



MARKET ACCESS FOR PHARMACEUTICALS IN TÜRKİYE: A COMPREHENSIVE OVERVIEW

TÜRKİYE'DE İLAÇLARIN PAZARA ERİŞİMİ: KAPSAMLI BİR İNCELEME

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ABSTRACT

Objective: This study provides a detailed analysis of the market entry processes for pharmaceuticals in Türkiye, examining the key factors shaping these processes and their alignment with international standards. The aim is to highlight the significance of regulatory mechanisms, economic strategies, and health technology assessment (HTA) in ensuring patients' access to high-quality medicines.

Result and Discussion: The pharmaceutical sector in Türkiye has evolved into a dynamic and growing industry, supported by significant contributions from both domestic and international stakeholders. Regulatory advancements, such as the establishment of the Turkish Medicines and Medical Devices Agency (TİTCK), have improved licensing, pricing, and reimbursement processes, aligning them with international practices. Additionally, HTA has emerged as a critical tool in evidence-based decision-making, optimizing the efficient use of healthcare resources and supporting sustainable access to innovative treatments. However, to maintain their effectiveness, these processes require continuous updates and improvements. Such efforts will provide significant benefits not only to the industry but also to patients and society as a whole.

Keywords: Health technology assessment (HTA), market access, pharmaceutical, pricing, reimbursement

ÖΖ

Amaç: Bu çalışma, Türkiye'deki ilaçların piyasaya giriş süreçlerini ayrıntılı bir şekilde inceleyerek, bu süreçleri şekillendiren ana unsurları ve uluslararası standartlarla olan uyum düzeylerini ele almaktadır. Çalışmanın hedefi, düzenleyici mekanizmaların, ekonomik stratejilerin ve sağlık teknolojisi değerlendirmesinin (STD), hastaların kaliteli ilaçlara erişimini sağlamadaki önemini ortaya koymaktır.

Sonuç ve Tartışma: Türkiye'deki ilaç sektörü, yerli ve yabancı paydaşların önemli katkılarıyla dinamik ve gelişen bir endüstri haline gelmiştir. Türk İlaç ve Tıbbi Cihaz Kurumu'nun (TİTCK) kurulması gibi düzenleyici yenilikler, ruhsatlandırma, fiyatlandırma ve geri ödeme süreçlerini geliştirerek uluslararası standartlarla uyumlu hale getirmiştir. Bunun yanı sıra, sağlık teknolojisi değerlendirmesi (HTA), kanıta dayalı karar alma süreçlerinde önemli bir araç olarak öne çıkmış, sağlık kaynaklarının verimli kullanımıyla yenilikçi tedavilere sürdürülebilir erişimi desteklemiştir. Ancak, bu süreçlerin etkili kalabilmesi için, sürekli olarak güncellenmesi ve iyileştirilmesi gerekmektedir. Bu tür çabalar yalnızca sektöre değil, aynı zamanda hastalara ve topluma da önemli faydalar sağlayacaktır.

Anahtar Kelimeler: Fiyatlandırma, geri ödeme, ilaç, pazara erişim, sağlık teknolojisi değerlendirmesi (STD)

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INTRODUCTION

Pharmaceutical industry is a part of medical sector that discovers, develops, produces, and markets pharmaceutical products intended to be used for the good of patients in terms of curing, preventing, or alleviating symptoms of diseases [1-3]. In Türkiye, the pharmaceutical industry is a dynamic sector where both domestic and foreign companies operate, with ensuring patient access to medicines being a primary goal [4-6]. According to the data from Pharmaceutical Industry Employers' Association (İEİS), as of the end of 2023, the industry comprises 870 organizations, including 109 pharmaceutical and radiopharmaceutical manufacturing facilities operating at international standards, 4 facilities producing specialized dietary foods for medical purposes, and 13 active ingredient manufacturing facilities [7]. This recent phase progress in pharma industry has made market access even more crucial than ever.

On the other hand, market access in Turkish pharmaceutical industry is influenced by various factors such as regulatory frameworks, economic policies, and the competitive environment [3].

