Аннотация

Севостьянова И. И. **Право на индивидуальное обращение в Европейский суд по правам человека: генезис, эволюция, современность.** — Статья.

Статья посвящена рассмотрению вопросов эффективной реализации права на индивидуальное обращение в Европейский суд по правам человека, его эволюции и значению.

Ключевые слова: Европейский суд по правам человека, право на индивидуальное обращение, Страсбургская правозащитная система.

Summary

Sevostianova N. I. **The Right for Individual Petition to the European Court of Human Rights: Genesis, Evolution, Contemporaneity.** — Article.

This article is devoted to the problem of effective realization of the right for individual petition to the European Court of Human rights, its evolution, scope and meaning.

Keywords: European Court of Human Rights, implementation of Convention on protection Human Rights and Fundamental Freedoms, Strasbourg human rights protection system.

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A. Voloc

HARMONIZATION OF THE UKRAINIAN LEGISLATIVE BASE OF ORGAN TRANSPLANTATION WITH THE LEGISLATION OF THE EUROPEAN UNION

Legal regulation of transplantology is continuing to be one of the most challenging issues worldwide in general and within Europe in particular. Every country is striving to adapt its legislative framework to its cultural, ethical and economic peculiarities, but at the same time it has to take into account the international requirements and the provisions of specific Conventions and Directives applicable to a group of states or internationally. After declaring its intention to integrate into Europe, Ukraine has to fulfill the prerequisite of harmonizing its legislation with the legislation of the European Union. This is in an equal measure applicable to the regulatory framework of transplantology as well as to other areas of activity.

Transplantology is considered a young but very successful and demanded specialty which is quickly developing by using the state-of-the-art scientific achievements. The vast majority of related legal documents emphasizes and supports the statement contained in the Directive of the European Parliament and the Council 2010/45/EU, that "*...Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment*" [1]. The international society fully supports this statement and undertakes all the steps to encourage its further development. However, given the specificity of transplantation, be it of organs, tissues or cells, it involves a range of legal aspects determining the main objectives on which the national legislation on transplantology is based. This includes

the protection of rights of at least two people involved in the process—the recipient and the donor; promotion of supply of high quality donor organs and their further efficient use. Protection is also required against potentially transmissible disease, forced involvement in the process of donation, organ and human trafficking, financial gain from organ donation, and disclosure of personal information of the recipient and the donor, etc. The recipients need guaranties that they will receive high quality organs, based on transparent and fair allocation of organs, while the donor needs to be sure that the procedure of organ/tissue/cells procurement is performed with minimal danger to his/her health, if it's a live donor, or that it will be performed with respect to a person's dignity after death, if it's a deceased donation [2]. These are only few issues which the legislative framework on transplantology is being encountering throughout its thorny development.

The history of regulatory and purely legal background of transplantology is quite dynamic and simultaneous to the scientific side of this field of medicine. An example of one of the earliest document adopted in the European community is the Resolution of the Council of Europe, Cabinet of ministers (78)29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances (adopted by the Cabinet of Ministers on 11 May 1978 at the 287th meeting of the Ministers' Deputies) [3]. Given the recommendatory character of the resolution, it leaves room for interpretation and freedom of whether to incorporate or not these provisions into the national legislation of the countries members of the Council of Europe. However, the society may be interested in gaining the rights provided for in this Resolution, which requires from the countries to ensure that their national legislation is developed in accordance with these provisions along with other international legal documents.

As a member of the Council of Europe as of 9 November 1995, Ukraine also had the option to take into account the provisions of the abovementioned Resolution while elaborating the Law of Ukraine on transplantation of organs and other human anatomical materials in 1999 and thereafter in the Civil Code of Ukraine in 2003, specifically its Article 290 on Organ Donation [4]. For instance, Article 13 of the Res (78)29 provides for: "*The identity of the donor must not be disclosed to the recipient and the identity of the recipient to the family of the donor*". At the same time, the Article 290 of the Civil Code of Ukraine in para.3 says: "*in case of implantation of organs and other anatomical materials the members of the family, close relatives of the donor have the right to know the name of the recipient*". This collision was approached only in 2010, following the Order of the Cabinet of Ministers of Ukraine of 16 June 2010, N 1231-p "On approval of the indicative plan of legislative work for the year of 2010" [5] by elaborating the draft of the Law of Ukraine "On amending the Civil Code of Ukraine", which is publicly disclosed on the website of the Ministry of Health of Ukraine [6]. The version of amendment has the following wording: "*neither the donor's identity should be disclosed to the recipient, nor the identity of the recipient to the donor's family, unless transplantation is done from a family related donor*". This amendment is in line with the Article 13 of Res (78)29 as long as the Law of Ukraine on transplantation

remains as it is now [7]. Specifically, according to this law, Ukraine allows live donation only from family related donors, while deceased donation does not have to be family related. In case of a future change of legislation of Ukraine which would allow unrelated live organ donation, the new wording of the Article 290 of the Civil Code of Ukraine makes it possible to disclose the identity of the recipient to the donor, but not to his/her family.

