POSITIVE OBLIGATIONS OF THE STATE TO ENSURE THE RIGHT OF A SERIOUSLY ILL PATIENT TO ACCESS TO A MEDICINAL PRODUCT OUT OF COMPASSION IN THE EU

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The article is devoted to the study of the positive duties of the state to ensure the right of a seriously ill patient to access to a medicinal product out of compassion in the EU, which corresponds to the right of every person in the presence of special needs to access to medicinal products, including - unregistered - for reasons of humanity.

The article analyzes the Directive of the European Parliament and the Council 2001/83/EC on the Community Code regarding medicinal products intended for human use, Regulation (EC) No. 726/2004 of the European Parliament and the Council of the EU.

The article also reveals the essence of the legitimate purpose of the admission to the market of an EU member state of a medicinal product that is not authorized in this state, but is authorized in another EU member state, and the admission of a medicinal product that is not authorized in any EU member state. Attention is focused on the legitimate expectations of patients and taking into account more and more rapid progress in science and treatment, tools to ensure compliance with the requirements of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code concerning medicinal products intended for human use upon authorization by an EU member state to its market of a medicinal product that is authorized in another EU member state.

According to the results of the study, the structural elements of the content of the obligation of the EU member state to ensure the access of a seriously ill patient to a medicinal product that is not allowed in this EU member state, but is allowed in another EU member state: 1) before granting a marketing authorization medicinal product to notify the holder of a marketing authorization for the medicinal product in the EU member state in which it is authorized, of a proposal for granting a marketing authorization; 2) to send a request to the national competent authority of the member state in which the drug is authorized, regarding the submission of: a) copies of the report on the evaluation results; b) a valid permit for the sale of a medicinal product; 3) to notify the Commission about the granting of a permit for the sale of a medicinal product that is permitted in another EU member state; 4) notify the Commission about the termination of the authorization for a medicinal product that is authorized in another EU member state. The structural elements of the EU member state's obligation to ensure access of a seriously ill patient to a medicinal product out of compassion in accordance with Regulation (EU) No. 726/2004 of the European Parliament and the Council of the EU were also revealed: 1) inform the Agency about access; 2) take into account any conclusions of the Committee drawn up regarding the conditions of use of the medicinal product out of compassion, conditions of distribution and categories of patients; 3) monitor updates of the Committee's conclusions; 4) ensure that the conclusions of the Committee do not affect the civil or criminal liability of the manufacturer or the applicant who applied for a sales permit; 5) if a compassionate use program has been initiated - to ensure that patients participating in it also have access to the new medicinal product during the period between authorization and market entry; 6) apply the provisions of the Regulation without prejudice to Directive 2001/20/EC and Article 5 of Directive 2001/83/EC.

Key words: everyone's right to medical care, everyone's rights to the provision of medicines, the state, the duties of the state, access to medicine, medicine, compassionate medicine, legitimate purpose, humanity, EU member state, European integration.

Formulation of the problem

Today, the latest technologies are constantly developing, and in the treatment of diseases that were previously considered incurable, the latest drugs are often used. As you know, every state, in accordance with its international obligations on human rights, guarantees everyone the right to quality medical care, the structural element of which is the right to access to the medicine necessary for treatment. There are situations when a medicinal product has been developed and admitted to the medicinal product market in a certain EU member state, but has not yet received permission to be sold in another EU member state. In this case, the question arises: can a seriously ill patient from an EU member state in which this medicinal product is not yet registered, gain access to this medicinal product on the grounds that this medicinal product is registered in another member state? There are other situations – when there is a medicinal product that, in the opinion of the attending physician, can have an effect in the treatment of a seriously ill patient, but this medicinal product is not registered in any EU member state. Such compassionate medicine is the last hope of a critically ill patient. That is why the question arises – on the one hand, the state guarantees everyone the right to quality medical care, it is their constitutional right, and on the other hand, the state is entrusted with the responsibility of providing a person with access to medicine out of compassion.

