IEIS

PHARMACEUTICAL MANUFACTURERS
ASSOCIATION OF TURKEY

TURKISH PHARMACEUTICAL MARKET

2016

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2016

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INTRODUCTION

With its healthcare and treatment services playing a direct role in human life, high value-added and advanced technology-based structure, experienced human resources, well-established production culture and export potential, the pharmaceutical industry is a pioneering sector of strategic importance in terms of Turkey's goal of industrial transformation.

The Turkish pharmaceutical industry is proud to be contributing significantly to the Turkish economy with approximately 500 institutions, 69 facilities meeting the highest international standards, and 24 accredited R&D centers.

Our sector, which provides more than 11,000 products for the service of our people, is also proud to promote our economy through exports to over 150 countries, mainly in the European Union (EU), 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 the business conditions of its members and contributing to the development of healthcare policy within Turkey.

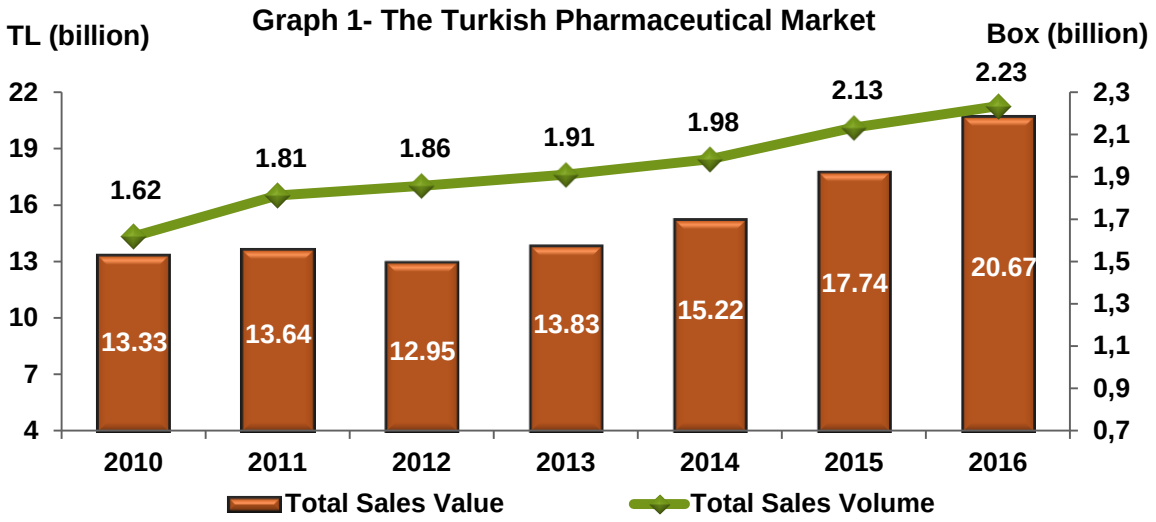
IEIS closely follows the interests of all segments of the pharmaceutical industry in seeking to realize the organization's larger goal of furthering the global presence of an industry strongly focused on both export-led growth and the production of higher value-added products, particularly those of a biotechnological nature, through extensive R&D activities.

We are hoping that you will review the Turkish Pharmaceutical Market Report 2016 in detail. While analyzing 2016, we also reviewed the 6 year-period between 2010 and 2016. In this study, we offer an in-depth analysis of the Turkish pharmaceutical market in different categories, including originator and generic products, import and local products, and biotechnological products both in terms of market structure and product prices. Furthermore, the Turkish medicinal product market is analyzed with a focus on biocidal products licensed by the Ministry of Health, certain medical devices in pharmaceutical form, specialty medical food, cosmetic and derma-cosmetic products; vitamins with permission from the Ministry of Food, Agriculture and Livestock, food supplements and infant formulas. Our report also features an analysis of data regarding production, R&D, investment incentives, employment, and foreign trade.

Serving the Turkish pharmaceutical sector, IEIS assumes the function of a reference institution for both the public and private sectors. By converting sectoral data into analyses, we are pleased to shed light on the future of our industry by regularly updating our stakeholders on sectoral developments.

1. The Turkish Pharmaceutical Market

In 2016, the Turkish pharmaceutical market grew by a total of 16.5% in the hospital and pharmacy channels, reaching a total value of 20.67 billion TL. Unit sales rose by 4.7% to 2.23 billion units. The hospital market constituted 13.2% of the total market and 12.4% of unit sales for the year.



Source: IMS, İEİS

An analysis of the 6 year-period between 2010 and 2016 indicates that the pharmaceutical market grew by 55%, rising to 20.67 billion TL in 2016 from 13.33 billion TL in 2010. This growth signifies a compound annual growth rate (CAGR) of 7.6%, whereas this corresponds to an increase of solely 1% in real terms when weighed against manufacturer price inflation for the same period, which was at 53.5%.

Due to dynamics such as the improvement in access to public health services and physicians as part of the Healthcare Transformation Program, the increase in average life expectancy, and a rising and aging population, the pharmaceutical sector grew by 38%, from 1.62 billion units in 2010 to 2.23 billion units within the course of the 6 years. This expansion equals a compound annual growth rate (CAGR) of 5.5%.

An analysis of the companies operating in the sector shows that their number rose from 441 in 2010 to 496 in 2016. As for the domestic-foreign capital breakdown, in 2010 the number of foreign companies operating in the sector totaled 109, whereas the number had soared to 124 by 2016. In the meantime, 40 local companies entered the market, bringing the number of local companies to 372 in 2016. Thus the market shares of foreign companies in value terms decreased by 2 percentage points over the past 6 years, receding to the level of 65%.

On the other hand, 50 companies constituted 90% of the market in 2010. In 6 years, the market shares of the prominent companies gradually decreased and the number of companies that constituted 90% of the market reached 66 in 2016. The share of multinational companies in this company portfolio is 68%.

An analysis of the breakdown of the pharmaceutical market shows that there has been a 0.7 percentage point rise in the share of prescription drugs. Among prescription products, non-reimbursed products gained a 4.1 percentage point share.

Table 1- Breakdown of pharmaceutical market

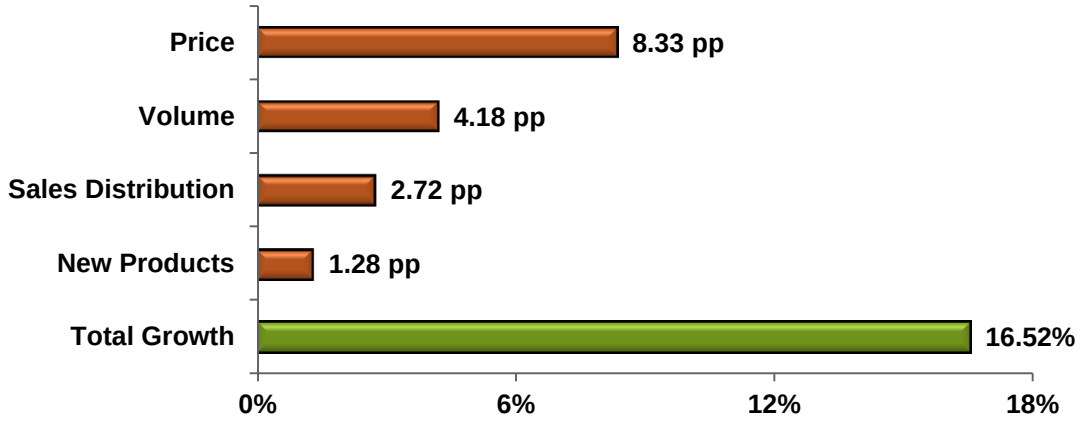
	2010		2016	
	Value (Billion TL)	Share	Value (Billion TL)	Share
Drugs	**13.33**	**100%**	**20,67**	**100%**
Prescription	**13.21**	**99.1%**	**20.63**	**99.8%**
Reimbursed	12.90	96.7%	19.29	93.3%
Non-reimbursed	0.31	2.3%	1.34	6.5%
Non- prescription	**0.12**	**0.9%**	**0.04**	**0.2%**
Reimbursed	0.10	0.8%	0.02	0.1%
Non-reimbursed	0.02	0.2%	0.02	0.1%

Source: IMS, İEİS

1.1. Market Growth and Sources

As sources of growth in the market are examined, 4 main factors are found to contribute to growth in value terms: Volume and price increases in the current portfolio, new products entering the portfolio, and changes in sales distribution.

Graph 2 - Sources of Growth



Source: IMS, İEİS

A. Price

In 2016, the factor that most contributed to growth of the pharmaceutical market was the price increase in current products, marking 8.33 percentage points (1,478 million TL) of the 16.5% growth (2,931 million TL). It is notable that in February 2016, the currency rate that established the pharmaceutical prices increased by 1.82%, while the discount rates in certain product groups were reduced. Additionally, price increases of between 10% and 20% were applied gradually to low-price products, whose retail sales price was 5.63 TL and below. Likewise, a 3% price increase was applied to twenty-year-old products, whose price range was between 5.64 and 10.77 TL. All of these factors contributed to the price level of the current portfolio.