The foundation of Turkey's organized healthcare system dates back to 1920s with the establishment of the Ministry of Health (MoH), aimed at post-war restoration and laying the system's essential structures. The 1961 Constitution recognized healthcare services as a core responsibility of the government toward its citizens. In 2003, supported by the World Bank (WB), the "Health Transformation Program" initiated a series of comprehensive reforms, fundamentally altering the financing structure, service provision, and accessibility of healthcare, resulting in significant improvements across the system [8-10].

In Türkiye, the Ministry of Health (MoH) serves as the primary health authority. Until 2011, the regulatory functions for pharmaceuticals and pharmacy services in Türkiye were conducted by the General Directorate of Pharmaceuticals and Pharmacy under the MoH. In 2011, these responsibilities were transferred to the newly established Turkish Medicines and Medical Devices Agency (TİTCK), an entity with a special budget and legal body under the MoH [8,11,12]. The Turkish Medicines and Medical Devices Agency (TİTCK) is responsible, on behalf of the MoH, for overseeing the pharmaceuticals and medical devices sectors, including clinical trial approvals, licensing, and pricing for pharmaceuticals and cosmetics. This agency conducts in other words conducts the Pharmaceuticals Electronic Tracking System (İTS), registers medical devices, operates the pharmacovigilance system, and evaluates applications for off-label medicine use, among other tasks. Additionally, the agency oversees market supervision and the surveillance of medicines. [11,13].

Further more with this article we aimed to detail the market access process of the pharmaceutical industry in Türkiye and the factors influencing these processes.

Definition of Market Access

In its broadest sense, "market access" refers to the degree to which a country's markets are open to foreign goods and services [14]. The World Trade Organization (WTO) initially introduced the concept of market access to define the competitive relationship between domestic and imported products within a country. This competitive relationship is governed by a series of measures designed to facilitate or restrict trade. In healthcare, market access aims to ensure that pharmaceuticals, in particular, achieve a reimbursable price through a health insurance system and can be prescribed [15].

In today's world, market access can be defined as the set of strategies, and processes developed by pharmaceutical and medical technology companies to ensure that their medicines or other medical technologies are accessible at affordable prices within a specific healthcare system [15,16]. In other words, market access can be defined as the comprehensive set of processes aimed at delivering a product to appropriate patients who are likely to benefit from it, in a cost-effective, timely, and sustainable manner.

Market access in the pharmaceutical industry is a global process which involves making medicines available for patients worldwide. This process requires taking into account regulatory rules, healthcare systems, and reimbursement policies in different countries [10,16,17].

The field of Market Access is no longer just about transforming a market authorization into health technology assessment (HTA) and reimbursement applications using health economic models. The

increasing focus on rare diseases and the shift to biotechnological solutions have brought Market Access departments to the forefront of product launch strategies, creating a need for Access Excellence. The target patient groups for innovative drugs are smaller, and prices are higher, while public health systems face limited resources in an aging society. Market access is becoming a leading interface that influences clinical development, regional marketing activities, patient engagement, and compliance with postmarket access requirements [18].

Scope of Market Access

A comprehensive market access strategy at both global and local levels forms the backbone of successful product launches and sustainable long-term efficiency. An effective global strategy should serve as a guiding framework for sub-strategies such as health economics and outcomes research (HEOR), pricing, and patient advocacy. These components must be integrated into a cohesive market access plan to ensure the successful introduction of global pharmaceutical products [10,18]. Market access encompasses a broad range of activities, including health economics, pricing, and reimbursement processes, which are critical for ensuring efficient resource allocation and patient access to innovative treatments. Specifically, in the pharmaceutical industry, these processes occur predominantly after a drug receives market authorization, making them integral to market access strategies [1,14-16].

Economics, at its core, addresses the scarcity of resources and the need for their efficient utilization across all sectors. Health economics applies these fundamental economic principles, theories, and practices to the healthcare domain. It plays a vital role in evaluating the cost-effectiveness of healthcare interventions, with pricing and reimbursement forming essential components of this discipline [19].

In many countries, pricing and reimbursement decisions are centralized at the national level. The growing prevalence of high-cost medicines has posed challenges even for well-resourced nations, prompting the development of policies aimed at enhancing access to medicines in a cost-effective manner [14,20]. Drug pricing policies are central to healthcare regulations, encompassing both price setting and reimbursement processes. These policies are shaped by economic and political considerations, with a primary objective of ensuring that patients have access to effective, safe, and affordable medications. The introduction of a drug to the market and its inclusion in reimbursement lists typically involves three key stages: registration, price determination, and reimbursement evaluation [12,20].

