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POSSIBLE IMPACT OF BIDEN ADMINISTRATION`S PHARMACEUTICAL POLICIES ON THE PHARMACEUTICAL MARKET TURKEY

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Possible Impact of Biden Administration`s Pharmaceutical Policies on the Pharmaceutical Market Turkey

January 2021

ECONiX Research

This report has been prepared by ECONiX Research, Analysis and Consultancy Inc., which provides tailored research, analysis, and consultancy services to healthcare providers including but not limited to market access, health economics, medical and business development for Turkey, Eastern Europe, North Africa, Middle East and Turkic Republics in public and academic institutions, pharmaceutical, medical device, and healthcare service providers.

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Pharmaceutical Market in the United States of America

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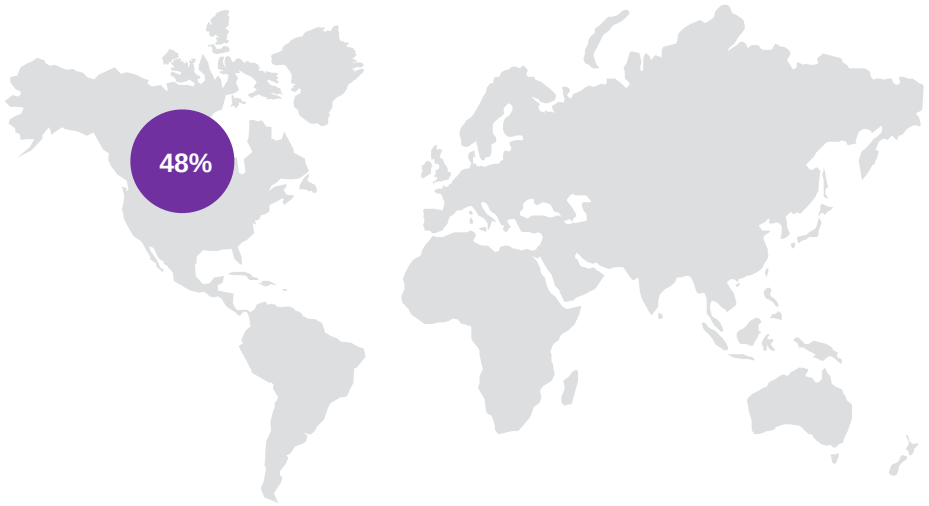
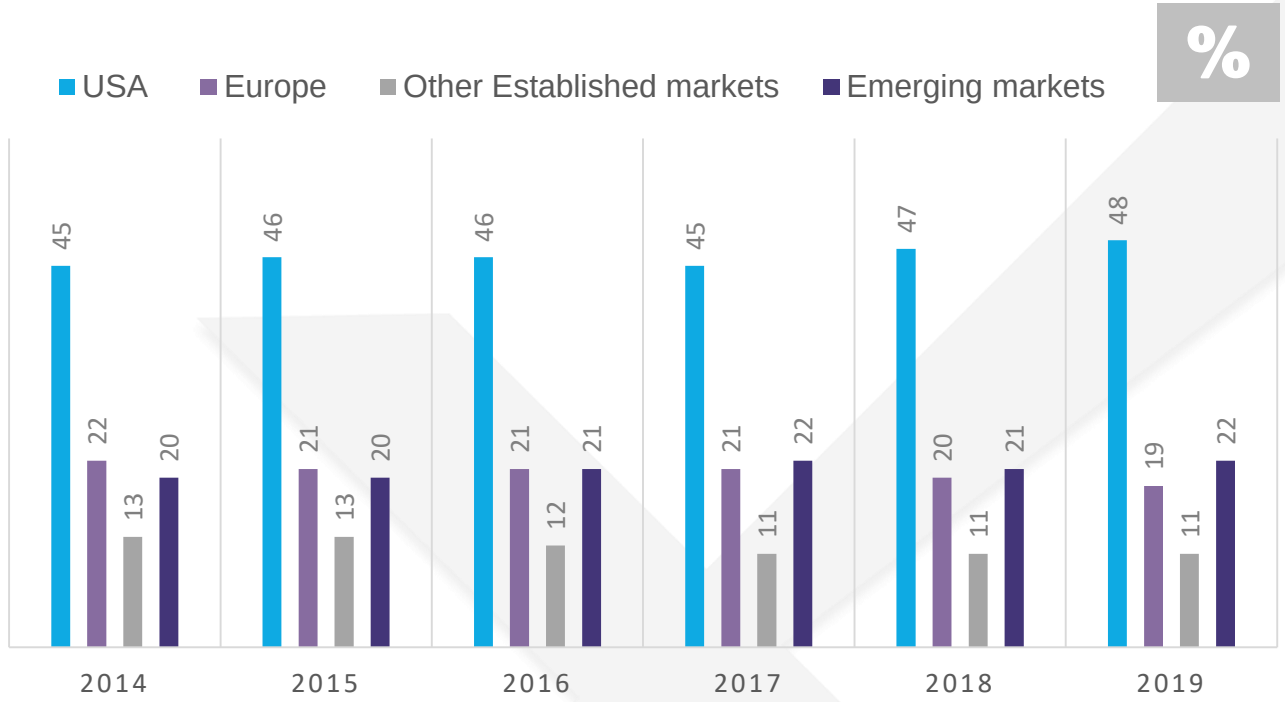
Graph 1 STATISTA

The Distribution of Total Global Pharmaceutical Market Sales between 2014-2019





48%

The USA constitutes 48% of the global pharmaceutical market.

