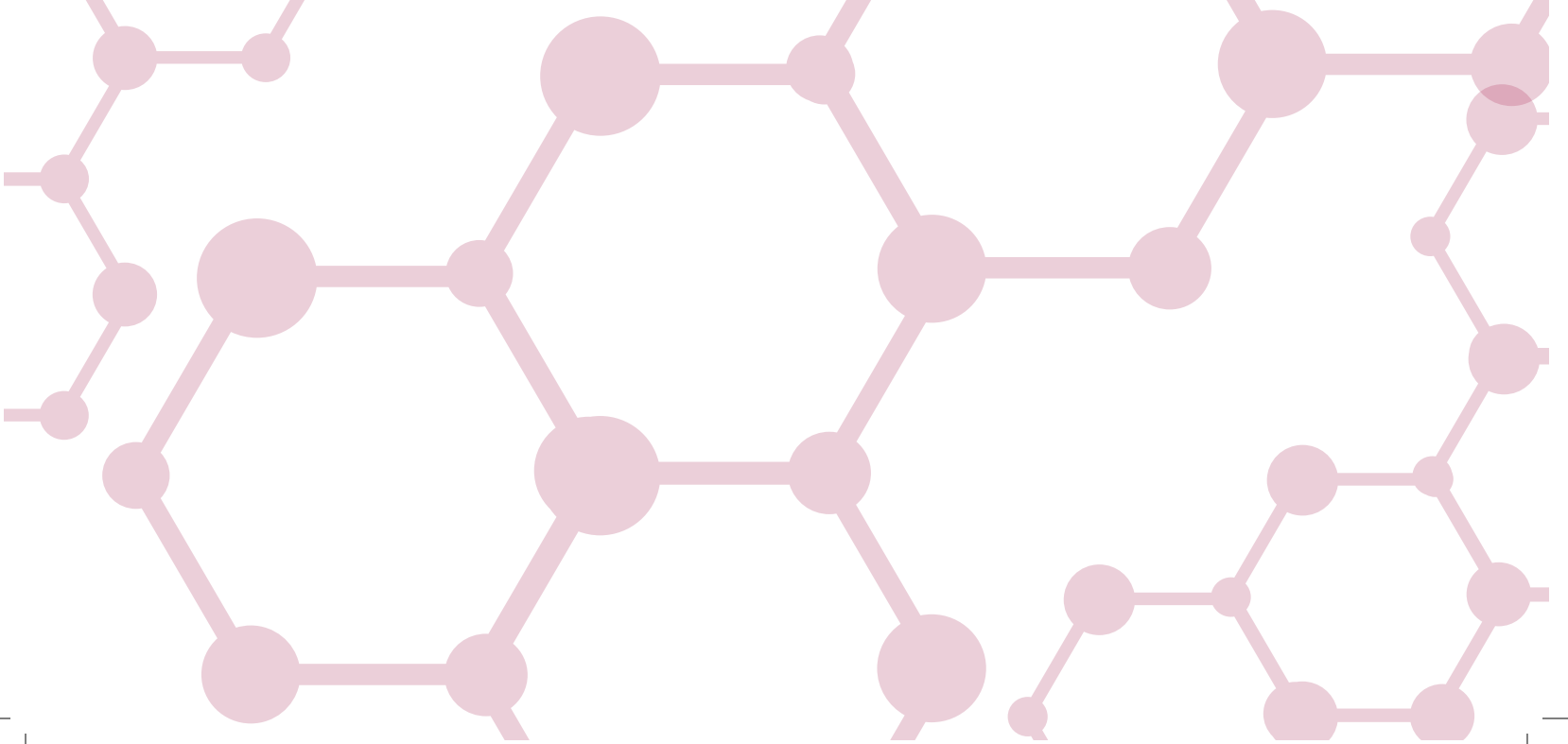
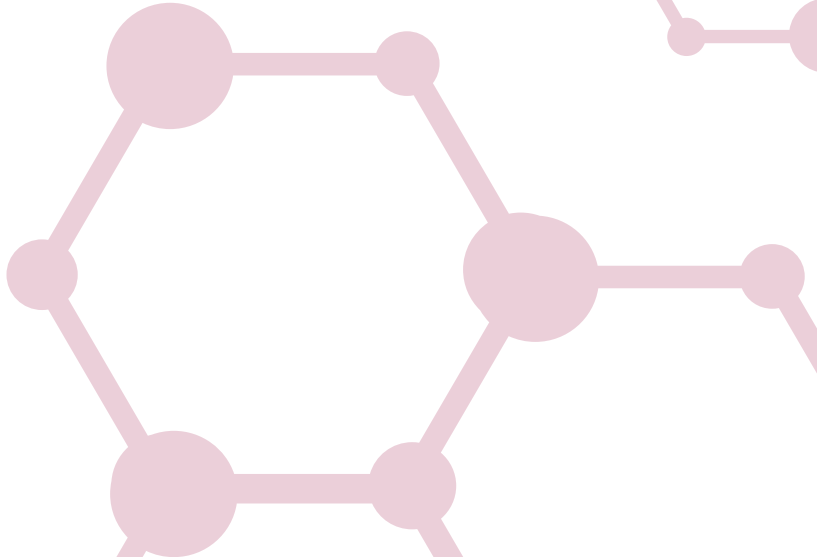
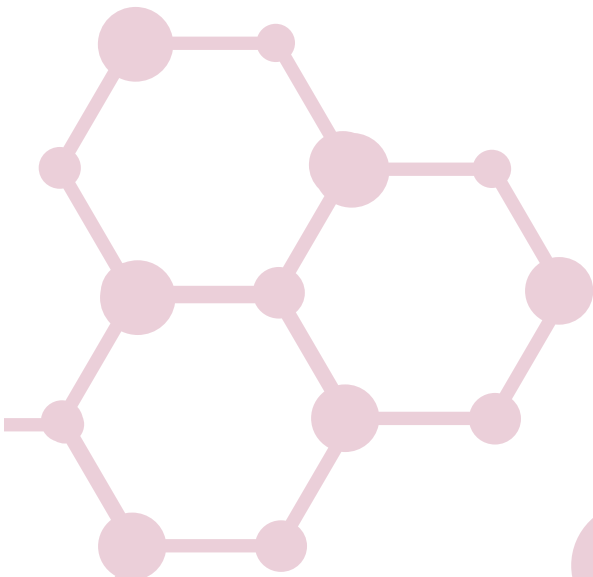
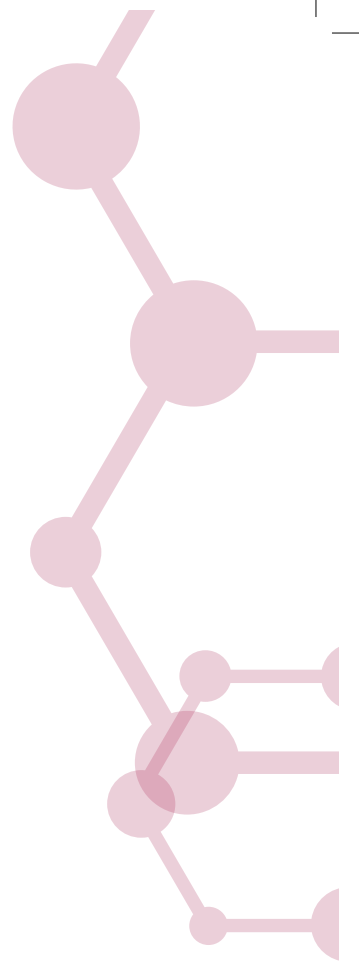
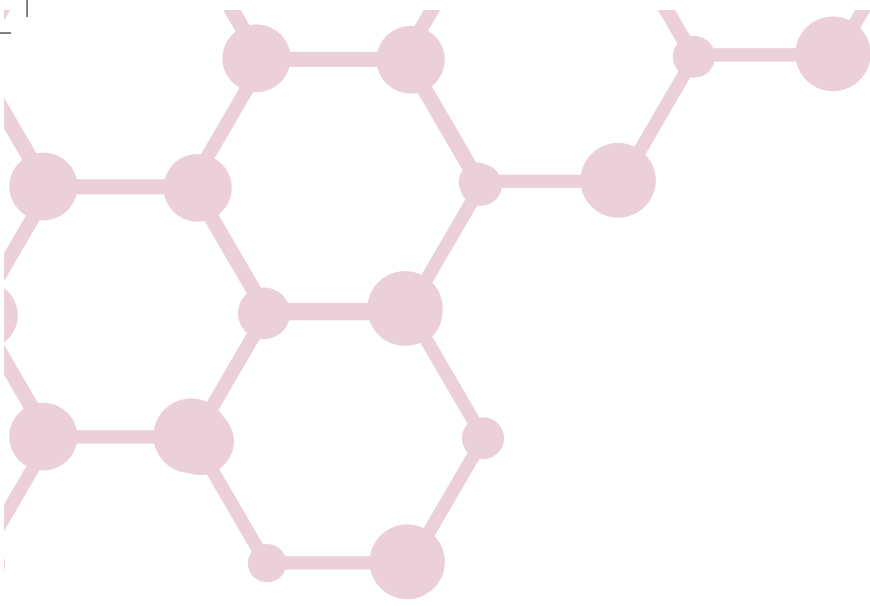


# **TURKISH PHARMACEUTICAL MARKET 2015**



**IEIS**

PHARMACEUTICAL MANUFACTURERS  
ASSOCIATION OF TURKEY



# TURKISH PHARMACEUTICAL MARKET

## 2015



*May, 2016*

[www.ieis.org.tr](http://www.ieis.org.tr)

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## INTRODUCTION

Pharmaceutical manufacturing, with its direct implications in the quality of human life, its high added value and cutting-edge technology, its experienced workforce and export potential, has been named a strategically important industry for its social and economic impacts. Growing in tandem with the expansion of the country's medical needs, the landscape of the Turkish pharmaceutical industry has changed quickly following the reform of the country's healthcare sector under the Turkish Ministry of Health's Health Transformation Program.

The Turkish pharmaceutical industry provides more than 11 thousand products to the service of our people produced at 67 facilities at international standards by approximately 300 companies and 31 thousand employees. The operational capabilities of the Turkish pharmaceutical manufacturer are based on decades of production experience which have engendered an industry strongly committed to upholding international quality standards. On par with products manufactured in developed markets and owing to the quality of Turkey's human capital as well as state-of-the-art technology, the industry's footprint now extends to 160 countries, including European Union (EU) members, the Commonwealth of Independent States (CIS), North Africa and the Middle East.

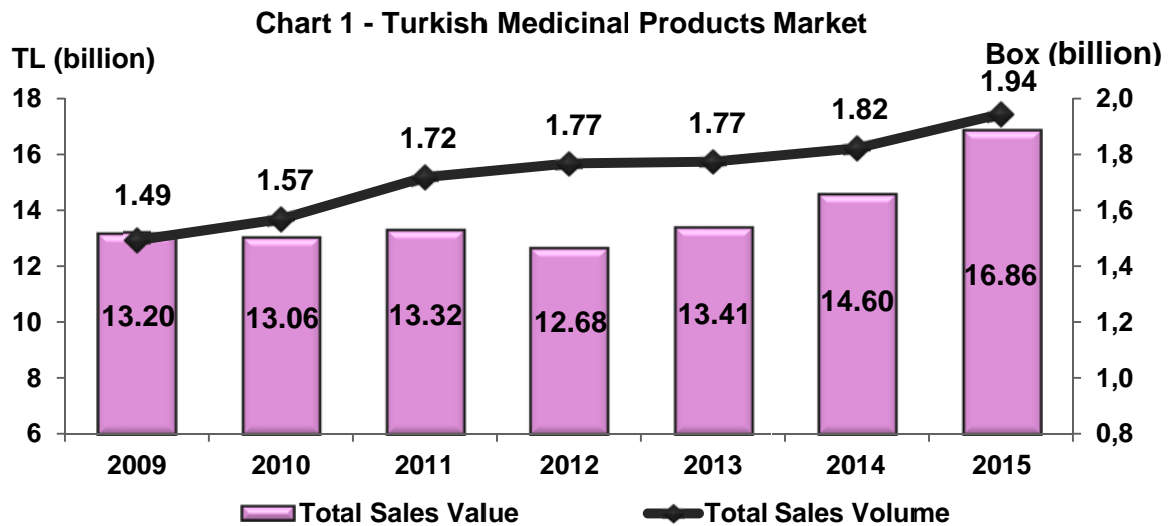
Established in 1964, the Pharmaceutical Manufacturers Association of Turkey (IEIS) is committed to improving business conditions of its members and contributing to the development of healthcare policies within Turkey. The core of the 52 IEIS members consists of pharmaceutical producers including local and multinational companies. IEIS provides services to the pharmaceutical firms that are active in widespread and different working areas, ranging from production and imports of originator products to branded generics, active ingredients as well as contract manufacturing. It closely follows the interests of all segments of the pharmaceutical industry in seeking to realize the organization's larger goal of furthering the global presence of an industry strongly focused on both export-led growth and the production of higher value-added products especially biotechnologicals through extensive R&D activities.

