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ORIGINAL ARTICLE / ÖZGÜN MAKALE

TURKISH EXAMPLE OF PRIORITIZATION AND RESTRICTION DECISIONS IN MEDICINE ACCESS: EVALUATION BASED ON TWO INNOVATIVE DRUGS

İLAÇ ERİŞİMİNDE ÖNCELİKLENDİRME VE KISITLAMA KARARLARINA İLİŞKİN TÜRKİYE ÖRNEĞİ: İKİ YENİLİKÇİ İLACA DAYALI DEĞERLENDİRME

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ABSTRACT

Objective: *Drug licensing, price, and reimbursement are essential for medical access. This study examines US, EU, and Turkish reimbursement for innovative medicines and evaluates Türkiye's recent licensing and reimbursement decisions.*
Material and Method: *Nivolumab, an anticancer medicine, and Evolocumab, a hyperlipidemia treatment, were studied. Web-based searches of FDA, EMA, and TİTCK offical websites revealed authorized indications and approval dates for chosen medications.*
Result and Discussion: *Nivolumab has been authorized for 11 indications by the FDA and 10 by the EMA, although it is only approved for 8 in Türkiye. Evolocumab has been authorized for three indications by the FDA, three by the EMA, and two in Türkiye. Nivolumab was approved in Türkiye an average of 24.0 months after the FDA and 20.4 months after the EMA. In Türkiye, the indications for this medicine were reimbursed 27.6 and 25.2 months later, respectively. The FDA and EMA authorized the indications for evolocumab in Türkiye 10 months and 13.2 months later, respectively. The FDA and EMA authorized evolocumab's single reimbursement indication in Türkiye after 72.0 and 74.4 months, respectively. Our investigation found that some patient groups were given priority by limiting pharmaceuticals with high budget expectations, and these prioritizing decisions were made to secure patients' access to therapy.*
Keywords: *Drug access, innovative drugs, licensing, reimbursement*

ÖZ

Amaç: *İlaca erişimde ilaç ruhsatlandırması, fiyatlandırması ve geri ödenmesi kritik öneme sahiptir. Bu çalışmadaki amaç; Amerika Birleşik Devletleri, Avrupa Birliği ve Türkiye arasında seçilmiş yenilikçi ürünlerin geri ödeme koşullarını karşılaştırmak ve Türkiye'nin son yıllardaki ruhsat ve geri ödeme kararlarını değerlendirmektir.*
Gereç ve Yöntem: *Bu çalışmada onkoloji ve hiperlipidemi tedavileri çalışma alanı olarak*

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belirlendi. Onkoloji alanında birden fazla endikasyonu olan Nivolumab ve hiperlipidemi alanında kullanılan Evolokumab çalışma ilaçları olarak seçildi. Seçilen ilaçların onaylı endikasyonları ve endikasyon onay tarihleri web tabanlı taranan FDA, EMA ve TİTCK resmi internet sitelerinden elde edildi

Sonuç ve Tartışma: *Nivolumabın FDA tarafından 11, EMA tarafından 10 endikasyonu onaylıyken, Türkiye'de 8 endikasyonu onaylıdır. Evolokumabın FDA tarafından 3, EMA tarafından 3 endikasyonu onaylıyken, Türkiye'de 2 endikasyonu onaylıdır. Nivolumabın, Türkiye'de ruhsat alması, ortalama FDA'den 24.0 ve EMA'dan 20.4 ay sonra gerçekleşmiştir. Bu ilacın endikasyonlarının Türkiye'de geri ödenmesi de sırasıyla 27.6 ve 25.2 ay sonra gerçekleşmiştir. Evolokumab'ın Türkiye'deki endikasyonları FDA ve EMA'dan sırasıyla 10 ay ve 13.2 ay sonra onaylanmıştır. Evolokumab'ın Türkiye'de geri ödenen tek endikasyonu, FDA ve EMA tarafından onaylandıktan sonra sırasıyla 72.0 ve 74.4 ay sonra ödemeye girmiştir.*

Çalışmamızda incelenen ilaçlar üzerinden bütçe beklentisi yüksek olan ilaçlara yapılan kısıtlamalarla belirli hasta gruplarına öncelik verilmiş olduğu ve bu önceliklendirme kararları ile hastaların tedaviye erişimi sağlanmaya çalışıldığı görülmektedir.