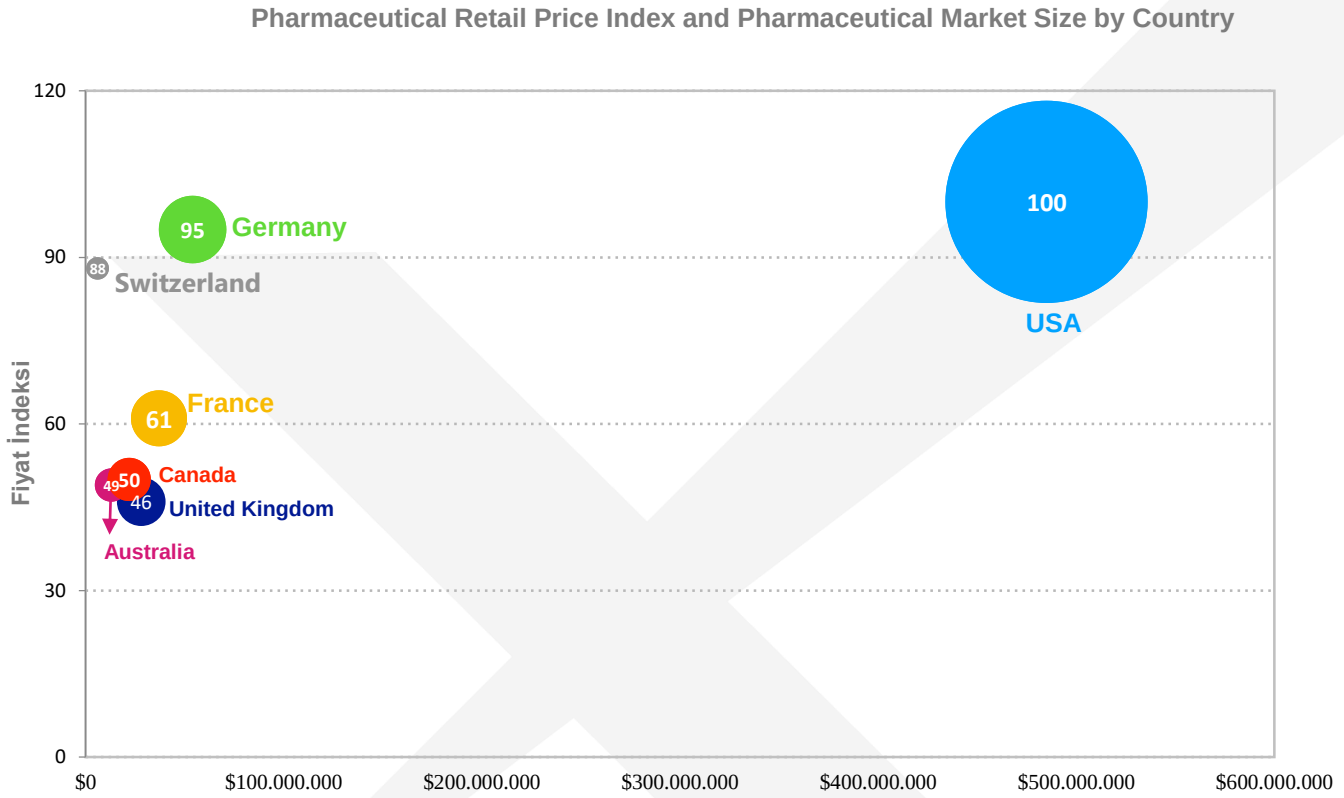
According to data published by Statista, the US was the largest pharmaceutical market with 48% of drug sales worldwide in 2019. (Statista, 2020) (Graph 1).

statista 2020

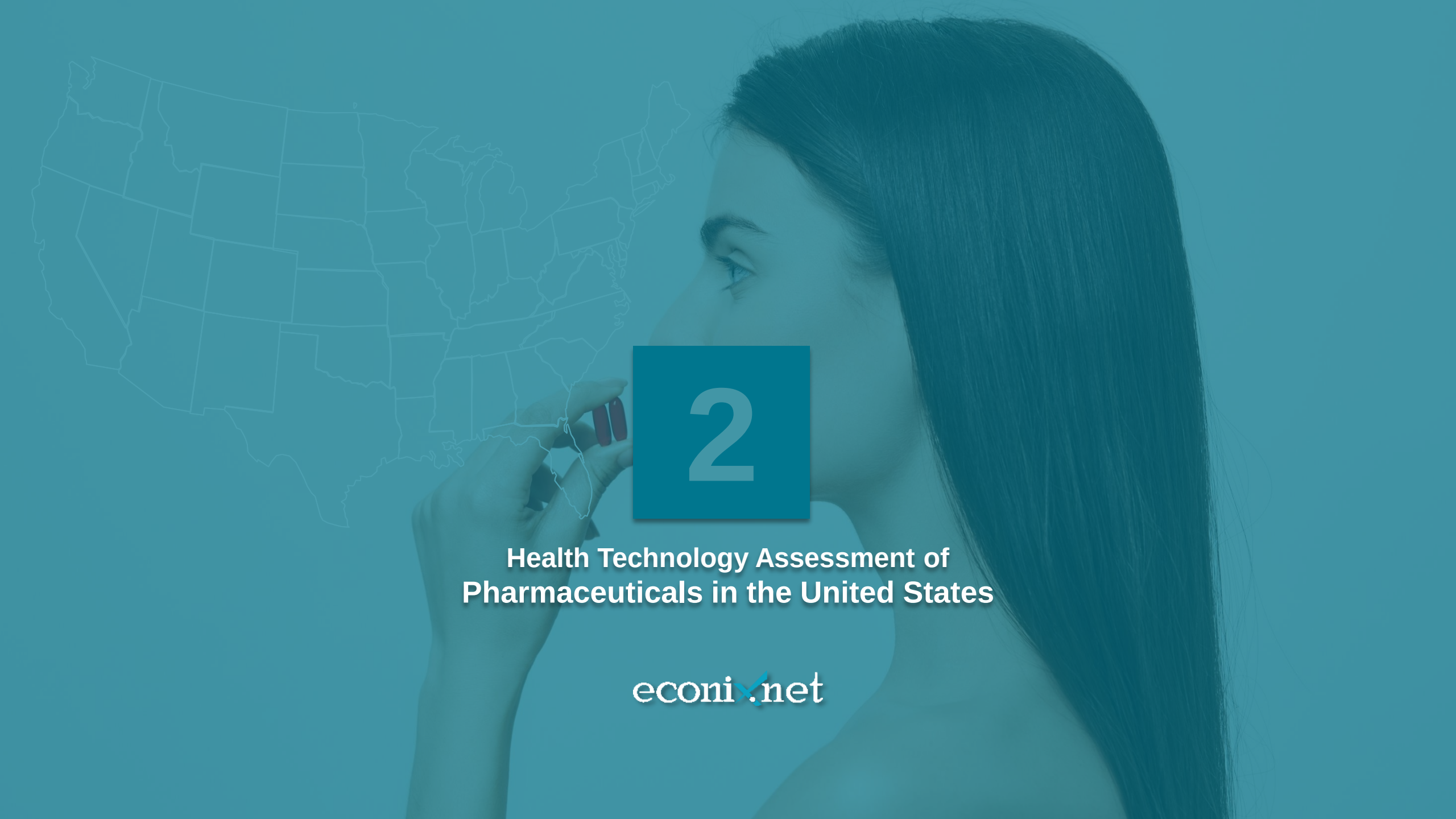
The Pharmaceutical Market in the United States

According to the report published by The Commonwealth Fund, pharmaceutical spending has a significant share in health spending. Besides, the US is the country with the highest pricing worldwide in terms of average drug prices.