The process of harmonization of legislation of Ukraine with the legislation of other states within the European community is not only related to the Council of Europe, but also to the European Union. Ukraine aims at European integration, officially since 1998, when the President of Ukraine has signed the Decree of the President of Ukraine «On approbation of the Strategy of Ukraine's integration into the European Union of 11.06.1998 N 615/98 [8]. Given that health among others has been listed as a priority area of adaptation of its legislation to the legislation of the European Union (Part I, Art. 1, Para 2 of the Strategy), Ukraine should take into account the provisions of the relatively new Directive 2010/45/EU of the European Parliament and the Council on standards of quality and safety of human organs intended for transplantation of 7 July 2010 [1]. This Directive has entered into force on 27 July 2010, and "*...[the] Member States [of the European Union] shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 27 August 2012*". To maximize the value of this analysis and to go from the descriptive approach to an applicative one, the author has intended to describe how the Directive could impact the Ukrainian normative base of organ transplantology.

The Directive 2010/45/EU consists of a preamble, 7 chapters, 33 articles and 1 annex. It was elaborated having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4) thereof [ ], to the proposal from the European Commission, to the opinion of the European Economic and Social Committee [9], to the opinion of the European Data Protection Supervisor [10], and after consulting the Committee of the Regions. The Directive recognizes the "*immense benefits to hundreds of thousands of patients*" brought by organ transplantation over the last 50 years.

The main reason of elaborating this Directive derives from its title and is based on the demand to standardize the quality and safety of organs used in transplantation in a way that could minimize the risks of disease transmission. This should be realized by means of "*well organised national and international transplantation systems and [the] use of the best available expertise, technology and innovative medical treatment*". The standards must exist and be followed by all Member States of the European Union regardless of the jurisdictions the hospitals carrying out transplantation fall under. The standards cover the process of "*donation, testing, characterization, procurement, preservation, transport and transplantation of organs intended for transplantation*" at Union level. Compliance to their provision should be supervised by competent authorities with a proper organization, suitably qualified or trained and competent personnel and adequate facilities and material.

Special interest represents the Article 3 "Definitions" which among the usual terms and concepts encountered in the Ukrainian transplant legislation and corresponding to the internationally accepted ones (authorization, donor, donation, preservation, recipient, operating procedures, transplantation, transplantation centers) also contains such terms as 'disposal', 'European organ exchange organization', 'procurement', 'procurement organization', 'serious adverse event', 'serious adverse reaction', and 'traceability', which are not included in the Ukrainian law on transplantation, and should be taken into account when planning amendments to the law or other normative acts, and when designing and implementing organizational reforms in the area of organ transplantation in Ukraine in order to abide to the European terminology and to harmonize the national one.

The general purpose of the Directive is contained in its Chapter II, which sets out the requirements for quality and safety of organs. It requires the Member States to ensure the establishment of a framework for quality and safety which shall provide for the adoption and implementation of operating procedures for verification of donor identity, the details of the donor's or the donor's family's consent, authorization or absence of any objection when donation and procurement is to take place. At this level the Directive provides room for differences among Member States, given that the national rules are different in regards to consent required in case of post-mortem donation. However, the authorities should ensure that those national provisions are strictly complied with. As for Ukraine, currently there are general provisions regarding the informed consent in case of live or deceased donation, but the operational procedures related to all the steps of donation and the required information to be collected (detailed in the Annex of the Directive) are still in the process of elaboration.

The main requirements for the procurement of organs and the organizations performing it are stated in Articles 5 and 6, Chapter II. In this direction Ukraine complies with these provisions already, given that the procurement of organs is performed only in authorized medical institutions, in proper conditions, and following the decision of qualified medical doctors. Nonetheless, it should be emphasized that the organ procurement process from deceased donors is stagnating throughout the whole country given the existence of a range of challenges of social, organizational and medical character. The specification of these problems is beyond the scope of this article, but close collaboration of Ukrainian specialists and authorities with European counterparts in the field of organ procurement is highly desirable, especially during the process of Directive's implementation in the European Union. This also includes the provisions of Article 18 «Records and reports concerning procurement organisations and transplantation centres» that should be taken into account by Ukraine as well.

