

***TURKISH
PHARMACEUTICAL
INDUSTRY
2021***



IEIS

PHARMACEUTICAL MANUFACTURERS
ASSOCIATION OF TURKEY

TABLE OF CONTENTS

Introduction	4
1. Turkish Pharmaceutical and Medicinal Products Market	6
1.1 Turkish Pharmaceutical Market	7
1.1.1 Market Growth and Resources	8
A. Price	9
B. Volume	9
C. Sales Distribution	9
D. New Product	9
1.1.2. Market Structure	10
A. Originator – Generic Products	10
B. Import – Local Products	13
C. Biotechnological Products	16
D. Therapeutical Groups	20
E. Average Prices	22
F. Retail Price Ranges	22
1.2. Medicinal Nutrition Market	25
1.3. Medicinal Products Market	26
2. Licensing	29
3. Investment Incentives	29
4. R&D	30
5. Production	31
6. Employment	32
7. Foreign Trade	33
8. Price Policies	39
9. Conclusion and Evaluation	43

CHARTS LIST

Chart 1 - Turkish Pharmaceutical and Medicinal Products Market	6
Chart 2 - Turkish Pharmaceutical Market	7
Chart 3 - Resources of Growth	8
Chart 4 - Originator - Generic Drugs (Value)	10
Chart 5 - Originator - Generic Drugs (Volume)	11
Chart 6 - Originator - Generic Drugs Market Share (Value)	11
Chart 7 - Originator - Generic Drugs Market Share (Volume)	12
Chart 8 - Import-Local Products (Value)	13
Chart 9 - Import-Local Products (Volume)	14
Chart 10 - Import-Local Products Market Share (Value)	14
Chart 11 - Import-Local Products Market Share (Volume)	15
Chart 12 - Biotechnological Products (Value)	17
Chart 13 - Biotechnological Products (Volume)	17
Chart 14 - Reference-Biosimilar Products Market Share (Value)	18
Chart 15 - Reference-Biosimilar Products Market Share (Volume)	18
Chart 16 - The Share of Imported Biopharmaceuticals Among Imported Products (Value)	19
Chart 17 - The Share of Imported Biopharmaceuticals Among Imported Products (Volume)	19
Chart 18 - Therapeutical Groups on Value Scale	21
Chart 19 - Therapeutical Groups on Volume Scale	21
Chart 20 - Retail Price Distribution	23
Chart 21 - Price Breakdown of Originator Products	23
Chart 22 - Price Breakdown of Generic Products	24
Chart 23 - Price Breakdown of Imported Products	24
Chart 24 - Price Breakdown of Local Products	25
Chart 25 - Medicinal Nutrition Market	25
Chart 26 - Source of Medicinal Nutrition Market Growth	26
Chart 27 - Medicinal Products Market	26
Chart 28 - Sources of Medicinal Products Market Growth	27
Chart 29 - Medicinal Products Market Value	27
Chart 30 - Medicinal Products Market Volume	28
Chart 31 - Medicinal Products Market Average Price Distribution	28
Chart 32 - Number of Novel Product Licenses	29
Chart 33 - Number of Accredited R&D Centers in the Pharmaceutical Industry	30
Chart 34 - Pharmaceutical Industry R&D Expenditure	31
Chart 35 - Number of Production Facilities	32
Chart 36 - Industry Production Index Change (2015-2021)	32
Chart 37 - Employment in the Pharmaceutical Industry	33
Chart 38 - Employment Index Change (2015-2020)	33
Chart 39 - Export Value in the Pharmaceutical Industry	34
Chart 40 - Import Value in the Pharmaceutical Industry	34
Chart 41 - Pharmaceutical Industry in Turkish Foreign Trade	35
Chart 42 - Finished Product vs Raw Material in Pharmaceutical Industry	35
Chart 43 - Export Amount in the Pharmaceutical Industry	36
Chart 44 - Pharmaceutical Export Price Per Kilo	36
Chart 45 - Export Price per Kilo in Various Sectors	37
Chart 46 - Currency Trends (Euro/TRY)	40
Chart 47 - Pharmaceutical Pricing	41
Chart 48 - Real Changes in Net Sales (2015-2020)	41
Chart 49 - Real Changes in Equities (2015-2020)	42
Chart 50 - SSI Monthly Prescription Number	42
Chart 51 - The Pharmaceutical Exchange Rate / The Average February and December Exchange Rate	44

TABLE LIST

Table 1- Breakdown of the Pharmaceutical Market	8
Table 2- Unit Distribution of New Products in the Market	9
Table 3- Originator-Generic Products Breakdown	12
Table 4- Import-Local Products Breakdown	15
Table 5- Biotechnological Products	20
Table 6- Distribution of Average Product Prices	22
Table 7- Investment Incentives in the Pharmaceutical Industry	30
Table 8- First Twenty Countries in Pharmaceutical Export	37
Table 9- First Twenty Countries in Pharmaceutical Import	38
Table 10- First Five Products in Pharmaceutical Export	39
Table 11- First Five Products in Pharmaceutical Import	39

Introduction

The pharmaceutical industry is one of the few industries with critical importance for countries strategically and economically, due to both its role in ensuring the continuity of healthcare services and its high value-added, high-tech nature.

Turkish pharmaceutical industry is one of the most well-established and dynamic industries in the country, boasting the potential to compete with developed countries, a deep-rooted expertise of production, and a competent human resource.

During the severe global challenge of the COVID-19 pandemic, Turkish pharmaceutical industry once again proved its quality and resilience by taking rapid action in the development of new medicines and domestic vaccines and ensuring the highest level of supply security despite increasing logistics and supply costs and production issues.

Turkish pharmaceutical industry comprises approximately 785 companies, 96 pharmaceutical and radiopharmaceutical manufacturers that operate at international standards, and 12 raw material production facilities. With more than 42,000 employees, the pharmaceutical industry provides Türkiye's growing and aging population with more than 14,000 thousand products, which are also exported to around 190 countries across the globe.

Our goals are to enhance the value-added of our industry with a stronger focus on R&D, enhance the industry's momentum, especially in biotech, by taking advantage of the trend of high-value investment in recent years, and transform Türkiye into a regional, and later, global hub of pharmaceutical production and export with further investments supported by public policies.

Operating through the platforms it has established, namely the Turkish Biopharmaceuticals and Vaccines Platform and the Turkish Pharmaceutical Exporters Platform, the Pharmaceutical Manufacturers' Association of Türkiye (IEIS) continues to work diligently to achieve these goals and to promote regulations that will facilitate the industry's growth.

Accordingly, one primary area of activity for IEIS is the compilation of market and macroeconomic data on the pharmaceutical industry, which are then used as inputs for comprehensive analyses that will guide the industry's future.

These efforts culminate in the Turkish Pharmaceutical Industry Report, which, in this year's edition, provides an in-depth analysis of the industry in 2021 and in the past seven years. The report offers a comprehensive analysis of the pharmaceutical and healthcare products market, focusing on the pharmaceuticals, medical foods, and healthcare products sectors in separate sections. The analysis involves a comprehensive look at the market in terms of both structure in prices in several categories, such as originator/generic products, imported/local products, and biotech pharmaceuticals.

The report also evaluates the medical foods market as well as the healthcare products market, which consists of Ministry of Health-approved herbal medicines, certain pharmaceutical devices, and Ministry of Agriculture and Forestry-approved vitamin and dietary supplements and baby formulas.

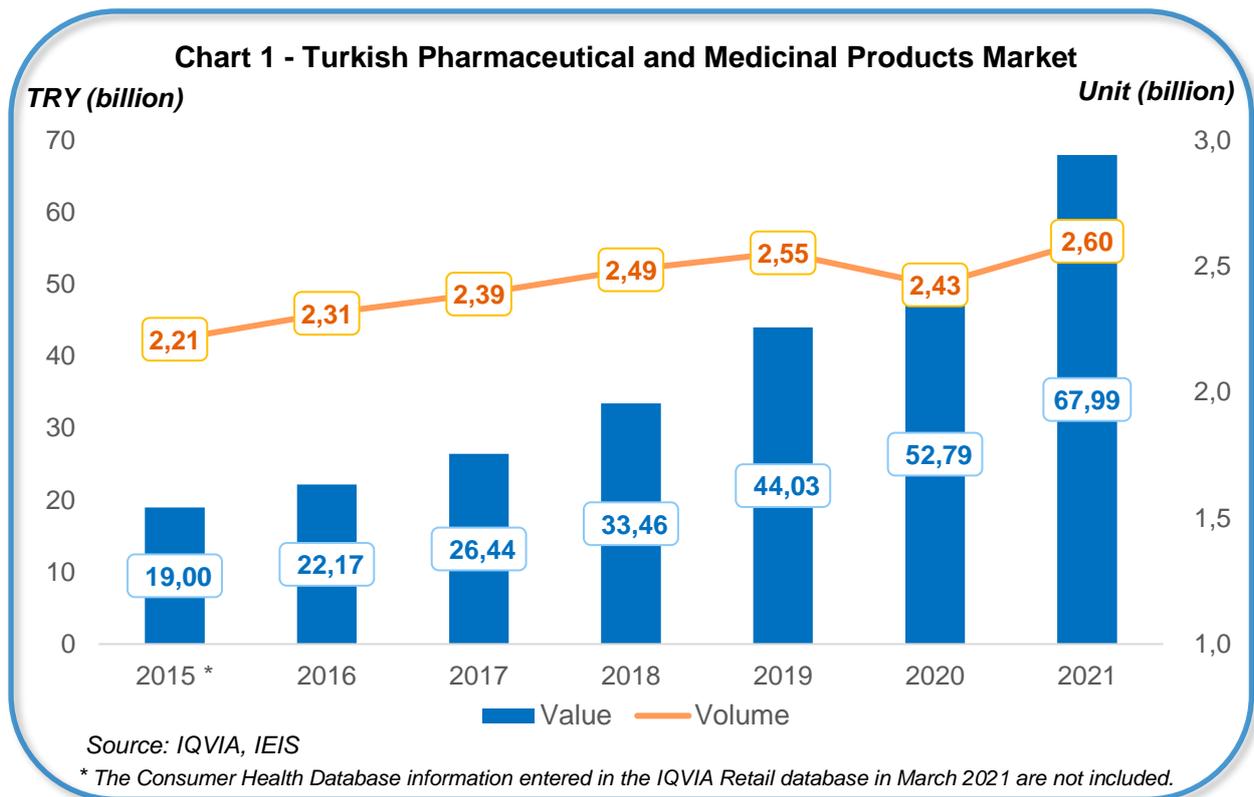
The report contains information on pharmaceutical licensing, investment incentives, R&D, employment, pricing, financials, and foreign trade.

We are delighted to be presenting our 2021 Turkish Pharmaceutical Industry Report to our public, academic and private stakeholders in the hope that the information contained herein will be translated into concrete steps towards our industry's growth and its contribution to the national economy.



1. Turkish Pharmaceutical and Medicinal Products Market

In 2021, the Turkish pharmaceutical and healthcare products market grew 28.8% in value to reach TRY 68 billion, and 7.1% in units to hit 2.6 billion units. The healthcare products market, which encompasses pharmaceuticals, Ministry of Health-approved products such as herbal medicines, diet food for special medical purposes and Ministry of Agriculture and Forestry-approved baby formulas, vitamins and dietary supplements, shrank 5% in units while growing 19.9% in value.

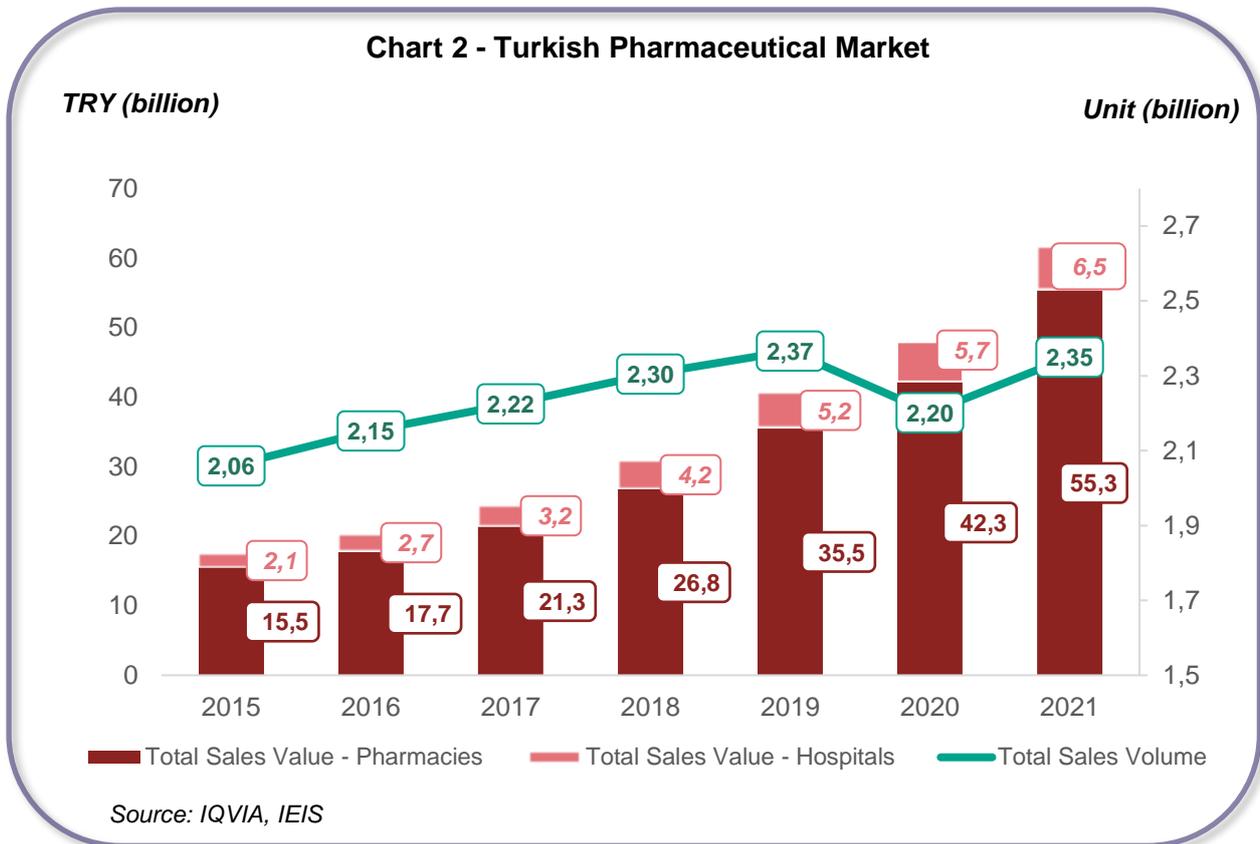


During the seven-year period from 2015 to 2021, the pharmaceutical and healthcare products market posted a growth of 258%, from TRY 19 billion in 2015 to TRY 68 billion in 2021. This result indicates a compound annual growth rate (CAGR) of 23.7%, and a shrinkage of 12.7% in real terms when producer price inflation is taken into consideration.

In terms of volume, total units rose 17.6% from 2.21 billion in 2015 to 2.6 billion in 2021. This growth rate indicates a CAGR of 2.7%. The main factors in the growth in pharmaceuticals were the increased access to public healthcare services, higher demand from a growing and aging population, and the diversifying range of natural supplements and vitamins on the market.

1.1 Turkish Pharmaceutical Market

In 2021, the Turkish pharmaceutical market recorded a 28.8% growth in value in hospitals and pharmacies, reaching a total value of TRY 61.7 billion. In unit terms, the market returned to its pre-pandemic level with unit sales of 2.35 billion, indicating a 6.9% growth. In 2021, the market share of hospitals was 10.5% in terms of value and 9.9% in terms of unit.



An analysis of the pharmaceutical market in the seven-year period from 2015 to 2021 shows a 251.8% growth, up from TRY 17.6 billion in 2015 to TRY 61.7 billion in 2021. This result indicates a compound annual growth rate (CAGR) of 23.3%, and a shrinkage of 14.2% in real terms when the producer price inflation of 310% for the period is taken into consideration. Due to the rapid increase in exchange rates and costs in the final quarter of 2021, and the lack of sufficient change in price policies in response to these developments, the pharmaceutical industry recorded a significant loss, falling behind 2015 results in terms of value.

In terms of volume, total units rose 14.3% from 2.06 billion in 2015 to 2.35 billion in 2021. This growth rate indicates a CAGR of 2.3%.

The pharmaceutical industry recorded a shrinkage in unit terms as a result of the pandemic measures after March 2020, whereas the gradual normalization in 2021 returned the market to its 2019 levels.

An analysis of the market concentration reveals 258 distributors in the Turkish pharmaceutical market; 55 of these have a product portfolio made up of imported products exclusively, while 128 firms have a portfolio of exclusively local products. The remaining 75 firms account for over 60% of the medicines on the market with a blended portfolio of imported and local products, representing 69% of the market by value and 72% by volume. In 2021, the top 50 firms by value accounted for 85% of the total market value, and 80% of total market volume.

Total market value of pharmaceutical products that fall within the scope of the medicine reimbursement system was TRY 59 billion in 2021. Strikingly, the average price of non-reimbursed medicines are almost triple that of reimbursed medicines.

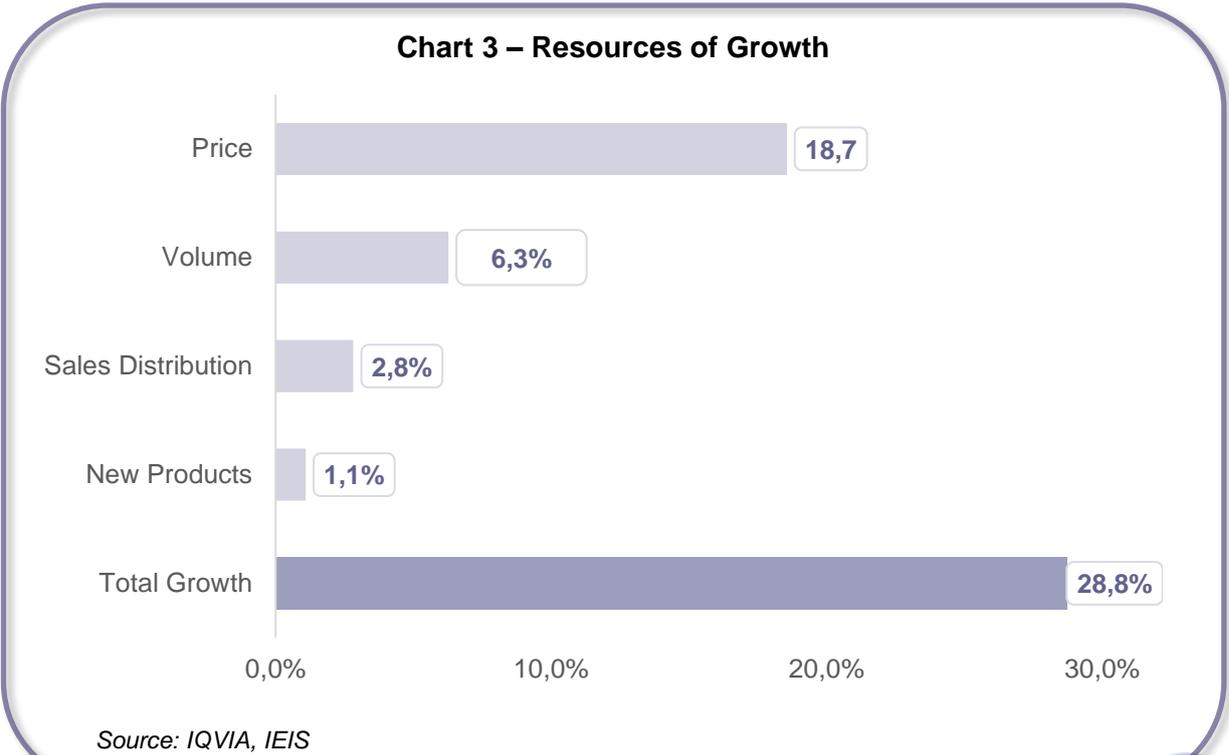
Table 1- Breakdown of the Pharmaceutical Market (2021)

	Volume (Billion Unit)	Value (Billion TRY)	Average Price (TRY)
Turkish Pharmaceutical Market	2,35	61,74	26,2
Prescription	2,32	61,19	26,3
Reimbursed	2,29	58,73	25,7
Non-Reimbursed	0,03	2,46	72,2
Non-Prescription	0,03	0,55	17,6
Reimbursed	0,02	0,26	12,3
Non-Reimbursed	0,01	0,29	29,5

Source: IQVIA, IEIS

1.1.1 Market Growth and Drivers

In 2021, there were four main drivers of the market’s value growth. These were: the volume of the existing portfolio, increase in prices, changes in sales breakdown, and new products added to the portfolio.



A. Price

The annual EUR exchange rate used for determining pharmaceutical prices was increased by 20% in February 2021, and the subsequent price hike (equivalent to TRY 8,898 million) accounted for 18.7 percentage points of the annual market growth of 28.8%.

B. Volume

2021 saw a limited return to pre-pandemic levels, with pharmaceutical market volume driving growth by 6.3 percentage points (equivalent to TRY 3,006 million).

C. Sales Breakdown

The change in the breakdown of existing product sales was the third biggest driver of market growth in 2021. During the year, sales shifted from cheaper products to more expensive products, driving growth by 2.8 percentage points (equivalent to TRY 1,352 million).

D. New Products

During 2021, 290 new products, 273 conventional and 17 biotech, entered the market, driving growth by 1.1 percentage points (equivalent to TRY 520 million).

A unit breakdown of new products entering the market shows that oncology drugs had the highest share. In 2021, 26 oncology drugs (9%), 25 cardiovascular drugs (8.6%), 23 neurological drugs (7.9%), 19 antirheumatic drugs (6.6%), 19 dermatological drugs (6.6%), and 18 urinary drugs (6.2%) entered the market. In total, these treatment groups represented 44.8% of all newly introduced medicines in 2021.