If the value of the price index in the US is considered as 100, the price index for countries is reported as Germany 95, Switzerland 88, France 61, Canada 50, Australia 49, and the United Kingdom 46. The sizes of the bubbles shown in the graph show the inflation rate of the pharmaceutical market of the respective countries in the global pharmaceutical industry. Accordingly, the US has the most expensive drug prices and dominates the global pharmaceutical industry.



The Commonwealth Fund, 2017



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Health Technology Assessment of Pharmaceuticals in the United States

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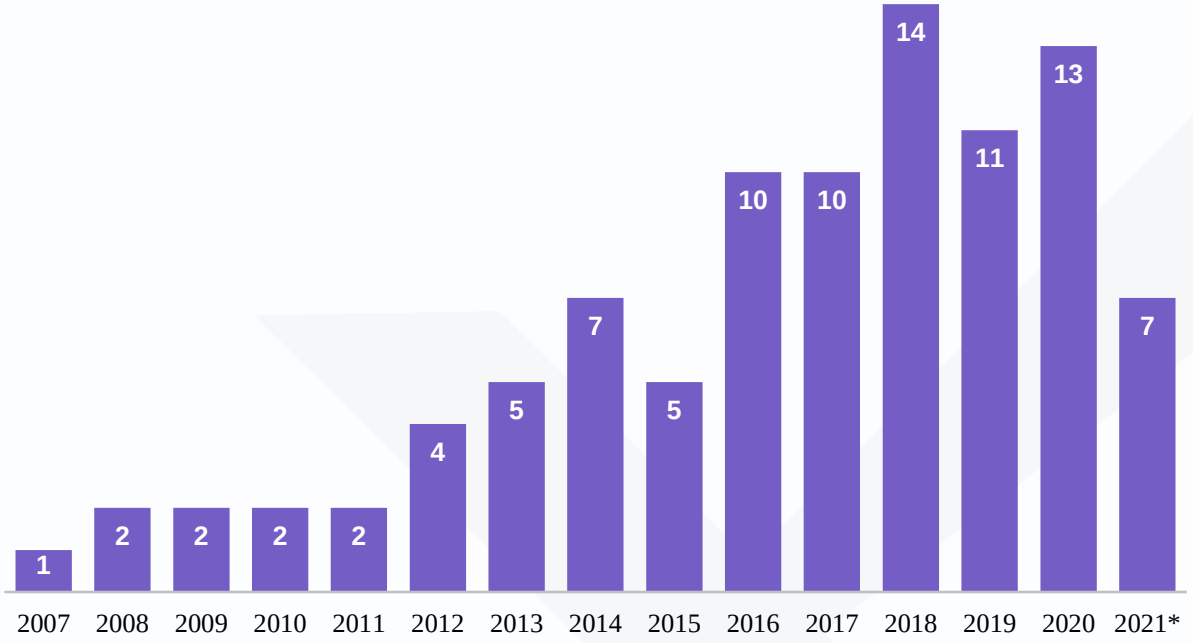
Over the years, a total of 88 research reports on topics such as cancer, cardiovascular disease, and Alzheimer's disease have been prepared by ICER. 11 more reports are currently being prepared. It has been observed that these reports have increased in recent years. While a total of 7 reports were published between 2007 and 2010, more than 10 reports were published each year during the last 5 years (ICER, 2020).



Number of Reports Published by ICER Institution by Years

ICER INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW 2020

* The number of reports that started in 2020 and will be published in 2021

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Possible Changes in

Pharmaceutical Policy in the United States

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Possible Changes in Pharmaceutical Policy in the United States

Controlling the unstoppable rise of health expenditures in the USA has been among the election promises of both the Republican Party and the Democratic Party during the last election period. Biden, the new President of the United States, evoqued this situation many times during the election period and mentioned/suggested some policies, especially for pharmaceutical pricing, supply, and reimbursement.

Plans have been proposed by the Trump administration in recent years to cut pharmaceuticals' costs. With the election of Biden, comprehensive pharmaceutical pricing legislation is expected to accelerate this process and to provide reasonable and acceptable pricing. However, due to COVID-19 priorities, such regulation is expected to occur in late 2021 at the earliest.

When these policies are examined, it is noticed that three different themes come up in the report prepared by CB Partners regarding the efforts to reduce drug prices.

These themes are:

1. International Reference Pricing (IRP)
2. Transparent Pricing
3. Pharmaceutical Import.

The main changes expected after the US Elections are international reference pricing, more transparency, and direct pharmaceutical imports to the USA.

International Reference Pricing

Both parties made the issue of International Reference Pricing the main agenda for pharmaceutical pricing reform before the November 2020 elections. Although the details are limited, the International Reference Pricing policy is intended to formally apply pricing frameworks as a tool to help address Medicare spending trends resulting from high pharmaceutical prices and the burden of increased out-of-pocket spending. The fact that both parties think similarly about this issue gives the impression that the result will be the same even though the suggested ways may be different.

It is important to evaluate and know the proposals of both parties in the pre-election period, since the arrangements made in the United States are the result of mutual evaluations and negotiations of all parties.