Turkey's medicinal products market consists of pharmaceuticals and non-pharmaceuticals. Non-pharmaceutical products include biocidal products; some medical devices in pharmaceutical form; foods for special medicinal purposes; cosmetic and dermocosmetic products licensed by the Ministry of Health; and the vitamins, food supplements, and baby formulas approved by the Ministry of Food, Agriculture, and Livestock. This report prepared by IEIS scrutinizes the prescription and non-prescription drugs market and non-pharmaceutical products over the course of the past six years, which was the execution of the global budget period.

Turkish pharmaceutical has been evaluated in the categories of prescription, originator-generic, import-local, and biotechnological drugs. The analyses of production, R&D, and foreign trade of pharmaceutical sector are other significant sections of the report.

# 1. Turkish Medicinal Products Market

The Turkish medicinal products market, including drugs licensed by the Ministry of Health and non-pharmaceutical medicinal products, attained double-digit growth and reached 16.86 billion Turkish Liras (TL) with a growth rate of 15.5% in 2015. Unit sales rose by 6.7% over the same period, reaching 1.94 billion units.



Source: IMS, IEIS

In view of the six-year global budget period between 2009 and 2015, the entire market has increased from the level of 13.2 billion TL in 2009 to 16.86 billion TL with 27.7% growth rate in 2015. This growth means an annual 4.2% rise in annual compound growth rate (CAGR) and a decline of 16% in real terms when weighed against wholesale inflation over this six-year period.

In the same period, the sector sold 1.94 billion boxes, constituting a 30.3% increase from 1.49 billion boxes in 2009. Annual growth rate on compound basis in unit term is 4.5%, and such increase is the growth of demands stemming from the increasing and ageing population in Turkey, increase in average life expectancy, and significant improvement in public health services and drugs.

In terms of the concentration on the entire market, the number of the foreign firms operating in the Turkish market increased from 73 in 2009 to 118 in 2015. In addition, 100 local firms accessed the market in the respective period; the number of local firms reached 337 in 2015. Hence, the market share of foreign firms within the value scale has declined by one point for the last six years to become 67% in 2015. On the other hand, market concentration intensified. While 45 companies made up 90% of the total market for pharmaceuticals in 2009, six years later, 60 companies now control this same proportion, 70% of which are multinationals.

When breakdowns of the entire medicinal product market are examined, it is observed that the share of the prescription and non-prescription drugs has declined while that of the non-pharmaceutical products has increased. Another issue that attracts attentions is that non-reimbursed products have grown within the last six years.



**Table 1- Overall Market Sub Distributions**

	2009		2015	
	Value (Billion TL)	Share	Value (Billion TL)	Share
<b>Medicinal Products Market</b>	<b>13.20</b>	<b>100%</b>	<b>16.86</b>	<b>100%</b>
<b>Drugs</b>	<b>12.71</b>	<b>96.3%</b>	<b>15.87</b>	<b>94.1%</b>
<b>Prescription Drugs</b>	<b>12.60</b>	<b>95.5%</b>	<b>15.82</b>	<b>93.8%</b>
Reimbursed	12.35	93.6%	14.67	87.0%
Non- reimbursed	0.25	1.9%	1.15	6.8%
<b>Non- prescription Drugs</b>	<b>0.10</b>	<b>0.8%</b>	<b>0.04</b>	<b>0.3%</b>
Reimbursed	0.10	0.8%	0.02	0.1%
Non- reimbursed	0.00	0.0%	0.03	0.2%
<b>Non- pharmaceutical Drugs</b>	<b>0.49</b>	<b>3.7%</b>	<b>0.99</b>	<b>5.9%</b>
Reimbursed	0.04	0.3%	0.00	0.0%
Non- reimbursed	0.46	3.5%	0.99	5.9%

Source: IMS, IEIS

### a. New Product Entries on the Market

A total of 552 new products were launched on the medical product market in 2015, of which 358 were licensed drugs and 194 were non-pharmaceutical products such as food supplements. The number of the products reimbursed as of 2015 was 8,104, and 292 of the products added to the market were included on the reimbursement list.

**Table 2- Quantitative Distribution of the Products in the Market**

	2015
<b>Market Total</b>	<b>11,233</b>
<b>Entries</b>	<b>552</b>
<b>Drugs</b>	358
<b>Non- pharmaceutical Drugs</b>	194
<b>Reimbursement List</b>	<b>8,104</b>
<b>Entries</b>	292
<b>Withdrawals</b>	532

Source: IEIS

### b. Average Prices

While prices of non-pharmaceutical products increased between the years 2009 and 2015, the prices of drugs declined. Average price on the medicinal products market was approximately 9 TL, which was 8.5 TL in drugs and 14 TL in non-pharmaceutical products.

**Table 3- Average Price Distribution**

Years	Medicinal Products	Drugs	Non- pharmaceutical products
<b>2009</b>	8.84	8.85	8.53
<b>2010</b>	8.33	8.31	8.63
<b>2011</b>	7.75	7.66	9.51
<b>2012</b>	7.17	7.05	9.71
<b>2013</b>	7.56	7.38	12.18
<b>2014</b>	8.01	7.83	12.78
<b>2015</b>	8.67	8.47	14.03

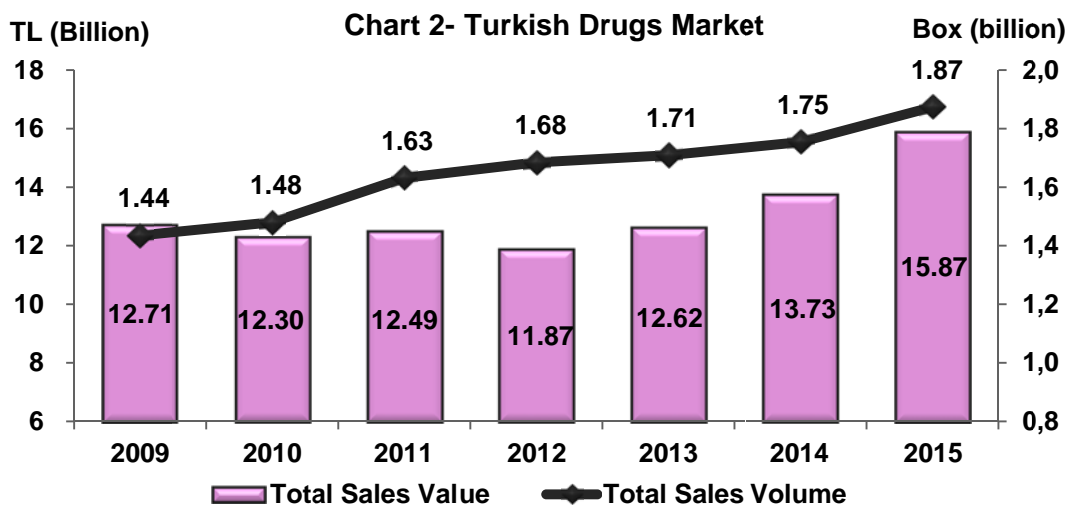
**Table 4- Average Price Change**

Change	Medicinal Products	Drugs	Non- pharmaceutical products
2009-2015	-1.9%	-4.4%	64.5%
2014-2015	8.2%	8.2%	9.8%

Source: IMS, IEIS

## 1.1. Turkish Drugs Market

Turkey's pharmaceuticals market reached a size of 15.87 billion TL in 2015, growing by 15.6% from the previous year. Unit sales rose by 6.8% over this same period, reaching 1.87 billion units.

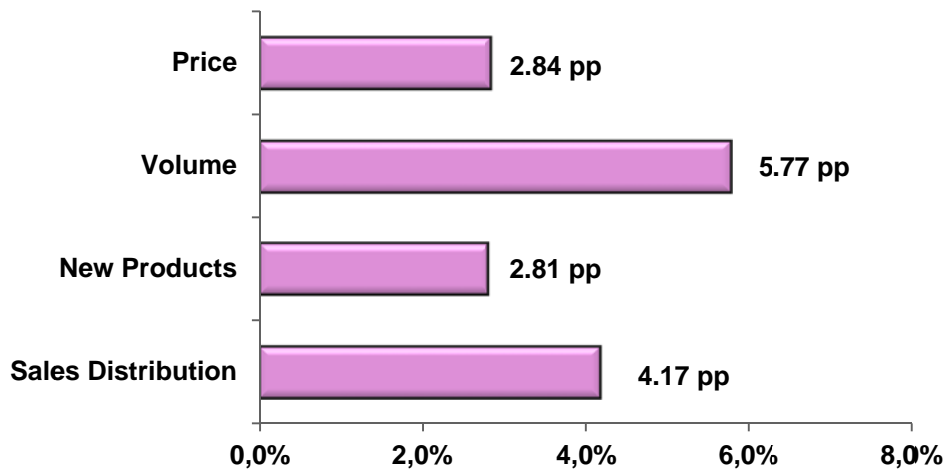


Source: IMS, IEIS

Regarding the sources of growth on the market, there are four main factors that contribute to growth in the value scale. These are the volume and price increases in the current portfolio, new product entries into the portfolio, and changes in sales distribution.

In this context, 2.84 percentage points (390 million TL) of the 15.6% growth (2.140 million TL) on the pharmaceuticals market resulted from price increase. It is notable that in April and July 2015, there was a total increase of 6.08% in the Euro value. The volume increase in the current product portfolio was the main factor that provided the foremost contribution to market growth. 5.8 pp (792 million TL) in market growth resulted from increases in volume and the products entered the market for the first time in 2015 contributed to the growth of the market by 2.8 percentage points (386 million TL). However, changes in the sales distribution of current products on the market, i.e. the change in sales volume toward expensive or cheap products, provided 4.17 percentage points (572 million TL) of contribution to growth.

**Chart 3- Sources of Growth**



Source: IMS, IEIS

Between 2009 and 2015, the pharmaceuticals market grew by 24.9% from 12.71 billion TL in 2009 to 15.87 billion TL in 2015. Unit sales rose by 30.6% over this six-year period, reaching 1.87 billion units.

### **1.1.1. Market Distribution**

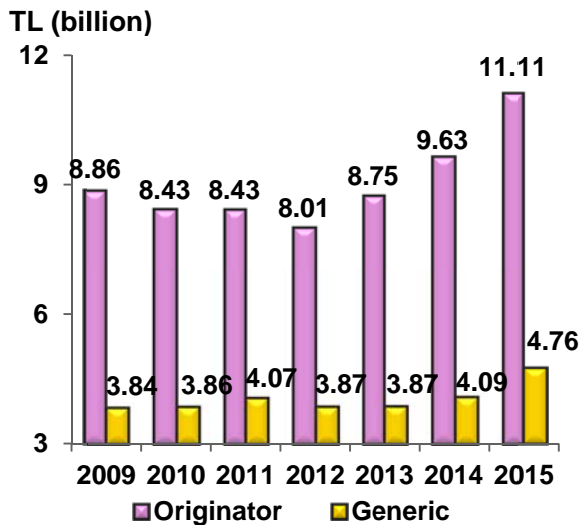
#### **a. Originator - Generic Drugs**

The originator drug market, which stood at a value of 9.63 billion TL in 2014, reached 11.11 billion TL in 2015. An increase of 15.3% from the previous year, this growth was primarily spurred by increased sales of imported originator drugs, which in itself grew by 16.6%. Generics in Turkey achieved a growth above the pharmaceuticals market in 2015, reaching 4.76 billion TL with a 16.4% increase.

In unit terms, the growth of originator and generic drugs was dormant in 2011 following increases by 11% and 10% respectively. In 2015, this growth reached its highest level of increase since 2012. The originator and generic drugs respectively grew by 5% and 8%.

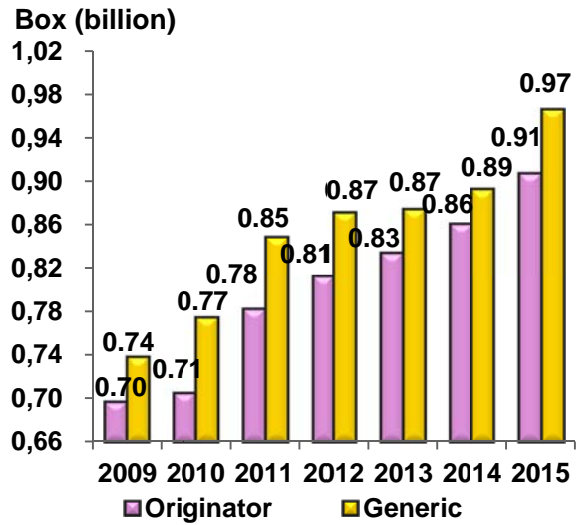
Due to the factors like the cost oriented price policies implemented in the period between 2009 and 2015, the omission of Euro value in determining update that determines the drug prices, despite the fulfillment of the conditions sought in the legislation, and the increase of the discount rates, the growth in the originator and generic drugs for the initial 5 years have taken place in limited ratios and they have increased in total by 25.3% and 23.9% in value, respectively, due to the recovery that followed a slight increase in the Euro value in 2015. Unit sales rose by 30.2% in originator drugs and 30.9% in generic drugs in the same period.