Globally, the market access process for drugs and devices can be categorized into three primary steps. First, companies submit a dossier containing efficacy, safety, and tolerability data to regulatory agencies to obtain market authorization (Figure 1) [15]. Following approval, applications for pricing and reimbursement are prepared to establish the drug's financial and accessibility frameworks. Lastly, logistics and supply chain activities are organized to ensure the product is marketed and distributed without interruption [16].



Figure 1. Market access process

The ultimate goal of market access is to ensure that all eligible patients who can benefit from a new product have continuous access to it at reasonable prices. This objective underscores the importance of aligning regulatory, economic, and logistical strategies to create a sustainable healthcare system that balances innovation with affordability.

Factors Affecting Market Access

Licencing

In Türkiye, the drug authorization process is carried out in accordance with European standards. This process is supported by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and memberships, and it is standardized using the Common Technical Document (CTD). Licensing applications include Good Manufacturing Practices (GMP) inspections of manufacturing facilities and priority evaluation processes [1,11,21,22].

During the licensing process, GMP inspections of products are conducted first. For conventional products, only the finished product GMP inspection is required, while for biological or biotechnological products, both active ingredient and finished product GMP inspections are required. Inspection processes consist of pre-assessment, scientific evaluation, and administrative evaluation steps. In the pre-assessment, the integrity of the documentation is examined; in the scientific evaluation, quality, efficacy, and safety are assessed; and in the administrative evaluation, common controls are done [5,21,22].

Pricing

External price referencing (EPR) serves as a widely utilized strategy for regulating pharmaceutical costs, aiming to contain expenditures by referencing drug prices across different markets. This approach provides payers and regulators with a reference point for setting or negotiating the price of identical products within their own market [23-25].

In Türkiye, The Turkish Medicines and Medical Devices Agency (TİTCK) is responsible for pricing of pharmaceuticals on behalf of the Ministry of Health. Since 2004, the Reference Price System is being used for drug pricing in Türkiye. The countries (Spain, France, Greece, Italy, Portugal) taken as reference in the Reference Price System are selected from EU member states those show similar socioeconomic status like Türkiye. Pricing is done using a fixed Euro value and varies according to whether the product is imported or locally manufactured and whether it is original or generic. Special condition product groups are also considered in pricing [5,11,12,20,26-30].

Pricing for locally manufactured products can be done using the card of manufacturing costs. Original products are priced at 100%, while generic products are priced at 60%. The price of the original product is also reduced to 60%. For price-protected products, this rate is set at 80%. Price updates are made by updating the fixed Euro value within the first 45 days of each year. Drug price research is conducted annually during the real source price change period, and increases or decreases are applied to the products [11,12,27,31].

The Pricing Evaluation Commission, coordinated by the MoH with representatives from the Social Security Institution (SGK), the Ministry of Treasury and Finance, and the Presidency of Strategy and Budget, makes decisions on increasing, decreasing, or maintaining prices when deemed necessary [12,31].

Reimbursement

Reimbursement can be defined as the full or partial payment of the cost of a medical product by the insurance institution. In Türkiye, Social Security Institution (SGK) is the governmental institution responsible for reimbursement [9,11]. Regulations on which drug expenses used in treatment are covered and to what extent are included in the Drug Reimbursement Regulation. The deadline for reimbursement applications for each year is the last day of March and July [32].

The drug must first be licensed, published on the price list, and have a sales permit to apply for the consideration to reimbursement [9]. Since 2005, the reimbursement system has been based on a positive list, which categorizes medicines into groups according to their active ingredient,

pharmaceutical form, and dosage [5,11]. The reimbursement status and discounts for licensed drugs in our country are updated every Wednesday on the Institution's official website under the Announcements section as the positive (Attachment-4A) list (Figure 2). For products on overseas drug lists, the reimbursement status is shared with Attachment-4C lists [5,32,33].