Republican Party

Benefiting from International Reference Pricing for Medicare reimbursement only

Aims to reference the lowest price compared to developed OECD countries

Democratic Party

Benefiting from International Reference Pricing that includes Medicare and Private reimbursement

Aims to reference average price compared to developed OECD countries

Possible Changes in Pharmaceutical Policy in the United States

International Reference Pricing

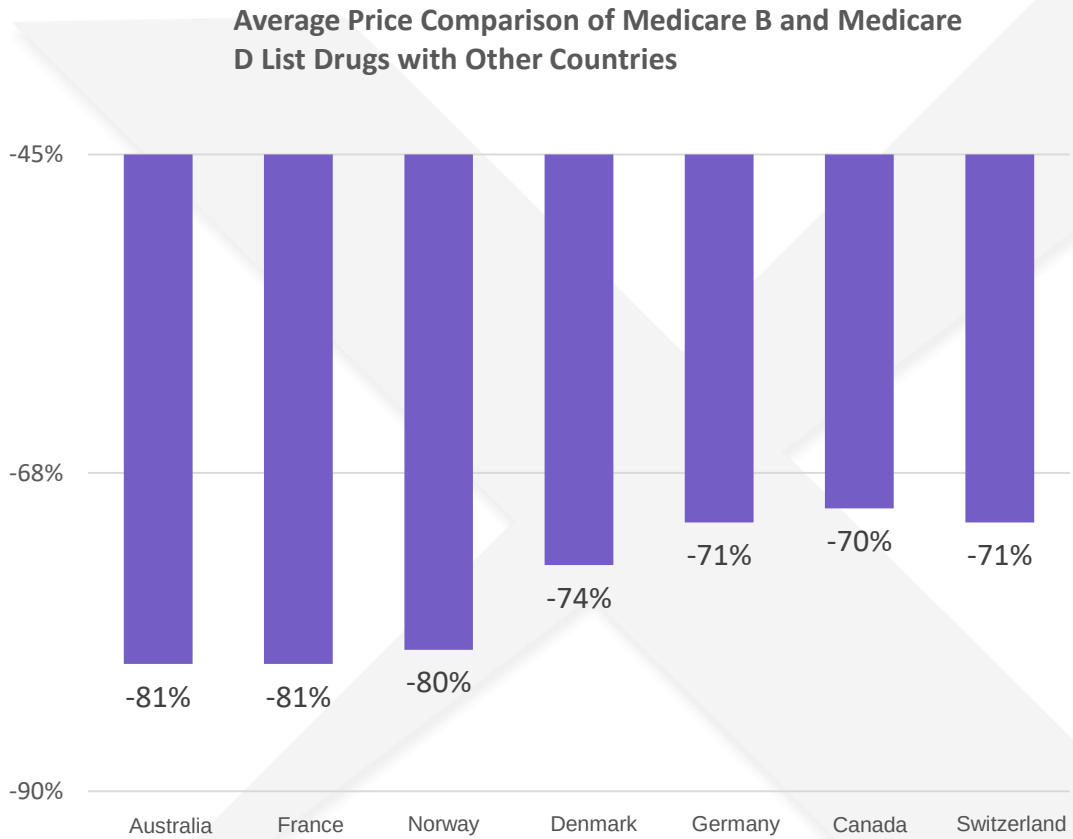
In the analysis made by IHS Markit, the prices of the top 20 pharmaceuticals with the highest expenditure under Medicare B and D were compared with countries such as Australia, Canada, Denmark, France, Germany, Norway, and Switzerland with this perspective. According to the report, the prices of the relevant products in these countries are 29% to 98% lower than the prices in the USA. In the report, it was stated that a 70-80% price decrease is expected with the gradual IRP approach in Medicare B and D drugs, which make up 50% of the US pharmaceutical expenditures.

Considering the magnitude of the impact of the formalization of the IRP on the US drug pricing situation, it can be said that the forward process can be difficult. Although both parties have proposals under a similar heading, these proposals may differ in the end from their current state through mutual consultation and negotiations.

Even if there are significant legal obstacles for any IRP proposal, the fact that both parties included IRP among the election promises shows that reference pricing will be implemented in the USA in the upcoming period. The excess of necessary updates covering the health sector will require coordination between both government and private institutions. The dispersed system of the USA compared to Europe is an important obstacle to this. These regulations will eventually require Congressional approval.

On the other hand, considering that IRP policies are on the agenda, it makes us think that the effects of a possible reference pricing change in the USA may be even greater in future. Because Spain is one of IRP lead country, but now going to implement IRP for the ATC4 group.

As a result, it remains unclear how the IRP to be implemented in the USA will affect certain market access dynamics (for example, the ranking of manufacturers to market) or to what extent the negative impact of access to innovative drugs in the USA will be, especially if OECD countries are used as a reference.



IHS Markit 2020

Pharmaceutical Import

Pharmaceutical import policy, from other countries to the USA has been one of the important points in the election campaigns of the Republican and Democratic parties. Both presidential candidates in the 2020 election advocated import policies as part of their healthcare agenda to lower pharmaceutical prices. Accordingly, the Trump administration legalized a framework in September 2020 that allows states and pharmaceutical companies to apply to the FDA to import pharmaceuticals from Canada.

The Biden campaign proposes to allow “safe prescription pharmaceuticals” to be purchased from other countries, but further details on implementation plans have not been released yet. However, studies on pharmaceutical imports are still ongoing.

Trump's vision of pharmaceutical imports is mainly based on the proposals of Democratic party senator Sanders' plan. Pharmaceutical import requires cooperation with other countries. In response to Trump's policy, Canadian Prime Minister Trudeau stated that the United States would be open to assessing pharmaceutical demands, but would prioritize the needs of his nation. Besides, Canadian pharmaceutical companies have expressed their concerns that their supply chains will be insufficient to meet the US demand. Also, the impact of import policies on high-cost treatments is limited if pharmaceuticals are not available in the generic or bio-similar form, as the current law only allows the import of non-biological pharmaceuticals and insulin.

Despite the strong interest in pharmaceutical imports to the US, its applicability as a means of reducing drug costs remains limited and does not address systemic issues of how drugs are priced in the US. However, the implementation of the proposals put forward by Trump and based on the bill of Democratic party senator Sanders is expected to be accelerated by Democratic President Biden with a high priority. Considering that the correct and logical suggestions in the USA are evaluated and decided upon by the negotiations made by all parties, it can be said that pharmaceutical imports policies will be implemented in the coming period. Manufacturers should evaluate the impact of these policies on their product portfolio and trade dynamics.

Republican Party

It aims to facilitate cheaper access for patients to medicines by allowing states, pharmacies, and drug distributors to apply for drug import authorization granted by the FDA.

Democratic Party

It aims to allow consumers to purchase prescription drugs from other countries where they can be purchased at lower prices, provided that the FDA approves the drugs as safe.