**Chart 4- Originator-Generic Drugs (Value)**



Source: IMS, IEIS

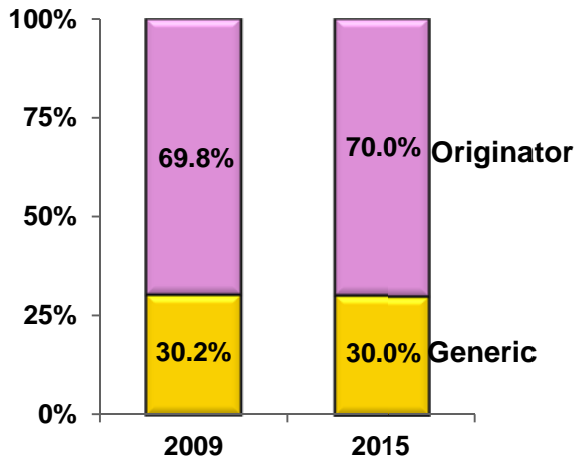
**Chart 5- Originator-Generic Drugs (Volume)**



Source: IMS, IEIS

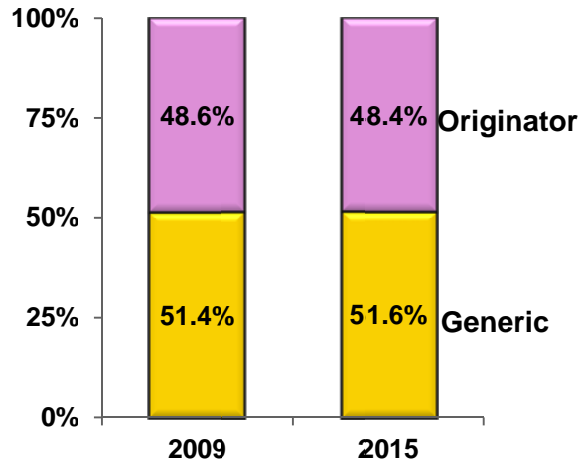
On the entire market, the market shares of generic and originator drugs did not change significantly over the course of the past six-year period. Originator drugs received 48% of the total market share but comprised 70% of total market value.

**Chart 6- Market Share of Originator-Generic Drugs (Value)**



Source: IMS, IEIS

**Chart 7- Market Share of Originator- Generic Drugs (Volume)**



Source: IMS, IEIS

When the import-local distinction of the originator-generic drugs is examined, it is observed that the shifting tendency of originator drugs toward import and of generic drugs toward local production is ongoing. It is thought that in the downsizing of imported generic drugs, the abroad GMP inspections carried out by the Ministry of Health have been effective.

**Table 5- Sub Distributions of Originator-Generic Drugs**

	ORIGINATOR DRUGS				GENERIC DRUGS			
	2009		2015		2009		2015	
	Import	Local	Import	Local	Import	Local	Import	Local
<b>Box (mn)</b>	37%	63%	49%	51%	6%	94%	3%	97%
	258	439	445	462	46	692	27	939
<b>TL (mn)</b>	75%	25%	79%	21%	12%	88%	5%	95%
	6,644	2,220	8,797	2,309	472	3,371	232	4,530

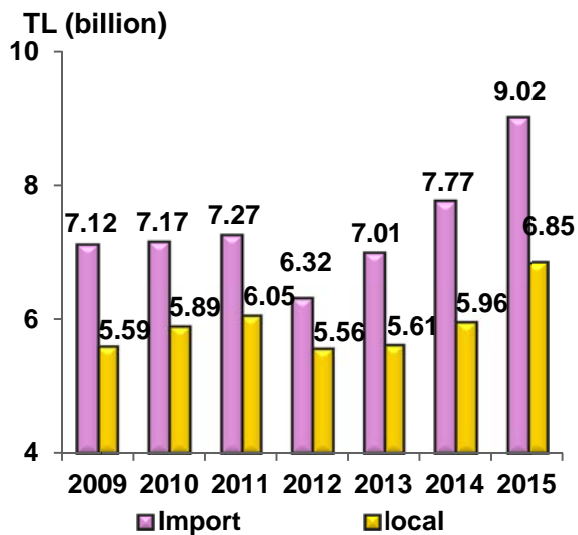
Source: IMS, IEIS

**b. Import-Local Drugs**

The growth in import drugs, stagnant until 2012, has started to exhibit a rising trend over the last three years. In 2015, imported drug sales reached 9.02 billion TL through 16% growth; they have provided totally 26.7% of growth within the six-year period. By volume, the imported drugs, which had 0.33 billion-box sales in 2009 in line with the increase in demand for pharmaceuticals, reached a volume of 0.47 billion boxes through 55.7% increase in 2015.

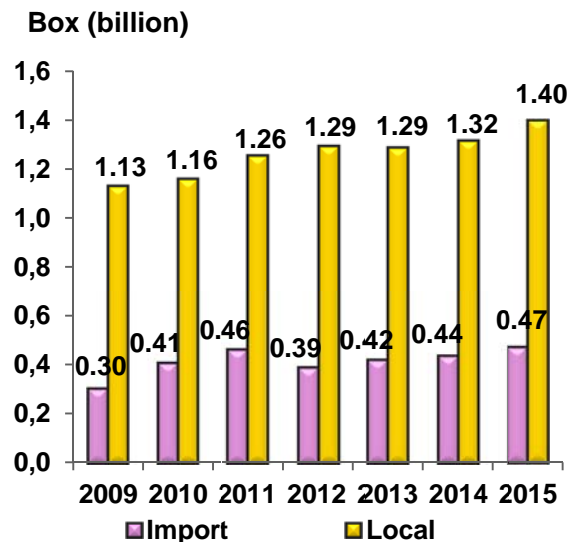
Nevertheless, drugs manufactured locally have increased in the last six years by 22.5% aggregately to reach 6.85 billion TL. In unit terms, a total of 23.8% growth was realized, and a volume of 1.4 billion boxes was attained throughout the global budget period.

**Chart 8- Import-Local Drugs (Value)**



Source: IMS, IEIS

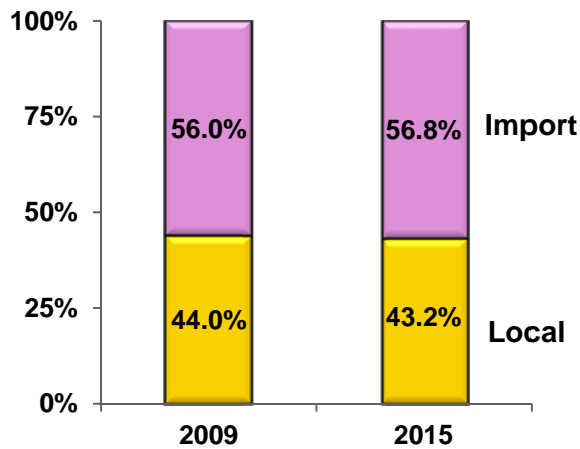
**Chart 9- Import-Local Drugs (Volume)**



Source: IMS, IEIS

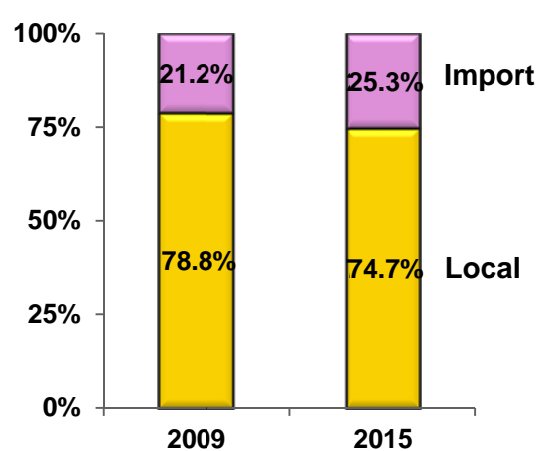
The imported drugs market continues to increase its share particularly by volume.

**Chart 10- Market Share of Import-Local Drugs (Value)**



Source: IMS, IEIS

**Chart 11- Market Share of Import-Local Drugs (Volume)**



Source: IMS, IEIS

Almost all imported products were constituted by originator drugs, and they continue to have a smaller share in local production. In 2015, 66% of drugs manufactured in Turkey in value terms and 67% of drugs in volume terms were generic pharmaceuticals.

**Table 6- Sub-Distributions of Import-Local Drugs**

	Import Drugs				Local Drugs			
	2009		2015		2009		2015	
	Ori.	Gen.	Ori.	Gen.	Ori.	Gen.	Ori.	Gen.
<b>Box (mn)</b>	85%	15%	94%	6%	39%	61%	33%	67%
	258	46	445	27	439	692	462	939
<b>TL (mn)</b>	93%	7%	97%	3%	40%	60%	34%	66%
	6,644	472	8,797	232	2,220	3,371	2,309	4,530

Source: IMS, IEIS

### c. Biotechnological Drugs

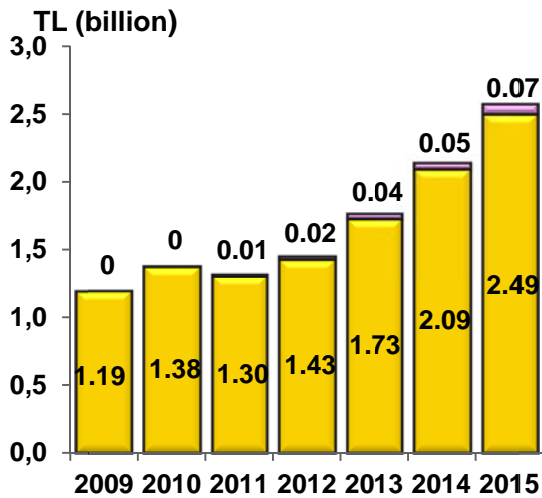
183 reference biotechnological and 38 biosimilar drugs are available on Turkey's pharmaceutical market and the production of 13 (34%) of the biosimilar drugs is produced in our country. Biotechnological drugs constituted 17% of prescription drugs with 2.57 billion TL in 2015.

The reference biotechnological pharmaceutical market, which was 2.09 billion TL in 2014, grew by 19.4% in 2015 to total 2.5 billion TL. The share of these drugs on the prescription drugs market increased to 16.6% in 2015.

In Turkey, biosimilar products containing abciximab, enoxaparin sodium, epoetin alpha, erythropoietin, erythropoietin alpha, filgrastim, infliximab, and somatropin have been licensed and, among them, those produced in Turkey contain the active substances of enoxaparin sodium, epoetin alpha, and infliximab. It is expected that the number of biosimilar products will increase rapidly in the forthcoming period upon the expiry of the patent periods of the reference biotechnological drugs.

Biosimilar drugs market increased by 59.3% to reach 73.6 million TL in 2015.