Ukraine is integrating with the EU. Therefore, from a practical point of view, it is relevant to study the issue of the positive obligations of the state to ensure the right of a seriously ill patient to access to a medicinal product out of compassion in the EU with the aim of improving the legislation of Ukraine and the practice of its application. Undoubtedly, this issue is multidimensional, complex and requires comprehensive research. This article will present the results of the research on the positive obligations of the EU member state to ensure the right of a seriously ill patient to access to a compassionate medicine in the EU, based on the analysis of directives and other EU documents. Other published scientific studies will be devoted to other issues of ensuring the right of a seriously ill patient to access a medicine on a compassionate basis.

State of problem research

The issue of everyone's right to access to medicinal products as a structural element of the right to medical assistance was studied in the works of professors L. Deshko [1-3], O. Vasylchenko [4], S. Bulets [5], V. Zaborovskyi [6] and others domestic scientists. Scientists also studied the legal regulation of the transfer of technologies for the production of medicinal products (for example, the works of L. Deshko, Yu. Bysaga, S. Kalyniuk [7; 8]), the requirements of EU law for the circulation of medicinal products [9], etc. During 2022-2023 and currently, at the beginning of 2024, a number of collective scientific studies were published, in which the issues of international cooperation of states to ensure the right of an individual to access medicines out of compassion, the issue of ensuring access to medicines out of compassion in Ukraine were raised (the works of S. Buletsa, M. Menzhul, V. Pashkov, S. Stetsenko, etc. [10; 11]). At the same time, they do not comprehensively analyze the directives and other EU documents in the context of the positive duties of the state to ensure the right of a seriously ill patient to access to a medicinal product out of compassion in the EU.

The purpose of the study is to establish the elements of the EU member state's obligation to ensure access of a seriously ill patient to a medicinal product that is not permitted in this EU member state, but is permitted in another EU member state; to establish elements of the content of the obligation of the EU member state to ensure the access of a seriously ill patient to a medicinal product out of compassion in accordance with Regulation (EC) No. 726/2004 of the European Parliament and the Council of the EU.

Presenting main material.

Each EU member state guarantees every person the right to quality medical care, one of the structural elements of which is the possibility of access to medicines. As is known, this human right corresponds to the duty of the state to ensure the availability of appropriate medicinal products or their analogues on the domestic market of the state. Directive 2001/83/EC of

the European Parliament and of the Council on the Community Code on Medicinal Products for Human Use [12] does not contain a rule of law that would allow or prohibit a member state of the EU from providing an opportunity to a seriously ill patient in his personal situation to receive a drug not authorized by the competent authorities of this state, the drug through a number of programs, including "compassionate application."

In Directive 2001/83/EC of the European Parliament and of the Council on the Community Code regarding medicinal products intended for human use, there is Article 126a, according to which rules an EU member state is allowed to place on its market a medicinal product that is authorized in another EU member state under certain conditions. 126a of the Directive "In the absence of a marketing authorization or pending application for a medicinal product authorized in another Member State in accordance with this Directive, a Member State may, for justified reasons related to the protection of public health , to allow the introduction of such a medicinal product into circulation" [12]. Therefore, the legitimate purpose of the admission to the market of an EU member state of a medicinal product, which is not authorized in this state, but is authorized in another EU member state, is the protection of public health.

Instruments to ensure compliance with the requirements 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 the event of admission by an EU member state to its market of a medicinal product that is authorized in another EU member state, in the presence of justified reasons , related to the protection of public health [12], are as follows: 1) labeling and leaflet-tab; 2) classification of medicinal products; 4) advertising; 5) supervision and sanctions.

The content of the obligation of an EU member state to ensure access of a seriously ill patient to a medicinal product, which is not permitted in this EU member state, but is permitted in another EU member state, contains the following structural elements: 1) before granting permission for the sale of the medicinal product, notify to the holder of a permit for the sale of a medicinal product in the EU member state in which it is permitted, a proposal for granting a permit for its sale in accordance with Art. 126a of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code regarding medicinal products intended for human use; 2) to send a request to the national competent authority of the member state in which the drug is authorized, regarding the submission of: a) copies of the report on the evaluation results; b) a valid permit for the sale of a medicinal product; 3) to notify the Commission about the granting of a permit for the sale of a medicinal product that is permitted in another EU member state; 4) notify the Commission about the termination of the authorization for a medicinal product that is authorized in another EU member state.