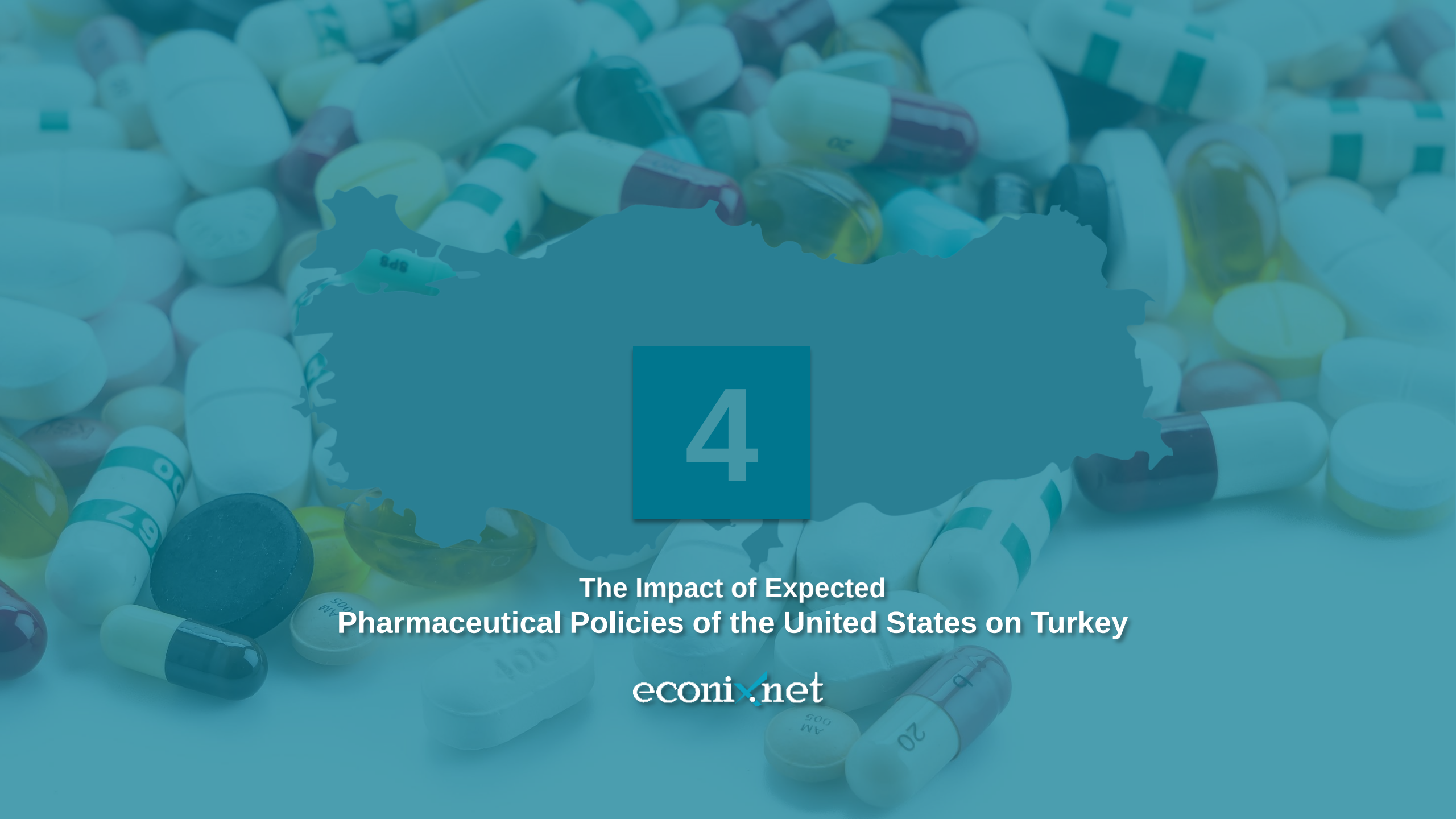
The Future of Pharmaceutical Policies

It is observed that the presidential elections are one of the rare events that both parties are interested in the future health reform route in the USA and have agreed on almost everything in recent years. The debate over pharmaceuticals' expenditures and policy pathways to address price differences between the US and other countries is a growing legislative focus in the Senate and the White House.

The legalization of pharmaceuticals imports and the ongoing pricing transparency initiatives show that there will be significant changes in the overall pricing and access framework in the US. The formalization of IRP policies, which will restrict the free pricing environment in the US, has the potential to have a much more severe impact on pharmaceuticals. It should be noted, however, that the IRP implementation feasibility remains a challenge, given the legal challenges, anticipated industry response, and the fact that the transition will eventually require Congressional approval, as the similar title in both parties but suggests different paths.

The long-term effects on pricing and market access remain uncertain, given the varying candidate proposals across various channels of the pharmaceutical pricing debate. It can be said that pharmaceutical developers and their official representatives are strong in lobbying over the process, especially during the COVID-19 pandemic. Pharmaceutical manufacturers must be prepared to consider strategic implications and priority actions to ensure readiness for a potentially changing regulatory and pricing environment.

Products in the US market do not exist or enter the market too late in OECD countries and most of the reference countries. Reimbursement rates and insurance coverage for pharmaceuticals differ in these countries. The USA's transition to the IRP may cause these products not to enter the market in other countries.



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The Impact of Expected Pharmaceutical Policies of the United States on Turkey

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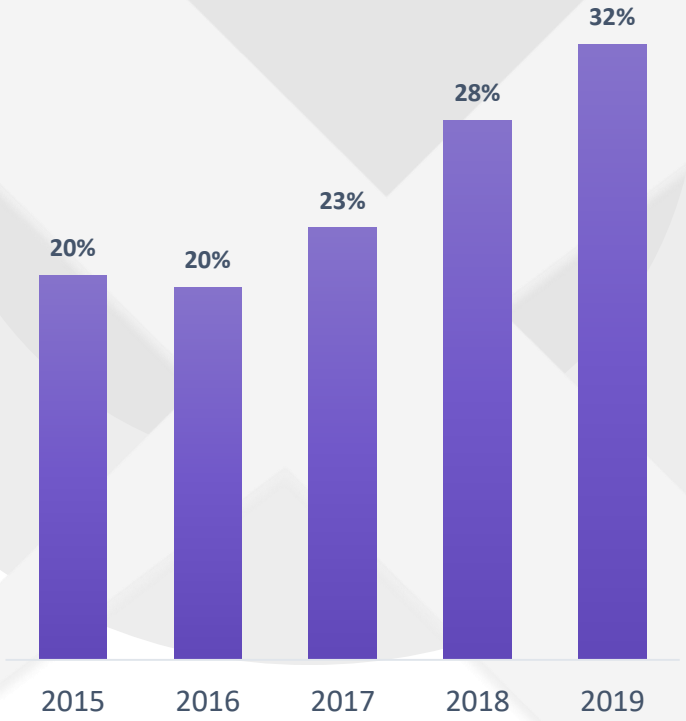
Impact of Expected Pharmaceutical Policy Changes in the United States on Turkey

