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Regulation of parallel imports of medicinal products: international and foreign experience

The article is devoted to a comprehensive study of international and foreign legal regulation of the parallel import of pharmaceuticals. The purpose of the research is to identify the legal features and challenges of applying parallel import in the pharmaceutical sector, as well as to determine ways to improve Kazakhstan's national legislation, taking into account international experience. The study employs comparative legal and systemic analysis methods, as well as a formal legal approach. The provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which establish the principle of exhaustion of rights, are examined, along with various models of its implementation — regional in the European Union, national in the United States, and mixed in the EAEU member states. It is established that in Kazakhstan, the legal regulation of parallel imports of pharmaceuticals is still evolving and requires harmonization with EAEU norms. Legal conflicts related to trademark protection and registration procedures are identified. Based on the analysis, it is concluded that a balanced mechanism should be developed to ensure both the protection of intellectual property rights and the public's access to essential medicines.

Keywords: medicinal products, parallel import, intellectual property, trademark, international trade, national treatment, exhaustion of rights, TRIPS Agreement, EAEU, WTO.

Introduction

Currently, the issue of parallel import of pharmaceuticals is one of the most pressing topics in the global trade system and national pharmaceutical markets. Especially in the post-pandemic period, finding a balance between ensuring access to medicines, maintaining price stability, and protecting intellectual property rights has become a key challenge. Parallel import refers to the importation of goods, including pharmaceuticals, from other countries without the consent of the original manufacturer, representing a complex legal institution situated at the intersection of international trade and patent law. On the one hand, emphasis is placed on the necessity of protecting consumers from misconceptions or misleading practices concerning the authenticity and origin of goods. On the other hand, while the prevention of infringements of intellectual property rights remains important, it is widely argued that copyrights and trademarks should not be employed as instruments of artificially segmenting markets and obstructing free trade [1].

The aim of this research is to conduct a comprehensive analysis of international and foreign legal regulation in the field of parallel import of pharmaceuticals and to identify an optimal legal model suitable for Kazakhstan.

Research objectives:

-To examine the legal nature of the concept of parallel import and the international legal norms governing it;

-To conduct a comparative legal analysis of the regulatory approaches applied in the European Union, the United States, and the EAEU member states;

-To identify the specific features and challenges of legal regulation of parallel import in the Republic of Kazakhstan;

-To propose directions for improving national legislation.

From a theoretical perspective, scholarly discussions demonstrate deep contradictions. Some authors, such as H. Skoko, K.E. Maskus consider parallel import an effective tool for fostering market competition, increasing access to essential medicines, and promoting consumer welfare. In contrast, S.K. Verma and C. Heath emphasize that excessive liberalization of parallel import may erode the exclusive rights of patent holders and weaken incentives for innovation, particularly in the pharmaceutical sector where research and

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development costs are high. This theoretical duality reflects the fundamental tension between the principles of free trade and the doctrine of intellectual property rights exhaustion.

Methodologically, two dominant approaches can be distinguished in the literature. The economic approach focuses on the impact of parallel imports on prices, competition, and innovation (K.R. Brekke et al., K.E. Maskus), whereas the legal approach emphasizes compliance with international and regional norms such as the TRIPS Agreement, the Doha Declaration on TRIPS and Public Health, and the Directive 2008/95/EC of the European Parliament. However, many studies treat these aspects in isolation, leading to methodological fragmentation and inconsistent conclusions.

In practical terms, the divergence between international and national regulatory regimes further complicates the issue. For example, the European Union generally applies a regional exhaustion principle that permits parallel trade within the European Economic Area (Directive 2008/95/EC), while the United States follows a more restrictive model based on national exhaustion (U.S. Code Title 17). The EAEU and Kazakhstan remain in a transitional phase, seeking to reconcile international obligations under TRIPS Agreement with domestic policy priorities, including the availability of medicines and public health protection (G.P. Ivliev, B.A. Shakhnazarov, Zh.O. Abylkhanova, Ma Xuxia).

