РОЗДІЛ ІІ. КОНСТИТУЦІЙНЕ ПРАВО; МУНІЦИПАЛЬНЕ ПРАВО

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CRITERIA FOR GRANTING ACCESS BY AN EU MEMBER STATE TO A SEVERELY ILL PATIENT TO AN UNAUTHORIZED MEDICINE

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Basalaeva A. Criteria for granting access by an EU member state to a severely ill patient to an unauthorized medicine.

The article focuses attention on the fact that a structural element of everyone's subjective legal right to medical care is the right to access to a medicinal product. It is emphasized that the Covid-19 pandemic, the increase in the spectrum of incurable diseases and the number of patients suffering from them, Russia's aggression against Ukraine, the consequences of which are an increase in the number of military personnel and civilians who need the use of medicinal products created using the latest technologies, but which (medicines) are still not allowed in the state, the integration of Ukraine with the EU became the factors that actualized the discussion of scientists and practitioners on the issue of the conditions that must be observed by the EU member state in order to apply the provisions of Article 1. 5 of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code regarding medicinal products intended for human use, the exception is to provide an EU member state with access to a patient to a medicinal product not authorized by the competent authorities of such a member state and thereby fulfill its obligation to provide everyone's constitutional right to medical care.

The conditions that must be observed by the EU member state in order to apply the provisions of Article 1. 5 of the Exclusion Directives – for an EU member state to provide a patient with access to a medicinal product that is not authorized by the competent authorities of such a member state: 1) the presence of a norm of national law that allows the supply of a medicinal product for which a permit was not granted; 2) the goal is to meet the special needs of a specific seriously ill patient (private interest) and ensure the protection of public health (public interest); 3) be due to the absence on the national market of any authorized medicinal product - the equivalent of an unauthorized medicinal product; 4) delivery is made in response to a bona fide order on one's own initiative; 5) supply is carried out according to the prescription in accordance with the specifications of the authorized medical worker; 6) an unauthorized medicinal product is prescribed for use by a specific patient under his direct personal responsibility.

The signs of the patient's special needs are highlighted: 1) the specific situation of the patient's state of health and the course of his illness; 2) medical reasoning, which is justified; 3) the patient's need for a certain medicinal product. The grounds for an unregistered medicinal product to be prescribed by a doctor are: the doctor's therapeutic considerations; results of research, analyzes of the patient.

In a situation where there are authorized medicinal products on the market of an EU member state - analogues of prohibited medicinal products - the import of unauthorized medicinal products can be qualified as an act of non-fulfillment by the EU member state of its obligations, provided for in Article 1. 6 Directives.

Key words: everyone's constitutional right to medical care, the right to access to a medicinal product, the state's duty to ensure human rights, an illegal medicinal product, a patient, a doctor, the special needs of a patient, public health protection, a permit for sale.

Басалаєва А. Критерії надання державою-членом ЄС доступу тяжкохворому пацієнту до недозволеного лікарського засобу.

В статті акцентується увага на тому, що структурним елементом суб'єктивного юридичного права кожного на медичну допомогу є право на доступ до лікарського засобу. Під-

креслюється, що пандемія Covid-19, збільшення спектру невиліковних хвороб і кількості пацієнтів, які на них страждають, агресія росії щодо України, наслідками якої є збільшення кількості військовослужбовців та цивільних осіб, які потребують застосування в лікуванні лікарських засобів, створених з використанням новітніх технологій, але які (лікарські засоби) ще є не дозволеними в державі, інтеграція України з ЄС стали чинниками, які актуалізували дискусію науковців та практиків з питання умов, яких необхідно дотриматись державі-члену ЄС, щоб застосувати передбачене п. 1 ст. 5 Директиви Європейського Парламенту і Ради 2001/83/ЄС про Кодекс Співтовариства щодо лікарських засобів призначених для застосування людиною виключення - надати державою-членом ЄС доступу пацієнту до недозволеного компетентними органами такої держави-члена лікарського засобу і тим самим виконати свій обов'язок з забезпечення конституційного права кожного на медичну допомогу.