According to the Turkish Pharmaceutical Market (2010-2019) report published by the Pharmaceutical Manufacturers Association of Turkey (IEIS), Turkey reached 40.7 billion TL in value in 2019 and 2.37 billion units, reaching its highest volume between 2010 and 2019. Although the import / export coverage ratio of the pharmaceuticals is still low in Turkey, it is increasing every year.

In Turkey, manufacturing under license, contract manufacturing, manufacturing of generic drugs, and active substances, especially antibiotics, analgesics are carried out. Within the scope of the domestic manufacturing project of pharmaceuticals led by Ministry of Health in Turkey, the market for domestic manufactured pharmaceuticals is increasing every year.

Export-Import Coverage Ratio of Pharmaceuitcals in Turkey by Years (%)



Republic of Turkey Ministry of Health Budget Report. 2021

Impact of Expected Pharmaceutical Policies in the United States on Turkey

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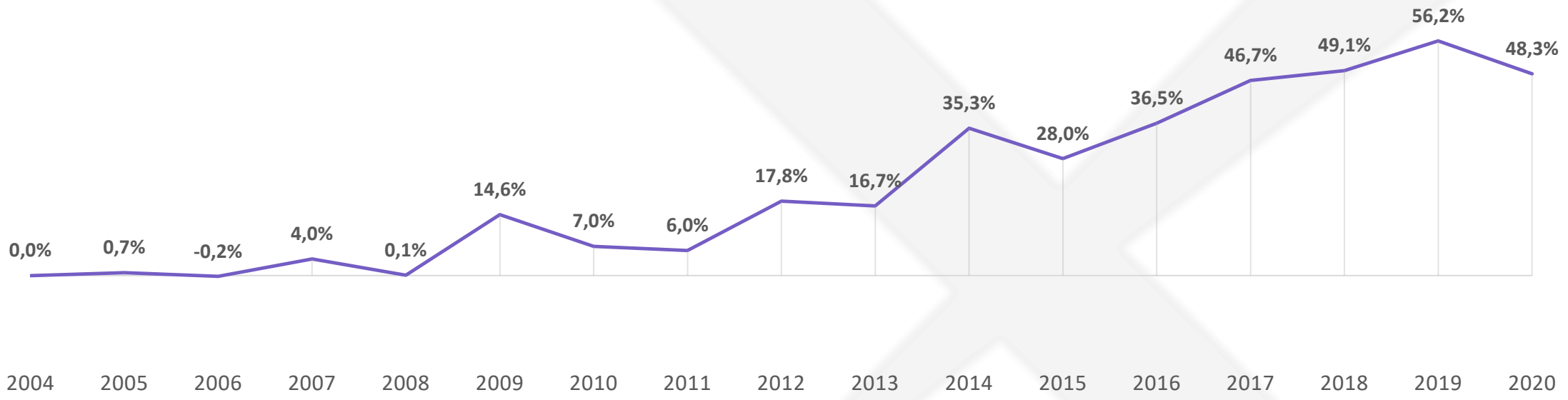
Percentage of Difference Between the Fixed Euro Rate and the Average Free Exchange Rate in Pharmaceuticals by Years



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These are data for the 1st of January of each year.

Impact of Expected Pharmaceutical Policies in the United States on Turkey

Turkey Pharmaceuticals and Medical Devices Agency (TITCK) calculates every year the price of pharmaceuticals with a fixed Exchange rate for Euro / TL. Fixed exchange rate application is a way to avoid being affected by exchange rate fluctuations during the year (TITCK, 2015).

The Fixed Euro exchange rate is calculated as 60% of the average rate of the previous year. Although the fixed exchange rates determined each year are updated at the beginning of the year, pharmaceutical companies are negatively affected by the exchange rate increases in the following year, as they are based on the average exchange rate of the previous year.

The exchange rate difference, which should be 40%, reaches almost 60% at the end of the year due to the foreign exchange fluctuation. This causes a cost increase up to 20% for pharmaceutical companies, mainly due to importation of both finished products and raw materials.

It is very likely that the Turkish pharmaceutical market will be affected by the expected pharmaceutical policies in the United States. As the United States will use other countries in reference pricing, its transparency may increase, and pharmaceuticals import policies may have significant implications.

Impact of Expected Pharmaceutical Policies in the United States on Turkey

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It is important that the United States will switch to reference pricing, and for this purpose, it will use OECD countries, including Turkey, as mentioned in the proposals of both parties. In this case, it can be said that pharmaceutical companies in OECD countries, including Turkey, will be more careful about publishing list prices. It is one of the first scenarios that come to mind that it may show higher list prices by making changes in market access scheme and by making more market access agreements in OECD countries.

The use of OECD countries in international reference pricing in the USA will increase the importance of market access agreements across the countries.

Related to Pharmaceutical Reimbursement Application Procedures carried out by SGK in Turkey, the pharmaceutical companies are obliged to provide the pharmaceutical cost-effectiveness and budget impact analysis, while pricing is the main factor that determines the budget impact (Koçkaya and Ökçün, 2020). Market access agreements are a form of guarantee for pharmaceutical companies and SGK for new and costly products to eliminate uncertainties that may affect the budget. Market access agreements can be evaluated as sharing the risks foreseen for a pharmaceutical in terms of cost-effectiveness and budget impact. With these agreements, both parties aim to eliminate the uncertainty from their perspective.

Market Access agreement can allow to list a higher list price than the real reimbursement price. Depending on that, pharmaceutical companies may request market access agreements in OECD countries more than ever for maintaing the USA`s high prices. This situation can be expected to result in higher list prices for all pharmaceuticals, including generic products that fall outside market access agreements.