In 2021, 31 originator products, 23 conventional and 8 biotech, entered the market. All 31 of these products are imported, with generics available for 9 of them.

Of the remaining 259 generics, 250 are conventional drugs and 9 are biosimilars. 11 of these generics are imported. In other words, generics have the highest share among new pharmaceuticals with a share of 85.5%.

Table 2- Unit Distribution of the New Products in the Market (2021)

Drug	290
Reference	31
▪ Generic exists	9
Import	9
▪ Generic non-existing	22
Import	22
Generic	259
▪ Import	11

Source: IQVIA, IEIS

1.1.2. Market Structure

A. Originator - Generic Products

In 2021, the originator medicines market climbed by 28.1% from TRY 32.7 billion to TRY 41.9 billion. On a unit basis, the originator products market grew 7.2% to reach 0.95 billion units.

In 2021, the generic medicines market grew 30.4% from TRY 15.2 billion to TRY 19.8 billion. On a unit basis, the generic products market grew 6.7% to reach 1.4 billion units.

Between 2015 and 2021, the value of the originator medicines market grew 244.5% in total. This growth is equivalent to a CAGR of 22.9%, and indicates a contraction of 15.9% when adjusted for inflation. On a unit basis, originator products market saw a decrease of 6.2% in the same period.

Generic medicines outperformed originator products in the 2015-2021 period, recording a growth rate of 268.1%. This growth is equivalent to a CAGR of 24.3%. When adjusted for inflation, this result indicates a shrinkage of 10.2%. Between 2015 and 2021, generic medicines recorded a volume growth of 20.6%.

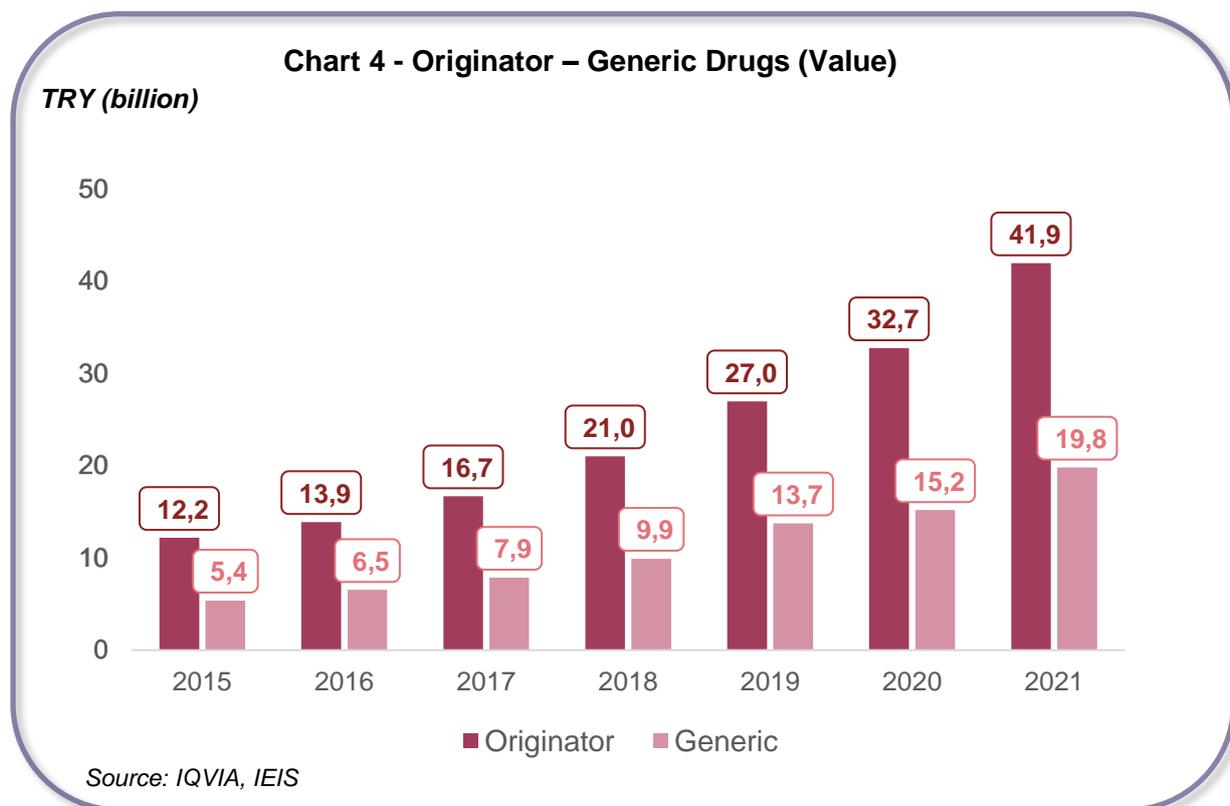
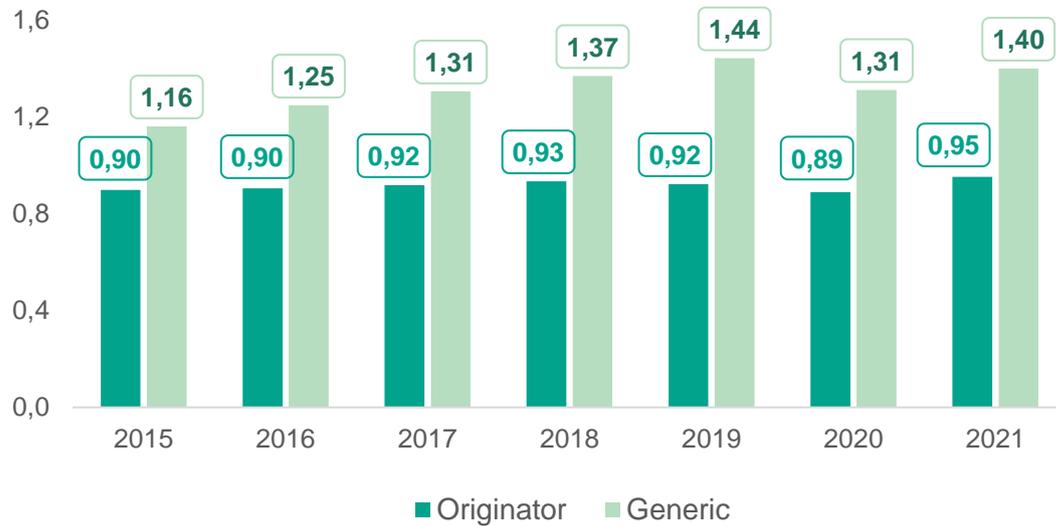


Chart 5 - Originator – Generic Drugs (Volume)

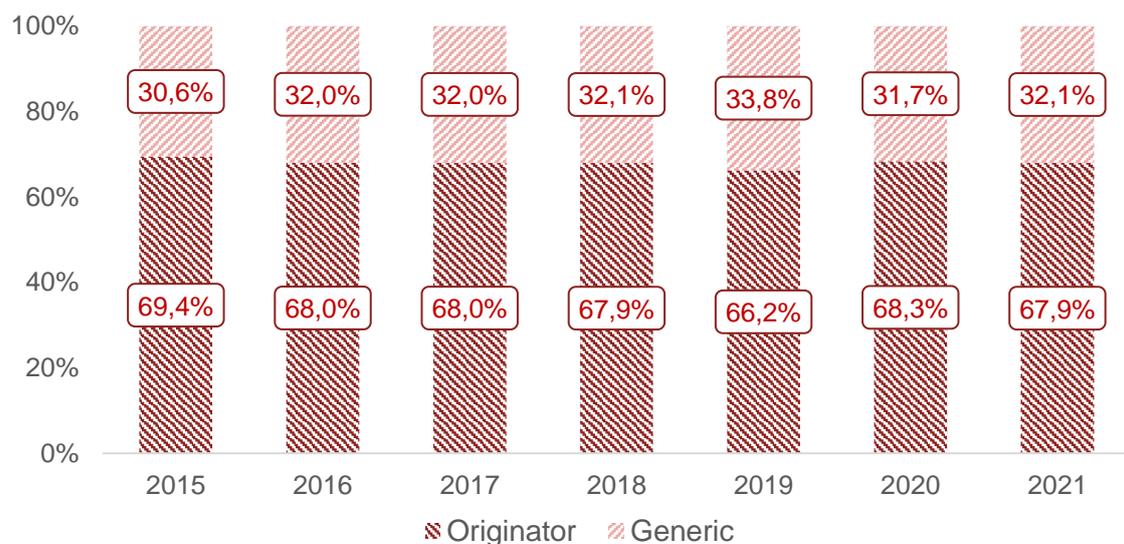
Units (billion)



Source: IQVIA, IEIS

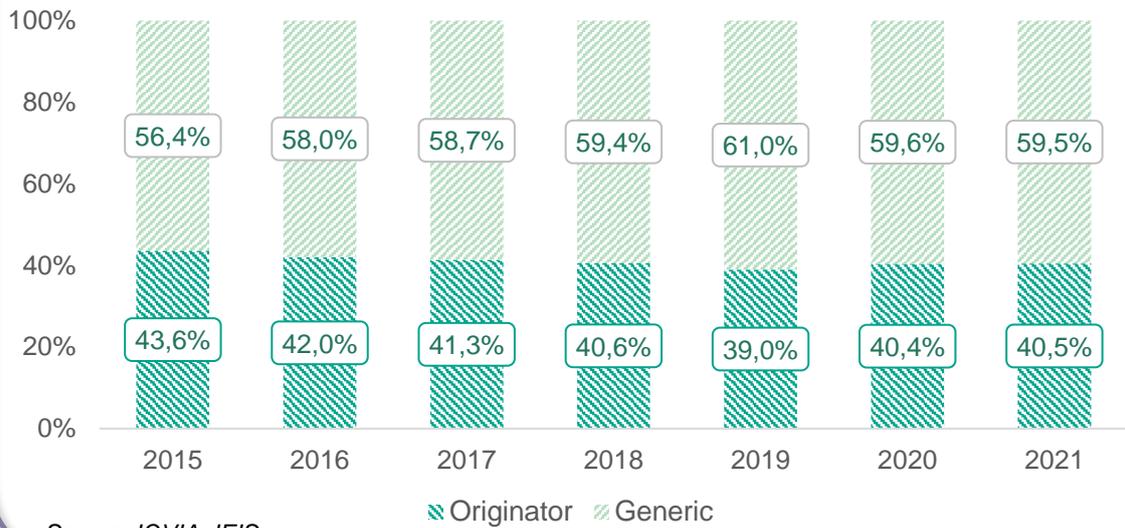
The market share of generic medicines, which was 30.6% in value and 56.4% in volume in 2015, rose to 32.1% in value and 59.5% in volume in 2021.

Chart 6 - Originator-Generic Products Market Share (Value)



Source: IQVIA, IEIS

Chart 7 - Originator-Generic Products Market Share (Volume)



Looking at the imported-local breakdown of originator-generic medicines, in 2021, imported products accounted for 68% of originator products in terms of value, and 26% in terms of units. On the other hand, almost the entirety of the generic products is local. Overseas GMP audits are thought to be effective in shrinking the market share of imported generics.

Table 3 - Originator - Generic Products Breakdown

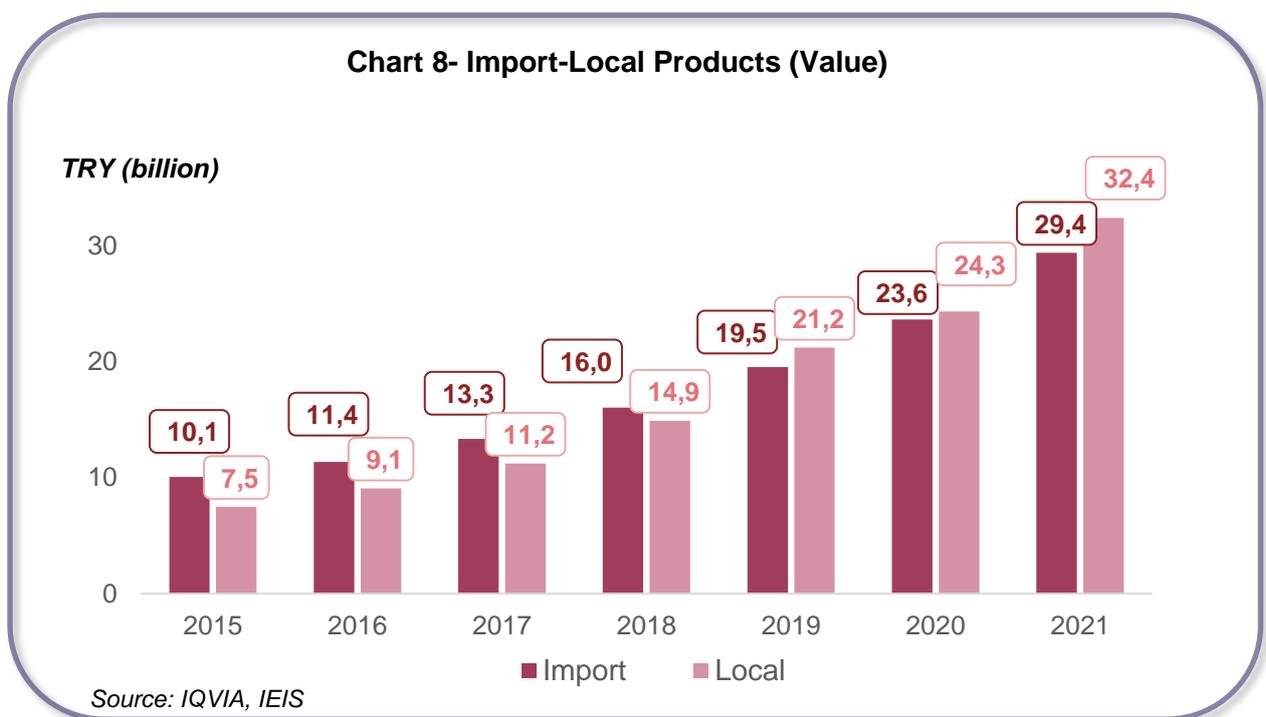
Value	Originator		2015	2016	2017	2018	2019	2020	2021
		Import	80%	79%	78%	74%	71%	70%	68%
Billion TRY	9,74	11,00	12,94	15,60	19,05	23,03	28,55		
Local	20%	21%	22%	26%	29%	30%	32%		
Billion TRY	2,44	2,90	3,75	5,42	7,93	9,71	13,39		
Generic	Import	6%	5%	5%	4%	3%	4%	4%	
	Billion TRY	0,34	0,35	0,39	0,43	0,48	0,59	0,83	
	Local	94%	95%	95%	96%	97%	96%	96%	
	Billion TRY	5,04	6,17	7,47	9,49	13,27	14,60	18,97	
Unit	Originator	Import	43%	44%	43%	37%	29%	28%	26%
		Billion Units	0,39	0,40	0,39	0,35	0,27	0,25	0,25
		Local	57%	56%	57%	63%	71%	72%	74%
		Billion Units	0,51	0,51	0,52	0,59	0,65	0,64	0,71
	Generic	Import	3%	3%	3%	2%	2%	2%	2%
		Billion Units	0,04	0,04	0,04	0,03	0,02	0,02	0,02
		Local	97%	97%	97%	98%	98%	98%	98%
		Billion Units	1,12	1,21	1,27	1,34	1,42	1,29	1,38

Source: IQVIA, IEIS

B. Imported - Local Products

In 2021, imported medicines grew 24.4% to reach TRY 29.4 billion. Between 2015 and 2021, imported products recorded a 191.6% increase in value. This indicates a CAGR of 19.5%, and a shrinkage of 28.9% when adjusted for inflation.

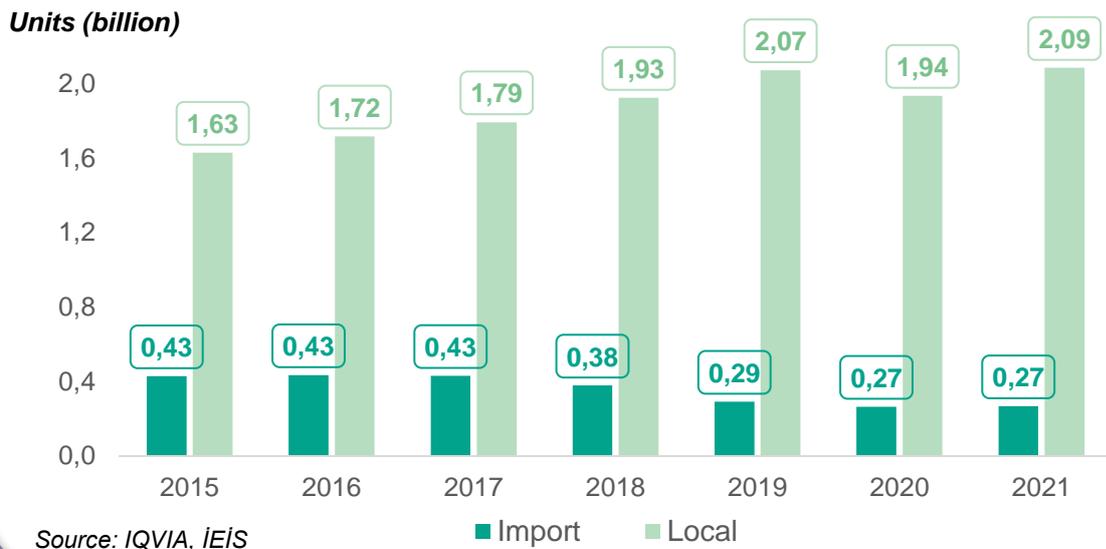
In 2021, local medicines surpassed average growth by achieving a growth rate of 33.2%, reaching TRY 32.4 billion in value. Between 2015 and 2021, local products recorded a 332.9% increase in value. This growth is equivalent to a CAGR of 27.7% and indicates a limited increase of 5.6% in real terms when local producers' prices are considered.



In terms of volume, imported products saw a 1% increase in 2021, reaching 0.27 billion units. Between 2015 and 2021, imported medicines fell 37.6% in terms of volume.

Local products, on the other hand, achieved a 7.8% growth, with 2.09 billion units sold. Between 2015 and 2021, local products recorded a 28% increase.

Chart 9- Import-Local Products (Volume)



The localization initiative commenced in 2016 resulted in a rapid growth of local medicine market share, from 42.6% in 2015 to above 50% for the first time in 2019. However, the initiative was abandoned before localization was completed, and as a result, the share of local medicines remained relatively stable at 52%. In terms of units, the share of local medicines increased from 79.2% in 2015 to 88.6% in 2021.

Chart 10 - Import-Local Products Market Share (Value)

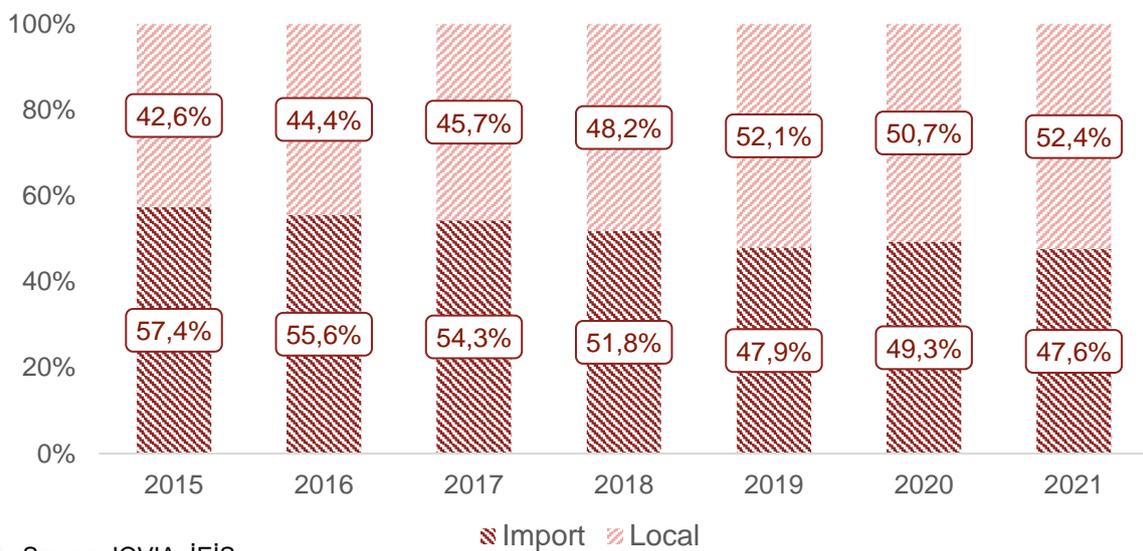
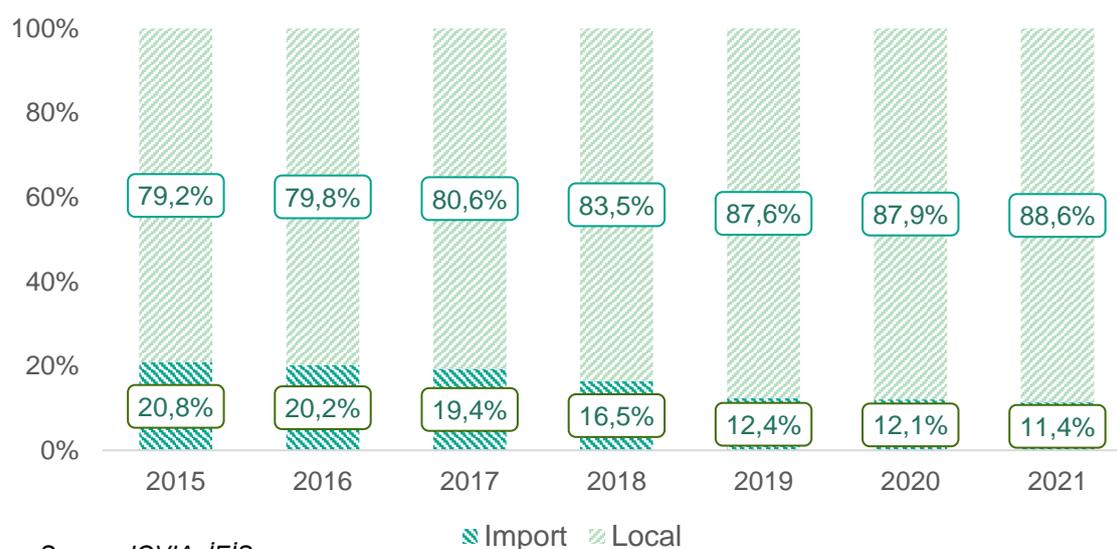


Chart 11 - Import-Local Products Market Share (Volume)



In terms of value, originator products account for 97% of imported medicines and 41% of local medicines. Generic products represent 3% of imported products and 59% of local products. In terms of volume, originators correspond to a stable share of 92% of imported products, whereas their share among local products has risen to 34%. Looking at the medicine produced in Türkiye in 2021, generic products accounted for 59% in terms of value, and 66% in terms of volume.

