzat Ecza

- Nevzat Ecza was founded in 1962 by Nevzat Karpuzcu.
- The company has 24 warehouses, over 1,000 employees, 300 vehicles and serves 60 cities across Turkey.
- Nevzat Ecza was ranked 219th on the Fortune 500 list in 2011.

2012 Turnover:
USD 404 million

NEVZAT ECZA DEPOSU

Öz-Sel Ecza

- Öz-Sel Ecza A.Ş. was established in 1977 by a joint decision of the executives of the Nevzat and Selçuk Ecza Deposu.
- Öz-Sel serves the hospital market.
- It has 11 sales points and it receives more than 2,500 contracts per year. Öz-Sel has over 1,000 clients consisting of public and university hospitals.

2012 Revenue:
USD 135 million

ÖZ-SEL

Note: Year-end exchange rates are obtained from Central Bank of Turkey. The TL/USD value for 2011 is 1.89

Success Story: Hedef Alliance Group

"Turkey, with a growing population of over 72 million, is one of the fifteen largest pharmaceutical markets in the world. The Turkish pharmaceutical market has favorable long term growth characteristics driven by the expansion of both the population and their healthcare provisions. State health insurance has been extended so that it now covers most of the population. Hedef Alliance is one of two large pharmaceutical wholesalers in Turkey, each of whom has around a third of the market."

Alliance Boots website, February 2011

HEDEF ALLIANCE

- Hedef Alliance Holding was founded by Es Ecza in 1987 in Istanbul. The company became Hedef Ecza Deposu in 1993.
- In 2001, Hedef Group became partners with Alliance Boots, a European pharmaceuticals retailer founded in 1849.
- Currently, Hedef Alliance is one of Turkey's largest pharmaceutical wholesalers and has 68 sales points across Turkey servicing 17,000 pharmacies with its 4,000 employees.
- In 2011, Alliance Boots raised its share in the company to 70%. During the same year Hedef Alliance reached revenues of about USD 3.2 billion.

Source: Alliance Boots

The pharmacy market is fragmented in Turkey and includes more than 24,000 pharmacies

- Apart from retail sales of drugs, pharmacies are cross selling products by offering cosmetics, toiletries, healthy snacks and the like, which have better margins and are sold on a cash/credit card basis.

Table 10: Profit Rate of Pharmacists in Turkey

Ex- Factory Price	Profit Rate of Wholesaler
< TL 10	25%
TL 10-50	25%
TL 51-100	25%
TL 101-200	16%
> TL 200	12%

- In Turkey, pharmacy mark-ups are regulated, and changes are based on the price of the pharmaceuticals.
- Pharmacies can also participate in hospital tenders for bulk sales.

Table 11: Top 10 Cities in the Pharmaceutical Market

City	# of Pharmacies	% of Total Market
Istanbul	5,118	20.9%
Ankara	2,019	8.2%
Izmir	1,737	7.1%
Antalya	985	4%
Bursa	814	3.3%
Konya	734	3%
Adana	638	2.6%
Mersin	561	2.3%
Gaziantep	452	1.8%
Hatay	446	1.8%

- The total number of pharmacies in Turkey is more than 24,000.
- Istanbul has the highest number of pharmacies followed by Ankara, Izmir and Antalya. This shows that geographical coverage of pharmacies is in line with the population distribution and 55% of the total pharmacies in Turkey are in the top 10 most populous cities.

Source: AIFD, TPA, Deloitte Analysis

Major Stakeholders in the Pharmaceutical Sector (1)

Name	Logo	What They Do	Website
The Ministry of Health of Turkey		The Ministry of Health has crucial tasks it performs within the health sector. The mission of the Ministry of Health is the continuous improvement of the health of its citizens, through the prevention of disease and the provision of a high level of health care to every citizen.	www.saglik.gov.tr
Turkish Medical Association		The Turkish Medical Association (TTB) is the unified body of physicians in Turkey under the constitution of the government of Turkey. It is a public association founded under Law No. 6023 and 80% (approximately 83,000) of country's physicians are members of TTB. Its main source of income are membership fees and it does not receive funding from the government.	www.ttb.org.tr
Private Hospitals and Health Institutions Association		The Private Hospitals Association, the Health Institutions Association, the Tourist Regions Health Institutions Association and the Southeast Anatolia Private Health Institutions Association have united to found the Private Hospitals and Health Institutions Association. Through this merger, 80% of hospitals within the private health sector and 850 other health institutions have been gathered under one association.	www.ohsad.org
Pharmaceutical Manufacturers Association of Turkey		İEİS is the representative body of the Turkish generic pharmaceutical sector. It was founded in 1964 in Istanbul with the purpose of sustaining the development of the local pharmaceutical sector. It plays an important role in healthcare policy-making and promotes the use of generic medicines. It currently has 43 member companies.	http://www.ieis.org.tr/ieis/tr

Major Stakeholders in the Pharmaceutical Sector (2)

Name	Logo	What They Do	Website
Social Security Institute		Social Security Institute was established by the Social Security Institution Law No: 5502 and brings the Social Insurance Institute, the General Directorate of BağKur and General Directorate of Emekli Sandığı under a single roof.	www.sgk.gov.tr
Health Industry Employers' Association of Turkey		Companies operating in the medical devices sector have been organized under the Health Industry Employers' Association of Turkey (SEİS), local organizations and the Medical Device Manufacturers and Suppliers Association (TÜMDEF).The aim of SEİS is to operate a nationwide non-governmental organization to represent the medical sector and gather the companies together.	www.seis.org.tr
Medical Device Manufacturers and Suppliers Association		Established in 2004, TÜMDEF operates as a non-governmental organization with 16 member associations and over 1,500 companies within these associations.	www.tumdef.org
Association of Research-Based Pharmaceutical Companies		Established in 2003 by research-based pharmaceutical companies operating in Turkey, AİFD pursues its activities through its head office in Istanbul and its representative office in Ankara. Its mission is to contribute to the healthcare sector in Turkey, by enhancing access to "innovative" products, technology and information in the Turkish medical field and creating an "ethical and transparent" environment in the healthcare sector.	www.aifd.org.tr
Turkish Drug And Medical Device Institution		The Turkish Drug and Medical Device Institution provides permission for, and oversees clinical trials concerning medical devices. It is also responsible for certifying that a device manufacturer has taken steps to ensure compliance with regulations.	www.iegm.gov.tr