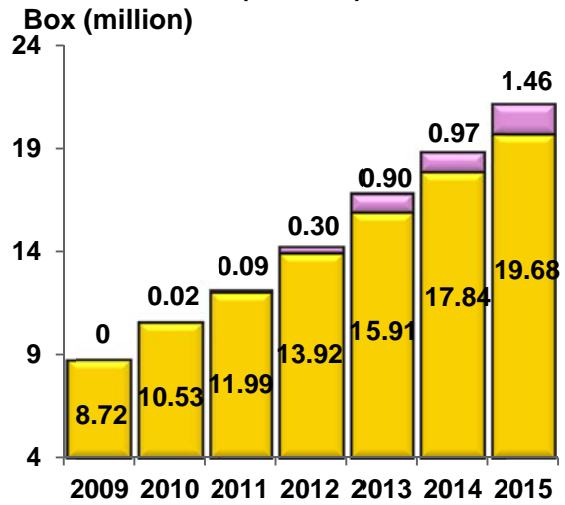
**Chart 12- Biotechnological Drugs (Value)**



■ Reference ■ Biosimilar

Source: IMS, IEIS

**Chart 13- Biotechnological Drugs (Volume)**

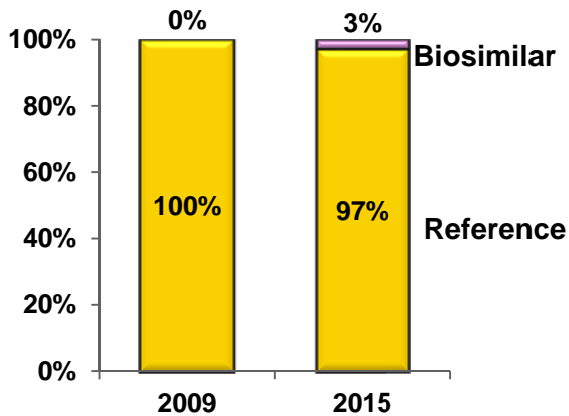


■ Reference ■ Biosimilar

Source: IMS, IEIS

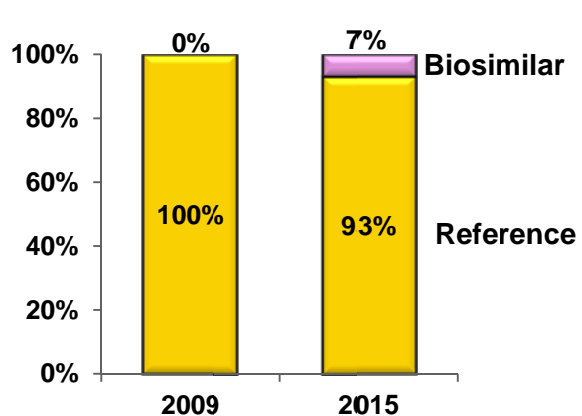
In 2009, biosimilar drugs were hardly present among the biotechnological drugs, and their share became 3% in terms of value and 7% in terms of boxes in 2015.

**Chart 14- Market Share of Reference-Biosimilar Drugs (Value)**



Source: IMS, IEIS

**Chart 15- Market Share of Reference-Biosimilar Drugs (Volume)**



Source: IMS, IEIS

When biotechnological products are classified on the basis of the ATC 2 group, it appears that antianemic preparations and antithrombotic drugs have increased their proportion among biosimilar products significantly in six years. On the reference biotechnological product market, the immunomodulator agents, insulin groups, and their analogs are at the forefront. The insulin groups and their analogs and antineoplastic drugs have the share of 26% and 10% respectively among reference drugs. These groups are not present within the biosimilar products group.

**Table 7- Biotechnological Drugs**

	Box		Value	
	2009	2015	2009	2015
<b>Biosimilar</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Antianemic Preparations	0%	14%	0%	39%
Antithrombotic Drugs	0%	75%	0%	27%
Immunomodulator Agents	100%	8%	100%	22%
Pituitary and Hypothalamus Hormones and Analogues	0%	4%	0%	12%
<b>Reference</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Immunomodulator Agents	8%	7%	34%	32%
Insulin and Analogues	62%	61%	25%	26%
Antineoplastic Drugs	2%	1%	15%	10%
Ophthalmologics	0%	1%	1%	7%
Digestive System and Metabolism	0%	0%	2%	5%
Vitamine K and other hemostatics	0%	1%	1%	5%
Antianemic Preparations	4%	2%	10%	3%
Antithrombotic Drugs	17%	20%	3%	3%
Sex hormones and Genital System Modulators	2%	2%	4%	3%
Pituitary and Hypothalamus Hormones and Analogues	3%	4%	4%	3%
Other systemic drugs for obstructive airway diseases	0%	0%	0%	2%
Serum Immune Globulins	0%	0%	1%	1%

Source: IMS, IEIS

#### d. New Drug Entries on the Market

The treatment group that has the highest proportion on quantity basis among the 358 drugs newly launched on the market has been the drugs for nervous system. 47 nervous system drugs, 42 antirheumatic drugs, 39 antibiotic drugs, 34 common cold medications and cough medicines, 27 vitamins and minerals, and 26 oncology drugs have entered the market during the last year.

A total of 76 pieces of originator products, 2 of which were biotechnological and 74 chemical, entered the market in 2015. 65 (86%) of the products in question do not have a generic competitor; only 2 are produced in Turkey. The average price of the 65 products is 81 TL.

282 generic drugs newly accessed the market, of which only 16 are imported. The average price of these 282 drugs is 8.5 TL.

**Table 8- Quantitative Distribution of Drugs in the Market**

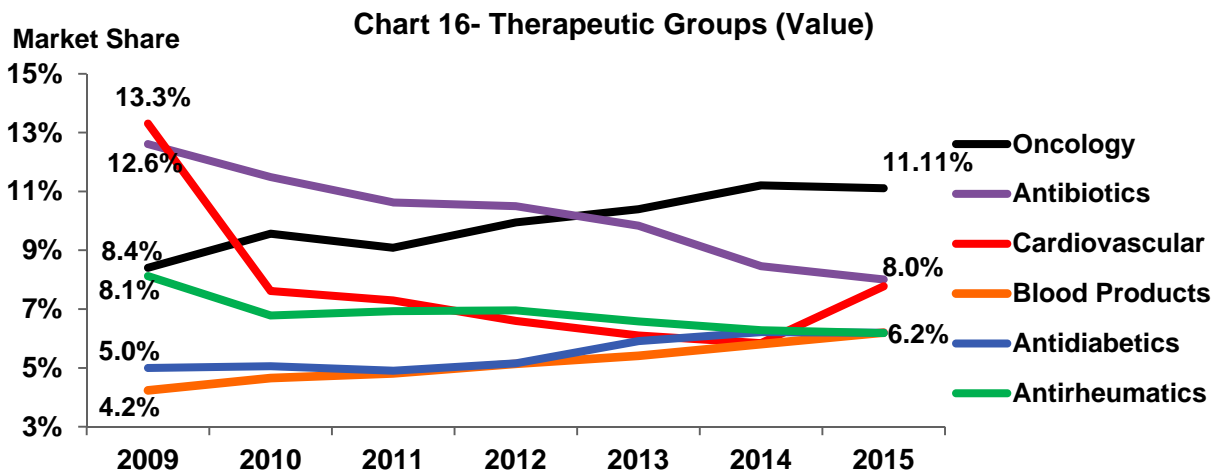
	2015
<b>Market Total</b>	<b>11,233</b>
<b>Entries</b>	<b>552</b>
<b>Drugs</b>	<b>358</b>
<b>Original</b>	<b>76</b>
<i>With Generics</i>	11
<i>Without Generics</i>	65
<b>Generic</b>	<b>282</b>
<i>Import</i>	16
<i>Local</i>	266

Source: IEIS



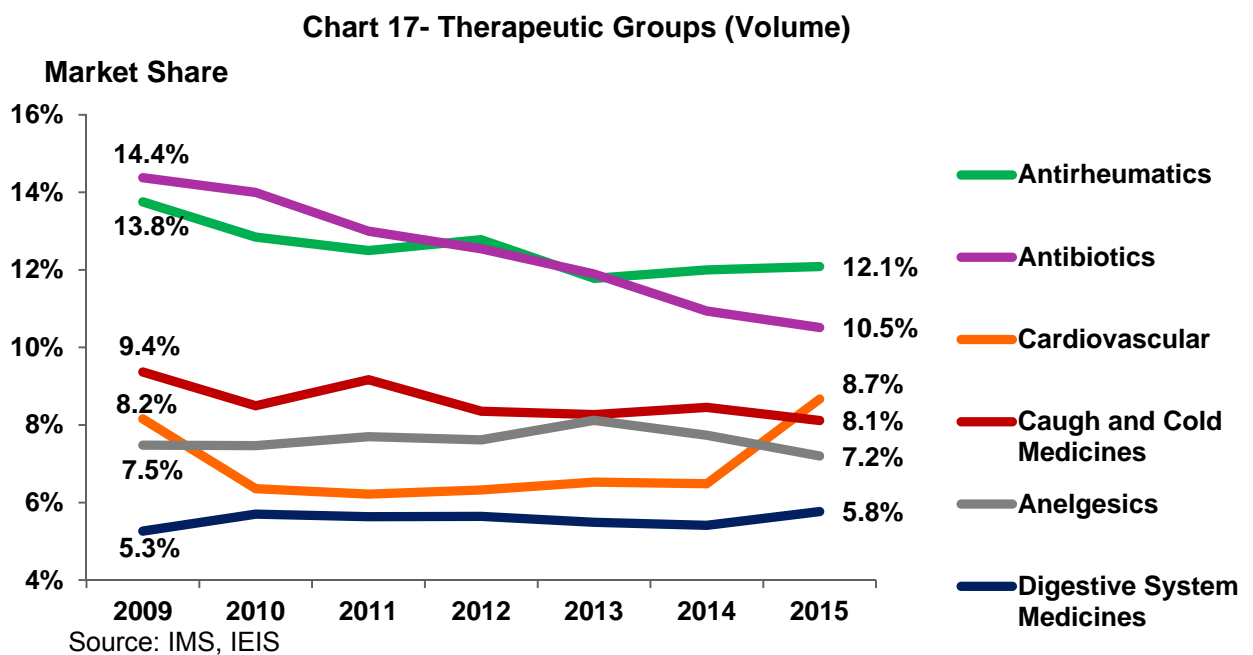
### e. Treatment Groups

A scrutiny of the market in terms of treatment groups will demonstrate that oncology and blood products have tended to increase, but antibiotics and antirheumatics have been prone to decrease in the last six years. The group that had the highest share on the market was the oncology products group with 11.1% proportion in 2015. The group that increased most in 2015 was the cardiovascular products group with a 54% increase.



Source: IMS, IEIS

In unit terms, antibiotics continued their tendency to decrease in 2015 as well and became the second most widely consumed treatment group with 10.5% proportion. The antirheumatic product group continued to increase its market share as it maintained its position in the top rank. The product group that exhibited the highest level of increase in 2015 by volume became the cardiovascular drugs.



Source: IMS, IEIS

## 1.1.2. Drug Prices

### a. Pharmaceutical Price Legislation

Price reference system was first introduced in 2004 in Turkey with the intent of checking governmental healthcare expenditures through associating the price of pharmaceuticals to the lowest price at which a similar pharmaceutical product is produced within a basket of five European nations (France, Greece, Italy, Portugal and Spain). Whichever region produces a specified pharmaceutical at the lowest price, that price is taken to be the reference price for producer prices in Turkey.

Once a reference price has been set, official prices of products in different categories are established based on a fraction of the reference price. For example, while an originator product with no generic competitor may have the right to receive 100% of the reference price, an originator and generic product that compete against one another are subject to 60% of the reference price. In effect, the result of this is that as soon as a generic drug that competes against an originator product is introduced on the local market, the price of the originator product falls by 40%. Since the source prices are traced in Euro currency, a fixed foreign currency exchange rate in Euro is determined by the Price Assessment Commission to convert them into TL. This value is determined as 70% of the Euro average of the previous year. For 2016, the conversion Euro value is 2.1166 TL.

**Table 9- Reference Price Ratios**

	Producer Price (TL)	2009	2010 - 2011	2012 - 2014	Producer Price (TL)	2015	Producer Price (TL)	2016
Originator	3.55 and below	100	100	100	3.62 and below	100	3.83 and below	100
	3.56- 6.78	100	100	100	3.63- 6.92	100	3.84-7.32	100
	6.79 and over	100	100	100	6.93 and over	100	7.33 and over	100
Originator with Generic and the Generic Product	3.55 and below	100	100	100	3.62 and below	100	3.83 and below	100
	3.56- 6.78	80	66	60	3.63- 6.92	60	3.84-7.32	60
	6.79 and over	80	66	60	6.93 and over	60	7.33 and over	60
Twenty Years	3.55 and below	100	100	100	3.62 and below	100	3.83 and below	100
	3.56- 6.78	100	100	100	3.63- 6.92	100	3.84-7.32	100
	6.79 and over	100	100	80	6.93 and over	80	7.33 and over	80

Source: TITCK (Ministry of Health, Medicines and Medical Devices Agency of Turkey)

Once a producer price is established by the Ministry of Health, discount rates are applied by the Social Security Institution (SSI) for granting reimbursement status. The following table shows discount rates applied for different product groups.

The discount thresholds have been updated in parallel with the exchange rate increase in order to be valid from February 22, 2016, and the discount ratios in some product groups have been reduced as well. Additionally, price increases between 10% and 20% were applied gradually to the low-price products whose retail sales price was 5.63 TL and below. Likewise, a 3% price increase was applied to the twenty-year-old products whose price range was between 5.64 and 10.77 TL.

The recent changes in our sector are promising. Such developments will pave the way for our country to be a more powerful producer and exporter of pharmaceuticals.