Table 4 - Import-Local Products Breakdown

			2015	2016	2017	2018	2019	2020	2021
Value	Import	Generic	3%	3%	3%	3%	2%	2%	3%
		Billion TRY	0,34	0,35	0,39	0,43	0,48	0,59	0,83
		Originator	97%	97%	97%	97%	98%	98%	97%
		Billion TRY	9,74	11,00	12,94	15,60	19,05	23,03	28,55
	Local	Generic	67%	68%	67%	64%	63%	60%	59%
		Billion TRY	5,04	6,17	7,47	9,49	13,27	14,60	18,97
		Originator	33%	32%	33%	36%	37%	40%	41%
		Billion TRY	2,44	2,90	3,75	5,42	7,93	9,71	13,39
Unit	Import	Generic	9%	9%	8%	8%	8%	8%	8%
		Billion Units	0,04	0,04	0,04	0,03	0,02	0,02	0,02
		Originator	91%	91%	92%	92%	92%	92%	92%
		Billion Units	0,39	0,40	0,39	0,35	0,27	0,25	0,25
	Local	Generic	69%	70%	71%	70%	69%	67%	66%
		Billion Units	1,12	1,21	1,27	1,34	1,42	1,29	1,38
		Originator	31%	30%	29%	30%	31%	33%	34%
		Billion Units	0,51	0,51	0,52	0,59	0,65	0,64	0,71

Source: IQVIA, İEİS

C. Biopharmaceuticals

The basic definition of a biopharmaceutical is a drug produced using living systems and organisms. The production of biopharmaceuticals dates to the discovery of penicillin by Alexander Fleming in 1928, and in early 1980s, recombinant human insulin became the first biopharmaceutical product approved for therapeutic purpose.

Since biopharmaceuticals, or biologics, are based on living organisms rather than chemical compounds, both the development and production of these products require a significant innovation, technological know-how, and investment.

Biopharmaceuticals are shaping the present and future of the global pharmaceutical industry. These products have enabled treatment of various diseases that cannot be cured with conventional medicines. As a result, the share of biopharmaceuticals in the overall pharmaceutical market, local and global, has been increasing continuously. Today, global market share of biopharmaceuticals has exceeded 30 percent, and this share is expected to continue to increase further in the coming years.

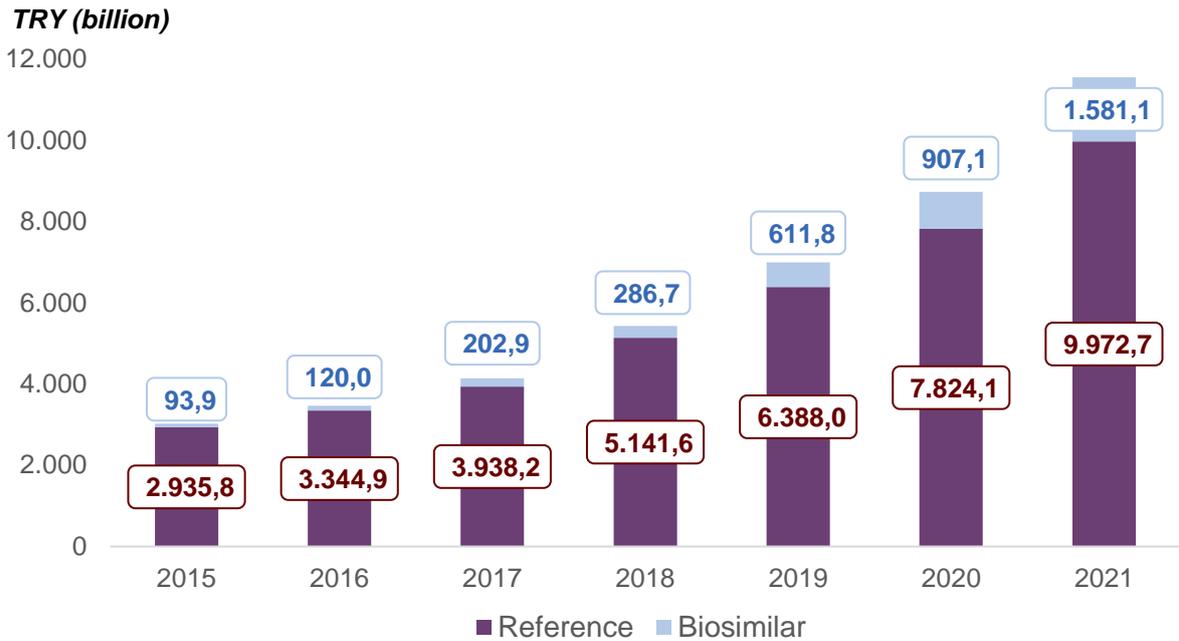
The same applies for the Turkish market as well. In 2021, biopharmaceuticals accounted for around 18.7% of the Turkish pharma market, which was TRY 11.6 billion.

As of the end of December 2021, there are 259 forms of reference biopharmaceuticals under 124 licensed brands in Türkiye, and 104 forms of biosimilars under 31 brands. In total, the biopharmaceutical market consists of 363 forms under 155 brands. There are 31 types of biosimilars under 8 different brands manufactured in Türkiye.

The development and production of these products in our country, which we depend on imports, will not only facilitate patients' access to these drugs, but will also make a significant contribution to the country's economy by reducing the foreign trade deficit.

Looking at the biopharmaceuticals market in 2021, reference biopharmaceuticals grew 27.5% to reach TRY 9.97 billion. Meanwhile, the biosimilars market grew 74.3% to TRY 1.58 billion.

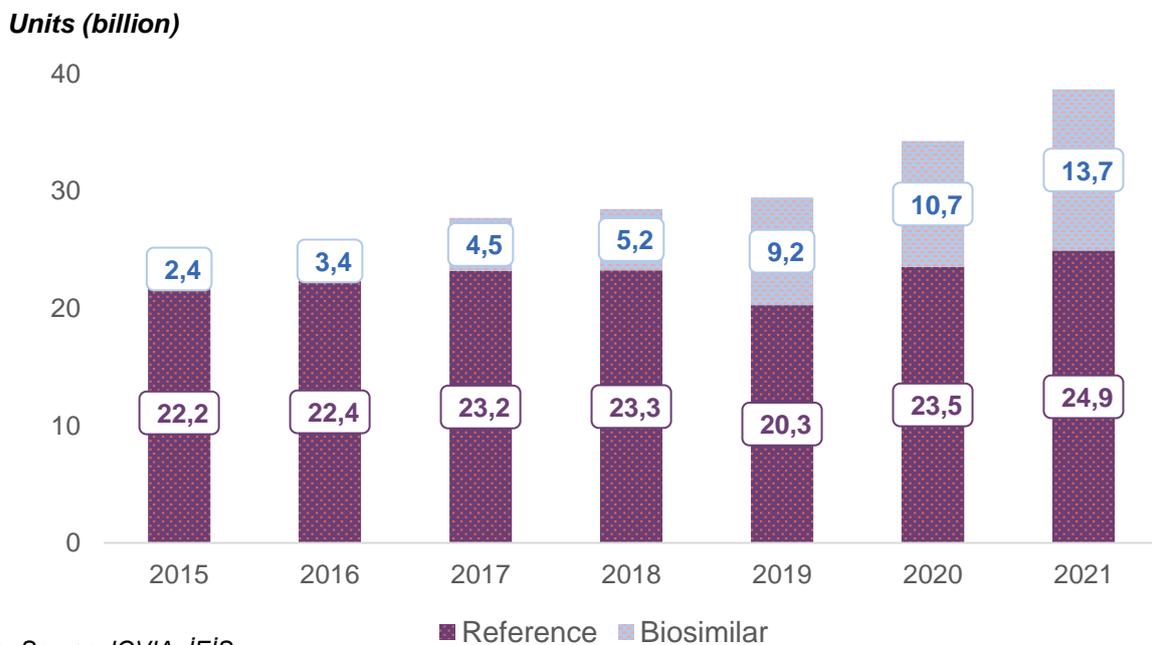
Chart 12- Biotechnological Drugs (Value)



Source: IQVIA, IEIS

In terms of volume, biopharmaceuticals grew 12.9% in 2021 to reach 38.7 billion units. Unit sales of reference biopharmaceuticals climbed by 5.9% year-over-year, compared to 28.2% for biosimilars. In 2021, 13.7 million units of biosimilars were sold.

Chart 13- Biotechnological Drugs (Volume)

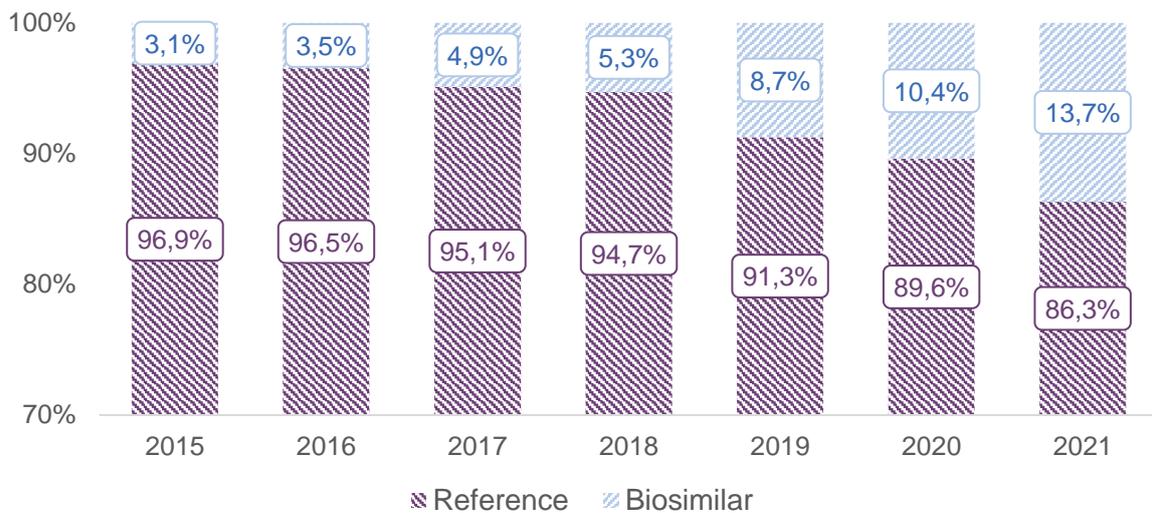


Source: IQVIA, IEIS

Biosimilars containing absiksimab, adalimumab, bevacizumab, enoxaparin sodium, epoetin alfa, epoetin zeta, etanercept, filgrastim, infliksimab, insulin glargine, rituksimab, somatropin, trastuzumab have been licensed, whereas biosimilars containing enoxaparin sodium, epoetin alfa, filgrastim, infliksimab, insulin glargine and trastuzumab are also manufactured in Türkiye. The range of biosimilar products is expected to increase rapidly in the coming years.

Value share of biosimilar products among biologics climbed more than four-fold between 2015 and 2021, from 3.1% to 13.7%.

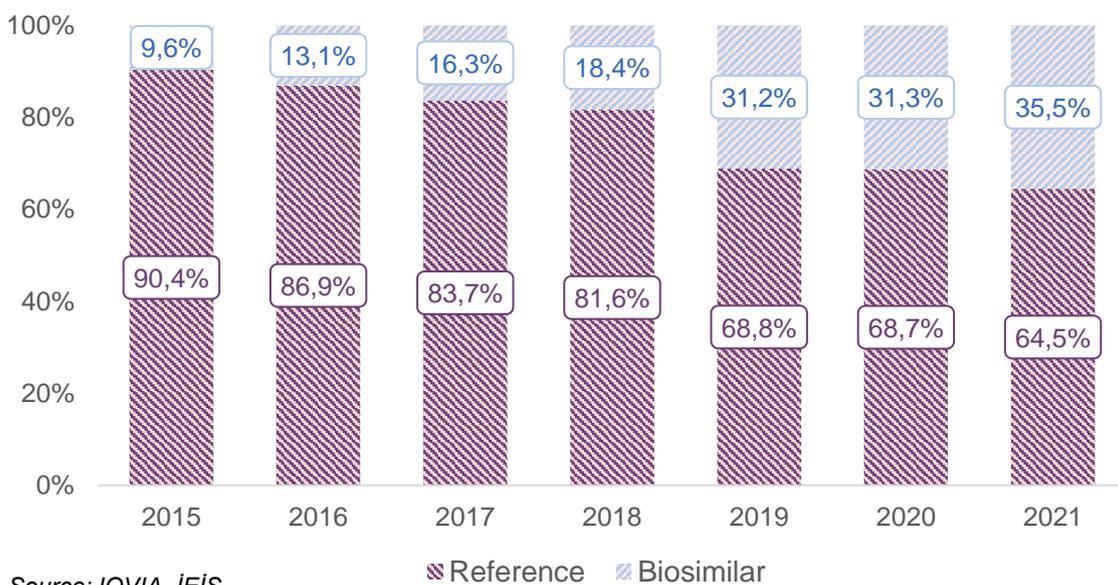
Chart 14 - Reference-Biosimilar Products Market Share (Value)



Source: IQVIA, İEİS

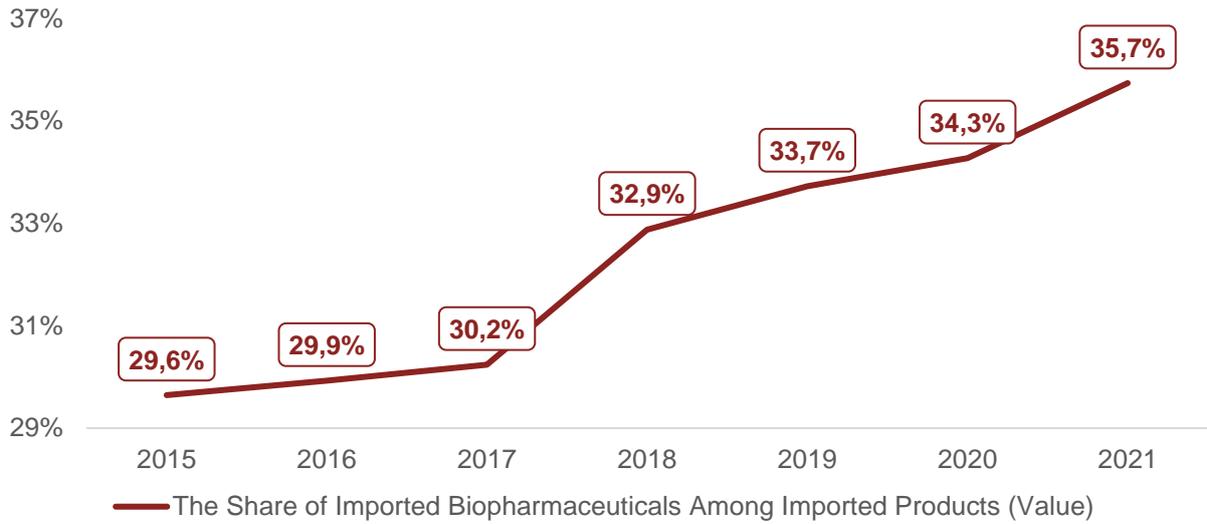
In terms of units, the share of biosimilars increased from 9.6% in 2015 to 35.5% in 2021.

Chart 15- Reference-Biosimilar Products Market Share (Volume)



Source: IQVIA, İEİS

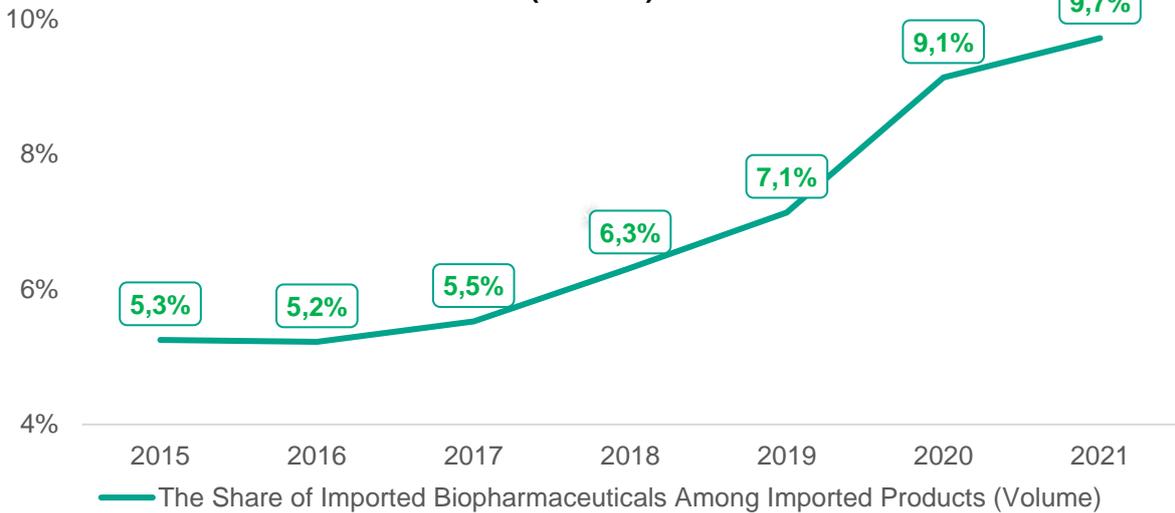
Chart 16- The Share of Imported Biopharmaceuticals Among Imported Products (Value)



Source: IQVIA, İEİS

The share of biopharmaceuticals in Turkish pharma market has been increasing consistently. The share of imported products, which accounted for 29.6% of the market in value and 5.3% in units in 2015, rose to 35.7% in value and 9.7% in units in 2021.

Chart 17- The Share of Imported Biopharmaceuticals Among Imported Products (Volume)



Source: IQVIA, İEİS

Blood and hematopoietic medicines have a significant share in the biosimilars market. In the reference biopharmaceuticals market, antineoplastics and immunomodulators and gastrointestinal and metabolic products have the top two spots in terms of value.