The same effect could be observed for keeping France, Spain, Italy, Portugal, and Greece in the international reference pricing basket to Turkey. However, the solution to this situation is not to exclude developed countries from the reference pricing basket. Because, in any case, each country will keep another country in its reference basket and this will affect other countries indirectly.

On the other hand, the clear recommendation of both parties in the US for international drug pricing is to include OECD countries in the reference basket. Although for now countries with a GDP per capita of up to 60% of the US will be included in the IRP study, this limit may be changed in the future.

In this case, pharmaceutical companies may avoid to launch new products in Turkey like OECD countries with low health care expenditure per capita, low pharmaceutical prices, etc.

In this case, the current delays for accessing innovative treatments in developing countries such as Turkey may be longer for innovative medicines.

It may be suggested that Turkey find a new pricing method beyond international reference pricing. In this way, it will be least affected by the global pharmaceutical price change that may occur with the new pricing policy, regardless of international reference pricing.

On the other hand, there is a failure to ensure public reimbursement processes available in the distribution channel in Turkey because of the price, as requested confidentiality, whole salers and pharmacies' profitability and influence the price. This may cause a decrease in wholesalers and pharmacies' income. As an off-set for that it may be beneficial to switch from an income model in terms of "profitability" to healthcare service fee with a new distribution model and free pricing for non reimbursed pharmaceuticals.

While new pricing and distribution channel arrangements may be planned in the medium-long term, more market access agreements may be considered in the short term. Thus, even if the published list prices are increased, confidential pricing will be provided for government reimbursement of pharmaceutical prices regardless of the possible price increase accross OECD countries.

Possible Effects of International Reference Pricing, Expectations, and Recommendations

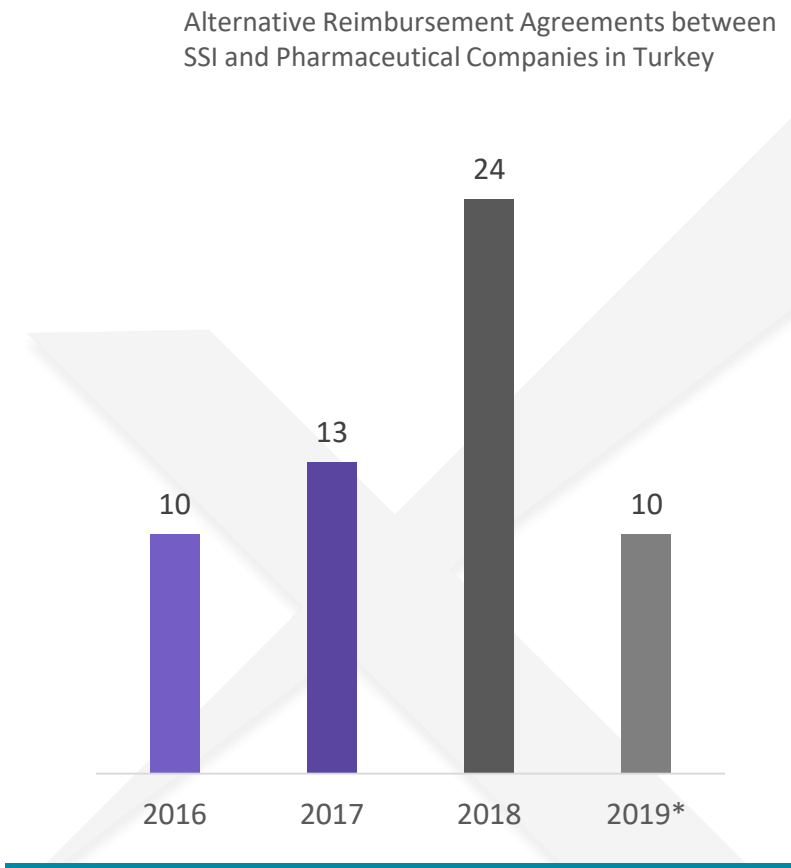
Market access agreements were signed between SSI and pharmaceutical companies for alternative reimbursement for 57 drugs between June 2016 and May 2019 (Koçkaya et al 2020). Currently, new alternative repayment agreements continue to be signed. The number of alternative repayment agreements by years is presented in Graph 7.

All the agreements made since 2016 are financially based. Making these agreements not only financially based but also performance-based or using both performance and financial methods together will give the public more savings in possible list price increases. To do this, it is necessary to share the clinical results with pharmaceutical companies anonymously in performance-based agreements. However, legislative arrangements are required for this. Especially by the Personal Data Protection Law, which has been on the agenda in recent years, it is necessary to make secondary legislation arrangements based on both the Social Security Institution Law and these laws.

It has been observed that the existing market access agreements were made for original products, with very few examples. However, it can be observed that generic products for which reference pricing is used may also be affected by possible reference pricing policies and their prices may increase. In this case, it can be said that generic drug prices may increase if it is assumed that no new strategies are formed in terms of price competition.

As a result of ensuring that drug prices rise by pharmaceutical companies in OECD countries with the adoption of IRP policies of the United States, it can be expected that Turkey, which uses these countries as a reference, will improve profitability in terms of the pharmaceutical sector due to the low drug pricing policies implemented, with an increase in possible drug prices. However, for the public, this will cause an increase in the pharmaceutical budget. For this reason, in the upcoming period, it will be beneficial for SSI to bring Alternative Reimbursement Agreements for generic products to the agenda or to implement the "Health Market" application initiated by the Ministry of Health for drugs and to spread it as soon as possible.

As a result, even if the USA will switch to international reference pricing causes a decrease in drug prices due to current prices in the short term, an increase in list prices can be expected as a result of possible changes in the policies of pharmaceutical companies in the pricing of new drugs in the medium and long term. At first, it was reported in the literature that the application of IRP declined, but then an example of the decrease in the effect of this decrease due to IRP also occurred for Turkey due to previous policies (Koçkaya et al., 2013).