From the author's perspective, the fragmentation of both theory and practice demonstrates the need for a comprehensive legal model that harmonizes intellectual property protection with public health objectives. Legal regulation should not be confined solely to safeguarding the interests of patent or trademark owners; it should also incorporate socially significant priorities—ensuring equitable access to essential medicines, maintaining affordability, and supporting the sustainability of national healthcare systems.

Methods and materials

This research is based on the use of comparative legal, systemic, normative legal, structural, as well as logical and deductive methods of scientific inquiry. The theoretical foundation of the study consists of the works of foreign and domestic scholars, international treaties, and acts of supranational organizations regulating issues related to the parallel import of pharmaceuticals.

Among the key scholarly and regulatory sources forming the foundation of this research are the following:

– publications by N. Skoko, C. Heath, B.C. Christopher, S.K. Verma, G.P. Ivliev, B.A. Shakhnazarov, and Zh.O.Abylkhanova;

– the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health, which provided the international legal basis for the study;

– empirical data from the Report on the State of law enforcement practices in the field of intellectual property protection in the member states of the Eurasian Economic Union for 2023;

– regulatory acts governing the pharmaceutical market, including Decision No. 78 of the EEC Council "On the Rules for Registration and Examination of Medicinal Products", Decree of the Government of the Russian Federation No. 506 of March 29, 2022, and Order of the Minister of Health of the Republic of Kazakhstan No. KR DSM-237/2020 of December 8, 2020;

– analytical studies on the impact of parallel import on the pharmaceutical market, including works by K.E. Maskus, K.R. Brekke et al., as well as publications by J. Grigienė, J. Jacunskaitė, and Ma Xuxia.

The comparative-legal method was employed to identify similarities and divergences between legal systems by analyzing the specific features of the regulation of parallel import across different jurisdictions. The systemic method enabled the structured assessment of legal norms with a view to evaluating the impact of the mechanism of parallel import on the accessibility of pharmaceutical products. By applying the normative-legal method, relevant provisions of international treaties, domestic legislation, and regulatory instruments were examined, and their applicability to the regulation of parallel import was assessed. Finally, logical and deductive methods were used to analyze the transition from general legal principles to the specific modalities of their implementation within individual jurisdictions.

Results

The conducted research made it possible to comprehensively analyze international and national approaches to the regulation of parallel importation, identify its development trends, and determine possible directions for improving the legislation of the Republic of Kazakhstan in this area. The obtained results are

based on a comparative legal and structural-functional analysis of international treaties, WTO and EAEU acts, as well as the legislation of individual states.

Firstly, the study clarified the legal nature of parallel importation as a specific mechanism of goods circulation situated at the intersection of international trade and intellectual property protection. The author concluded that, despite the absence of direct regulation in the Paris Convention, its principles—national treatment and protection of industrial property—indirectly influence the formation of national legal systems in this field. A stable trend has been observed toward using parallel importation as an instrument for trade liberalization and improved access to goods, particularly in the pharmaceutical sector.

Secondly, the analysis of the TRIPS Agreement and the Doha Declaration established that the principle of exhaustion of rights is the central element determining the admissibility of parallel importation. The TRIPS Agreement does not impose a uniform standard, allowing states to choose between national, regional, and international regimes of exhaustion. The author's observation indicates that such flexibility contributes to the adaptation of international norms to the socio-economic conditions of each country, which is particularly relevant for Kazakhstan as a member of both the EAEU and the WTO.

Thirdly, the study of the European Union's legal system revealed that the regional exhaustion regime, enshrined in Protocol 28 to the Agreement on the European Economic Area and Article 7 of Directive 2008/95/EC, ensures a balanced approach between free trade and the protection of intellectual property rights. The author notes that this model contributes to the formation of a stable internal market and may serve as a conceptual foundation for improving the legal regulation of parallel importation within the EAEU framework.

