SECTION 1

CURRENT ISSUES OF CONSTITUTIONAL AND LEGAL STATUS OF HUMAN AND CITIZEN

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MEDICINES: CONSTITUTIONAL AND LEGAL REGULATION ON RESTRICTION
OF THE PROPERTY RIGHT CONCERNING TECHNOLOGY TRANSFER SUBJECTS AND
THE RIGHT TO CONDUCT ENTREPRENEURSHIP ON IMPORT OF MEDICINAL PRODUCTS
IN CONDITIONS OF CONFLICT AND TEMPORARY OCCUPATION

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Summary

The purpose of this article is to identify the features of restriction of ownership on the subjects of technology transfer regarding production of medicines and the right to run business on the import of medicines in conditions of conflict and temporary occupation.

The methodological basis of the conducted research is the general methods of scientific cognitivism as well as concerning those used in legal science: methods of analysis and synthesis, formal logic, comparative law etc.

When determining the legitimate purpose of restriction, it is necessary to apply the principle of proportionality, which is the concordance of measures applied to the above entities in order to limit the exercise of their rights with those public values that are protected by such restriction. On the procedural level, the State having realized the right for withdrawal has to comprehensively inform the General Secretary of the Council of Europe as for the measures taken and the reasons for them, as well as the time when those measures have ceased to apply and the provisions of the Convention are profoundly applied again. As the case law of the European Court of Human Rights shows, the derogation from the obligations under the Convention must have territorial and temporal specifications.

The following features of the constitutional and legal regulation of restriction of property rights for subjects of technology transfer to the production of medicines are revealed:

1) restrictions on the implementation of these rights should be provided by the law, which must meet the following requirements: clarity, accuracy, accessibility; 2) the measure is a temporal one; 3) the range of entities in respect of which it is applied to are the subjects of technology transfer being residents of the aggressor country; 4) legitimate purpose of implementation is protection of public values (national security, life and health of persons staying on the territory of Ukraine, territorial integrity, etc.); 5) necessary in democratic society.

The following features of the constitutional and legal regulation of restrictions on the right for running business activities regarding import of medicines during conflict and temporary occupation of the part of the territory of Ukraine by the Russian Federation are revealed: 1) restrictions on the exercise of these rights are provided by the Law of Ukraine "On Foreign Economic Activity" from 04.07.2017 №18.1-07/18369, which meets the following requirements: clarity, accuracy, accessibility; 2) the measure is temporal one; 3) the range of entities in respect of which it is applied to is addressed to the applicants of medicinal products, alternative and/or potential manufacturers, applicants-holders of registration certificates of which are the subjects of the Russian Federation; 4) legitimate purpose of implementation is protection of life and health of persons staying on the territory of Ukraine in connection with the impossibility of providing Ukraine with proper control over the quality of production of medicines within the Russian Federation; 5) necessary in democratic society.

Key words: medicines; human rights; the field of technology transfer; international cooperation; derogations; the right to entrepreneurial activity; the right to health care, medical aid and medical insurance.

1. Introduction

In conditions of conflict between Ukraine and the Russian Federation and temporal occupation of a part of the territory of Ukraine by the Russian Federation, the issues of state obligations to protect property of business entities in pharmaceutical sector, as well as the legal balance of private and public interests within health care system have become relevant up to date.

Indeed, it is well known that the implementation of business activities for the production of medicines requires significant resources (Buletsa, 2018; Volkov, 2006; Volkov, 2007; Deshko, 2007). The development of new technologies through pharmaceutical sector is resource-intensive (Buletsa, 2019; Deshko, 2014). At the same time, there are no guarantees of rapid implementation of the results and reimbursement of costs incurred by the business entity. Moreover, under certain requirements the State may apply derogation which may result in a ban on the transfer of technology for the production of medicinal products (or their components) by enterprises, research institutions, organizations, higher education establishments and other legal entities of the aggressor state, regardless of ownership property rights to use the objects of intellectual property rights, that are components of technology; prohibition on the importation of medicinal products manufactured on the territory of the aggressor state into its territory, etc.