B. Volume

Of total market growth 4.18 percentage points (742million TL) stemmed from the volume (boxes) increase in the current product portfolio in tandem with the rise in the demand for medicine.

C. Sales Distribution

Changes in the sales distribution of current products in the market, in other words changes in the sales volume towards expensive or inexpensive products, contributed 2.72 percentage points (483million TL) to growth.

D. New Products

Moreover, new products entering the market in 2016 offered a 1.28 percentage point (227 million TL) contribution to growth.

An analysis of the distribution of products that are new in the market shows that in 2016, 440 licensed products entered the market, 3 of which were non-prescription with the remaining 437 being prescription products. Out of the 440 products 427 were chemical, whereas 13 were biotechnological.

Among the new products launched, the highest market share went to the therapeutic groups of oncology and nervous system products. 57 oncology products (13.0%), 48 nervous systems products (10.9%), 35 digestion system products (8.0%), 33 antibiotics (7.5%), 28 cardiovascular products (6.4%), and serums and vaccines (5.9%) entered the market.

In 2016, a total of 85 originator products entered the market with 76 chemical and 9 reference biotechnological products. Only 3 out of these 85 originator products have a generic competitor, and just 7 of them are manufactured in Turkey. The average price of these 85 products is 66.4 TL.

During the same period, a total of 355 generic products entered the market, out of which 4 were biosimilars, and 351 were chemical products. Merely 21 of these 355 products are in the import products category. Therefore, there is a trend towards generic local products among the new market entrants. The average price of generic products is 10.2 TL.

All these products have led to a 1.3 percentage point increase in the pharmaceutical market.

Table 2- Unit distribution of the products in the market

	2016
Products	**440**
Originator	**85**
▪ **With generic**	**3**
▪ **Without generic**	**82**
Generic	**355**
▪ **Import**	**21**
▪ **Local**	**334**

Source: IMS, İEİS

1.2. Market Structure

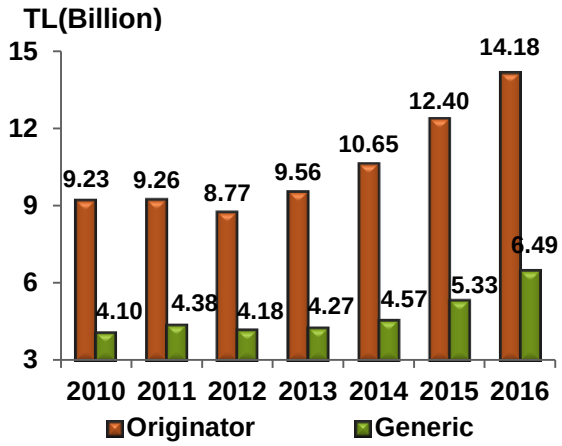
A. Originator-Generic Products

In 2015, the originator product market was at 12.40 billion TL and reached 14.18 billion TL with a 14.3% increase in 2016. On a unit basis, 0.99 billion units were sold, marking growth of 1.2%.

As for the generic product market, in 2016, the figure has reached 6.49 billion TL on an increase of 21.7%. In unit terms, generic products grew by 7.6% reaching a volume of 1.24 billion.

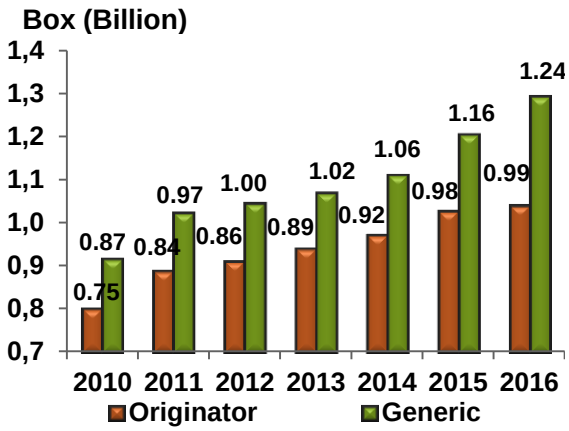
The rise in discount rates between 2010 and 2014, reduction in reference price rates, and no update of the Euro value that sets the product price, despite meeting legislative conditions, were some of the price policies aimed at cost-reduction. With the impact of such policies, there were significant losses in originator and generic products. In 2015 and 2016, a minor update in the Euro value, reduction of the discount rates in certain product groups, and the impact of the price increase in low-priced products led to a rise of 53.6% and 58.2% in originator and generic products, respectively. And although the pharmaceutical market has somewhat recovered over the past two years with the impact of such development, when the inflation effect is discounted, the real increase in both product groups is merely 0.1% and 3%, respectively. On the box scale, in reference products 31.7% growth was observed, whereas 43.4% growth was realized in generic products.

Graph 3- Originator-Generic Products (Value)



Source: IMS, İEİS

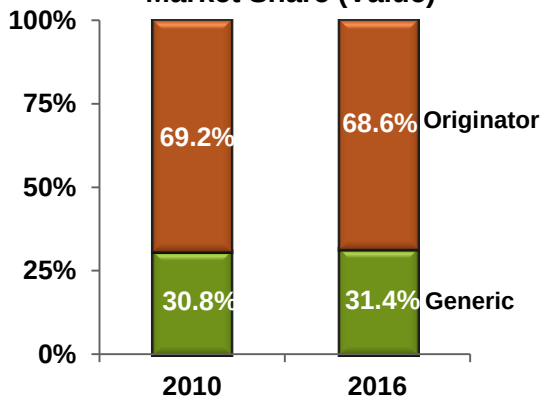
Graph 4- Originator-Generic Products (Volume)



Source: IMS, İEİS

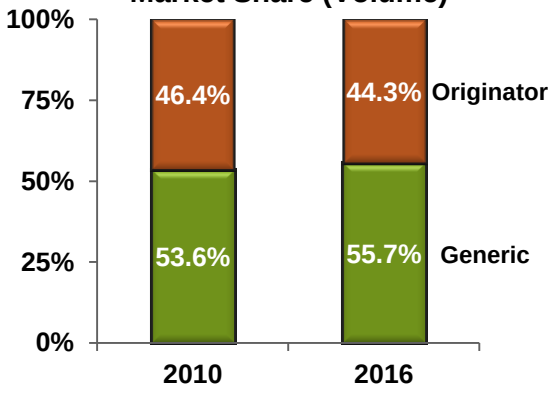
On the value scale, generic products have been losing market share to originators since 2012. However, over the past two years they have increased their market share by registering growth in excess of the pharmaceutical market itself. On a unit scale, following the 8.8% increase in generics in 2015, growth has decelerated in 2016, remaining at 7.6%. Generic products had a value of 31.4% and a unit share of 55.7% in 2016.

Graph 5- Originator-Generic Products Market Share (Value)



Source: IMS, İEİS

Graph 6- Originator-Generic Products Market Share (Volume)



Source: IMS, İEİS

As for the import-local breakdown of originator-generic products, in 2016, these products made up 80% of total value, whereas 49% were import products on a unit basis. On the other hand, almost all generic products are locally manufactured. It is thought that the foreign GMP inspections carried out by the Ministry of Health play a role in the downsizing of the import generic products market.

Table 3- Originator-Generic Product Breakdown

	Originator Product				Generic Product			
	2010		2016		2010		2016	
	Import	Local	Import	Local	Import	Local	Import	Local
Box	**42%**	**58%**	**49%**	**51%**	**8%**	**92%**	**3%**	**97%**
(mn)	315	436	483	506	74	794	37	1,207
TL	**74%**	**26%**	**80%**	**20%**	**13%**	**87%**	**5%**	**95%**
(mn)	6,798	2,428	11,323	2,853	541	3,564	355	6,138

Source: IMS, İEİS

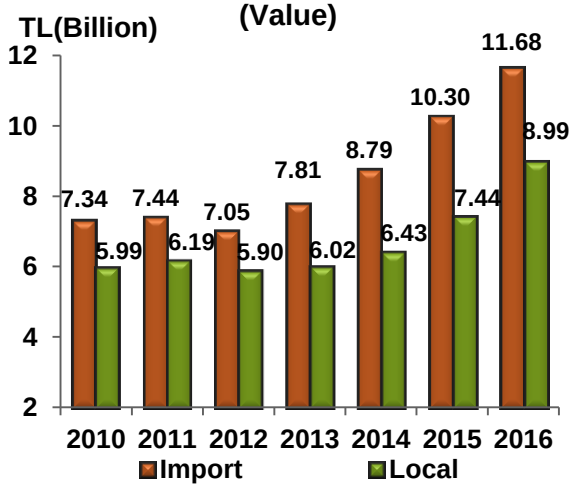
B. Imported-Local Products

Since 2013, import products have displayed an upward trend. However, in 2016 there was a slowdown in growth. These products printed a 13.4% rise in value terms and 3.2% in unit terms, indicating growth below that of the pharmaceutical market. In 2016, import products reached a volume of 11.68 billion TL in terms of value and 0.52 billion in terms of units sold.