Fourthly, the analysis of legislation and law enforcement practices in the EAEU Member States demonstrated that the Union adheres to the principle of regional exhaustion of rights. However, the absence of a unified mechanism at the Union level creates legal uncertainty. In particular, differences between the approaches of Kazakhstan, Russia, Belarus, and Armenia reduce the effectiveness of parallel importation as a tool to ensure access to essential medicines. The author's observation confirms the need to develop a unified regulatory model combining economic feasibility with the requirements for the protection of intellectual property rights.

The scientific novelty of the research lies in the following:

– The content and significance of the principle of exhaustion of rights in the context of international regulation of parallel importation have been clarified;

– Directions for harmonizing the norms of the TRIPS Agreement and EAEU legislation in the field of parallel importation have been identified;

– Factors hindering the unification of national regimes of exhaustion have been determined, and legal mechanisms to overcome them have been proposed;

– The necessity of amending Kazakhstan's legislation has been substantiated to strengthen legal certainty and enhance the transparency of parallel import mechanisms for pharmaceuticals.

The research results fully correspond to the stated aims and objectives, as they are directed toward identifying the essence of parallel importation, analyzing international and regional exhaustion regimes, examining the specifics of legal regulation in Kazakhstan, and formulating proposals for its improvement.

The practical significance of the findings lies in the fact that the proposed provisions and conceptual approaches can be applied:

– by EAEU authorities in developing a unified regime of exhaustion of rights;

– in judicial practice when resolving disputes concerning "likelihood of confusion" and the legality of parallel importation;

– in scientific and educational activities aimed at further developing the theory of intellectual property and international trade law.

Thus, the study demonstrates that the formation of a balanced system for regulating parallel importation in Kazakhstan requires the combination of international standards with regional particularities. The implementation of the proposed concept will enhance the competitiveness of the domestic market, ensure access to essential medicines, and at the same time maintain an adequate level of intellectual property protection.

Discussion

Although the Paris Convention does not directly address the issue of parallel importation, a number of other international treaties may influence national legislation in this regard. One of the most significant international instruments in the field of intellectual property is the Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS Agreement), adopted in 1994 within the GATT/WTO framework. It was initially expected that such a comprehensive agreement, covering virtually all aspects of intellectual property rights, would also provide a clear framework for regulating parallel importation. However, this expectation was not realized. The TRIPS Agreement does not contain specific provisions governing parallel import. Despite the recognition that parallel importation is consistent with the objectives of free international trade, the adoption of a uniform international instrument providing for its general admissibility has not been achieved [2].

To address this lacuna, the interpretative note to Article 28 (1)(a) of the TRIPS Agreement explicitly refers to Article 6, clarifying that the right of a patent holder to control importation is subject to the principle of exhaustion of rights. Article 6 acknowledges the "exhaustion of rights" issue but refrains from laying down substantive rules. Instead, it states that: "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights" [3]. Accordingly, at the international level, the permissibility or prohibition of parallel importation remains within the exclusive competence of domestic jurisdictions. The flexibility afforded to WTO Members in this respect is constrained by the national treatment and most-favoured-nation principles embodied in Articles 3 and 4 of the TRIPS Agreement. In other words, when regulating parallel importation, Member States are obliged to grant right holders from other WTO Members the same level of legal protection as their own nationals and to refrain from granting preferential treatment to one Member over another [3].

The TRIPS Agreement thus recognizes the right of each Member to determine its own exhaustion regime in accordance with domestic needs, without prescribing a uniform standard. This principle was further clarified and reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health. Paragraph 5(d) of the Declaration states: "the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge" [4]. Consequently, the authority to permit or restrict parallel importation has been formally acknowledged as falling entirely within the legislative discretion of national authorities. With regard to dispute settlement, the WTO Dispute Settlement Understanding generally permits any Member State to initiate proceedings if another Member fails to comply with its obligations under GATT/WTO agreements. However, Article 6 of the TRIPS Agreement expressly precludes dispute settlement with respect to the exhaustion of rights, regardless of the national position adopted. This provision unambiguously confirms that a Member cannot be held internationally accountable for supporting or opposing an international exhaustion regime [3]. Nevertheless, this neutrality does not imply that the TRIPS Agreement endorses or rejects any specific approach. Rather, it maintains an impartial stance, leaving States with the discretion to establish legal regimes in accordance with their particular interests and policy objectives.