Thus, according to Art. 49 of the Constitution of Ukraine, everyone has the right to health care, medical aid and medical insurance. A structural element of the subjective legal right to health care is the right of everyone to be provided with quality medicines (Deshko, 2018; Deshko, 2020). Accordingly, the state is obliged to create effective constitutional and legal mechanism to ensure these rights. At the same time, the Constitution of Ukraine guarantees everyone the right to entrepreneurial activity, which is not prohibited by law. Accordingly, the state is also obliged to create an effective constitutional and legal mechanism to ensure this right.

In the context of the armed aggression of the Russian Federation, Ukraine has withdrawn from its obligations to protect the property of business entities in pharmaceutical sector – the Ministry of Health of Ukraine has taken measures to withdraw from circulation of drugs in Ukraine, that manufactured in the Russian Federation and in Ukrainian territoties, which are not under the control of the Government of Ukraine.

In science on constitutional law the issue of withdrawal of the state from the obligations to protect the property of business entities within pharmaceutical sector is not sufficiently disclosed. This issue is considered individually by some constitutional scholars through the study of the constitutional and legal mechanism for

ensuring property rights in Ukraine; the right of everyone to apply onto international judicial institutions and international organizations, etc.

The purpose of this article is to identify the features of restriction of ownership on the subjects of technology transfer regarding production of medicines and the right to run business on the import of medicines in conditions of conflict and temporary occupation.

2. Legal, economic, organizational and financial principles of state regulation as for activities in the field of technology transfer

The Law of Ukraine "On State Regulation of Activity in the Sphere of Transfer of Technologies" defines legal, economic, organizational and financial principles of state regulation as for activities in the field of technology transfer and aims to ensure effective use of scientific, technical and intellectual potential of Ukraine, as well as the protection of property rights for domestic technologies and/or their components on the territory of the states where their use is planned or being carried out, expansion of international scientific and technical cooperation in this field. Legislation on state regulation of activities in the field of technology transfer is based on the Constitution of Ukraine, the Civil Code of Ukraine, the Economic Code of Ukraine, the laws of Ukraine "On Foreign Economic Activity", "On Scientific and Scientific and Technical Expertise", "On Scientific and Scientific and Technical Activity", "On Protection Against Unfair Competition", other normative legal acts, as well as current international treaties of Ukraine, consent for obligation of which was approved by the Verkhovna Rada of Ukraine (Parliament of Ukraine) in the field of scientific and technical cooperation, innovation, technology transfer.

By ratifying international treaties such as the International Covenant on Civil and Political Rights and the Convention for the Protection of Human Rights and Fundamental Freedoms, Ukraine has committed itself to internationally establishing on effective domestic mechanism to ensure the human rights guaranteed by them. During armed conflict and other public insecurity that threatens the life of the nation, the state has the right to withdraw from certain agreed obligations. This is provided by the

above-mentioned international documents. In 2015, Ukraine applied the derogation. Thus, on May 21, 2015, the Verkhovna Rada of Ukraine adopted a resolution "On the Statement of the Verkhovna Rada of Ukraine "On Ukraine's waiver of certain obligations under the International Covenant on Civil and Political Rights and the Convention for the Protection of Human Rights and Fundamental Freedoms". The Statement approves that "in order to ensure the vital interests of society and the state is facing armed aggression by the Russian Federation, the Verkhovna Rada of Ukraine, the Cabinet of Ministers of Ukraine and other public authorities have to make decisions that derogate from Ukraine's obligations under the International Covenant on Civil and Political Rights and the Convention for the Protection of Human Rights and Fundamental Freedoms".