Виділено умови, яких необхідно дотриматись державі-члену ЄС, щоб застосувати передбачене п. 1 ст. 5 Директиви виключення – надати державою-членом ЄС доступ пацієнту до недозволеного компетентними органами такої держави-члена лікарського засобу: 1) наявність норми національного права, яка дозволяє постачання лікарського засобу, для якого не був наданий дозвіл; 2) мета – задоволення особливих потреб конкретного тяжко хворого пацієнта (приватного інтересу) та забезпечення охорони громадського здоров'я (публічного інтересу); 3) бути обумовлене відсутністю на національному ринку жодного дозволеного лікарського препарату - еквівалента недозволеного лікарського засобу; 4) постачання здійснюється у відповідь на bona fide замовлення з власної ініціативи; 5) постачання здійснюється за рецептурою відповідно до специфікацій уповноваженого медичного працівника; 6) недозволений лікарський засіб призначається для використання конкретним пацієнтом під його безпосередню особисту відповідальність.

Виділено ознаки особливих потреб пацієнта: 1) конкретна ситуація стану здоров'я пацієнта та перебігу його хвороби; 2) медичне міркування, яке є виправданим; 3) потреба пацієнта в певному лікарському засобі. Підставою для того, щоб незареєстрований лікарський засіб був виписаний лікарем є: терапевтичні міркування лікаря; результати досліджень, аналізів пацієнта.

В ситуації, коли на ринку держави-учасниці ЄС є дозволені лікарські засоби – аналоги недозволених лікарських засобів, – імпорт недозволених лікарських засобів може кваліфікуватися як дії з невиконання державою-членом ЄС зобов'язань, передбачених п. 1 ст. 6 Директиви.

Ключові слова: конституційне право кожного на медичну допомогу, право на доступ до лікарського засобу, обов'язок держави з забезпечення прав людини, недозволений лікарський засіб, пацієнт, лікар, особливі потреби пацієнта, охорона громадського здоров'я, дозвіл на реалізацію.

Formulation of the problem.

The Covid-19 pandemic, an increase in the spectrum of incurable diseases and the number of patients suffering from them, Russia's aggression against Ukraine, the consequences of which are an increase in the number of military personnel and civilians who need the use of medicinal products created using the latest technologies, the integration of Ukraine with The EU testifies to the relevance of the issue of the regulatory and legal mechanism for ensuring the receipt of an unauthorized medicinal product through the programs «use by an individual patient», «use on compassion» or «use outside the approved indications for use» in the EU.

In legal science, S. Buletsa [1], R. Grevtsova [2], L. Deshko [3-5], V. Zaborovskyi [6], M. Menzhul [7] studied the issue of the right to access to medicines as a guarantee of the right to medical care, I. Senyuta [8] and others. The issues of technology transfer in the production of medicinal products, transfer of ownership rights to registration certificates and transfer of production in the context of modern challenges to international and national security were studied in the scientific works of L. Deshko [9], O. Vasylchenko [10] and others. On the other hand, the issue of the regulatory and legal mechanism of ensuring the receipt of an unauthorized medicinal product through the programs «use by an individual patient», «use out of compassion» or «use outside of the approved indications for use» in the EU has not been comprehensively investigated.

The purpose of this article is to highlight the conditions that must be observed by the EU member state in order to apply the provisions of Article 1. 5 Exclusion Directives – to provide an EU member state with access to a patient to a medicinal product not authorized by the competent authorities of such a member state.

Presenting main material.