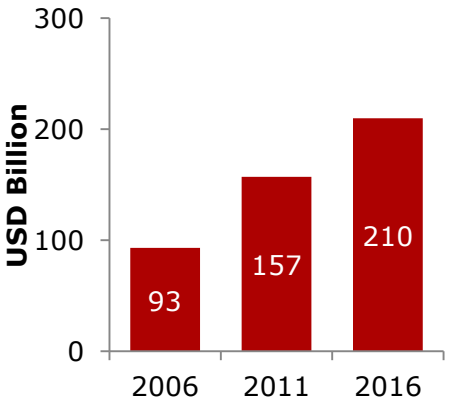
Major Stakeholders in the Pharmaceutical Sector (3)

Name	Logo	What They Do	Website
The Healthcare Products Manufacturers & Representatives Association		SADER is a non-profit association which was founded in 1993 by 14 leading firms in the Turkish medical sector. SADER's main objective is to "provide co-ordination between, encourage and raise awareness of persons or firms engaged in importation, exportation, representation, maintenance, repairing, sale in-bulk or in retail of any medical materials, devices & equipment in addition to protecting the rights and interests of such persons and/or firms to the extent envisaged by relevant laws." It also "provides society with useful work and achievement by directly assisting in education, health and in several social projects or through assistance to existing organizations."	www.sader.org.tr
Turkish Pharmacists' Association		The Turkish Pharmacists' Association was established in Istanbul by the Law of the Turkish Pharmacists' Association, which was published in the Official Journal of February 2nd in 1956. The Turkish Pharmacists' Association works to supply the needs of pharmacists all over the country, to codify professional practices, to implement improvements for the general benefit of the profession and to build and foster relationships among its members. There are 51 pharmacist chambers established all over Turkey. The chambers are directly attached to TPA (the Turkish Pharmacists' Association) by Law.	http://www.teb.org.tr/en/

Special Focus: Biological products, oncological drugs and blood products

Figure 32: Comparison of the Global and Turkish Biological Drug Markets

Global Biological Drugs Market VS **Turkey's Biological Drugs Market, 2012**



Total value: USD 703.2 million

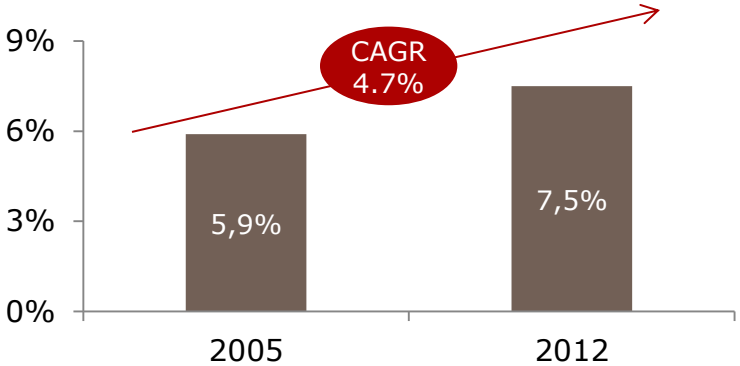
Share of biological drugs in the pharmaceuticals market: 9%

Share of biosimilars in the pharmaceuticals market: 1.4%

- The share of biological drugs in the global pharmaceutical market is increasing rapidly. The biological drug market expanded with a CAGR of 11% between 2006 and 2011, and is expected to continue its expansion through to 2016 at a CAGR of 6%.
- Similarly, the share of oncological drugs in the Turkish pharmaceuticals market also is on a rise as it grew at a CAGR of 4.7% between 2005 and 2015.

Source: IMS Health, Ministry of Science, Industry and Technology

Figure 33: Share of Oncological Drugs in the Turkish Pharmaceutical Market



- Even though biological products, oncological drugs and blood products are increasing their market share in the Turkish pharmaceutical market, Turkey currently does not manufacture these products.
- For this reason, the incentive plan adopted in 2012 classifies biological products, oncological drugs and blood products as strategic investment areas. Accordingly, investments worth more than TL 20 million are eligible for the incentive package implemented in the fifth region, which includes certain tax allowances, customs duty exemption, value added tax (VAT) exception, support for the employer share of insurance premiums, land allocation and interest support.