3. The point of view on derogations

As E. M. Hafner-Bjorton, L. R. Helfer, and S. J. Fariss rightly point out, derogations belong to the "rescue mechanisms" for the state, which perform several beneficial functions (Hafner-Bjorton, 2011). The flexibility they provide acts as an "insurance policy", reassuring governments that they can legitimately waive certain contractual obligations during a crisis. Constitutional scholars and scientists of international law come to agreement that provisions to derogate from human rights obligations, especially in such a sensitive area as health care, must meet strict international standards and be subject to strict monitoring mechanisms (Hafner-Bjorton, 2011; Khrystova, 2018).

Article 29 of the Law of Ukraine "On Foreign Economic Activity" provides for measures taken by Ukraine in response to discriminatory and/ or unfriendly actions against Ukraine applied by the state and recognized by the Verkhovna Rada of Ukraine as an aggressor state and/or an occupying state. The Article 21 of the Law of Ukraine "On State Regulation of Activity in the Sphere of Transfer of Technologies" does not allow the conclusion of agreements on technology transfer, which provide for the import of technologies and/or their components into Ukraine that may harm the environment or human health. The measures taken by the Ministry of Health of Ukraine to withdraw from circulation on the

territory of Ukraine medicines manufactured on the territory of the Russian Federation, as well as on the territories of Ukraine not controlled by the Government of Ukraine is legitimate right of Ukraine as a sovereign state to protect its constitutional and democratic order. With these measures, Ukraine not only publicly demonstrates its "repressive" policy, aligning its actions with international standards, but also aims to reduce the prevalence and scale of potential human rights violations in the field of health care.

In this regard, the point of view of E. M. Hafner-Bjorton, L. R. Helfer, and S. J. Fariss on derogations that are to be the rational response to internal political uncertainty (Hafner-Bjorton, 2011). On the contrary, they seem to be evidence of political determination and the desire of the state to fulfill properly its international obligations in conditions of conflict and temporary occupation.

4. The application of derogations under the Convention for the Protection of Human Rights and Fundamental Freedoms

We also agree with G. Hristova that the restrictions should be necessary, temporary and lawful and be carried out within the legal framework, in compliance with the requirements set by them (Khrystova, 2018). The application of derogations under the Convention presupposes compliance with the following procedural and substantive conditions: the right for withdrawal may be exercised only during war or other public insecurity threatening the life of the nation; the State may take measures to derogate from its obligations according to the Convention only to the extent required by the urgency of the situation; any derogations may not be incompatible with other obligations of the State under international law (Deshko, 2018; Deshko, 2020; Khrystova, 2018; Nechyporuk, 2020).

T. Slinko draws attention to the fact that "... in accordance with the Constitution of Ukraine, owners, exercising the right for ownership, must comply with the Constitutional provisions on ownership obligations. It must not be used to the detriment of person or society. Also, the use of property may not harm the rights and freedoms and dignity of citizens, the interests of society. ... it follows from the systematic analysis

of the provisions of the Constitution of Ukraine that the right for ownership may be limited. The right of a state to restrict the possession, use and disposal of property is also defined by the First Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms. ... The state has the right to "enact such laws as it deems necessary to control the use of property in accordance with the general interest (Slinko, 2018).

This view is seen debatable as for ownership of technology and medicines transfer. First, the right for medicines is a structural element of the right for medical aid, and the right for medical aid is a guarantee of the right for life. The Convention for the Protection of Human Rights and Fundamental Freedoms does not allow any non-derogative rights regarding the right for life, except in cases of death as the consequence of lawful hostilities. Thus, if a patient is not provided with quality medical care due to a state's ban on the transfer of medicinal product or the transfer of the manufactured product from another country, which would violate the right for life, the Convention does not allow such a derogation from the right for life. It is also not allowed to deviate from the prohibition of torture and cruel or degrading treatment in connection with the state's ban on the transfer of medicinal product manufacture or transfer of products from another country, so the patient is not provided with quality medical care and the patient is subjected to suffer due to the lack of treatment with this drug (s), which is tantamount to torture, humiliating or degrading treatment.