Since this exception is of a procedural nature, it merely implies that, irrespective of the position taken by WTO Members with respect to the exhaustion of intellectual property rights, they cannot be subjected to sanctions under the GATT/WTO framework. Nevertheless, the Agreement may directly or indirectly influence the resolution of issues concerning the exhaustion of rights and parallel importation.

It is evident that States have failed to reach a uniform position on the matter of parallel importation. Several jurisdictions, including Germany, Japan, Finland, Norway, and others, endorse the doctrine of international exhaustion of intellectual property rights and favor the legalization of parallel imports. In contrast, the United States, Canada, France, Australia, and other countries advocate restrictive measures, arguing for the necessity of limiting parallel importation [5].

The doctrine of international exhaustion is undeniably more conducive to the free circulation of goods in international trade compared to the doctrine of national exhaustion. However, States that do not recognize the principle of international exhaustion may prohibit the importation of goods placed on the market in another country without the express consent of the trademark holder, thereby preventing the parallel entry of such products into their domestic markets [6].

Legislation and public policy regarding parallel imports differ significantly across jurisdictions. Some States impose restrictions or outright prohibitions on parallel importation in certain sectors or with respect to specific categories of goods. Nevertheless, in the majority of countries, this mechanism is permitted to some extent. Parallel import functions not only as an effective instrument for fostering international trade and improving access to goods in various markets but also as a mechanism of international competition. At the same time, it gives rise to a range of complex legal challenges. Addressing these challenges is of critical importance for maintaining stability in international trade relations, ensuring the availability of goods in national markets, and safeguarding the intellectual property rights of right holders [7; 56–67].

Certain pharmaceutical companies advocate restrictions on parallel trade in order to prevent the flow of lower-priced medicines from developing countries into the markets of economically developed States. However, the national legislations of the European Union, the United States, Japan, and other economically advanced jurisdictions do not permit the introduction of such restrictions. In fact, there is insufficient legal or economic justification to prohibit developing and transition economies from engaging in parallel trade. This is largely due to the fact that in developed markets original pharmaceutical products are typically sold at comparatively lower prices, a situation attributable to the strong competitive pressure exerted by generic medicines in both the European and U.S. markets [8].

Among the jurisdictions that impose certain limitations on parallel imports are several EU Member States, the United States, and other countries. Nevertheless, even within these jurisdictions, the applicable legislative and regulatory frameworks are not uniform, but rather vary depending on specific sectors or categories of products. Consequently, within a single jurisdiction, the legal regime governing parallel imports may be applied differently across various industries. For this reason, in order to determine the precise scope of restrictions on the parallel importation of medicinal products, it is essential to examine the specific legislative instruments and regulatory provisions of each State concerned.

At present, the European Union constitutes the only jurisdiction in which a clear and uniform legal framework has been established with regard to parallel importation. The key provisions governing parallel imports within the EU are enshrined in Protocol 28 to the Agreement on the European Economic Area [9] and Article 7 of Directive 2008/95/EC [10]. Both instruments codify the principle of trademark rights exhaustion. Under this principle, goods placed on the market with the consent of the trademark owner may be freely imported into other Member States within the EU, and the trademark proprietor cannot prohibit such importation—provided that the condition or quality of the goods has not changed or deteriorated after they were first marketed [9].

Although the principle of exhaustion of rights is generally recognized within the framework of the European Economic Area, parallel importation may be restricted or even prohibited where there is a risk of compromising the quality of goods, their packaging, or the reputation of the trademark.

This legal mechanism serves as an effective instrument for regulating pricing policies and ensuring fair competition within the EU internal market. At the same time, it is grounded in a legal balance that takes into account both the protection of intellectual property rights and the preservation of the economic interests of rights holders.