III. Competitiveness of Turkey

A. Labor Force

B. Population Demographics

C. Incentive Plan

D. Geographical Advantage

E. Ease of Doing Business

F. Special Focus on Free Healthcare Zones

A positive outlook on the human resources side: young and cost effective labor…

Figure 34: Employed Population, 2012

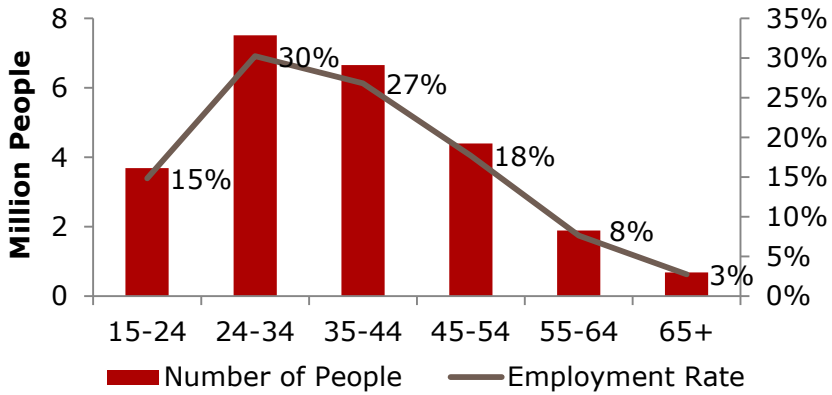
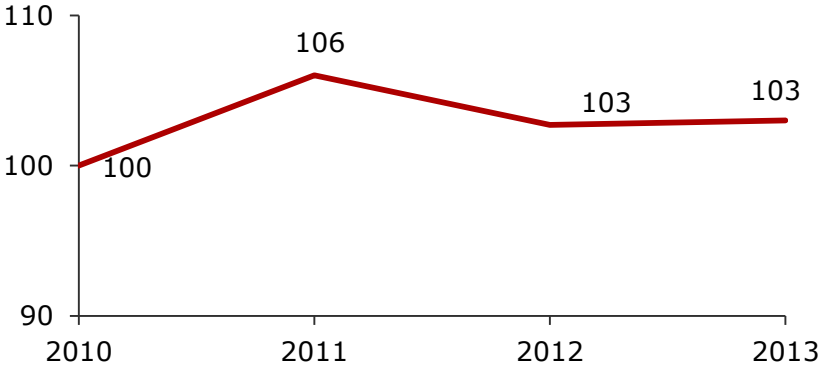


Figure 35: Employment Index (2010=100)

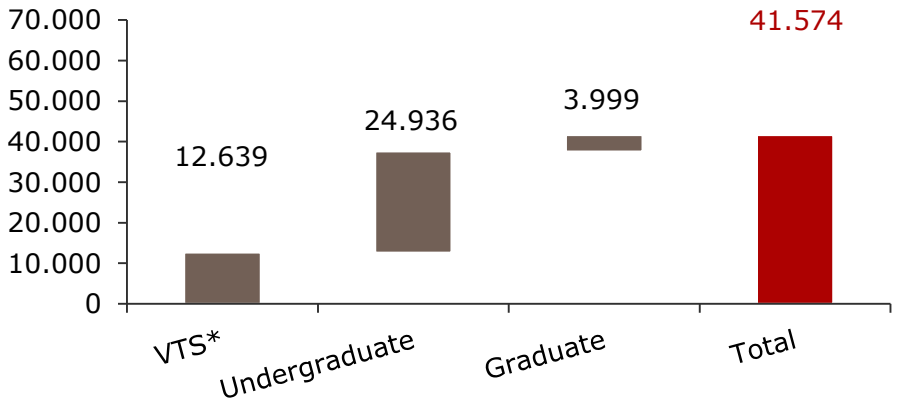


Source: Euromonitor, CBRT
TurkStat NACE Rev. 2 Code 21
Note: 2013 data reflects the first quarter.

- The workforce in Turkey is one of the **youngest and largest** in **Europe**, with the necessary education, knowledge and skills.
- **More than 65%** of the population is aged **between 24 and 54** giving Turkey a huge advantage in terms of workforce availability.
- From 2012 to 2013, the employment rates in the pharmaceutical sector increased 3%.
- According to the Pharmaceutical Sector Report of the Ministry of Science, Industry and Technology, the sector employs 30,000 people, of which 50% have higher education degrees. The majority of the employees work in permits, pricing, marketing and sales departments.
- TurkStat data indicates that the employment index for the manufacture of basic pharmaceutical products and pharmaceutical preparations increased 6% in 2011, reaching a peak of 106 basis points. Before decreasing slightly to 103 basis points in 2013.