On March 31, 2004, Resolution (EU) No. 726/2004 of the European Parliament and the Council of the EU was adopted [13]. It established EU procedures for authorization and control of medicinal products for humans and veterinary medicine. The preamble to Regulation (EC) No. 726/2004 states that "in order to ensure, in particular, the legitimate expectations of patients and to take into account the increasingly rapid progress in science and treatment ... in the field of medicinal products for human use, the general approach to the criteria and conditions for the use of new compassionate medicines in accordance with the legislation of the Member States" (§33). In clause 1 of Art. 83 of the Resolution states that "as an exception to Article 6 of Directive 2001/83/EC, Member States may make human medicinal products available for compassionate use..." [13]. But we are not talking about the state's obligation to grant such permission, but about its right. Also, such authorization does not cover all patients, but only patients with an illness that is chronic or seriously debilitating, or has a life-threatening diagnosis, and cannot be satisfactorily treated with an approved drug.

In clause 2 of Art. 84 of the Regulation states that "compassionate use" means providing access for humanitarian reasons to a medicinal product…to a group of patients with a chronic/severe debilitating disease or a diagnosis considered life-threatening and who cannot be sat-

isfactorily treated with an authorized medicinal product . Such a medicinal product must be the subject of an application for a permit for the right to sell in accordance with Article 6 of this Decree or must undergo clinical trials" [13].

The content of the obligation of an EU member state to ensure access of a seriously ill patient to a medicinal product out of compassion in accordance with Regulation (EU) No. 726/2004 of the European Parliament and the Council of the EU [13] contains the following structural elements: 1) inform the Agency about this; 2) take into account any conclusions of the Committee drawn up regarding the conditions of use, conditions of distribution and categories of patients to whom it applies; 3) monitor updates of the Committee's conclusions; 4) ensure that the conclusions of the Committee do not affect the civil or criminal liability of the manufacturer or the applicant who applied for a sales permit; 5) if a compassionate use program has been initiated – to ensure that patients participating in it also have access to the new medicinal product during the period between authorization and market entry; 6) apply the provisions of the Regulation without prejudice to Directive 2001/20/EC and Article 5 of Directive 2001/83/EC.

Conclusions

The structural elements of the content of the EU member state's obligation to ensure access of a seriously ill patient to a medicinal product that is not permitted in this EU member state, but is permitted in another EU member state, are as follows: 1) before granting permission for the sale of the medicinal product to notify the holder of the authorization for the sale of the medicinal product in the EU member state in which it is authorized, the proposal for granting the authorization for its sale; 2) to send a request to the national competent authority of the member state in which the drug is authorized, regarding the submission of: a) copies of the report on the evaluation results; b) a valid permit for the sale of a medicinal product; 3) to notify the Commission about the granting of a permit for the sale of a medicinal product that is permitted in another EU member state; 4) notify the Commission about the termination of the authorization for a medicinal product that is authorized in another EU member state.

The structural elements of the content of the obligation of the EU member state to ensure the access of a seriously ill patient to a medicinal product out of compassion in accordance with Regulation (EC) No. 726/2004 of the European Parliament and the Council of the EU are as follows: 1) inform the Agency about access; 2) take into account any conclusions of the Committee drawn up regarding the conditions of use of the medicinal product out of compassion, conditions of distribution and categories of patients; 3) monitor updates of the Committee's conclusions; 4) ensure that the conclusions of the Committee do not affect the civil or criminal liability of the manufacturer or the applicant who applied for a sales permit; 5) if a compassionate use program has been initiated – to ensure that patients participating in it also have access to the new medicinal product during the period between authorization and market entry; 6) apply the provisions of the Regulation without prejudice to Directive 2001/20/EC and Article 5 of Directive 2001/83/EC.