Table 5- Biotechnological Products

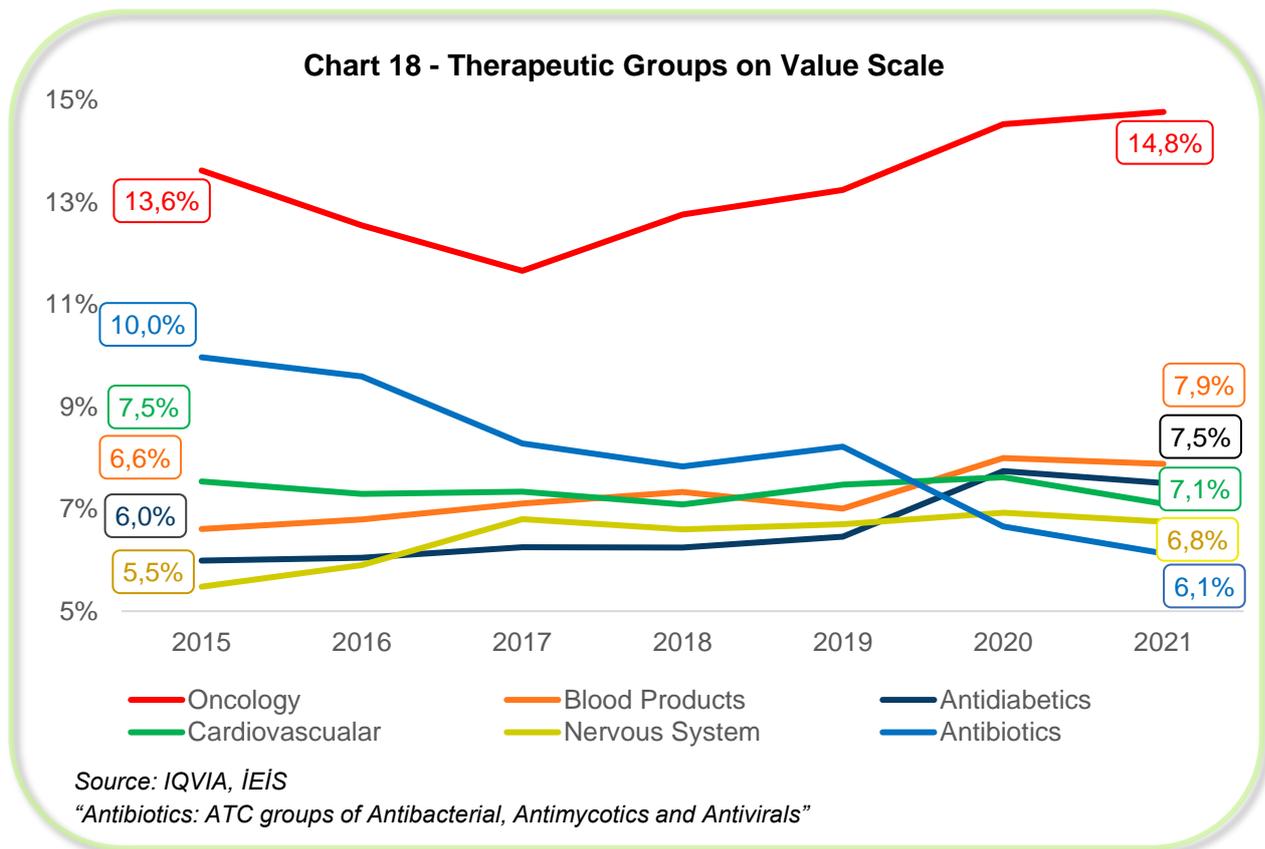
	Unit	Value
Biosimilar	100%	100%
Blood and hematopoietic organs	89,6%	59,2%
Antineoplastics and immunomodulatory agents	7,0%	36,1%
Systematic Hormonal Preparations (Excluding Sex Hormones and Insulins)	0,9%	2,7%
Digestive system and metabolism products	2,5%	2,0%
Reference	100%	100%
Antineoplastics and immunomodulatory agents	9,8%	42,0%
Digestive system and metabolism products	73,8%	26,7%
Blood and hematopoietic organs	2,3%	8,1%
Nervous System	0,5%	5,9%
Respiratory System	1,9%	3,8%
Genito Urinary System and Sex Hormones	5,8%	3,0%
Sensory Areas	0,8%	3,0%
Systematic Hormonal Preparations (Excluding Sex Hormones and Insulins)	3,2%	3,0%
Muscle-Skeleton System	1,3%	2,4%
Systematically Used Anti-infectives	0,5%	1,2%
Dermatology	0,1%	0,9%
Cardiovascular System	0,0%	0,0%

Source: IQVIA, IEIS

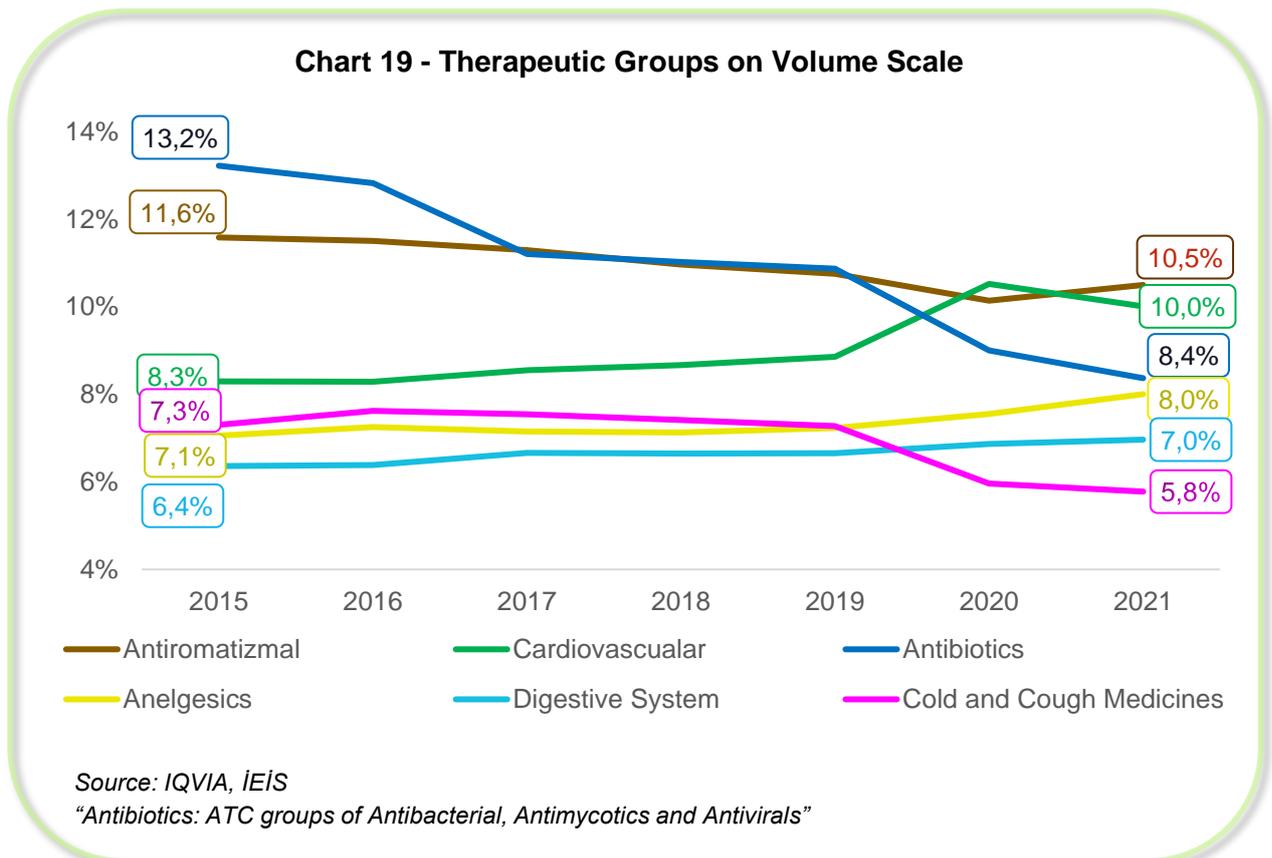
D. Therapeutic Categories

Looking at the top six therapeutic categories, which collectively represent 50.1% of the market by value, oncology drugs has maintained its clear leadership, increasing their market share from 13.6% to 14.8% in the last seven years. One of the key reasons behind the high market share of oncology drugs is the fact that they also account for the highest share among biologics by value.

Between 2015 and 2021, all therapeutic categories other than antibiotics and cardiovascular drugs saw an increase in market share.



In 2021, the market leading therapeutic category in terms of units were antirheumatic drugs with 10.5% and cardiovascular drugs with 10%. The decline in the market shares of antibiotics and cold medicine can be attributed to the pandemic measures and reduced access to hospitals due to COVID-19.



E. Average Prices

Between 2015 and 2021, average drug price climbed by 208% to TRY 26.23. This indicates a real drop of 24.9% when adjusted for inflation. From 2015 to 2021, only imported medicines saw an increase in prices in real terms, by recording 13.9% growth above inflation.

A comparison of average drug prices between 2020 and 2021 reveal a 20.5% growth in the pharmaceutical market as a whole; 19.5% in originators; 22.1% in generics; 23.2% in imported drugs; and 23.6% in local drugs.

Adjusted for inflation, these results indicate a 33% price drop in the overall pharmaceutical market; 33.5% in originators; 32.1% in generics; 31.5% in imported drugs; and 31.3% in local drugs.

Table 6 - Distribution of Average Product Prices

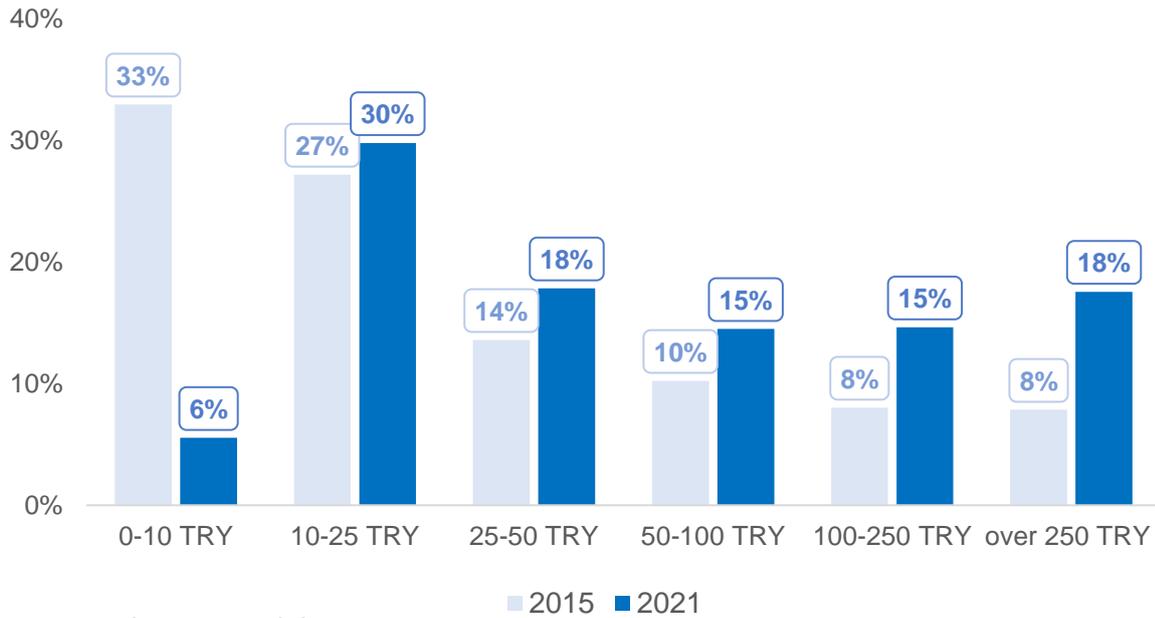
	Medicine	Originator	Generic	Import	Local
2015	8,52	13,55	4,63	23,50	4,59
2016	9,49	15,36	5,23	26,10	5,28
2017	11,03	18,16	6,02	30,94	6,25
2018	13,43	22,49	7,24	42,25	7,75
2019	17,21	29,23	9,53	66,82	10,22
2020	21,77	36,81	11,57	89,01	12,55
2021	26,23	44,00	14,13	109,69	15,51
Change Rate					
2015-2021	208%	225%	205%	367%	238%
2020-2021	20,5%	19,5%	22,1%	23,2%	23,6%
Real Change Rate					
2015-2021	-24,9%	-20,8%	-25,6%	13,9%	-17,6%
2020-2021	-33,0%	-33,5%	-32,1%	-31,5%	-31,3%

Source: IQVIA, IEIS

F. Retail Price Ranges

Looking at the retail price ranges for medicine in the 2015-2021 period, the percentage of products priced between TRY 0-10 show a 27% drop as a result of price increases due to exchange rate changes. In 2021, the market share of products priced at TRY 25 or less fell to 36%. Products priced between TRY 10-25 had the highest market share in 2021, with 30%.

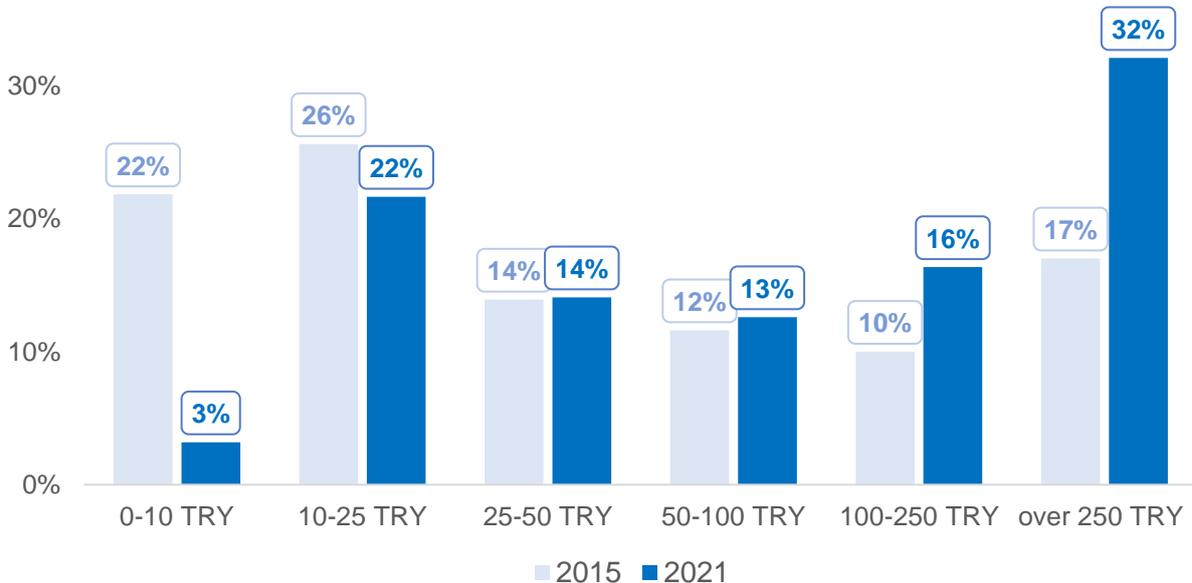
Chart 20- Retail Price Distribution



Source: TITCK, IQVIA, IEIS

The market share of originator drugs priced under TRY 25 saw a decline in market share in the last seven years, whereas the share of originators priced above TRY 50 increased. The highest increase was seen in the originator drugs prices above TRY 250, with 15 percentage points.

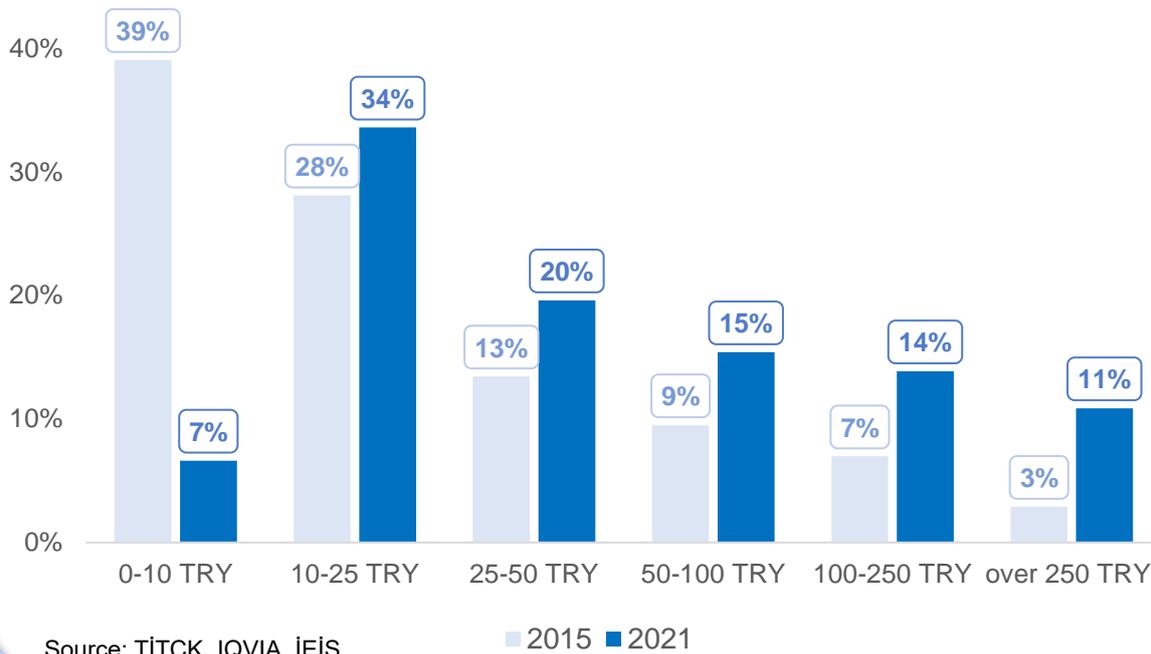
Chart 21 - Price Breakdown of Originator Products



Source: TITCK, IQVIA, IEIS

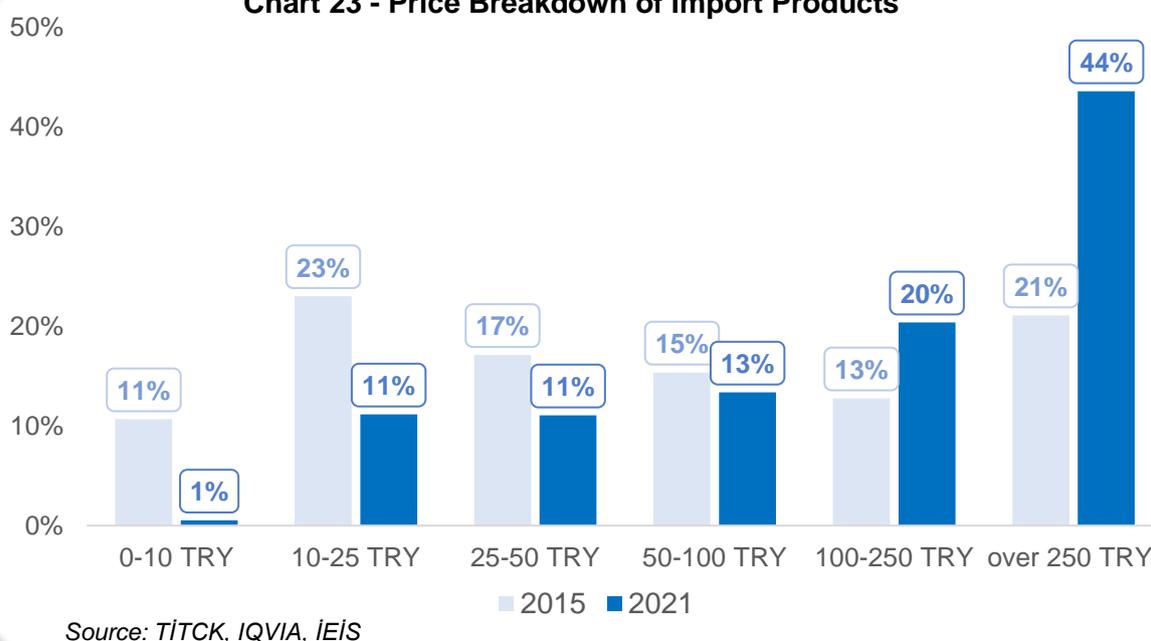
In generic drugs, products priced between TRY 10-25 had the highest market share in 2021, with 34%. Meanwhile, products priced between TRY 0-10 saw 32 percentage points shrinkage.

Chart 22- Price Breakdown of Generic Products



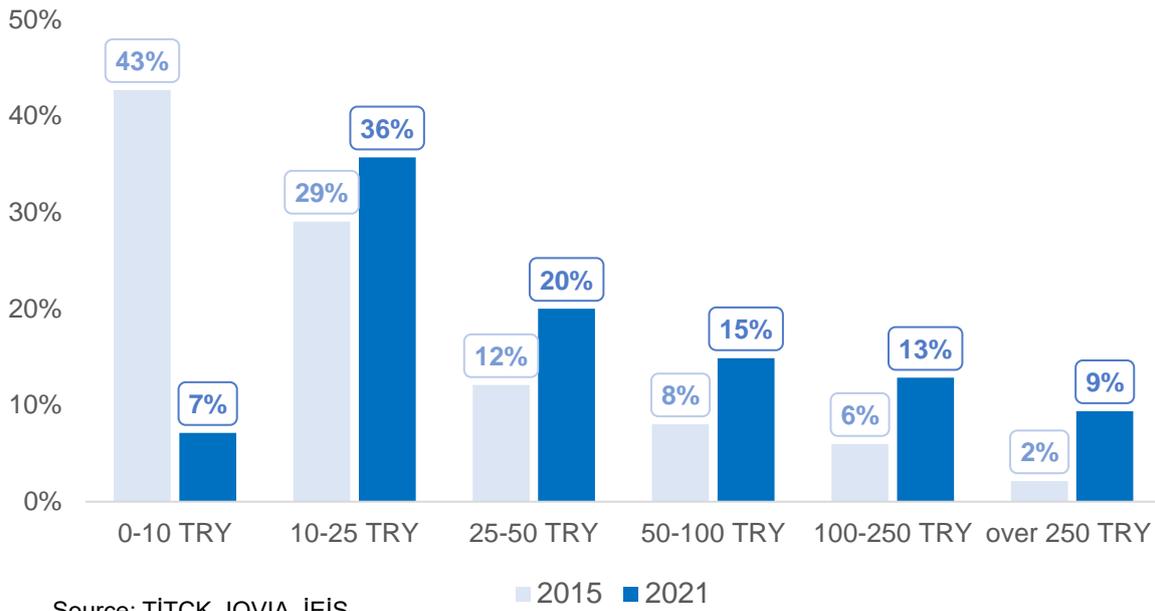
In imported products, the highest share increases in unit terms between 2015 and 2021 was achieved by products priced above TRY 100, while products priced above TRY 250 had the highest share in the same period with a rate of 44%.

Chart 23 - Price Breakdown of Import Products



In local products, products priced between TRY 10-25 had the highest market share with 36%. In 2021, products priced under TRY 25 accounted for 43% of the local drugs market. Looking at the breakdown of average imported and local prices, the importance of policies towards localization is made apparent once again.