Figure 2. Positive List on Social Security Institution Website (taken from sgk.gov.tr)

When considering reimbursement, it is important to take into consideration several key terms. The Therapeutic Reference (TR) Group is the grouping of products containing the same active ingredient and the same indication for price comparison purposes. The TR Band Range (Base price application) is the public payment of up to 5% more than the unit price of the lowest-priced drug. The yellow band is used for products that have not achieved a 1% market share and are not considered in the base price/band calculation. The public sector statutory rebate is the discount rate determined according to the wholesaler's (ex-factory) price of the drug and its reference/equivalent status. The Public Price (Reimbursed price) is the price obtained by applying the public sector statutory rebate to the retail sales price [29,34].

The Drug Reimbursement Commission is chaired by the General Director of General Health Insurance, with representatives from the General Health Insurance Directorate, the Ministry of Treasury and Finance, the Ministry of Health, and the Presidency of Strategy and Budget. The Medical and Economic Evaluation Commission is responsible for scientific and economic evaluation. The Alternative Reimbursement Commission is chaired by the General Director of General Health Insurance, with representatives from the General Health Insurance Directorate, the Ministry of Treasury and Finance, the Ministry of Health, and the Presidency of Strategy and Budget. The commission process and the decisions made by the commission are confidential for all times [5,12,29,32].

Health Technology Assessment (HTA)

A key aspect of market access is the clinical, economic and humanistic evaluation of drugs, which involves analyzing their effectiveness and cost-effectiveness using real-world data. Clinical evaluation relies on scientific evidence to confirm a drug's safety and efficacy, while economic evaluation assesses its cost-effectiveness and impact on health economics [15,35,36].

According to the definition on the official HTA Glossary website, operated in collaboration with Health Technology Assessment International (HTAi) and the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment (HTA) is defined as a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. In HTA process the aim is to inform decision-making in order to promote and provide an equitable, efficient, and high-quality healthcare services [37,38]. HTA is a multidisciplinary field that is integral to this process, evaluating drugs from clinical, economic, ethical, and social perspectives. HTA informs pricing and reimbursement decisions, emphasizing cost-effectiveness and health outcomes [14,15,35,38-40].

According to the Directorate of Research, Development, and Health Technology at the General Directorate of Health Services, which operates under the Ministry of Health, Health Technology Assessment (HTA) is defined as "the examination and interpretation of various aspects of technologies used in healthcare. While this assessment is primarily conducted to inform decision-making mechanisms, it also aims to ensure that all stakeholders are adequately informed about the technology in question" [38,40].

In other words, HTA allows governments to indirectly control drug prices. Although its influence on pricing can be vague, there is a clear pattern: a lower assessment value increases the likelihood that a drug will be either not purchased or bought at a lower price. This system prioritizes valuable and cost-effective medications for procurement. [1,14,15,39,40].

Since the late 1980s, health technology assessments have rapidly developed and became institutionalized in advanced economies. In our country, such assessments came into the agenda starting in 2003 with the implementation of the "Health Transformation Program" and the associated health reforms. The institutionalization of HTA in Türkiye began and continues with the support and leadership of the Evidence-Based Medicine Association, established in late 2007. The first legal regulation regarding HTA's institutional framework was introduced in 2011 with Decree Law No. 663 [41].

Türkiye acknowledges the necessity of conducting Health Technology Assessments (HTA) to evaluate and improve the capacity of health technologies. The country has established three key HTA bodies: the Turkish Medicines and Medical Devices Agency (TITCK), which operates under the Ministry of Health and focuses on health policy; the Directorate General for Health Research, also affiliated with the Ministry of Health, specializing in clinical processes; and the Social Security Institution (SGK), under the Ministry of Labor and Social Security, which has yet to publish any reports. [11,40].

Logistics and Supply

Considering the definition of market access, it is evident that logistics play a crucial role in the success of a market access strategy. In the drug supply process, coordination with stakeholders is essential to address shortages of unavailable medications. Conducting a thorough research and maintaining effective stock control are the key elements to ensure patients receive necessary drugs promptly [15].