Secondly, indeed, the Article 1 of Protocol No. 1 of the Convention guarantees everyone the right for owning property peacefully. In particular, this statement can be applied to the object of technology, i. e. scientific and scientifically applied results, objects of intellectual property rights, which reflect the list, timing, procedure and sequence of operations, the process of production and/or sale and storage of products, provision of services, etc. Technology transfer involves the transfer of technology, which is formalized by concluding a bilateral or multilateral agreement between individuals and/or legal entities, which establishes changes or terminates property rights and obligations in relation to technology and/or its components.

At the same time, with regard to the transfer of technology for the production of medicines, the transfer of medicines, the right for peaceful property owning, which is guaranteed by the Article 1 of Protocol No. 1 to the Convention, is the guarantee of realization of the right for life and the prohibition of torture and cruel or degrading treatment, and the State may not derogate from it if it may or it does violate the above-mentioned rights by preventing improper quality medical treatment.

5. Conclusions

When determining the legitimate purpose of restriction, it is necessary to apply the principle of proportionality, which is the concordance of measures applied to the above entities in order to limit the exercise of their rights with those public values that are protected by such restriction. On the procedural level, the State having realized the right for withdrawal has to comprehensively inform the General Secretary of the Council of Europe as for the measures taken and the reasons for them, as well as the time when those measures have ceased to apply and the provisions of the Convention are profoundly applied again. In addition, as the case law of the European Court of Human Rights shows, the derogation from the obligations under the Convention must have territorial and temporal specifications.

6. Results

The following features of the constitutional and legal regulation of restriction of property rights for subjects of technology transfer to the production of medicines are revealed: 1) restrictions on the implementation of these rights should be provided by the law, which must meet the following requirements: clarity, accuracy, accessibility; 2) the measure is a temporal one; 3) the range of entities in respect of which it is applied to are the subjects of technology transfer being residents of the aggressor country; 4) legitimate purpose of implementation is protection of public values (national security, life and health of persons staying on the territory of Ukraine, territorial integrity, etc.); 5) necessary in democratic society.

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Bibliography:

- **1. Волков, В. & Дешко, Л.** (2006). На захист медичного права. *Юридичний Вісник України*, 8, С. 8.
- **2. Волков, В. & Дешко, Л.** (2007). Медичне право реальність сьогодення. *Інформаційний правовий простір*, 18, С. 45-48.
- **3. Дешко, Л.** (2007). Державне регулювання системи цін на лікарські засоби в Україні. *Підприємництво, господарство і право*, 6, С. 21-30.
- **4. Дешко, Л.** (2007). Державне регулювання ціноутворення на лікарські засоби в країнах Європейського Співтовариства та інших країнах. *Підприємництво, господарство і право*, 5, C. 113–119.
- **5. Дешко, Л.** Правове регулювання господарювання в сфері охорони здоров'я: проблеми вдосконалення спеціального законодавства. *Підприємництво, господарство і право*, 5, С. 57-62.
- **6. Дешко, Л.** (2018). Restitutio in integrum: підходи Європейського суду з прав людини. *Порівняльно-а-налітичне право*, 5, С. 365–368.
- Конвенція про захист прав людини і основоположних свобод (1950). URL: https://zakon.rada.gov.ua/ go/995_004.
- 8. Конституція України (1996) URL: https:// zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80#Text
- 9. Лист Міністерства охорони здоров'я України (2017). No 18.1-07/18369. URL: https://moz.gov.ua
- **10.** Нечипорук, Г. Ю., Бисага, Ю. М., Берч, В. В., Дешко, Л. М., Бисага, Ю. Ю., Нечипорук, К. О. (2020) *Консти*-