Within a period of 6 years, import products realized an increase of 59.1% in total. This means an 8% CAGR growth. On a unit basis, there has been 33.9% growth in these products over the abovementioned years based on increased demand. On the other hand, locally-manufactured products showed the highest increase within the span of 6 years, reaching 8.99 billion TL on a growth rate of 20.9%. In unit terms, on 5.2% growth 1.71 billion units were sold.

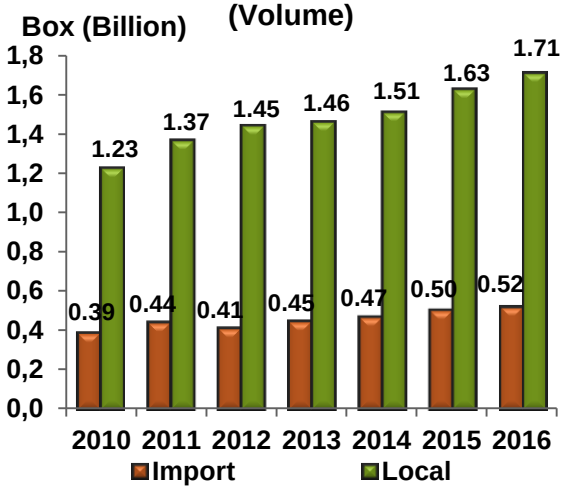
Over the past 6 years, there has been a 50% and 39.3% increase in locally-manufactured products in value and unit terms, respectively.

Graph 7- Import-Local Products (Value)



Source: IMS, İEİS

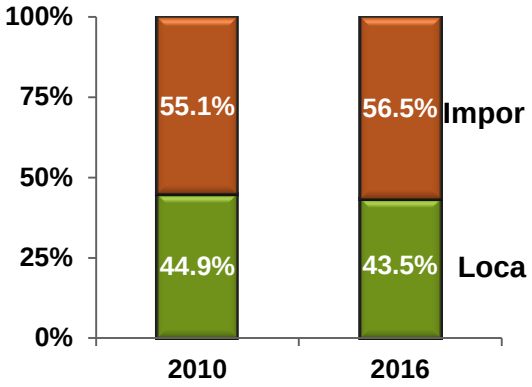
Graph 8- Import-Local Products (Volume)



Source: IMS, İEİS

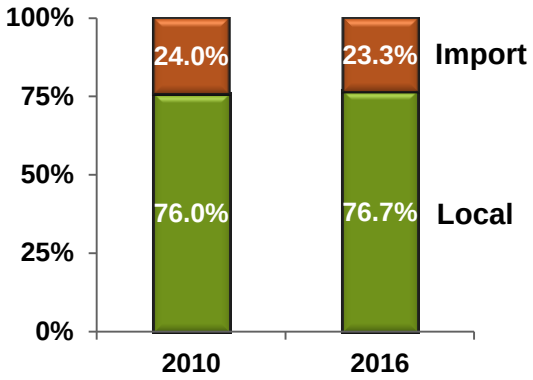
In 2016, import products made up 56.5% of the pharmaceutical market in value terms and 23.3% in unit terms.

Graph 9- Import-Local Products Market Share (Value)



Source: IMS, İEİS

Graph 10- Import-Local Products Market Share (Volume)



Source: IMS, İEİS

Among local products, generic products that take up a dominant share having bolstered their position on both a value and unit basis over the past 6 years. The share of generic products within import products has declined gradually. In 2016, 70% of locally-manufactured products were generics in value terms, and 68% in unit terms.

Table 4- Import-Local Products Breakdown

	Import Products				**Local Products**			
	2010		**2016**		**2010**		**2016**	
	Originator	Generic	Originator	Generic	Originator	Generic	Originator	Generic
Box (mn)	**81%**	**19%**	**93%**	**7%**	**35%**	**65%**	**30%**	**70%**
	315	74	483	37	436	794	506	1,207
TL (mn)	**93%**	**7%**	**97%**	**3%**	**41%**	**59%**	**32%**	**68%**
	6,798	541	11,323	355	2,428	3.564	2,853	6,138

Source: IMS, İEİS

C. Biotechnological Products

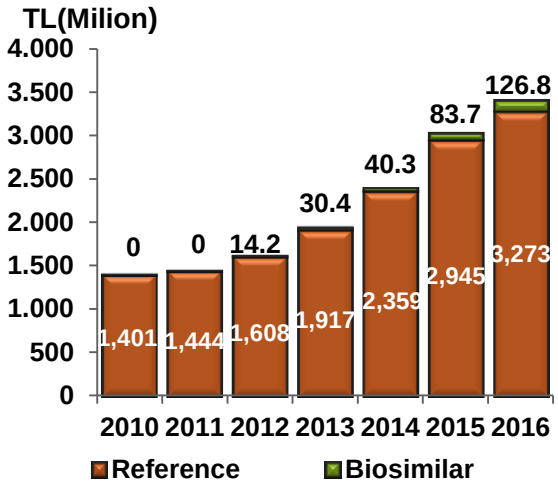
In the Turkish pharmaceutical market, together with all product forms, there are 191 originator biotechnological products (86 different brands) and 38 biosimilar products (13 different brands), making a total of 229 (99 different brands) biotechnological products. Among biosimilars, there are 13 (5 different brands) products in the local market.

In 2016, biotechnological products recorded a 12.3% increase to 3.40 billion TL, with a 16.5% share within prescription drugs. An analysis of reference biotechnological products shows that the market, at around the 2.94 billion TL level in 2015, grew by 11.1% in 2016, reaching a total of 3.27 billion TL. The biosimilar pharmaceutical market exhibited a 51.4% increase, rising to 126.76 million TL.

In unit terms, biotechnological products reached a volume of 25.65 million units on a 4.6% increase in 2016. While there was no change in the sales of originator biotechnological products, biosimilar unit sales realized an increase of 48.9%, with 3.43 million units sold in 2016.

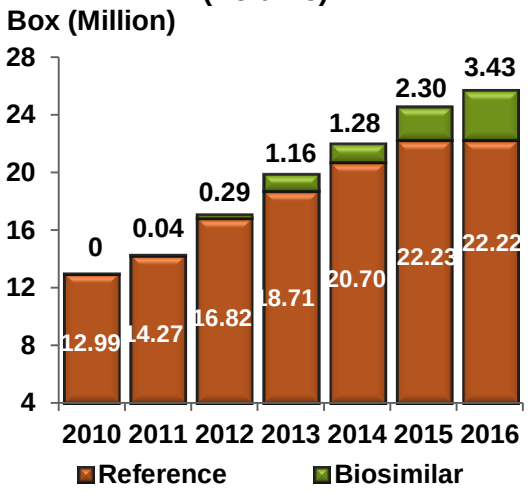
In Turkey, biosimilars comprising *abciximab, epoetin alfa, filgrastim, insulin glargine, somatropin, infliximab, enoxaparin sodium*are are licensed. Among them, those manufactured in Turkey include the active ingredients of *enoxaparin sodium, epoetin alfa, filgrastim and infliximab*. With the patent expiration of reference biotechnological drugs, it is expected that the number of biosimilars will increase over the forthcoming period.

Graph 11- Biotechnological Products (Value)



Source: IMS, IEIS

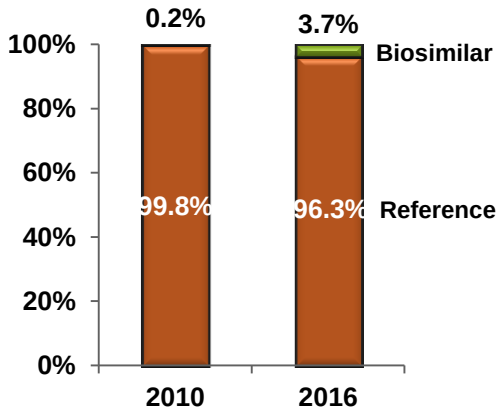
Graph 12- Biotechnological Products (Volume)



Source: IMS, IEIS

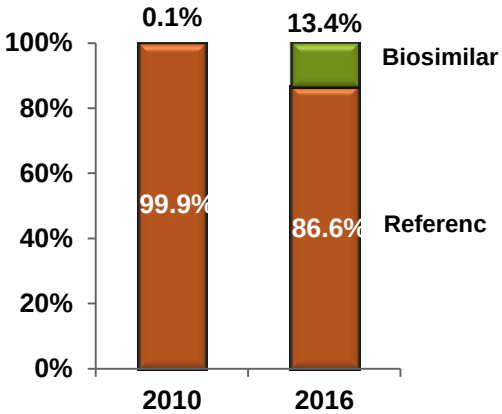
In 2010, biosimilars were almost non-existent in the biotechnological products market. Yet in 2016, they took up a 3.7% share in value terms and 13.4% in unit terms.