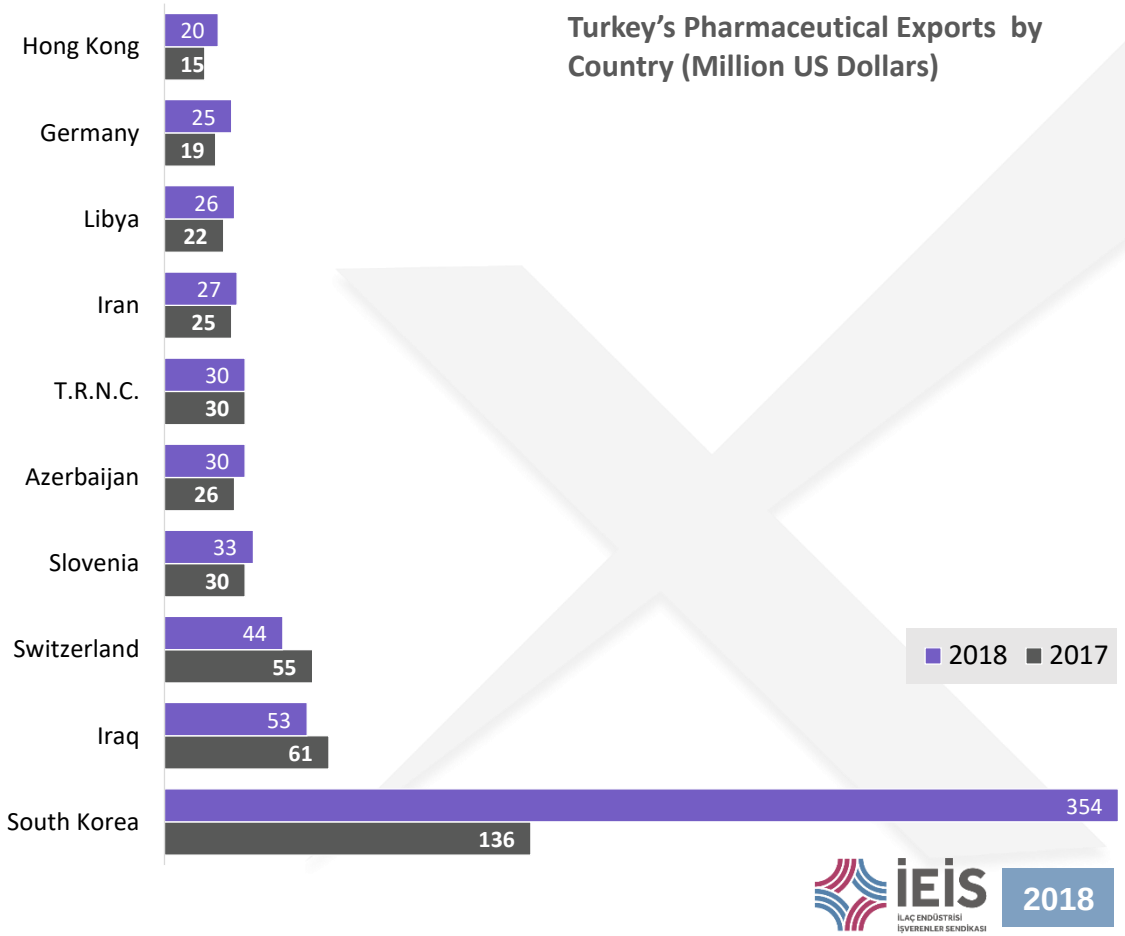
Analysis of Market Access Agreements in Turkey, Koçkaya et al, 2020
*Data for January-May 2019, not covering the whole year.

Possible Effects of Pharmaceutical Exports, Expectations, and Recommendations

The fact that the United States allows the import of products with high potential patent protection from countries producing acceptable quality, especially Canada, is basically of great importance for Turkey, which wants to be a leading country in the production of generic drugs.

In such a case a significant export opportunity for pharmaceutical companies in Turkey is expected to be built. For this to happen, first of all, Turkey-based pharmaceutical companies must prove that they can produce high quality products with the FDA and the European Medicines Agency (EMA) approvals. In this process, it is necessary to make a capacity investment that can produce at the desired quality. Besides, the government should offer these companies non-refundable and/or refundable incentives for this capacity investment.

As can be seen from the graph, Turkey has the capacity to produce acceptable quality with a reasonable pricing that ables to export to developed countries such as Switzerland and Germany.



Possible Effects of Pharmaceutical Exports, Expectations, and Recommendations

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In 2020, the importance of expanding international activities is increasing such as purchasing and collaborating with international companies and research laboratories announced by Abdi İbrahim and Gen İlaç, and operating directly with in other countries such as Nobel İlaç. Thus, domestic pharmaceutical companies can gain experience and more competitive power while opening up to international markets. These collaborations can be used for direct exports to the USA.

Incentives given by the government includes not only domestic pharmaceutical companies but also international pharmaceutical companies based in Turkey. These companies already have brand awareness in the international market, better perception about the quality, already in the United States. International companies can easily use these advantages to plan the export of their products produced in Turkey to the United States.

As these steps are completed, activities must be carried out simultaneously using international relations and diplomacy to allow the United States to export drugs produced in Turkey to the United States.

Otherwise, countries that can export to the United States may act more quickly. Due to that, Turkey has the necessary to be proactive for these coming policies.

Conclusions

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Conclusions

Innovative pharmaceutical companies launch their new pharmaceuticals primarily in the USA. In many reports, the main reason for this was stated as the free pricing and easy Access of pharmaceuticals in the USA. However, the IRP and other elements in US pricing decisions may end the free pricing environment. The easiest way to avoid free pricing is market access agreements in the short term, while new pricing, distribution, revenue model, and profitability arrangements may be implemented in the long term.

Market access agreements protect pharmaceutical prices with confidential pricing regardless of the list price. In such a case, the pharmaceutical companies may ask to make more market access agreements in OECD countries including Turkey.

It should be considered to switch to a healthcare service fee-based income model instead of a profit-based income model for wholesalers and pharmacies. In additional, free pricing for non-reimbursed pharmaceuticals may be another policy to be implemented.

To be able to turn the obstacles of expected drug policies in the United States into opportunities;

1. New methods need to be developed in pharmaceutical pricing, distribution, and reimbursement processes.
2. To facilitate the export of medicines from Turkey to the United States, it is important to encourage domestic companies and international companies based in Turkey with incentives.

> Turkey needs to do the necessary planning for the upcoming policy changes in USA.
>
> Otherwise, the opportunity window may be used by other countries and Turkey will have difficulty in reaching the goals set in pharmaceutical exports.

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