Chart 24- Price Breakdown of Local Products

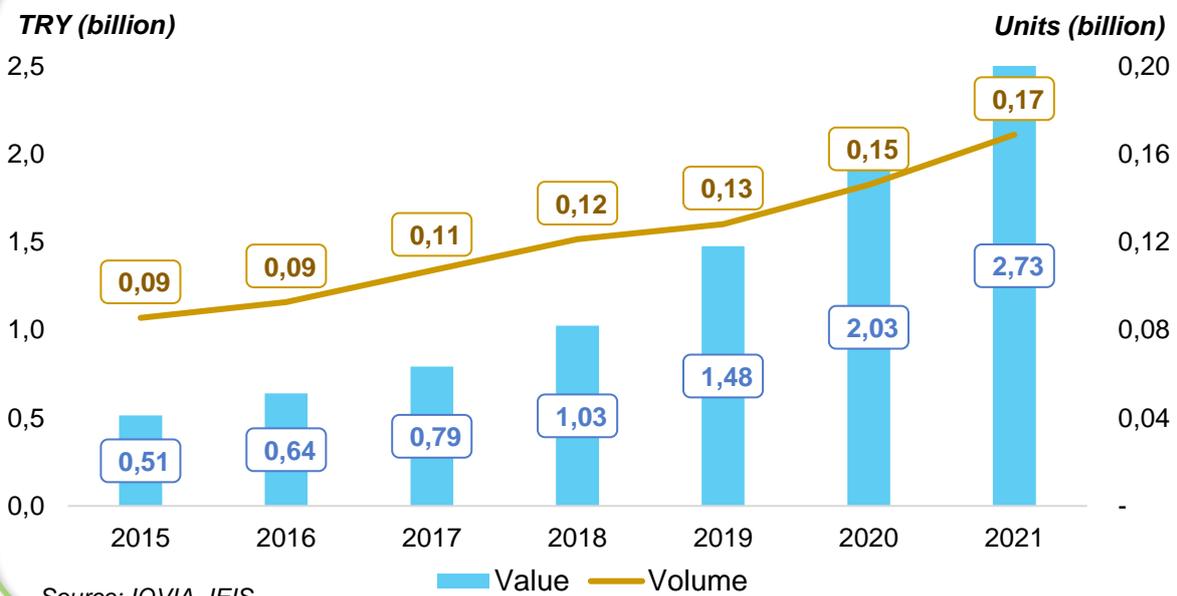


1.2. Medicinal Nutrition Market

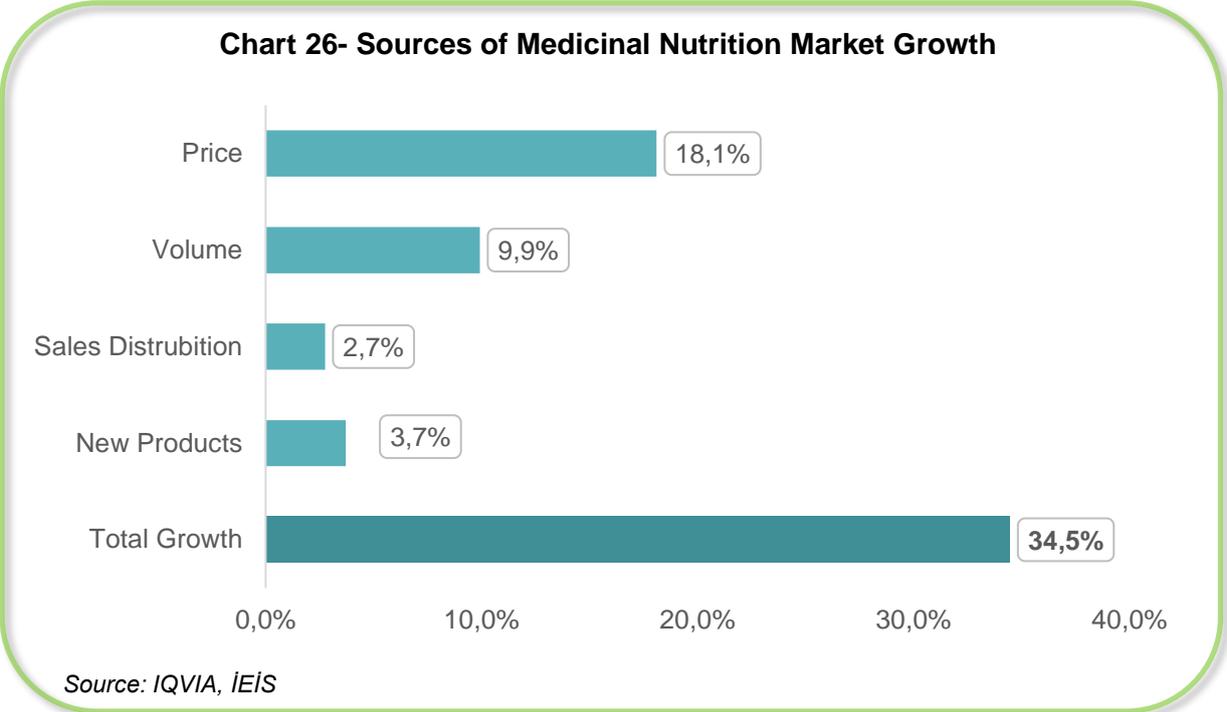
Medicinal nutrition market consists of Ministry of Health-approved enteral nutrition products and medical formulas. These products are developed to help meet the special nutritional or dietary needs of patients living with a disease, medical condition, or nutrition disorder, and form part of supportive care.

Imported originator products account for the entirety of the market in Türkiye, and 98.5% of these products are not included in the reimbursement scheme. In 2021, medical foods recorded 34.5% growth in value, reaching TRY 2.7 billion. Total growth between 2015 and 2021 is 431.5%, indicating a CAGR of 32.1%. Adjusted for inflation, this result is equivalent to a growth of 29.7% in real terms.

Chart 25- Medicinal Nutrition Market

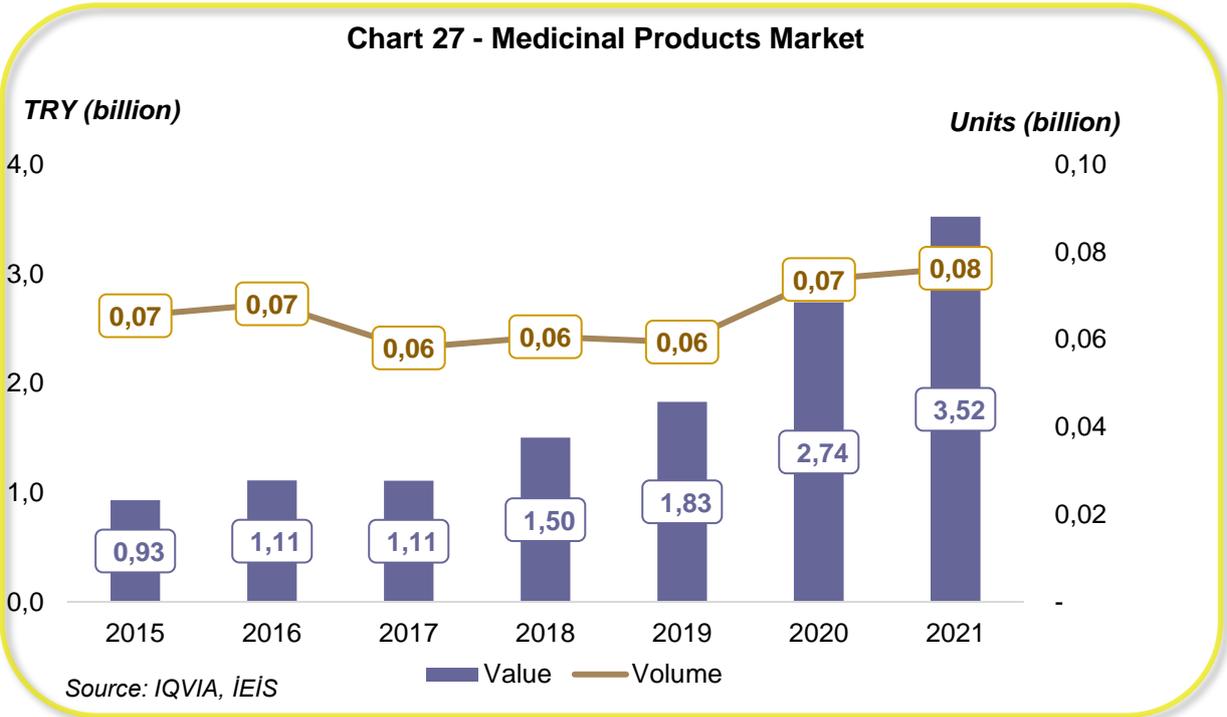


In 2021, the market saw a 15.7% growth in terms of units, whereas the overall volume growth between 2015 and 2021 was 97.4%. Average prices, on the other hand, rose from TRY 6 in 2015 to TRY 16.2 in 2021.

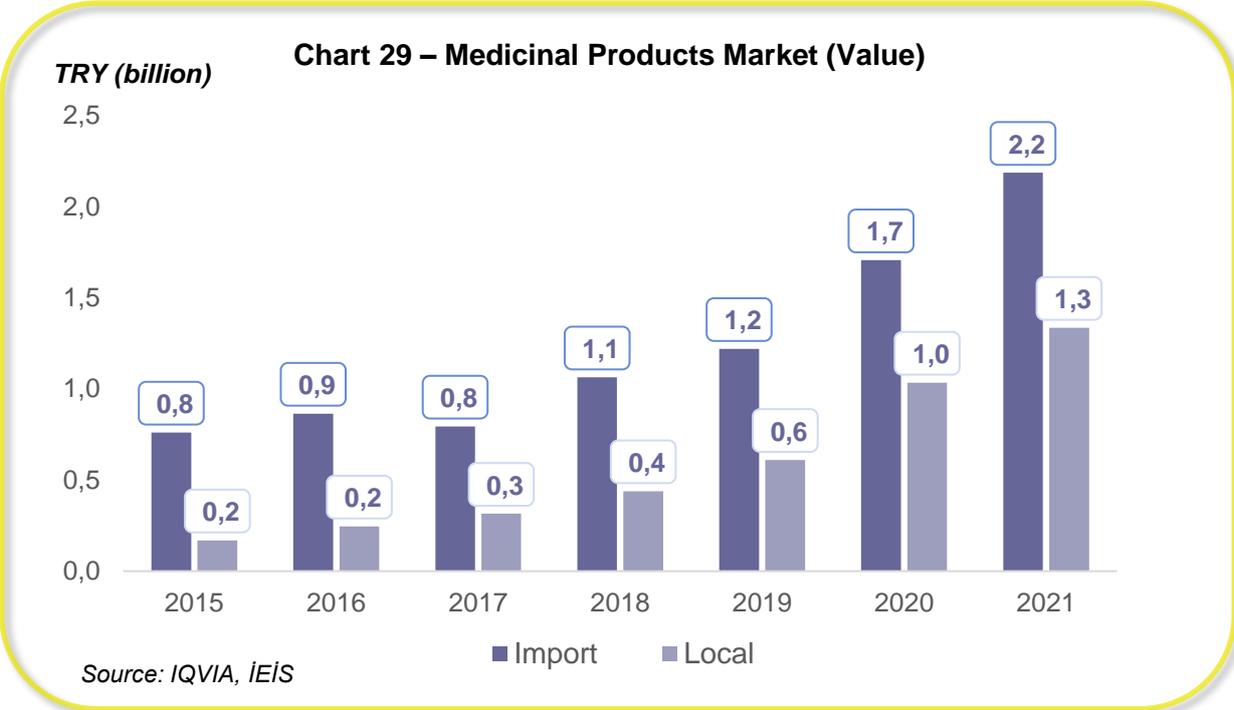
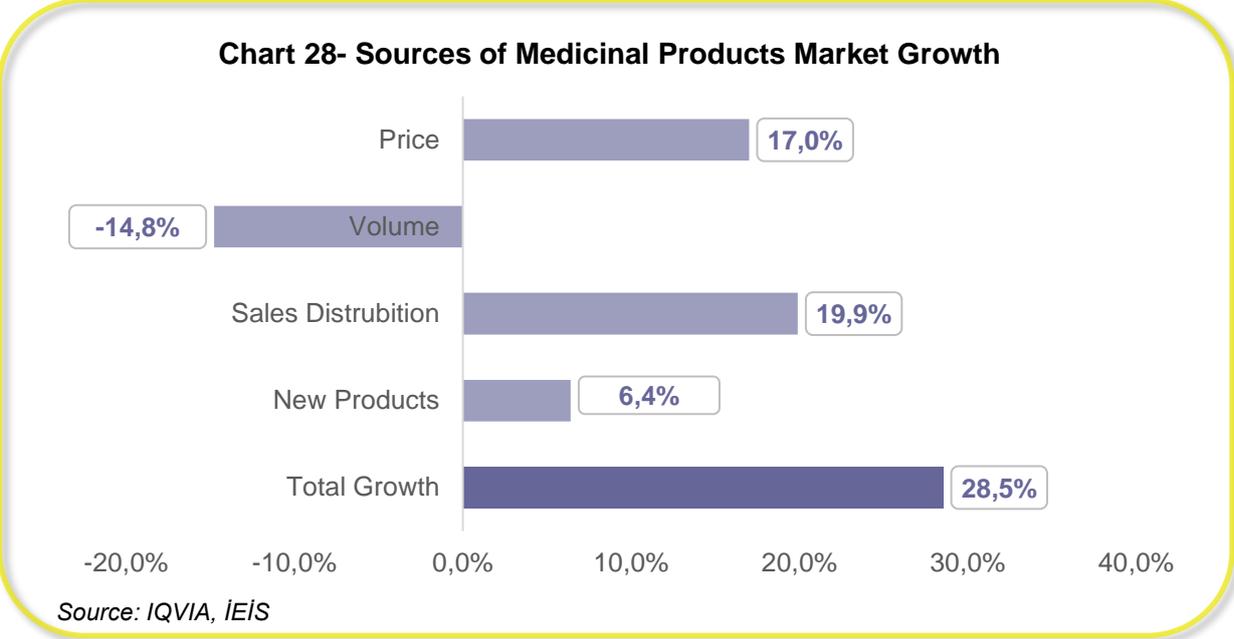


1.3. Medicinal Products Market

The market consists of Ministry of Health-approved herbal medicines, certain pharmaceutical devices, and Ministry of Agriculture and Forestry-approved vitamin and dietary supplements and baby formulas.



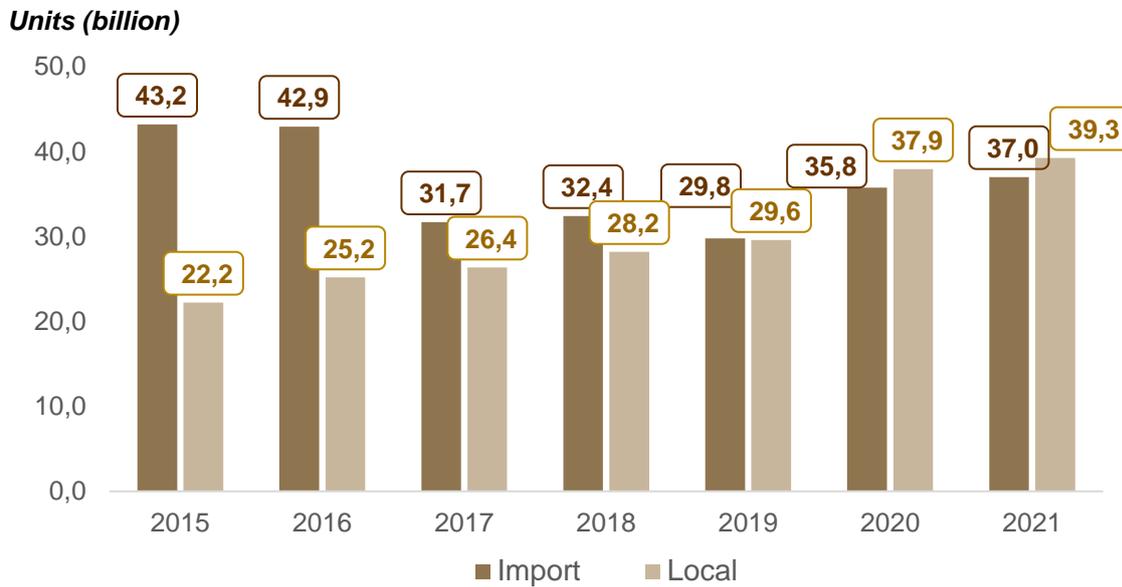
The market posted a significant expansion in 2020 because of the COVID-19 pandemic, which reduced access to physicians and hospitals and created widespread awareness on the importance of immunity, growing 3.5% in units to 76 million boxes and 28.5% in value to TRY 3.52 billion in 2021. Vitamins and dietary supplements comprise 68% of the healthcare products market, which grew three-fold in the past seven years.



In 2021, imported healthcare products grew 28.1% in value to reach TRY 2.2 billion, while local products grew 29.1% in value to reach TRY 1.3 billion. Looking at the 2015-2021 period, imported products grew 187% in value, locals 689%, whereas the overall market grew 278%.

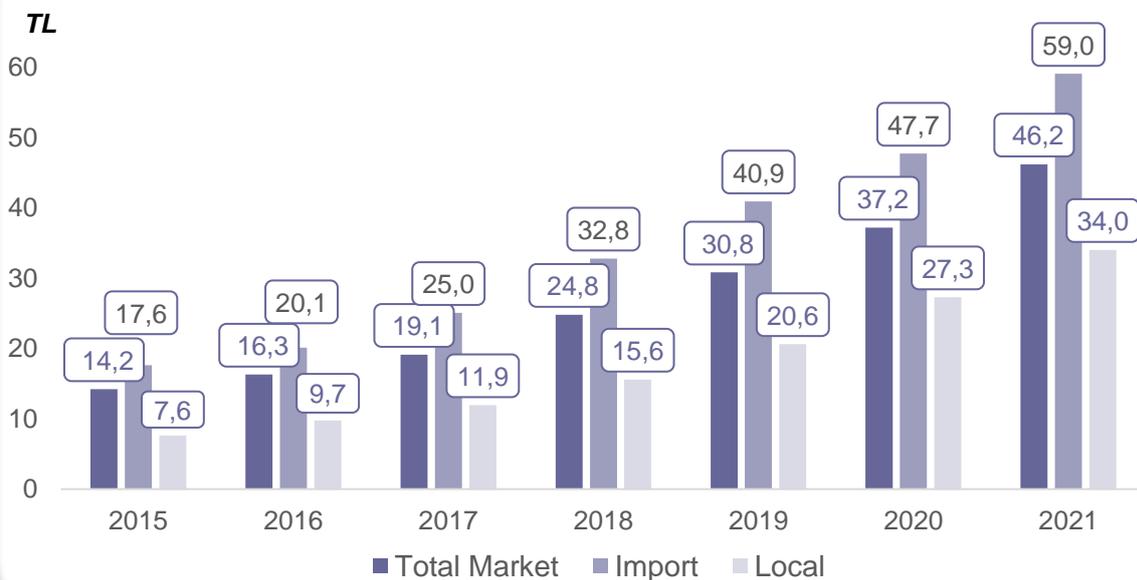
In terms of units, the medicinal products market saw 3.5% growth in both imported and local products, which reached 37 million and 39.3 million units, respectively. Between 2015 and 2021, imported products shrank by 14.3% while local products grew 76%, whereas the overall healthcare products market posted a growth of 16.6%.

Chart 30 – Medicinal Products Market (Volume)



Source: IQVIA, İEİS

Chart 31 - Medicinal Products Market Average Price Distribution



Source: IQVIA, İEİS

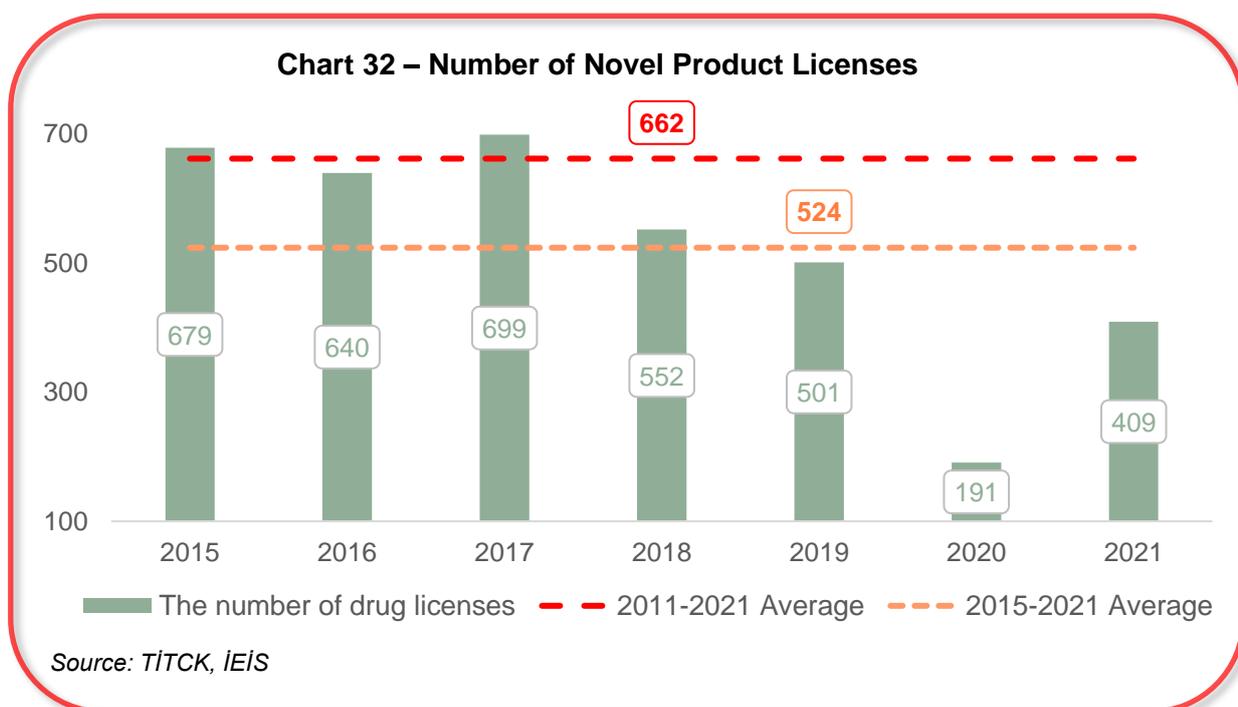
The average price climbed from TRY 14.2 in 2015 to TRY 46.2 in 2021 with a 225% increase. During the same period, average price of imported products rose 235%, compared to 347% for local products.

2. Licensing

In the process of approving new product licenses, which has slowed down considerably in recent years, 2021 closed with 409 new licenses, still below the average yearly number of 622 licenses for the 2011-2021 period.