Graph 13- Reference-Biosimilar Products Market Share (Value)



Source: IMS, İEİS

Graph 14- Reference-Biosimilar Products Market Share (Volume)



Source: IMS, İEİS

When classified on an ATC 2 group basis, it appears that blood and hematopoietic biotechnological products have undergone a major increase in market share within the biosimilars category. As for the reference biotechnological products market; antineoplastics, immunomodulatory agents, digestive system and metabolism products rank at the top.

Table 5- Biotechnological Products

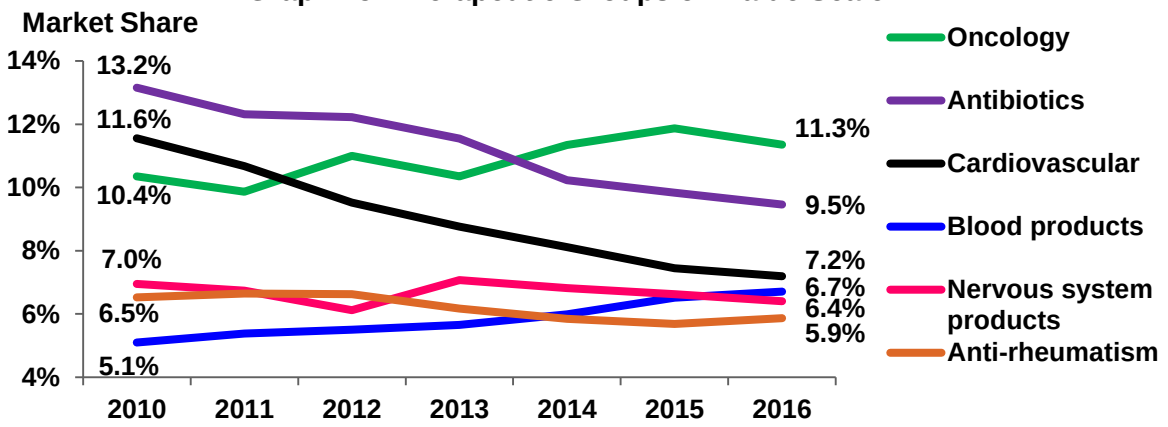
	Box		Value	
	2010	2016	2010	2016
Biosimilars	**100%**	**100%**	**100%**	**100%**
Blood and hematopoietic organs	0.00%	90.24%	0,00%	56.59%
Antineoplastics and immunomodulatory agents	100.00%	7.27%	100.00%	34.08%
Systematic hormonal preparations (excluding sex hormone and insulins)	0.00%	1.90%	0.00%	8.22%
Digestive system and metabolism	0.00%	0.59%	0.00%	1.11%
Reference	**100%**	**100%**	**100%**	**100%**
Antineoplastics and immunomodulatory agents	8.24%	9.41%	47.58%	45.94%
Digestive system and metabolism	51.11%	59.32%	24.37%	27.53%
Blood and hematopoietic organs	35.08%	23.13%	17.15%	11.27%
Ophthalmological	0.12%	1,00%	1.49%	6.43%
Systematic hormonal preparations (excluding sex hormone and insulins)	1.88%	2.43%	4.10%	2.82%
Genital-urinary system and sex hormones	3.29%	3.78%	3.73%	2.34%
Respiratory system	0.07%	0.66%	0.35%	2.02%
Systematic anti-infectives	0.22%	0.24%	1.24%	1.09%
Dermatological products	0.00%	0.03%	0.00%	0.55%
Musculoskeletal system	0.00%	0.01%	0.00%	0.02%

Source: IMS, İEİS

D. Therapeutic Groups

An analysis of the pharmaceutical market from the perspective of therapeutic groups indicated an upward trend in oncology and blood products over the past 6 years. Although oncology products lost 0.5 percentage points compared to the previous year, with an 11.3% share, in 2016 it has been the therapeutic group with the highest sales in value terms.

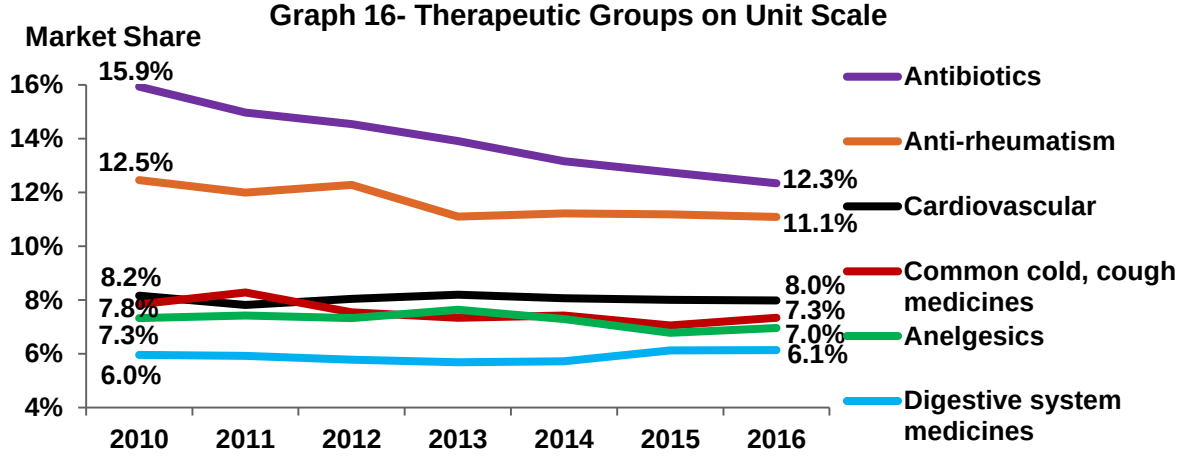
Graph 15- Therapeutic Groups on Value Scale



Source: IMS, İEİS

When analyzed on a unit basis, there is a declining trend in the therapeutic groups that lead the market. Since 2010, the group of products recording the highest decline rate was antibiotics. Despite that, in 2016, the products that had the highest consumption rate on a unit basis were, again, antibiotics with a 12.3% share.

Graph 16- Therapeutic Groups on Unit Scale



Source: IMS, İEİS

E. Average Prices

Average prices have shown an upward trend since 2013. Between 2010 and 2016, the average price of drugs increased by 12.4% to 9.25 TL. In the same period, the product group registering the highest increase was imported drugs with 18.8%.

An analysis of the change between 2015-2016 shows that with the impact of the rise in the conversion currency used in product pricing, there has been an 11.3% increase in average prices in the pharmaceutical market as a whole. Average originator and generic product prices have both registered higher growth rates of 12.9% and 13.1%, respectively. Imported drug prices have increased 9.9%, while locally-produced drug prices have grown 14.9%.

Table 6- Distribution of Average Drug Prices

TL	Drug	Originator	Generic	Import	Local
2010	**8.24**	**12.29**	**4.73**	**18.89**	**4.87**
2011	**7.52**	**11.04**	**4.50**	**16.83**	**4.52**
2012	**6.97**	**10.19**	**4.20**	**17.13**	**4.08**
2013	**7.24**	**10.75**	**4.18**	**17.51**	**4.11**
2014	**7.67**	**11.56**	**4.30**	**18.72**	**4.25**
2015	**8.32**	**12.70**	**4.61**	**20.42**	**4.57**
2016	**9.25**	**14.33**	**5.22**	**22.44**	**5.25**

Source: IMS, İEİS

Table 7- Changes in Average Drug Prices

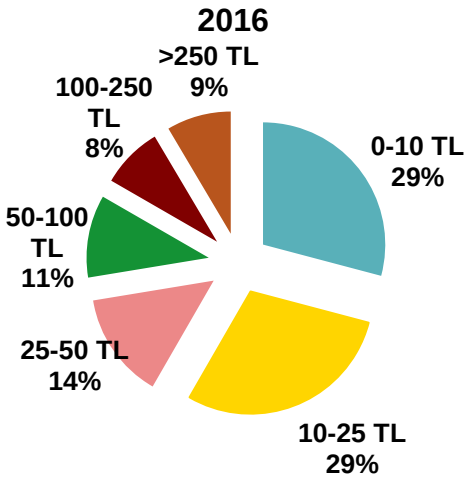
Change	Drug	Originator	Generic	Import	Local
2010-2016	**12.4%**	**16.6%**	**10.3%**	**18.8%**	**7.7%**
2015-2016	**11.3%**	**12.9%**	**13.1%**	**9.9%**	**14.9%**

Source: IMS, İEİS

F. Retail Price Ranges

As for the retail sales price distribution of products in the market, in 2016, 72% of the pharmaceutical market was made up of products priced at 50 TL and less. In 2016, the products with the highest share in the market (29%) were those priced at 0-10 TL and 25-50 TL.