The informational aspect of transplantation, including data recording, storing, reporting, exchange of information is approached in the Directive at all stages of the transplantation process. Article 7 «Organ and donor characterisation» clearly sets the requirement to "*[characterize] all procured organs and donors thereof before transplantation through the collection of the information set out in the*

Annex". The Directives defines the minimal amount of information to be collected during the pre-transplant evaluation of a donor which would suffice for the transplantation centers in order to allow the clinicians undertaking a proper risk-benefit analysis before transplantation. It is still emphasized that "*if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available*". This paragraph depicts one of the main principle of the Directive, that is its "content [...] should be limited to establishing a basic quality and safety framework for Europe and, at the same time, it should respect clinical practice. Binding requirements should not create any barriers for organ donation, including the use of the so-called «expanded criteria donors» under specific circumstances" [11].

The information must accompany the organ be it within one transplantation center or throughout an organ exchange process among Member States (Article 9, 19). Rules for transportation in relation with timeframes, labeling and accompanying documentation are provided to reduce organ damage and to maintain confidentiality. Article 10 addresses an important aspect that should be ensured i.e., the traceability of organs in order to safeguard the health of donors and recipients. This again should be done without affecting the confidentiality and data security in compliance with Union and national provisions referred to in Article 16 of the Directive, and requires from the Member States to ensure the implementation of a donor and recipient identification system. In regards to Ukraine, the concept of traceability needs to be applied and specified in operational procedures of similar instructions, in accordance with the national legislation, but also taking into account the provisions of this Directive. The Chapter V Article 20 on organ exchange with third countries also uses the notion of traceability in the context that "*Organ exchange [with third countries], as referred to in paragraph 1, shall be allowed only where the organs [...] can be traced from the donor to the recipient and vice versa*".

Similarly to the requirements detailed in paragraph 2, Article 10 for the Member States of the European Union, Ukraine should "*ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it*". One should note that the information for all the stages related to transplantation is duly recorded and stored in Ukraine. However, the electronic form of storage of any medical information is in the process of development and implementation and not all the health care facilities have resources and the will to keep electronic medical records of all medical information, or to exchange it with other facilities. Paragraph 3(b) of the Article 10 creates additional incentives for this direction of development in Ukraine during the process of European integration.

Regarding the healthcare personnel, the requirement for which are detailed in Article 12 of the Directive, with reference to Article 4(3), include the goals set for the development of specific training programs for such personnel, and Ukraine is

actively working in this direction as well. However, in order to be closer to the European standards further professional and educational exchange is required among the European Member States and Ukraine by means of educational exchange programs at the official state level. Another issue related to the personnel involved in transplantation is the necessity to create the position of a donor-coordinator in Ukraine, which is currently absent but actively requested by the transplantation centers of the country. The paragraph 17 of the preamble of the Directive clearly states this need for the European Union and the members of the Council of Europe as well: "*The importance of donor coordinators, appointed at hospital level, has been acknowledged by the Council of Europe. The role of the donor coordinator or coordination team should be recognised as key to improving not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted*".

The role of the society which should be prepared to donate organs for transplantation in order to increase their overall availability is emphasized in paragraph 3 of the preamble of the Directive. This evident, but still problematic issue is one of the main problems creating challenges to the Ukrainian transplantology from evolving at a larger pace. The experience of the European Union in promoting organ donation should be taken into consideration by the Ukrainian authorities, and implemented in the legal framework of transplantation at the national level. it is important to note, that in the European Union the Treaty on the Functioning of the European Union Article 168 (4a) provides for that the "*European Parliament and the Council [...] shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures*" [12]. This may be applied to Ukraine as well in the process of harmonization of legislation on the way to European integration. Thus, Ukraine should take into account the European Directive 2010/45/EU while amending its legislative framework on transplantology, and maintain a continuous consultation process with the Member States of the European Union, which have a larger experience in improving the situation in transplantology at the national and the European community level.

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Summary

Voloc A. **Harmonization of the Ukrainian Legislative Base of Organ Transplantation with the Legislation of the European Union.** — Article.