Anahtar Kelimeler: *Geri ödeme, ilaç erişimi, ruhsatlandırma, yenilikçi ilaçlar*

INTRODUCTION

Different interventions are made by public decision makers all over the world to effectively use limited resources in health economics. Restriction and prioritization decisions aim to distribute financial resources equally to target patient groups and ensure early access to medicine. However, over time, the scope of priority areas is being expanded with reimbursement agreements that include new evidence of effectiveness and safety. The demographic pyramid, disease incidence, and health economic findings influence the scope of each country's prioritization decision for the new molecule. Due to the continuous increase in health expenditures and the increasing cost of health services, policy makers all over the world have had to implement various mechanisms. To ensure access to innovative medicines, risk-sharing agreements are made with financial or performance-based models in different countries [1,2]. Countries might prioritize distinct therapeutic drug classes to provide effective access to medicines with limited resources. A study investigating the access to antineoplastic drugs in various European countries shows that access to antineoplastic drugs is prioritized through practices in reimbursement and pricing [3]. Another study evaluating ten country examples revealed that country authorities use budget impact, clinical effectiveness, disease burden, ethics, evidence and many other parameters for determining priorities of medicine access in the health technology assessments [4].

Drug licensing, pricing, and reimbursement are critical for access to medicine. Licensing and pricing activities of drugs in Türkiye are carried out by the Turkish Medicines and Medical Devices Agency (TITCK). The retail sales price of drugs is determined by the external reference pricing system [5]. Countries followed by external reference pricing systems are France, Spain, Italy, Portugal, and Greece. However, if any drug is imported from outside these countries, the price in the country where that drug is manufactured or imported can also be taken as a reference. The sales price to the cheapest warehouse in these monitored countries is taken in euros as the reference price. Then, this value is multiplied by the periodic Euro value, and the sales price to the warehouse is determined in Turkish Lira. Periodic euro value; Each year, it is determined as 60% of the average euro sales value of the previous year, based on the euro sales value announced by the Central Bank of the Republic of Türkiye. [6].

Reimbursement of medications is regulated by the Social Security Institution (SSI). Companies apply to SSI for drugs that receive licenses and prices. Taking into account the discount rates specified in the Health Practice Communiqué (SUT), public prices of drugs are determined and a reimbursement list, which is a positive list, is created [7]. Medicines that have been licensed and priced are added to the reimbursement list according to their characteristics, by the Institution or by the commissions whose secretariat is managed by the Institution (Medical and Economic Evaluation Commission, Drug Reimbursement Commission). Positive decisions taken by the commissions are published in the SSI Health Implementation Communiqué [8]. In order for agreements similar to risk-sharing agreements to be made in Türkiye, an alternative reimbursement commission (AGÖK) within the SSI was established

in 2016 and its legislation was published [9]. Medicines included in the reimbursement are made available to insurance patients with indications approved by the Ministry of Health and with the discount rates specified in Article 4.4.1 of the Health Practice Communiqué. For drugs whose use requires special regulation, the reimbursement criteria are explained in the article "Regulations regarding some special diseases and drugs". This article explains at what stage of treatment or under what conditions the drug can be accessed under insurance [8].

In Canada, a study that evaluated the reimbursement assessment times of some antineoplastic drugs demonstrated that delays caused losses in life years and QALY values [10]. Another study investigating the group of innovative antineoplastic drugs reimbursement processes in Australia and the United Kingdom stated that using risk sharing or manage entry agreements in the reimbursement processes could provide early and easy access for patients to these medicines [11]. Nivolumab, one of the innovative drugs evaluated in the above studies, is an antineoplastic medicine and a human immunoglobulin monoclonal antibody. Nivolumab binds to the programmed death-1 (PD-1) receptor and blocks the binding of PD-1 to PD-L1 and PD-L2 ligands, thereby exerting antitumor activity [12]. There are also innovative drugs used in the treatment of different diseases including a human IgG2 monoclonal antibody evolocumab. Evolocumab binds to circulating human proprotein convertase subtilisin kexin type 9 (PCSK9). It inhibits PCSK9 binding to the low-density lipoprotein receptor (LDLR) and reduces the LDL levels in the blood [13]. A study reported the high cost of evolocumab in Italy and stated that using the drug in high-risk subgroups could help reduce costs [14].