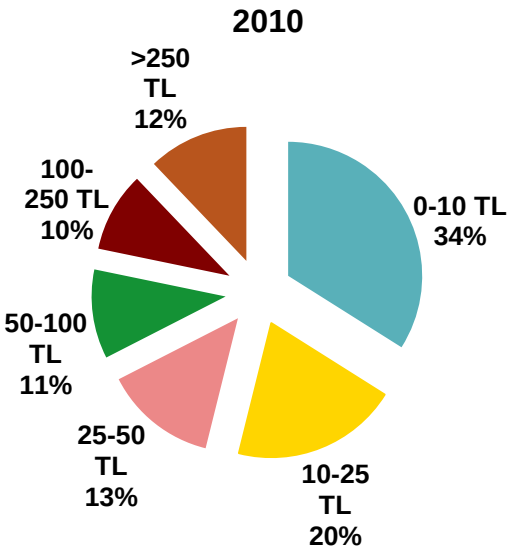
Graph 17- Retail Price Breakdown



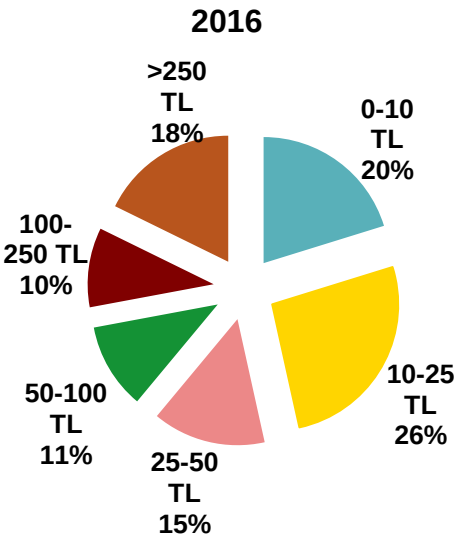
Source: Turkish Medicines and Medical Devices Agency (TMMDA), İEİS

In originator products, there has been a decline in the share of products priced between 0-10 TL over the past 6 years, whereas the share of product groups excluding the 100-250 TL group has increased. In originator products, the group with the highest share (26%) was those products priced at 10-25 TL.

Graph 18- Price Breakdown of Originator Products



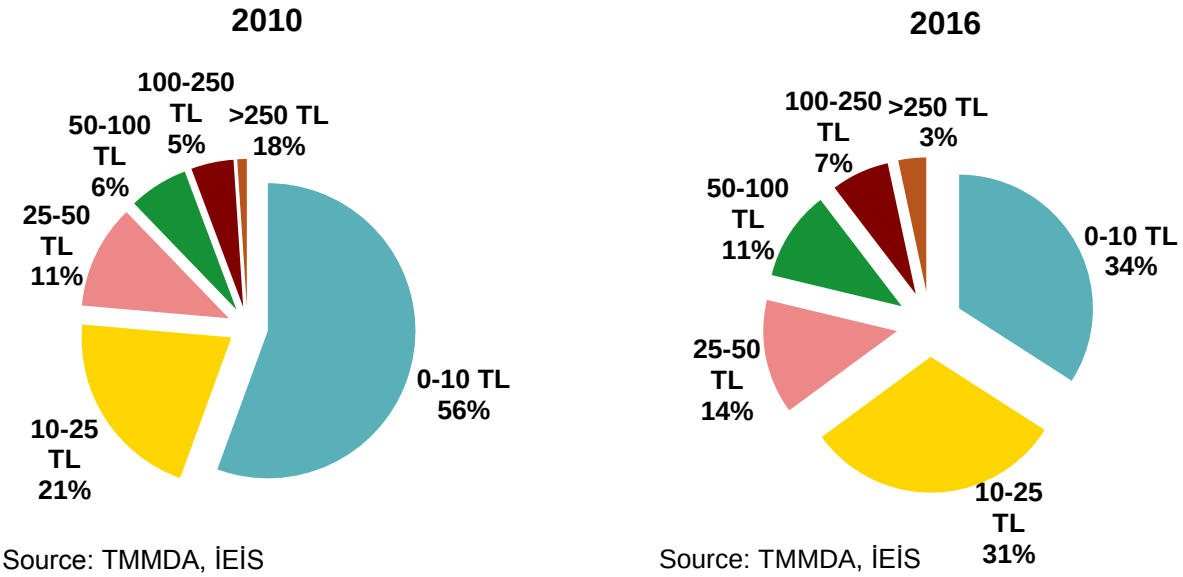
Source: TMMDA, İEİS



Source: TMMDA, İEİS

An analysis of the price range for generic products indicates that as per 2016 the products priced between 0-10 TL had the highest market share of 34%.

Graph 19- Price Breakdown of Generic Products

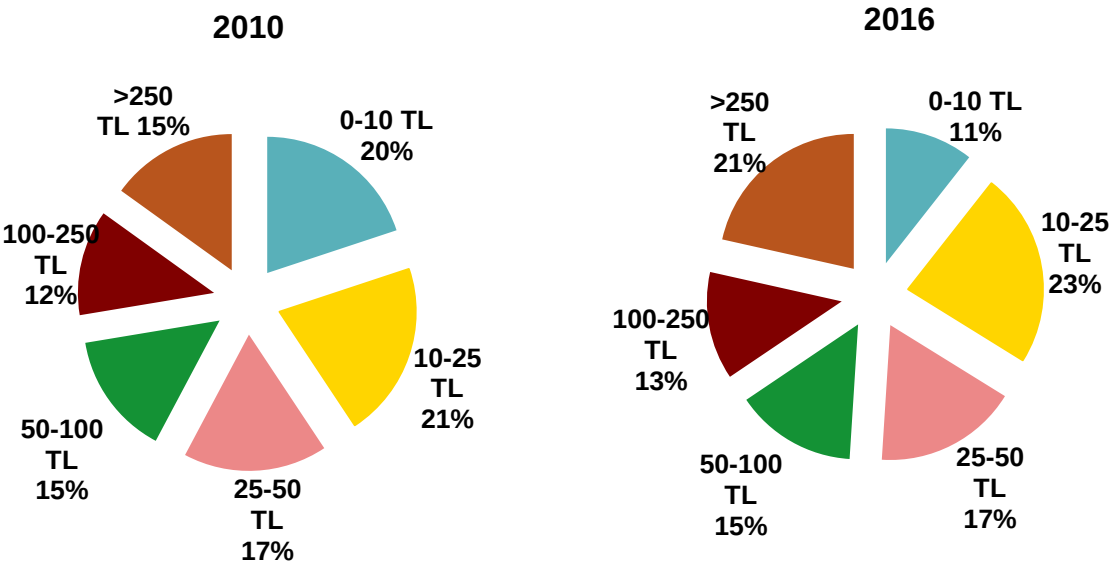


Source: TMMDA, İEİS

Source: TMMDA, İEİS

In 2016, the highest share (23%) in import products on a unit basis were those products priced between 10-25 TL and those priced at above 250 TL (21%). Compared to 2010, the products above 250 TL increased by 6 percentage points, while those priced at less than 10 TL decreased by 9 percentage points.

Graph 20- Price Breakdown of Import Products

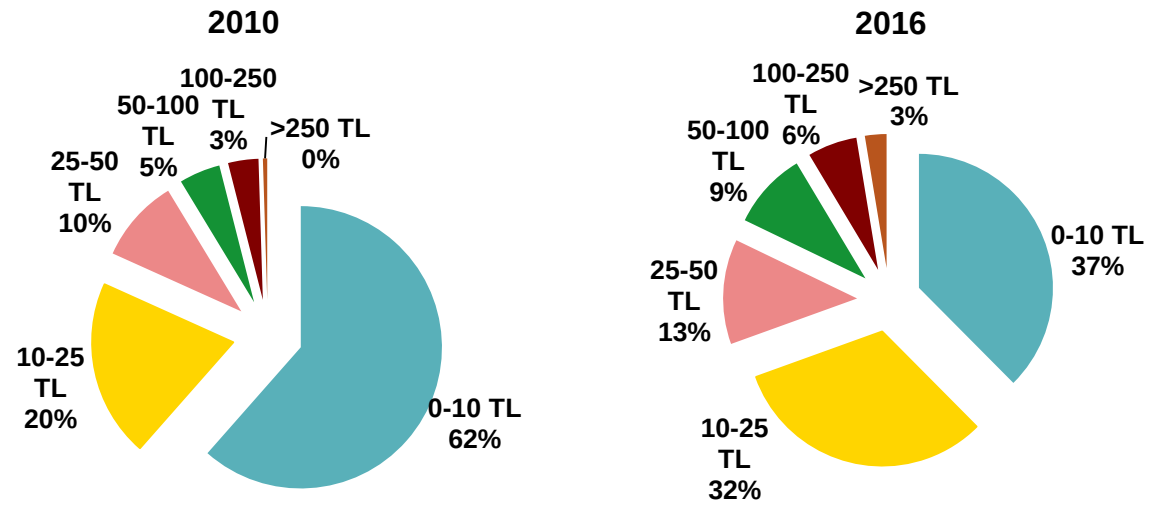


Source: TMMDA, İEİS

Source: TMMDA, İEİS

Among local products, the group with the highest share was the 0-10 TL group on 37%. In this group, products priced lower than 25 TL made up 69% of the pharmaceutical market. In 2010, there were almost no import products that cost more than 250 TL, while in 2016 they took up a share of 3%.