…coupled with the necessary know-how of qualified graduates

Figure 36: 2011-2012 Academic Year Graduates in Pharmaceuticals Sector



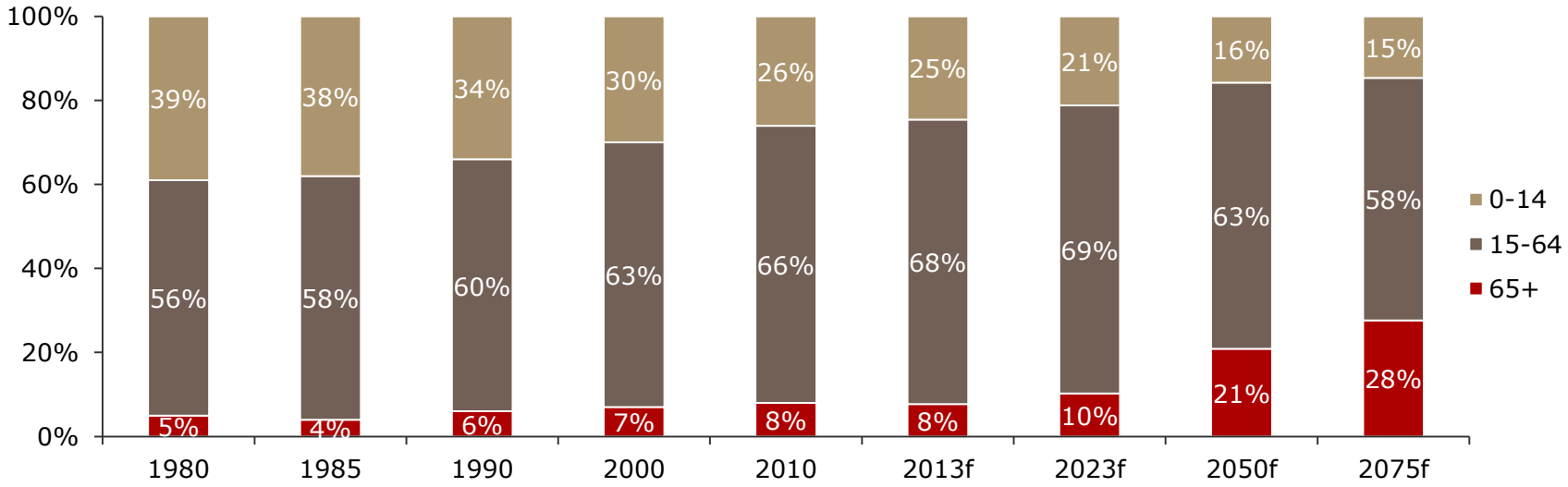
* Vocational Training Schools

- There were a total of more than 41,000 students that graduated from vocational training schools and universities in the 2011-2012 academic year from fields that are related to the pharmaceutical sector. The graph provides statistics on students that are educated in Turkey's universities specifically for the pharmaceutical or related sectors.
- Turkey is continuing to put emphasis on education to improve the quality of its workforce. There are many departments that are related to pharmacology and large amounts of investments are made to open new universities.
- These departments are generally classified within the health sciences and include branches of medical sciences, nursery, veterinary sciences, pharmacy, dentistry and the like. It also includes natural sciences such as chemical engineering, molecular biology, genetics and bioengineering.

Source: OSYM, Deloitte Analysis

The workforce will decrease slightly in the following years but an increase in the aging population will fuel pharmaceutical spending

Figure 37: Population Range in Turkey



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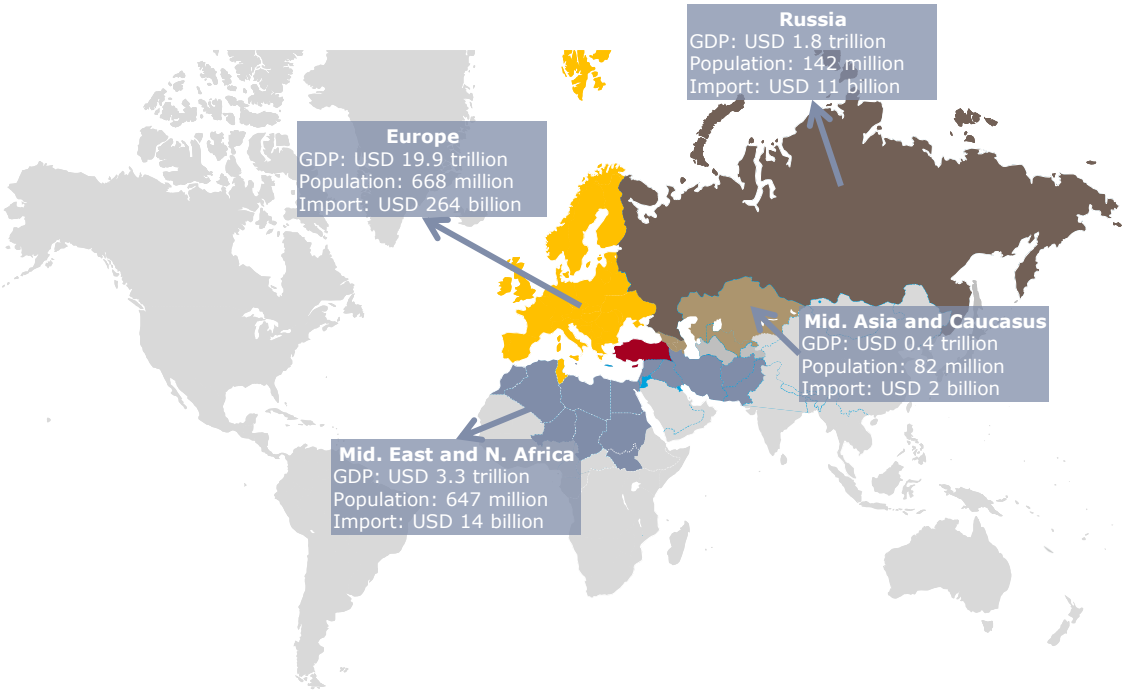
Note: Slight differences may exist due to rounding percentages.

- People aged 65+ in Turkey will be a large part of the total population, accounting for 28% in 2075.
- The aging population will, in turn, increase pharmaceutical expenditure in Turkey. Despite the aging population, the young and dynamic working population will only decrease slightly from 68% in 2013 to 58% in 2075. Thus, the working population will able to continue supporting the elderly and contributing to the social security system.

Source: TurkStat, Deloitte Analysis

Turkey's advantageous geographical location presents a total pharmaceutical market of USD 300 billion

Figure 38: Pharmaceutical Market Potential to Neighboring Regions

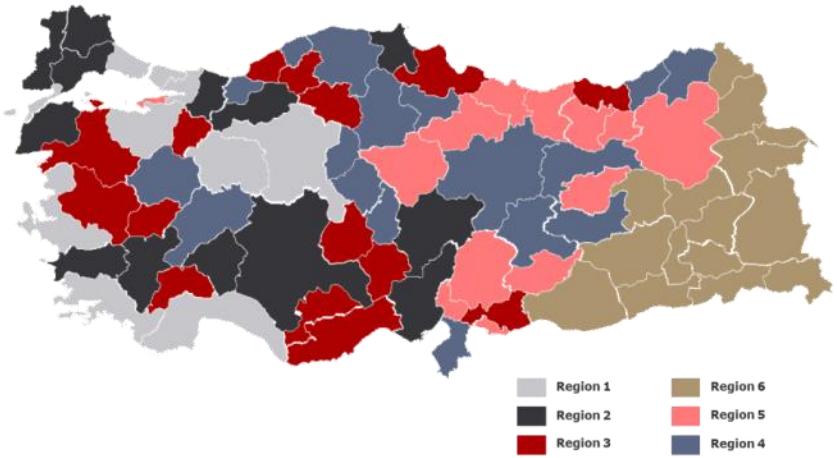


- Countries in Europe, the Near East, Asia and North Africa that are close to Turkey have a total of USD 300 billion pharmaceutical market volume.