The aim of this article is to assess the impact of the new Directive of the European Parliament and the Council 2010/45/EU of 7 July 2010 on standards of quality and safety of human organs intended for transplantation on the further harmonization of the Ukrainian legislation regulating organ transplantation with the European legislation within the scope of the official direction of Ukraine towards European integration. The article also describes the role of the Resolution of the Council of Europe, Cabinet of ministers (78)29 «on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances» on the amendment of the Civil Code of Ukraine, Article 290, proposed by the Ministry of Health of Ukraine.

Keywords: organ transplantation, removal and transplantation of human substances, Directive of the European Parliament and the Council, harmonization of legislation, European integration, Civil Code of Ukraine.

Анотація

Волок О. О. **Гармонізація законодавчої бази України щодо трансплантації органів з законодавством Європейського Союзу.** — Стаття.

У статті оцінюється вплив нової Директиви Європейського парламенту та Ради 2010/45/ЕU від 7 липня 2010 року про стандарти якості та безпеки органів людини, призначених для трансплантації, на українське законодавство, що регламентує трансплантацію органів і процес його гармонізації з європейським законодавством, в рамках офіційного курсу України до європейської інтеграції. Також описується роль Постанови Ради Європи, Кабінету міністрів (78)29 «Про приведення у відповідність законодавств держав-учасниць з питань вилучення, пересадки і трансплантації матеріалів організму людини» у внесенні зміни до Цивільного кодексу України, статті 290, запропонованої Міністерством охорони здоров'я України.

Ключові слова: трансплантація органів, вилучення і трансплантація матеріалів організму людини, директива Європейського парламенту і Ради, гармонізація законодавства, євроінтеграція, Цивільний кодекс України.

Аннотация

Волок А. А. **Гармонизация законодательной базы Украины по трансплантации органов с законодательством Европейского Союза.** — Статья.

В статье оценивается воздействие новой Директивы Европейского парламента и Совета 2010/45/EU от 7 июля 2010 года по стандартам качества и безопасности органов человека, предназначенных для трансплантации, на украинское законодательство, регламентирующее трансплантацию органов и процесс его гармонизации с европейским законодательством, в рамках официального курса Украины к европейской интеграции. Также описывается роль Постановления Совета Европы, Кабинета министров (78)29 «О приведении в соответствие законодательств государств-участников по вопросам изъятия, пересадки и трансплантации материалов организма человека» во внесении изменения в Гражданский кодекс Украины, статью 290, предложенного Министерством здравоохранения Украины.

Ключевые слова: трансплантация органов, изъятие и трансплантация материалов организма человека, директива Европейского парламента и Совета, гармонизация законодательства, европейская интеграция, Гражданский кодекс Украины.

УДК 340.116: 316.4

О. О. Терзі

ПРОБЛЕМА ВИЗНАЧЕННЯ МІСЦЯ ІНТЕГРАЦІЙНОГО ПРАВА В СИСТЕМІ ПРАВА УКРАЇНИ: ЗАГАЛЬНОТЕОРЕТИЧНІ ОСНОВИ

В теорії права поняття системи права є взаємозв'язаною сукупністю правових норм, впорядкованою по галузях права і інститутах права, що входять до їх складу. Галузі права об'єднують правові норми, що відносяться до якої-небудь певної, досить відособленої сфери діяльності. Система права з часом змінюється. Так, у міру розвитку використання найманої робочої сили, з цивільного права в самостійну правову галузь виділилося трудове право. Розпад радянської системи привів до відмирання колгоспного права. Становлення і розвиток місцевого самоврядування зумовило виникнення права муніципального права. У стадії активного розвитку знаходиться космічне право. В той же час такі галузі права, як державне (конституційне), цивільне, адміністративне, карне, сімейне, в історичному аспекті є стійкими.

Як відомо, критерій виділення галузей права не встановлений і законодавцем. Проте в теорії відповідними такими критеріями служать предмет і метод правового регулювання. Предметом правового регулювання в галузях права є визначені сукупності однорідних громадських стосунків: майнові, фінансові, адміністративні, бюджетні, трудові, транспортні, сімейні, карні і ін., на підставі яких отримує назву відповідна галузь права. Методи правового регулювання є сукупністю способів дії правових норм на дані громадські стосунки. Теоретично методи правового регулювання підрозділяють на імперативні і диспозитивні. Імперативні методи виходять з механізму владної дії на суб'єкти правовідносин. Диспозитивні методи засновані на наданні рівноправним суб'єктам правовідносин можливості самостійного вибору форми організації і здійснення їх стосунків в межах, обмежених правовими нормами.