Within the EU territory, the parallel importation of medicinal products is permitted; however, the process is subject to strict regulation. Imported medicines must fully comply with the safety and quality standards established by the European Medicines Agency. In addition, the composition of parallel-imported medicines must be identical to that of analogous medicinal products already registered and marketed within the EU. Furthermore, they must be properly packaged in accordance with local legislative requirements, including norms on labeling and presentation.

In practice, however, these requirements are not always strictly adhered to. When medicinal products are introduced into the markets of other EU Member States under parallel import schemes, there often arises a necessity to adapt to the national particularities of the importing country. For example, some jurisdictions impose specific requirements concerning labeling in the national language. Consequently, parallel importers may be obliged to relabel or repackage the medicinal product. This, in turn, creates certain legal risks in the field of trademark protection, since the chosen method of repackaging or relabeling must not infringe upon the rights of the trademark holder. Accordingly, any modification to the packaging of medicinal products under parallel import must be carried out in a lawful manner and in such a way that does not impair the reputation of the trademark [11]. The EU's approach in this respect is often assessed as effective, owing to the fact that its requirements regarding parallel imports from non-EU countries are significantly stricter. In such cases, the trademark proprietor retains the right to authorize or prohibit parallel importation. Since the trademark owner is not forced to compete directly with their own products, this framework incentivizes them to invest more extensively in research and the development of new technologies. Conversely, consumers may also benefit from this approach by gaining access to the outcomes of such innovative advancements [12; 123]. In the European Union, the principle of regional exhaustion of rights and the doctrine of free movement of goods form a coherent legal mechanism that successfully combines the protection of trademark rights with the maintenance of fair competition. The EU model demonstrates that legalizing parallel imports, accompanied by strict quality control and consumer protection mechanisms, does not undermine, but rather strengthens, the economic stability of the common market.

In contrast, in the United States, the trademark owner can prevent parallel imports if the product was intended for sale abroad and differs significantly from the version intended for the US market. In such cases, the use of the trademark on the parallel-imported product may be deemed misleading to consumers as to the origin or quality of the goods.

Accordingly, if a foreign-manufactured product differs significantly from its U.S. counterpart in terms of composition, quality, packaging, or service conditions, these discrepancies may result in consumer confusion and the purchase of goods of different quality. For this reason, U.S. law grants trademark owners the right to prohibit parallel imports in such circumstances. This rule is intended to safeguard intellectual property rights and prevent consumer deception (Chapter 1, Paragraph 109) [13].

The parallel importation of pharmaceuticals in the United States is strictly regulated. The Food and Drug Administration, as the supervisory authority for the safety and quality of food and medicines, monitors the safety and compliance of imported pharmaceuticals with applicable standards. Unauthorized medicines may be subject to seizure. From an economic perspective, price regulation and parallel trade constitute one of the most controversial issues in pharmaceutical markets. On the one hand, these policy instruments can enhance static efficiency: price regulation constrains the market power of pharmaceutical companies and brings prices closer to marginal production costs, while parallel trade fosters intra-brand competition in the importing country and reduces price disparities between high- and low-income countries. On the other hand, price regulation and parallel trade may negatively affect dynamic efficiency [14]. Thus, in the American model, consumer protection and the preservation of the information function of trademarks are prioritized over trade liberalization.

Under the law of the Eurasian Economic Union, the parallel importation of pharmaceuticals is permitted, provided that the product has been placed on the market within the territory of a Member State (or with the consent of the rights holder). This means that medicines imported into one EAEU country may also circulate freely across the territories of other Member States, even if they were originally intended for marketing elsewhere [15].

The EAEU follows the principle of regional exhaustion of rights. Thus, once a pharmaceutical product is lawfully placed on the market within the EAEU (by the rights holder or with their consent), it may circulate freely among Member States. Nevertheless, certain requirements must be observed for the lawful parallel importation of pharmaceuticals. In particular, the imported medicine must be authentic and fully compliant with the legislative requirements of the importing state.