Source: AIFD, Vision 2023 Report

Moreover, several incentive plans are available to investors through the Turkish Investment Incentive Program

Figure 39: Incentive Regions



- The investment incentive program of 2012 comprises 4 different plans: general, regional, large scale and strategic. Moreover, specific priority investments are supported by Region 5 measures even if they are made in Regions 1, 2, 3 and 4.
- All investment types, except the ones that are specifically excluded from the investment incentive program, will be supported through the General Investment Incentives Program. Under this scope, the minimum fixed investment amount is TL 1 million in Region 1 and 2 and TL 500,000 in Regions 3, 4, 5 and 6.

Support Measures	General Inv.	Regional Inv.	Large Scale Inv.	Strategic Inv.
Vat Exception	✓	✓	✓	✓
Customs Duty Exemption	✓	✓	✓	✓
Tax Deduction	✗	✓	✓	✓
Land Allocation	✗	✓	✓	✓
Interest Support	✗	✓	✗	✓
Vat Refund	✗	✗	✗	✓
Employer's Social Security Premium Support	✗	✓	✓	✓
Only For Region 6				
Income Tax Withholding Support	✓	✓	✓	✓
Employees' Social Security Premium Support	✗	✓	✓	✓

REGIONAL INVESTMENTS INCENTIVE SCHEME MEASURES							
Region	OIZ	1	2	3	4	5	6
Tax Reduction (%)	Out of OIZ	15	20	25	30	40	50
	Within OIZ	20	25	30	40	50	55
Employer's Social Security Premium Support Period (years)	Out of OIZ	2	3	5	6	7	10
	Within OIZ	3	5	6	7	10	12

Pharmaceuticals and high precision medical and optical equipment are incentivized through this program

- Certain investment categories are supported by the **Large Scale Investment Incentive Plan** with minimum investment amounts varying by industry. **The table shows** the industries that may receive state support depending on their investment amount.
- Strategic investment incentives are given to support production of intermediate and final products with high import dependence with a view to reduce current account deficit. The criteria to gain this support would be: production of intermediate and final goods with high import dependence of which more than **50% of these goods** are supplied by imports, to have a minimum investment amount of **TL 50 million**, to create a minimum **40% value added** (not applicable to refined petroleum and petrochemicals production investments), to have an import amount of at least **TL 89 million** for goods to be produced in the previous one year period (not applicable to goods with no domestic production).
- More specifically, the plan allows investments in the fields of biotechnological and oncological drugs, and blood products to be considered strategic investments benefiting from the incentives available in the fifth region provided that the fixed investment amount is above TL 20 million.

Table 12: Large Scale Investment Requirements

Investment Subject	Minimum Investment Amount (TL Million)
Pharmaceuticals	50
High Precision Medical and Optical Equipment	50

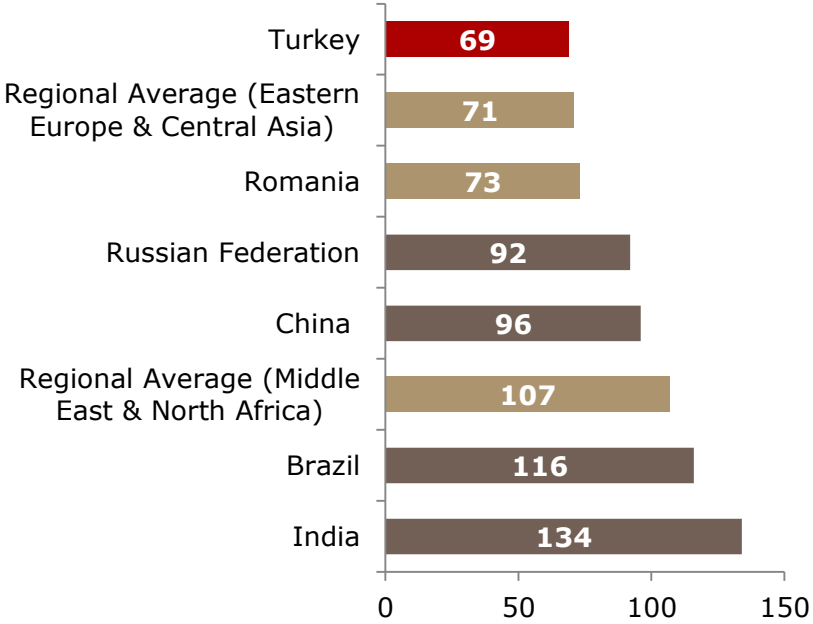
Source : Ministry of Economy

Overall, Turkey is 69th in Doing Business 2014 Report

- Foreign Direct Investment Law in Turkey – which complies with international standards- came into force in 2003. The objective of this Law is to regulate the principles to encourage foreign direct investments; to protect the rights of foreign investors; to define investment and investor in line with international standards; to establish a notification-based system for foreign direct investments rather than screening and approval; and to increase foreign direct investments through established policies.
- With this law, unless stipulated by international agreements and other special laws:
  1. Foreign investors are free to make direct investments in Turkey,
  2. Foreign investors shall be subject to equal treatment with domestic investors.
- As a result, the number of expats has increased significantly. According to the Ministry of Labor and Social Security, number of work permits given to foreigners increased by 86% in 2012 reaching 32,272. Since 2003 a total of 125,697 permits were provided to foreigners.
- It is also crucial to note that the availability of free transfer of funds in Turkey adds positively to its investment friendly environment.