Graph 21- Price Breakdown of Local Products



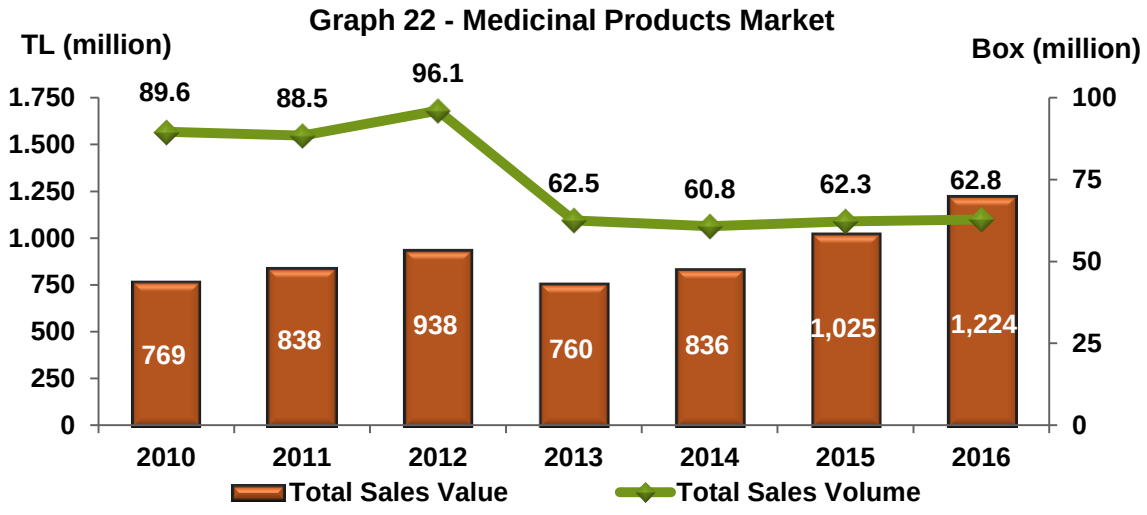
Source: TMMDA, İEİS

Source: TMMDA, İEİS

2. Medicinal Products Market

Medicinal products that are within the portfolio of pharmaceutical companies, yet that are not classified as pharmaceutical products are as follows: Biocidal products licensed by the Ministry of Health, certain medical devices in pharmaceutical form, medical infant formulas, cosmetic and derma-cosmetic products; vitamins with permission from the Ministry of Food, Agriculture and Livestock, food supplements, and infant formulas. These products scored 19.4% growth in 2016 and reached a value of 1.22 billion TL on a 1% increase in unit terms with sales of 63 million units.

Graph 22 - Medicinal Products Market



Source: IMS, IEIS

An analysis of the breakdown of medicinal products indicates that over the past 6 years there has been a major shift towards non-reimbursed products.

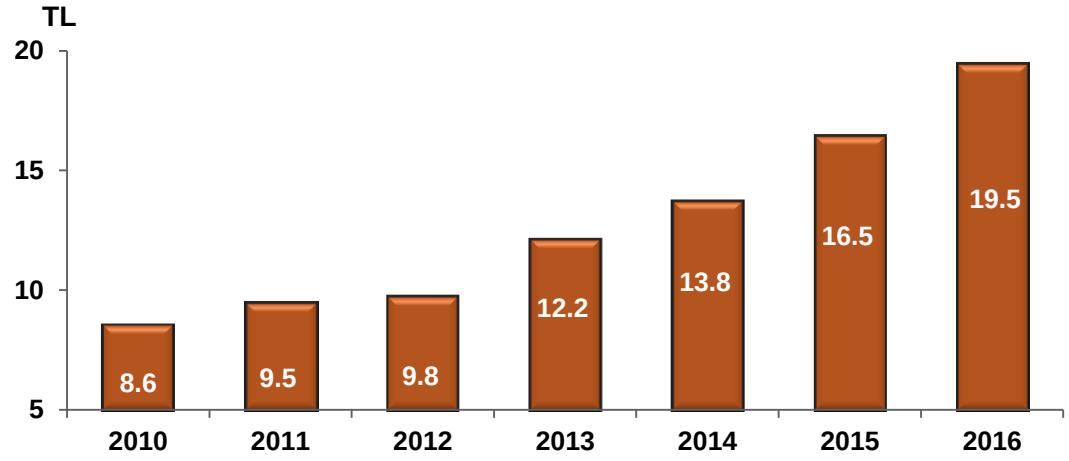
Table 8- Breakdown of the Medicinal Products Market

	2010		2016	
	Value (Billion TL)	**Share**	**Value (Billion TL)**	**Share**
Non-medical products	**0.77**	**100%**	**1.22**	**100%**
Reimbursed	0.19	24.2%	0.01	0.9%
Non-reimbursed	0.58	75.8%	1.21	99.1%

Source: IMS, İEİS

The average price of medicinal products was 8.6 TL in 2010, whereas in 2016 it reached 19.5 TL on a 126.7% increase within the span of 6 years.

Graph 23 - Average Price Breakdown of Medicinal Products



Source: IMS, İEİS

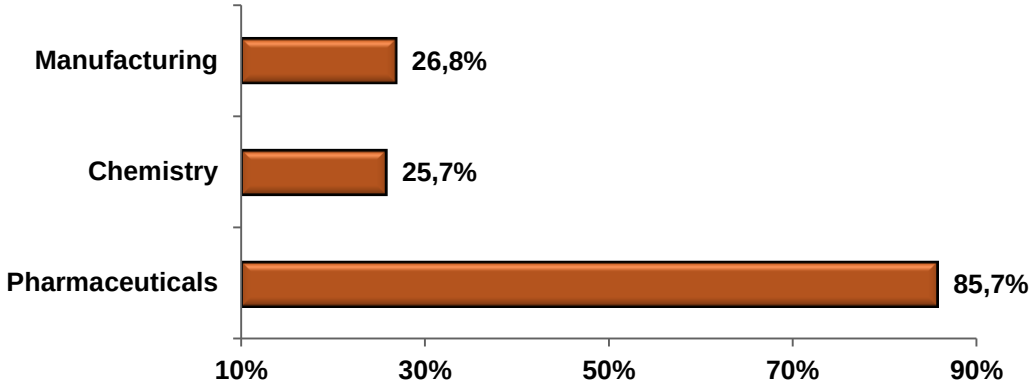
3. Production

Based on industrial production index data, the pharmaceutical industry has achieved a double-digit growth since 2014. In 2016, production increased by 14.8% compared to the previous year. Meanwhile, by comparison production rose by 1.4% in the manufacturing industry, and 3.9% in the chemical industry. In 2016, the pharmaceutical sector offered the highest contribution to growth in the manufacturing industry. Within this framework, 0.6 points of the 1.4% increase was realized through the contribution of the pharmaceutical industry.

As for the period between 2010 and 2016, production in the manufacturing industry increased by 26.8%, while manufacturing in the chemicals industry at the mid-technology level was 25.7%, and growth in the pharmaceutical sector was realized at 85.7%.

As included in the government action plan, new public policies were put into effect to support local manufacturing. Accordingly, local production is expected to increase further over the coming years.

Graph 24- Industry Production Index Change (2010-2016)



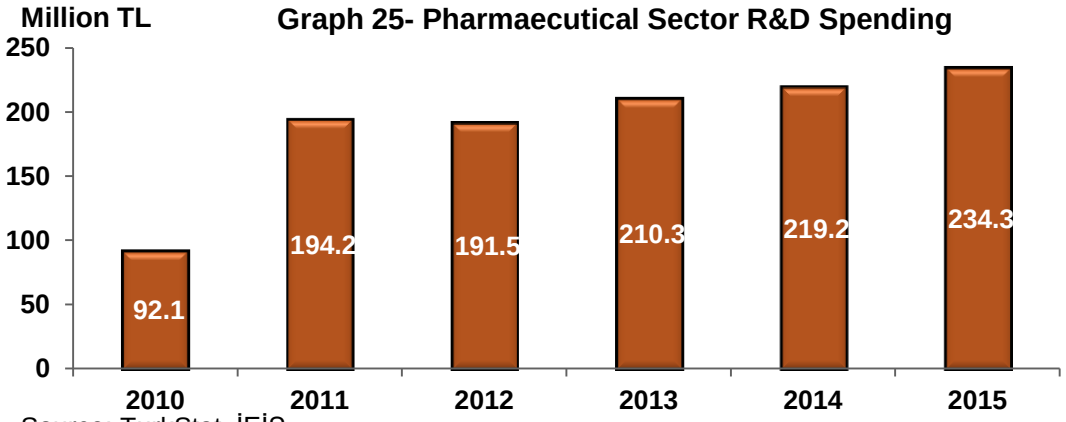
Source: TurkStat, İEİS

4. R&D

The pharmaceutical industry ranks among the top priority sectors contributing to the industrial transformation of our country, with 24 accredited centers, 1,053 employees, 571 ongoing projects, 126 applications, and 9 registered patents. And with progress made in R&D, it will be possible to locally manufacture major products for which we are currently dependent on imports.