In Türkiye, MoH works efficiently to make sure sustainability by using Electronic Tracking System (ETS, ITS) to control stock in the market [11,42]. ITS ensures the procurement of original and reliable pharmaceuticals by preventing drug counterfeiting and trafficking [42]. The adoption of ITS has resulted in numerous benefits, notably the optimization of pharmacy operations and the improvement of medication safety and accessibility for patients [36]. Additionally, it is possible to facilitate access to medications not licensed in our country.

The Overseas Medicine Supply (Medicines Brought From Abroad, MBFA) is used for unlicensed drugs and licensed molecules that are unavailable in the market due to various reasons. It is standard policy that drugs can only be marketed after receiving marketing authorization from the Turkish Medicines and Medical Devices Agency. However, the MBFA pathway allows access to specific medicines with high medical need, even in the absence of marketing authorization or when a marketing authorization has been granted, but the drug is not commercially available [9,43]. Through close collaboration with international suppliers and the MoH, these medications are delivered to patients efficiently. The Ministry ensures that all aspects, including the source of the medication and compliance with Good Distribution Practices (GDP), are meticulously monitored and approved [43].

Medicines brought from abroad are subject to patient-specific procedures. While MBFA differs from Compassionate Use, it can be categorized under the Named-Patient Program, which is granted in response to requests by physicians on behalf of specific or "named" patients [9,43,44].

Under European Regulation 726/2004/EC, the European Union defines Compassionate Use as the provision of unauthorized medicinal products to patients who suffer from chronic or seriously debilitating conditions or life-threatening diseases, where no satisfactory authorized treatments are available [15].

In Türkiye, Compassionate Use is a program for the application of drugs that have completed at least Phase II studies worldwide or have obtained efficacy and safety data that allow for the advancement to the later phase of the study in which Phase II and III are conducted together. These programs are used in the treatment of individuals with life-threatening or severely quality-of-life impairing diseases those have not been successful with available treatments in our country. These programs aim to ensure that drugs reach patients quickly and safely [44]. A similar program, titled the "Temporary Utilization Program (ATU)," has been implemented in France since 1992 to improve early access to medicines authorized abroad. Similarly, the United Kingdom government launched the Early Access to Medicines Scheme (EAMS) to provide patient access to new medicines before marketing authorization. EAMS is a voluntary program, and the manufacturer provides the medicine free of charge, just like the Compassionate Use Program in Türkiye [9,44].

Global Insights on Market Access

Türkiye, as a prominent emerging market, shares several characteristics with well-established pharmaceutical markets, such as those in the USA, Europe, the UK, and Japan, but also faces distinct challenges influenced by its unique economic and healthcare contexts.

The Turkish Medicines and Medical Devices Agency (TITCK) governs the pharmaceutical approval process in Türkiye, aligning it with European Medicines Agency (EMA) standards. However, the approval timelines in Türkiye tend to be longer, averaging between 18 and 24 months [5,11,21,22]. In contrast, the U.S. Food and Drug Administration (FDA) offers expedited pathways, such as Priority Review and Breakthrough Therapy Designation, which allow critical drugs to be approved within 10 months or less [45,46]. In the European Union, the EMA provides centralized approval for medicinal products, but individual member states maintain independent processes for pricing and reimbursement. Approval timelines within the EU are generally similar to those in Türkiye, averaging 1–2 years [46-48]. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) has introduced the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate drug approvals and facilitate quicker patient access [46,49]. Similarly, Japan, the world's third-largest pharmaceutical market, has a Pharmaceuticals and Medical Devices Agency (PMDA) that prioritizes expedited market access for innovative drugs, offering conditional early approvals for treatments addressing rare diseases or unmet medical needs. [46,50].

In terms of pricing, Türkiye utilizes an external reference pricing (ERP) system, which benchmarks drug prices against the lowest prices in a basket of European countries. While this system ensures affordability for patients, it restricts profitability for pharmaceutical companies, often deterring the introduction of innovative therapies [5,11,12,20,23-30]. In contrast, the U.S. follows a market-driven pricing model, allowing pharmaceutical companies to set their own prices. This results in higher drug prices but also fosters innovation and significant investment in research and development (R&D) [45,46]. Most European countries implement ERP, but many combine it with value-based pricing, which aligns the cost of drugs with their clinical benefits [46-48]. The UK utilizes the National Institute for Health and Care Excellence (NICE) to assess the cost-effectiveness and clinical benefits of treatments, ensuring affordable healthcare within the National Health Service (NHS) [46,49]. Japan, similarly, conducts biennial price reviews, regularly reducing reimbursement rates for less innovative drugs, thus maintaining affordability while incentivizing ongoing R&D [46,50].