- According to Doing Business 2014 report by the World Bank, Turkey is ranked 69th among 189 countries on the ease of doing business.
- Turkey has a higher ranking compared to BRIC countries. The averages of Eastern & Central Asia and Middle East & North Africa are ranked 71st and 107th respectively, below the rank of Turkey.

Figure 48: Ease of Doing Business Analysis Ranking, 2014

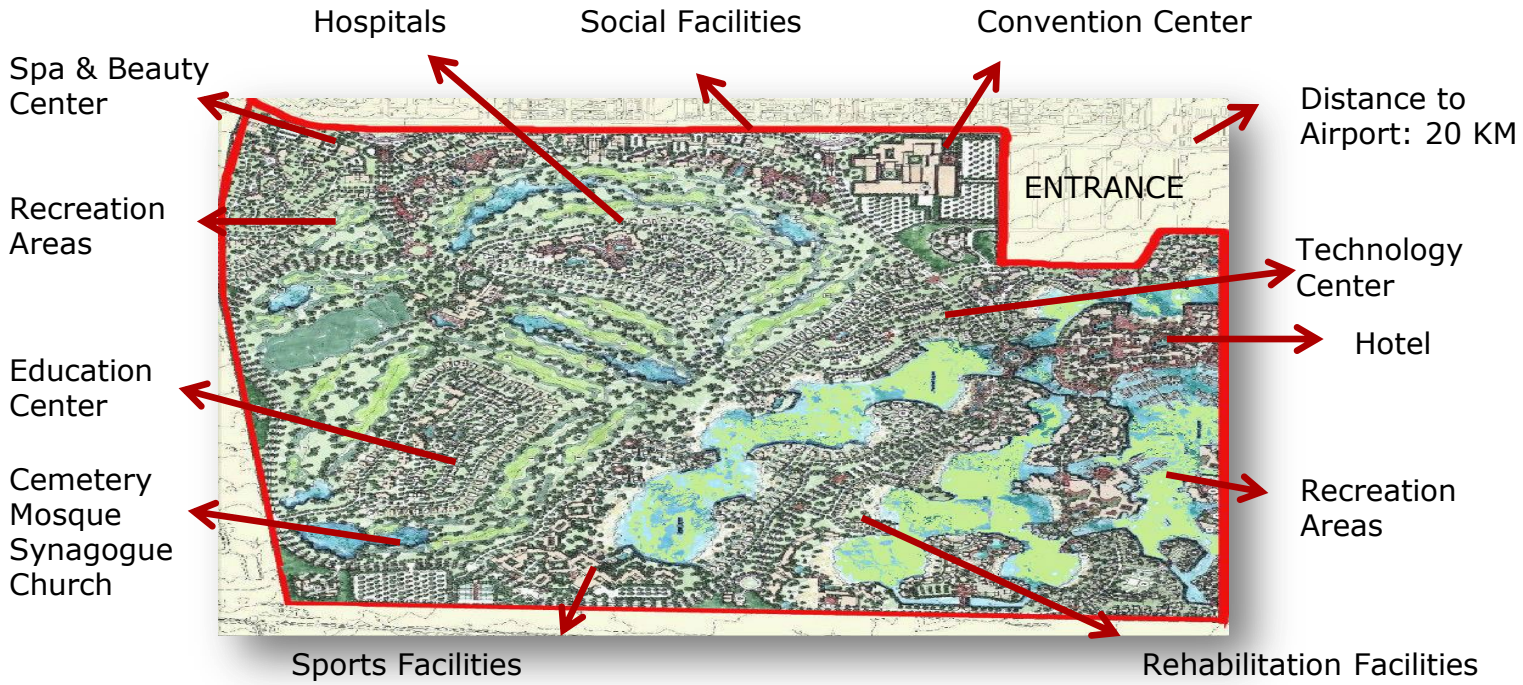


Source: Doing Business 2014, The World Bank

Turkey's free healthcare zones will create economies of scale by providing healthcare clusters

- The main idea behind health-related free zones is to implement market principles to an area where all the activities are related to health. Free healthcare zones would not be limited to hospitals and health facilities. The area would include spas, education centers, technology development zones, R&D centers, hotels and sports facilities. Even though there are no establishments currently operating in free healthcare zones, there are Ministry projects that are expected to begin construction in Antalya, Bursa and Izmir by the end of 2013.

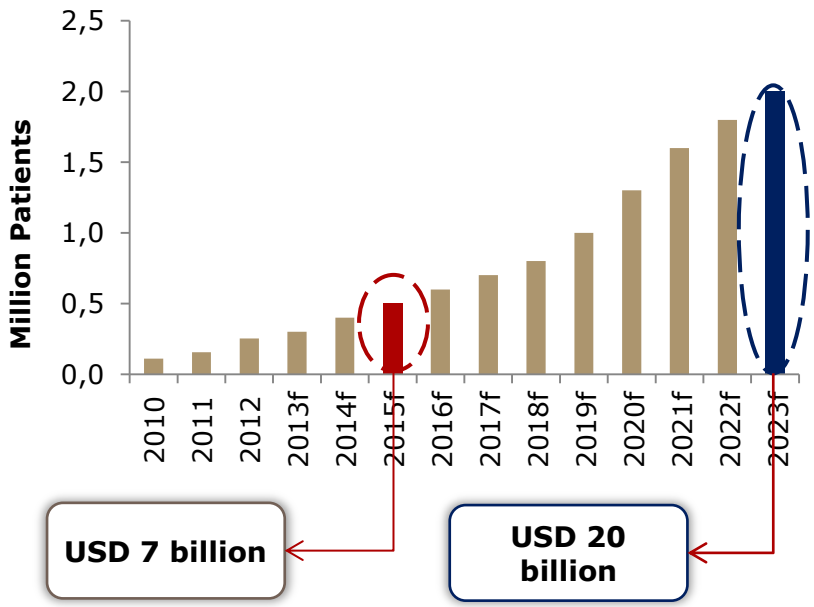
Figure 41: Free Healthcare Zones



Source: Ministry of Health

Turkey plans to build free healthcare zones targeting foreign patients with a projected USD 20 billion in revenue by 2023