Challenges associated with new drug licensing have intensified over the years to become one of the main obstacle to the development of the industry. The problem peaked in 2020, and despite a brief recovery in 2021, there remains a need for expedited processes if the backlog is to be reduced. The Regulation on the Registration of Medicinal Products for Human Use, published in the Official Gazette dated 11 December 2021 and numbered 31686 is expected to have a positive impact on the licensing processes.

Prolonged licensing process and the lack of new drugs introduced to the market affect the long-term investment and planning of companies while also reducing consumers' access to alternative medications. Furthermore, the lack of new drugs on the market have also negative impacts on public budget and exports due to impact on production, employment, and SSI procurements.



3. Investment Incentives

The Cabinet Decree No. 2009/15199, which entered into force in 2009, introduced several large-scale improvements aimed at investment incentives, bringing together individual incentives previously granted by various public agencies under the centralized control of the Ministry of Trade. In addition to general and local incentives aimed at the pharmaceutical industry, this decree also involved giving priority investment status to biopharmaceutical, oncology and hematopoietic drugs.

In 2015, Cabinet Decree No. 2012/3305 made it possible for pharmaceutical investments to benefit from the Fifth Region incentives. As a result of these changes, the pharmaceutical industry received TRY 35.4 billion in fixed investment incentives between 2015 and 2021. The investments enabled by these incentives is expected to create 11,830 new jobs.

Total value of fixed investments, which stood at TRY 817 million in 2015, reached TRY 4 billion TL in 2021 with a 388% increase. The investments led to the creation of 2,473 new jobs with a 156% increase.

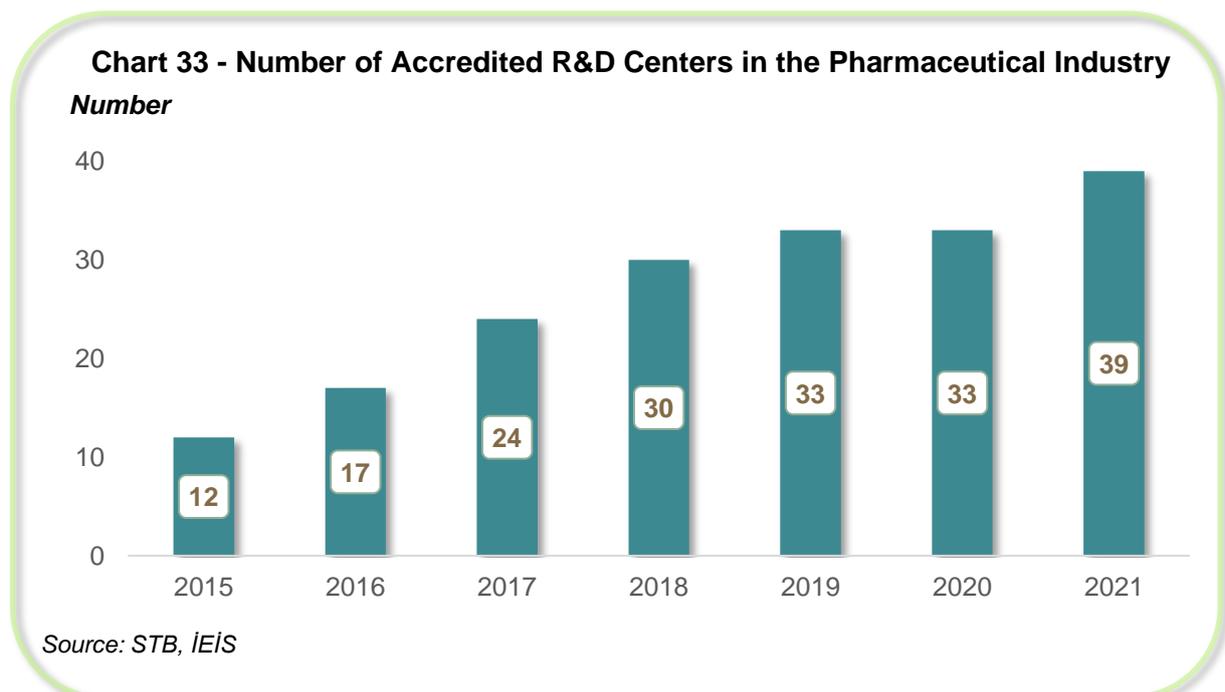
Table 7- Investment Incentives in the Pharmaceutical Industry

	Number of Documents		Fixed Investment (Million TRY)			Employment via Investment		
	Medicine	Total	Medicine	Total	Share	Medicine	Total	Share
2015	21	4.182	817	114.501	0,71%	965	144.319	0,67%
2016	15	4.944	1.209	120.008	1,01%	865	155.149	0,56%
2017	31	7.219	13.445	213.979	6,28%	1947	226.570	0,86%
2018	28	5.720	1.453	196.436	0,74%	1117	247.172	0,45%
2019	36	5.606	5.200	189.261	2,75%	1072	200.930	0,53%
2020	49	10.412	9.302	286.829	3,24%	3391	295.276	1,15%
2021	41	12.714	3.984	284.204	1,40%	2473	380.037	0,65%

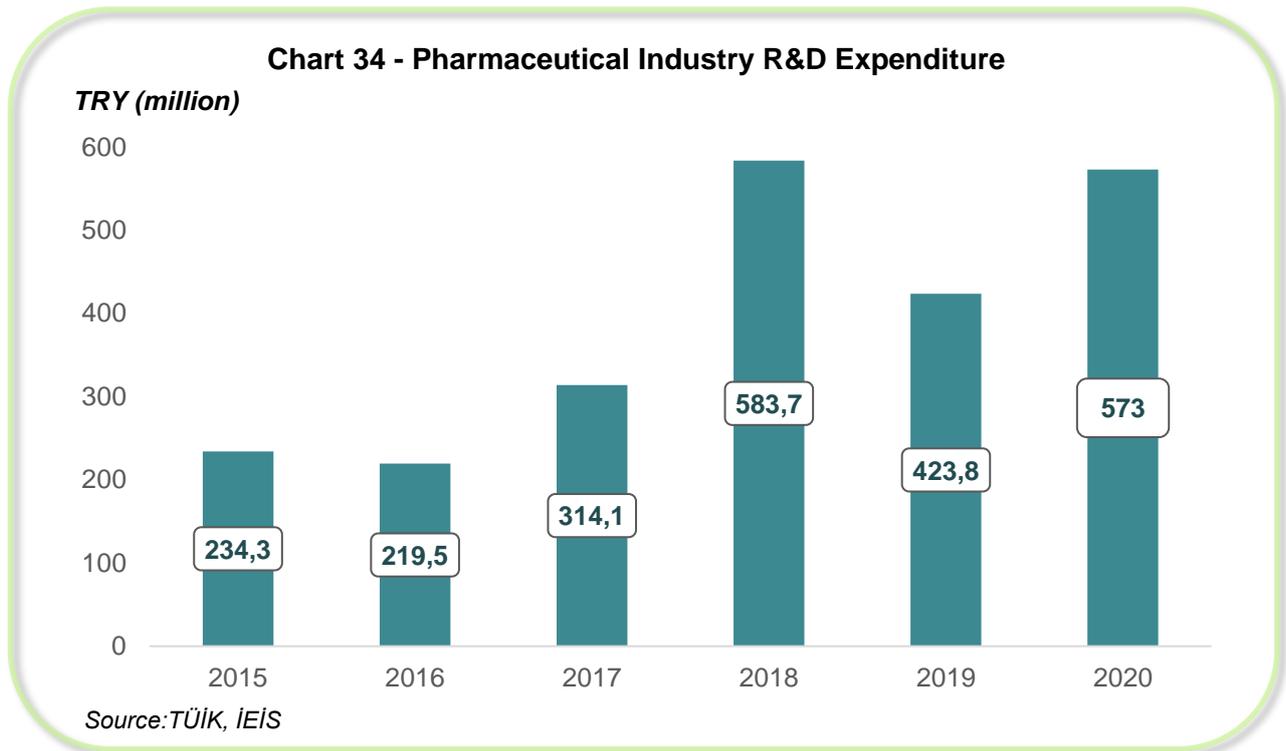
Source: Ministry of Industry and Technology, IEIS

4. R&D

The pharmaceutical industry is one of the key drivers of Türkiye's industrial transformation with 39 Ministry of Industry and Technology-accredited R&D centers employing approximately 1.575 personnel in total. The advances in R&D will enable domestic manufacturing of products for which Türkiye is currently dependent on imports.



The number of incentives granted to pharmaceutical R&D centers climbed from TRY 234.3 million in 2015 to TRY 573 million in 2020 with a 145% increase.



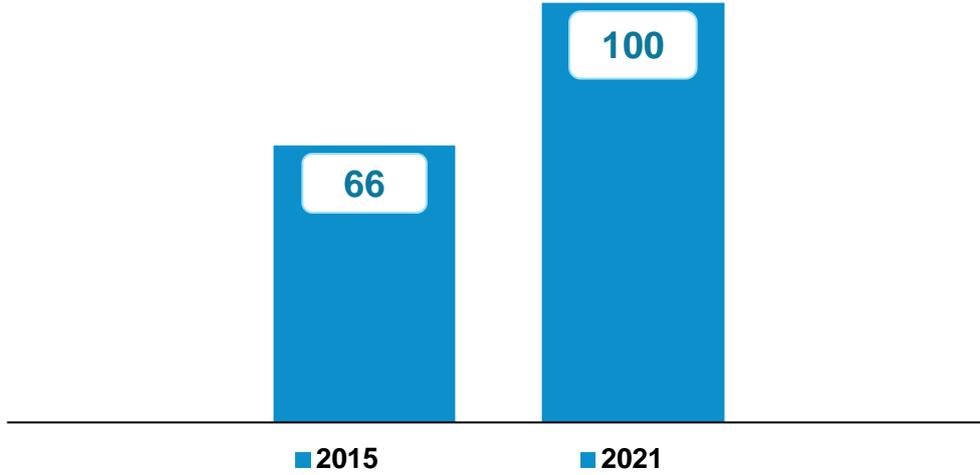
5. Production

The Turkish pharmaceutical industry is characterized with long standing historical background, high production capacity, and a strong technology base. Our country has 100 pharmaceutical and radiopharmaceutical and 12 raw material production facilities at international standards.

One of the priority agenda items of the industry is local production. The localization initiative commenced by the Ministry of Health in 2016 had a significant impact on the country's pharmaceutical industry. The initiative paved the way for investments in new technologies, which in turn improved capacity utilization and employment. Naturally, the investments and the subsequent capacity increases had a positive impact on foreign trade.

However, after successful phase 1 and phase 2 runs, phases 3 and 4 of the initiative were abandoned due to the complaint filed by the European Union before the World Trade Organization (WTO). Yet, the Healthcare Industries Guidance Committee (SEYK) meetings in June and July 2021 decided that the localization initiatives continue from where they were left off, independently from the WTO processes. We expect that the localization policy, which was executed meticulously during its implementation, to be pursued with the same determination.

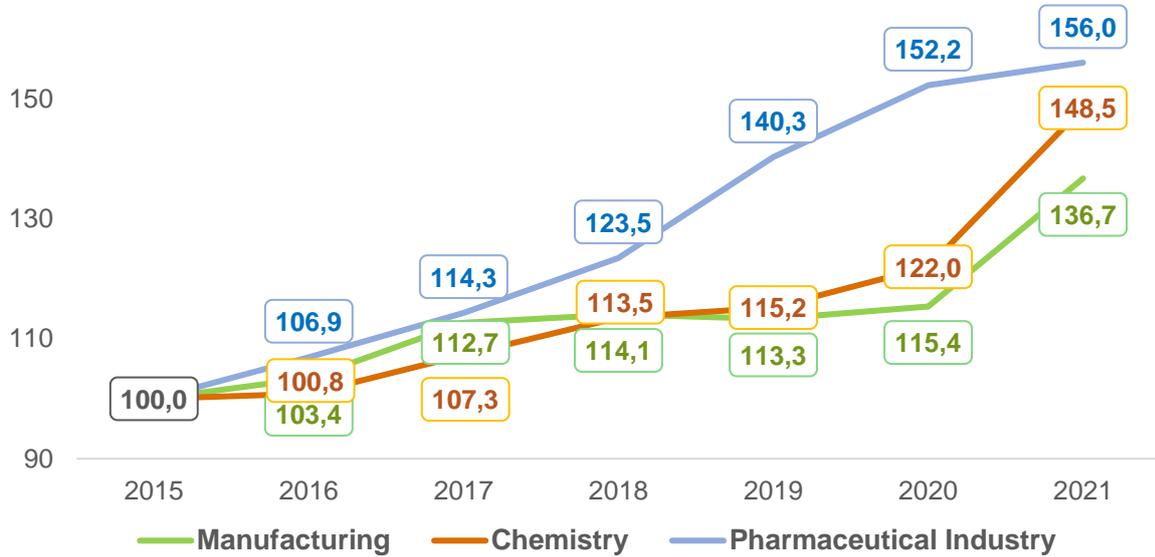
Chart 35 - Number of Production Facilities



Source: TITCK, IEIS

According to the industry production index data for 2021, manufacturing industry grew 18.5% to 136.7 points, chemicals industry grew 21.7% to 148.5 points, whereas the pharmaceutical industry's growth was limited to 2.5%, bringing it to 156 points. Between 2015 and 2021, manufacturing industry recorded 35.9% growth, compared to the medium-technology chemicals industry with 47.7% and the pharmaceutical industry with 55.5%.

Chart 36- Industrial Production Index Change (2015-2021)



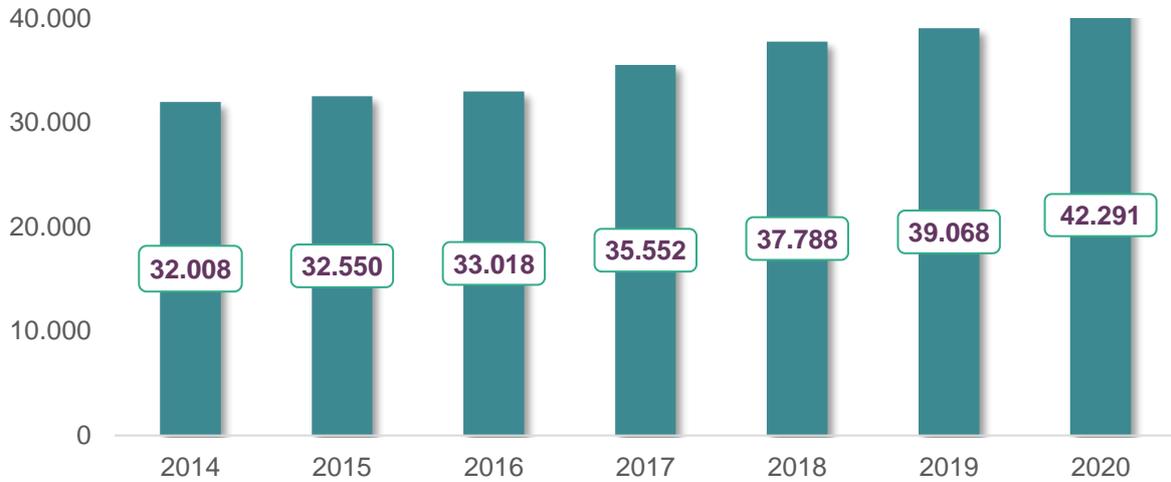
Source: TÜİK, IEIS

6. Employment

In 2020, total employment in Türkiye increased 1.9% year-over-year. During the same year, total employment in the pharmaceutical industry grew 8.2% to 42,291.

Chart 37 - Employment in the Pharmaceutical Industry

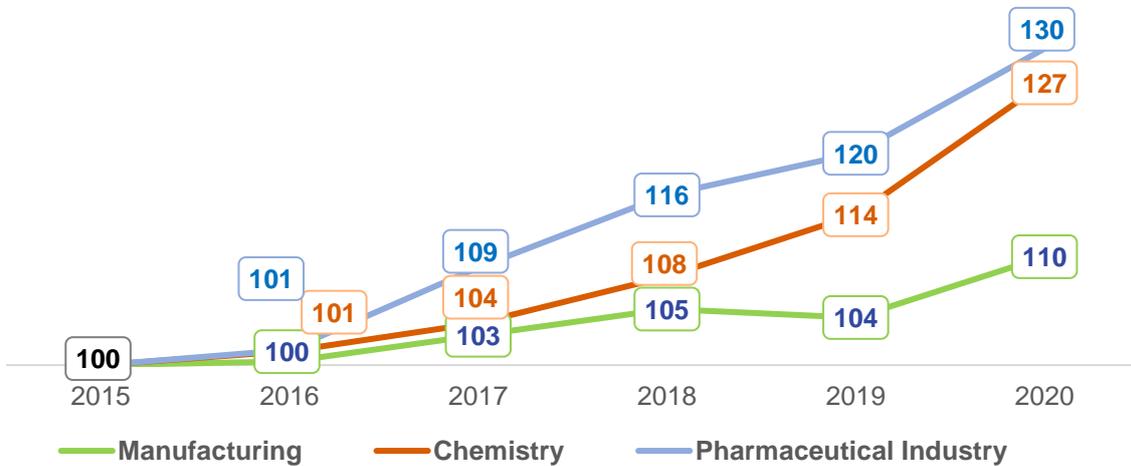
Number of people



Source:TÜİK, İEİS

Based on the employment indices for the 2015-2020 period, the pharmaceutical industry's employment growth rate is 30%, which is above Turkish average.

Chart 38- Employment Index Change (2015-2020)

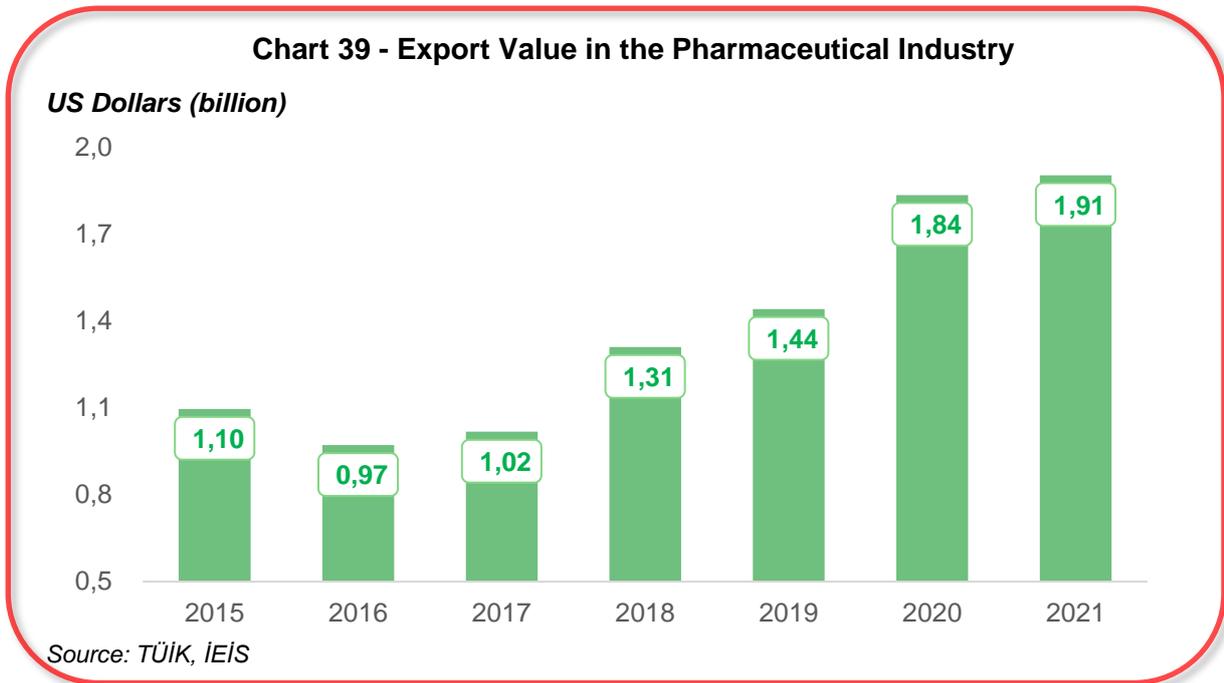


Source:TÜİK, İEİS

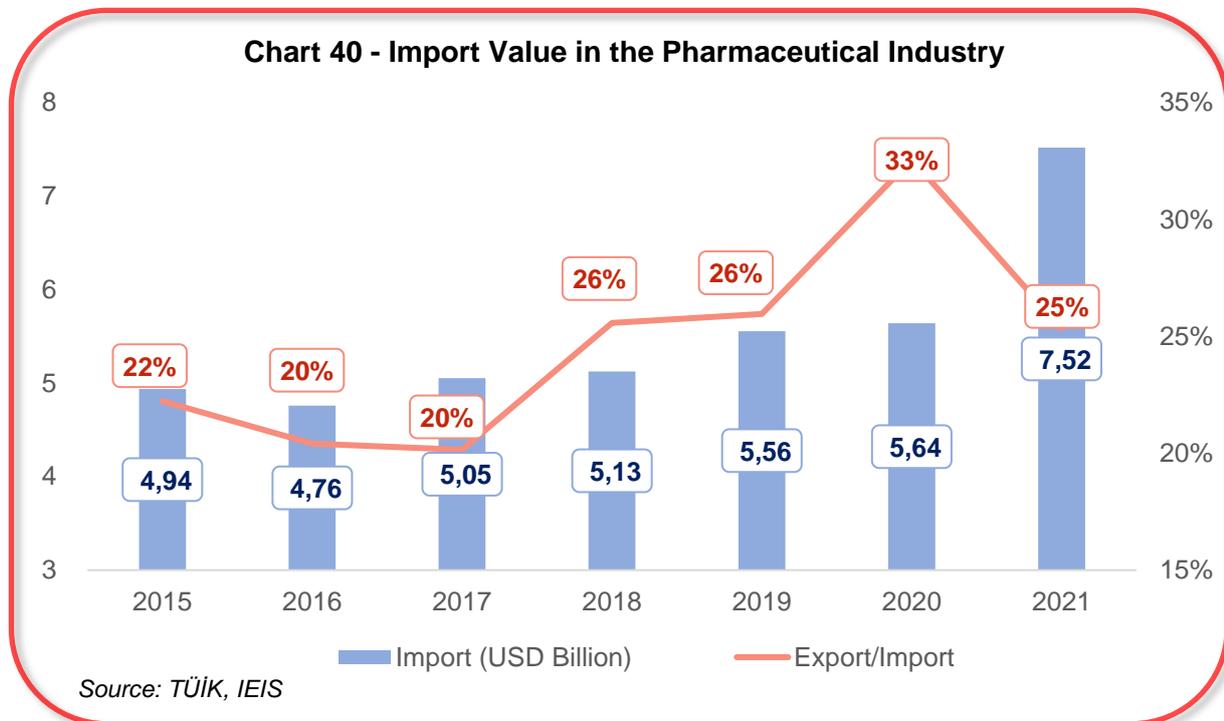
7. Foreign Trade

The pharmaceutical industry has seen a strong upwards trend in recent years with the introduction of the localization policies in 2016, contributing to the country's exports by breaking its export records each year. In 2021, pharmaceutical exports grew 3.7% to reach the USD 1.91, an all-time high. Between 2015 and 2021, when Türkiye's exports surged 49.2% in total, pharmaceutical exports managed to outperform the country's average with a 73.7% growth rate.