As the years progress, the number of drugs on the reimbursement list and the number of paid indications for drugs currently on the reimbursement list increase. In order to prevent the unforeseen budget burden that these increases will create, some limitations are imposed. The aim of this study is; To compare the reimbursement conditions of selected innovative products between the United States of America (USA), the European Union, and Türkiye and to evaluate Türkiye's reimbursement decisions in recent years.

MATERIAL AND METHOD

It is predicted by IQVIA that the oncology and immunology treatment fields will grow at a CAGR of 9-12% and 6-9% by 2026 [15]. Therefore, oncology and hyperlipidemic treatments were determined as the study area in this study. Both direct and indirect health costs of these two health problems continue to increase day by day. In recent years, the market shares and budget burdens of drugs produced by biotechnological methods have been increasing rapidly all over the world. Therefore, drugs with a non-biosimilar monoclonal antibody structure used in these indications have been examined. As a result of all these examinations, Nivolumab, which has multiple indications in the field of oncology [12, 16], and Evolocumab, used in the field of hyperlipidemia, were selected as study drugs [13,17].

Approved indications and indication approval dates of the selected drugs were obtained from the web-based scanned EMA, FDA, and TITCK official websites [16-23]. Reimburst indications and reimbursement dates in Türkiye; It was obtained from the Communiqué on Amendments to the Health Implementation Communiqué published in the Official Gazette and its annexes, as well as from the web-based scanned SSI official website [24].

RESULT AND DISCUSSION

There are 70 headings in the Health Practice Communiqué in the section on regulations regarding some special diseases and drug use. These topics include many topics such as antineoplastic drugs, enteral and parenteral nutrition products, and congenital metabolic diseases.

In the Health Practice Communiqué, regulations regarding Nivolumab are included under the title "4.2.14 - Principles of drug use in cancer treatment", while Evolocumab is included under the title "4.2.28 - Principles of use of lipid-lowering drugs".

While Nivolumab is reimbursed in 4 indications, Evolocumab is reimbursed in 1 indication. The approved indications of these drugs in the USA (FDA) and Europe (EMA) are shared in the Table 1 below.

Table 1. Number of indications for which Nivolomab and Evolocumab are licensed

	FDA	**EMA**	**TİTCK**
Nivolumab	11	10	8
Evolocumab	3	3	2

Nivolumab; After being approved by the FDA and EMA, it took an average of 24.0 and 20.4 months for it to be licensed in Türkiye, respectively. In addition, the reimbursement of the indications of this drug in Türkiye took place after 27.6 and 25.2 months, respectively (Table 2).

Evolocumab has two approved indications in Türkiye, and these indications were approved in Türkiye 10 months and 13.2 months after the FDA and EMA, respectively. The only reimbursed indication of evolocumab in Türkiye was 72 months and 74.4 months after approval by the FDA and EMA, respectively (Table 2).

Table 2. Registration dates of Nivolumab and Evolocumab indications in FDA, EMA, and Türkiye

		FDA	**EMA**	**Türkiye**	
	Indications			**Approval**	**Reimbursement**
Nivolumab	Malignant melanoma	12.2014	04.2015	04.2017	04.2018
	Non-small cell lung cancer	09.2015	09.2015	07.2018	02.2022
	Renal cell cancer	11.2015	02.2016	04.2017	04.2018
	Hodgkin Lymphoma	05.2016	10.2016	07.2018	04.2018
	Head and neck squamous cell carcinoma	11.2016	03.2017	07.2018	-
	Urothelial carcinoma	02.2017	04.2017	-	-
	Colorectal cancer	07.2017	05.2021	-	-
	Hepatocellular carcinoma	09.2017	-	-	-
	Esophageal cancer	06.2020	10.2020	02.2022	-
	Pleural malignant mesothelioma	10.2020	04.2021	12.2022	-
	Gastric cancer	04.2021	09.2021	-	-
Evolocumab	Hypercholesterolemia and mixed dyslipidemia	12.2017	05.2015	-	-
	Homozygous familial hypercholesterolemia	08.2015	05.2015	06.2016	08.2021
	Established atherosclerotic cardiovascular disease	08.2015	03.2018	06.2016	-

Program Budgeting and Marginal Analysis, Health Technology Assessments, and Multi-Criteria Decision Analysis methods are frequently used in high-income countries to determine priority decisions regarding resource allocation in health. The aim is to provide transparent and accurate justification of the decisions taken within the healthcare system [25].