**Table 10- Discount Rates**

Producer Price(TL):			2009	2010	2011	2012	2013 - 2014		2015		2016
Originator	3.55 and below		4	4	4	4	0	3.62 and below	0	3.83 and below	0
	3.56-6.78		24	23	32,5	41	20	3.63-6.92	20	3.84-7.32	10
	6.79 and over		24	23	32,5	41	41	6.93 and over	41	7.33-11.02	31
Originator with Generic and the Generic Product	3.55 and below		4	4	4	4	0	3.62 and below	0	3.83 and below	0
	3.56-6.78		11	11	20,5	28	20	3.63-6.92	20	3.84-7.32	10
	6.79 and over		11	11	20,5	28	28	6.93 and over	28	7.33-11.02	18
Twenty Years	3.55 and below		4	4	4	4	0	3.62 and below	0	7.32 and below	0
	3.56-6.78		11	11	11	11	7	3.63-6.92	7	7.33-11.02	10
	6.79 - 10.21	Local	-	-	-	28	20	6.93 - 10.42	20		10
		Reference price available	11	11	20,5	28	20		20	10	
		No reference price	24	23	32,5	40	20		20	10	
	10.22 and over	Local	-	-	-	28	28	10.43 and over	28	28	
		Reference price available	11	11	20,5	28	28		28	28	
No reference price		24	23	32,5	40	40	40		40		

Source: SSI Communique on Healthcare Practices

## b. Average Prices

The highest level of decrease in the average prices between 2009 and 2015 took place in the imported drugs. In 2015, the average price was approximately 8.5 TL on

the prescription market, 12 TL on the originator drugs market, 19 TL on the imported drugs market, and approximately 5 TL on the generic drugs market.

**Table 11- Drug Average Price Distribution (TL)**

Av. Price	Drug	RX	Originator	Generic	Import	Local
2009	8.85	9.16	12.71	5.21	23.38	4.94
2010	8.31	8.43	11.96	4.99	17.56	5.08
2011	7.66	7.76	10.77	4.79	15.71	4.82
2012	7.05	7.05	9.85	4.44	16.18	4.29
2013	7.38	7.38	10.48	4.43	16.65	4.36
2014	7.83	7.83	11.19	4.58	17.76	4.52
2015	8.47	8.47	12.24	4.93	19.03	4.89

Source: IMS, IEIS

**Table 12- Drug Average Price Change**

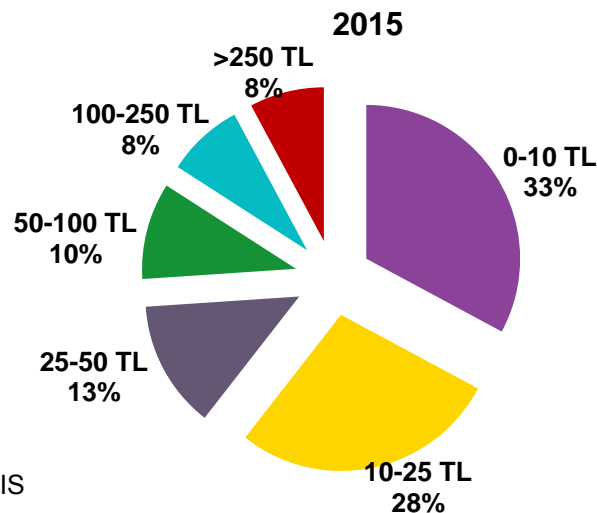
Change	Drug	RX	Originator	Generic	Import	Local
2009-2015	-4.4%	-7.6%	-3.7%	-5.4%	-18.6%	-1.0%
2014-2015	8.2%	8.2%	9.4%	7.5%	7.1%	8.2%

Source: IMS, IEIS

### c. Retail Price Ranges

As of the end of 2015, the retail price distribution of drugs on the pharmaceutical market is as follows. The products under 5 TL constitute 13% of the total number of drugs on the market and the products above 250 TL constitute 8% of the market. 61% of the entire market consists of products priced below 25 TL.

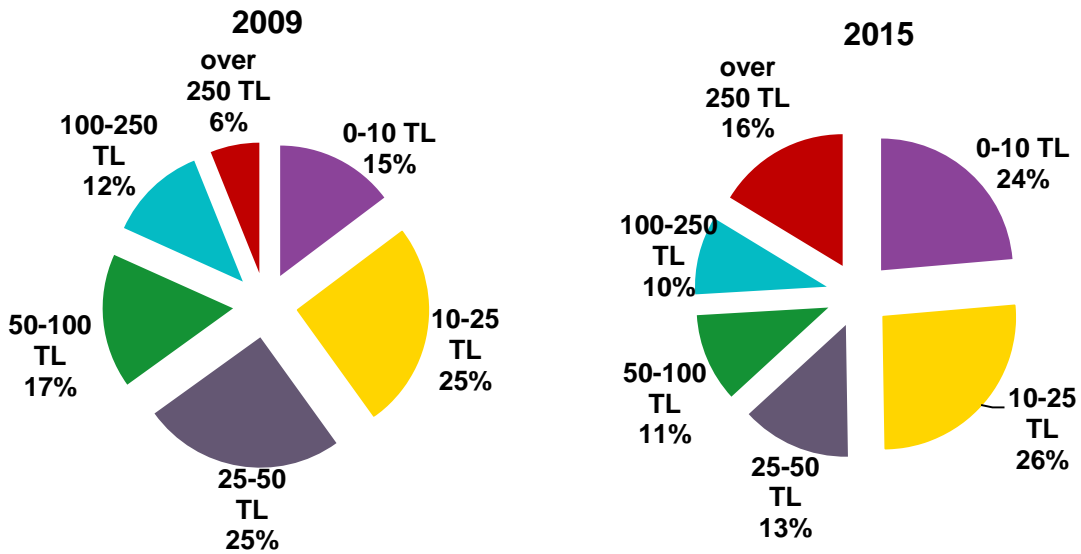
**Chart 18- Retail Price Distribution**



Source: TITCK, IEIS

Drugs above 250 TL and between 0 and 10 TL have increased their shares, whereas there has been a decline in the share of drugs priced in the 25-250 TL range on quantity basis within the originator drugs over the last six years. Drugs priced under 25 TL constitute half of this product group.

**Chart 19- Price Distribution of Originator Products**

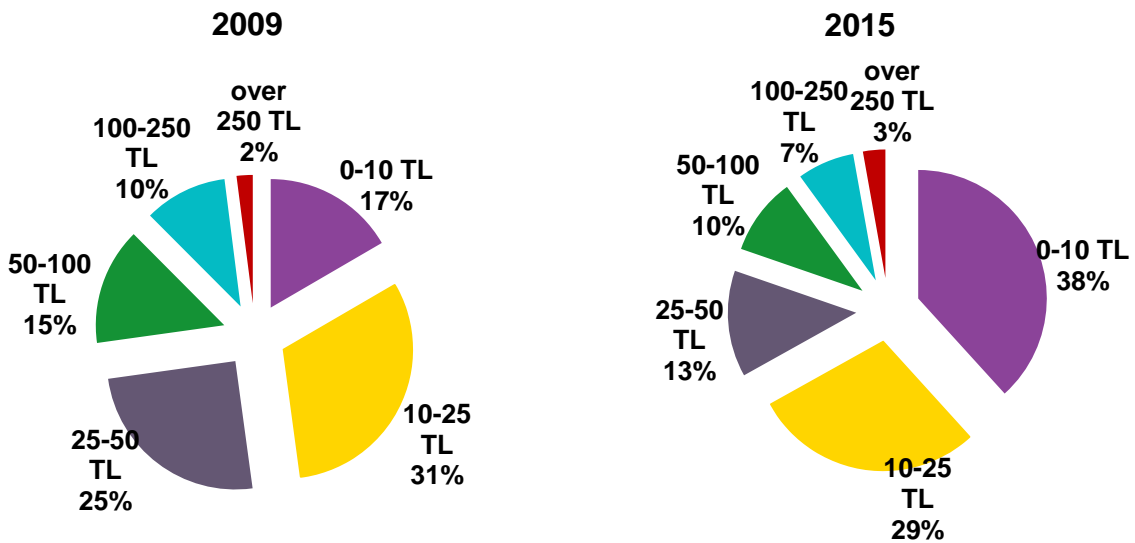


Source: TITCK, IEIS

Source: TITCK, IEIS

When the price ranges of generic drugs are examined, it is observed that generic drugs within 0-10 TL increased their share by 21 percentage points (pp) compared with 2009 and reached 38% as of 2015. A concentration on the 0-10 TL price range of generic products in the last six years is apparent.

**Chart 20 – Price Distribution of Generic Products**

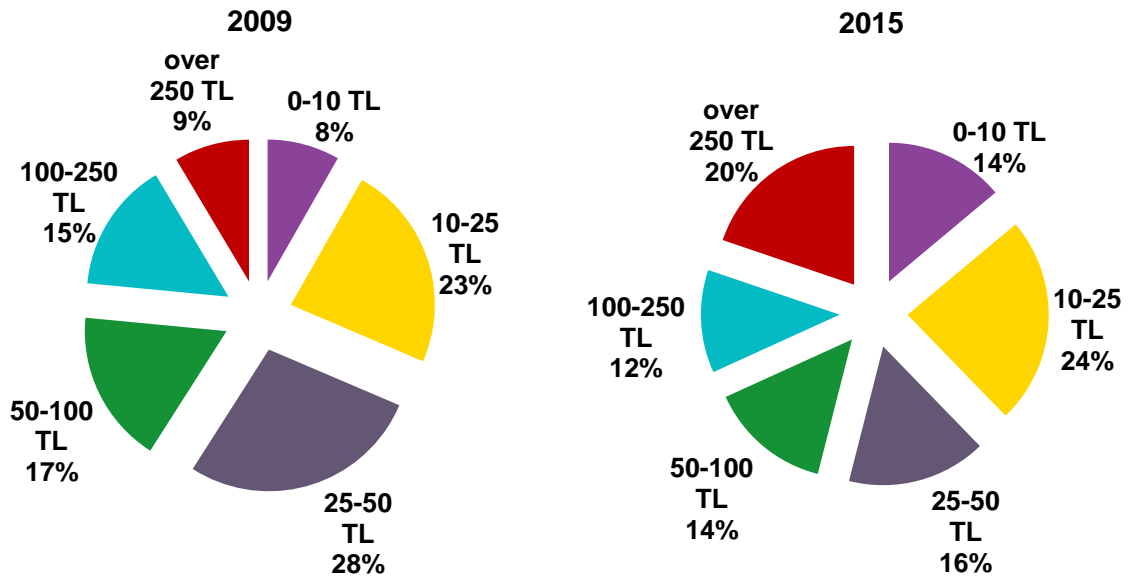


Source: TITCK, IEIS

Source: TITCK, IEIS

The highest share in 2015 was in the product groups between 10 and 25 TL with 24% and above 250 TL with 20%. In comparison with 2009, the products above 250 TL increased by 11 pp and the products between 0 and 10 TL by 6 pp; the products between 25 and 50 TL declined by 12 pp.

**Chart 21 - Price Distribution of Import Products**

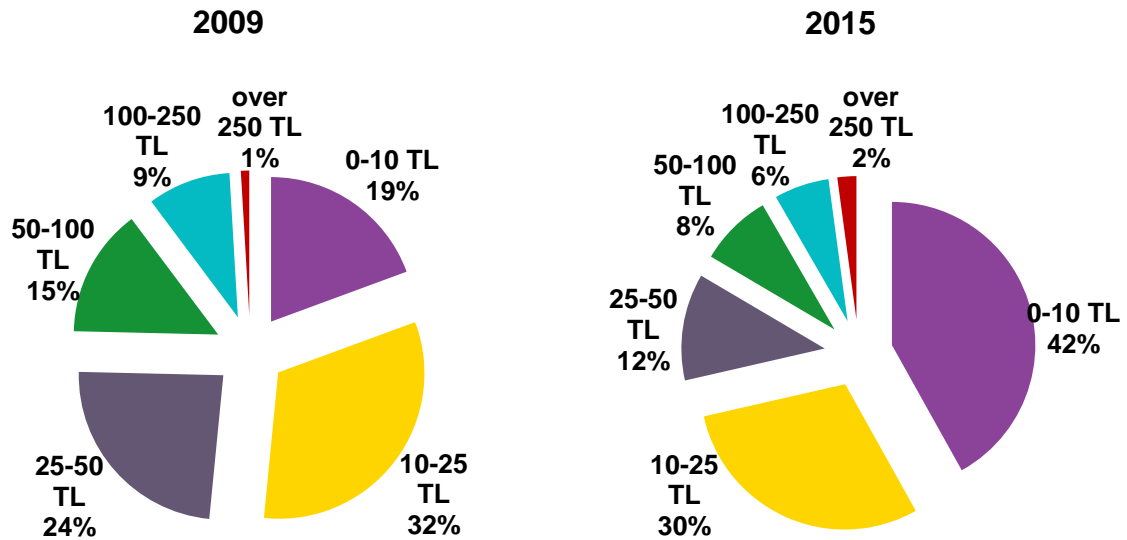


Source: TITCK, IEIS

Source: TITCK, IEIS

A similar situation manifests within the local products, as most of them are generics. The product group that has the highest proportion is the 0-10 TL product group with a ratio of 42%. This group has increased its shares by 23 pp since 2009. Products under 25 TL constitute 72% of local products.