- туційне право на звернення до Європейського суду з прав людини та механізм реалізації права на виконання його рішень. Ужгород, ТОВ «РІК-У», 2020.
- 11. Про відступ України від окремих зобов'язань, визначених Міжнародним пактом про громадянські і політичні права та Конвенцією про захист прав людини і основоположних свобод (2015): постанова Верховної Ради України «Про Заяву Верховної Ради України. URL: rada.gov.ua/laws/show/462-19#Text.
- 12. Про державне регулювання діяльності у сфері трансферу технологій (2006): Закон України. URL: rada. qov.ua/laws/show/143-16#Text
- 13. Про зовнішньоекономічну діяльність: Закон України. URL: rada.gov.ua/laws/show/959-12#Text
- 14. Слінько, Т. М. (2018). Правові підстави обмеження реалізації прав і свобод людини і громадянина. Україна і Європейський Союз: шлях до сталого розвитку: Збірник наук. статей за матер. І наук.-практ. конф. з європ. Права (41-46). Харків, 2018.
- **15. Христова, Г.** (2018).)Позитивні зобов'язання держави у сфері прав людини: сучасні виклики: монографія. Харків: Право, 2018.
- **16. Buletsa, S. & Deshko, L.** (2018). Comprehensive Reforms of the Health Care System in Different Regions of the World. *Medicine and Law.* 2018, 37, 4, P. 683-700.
- **17. Buletsa, S., Deshko, L. & Zaborovskyy, V.** (2019). The peculiarities of changing health care system in Ukraine. *Medicine and Law*, 2019, 38. 3, P. 427-442.
- **18. Deshko, L.** (2018). The principle of «de minimis non curat praetor» in International Law. Зовнішня торгівля: економіка, фінанси, право, 2018, 4, C. 5-15.
- **19. Deshko, L.** (2018). Patenting of medicinal products: the experience of implementation of the flexible provisions of the TRIPS-plus Agreement by foreign countries and the fundamental patent reform in Ukraine. *Georgian Medical News*, 9, P. 161-164.
- Deshko, L. (2018). Application of Legal Entities to the European Court of Human Rights: a Significant Disadvantage as the Condition of Admissibility. Croatian International Relations Review, 24 (83), P. 84-103.
- **21. Deshko, L.** (2014). Domestic remedies that have to be exhausted in Ukraine when everyone applying to international judicial institutions or to the relevant bodies of international organizations. *Вестник Пермского университета*, 1, Р. 332-336.
- Deshko, L., Bysaga, Y. & Bysaga, Y. (2019). Public procurement in the healthcare sector: adaptation of the administrative legislation of Ukraine to the EU legislation. Georgian Medical News, 6, P. 126-130.
- **23. Deshko L. M., Bysaga Y.M. & Zaborovskyy V.V.** (2019). Protection of human rights by the Constitutional Court

- of Ukraine in the field of health care. *Georgian Medical News*, 7, P. 160-166.
- 24. Deshko L., Bysaga Y., Vasylchenko O., Nechyporuk A., Pifko O. & Berch V. (2020). Medicines: technology transfer to production, cession of ownership rights for registration certificates and transfer of production in conditions of modern challenges to international and national security. *Georgian Medical News*, 10, P. 180-184.
- **25. Deshko, L.** (2018). Patenting of medicinal products: the experience of implementation of the flexible provisions of the TRIPS-plus Agreement by foreign countries and the fundamental patent reform in Ukraine. *Georgian Medical News*, 9, P. 161-164.
- **26. Ezer, T., Deshko, L., Clark, N. et al.** (2010). Promoting public health through clinical legal education: Initiatives in South Africa, Thailand, and Ukraine. *Human Rights Brief*, 17/27, P. 32. URL: http://www.wcl.american.edu/hrbrief/17/2ezer.pdf

References:

- 1. Volkov, V. & Deshko, L. (2007). Medychne pravo realnist sohodennia [Medical law is a reality of today] *Informatsiinyi pravovyi prostir*, 18, S. 45-48. [in Ukrainian].
- 2. Volkov, V. & Deshko, L. (2006). Na zakhyst medychnoho prava [In defense of medical law]. *Yurydychnyi Visnyk Ukrainy*, 8, 8. [in Ukrainian].
- **3. Deshko, L.** (2007). Derzhavne rehuliuvannia systemy tsin na likarski zasoby v Ukraini [State regulation of the price system for medicines in Ukraine]. *Pidpryiemnytstvo, hospodarstvo i pravo*, 6, 21-30. [in Ukrainian].
- **4. Deshko, L.** (2007). Derzhavne rehuliuvannia tsinoutvorennia na likarski zasoby v krainakh Yevropeiskoho Spivtovarystva ta inshykh krainakh [State regulation of pricing of medicines in the European Community and other countries]. *Pidpryiemnytstvo, hospodarstvo i pravo*, 5, 113-119. [in Ukrainian].
- 5. **Deshko, L.** (2007). Pravove rehuliuvannia hospodariuvannia v sferi okhorony zdorovia: problemy vdoskonalennia spetsialnoho zakonodavstva [Legal regulation of health care: problems of improving special legislation]. *Pidpryiemnytstvo, hospodarstvo i pravo*, 5, 57-62. [in Ukrainian].
- **6. Deshko, L.** (2018). Restitutio in integrum: pidkhody Yevropeys'koho sudu z prav lyudyny [Restitutio in integrum: approaches of the European Court of Human Rights]. *Porivnyal'no-analitychne pravo*, 5, 365-368. [in Ukrainian].
- Konventsiia pro zakhyst prav liudyny i osnovopolozhnykh svobod [Convention for the Protection of Human Rights and Fundamental Freedoms] (1950). URL: https://zakon. rada.gov.ua/go/995_004. [in Ukrainian].

- Konstytutsiia Ukrainy [Constitution of Ukraine] (1996). URL: https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80#Text. [in Ukrainian].
- Lyst Ministerstva okhorony zdorovia Ukrainy [Letter from the Ministry of Health of Ukraine] (2017). No18.1-07/18369. URL: https://moz.gov.ua. [in Ukrainian]
- 10. Nechyporuk, H. Iu, Bysaha Yu. M., Berch, V. V., Deshko, L. M., Bysaha Yu. Iu. & Nechyporuk, K. O. Konstytutsiine pravo na zvernennia do Yevropeiskoho sudu z prav liudyny ta mekhanizm realizatsii prava na vykonannia yoho rishen [The constitutional right to appeal to the European Court of Human Rights and the mechanism for exercising the right to enforce its decisions]. Uzhhorod, TOV «RIK-U», 2020. [in Ukrainian].
- 11. Pro vidstup Ukrainy vid okremykh zoboviazan, vyznachenykh Mizhnarodnym paktom pro hromadianski
 i politychni prava ta Konventsiieiu pro zakhyst prav liudyny i osnovopolozhnykh svobod [On Ukraine's withdrawal from certain obligations set out in the International Covenant on Civil and Political Rights and the
 Convention for the Protection of Human Rights and

- Fundamental Freedoms]. (2015): Postanova Verkhovnoi Rady Ukrainy. URL: rada.gov.ua/laws/show/462-19#Text. [in Ukrainian].
- 12. Pro derzhavne rehuliuvannia diialnosti u sferi transferu tekhnolohii [On state regulation of activities in the field of technology transfer] (2006): Zakon Ukrainy. URL: rada. gov.ua/laws/show/143-16#Text. [in Ukrainian].
- 13. Pro zovnishnoekonomichnu diialnist [On foreign economic activity] (1991): Zakon Ukrainy. URL: rada.gov. ua/laws/show/959-12#Text. [in Ukrainian].
- 14. Slinko, T. M. (2018). Pravovi pidstavy obmezhennia realizatsii prav i svobod liudyny i hromadianyna [Legal grounds for restricting the exercise of human and civil rights and freedoms]. *Ukraina i Yevropeiskyi Soiuz: shliakh do staloho rozvytku*: Zbirnyk nauk. statei za mater. I nauk.-prakt. konf. z yevrop. prava. (pp. 41-46). [in Ukrainian]
- 15. **Khrystova, H.** (2018). Pozytyvni zoboviazannia derzhavy u sferi prav liudyny: suchasni vyklyky: monohrafiia [Positive commitments of the state in the field of human rights: current challenges: a monograph]. Kharkiv: Pravo [in Ukrainian]