Figure 42: Patient and Revenue Projections in Health Tourism



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- The Ministry of Health is projecting USD 7 billion in revenues from 500,000 foreign patients in 2015 and USD 20 billion in revenues from 2 million foreign patients in 2023.

Source: Ministry of Health

- In order to achieve the aggressive goals for the pharmaceutical sector, the Ministry of Health will focus on marketing efforts and promotion co-operating with the Ministry of Economy and the Ministry of Culture and Tourism.
- According to the Strategic Plan published by the Ministry of Health, establishing Free Healthcare Zones is one of the primary objectives. One of the strategic objectives is to establish 4 free healthcare zones by 2017 and 10 by 2023.
- The Ministry of Health is planning to open **"free healthcare zones"**, which will include hospitals, rehabilitation centers, thermal tourism facilities, nursing houses, health techno-cities and R&D centers. These "free healthcare zones" will be built in big cities where transportation will be relatively easy.
- **60% of the labor force** will be provided by foreign doctors and medical personnel, since **85% of the patients** are expected to be foreigners.
- Tax and investment incentives will be provided to investors in health tourism.

IV. Strategic Plans and Targets for the Pharmaceutical Sector

A. Strategic Plans and Targets from the Ministry of Health and the Ministry of Science, Industry and Technology

B. 2023 Vision

The Turkish pharmaceutical sector will continue to improve under the strategic planning of the Ministry of Health

Improving public health is the main goal of the Ministry of Health for their 2013-2017 strategic plans and within this scope significant actions have been determined.

The pharmaceutical-focused objectives are as follows:

Accessibility, Safety, Efficency & Rational Use of Drugs

- To evaluate, monitor and improve quality standards for pharmaceuticals, biological products and medical devices,
- To develop, evaluate and monitor evidence-based implementation standards for medical devices used for treatment purposes,
- To organize awareness-raising events,
- To increase the number of inspections for GPvP, GCP and GMPs,
- To improve the evaluation of applications and licensing processes,
- To ensure the rational use of drugs and medical devices.

Contribution to the Economy

- To establish Free Healthcare Zones,
- To develop programs to increase exports of medical products and services,
- To establish a product tracking and tracing system for medical devices and cosmetic products and integrate these into the Pharmaceutical Track and Trace System (PTTS) as well as reducing the size of the informal sector.

The determined strategic implementations are as follows:

Description	2011	2017	2023
Average Time Needed for GMP Licensing	350	210	180
Export/Import Coverage Ratio	12.07	17%	22%
Share of Pharmaceuticals Sector in Total Exports	0.42%	0.54%	0.66%

Source: Ministry of Health Strategic Plan 2013-2017

The Ministry of Science, Industry and Technology has also set targets for the sector

- In order to create a pharmaceutical sector that is internationally competitive and export oriented, the Ministry of Science, Industry and Technology has identified 6 main strategic goals in its *Strategy Paper and Action Plan*.

1. **Improve regulations to meet the demands of public health as well as attracting investments.**
   - Regulations will be prepared to improve the pharmaceutical sector in Turkey.
   - Strategies to increase the export share in existing markets will be set and new export markets will be identified.

2. **Investment in qualified human resources.**
   - Attracting Turkish scientists who are working abroad to Turkey and ease the hiring process of qualified foreign employees to companies, while integrating the qualified workforce toward R&D projects.

3. **Improve cooperation among the public sector, the private sector and universities.**
   - Establishment of the Pharmaceutical Sector Technical Committee, which will develop policies and regulations to improve the industry.

4. **Educate doctors, pharmacists and consumers on safe and effective pharmaceutical use**
   - Educate public on the efficient and effective use of pharmaceuticals.
   - Include pharmaceutical waste management information on the prospectus of pharmaceuticals.
   - Develop pharmaceutical usage monitoring systems.