**Chart 22 - Price Distribution of Local Products**



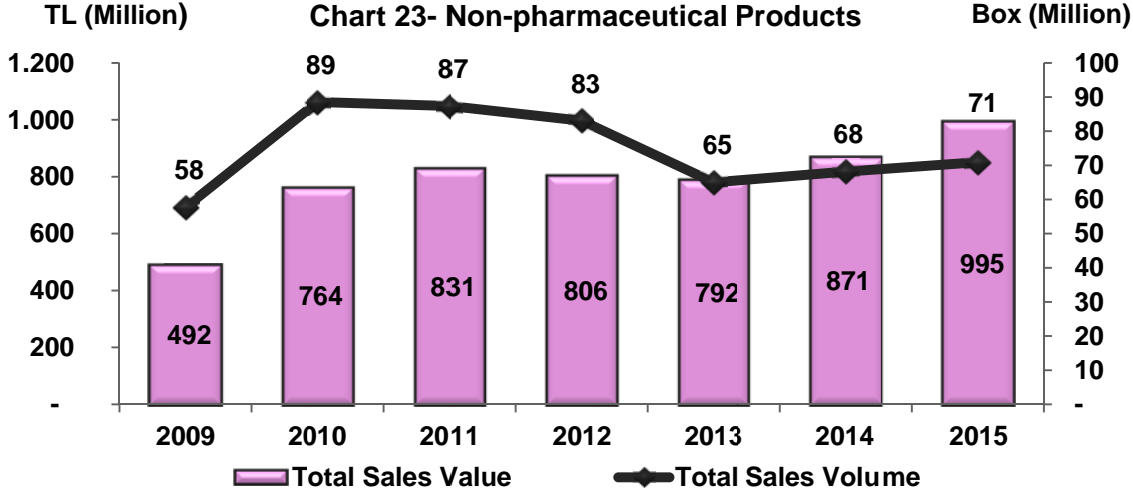
Source: TITCK, IEIS

Source: TITCK, IEIS

## 1.2. Non-pharmaceutical Products

Products available within the portfolios of pharmaceutical companies but which are non-pharmaceuticals include biocidal products licensed from the Ministry of Health, some medical devices in pharmaceutical form, medical formulas, cosmetics and

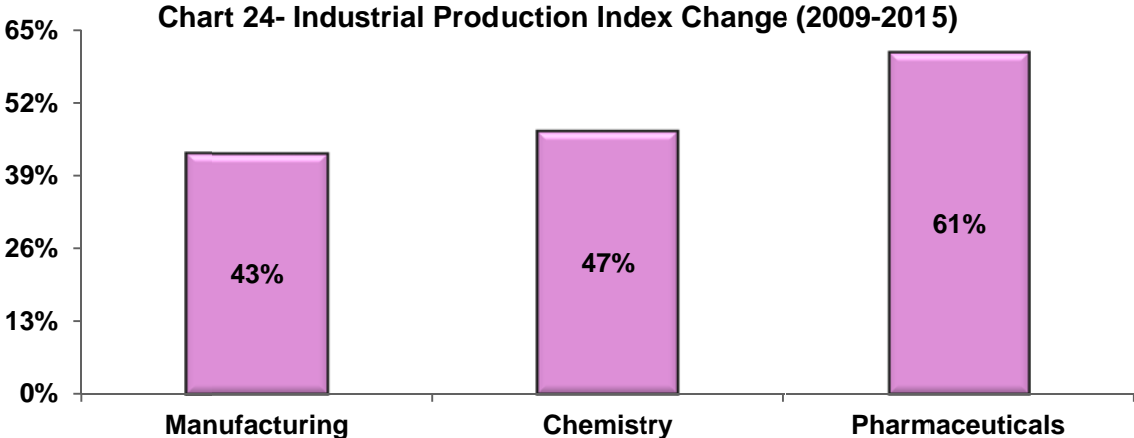
dermocosmetic products, food supplements and baby formulas licensed by the Ministry of Food, Agriculture, and Livestock. These products reached 995 million Turkish Liras in value through 14% growth and 71 million boxes of volume through 4% growth in terms of boxes in 2015.



Source: IMS, IEIS

## 2. Production

The industry production index data for the period between 2009 and 2015 demonstrates that, in comparison to mid-level technology industries such as manufacturing and chemical which grew by 43% and 47% respectively, the pharmaceutical industry based on high level technology grew by 61%. Public policy in support of local products has resulted in ongoing activities carried out under the heading of “Improving the Reimbursement, Pricing, and Licensing Processes of the Strategic and Local Drugs” in the Turkish government’s 2016 action plan. Accordingly, it is expected that local production will increase in our industry in the forthcoming years.

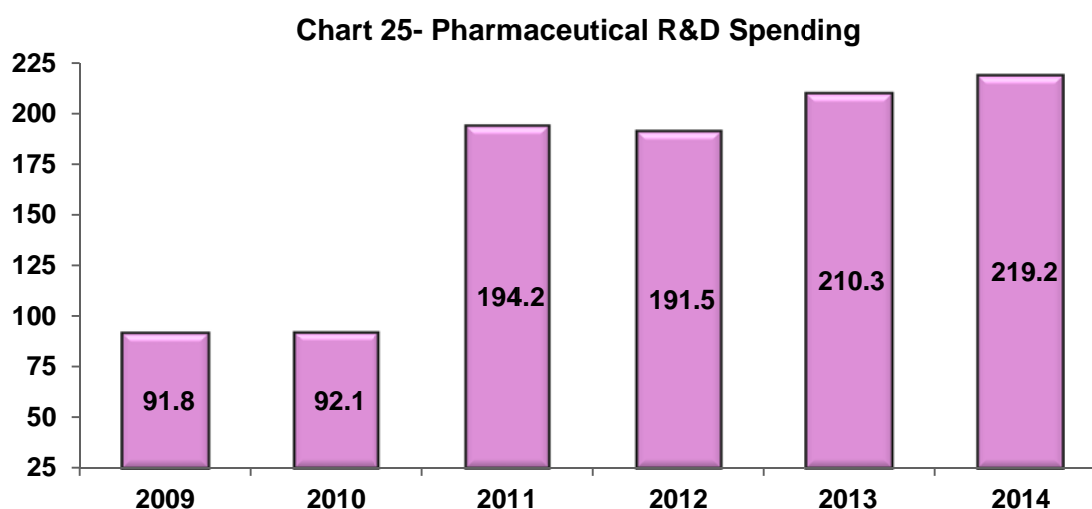


Source: TurkStat

### 3. Research & Development

The pharmaceutical industry is one of the primary sectors that will contribute significantly to the industrial transformation of Turkey, with its 13 accredited R&D centers, 892 employees, 432 completed and 316 ongoing projects, and 94 patents. Through the progress in the field of R&D, it will be possible to produce in Turkey the significant products which we are import dependent.

Pharmaceutical R&D expenditure increased 138% from 91.8 million TL in 2009 to 219.2 million TL in 2014. This increase means an annual 19% rise in annual compound growth rate (CAGR) and a rise of 66% in real terms when weighed against wholesale inflation over that five-year period.



Source: TurkStat

### 4. Foreign Trade

The industry's export of products to 160 countries, largely in the European Union (EU), MENA and CIS, accelerated significantly in 2015. During the same year, Turkey's total exports declined by 8.7%, while pharmaceutical exports increased by 9.1%

The export of pharmaceuticals, which was at the level of 474 million US dollars in 2009, increased in six years by 96% to reach 921 million US dollars in 2015. In the same period, Turkey's total exports grew by 41%. Thus the contribution of the pharmaceutical industry, exporting nearly twice as much as total national exports, to the Turkey's export increased from 0.46% to 0.64%. The foreign trade deficit in pharmaceuticals decreased by 6.9%.

On the other hand, pharmaceutical imports have not increased significantly in the last six years; growth rate has become aggregately 4.1%. While imports did increase from 2013 to 2014, they dropped to the level of 2.7% in 2015 and became 4.61 billion US dollars. As a result, the foreign trade deficit declined to the level of 3.68 billion US dollars in 2015, and export-import coverage ratio has increased by 9 points to reach 20% within six years.



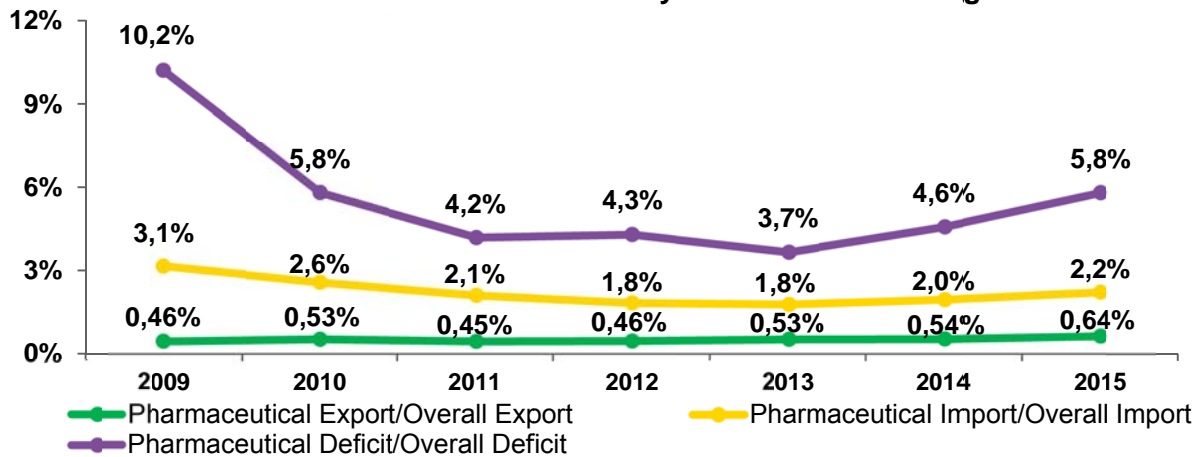
**Table 13- Import and Export of Pharmaceutical Products (Million USD)**

Year	Export	Change	Export	Change	Export/Import	Foreign Trade Deficit	Change
2015	921	9.1%	4,605	-2.7%	20.0%	-3.684	-5.2%
2014	845	5.6%	4,731	5.6%	17.9%	-3.887	5.6%
2013	800	12.9%	4,482	3.2%	17.8%	-3.682	1.3%
2012	709	16.2%	4,342	-14.4%	16.3%	-3.633	-18.6%
2011	610	1.2%	5,074	6.3%	12.0%	-4.464	7.0%
2010	603	28.3%	4,773	7.9%	12.6%	-4.171	5.4%
2009	470	1.4%	4,425	-6.5%	10.6%	-3.955	-7.4%

Source: TurkStat

When the contribution of the foreign trade deficit of the pharmaceuticals industry to Turkey's total foreign trade deficit is analyzed, it is observed that 5.8% of the 2015 total trade deficit resulted from the pharmaceutical industry. However, this ratio was at the level of 10.2% in 2009. In the rapid decline of the share in question, the industry's increasing exports and public sector policies for reducing imports have been effective.

**Chart 26- Pharmaceutical Industry within Turkish Foreign Trade**



Source: TurkStat

We hope that parallel to these positive developments in foreign trade our pharmaceutical industry will reduce the foreign trade deficit of Turkey by exporting products with higher added-value it will produce. It is one of the basic targets of our industry to be one of the leading producers and exporters of pharmaceuticals in the world but there are still some impediments to it. The targets of the industry can be achieved by overcoming such impediments. Low drug prices in our country, problems experienced in GMP inspections and licensing processes in the respective countries, and political and economic setbacks encountered on the target markets emerge as the most complicated obstacles to increasing pharmaceutical exports.

The low price policies applied in Turkey constitute one of the most significant factors in low export value. Adaptation of the drug prices in our country as source prices in other countries to which we export makes it difficult for Turkish pharmaceutical firms to access and compete in a market with suitable prices for the conditions of the country. In this case, our producers may prefer contract production to receive higher prices on the export markets where the possibility of production is available.

In addition, also for the same reason, export value per kilogram is declining on an annual basis. Our exports grow in terms of quantity, but such increase is not reflected into value. Hence, since 2010 such value has decreased by 16% to 27.2 US dollars from 32.3 US dollars.

**Table 14- Export Value per Kg (USD)**

2001-2005	2006-2010	2011-2014
32.5	32.3	27.2

Source:International Trade Center

One of the setbacks to overcome for increasing and facilitating the export of pharmaceuticals is that the GMP certificates granted to our production facilities by Turkey are not recognized by some health authorities in foreign markets. Currently, re-performance of inspection and reissuance of a GMP certificate by the recipient country inflict significant expenses and loss of labor and time.