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ПОЗИТИВНІ ОБОВ'ЯЗКИ ДЕРЖАВИ ІЗ ЗАБЕЗПЕЧЕННЯ ПРАВА ТЯЖКОХВОРОГО ПАЦІЄНТА НА ДОСТУП ДО ЛІКАРСЬКОГО ЗАСОБУ ЗІ СПІВЧУТТЯ В ЄС

Стаття присвячена дослідженню позитивних обов'язків держави із забезпечення права тяжкохворого пацієнта на доступ до лікарського засобу зі співчуття в ЄС, який кореспондує право кожного за наявності особливих потреб на доступ до лікарських засобів, у тому числі – не зареєстрованих – з міркувань гуманності.

У статті аналізуються Директива Європейського Парламенту і Ради 2001/83/ЄС про Кодекс Співтовариства щодо лікарських засобів, призначених для застосування людиною, Постанова (ЄС) №726/2004 Європейського Парламенту і Ради ЄС.

Стаття також розкриває сутність легітимної мети допуску на ринок держави-члена ЄС лікарського засобу, який не дозволений у цій державі, але дозволений в іншій державі-члені ЄС, та допуску лікарського засобу, який не дозволений у жодній державі-учасниці ЄС. Акцентується увага на законних очікуваннях пацієнтів та врахуванні все більш й більш стрімкого прогресу в науці та лікуванні, інструментах для забезпечення дотримання вимог Директиви Європейського Парламенту і Ради 2001/83/ЄС про Кодекс Співтовариства щодо лікарських засобів призначених для застосування людиною вразі допуску державою-членом ЄС на свій ринок лікарського засобу, який дозволений в іншій державі-члені ЄС.

За результатами дослідження було виявлено структурні елементи змісту обов'язку держави-члена ЄС із забезпечення доступу тяжкохворого пацієнта до лікарського засобу, який не дозволений у цій державі-учасниці ЄС, але дозволений в іншій державі-члені ЄС: 1) перед наданням дозволу на реалізацію лікарського засобу повідомити власнику дозволу на реалізацію лікарського засобу у державі-члені ЄС, у якій він дозволений, пропозицію з надання дозволу на його реалізацію; 2) направляти запит національному компетентному органу держави-члена, у якій дозволений лікарський засіб щодо подання: а) копій

звіту про результати оцінювання; б) дійсного дозволу на реалізацію лікарського засобу; 3) повідомити Комісію про надання дозволу на реалізацію лікарського засобу, який дозволений в іншій державі-члені ЄС; 4) повідомити Комісію про припинення дії дозволу на лікарський засіб, який дозволений в іншій державі-члені ЄС. Також виявлено структурні елементи змісту обов'язку держави-члена ЄС з забезпечення доступу тяжкохворого пацієнта до лікарського засобу зі співчуття відповідно до Постанови (ЄС) №726/2004 Європейського Парламенту і Ради ЄС: 1) проінформувати про доступ Агентство; 2) враховувати будь-які висновки Комітету, складені щодо умов застосування лікарського засобу зі співчуття, умов поширення і категорій пацієнтів; 3) моніторити оновлення висновків Комітету; 4) забезпечити те, щоб висновки Комітету не впливали на цивільну чи кримінальну відповідальність виробника чи заявника, що звернувся за дозволом на продаж; 5) якщо програма застосування зі співчуття була розпочата – забезпечити, щоб пацієнти, які беруть у ній участь, мали також доступ до нового лікарського засобу протягом періоду між дозволом і виходом на ринок; 6) застосовувати норми Постанови без шкоди для Директиви 2001/20/ЄС і для статті 5 Директиви 2001/83/ЄС.

Ключові слова: право кожного на медичну допомогу, права кожного на забезпечення лікарськими засобами, держава, обов'язки держави, доступ до лікарського засобу, лікарський засіб, ліки зі співчуття, легітимна мета, гуманність, держава-член ЄС, європейська інтеграція.