The pharmaceutical R&D spend printed a rise of 154%. The figure rose from 92.1 million TL in 2010 to 234.3 million TL in 2015. This increase corresponds to an 82% real growth in manufacturer price terms, and a 21% CAGR.

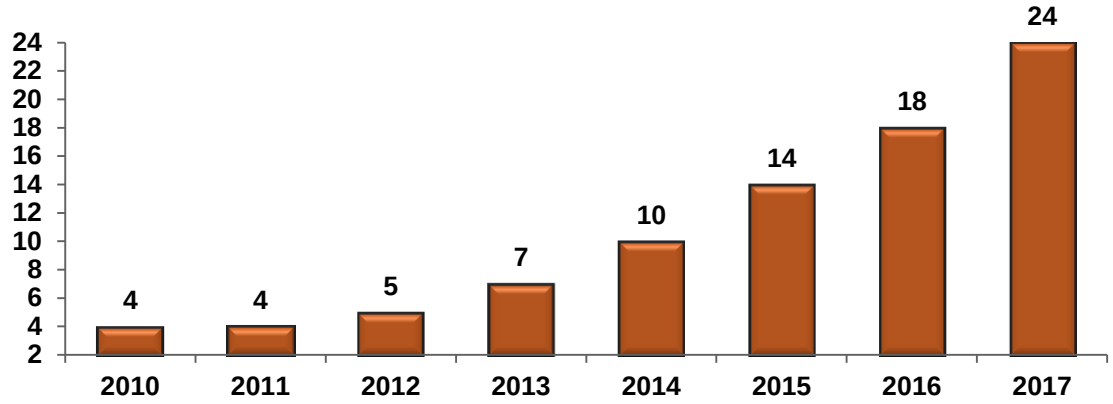
Graph 25- Pharmaecutical Sector R&D Spending



Source: TurkStat, İEİS

In 2010, there were 4 accredited R&D centers, whereas today the number has increased to 24.

Graph 26 - Number of Accredited R&D Centers in the Pharmaceutical Sector



Source: Ministry of Science, Industry and Technology , İEİS

5. Investment Incentives

Put into effect in 2009, Resolution no. 2009/15199 of the Council of Ministers brought about key changes of a positive nature. While previously there were a host of different practices in effect by various public institutions, following the resolution they have been managed single-handedly under the coordination of the Ministry of Economy. With the decree, aside from general and regional incentives, investments totaling over 20 million TL regarding biotechnological, oncological and blood products are included within priority investments, targeting higher incentives.

Later in 2012, Council of Minister Resolution no. 2012/3305 was put into effect, whereby pharmaceutical investments were offered 5th Region incentives, being classified as advanced technology.

Developments in incentive legislation enabled an increase in investments in the pharmaceutical industry, while there was a decline in 2015 and 2016 with the impact of economic developments. In the event that this negative situation is resolved, it is estimated that investments in the pharmaceutical sector will pick up again.

Table 9- Investment Incentives in the Pharmaceutical Industry

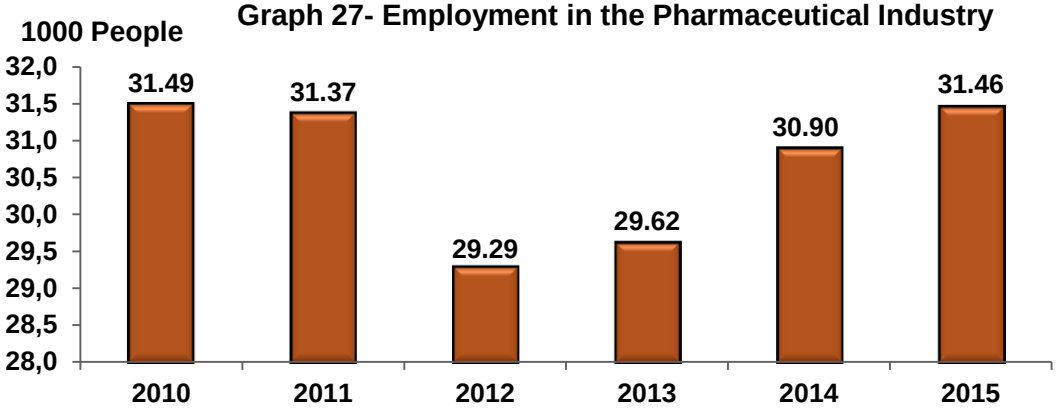
	No. of Documents		Fixed investments (million TL)			Employment via investment		
	Drug	Total	Drug	Total	Share	Drug	Total	Share
2010	14	3,581	272	67,439	0.40%	634	132,739	0.48%
2011	17	3,979	237	49,481	0.48%	600	119,903	0.50%
2012	20	4,025	672	61,794	1.09%	725	148,428	0.49%
2013	21	4,667	512	95,191	0.54%	672	189,260	0.36%
2014	17	3,959	1,707	64,503	2.65%	885	143,305	0.62%
2015	24	4,552	879	99,074	0.89%	956	141,771	0.67%
2016	15	5,161	327	97,780	0.33%	551	141,356	0.39%

Source: Ministry of Economy, İEİS

6. Employment

Based on Turkish Statistics Institute data, in 2015, approximately 31,500 people work in the pharmaceutical industry. The table below provides a summary of how employment in the pharmaceutical sector has changed over the years. The price-focused policies implemented during the global budget period had an inevitable impact on the employment data of the sector. As a matter of fact, the number of people employed in the sector has been eroded significantly since 2010. Only in 2015 could the sector recover to the human resources levels of 2010.

Graph 27- Employment in the Pharmaceutical Industry



Source: TurkStat

7. Foreign Trade

In 2010, pharmaceutical exports stood at 603 million USD. Yet within 6 years, they had surged by 43.1%, bringing the figure to 863 million USD. In the same period, the total exports of Turkey grew by 25.2%, bringing the national contribution of the pharmaceutical industry from 0.53% to the 0.60% level.

On the other hand, in 2016, medicinal exports marked no increase for the first time within the course of 6 years.

As for imports of medicine, following the 5.6% growth of 2014, a declining trend was observed, with further decline exhibited in 2016. Between 2010 and 2016, medicine imports showed a 5.3% decline, declining to the 4.5 billion USD level. As a result of these developments, the foreign trade deficit dropped to the 3.66 billion USD level in 2016, whereas the rate of exports meeting imports was realized at 19.1%.

Table 10- Export and Import of Pharmaceutical Products (Billion USD)

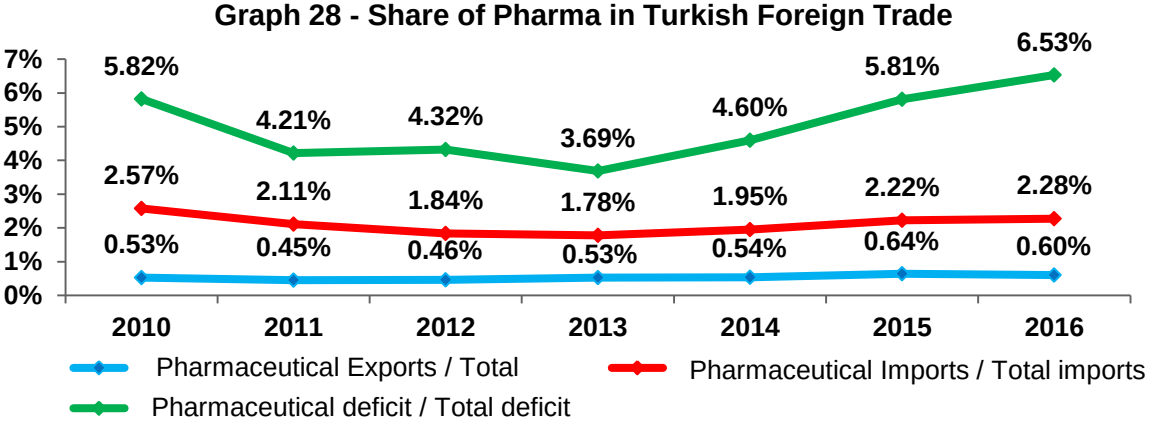
Product	Export	Change	Import	Change	Foreign Trade Deficit	Change	Export / Import
2010	603	28.3%	4,773	7.9%	-4,171	5.4%	12.6%
2011	610	1.2%	5,074	6.3%	-4,464	7.0%	12.0%
2012	709	16.2%	4,342	-14.4%	-3,633	-18.6%	16.3%
2013	800	12.9%	4,482	3.2%	-3,682	1.3%	17.8%
2014	845	5.6%	4,731	5.6%	-3,887	5.6%	17.9%
2015	921	9.1%	4,605	-2.7%	-3,684	-5.2%	20.0%
2016	863	-6.4%	4,521	-1.8%	-3,658	-0.7%	19.1%

Source: TurkStat, İEİS

An analysis of export markets indicates that in 2010 there were exports to a total of 137 countries, while a further 27 countries have been added to the list within the past 6 years. Factoring in the 11 countries to which exports were terminated, in 2016, exports were realized to 153 countries, mainly the Commonwealth of Independent States (CIS), North Africa and the Middle East. Additionally, in 2016, the sector is engaged in imports from 89 countries.