South Korea, the U.S.A., Iraq, Germany, Switzerland, and Azerbaijan were the countries to which the sector exported most in 2015. The most important import markets are Germany, U.S.A., Switzerland, France, and the United Kingdom.

**Table 15- Export on Basis of Countries (Million USD)**

Country	2015	2014	2015-2014 (%)
South Korea	225	110	104%
U.S.A.	53	45	18%
Iraq	52	48	8%
Germany	50	58	-13%
Switzerland	48	60	-20%
Azerbaijan	31	29	6%
Russian Federation	27	32	-18%
TRNC	26	29	-8%
Iran	25	44	-43%
Slovenia	21	18	18%

Source: TurkStat

**Table 16- Import on Basis of Countries (Million USD)**

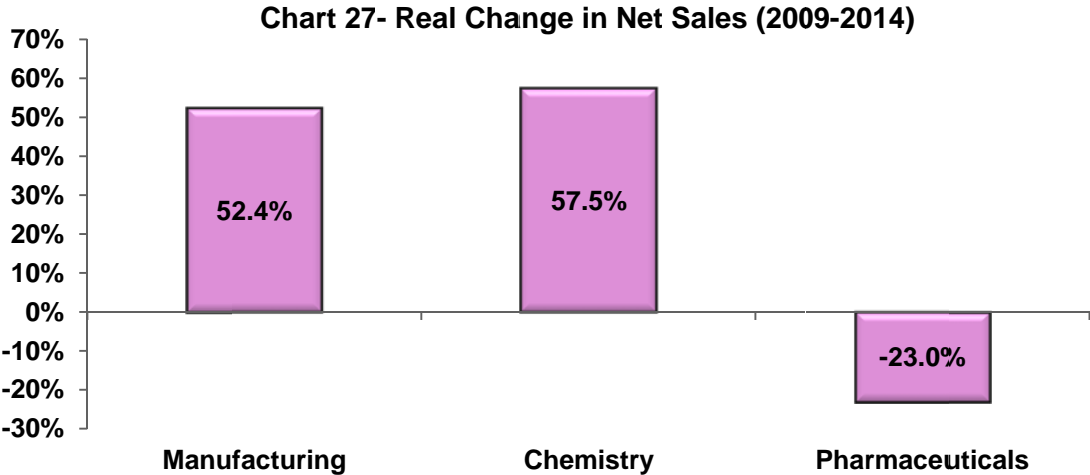
Country	2015	2014	2015-2014 (%)
Germany	817	883	-7%
U.S.A.	557	598	-7%
Switzerland	421	429	-2%
France	389	450	-14%
England	306	298	3%
Ireland	301	281	7%
Italy	298	326	-9%
South Korea	225	137	64%
Denmark	164	160	2%
Spain	164	135	22%

Source: TurkStat

# 5. Financial Results

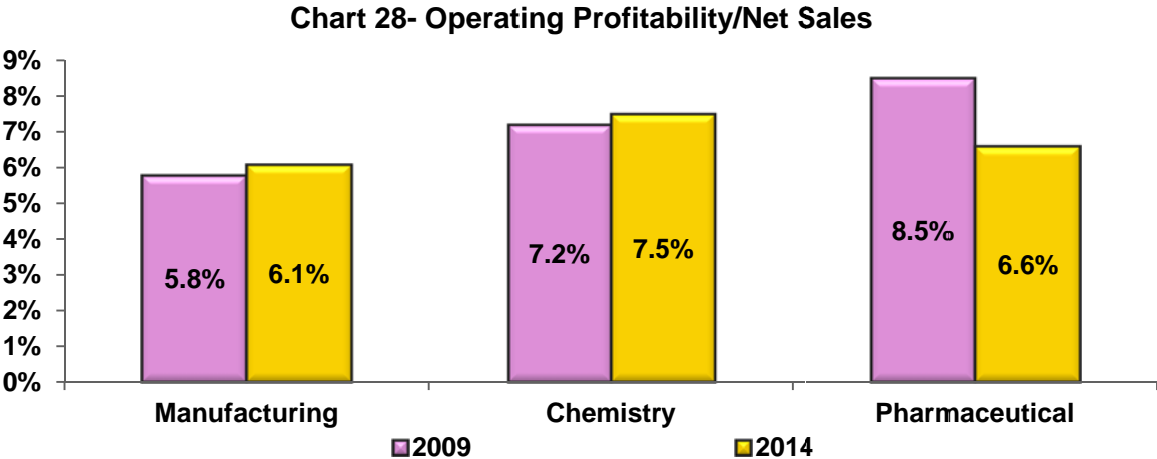
The price-oriented policies made under the global budget application inevitably had a negative impact on the financial performance of the pharmaceuticals sector. According to data published by the Ministry of Science, Industry, and Technology in 2015 as part of their “Entrepreneurs Information System,” the operating profitability of the pharmaceutical industry decreased between 2009 and 2014, marked by a steep decline in net sales and asset generation. The pharmaceutical sector remained behind the manufacturing and chemical industries.

These declines have been unique to the pharmaceutical industry, standing in contrast to other manufacturing industries that are less technologically intensive. This is obvious when pharmaceuticals are compared to the manufacturing and chemical industries. While net pharmaceutical sales declined by 23% in real terms between 2009 and 2014, net sales in manufacturing and the chemical industry grew by 52.4% and 57.5% respectively.



Source: Ministry of Science, Industry and Technology

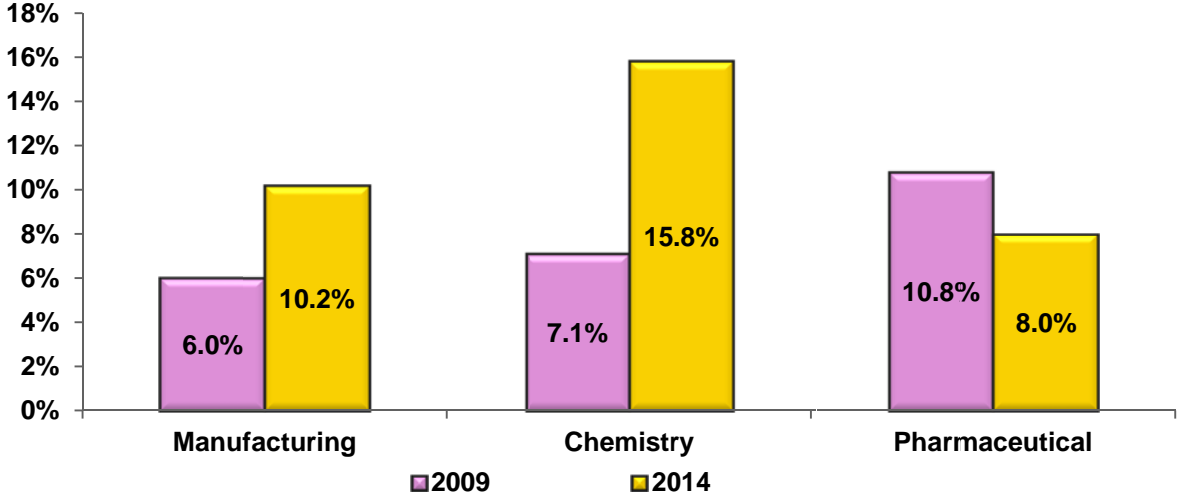
These declines are also observed in operating profitability. While the operating profitability of the entire manufacturing and chemical industries increased over this same period, it fell by 2 points in pharmaceutical industry.



Source: Ministry of Science, Industry and Technology

The situation was negative also in terms of net profitability within the pharmaceutical sector. Also in 2014, the manufacturing and chemical industries found the opportunity to increase their net profitability compared to 2009. The pharmaceutical sector, which operates in an advanced technology class, remained below the figures of 2009.

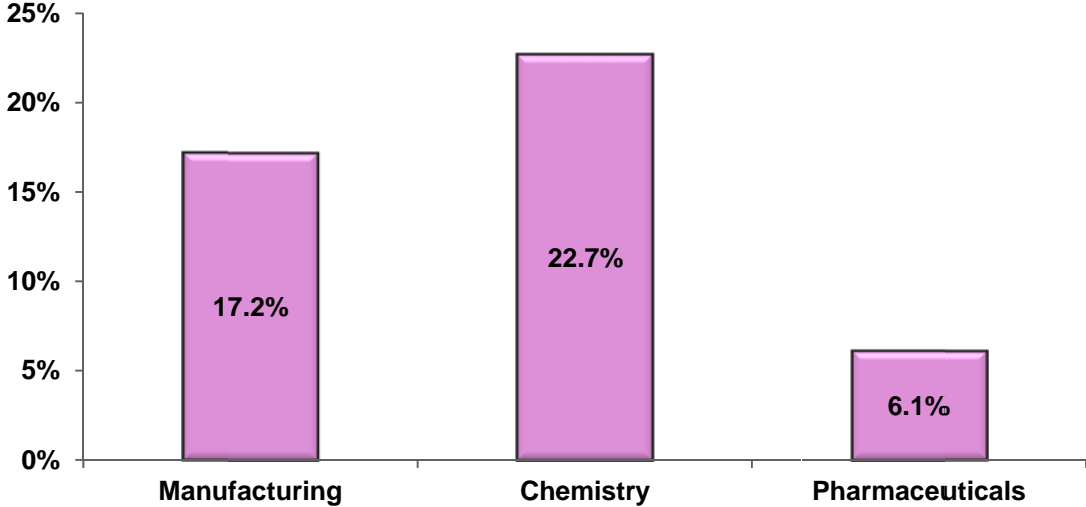
**Chart 29- Net Profitability/ Equity**



Source: Ministry of Science, Industry and Technology

Due to such negative developments in profitability, the equity capital of the pharmaceutical sector naturally did not grow as much as that of the manufacturing and chemical industries on real basis. This state of the equity capital is insufficient to support the sector and propel it on pace with technological developments necessary to develop new products with higher added value that will create difference on the foreign markets through the allocation of sufficient resources for R&D in the midterm.

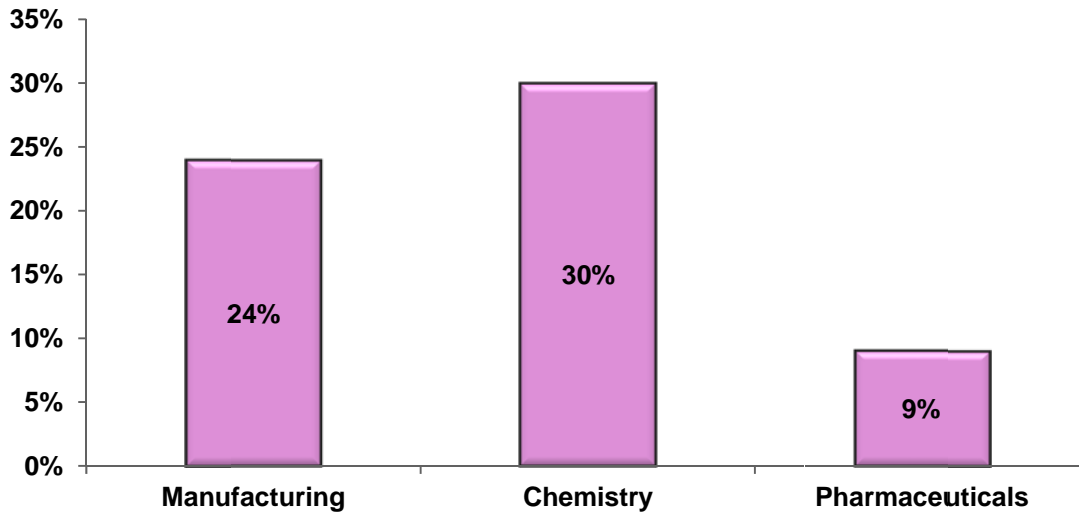
**Chart 30- Real Change in Equity (2009-2014)**



Source: Ministry of Science, Industry and Technology

Scrutiny of the material fixed asset investments shows that the pharmaceutical sector remained behind the increase in the chemical and manufacturing industries despite its 9% growth on real basis.