However, export growth rate in 2021 is behind those of previous years. In fact, the 2021 growth of 3.7% is significantly below the year-over-year increase recorded in 2020, which was at 32.1%.

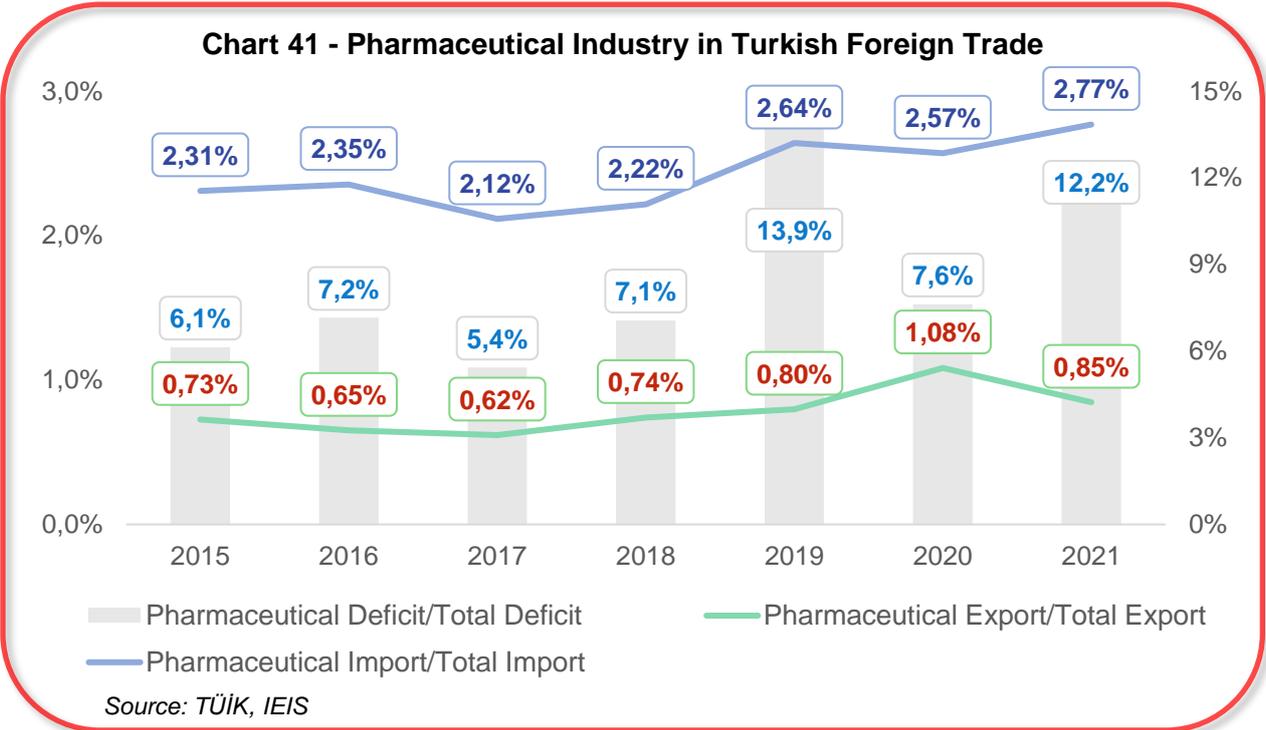


In 2021, pharmaceutical imports grew 33.3% to USD 7.52 billion. The growth rate of pharmaceutical imports was 52.3% between 2015 and 2021.

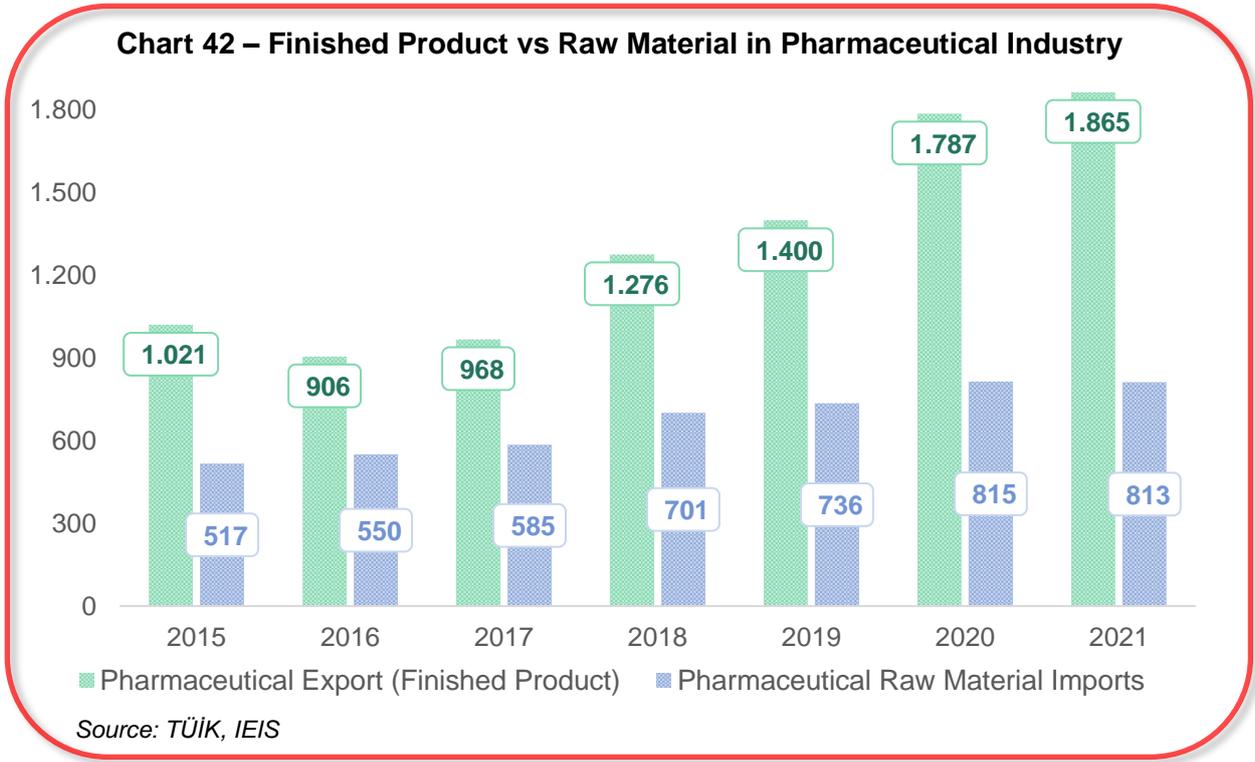


The share of pharmaceutical exports in Türkiye's overall exports exceeded 1% for the first time in history in 2020. In 2021, the share of pharmaceuticals in foreign trade climbed to 12.2% because of its 0.85% share in exports, and 2.77% share in imports.

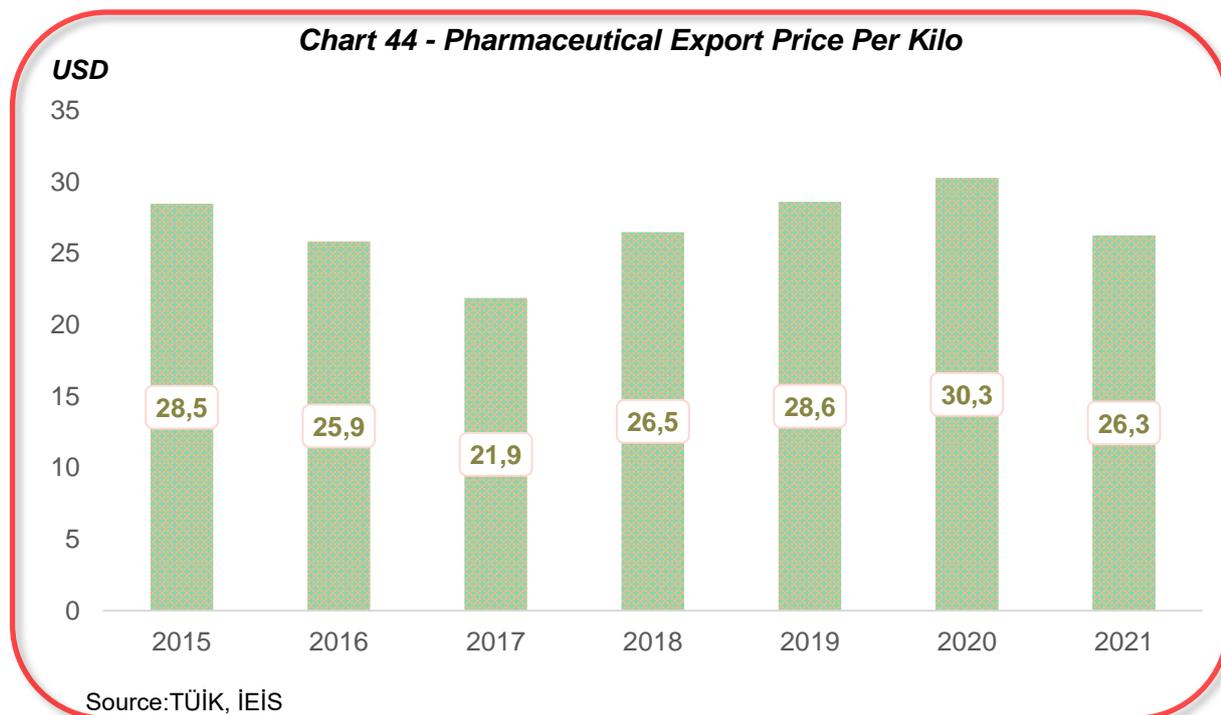
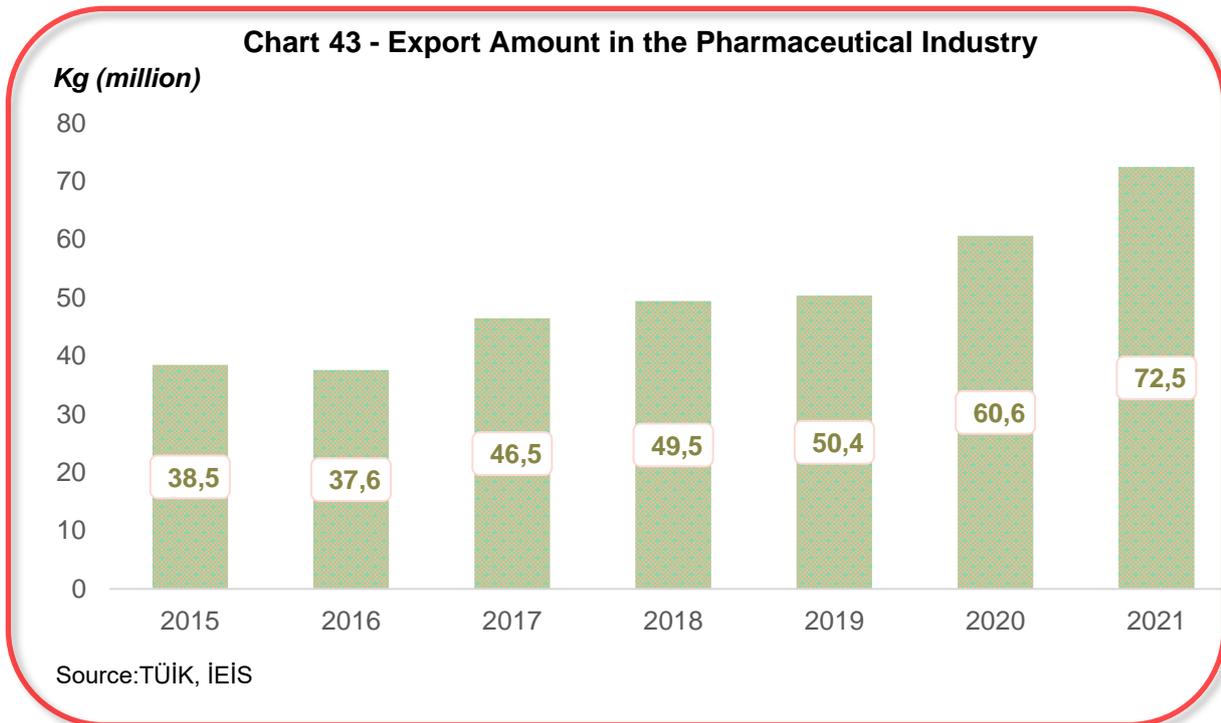
These rates show once again the strategic value and the high-value-added nature of the pharmaceutical industry.



An evaluation of the pharmaceutical raw material imports and finished product exports reveals the industry’s degree of contribution to the national economy. In 2021, the industry imported raw materials worth USD 813 million, and exported products worth USD 1.86 billion. Meeting the need for finished products through local production rather than imports would also drive-up exports and in turn reduce the foreign trade deficit.

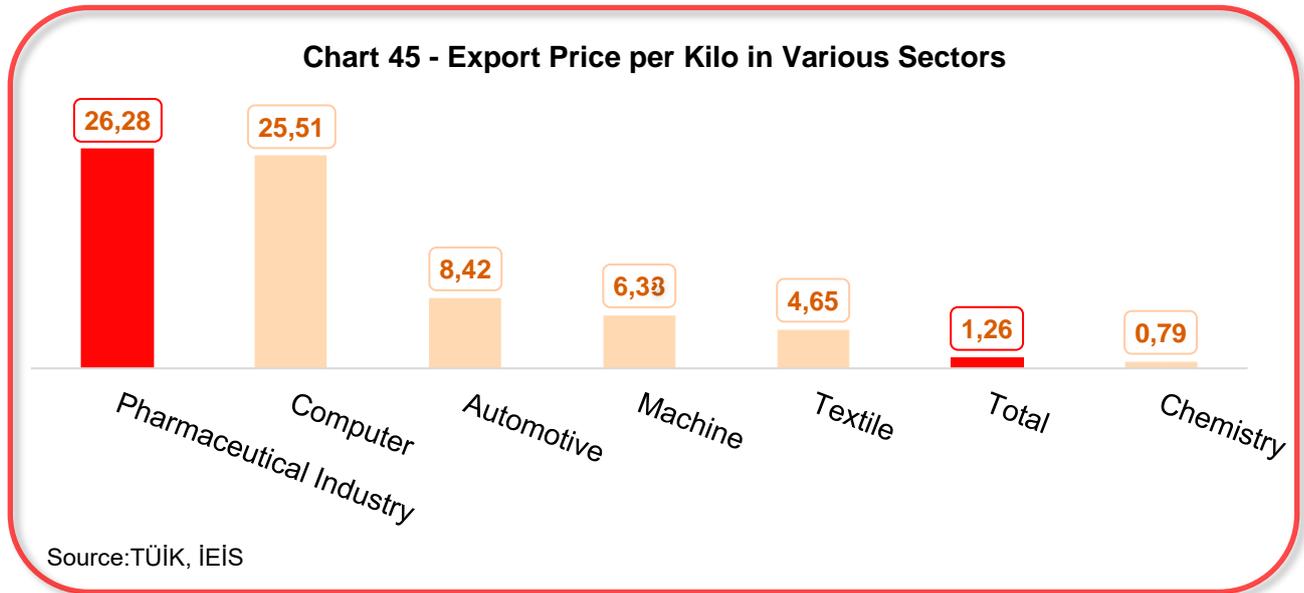


Looking at the export volumes between 2015 and 2021, pharmaceutical industry's exports climbed 88.3% from 38.5 million kg in 2015 to 72.5 million kg in 2021.



Pharmaceutical export is increasing based on kilogram but export price per kilogram is not increasing with the same rate. During the same period, per-kilogram export price fell 7.8%, down from USD 28.5 to USD 26.3. The price-oriented policies implemented in Türkiye stand out as the main reason behind the lower kilogram prices, and consequently, lower exports.

The per-kilogram export price of the pharmaceutical industry is higher than many other industries and above the Turkish average of USD 1.26, but still below the potential value-added of its products.



The fact that the drug prices in our country are accepted as reference/source in the countries to which we export to causes Turkish exporters enter other countries' markets with a price that is lower than it should. Challenges associated with licensing and customs procedures in export markets, as well as exports by unauthorized third-party sellers who take advantage of the pricing policies supported by pharmaceutical companies for public benefit are the main issues Turkish pharmaceutical industry must overcome if it is to become one of the top pharmaceutical manufacturers and exporters in the globe.

Looking at the export markets, in 2021, the industry exported its products to 190 countries, with the EU, CIS, North Africa and Middle East as the major destinations. Asia was the biggest pharmaceutical export market with 53.4% followed by Europe with 35.7%. The top 20 export markets in 2021 accounted for 70% of all pharmaceutical exports.

Table 8 – First Twenty Countries in Pharmaceutical Export

USD (million)	2020	2021	Share (2021)	Change
South Korea	616	368	19%	-40%
Azerbaijan	64	145	8%	127%
Iraq	92	109	6%	19%
Iran	38	100	5%	165%
Bulgaria	34	76	4%	121%
Kazakhstan	66	73	4%	10%
Uzbekistan	58	66	3%	14%
Georgia	48	45	2%	-8%
Albania	25	44	2%	78%

T. R. N. C	32	36	2%	11%
Germany	34	34	2%	2%
Poland	32	33	2%	1%
Switzerland	39	31	2%	-20%
Brazil	12	30	2%	153%
Syria	28	27	1%	-4%
Slovenia	33	27	1%	-20%
Moldova	20	26	1%	29%
Russian Fed.	18	23	1%	26%
Libya	24	24	1%	0%
Hong Kong	17	23	1%	38%
Total of List	1.331	1.339	70%	1%
Total Export	1.836	1.905	100%	4%

Source: TÜİK, IEIS

In 2021, Türkiye imported pharmaceutical products from 125 countries, with 64.5% of these imports originating in Europe, and 25.7% originating in Asia. The top 20 import destinations in 2021 accounted for 97% of all pharmaceutical imports.

Table 9 – First Twenty Countries in Pharmaceutical Import

USD (million)	2020	2021	Share (2021)	Change
Belgium	158	1.360	18%	760%
Germany	1.116	1.285	17%	15%
China	449	1.180	16%	163%
USA	543	564	8%	4%
Ireland	351	429	6%	22%
Italy	413	377	5%	-9%
Switzerland	342	365	5%	7%
South Korea	598	361	5%	-40%
France	299	304	4%	2%
India	233	213	3%	-9%
United Kingdom	188	168	2%	-11%
Spain	139	149	2%	8%
Brazil	91	86	1%	-5%
Sweden	85	75	1%	-12%
Austria	74	69	1%	-7%
Denmark	72	67	1%	-7%
Singapore	47	65	1%	39%
Japan	60	57	1%	-5%
Netherlands	91	50	1%	-46%
Greece	35	47	1%	34%
Total of List	5.384	7.271	97%	35%
Total Import	5.642	7.516	100%	33%

Source: TÜİK, IEIS

Table 10 – First Five Products in Pharmaceutical Exports - US Dollars (million)

CTSP	Product	2020	2021	Share (2021)	Change
3004	Medications prepared for usage in treatment or prevention (dosed)	1.076	1.262	66%	17%
3002	Human blood, animal blood, serum, vaccines, toxins, etc.	652	534	28%	-18%
3006	Pharmaceutical goods and ready-mades that are not included in any other part of the Tariff	43	54	3%	27%
3003	Medications mixed for usage in treatment or prevention (no dosage)	15	14	1%	-6%
2936	Pro-vitamins and vitamins	15	10	1%	-31%
Total of List		1.801	1.875	98%	4%
Total Export		1.836	1.905	100%	4%

Source: TÜİK, IEIS

Looking at the customs tariff statistical positions of pharmaceutical products in 2021, blood products, serums, vaccines, toxin products and medications for curative and preventative medicine accounted for 98% of exports and 91% of imports.