ЛІКАРСЬКІ ЗАСОБИ: КОНСТИТУЦІЙНО-ПРАВОВЕ РЕГУЛЮВАННЯ ОБМЕЖЕННЯ ПРАВА ВЛАСНОСТІ СУБ'ЄКТІВ ТРАНСФЕРУ ТЕХНОЛОГІЙ ТА ПРАВА НА ЗДІЙСНЕННЯ ПІДПРИЄМНИЦТВА З ІМПОРТУ ЛІКАРСЬКИХ ЗАСОБІВ В УМОВАХ КОНФЛІКТУ ТА ТИМЧАСОВОЇ ОКУПАЦІЇ

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Анотація

Мета цієї статті полягає в виявленні особливостей обмеження права власності суб'єктів трансферу технологій у виробництво лікарських засобів та права на здійснення підприємництва з імпорту лікарських засобів в умовах конфлікту та тимчасової окупації. Методологічною основою цього дослідження є загальні та спеціальні методи наукового пізнання: формально-логічний метод, порівняльно-правовий, структурно-логічний, інші.

Зазначається, що при визначенні легітимної мети обмеження необхідно застосовувати принцип пропорційності, що полягає у співрозмірності заходів, які застосовуються до вище зазначених суб'єктів з метою обмежити реалізацію їх прав, з тими суспільними цінностями, які захищаються шляхом здійснення такого обмеження. На процедурному рівні, держава, використавши це право на відступ, у повному обсязі повинна інформувати Генерального секретаря Ради Європи про вжиті нею заходи і причини їх вжиття, а також повідомити про час, коли такі заходи перестали застосовуватися, а положення Конвенції знову застосовуються повною мірою. Крім того, як свідчить практика Європейського суду з прав людини, відступ від зобов'язань за Конвенцією повинен мати територіальний і тимчасовий характер.

Виявлено такі особливості конституційно-правового регулювання обмеження права власності суб'єктів трансферу технологій у виробництво лікарських засобів: 1) обмеження щодо реалізації цих прав має бути передбачено законом, який має відповідати таким вимогам: ясність, чіткість, доступність; 2) захід ϵ заходом тимчасового характеру; 3) коло суб'єктів, щодо яких засосовується – суб'єкти трансферу технологій - резиденти країни-агресора; 4) легітимна мета здійснення - захист суспільних цінностей (національної безпеки, життя і здоров'я осіб, які перебувають на території України, територіальної цілісності тощо); 5) ϵ необхідним у демократичному суспільстві. Виявлено такі особливості конституційно-правового регулювання обмеження права на здійснення підприємницької діяльності з імпорту лікарських засобів в умовах конфлікту та тимчасової окупації Російською Федерацією частини території України: 1) обмеження щодо реалізації цих прав передбачається Законом України «Про зовнішньоекономічну діяльність», листом Міністерства охорони здоров'я України від 04.07.2017 року №18.1-07/18369, який відповідає таким вимогам: ясність, чіткість, доступність; 2) захід є заходом тимчасового характеру; 3) коло суб'єктів, щодо яких засосовується – адресований заявникам лікарських засобів, альтернативним та/або потенційним виробникам, заявникам-власникам реєстраційних посвідчень яких є суб'єкти Російської Федерації; 4) легітимна мета здійснення – захист життя і здоров'я осіб, які перебувають на території України у зв'язку з неможливістю забезпечення Україною належного контролю за якістю виробництва лікарських засобів в РФ ; 5) є необхідним у демократичному суспільстві.

Ключові слова: лікарські засоби; права людини; трансфер технологій; міжнародне співробітництво; дерогації; право на підприємницьку діяльність; право на охорону здоров'я, медичну допомогу та медичне страхування.