**Chart 31- Property Plant and Equipment (2009-2014)**



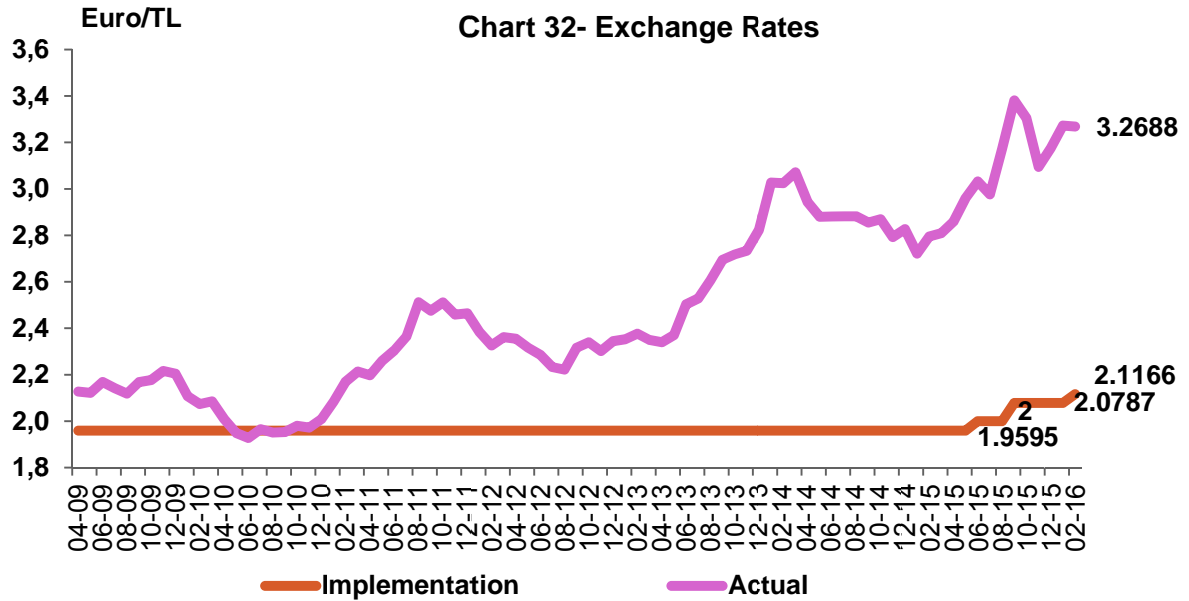
Source: Ministry of Science, Industry and Technology

## 6. Conclusion and Assessment

Subsequent to the global crisis and economic downturn experienced at the end of 2009, the public authority started to implement a global budget practice for the purpose of providing savings on pharmaceutical expenditures. However, some expansion occurred on the pharmaceutical market in line with improved service quality and access to physicians within the framework of the Health Transformation Program. Through inaccurate interpretation of this condition, the prices of medicines were decreased constantly and SGK discount rates were increased by reason of budget overrun for the pharmaceuticals.

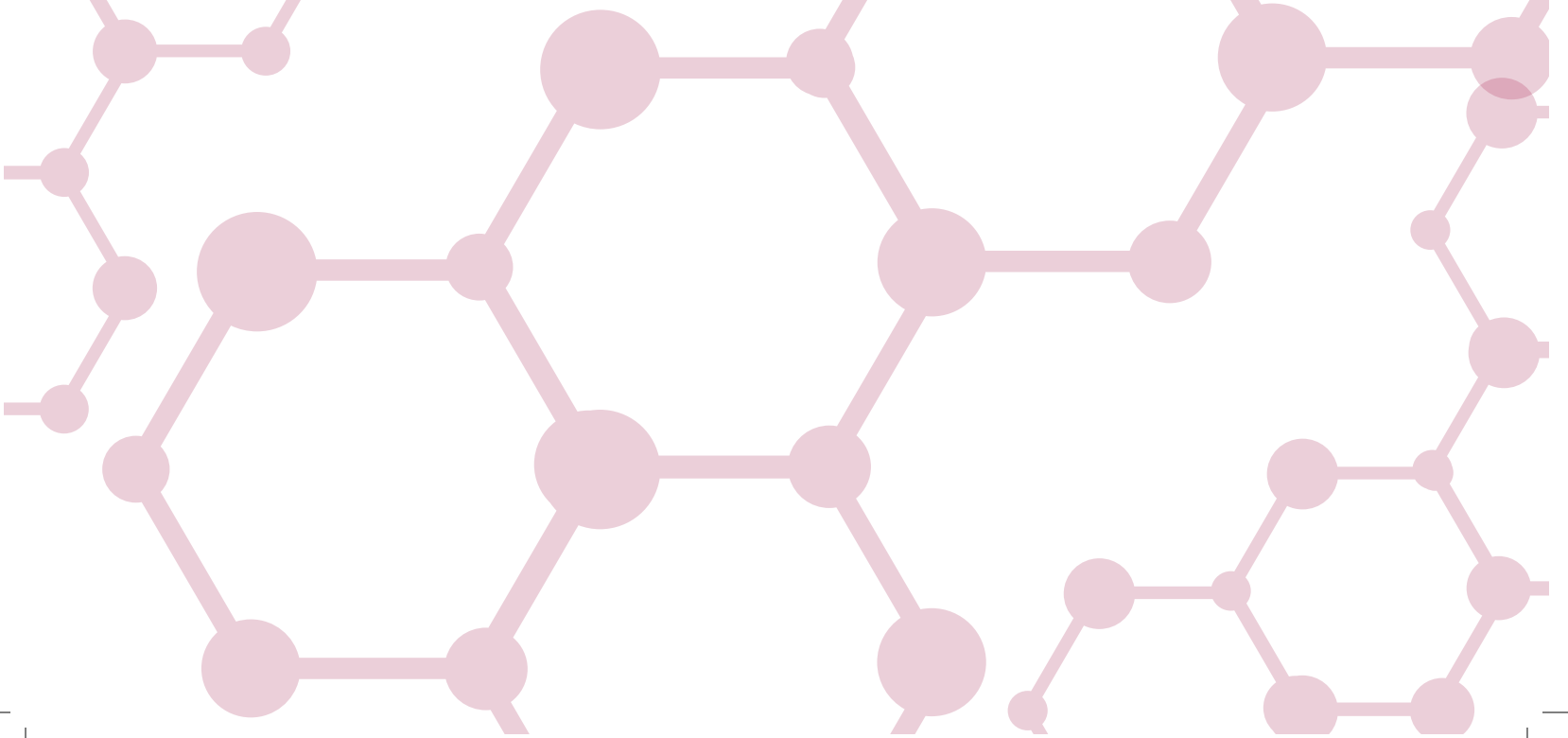
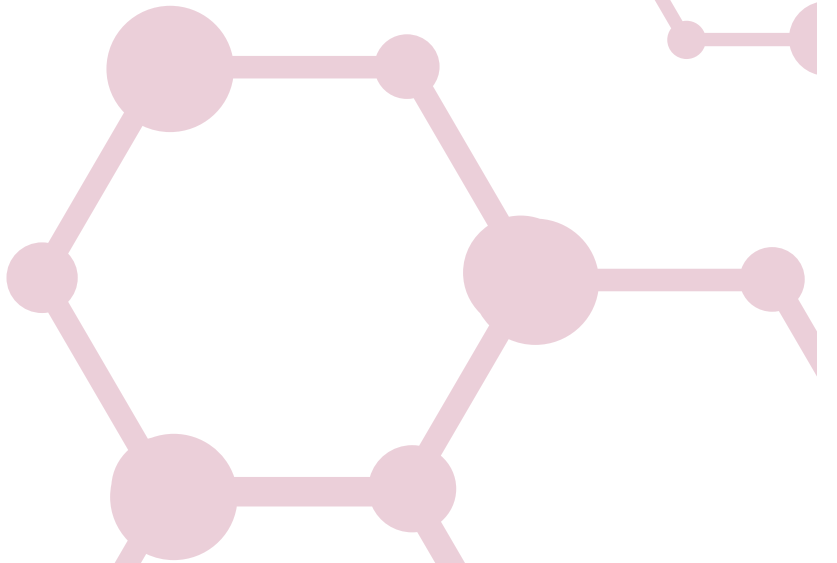
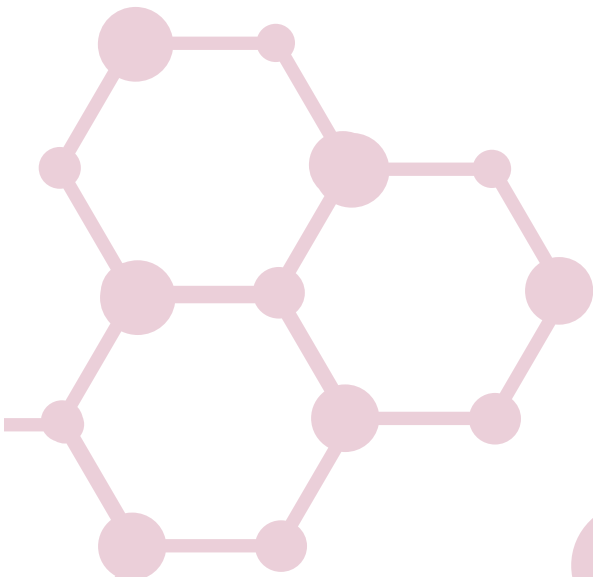
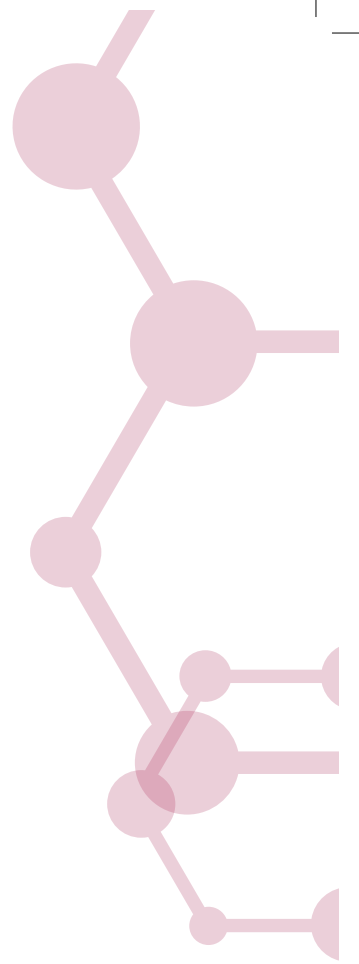
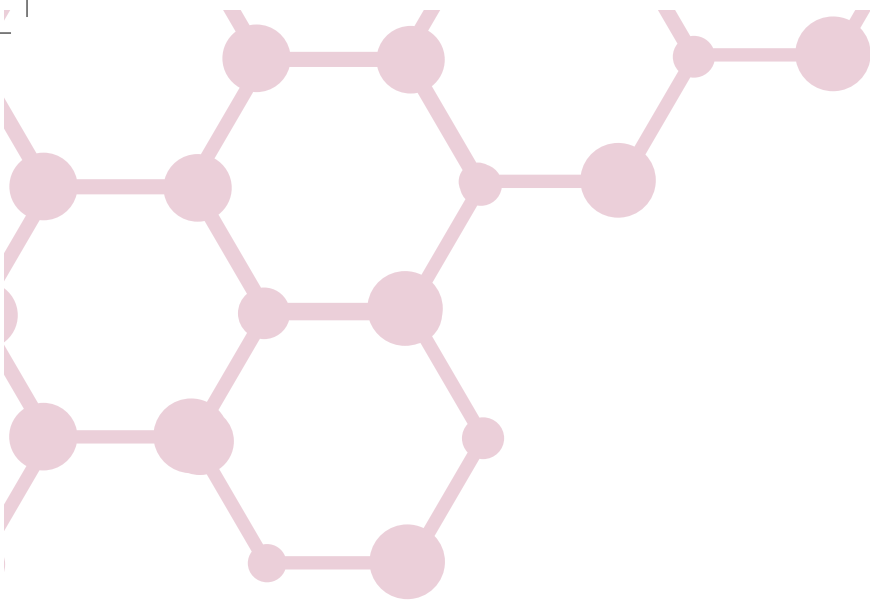
In addition, despite the fulfillment of conditions required in the legislation, the Euro value used for the conversion of the reference prices of pharmaceuticals into TL was not updated from April 2009 to May 2015 and kept fixed at the level of 1.9595 TL for the purpose of controlling pharmaceutical expenditures. The lawsuit filed by the industry for the update of the currency was concluded in April 2015 in favor of the pharmaceutical sector. Upon the objection raised by the industry, the conversion currency announced first as 2 TL was then determined as 2.1166 TL for 2016 by adaptation of 70% of the previous year's Euro average as the conversion currency.

The understanding of pricing that was far from the progress of the current exchange rate has brought the pharmaceutical industry into an unpredictable and unsustainable position on economic and commercial grounds. In this framework, it is necessary to take the average of the previous year rather than 70% into account.



Source: Central Bank of Turkey

In the period between 2009 and 2015, the market grew by nominal growth of 27.7% but declined to 16% in real terms adjusted for the manufacturer price inflation in the same period, which was at the level of 52%. The market that recorded significant losses between 2009 and 2014 demonstrated small recovery with the increase of the conversion rate in 2015 but it still shrinking on real basis.





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