Since 2017, a Common Market for medicines has been operating within the EAEU. This market establishes uniform rules for registration, manufacturing, and quality control of medicinal products. The EAEU also applies unified rules for the registration and examination of pharmaceuticals, which envisage various transitional periods for regulatory alignment:

– Until 1 January 2016, Member States independently regulated pharmaceutical registration;

– Until 31 December 2020, applicants could choose between national procedures or EAEU rules for registration. Importantly, a medicine registered in one Member State under national rules could circulate only within that state;

– Registration certificates issued by national authorities before 1 January 2016 may be extended until no later than 31 December 2025. After that, such medicines must undergo re-registration under EAEU procedures, otherwise the authorization will lapse [16].

Within the EAEU, a unified regime of rights exhaustion has not been adopted. Kazakhstan and Armenia adhere to the principle of regional exhaustion of rights after the first placement of goods on the EAEU market. This means that once a product is lawfully placed on the market in one EAEU country, it may be freely imported into other Member States. Since 2022, Russia has introduced a temporary mechanism allowing parallel imports of certain goods, including pharmaceuticals, as a response to sanctions. This measure was established by Government Decree No. 506 of 29 March 2022 [17]. Belarus also applies an authorization-based approach, which likewise extends to medicines. This demonstrates that legal approaches to parallel imports remain inconsistent among EAEU Member States.

Parallel importation of pharmaceuticals within the EAEU represents a potentially effective mechanism for ensuring access to essential medicines in times of crisis. However, the absence of a harmonized rights exhaustion regime and the persistence of differences in national regulations limit its functionality. Therefore, additional legal regulation is required to ensure its effective and lawful application.

On this basis, pharmaceuticals registered under a special “Eurasian procedure” with specific trademarks may be subject to parallel importation within the EAEU. In theory, this means that if a medicine is registered

under the same trade name in accordance with EAEU rules in two different Member States, an independent distributor could purchase it in the country with lower prices and supply it to a country with higher prices, thereby contributing to price reductions. In practice, however, the transfer of such medicines from one country to another may still require special permits. It is also important to note that the exhaustion of trademark rights does not imply the exhaustion of patent rights. In other words, if only the trademark rights are exhausted (but not patent rights), then before importing a medicine under the same trade name, it is necessary to ensure that the product is not protected by a patent in the importing country. If it is under patent protection, the national law of that country must be consulted to determine the applicable exhaustion regime for inventions (national, regional, or international).

Between 4 and 15 December 2023, the "STOP III" operation was conducted with the participation of 111 customs administrations. The IPR CEN comm Group secure communication tool was used to facilitate real-time exchange of seizure data. The main objectives of the operation were the application of best practices, modern risk management methods, and techniques for detecting and inspecting high-risk consignments in e-commerce. This was particularly important for combating illicit circulation of medicines, vaccines, medical devices, and everyday consumer goods posing risks to health and safety. As a result of the operation: 43.5 million prohibited medicines and medical devices were seized and 1.1 million goods infringing intellectual property rights were detected [18].

The Treaty on the EAEU in fact has an effect comparable to that of the Treaty on the European Union, ensuring the free movement of goods, services, capital, and labor within the Union.

At the same time, despite the authorization of parallel import among EAEU member states, the risk of trademark infringement remains if the imported goods create a "likelihood of confusion" among consumers. For instance, if the trademark owner grants licenses to different manufacturers located in two different countries, and due to variations in environmental conditions in those countries the products manufactured there differ in composition so as to meet local requirements, the question arises whether such non-physical differences could lead to a "likelihood of confusion". As previously noted, the set of criteria applied to determine the "likelihood of confusion" is closely linked to the discretionary authority of judges. In this process, foreign judicial practice is taken into account, subject to selective application and adaptation in line with the specific features of the national legal system [19; 184]. The Eurasian Economic Union is an intermediate model between the EU and the United States. Although the EAEU applies the principle of exhaustion of regional opportunities, its implementation remains inconsistent due to the lack of a unified national practice among the member States.