Table 11 – First Five Products in Pharmaceutical Import - US Dollars (million)

CTSP	Product	2020	2021	Share (2021)	Change
3002	Human blood, animal blood, serum, vaccines, toxins, etc.	2.151	3.963	53%	84%
3004	Medications prepared for usage in treatment or prevention (dosed)	2.422	2.487	33%	3%
2941	Antibiotics	184	144	2%	-22%
3001	Heparin And Its Salts; Other Human Or Animal Substances Prepared For Therapeutic Or Prophylactic Uses	108	143	2%	32%
3003	Medications mixed for usage in treatment or prevention (no dosage)	146	140	2%	-4%
Total of List		5.011	6.877	91%	37%
Total Import		5.642	7.516	100%	33%

Source: TÜİK, IEIS

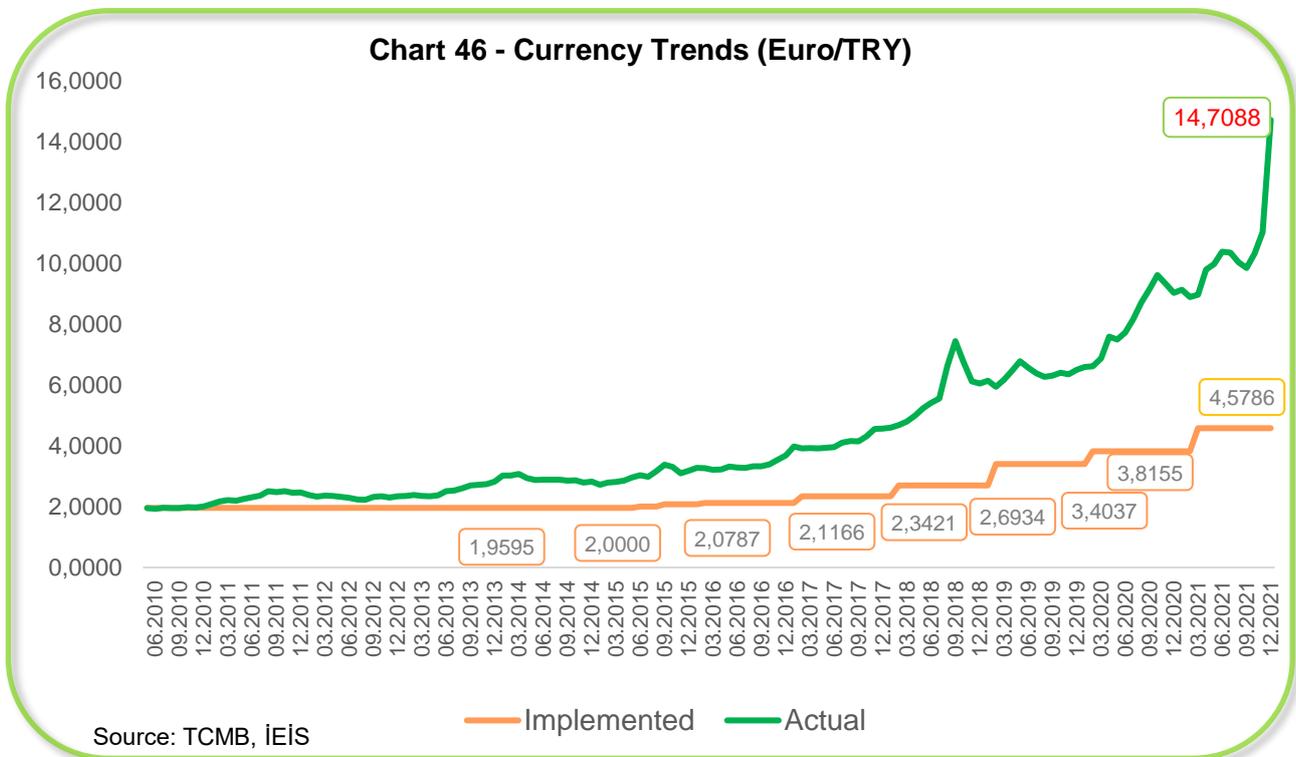
8. Price Policies

The global budgeting scheme, which was introduced in 2009 to alleviate the burden of the global economic crisis on public funds, attempted to control health expenditures exclusively through measures aimed at drug prices. This scheme involved drug budgets which were disproportionate with the level of services rendered and led to drug prices being lowered and SSI discount rates increased continuously on the grounds of overspending. Furthermore, the EUR-TRY exchange rate used for pharmaceutical products imported from the EU was kept at a fixed TRY 1.9595 for a significant amount of time between April 2009 and May 2015 to keep drug expenses

under control, even though the conditions for a price revision, as specified in the legislation, were met.

The pharmaceutical industry filed a legal petition demanding that the exchange rate be revised and was granted this request in April 2015. Consequently, the policy was revised to accommodate for a dynamic exchange rate, which would be equivalent to the 70% of the previous year's average. Accordingly, the exchange rate was set at TRY 2.3421 for the year 2017. However, in 2018, a provisional decree limited the exchange rate increase to 15% instead of the stipulated 23%, limiting the exchange rate at TRY 2.6934.

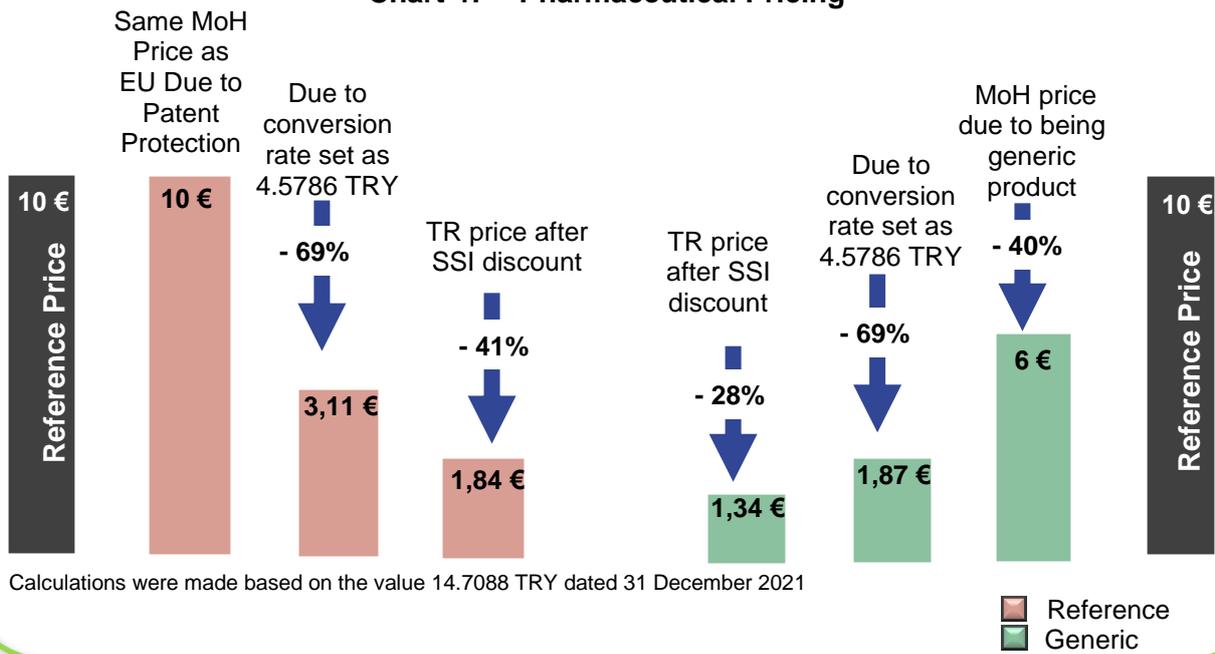
An amendment in 2019 reduced the coefficient used to calculate the annual exchange rate from 70% to 60%, resulting in the effective exchange rate to be TRY 3.4037 for the year, and in 2021, while there should be a 26.5% increase, once again another provisional decree limited the increase to 20% and fixed the exchange rate at TRY 4.5786 for the year.



Furthermore, the industry is subject to Social Security Institution (SSI) discounts that can reach 41%, and at times, exceed 50%, creating additional pressure. SSI's cost-oriented reimbursement system has caused the drug prices in Türkiye to fall behind not only Europe, which serves as a reference point for Türkiye, but also India, which Türkiye procures raw materials from.

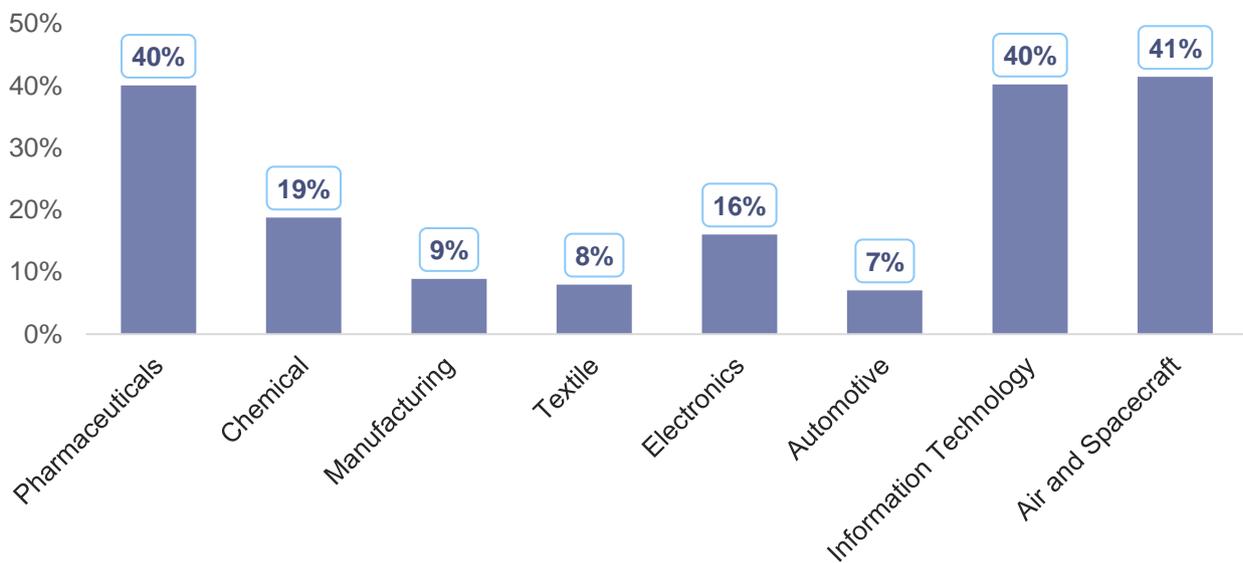
The graph below summarizes the pricing of a pharmaceutical product in Türkiye, which has a source price of EUR 10 as of December 31, 2021. The Turkish price of the originator product is EUR 1.84, while the generic product costs EUR 1.34.

Chart 47 – Pharmaceutical Pricing



In the 2015-2020 period, the pharmaceutical industry, which is categorized as a strategic high-tech industry, recorded a 40% change in net sales.

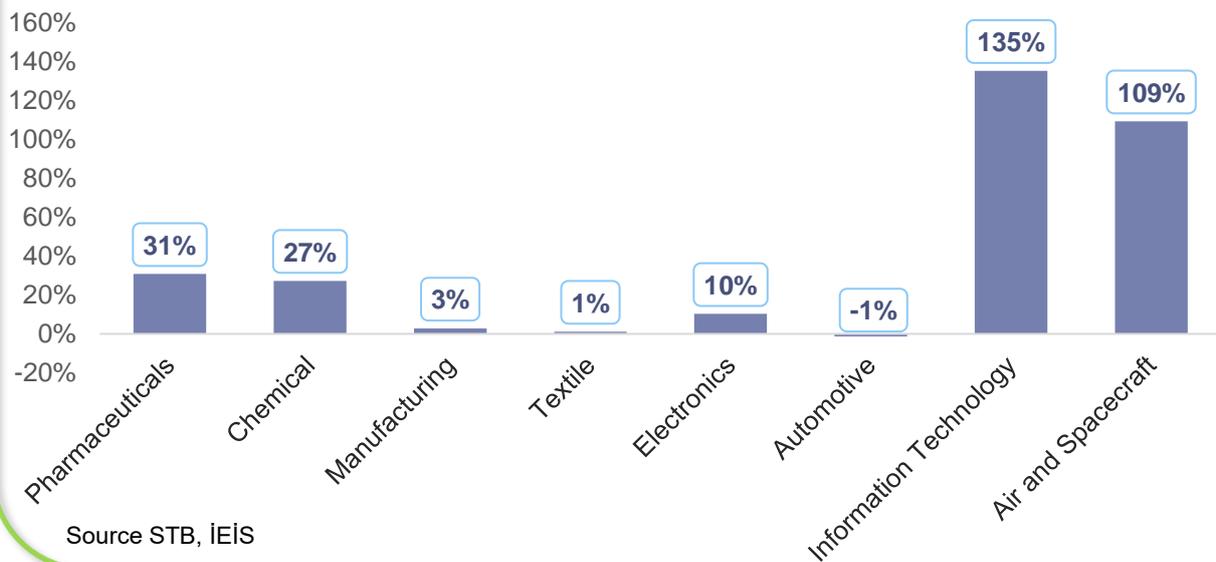
Chart 48- Real Changes in Net Sales (2015-2020)



Source: STB, İEİS

While this change in net sales is comparable to other high-tech industries, the pharmaceutical industry is limited in its capacity to secure sufficient capital to bolster its R&D capabilities.

Chart 49 – Real Change in Equities (2015-2020)

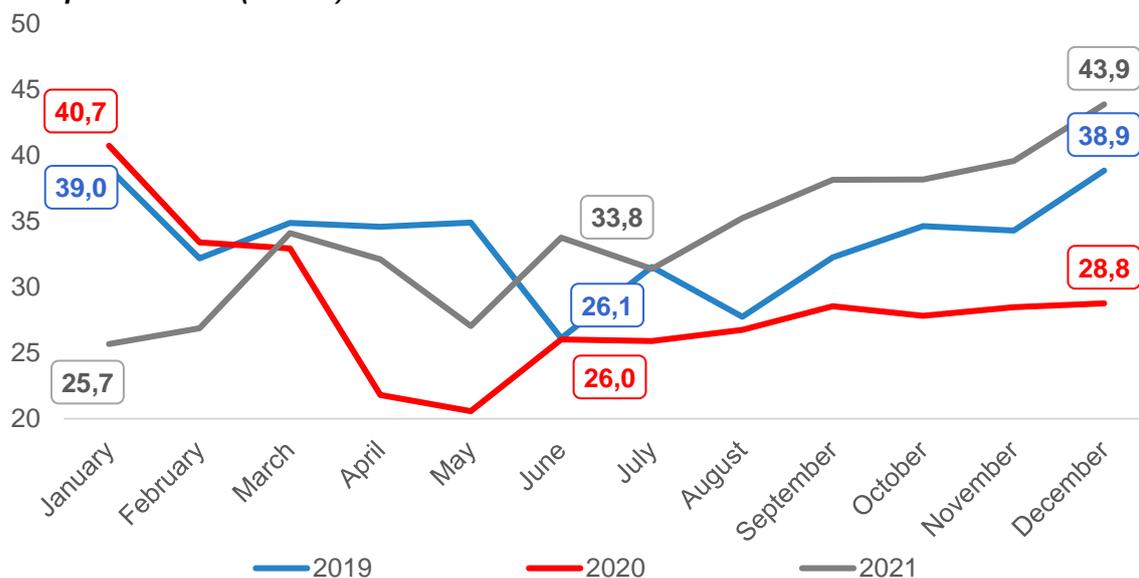


Despite the extraordinary impact of the COVID-19 pandemic on society and business in 2020 and 2021, raw material shortages and logistics problems, increasing costs and fluctuations in sales and several other challenges, the Turkish pharmaceutical industry maintained the continuity of its manufacturing operations and played a significant role in ensuring supply security of Türkiye.

With the gradual easing of lockdown measures after June 2021, the number of prescriptions began to return to pre-pandemic levels. After a 15% decline in the number of prescriptions, down from 410 million to 342 million in 2020, healthcare services saw a 19% surge in prescriptions, up to 406 million in 2021.

Chart 50 - SSI Monthly Prescription Number

Prescriptions in unit (million)



Source: SSI Health Statistics, IEİS

9. Conclusion and Evaluation

Pharmaceutical industry is a highly dynamic industry that has to keep pace with technological developments, which includes making new investments to adopt new technologies, and it also has to build new facilities and renovate existing ones in a systematic manner to expand its range of production continuously.

As is the case in the rest of the world, the pharmaceutical industry holds a strategic value for Türkiye, and the share and impact of biopharmaceuticals in the pharma industry has been growing with each passing day. Today, countries such as South Korea, India and Argentina benefit from legislative frameworks that are tailored to their unique conditions to build up their biopharmaceutical industry, making it a necessity for Türkiye to keep abreast of this global transformation and develop its own biopharmaceutical capacity. Similar to the defense industry, it is becoming more and more important for Türkiye to develop and produce its own biopharmaceuticals in accordance with its national interests.

IEIS is committed to transform into an industry that develops and produces high value-added conventional and biotechnological products with a higher share in exports. The goals of IEIS are fully aligned with the pharmaceutical localization initiative commenced in 2016 by the Ministry of Health. The positive impact of the policy on the pharmaceutical industry became apparent in a short amount of time after its implementation, resulting in a considerable growth in local production, utilization of idle capacity, advancements in production technologies, and an upwards trend in investment, employment and exports. This initiative has also enabled local production of otherwise imported products, thereby reducing current account deficit.

Accordingly, multiple pharmaceutical companies, both national and multinational, have engaged in investments and other efforts to contribute to this process, and expect the pharmaceutical localization initiative launched by the Ministry of Health in 2016 to continue with the same level of determination.

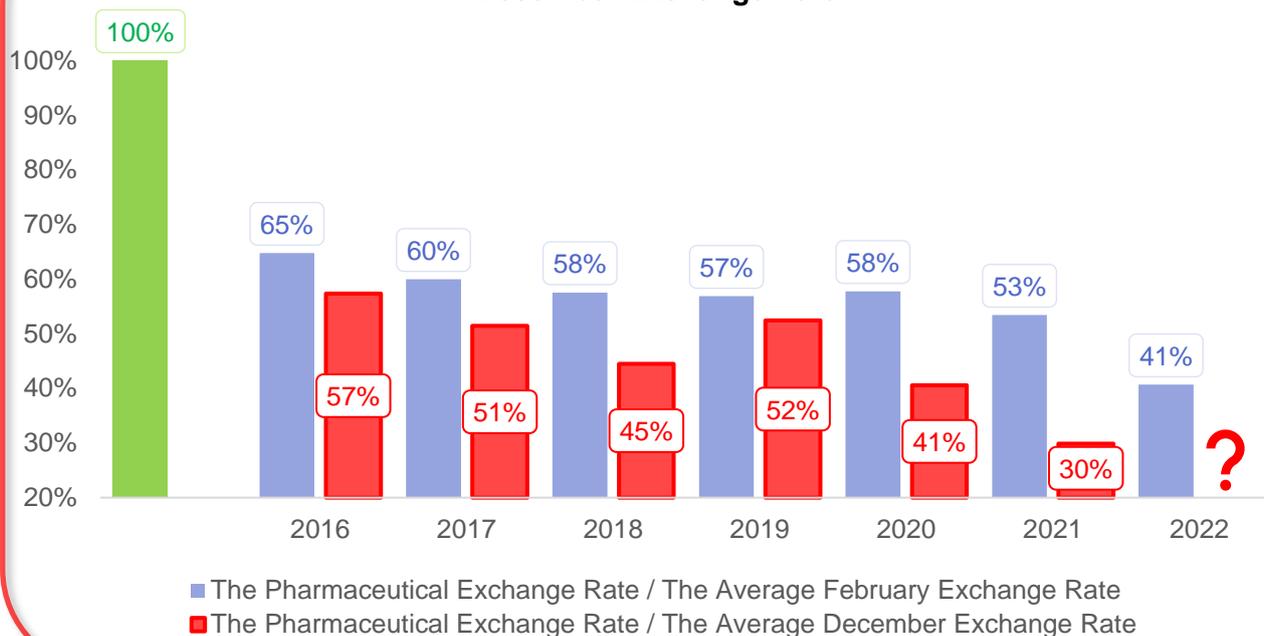
With the sharp increase in EUR-TRY exchange rate in the last months of 2021, the gap between the specified exchange rate to be used for drug imports and the actual exchange rate to widen.

In fact, the current EUR exchange rate as of the end of 2021 is 14.7088 and the average exchange rate for 2021 is 10.4875, yet the pharmaceutical exchange rate effective throughout 2022 will be 6.2925. This places a substantial financial burden on the industry, which is forced to use current market rate for material input.

The pharmaceutical exchange rate, set by the 2016 legislation at 70% of the average EUR-TRY exchange rate of the previous year, was later changed to 60% of the average in 2019. The fact that the pharmaceutical exchange rate comes into effect in the second half of February every year, leaving the industry exposed to exchange rate fluctuations, has been exerting an ever-increasing pressure on the industry.

The graph below, which shows the ratio of the pharmaceutical exchange rate to the average Euro value in February, when it is introduced, and in December by the end-of-year, clearly demonstrates the pressure on the industry.

Chart 51- The Pharmaceutical Exchange Rate / The Average February and December Exchange Rate



The pharmaceutical exchange rate set for 2020 (TRY 6.2925) is only 41% of the actual exchange rate recorded in February, signifying the enormous challenges the industry is likely to face throughout the year.

In order to protect the national pharmaceutical industry and facilitate its development, the fiscal discipline-oriented drug pricing policy must be abandoned, and the effective exchange rate must be revised multiple times throughout the year to shield the industry from the impact of cost and exchange rate increases.

The pharmaceutical industry needs effective support from public authorities. The physical investment incentives given to date have paved the way for considerable investments by our industry. Yet, the public incentive system is largely based on tax deductions and exemptions, which does not serve the needs of the industry, and there is still a need for cash financial support, especially in the field of biosimilars and other product types that require substantial long-term investment. It is essential for the industry that the obstacles that prevent new products from quickly and safely released to the market are removed.

With right policies, there is no obstacle in front of becoming a global industry that has accelerated its investments, allocates more resources to R&D, has even developed its own molecule, is strong in the field of biotechnology, produces and exports more.



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