According to the general rule in the EU, a medicine can be released on the EU market only when it has passed all centralized or national legalization procedures [11; 12]. On November 6, 2001, Directive 2001/83/EC of the European Parliament and the Council on the Community Code concerning medicinal products intended for human use was adopted [13]. Section 3 of the Directive is devoted to the introduction of medicinal products into circulation, and chapter 1 of this section is

devoted to marketing authorization. From clause 1 of Art. 6 of the Directive, it follows that the general conditions for placing a medicinal product on the market in an EU member state are as follows: 1) the object that is placed on the market must fall under the qualifying characteristics of the medicinal product; 2) prohibition to sell a medicinal product without a permit - the fact of having a permit must precede the fact of sale, even if the permit is in the process of being issued - the sale is prohibited until the permit is obtained; 3) the presence of special competent bodies of the EU member state, whose functional duty is to grant permission for the sale of the medicinal product; 4) the legal basis for granting permission is Directive 2001/83/EC of the European Parliament and of the Council on the Community Code concerning medicinal products intended for human use or Regulation of the European Parliament and of the Council (EU) No. 1901/2006 of December 12, 2006 on medicinal products for application in pediatrics and Regulation (EC) No. 1394/2007.

Chapter Two «Scope» of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to Medicinal Products for Human Use contains Article 5, which provides for exceptions that may be applied by EU Member States to the supply and distribution of a medicinal product for which permission was not granted. Yes, in accordance with Clause 1 of Art. 5 of the Directive «A Member State may, in accordance with current legislation and to meet special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide order on its own initiative, by prescription according to the specifications of an authorized medical professional for use by a specific patient under his direct personal responsibility» [13]. Therefore, Directive 2001/83/EC of the European Parliament and of the Council on the Community Code regarding medicinal products intended for human use leaves to the discretion of the EU member states the issue of providing the possibility or imposing a ban on the possibility for patients to obtain a medicinal product not authorized by the competent authorities of this state with the help of programs « individual patient use', 'compassionate use', 'off-label use'. EU law does not prohibit the use of drugs not officially approved by an EU member state by an individual patient.

In practice, the existence of such a norm necessitated its interpretation regarding the exact conditions that must be met by the EU member state in order to apply the exception provided for by it. Moreover, the application by an EU member state of the exclusion under clause 1 of Art. 5 of the Directive also raises the question of whether the state is trying to avoid fulfilling its obligation under Art. 6 Directives.

Thus, in the case «European Commission v. the Republic of Poland» [14], the question was raised whether the national law of Poland corresponded to the exclusion provided for in Article 1. 5 of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code regarding medicinal products intended for human use. In accordance with the national legislation, Poland as a member state of the EU allowed the importation and put into circulation medicinal products that did not have the permits of the special competent authorities of Poland. As a result of such actions, illegal medicinal products appeared on the market of Poland as an EU member state. They were similar in composition to medicines that had the necessary permits, and were cheaper in price. That is, on the market of medicinal products in Poland, medicinal products – analogs of non-approved medicinal products – were allowed by the competent authorities of Poland.

Since it was about the interpretation of the provision, which in its essence is an exception to the principle, according to the established jurisprudence of the Court of Justice, its interpretation was carried out strictly. Referring to its decision in the case C 143/06 «Ludwigs-Apteka», the Court of Justice noted that «...the possibility of importing unauthorized medicinal products, provided by national legislation for the implementation of the powers granted by this provision, must remain exclusive to ensure the practical effect of the commercial licensing procedure» [15]. Therefore, the application of Clause 1 of Art. 5 of the Directive on the import of unauthorized medicinal products should be an isolated exception, and the established practice of admitting an imported medicinal product to the market of an EU member state without applying the trade licensing procedure through the adoption of national legislation, which provides for the application of clause 1 of Art. 5 of the Directive, is incompatible with the purpose of the Directive, and undermines the practical effectiveness of the existing trade licensing procedure.