In Kazakhstan, as well as in other member states of the EAEU, the parallel importation of pharmaceuticals is regulated on the basis of the principle of regional exhaustion of rights. This means that if a medicinal product has been lawfully placed on the market in the territory of one of the EAEU member states (including Kazakhstan) with the consent of the rights holder, it may circulate freely among the other member states of the Union without additional restrictions. However, parallel import does not imply that any medicine can be brought in without limitation. It is important to take into account that certain rules and requirements apply with respect to the importation, registration, and labeling of pharmaceuticals. As an EAEU member, Kazakhstan adheres to the principle of regional exhaustion of rights for medicinal products [20]. In practice, this means that if a medicine has been officially placed on the market in any EAEU state (for example, Russia, Belarus, Armenia, or Kyrgyzstan), it can be imported into Kazakhstan without obtaining additional authorization from the rights holder.

This situation is comparable to that of the EU, where the principle of regional exhaustion of rights is also applied. Nevertheless, although parallel import is permitted within the EU, complex issues may arise concerning the verification of whether the imported product has been lawfully placed on the market and whether its importation creates a "likelihood of confusion" among consumers [19; 185].

Notwithstanding the principle of regional exhaustion of rights, the parallel importation of pharmaceuticals remains subject to a number of regulatory constraints and compliance obligations. Any medicinal products introduced into Kazakhstan via parallel import channels are required to undergo mandatory registration procedures. Moreover, such products must strictly conform to all applicable national standards, including those relating to quality, safety, and therapeutic efficacy [21].

For the judiciary of Kazakhstan, the assessment of the "likelihood of confusion" constitutes a particularly complex and discretionary task. This is due to the fact that the doctrine of regional exhaustion, while facilitating intra-EAEU trade in pharmaceuticals, does not entirely preclude the possibility of trademark infringement arising from parallel importation. Furthermore, the issue of resolving normative inconsistencies

between the TRIPS Agreement, the Treaty on the Eurasian Economic Union, and domestic legislation remains of pressing importance. In this context, the obligation of World Trade Organization member states to observe minimum standards for the protection of trademarks plays a pivotal role in the process of incorporating and adapting the provisions of the TRIPS Agreement within Kazakhstan's legal system [19; 184].

Conclusion

The conducted research made it possible to systematize and generalize international and national approaches to the regulation of parallel importation of pharmaceuticals, to identify the key patterns of its legal development, and to determine promising directions for improving the legislation of the Republic of Kazakhstan.

Firstly, it has been established that the international regulation of parallel importation is based on the principle of exhaustion of rights, as enshrined in the TRIPS Agreement and the Doha Declaration. This principle grants states the freedom to choose between national, regional, or international exhaustion regimes. Consequently, no universal international mechanism exists for regulating parallel importation—each country formulates its own legal model in accordance with its economic and social priorities.

Secondly, a comparative analysis of the legislation of the EU, the United States, and the EAEU revealed that the regional exhaustion regime represents the most balanced approach. In the EU, it promotes the free movement of goods, price reduction, and the creation of a stable internal market. Within the EAEU, the same principle is formally recognized; however, the absence of a unified enforcement mechanism and the inconsistency of national regulations significantly limit its practical effectiveness.

Thirdly, it has been established that Kazakhstan adheres to the regional principle of exhaustion of rights, which facilitates the free circulation of pharmaceuticals within the EAEU. Nevertheless, certain legal and procedural barriers persist, primarily due to differences in national procedures for registration, labeling, and quality control.

The scientific significance of this research lies in advancing theoretical understanding of the legal nature of parallel importation and clarifying the role of the exhaustion principle in international and regional law. The author substantiates the necessity of harmonizing approaches to parallel importation within the EAEU and proposes a conceptual framework for establishing a coherent legal regime that integrates international standards with regional specificities.