An analysis of the share of pharmaceutical industry within Turkey's foreign trade indicates a 2.28% share of total imports, and a 6.53% share within the pharmaceutical foreign trade deficit.

Graph 28 - Share of Pharma in Turkish Foreign Trade



Source: TurkStat, İEİS

Becoming global and ranking among the top pharmaceutical producers and exporters of the world are the main objectives of our industry. Yet there are certain barriers to overcome that currently prevent us from attaining these goals. The key obstacles to an increased level of exports are low product prices, problems in GMP inspection and licensing processes in relevant countries, as well as problems stemming from exports via depots without the permission of license owner companies.

A principal factor that will promote exports is the fact that the authorities of target markets recognize the GMP documents issued by the Ministry of Health. GMP is a set of international rules that ensure the production and control of pharmaceutical products in compliance with quality standards, and was put into effect in Turkey in 1984. Within that framework, pharmaceutical manufacturing facilities are inspected and accredited by Turkey's Ministry of Health, which carries out inspections in several countries across the world. However, this document is not recognized by the authorities of many countries. Instead they carry out their own inspection during the licensing process for export products in the relevant countries. This being the case, initiating the necessary steps with countries that could unilaterally or mutually recognize the GMP certificate issued by our Ministry of Health would contribute to an increase in our exports. Moreover, it is vital that steps are taken for the facilitation of a briefer licensing process in export markets.

Yet another problem to be overcome so as to promote our pharmaceutical exports is that pharmaceutical products manufactured for the domestic market are exported to foreign markets via wholesalers without the knowledge of the pharmaceutical companies themselves. This brings down the prices of pharmaceutical products, while also damaging the prestige of companies in foreign markets since the

compliance of their delivery process with Good Distribution Practices (GDP) may not be subject to inspection. The practice in question puts at stake the success of our brands in foreign markets, despite all promotional efforts and expenses that are also incentivized by the Ministry of Economy through programs such as Turquality. Therefore, this plight leads to the possible decline of our pharmaceutical exports in the long run. In order to eliminate the problems arising from this setback, the Ministry of Health allows exports to these depots. Where the written approval of the license owner companies is required, but is not listed among the application documents, it is necessary to establish the necessary arrangements so as not to grant permission for the export of the relevant products.

Another factor that plays an important role in the decrease in export value of pharmaceutical products is the low-price policies implemented in Turkey. Local product prices are accepted as the source price in export countries, which makes it challenging for Turkish pharmaceutical companies to enter the market at appropriate price levels required for the country to be competitive. Under such circumstances, our manufacturers may opt for third party production so as to achieve higher prices in the export markets where there is a possibility for manufacturing. Additionally, this leads to a decrease of the export value per kilo over the years. Our exports are increasing in volume terms, yet this increase has no repercussions in value terms. In fact, since 2012, the export value of the industry has decreased by 22% per kilo, dropping from 37.2 USD down to 29 USD. Furthermore, taking into account the fact that Turkey's average export value per kilo is 1.5 dollars, it is apparent that the sector creates a high added value.

Table 11- Export Value per Kilo (USD)

	2001-2004	2005-2008	2009-2012	2013-2016
Pharmaceutical Industry	47.6	45.6	37.2	29
Turkey	0.75	1.32	1.34	1.51

Source: International Trade Center, İEİS

On a country basis, an analysis of the export and import of pharmaceutical products indicates that the highest level of exports is to South Korea, Switzerland, Iraq and the USA.

Table 12- Exports per Country (Million USD)

Country	2015	2016	Change (%)
South Korea	225	165	-26.9%
Switzerland	48	60	25.0%
Iraq	52	46	-11.7%
USA	53	39	-25.6%
TRNC	26	29	12.0%
Slovenia	21	29	37.5%
Libya	17	26	52.7%
Iran	25	26	3.1%
Germany	50	25	-49.8%
Azerbaijan	31	22	-29.1%

Source: TurkStat, İEİS

Meanwhile, the most important import markets are Germany, USA, Switzerland, France and England.

Table 13- Imports per Country (Billion USD)

Country	2015	2016	Change (%)
Germany	817	849	3.9%
USA	557	559	0.4%
Switzerland	421	376	-10.6%
France	389	364	-6.5%
England	306	313	2.1%
Italy	298	301	1.0%
Ireland	301	269	-10.6%
South Korea	225	217	-3.5%
Denmark	164	157	-4.3%
Belgium	161	153	-5.1%

Source: TurkStat, İEİS

8. Conclusion and Evaluation

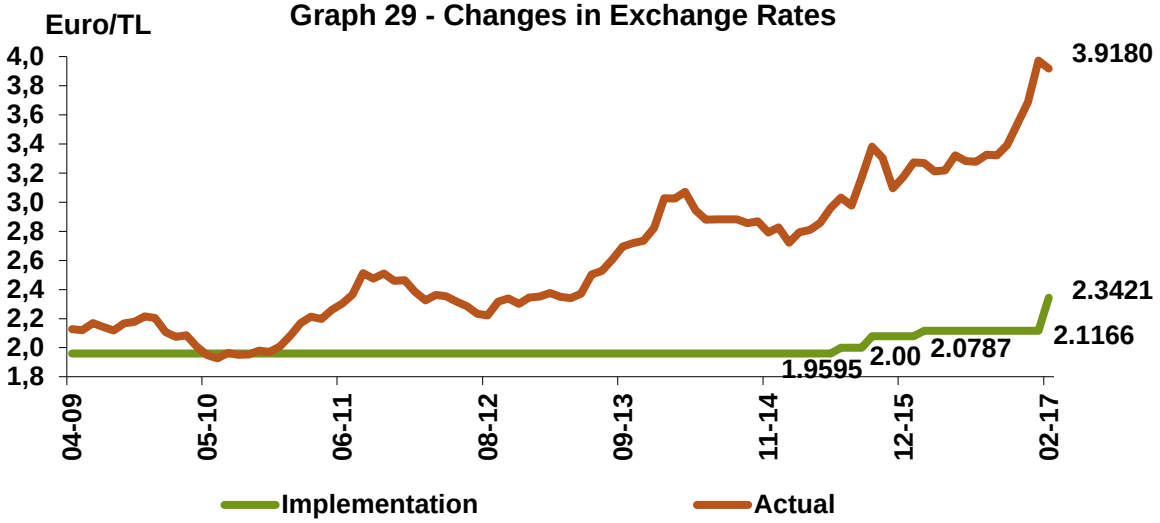
The global economic crisis that broke out in 2008 and gradually intensified affected our economy deeply. In the aftermath of the crisis, radical arrangements were kicked off in 2009 in order to overcome the challenges posed by public finance. As part of the Healthcare Transformation Program, service quality and access to healthcare were improved, and yet the only method of controlling rising expenses was measures regarding the prices of medicines. Product budgets were not proportional to the level of services offered. Furthermore, prices were constantly reduced based on the rationale that the product budget was exceeded, while the Social Security Institution discount rates were increased.

Additionally, although legislative requirements were fulfilled, the Euro exchange rate value used for TL conversion of EU-based product prices was kept constant from April 2009 to May 2015. It was fixed at the 1.9595 TL level so as to control pharmaceutical expenses. The lawsuit filed by the industry for an update of the exchange rate was finalized in favor of the pharmaceutical sector in April 2015. The conversion rate, which was initially announced as 2 TL, was subject to an objection by the industry, when set as 70% of the average Euro exchange rate of the previous year. This value was updated as 2.3421 TL for year 2017.

Considered by the government to rank among the strategic sectors, the pharmaceutical industry is marked by advanced technology and constant innovation, and needs to rapidly keep up with scientific and technological advancements and changes. Within such a structure, companies need to transfer their earnings back to the industry so as to preserve their competitive edge. However, the sector is weakening due to price-oriented policies.

Therefore, a Euro value that equals 70% of the previous year’s average Euro exchange rate is remote from economic realities. Within this context, the previous year's average should be brought up to 100% from 70%.

Graph 29 - Changes in Exchange Rates



Source: Ministry of Finance of the Republic of Turkey , İEİS

During the 2010-2016 period, excluding the impact of the inflation rate, the market grew only 1% in value terms. With the implementation of the global budget practice, the pharmaceutical industry was badly hit and the sector was unable to realize its development potential in exports, investment, and employment. There was an effort to reduce costs in the industry that had seen investments deferred and a decreased employment level.

In today's global pharmaceutical market, the Turkish pharmaceutical industry is ranked 16th in terms of market value. In order to boost the competitive edge of the industry, it is necessary to provide support, particularly in the fields of investment, exports and pricing. Reinforcing the efficiency of current incentives and devising different incentive mechanisms would help our country to gain a competitive edge. The R&D capabilities of the sector would be enhanced, allowing the production of higher value added products and clearing the path for Turkey to become a global manufacturer and exporter of pharmaceutical products.

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