The Advocate General in the case «European Commission v. Republic of Poland» noted in his Opinion that «... the possibility to avoid the application of the provisions of Directive 2001/83, which follows from the content of its Article 5(1), can be used only when it is necessary, taking into account attention to the specific needs of patients. Another interpretation would contradict the goal of public health protection, which is achieved by the harmonization of regulations on medicinal products, in particular those related to commercial licensing» [14]. Thus, the exception allowed by clause 1 of Art. 5 of the Directive refers to those unauthorized medicinal products that are necessary for the specific special needs of specific

patients. It is also seen that the application of this exception cannot be unlimited in time, because after importing an unregistered medicinal product for the special needs of patients and already using it in their treatment, nothing prevents this medicinal product from going through the licensing procedure and obtaining permission from the competent authorities of the EU member state. Undoubtedly, in a situation where there are authorized medicinal products on the market of an EU member state - analogues of unauthorized medicinal products - the import of unauthorized medicinal products can be qualified as an act of non-fulfillment by the EU member state of its obligations, provided for in Article 1. 6 Directives.

The concept of «special needs» referred to in clause 1 of Art. 5 of the Directive, «refers to purely specific situations justified by medical considerations and provides that the medicinal product is necessary to meet the needs of a particular patient,» the Court of Justice noted in its decision [14; 15]. Therefore, an unregistered medicinal product cannot be imported without the presence of special needs of the patient. The signs of the patient's special needs are as follows: 1) the specific situation of the patient's state of health and the course of his illness; 2) medical reasoning, which is justified; 3) the patient's need for a certain medicinal product.

In §35 of the decision in the case «European Commission v. Republic of Poland», the Court of Justice emphasizes that «the requirement for the supply of medicinal products «by individual order» means that the medicinal product must be prescribed by a doctor based on the results of an actual examination of his patient and on the basis of exclusively therapeutic considerations » [14]. That is, we are talking about the fact that the exclusion of clause 1 of Art. 5 The Directives apply to an unregistered medicinal product prescribed by a specific doctor for a specific patient – that is, there is a strict definition of the subject who prescribed the unregistered medicinal product and the subject who agreed to use it. An entity other than a doctor may not prescribe an unregistered medicinal product, including may not perform such actions, for example, an entity endowed with public-authority powers in the field of health care, or an entity of private law (for example, an institution Health Care). The grounds for an unregistered medicinal product to be prescribed by a doctor are: the doctor's therapeutic considerations; results of research, analyzes of the patient.

Also in §36 of the decision in the case «European Commission v. Republic of Poland», the Court of Justice emphasized that «it is clear from the set of conditions defined in Article 5(1) of Directive 2001/83, which should be read in the light of its fundamental objectives and, in particular, the objective public health protection, it appears that the exception provided for in this article can only apply to situations in which the doctor considers that the health condition of his particular patient requires the use of a medicinal product that has no authorized equivalent on the national market or that on this market does not exist» [14]. Thus, when the state applies the exception provided for in Clause 1 of Art. 5 of the Directive, both public interests must be respected - ensuring public health protection, and private interests – providing the patient with access to an unregistered medicinal product, there are no equivalents on the market of the participating state.

Conclusions.

The conditions that must be observed by the EU member state in order to apply the provisions of Article 1. 5 of the Exclusion Directives – for an EU member state to provide a patient with access to a medicinal product that is not authorized by the competent authorities of such a member state: 1) the presence of a norm of national law that allows the supply of a medicinal product for which a permit was not granted; 2) the goal is to meet the special needs of a specific seriously ill patient (private interest) and ensure the protection of public health (public interest); 3) be due to the absence on the national market of any authorized medicinal product – the equivalent of an unauthorized medicinal product; 4) delivery is made in response to a bona fide order on one's own initiative; 5) supply is carried out according to the prescription in accordance with the specifications of the authorized medical worker; 6) an unauthorized medicinal product is prescribed for use by a specific patient under his direct personal responsibility.

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In a situation where there are authorized medicinal products on the market of an EU member state - analogues of prohibited medicinal products - the import of unauthorized medicinal products can be qualified as an act of non-fulfillment by the EU member state of its obligations, provided for in Article 1. 6 Directives.

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