In determining which services to prioritize in determining health technologies, disease burden, clinical impact, alternative treatments, budget impact, economic impact, and the evidence obtained stand out as important topics that determine the decisions of decision makers [26].

Pricing of medicines in Türkiye is carried out by TITCK in accordance with the Decision on Pricing of Human Medicinal Products and the Communiqué on Pricing of Medicinal Products for Human Use. In 2004, the external reference system was introduced in drug pricing and the price of the drug in France, Spain, Italy, Portugal, Greece and the country where the drug was manufactured or imported can be taken as reference [27]. The external reference system is also widely used in European countries [28]. A recent study found that in countries where the external reference system is implemented, there are larger annual decreases in the list prices of medicines compared to other countries. However, it has been observed that in these countries, the launch of drugs on the market is

significantly delayed after they are licensed. In that study, it was calculated that in countries that apply the external reference system in pricing, the rate of drugs being released to the market 9 months after receiving a license decreases by over 70% compared to countries that do not [29]. While 4 of the 8 indications of nivolumab approved in Türkiye are reimbursed, the earliest of these indications to be reimbursed was 7 months after approval, and the latest to be reimbursed was 41 months after receiving approval. Only 1 out of 3 indications of evolocumab is reimbursed, and the time it takes for that indication to be reimbursed after it is licensed is more than 5 years. Access to expensive drugs, especially oncology drugs, is limited in many countries. A study found that strict price controls and reimbursement mechanisms in different countries such as India and Poland caused obstacles in access to medicine. On the other hand, it is stated that in the USA and Brazil, high drug prices and limited negotiations for reimbursement make access to medicine difficult [30]. For this reason, the interest of payers and companies in risk-sharing agreements has been increasing in developed countries since the early 2000s [2]. The aim of risk-sharing agreements is to limit the budget impact and access to innovative medicines, especially for patients who are more likely to benefit. It is stated that the companies aim to supply their drugs to the market faster with these agreements [1].

In Türkiye, AGÖK was established within the scope of SGK in 2016 and started to operate. The legislation of this commission is updated in line with needs. In this study, the registration and reimbursement dates of the two drugs were compared and it was determined that both drugs were licensed and reimbursed later in our country compared to both the USA and Europe. In addition, at the time of review of this study, some of the indications approved in the USA and Europe have not yet been added to the licenses of drugs in our country. As mentioned above, previous studies have shown that strict price controls, especially the external reference system, delay access to medicine in many different country examples [29,30]. In addition, a recent study has shown that strict pricing policies in Türkiye are a barrier to access to both innovative and generic drugs used in cancer treatment [31]. On the other hand, in order to solve the problems of access to medicines, access is provided from abroad on a prescription basis, with the permission of TITCK, for medicines that are not licensed or not available on the market in our country. However, this pathway constitutes a small proportion of public pharmaceutical expenditures [32].

The continuous increase in health expenditures and the increasing cost of health services all over the world are seen as important problems. In addition, the aging population and the increase in life expectancy increase the burden on healthcare systems both today and in the future. Health expenditures have been increasing in our country, as in the rest of the world, in recent years.

In conclusion, it can be seen that certain patient groups were prioritized through restrictions on drugs with high budget expectations over the drugs examined in our study, and these prioritization decisions attempted to ensure patients' access to treatment. Access to drugs can be prioritized in areas where they are the most effective among alternative treatments, where their cost effectiveness is highest, or where the budget impact is manageable. On the other hand; In the examples examined, it is seen that, similar to other countries, strict price controls delay access to innovative medicines in our country. Further studies are needed to evaluate access to new treatments and focus on the potential benefit to patient access to medicines.

AUTHOR CONTRIBUTIONS

Concept: E.H.V., E.K.K., E.K.A., B.G; Design: E.H.V., E.K.K., E.K.A., B.G.; Control: E.H.V., B.G.; Sources: E.H.V., B.G.; Materials: - ; Data Collection and/or Processing: E.H.V., E.K.K.; Analysis and/or Interpretation: E.H.V., E.K.K., E.K.A.; Literature Review: E.H.V., E.K.K.; Manuscript Writing: E.H.V., E.K.K.; Critical Review: E.H.V., E.K.K., E.K.A., B.G.; Other:-

CONFLICT OF INTEREST

The authors declare that there is no real, potential, or perceived conflict of interest for this article.

ETHICS COMMITTEE APPROVAL

The authors declare that the ethics committee approval is not required for this study.

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