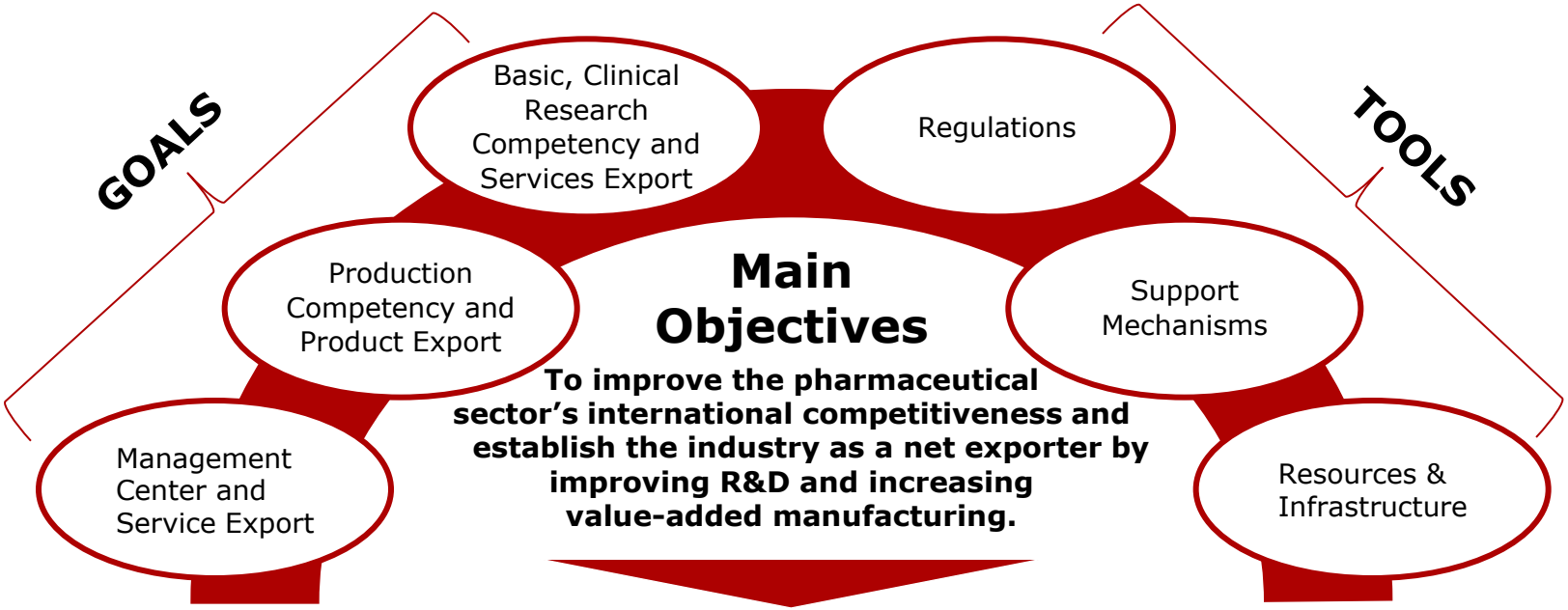
5. **Effective planning of R&D operations to produce high value added products.**
   - Improve R&D infrastructure by analyzing best practices.
   - Establishment of clinical research facilities.
   - Publish Turkish pharmaceutical inventory.

6. **Develop a sustainable financing model to support the industry.**
   - Improve incentive system in order to increase R&D, new investments and exports of the sector.
   - Support SMEs that work on new and innovative biotechnology products.

Source: Ministry of Science, Industry and Technology

The Government's 2023 Vision

Figure 43: Concepts in the 2023 Action Plan



Positioning the Turkish Pharmaceutical Industry as a global R&D and production hub as well as a regional management center.

Source: AIFD, Vision 2023 Report

Turkey has set clear goals in R&D using incentive plans and other regulations to improve the sector for 2023 and beyond

- To achieve 2023 targets, the following actions are suggested by the Association of Research-Based Pharmaceutical Companies (AIFD). These action plans are also compatible with the *Turkish Pharmaceutical Sector Strategy Paper and Action Plan* published by the Ministry of Science, Industry and Technology.

Regulations	Support Mechanisms	Resources & Infrastructure
• Government adoption of a central research policy on life sciences. • Developing a road map for life science clusters. • Implementing clinical research regulations in order to improve Turkey's competitive position. • Determining the priority fields of production. • Increasing the volume of export in alignment with the action plan. • Providing support for increased production volume. • Providing tax incentives to international life sciences executives and research personnel.	• Creating financial resources to support R&D. • Strengthening collaboration between universities and the pharmaceutical industry. • Incentivizing investment in priority production areas. • Incentivizing and facilitating knowledge transfer in high-technology production. • Preparing marketing plans to publicize the advantages of locating a company's headquarters and/or shared service center in Turkey.	• Improving the level of research of universities and research hospitals and integrating this research within global R&D networks. • Standardizing clinical trial procedures to match international standards. • Organizing infrastructure and the legal framework to support life sciences research. • Improving the education level of the work force based on industry needs. • Improving Turkey's competitive position with regard to human capital & working standards.

- Developing legal and administrative regulations that both align with Turkey's vision for the pharmaceutical industry and counterbalance the interests of the pharmaceutical sector and public health authorities.
- Developing regulations to increase patients' access to innovative healthcare products.
- Developing adequate and effective intellectual property rights.

Source: AIFD, Vision 2023 Report

A variety of KPIs have been defined in the Action Plan and there are ambitious goals for 2023

Table 13: Selected Key Performance Indicators (KPIs) from Action Plan

Key Performance Indicators	Current Status	Vision 2023
Innovation Capacity	71st	Top 20
Quality of Scientific Research Centers	89th	Top 30
Retaining Scientists and Engineers	35th	Top 20
Global Innovation	74th	Top 30
Number of New Local Molecules	0	At least 1
Pharmaceutical R&D Expenditures/GDP (2011)*	0.02%	0.1%
Pharmaceutical R&D Expenditures/Total R&D Expenditures (2011)*	0.04%	3.6%
Number of Clinical Trials Conducted Throughout a Year (2013)	1,267	≈3600
Pharmaceutical Exports as a Percentage of Pharmaceutical Imports (2010)	10%	107%
Number of Multinational Pharmaceutical Companies that Have Established Regional Management Centers in Turkey (2011)	3	20
Global Competitiveness	59th	Top 25
Ease of Doing Business (2013)	71st	Top 35
Duration of GMP Certification (2011)	350 days	‹210 days

*: Includes manufacture of basic pharmaceutical products and pharmaceutical preparations.
Note: Status is out of 142 counties

Source: AIFD, Vision 2023 Report; Ministry of Science, Industry and Technology, TurkStat, Deloitte Analysis

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