Regarding Health Technology Assessment (HTA), its role in Türkiye is relatively limited. The Social Security Institution (SGK) oversees reimbursement decisions, primarily based on pharmacoeconomic evaluations. This centralized approach often leads to delays in market access due to lengthy negotiations and stringent cost-containment measures [11,40]. In the U.S., HTA plays a minimal role, as reimbursement decisions are primarily determined through negotiations between private insurers and manufacturers. However, in several European countries, including Germany (via IQWiG) and France (via HAS), HTA is integral to the reimbursement process, assessing both clinical outcomes and economic considerations [14,47,48]. In the UK, NICE is a global leader in HTA methodologies, combining rigorous clinical and economic evaluations to make transparent, evidence-based reimbursement decisions [14,46,49]. Japan does not yet have a formal HTA agency like UK's NICE or Germany's IQWiG. Japan's approach to HTA is more selective but is gradually gaining prominence as

a tool for balancing cost-effectiveness with the need to maintain a sustainable, universal healthcare system [46,50].

This heading has been summarized in the table below (Table 1).

	Regulatory authority	Approval time	Pricing mechanism	Reimbursement	Access delays	Generic penetration
United States (USA)	FDA (Food and Drug Administration)	~10 months	Market driven	Private insurance, Medicare, Medicaid	Minimal	High (~90%)
Europe (EU)	EMA (European Medicines Agency) + National Agencies	1 – 2 years	HTA and reference pricing	Public reimbursement systems	Delays due to HTA and pricing reviews	Moderate (60–80%)
United Kingdom (UK)	MHRA (Medicines and Healthcare products Regulatory Agency	1 – 2 years	NICE-led cost effectiveness evaluations	NHS-funded reimbursement for approved drugs	Moderate delays due to NICE evaluations	Moderate (~60%)
Japan	PMDA (Pharmaceuticals and Medical Devices Agency)	~1 year	Price control via negotiations	National health insurance	Moderate post- approval delays	Moderate
Türkiye	TİTCK (Turkish Medicines and Medical Devices Agency)	~18 - 24 months	External reference pricing	SGK (Social Security Institution) centralized reimbursement	Significant delays due to reimbursement and pricing	High (~80%)

Table 1. Global insights on market access factors

RESULT AND DISCUSSION

Market access in the pharmaceutical industry in Türkiye is a multifaceted and complex process. Many factors, such as regulations, pricing and reimbursement policies, logistics, and supply processes, affect this process. Achieving and sustaining effective market access for pharmaceuticals in Türkiye requires a multifaceted approach that balances regulatory requirements, economic constraints, and healthcare needs. The dynamic landscape of Türkiye's pharmaceutical industry, with both domestic and international stakeholders, has made structured market access not only a goal but a necessity to ensure that the patient receives high-quality medicines. For the pharmaceutical industry to respond quickly and meeting patients' needs, these processes must be managed effectively. This is significant for improving public health and the sustainable growth of the pharma industry [5,11,51]. Türkiye's regulatory advancements, including the establishment of the Turkish Medicines and Medical Devices Agency (TİTCK), have streamlined processes for licensing, pricing, and reimbursement, bringing them in line with international standards. Additionally, the integration HTA has allowed for an evidence-based approach to drug evaluation, optimizing resource allocation and supporting cost-effective healthcare solutions.

Looking forward, Türkiye's healthcare policy and its commitment to innovation will likely enhance the role of HTA, addressing the challenges posed by the increasing prevalence of high-cost biotechnological treatments. Through coordinated regulatory frameworks and stakeholder engagement, Türkiye's healthcare system aims to not only improve accessibility but also to reinforce a sustainable model that upholds the principles of equity, efficiency, and quality in pharmaceutical access.

Türkiye has made significant steps and continues to make progress in market access in the pharmaceutical industry. However, these processes must be continuously updated and improved. This will be beneficiary not only for the industry but also for patients and society.

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CONFLICT OF INTEREST

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

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