The practical relevance of the results is reflected in their potential application:

– in the improvement of national legislation governing parallel importation and the circulation of pharmaceuticals;

– in the activities of EAEU institutions when developing a unified legal position on exhaustion of rights;

– in judicial practice concerning disputes over trademark infringement and the legality of parallel importation;

– in educational and research contexts to further develop the theory of intellectual property and international trade law.

Overall, the implementation of the research recommendations will enhance the transparency and predictability of the legal framework governing parallel importation, strengthen the competitiveness of Kazakhstan's pharmaceutical market, and ensure a balance between the protection of intellectual property rights and the public interest in access to medicines.

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Дәрілік препараттардың параллельді импортын реттеу: халықаралық және шетелдік тәжірибе

Мақалада дәрілік препараттардың параллельді импортының халықаралық және шетелдік құқықтық реттелуі жан-жақты зерттеу қарастырылған. Зерттеудің мақсаты — фармацевтикалық салада параллельді импортты қолданудың құқықтық ерекшеліктері мен өзекті мәселелерін анықтау, сондай-ақ халықаралық тәжірибені ескере отырып, Қазақстанның ұлттық заңнамасын жетілдіру жолдарын айқындау. Зерттеу барысында салыстырмалы-құқықтық және жүйелі талдау және формальды-құқықтық тәсіл қолданылған. Зияткерлік меншік құқықтарының Сауда аспектілері жөніндегі келісім

құқықтарының аяқталу қағидатын белгілейтін ережелері және оның іске асырудың түрлі модельдері — Еуропалық одақтағы аймақтық, АҚШ-тағы ұлттық және Еуразиялық экономикалық одақ елдеріндегі аралас модельдер талданды. Қазақстанда дәрілік препараттардың параллельді импортының құқықтық реттелуі қалыптасу сатысында екені және оны ЕАЭО нормаларымен үйлестіру қажеттілігі анықталды. Тауар таңбаларын қорғау мен тіркеу рәсімдеріне қатысты құқықтық коллизиялар айқындалды. Талдау нәтижесінде зияткерлік меншік иелерінің мүдделерін қорғауды және халықтың өмірлік маңызды дәрілік препараттарға қолжетімділігін қамтамасыз ететін теңгерімді тетік әзірлеу қажеттігі туралы қорытынды жасалды.

Кілт сөздер: дәрілік заттар, параллельді импорт, зияткерлік меншік, тауар белгісі, халықаралық сауда, ұлттық емдеу, құқықтардың аяқталуы, Сауда аспектілері жөніндегі келісім, ЕАЭО, ДСҰ.

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Регулирование параллельного импорта лекарственные средств: международный и зарубежный опыт

Статья посвящена комплексному исследованию международного и зарубежного правового регулирования параллельного импорта лекарственных средств. Целью исследования является выявление правовых особенностей и проблем применения параллельного импорта в фармацевтической сфере, а также определение путей совершенствования национального законодательства Казахстана с учетом международного опыта. В работе использованы методы сравнительно-правового и системного анализа, а также формально-юридический подход. Исследованы положения Соглашения по торговым аспектам прав интеллектуальной собственности (ТРИПС), закрепляющие принцип исчерпания прав, а также различные модели его реализации — региональная в Европейском Союзе, национальная в США и смешанная в странах ЕАЭС. Установлено, что в Казахстане правовое регулирование параллельного импорта лекарственных средств находится на стадии формирования и требует гармонизации с нормами ЕАЭС. Выявлены правовые коллизии, связанные с защитой товарных знаков и регистрационными процедурами. По результатам анализа сделан вывод о необходимости разработки сбалансированного механизма, который обеспечит защиту интересов правообладателей и доступ населения к жизненно важным лекарственным препаратам.

Ключевые слова: лекарственные средства, параллельный импорт, интеллектуальная собственность, товарный знак, международная торговля, национальный режим, исчерпание прав, Соглашение по ТРИПС, ЕАЭС, ВТО.

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