Аннотация

Чистякова Ю. В. **Правовая знаковая конструкция «право на жизнь» в разных правовых системах.** — Статья.

В статье осуществляется сравнительно-правовой анализ функционирования правовой знаковой конструкции «право на жизнь» в разных правовых системах с помощью семиотического подхода. Анализируется разница в восприятии означающей части и ее элементов (право на аборт, право на осуществление смертной казни, право на эвтаназию) данной конструкции в разных правовых системах современности.

Ключевые слова: семиотический подход, сравнительно-правовой анализ, правовая знаковая конструкция, право на жизнь, право на аборт, смертная казнь, эвтаназия.

Summary

Chistiakova J. V. **Legal sign construction «right on life» in different law systems.** — Article.

In the article the comparative-legal analysis of functioning of legal sign «right on life» in different legal systems is realized with the usage of semiotic approach. The difference in perception of signified part and it's elements (right on abortion, right on realization of death penalty, right on euthanasia) of this construction in the different legal systems of modern times is analysed.

Keywords: semiotic approach, comparative-legal analysis, legal sign construction, right on life, right on abortion, death penalty, euthanasia.

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COMPARATIVE LEGAL ANALYSIS OF THE REGULATORY FRAMEWORK OF TRANSPLANTATION IN THE EUROPEAN UNION

Organ, tissue and cell transplantation continues to be a challenging field of health care specifically from the legal point of view. Given the relatively short period of existence of transplantology its regulatory framework is still being actively discussed both by scholars and public authorities around the world, with following amendments to the national and regional regulations.

Issues related to legal regulation of transplantation became particularly interesting to scholars worldwide given the evolution of legal thought along with technical and medical progress of the area of transplantation. In Ukraine, the problems associated with the lack of legal regulation of transplantology were studied in the works of such well-known scientists in law, medicine and other fields like P. L. Alekseeva, G. V. Chebotareva, V. A. Glushkov, I. I. Gorelik, S. V. Grinchak, M. I. Korzhanskiy, A. A. Kostenko, O. G. Kotenko, A. V. Musienko, H. M. Nathan, Y. V. Polyachenko, R. V. Salutin, S. S. Tikhonova and other.

Extensive legal analysis of controversial issues arising during transplantation/ health care services provision has been performed by such foreign authors as A. Abadie, R. Abbing, J. N. Aleccia, K. S. Andersen, E. P. Aydin, N. R. Barshes, J. L. Bernat, M. M. Boucek, Brawer Ben-David, J. Chapman, R. Chen, A. Clemmons, R. Coppena, G. D. Curfman, P. de Cruz, E. N. Dorff, V. English, R. C. Fox, R. W. Gimbel, F. Goodlee, N. Guttman, S. D. Halpern, R. L. Horton, B. Hutt,

S. Klarenbach, R. Knox, L. Konis, M. N. Kurnit, T. Ligget, M. Liliana, A. Matas, E. B. McKinney, D. R. McNeil, H. N. Mocan, E. Mossialos, H. M. Nathan, M. A. Noorami, D. Orentlicher, T. D. Overcast, B. Patsner, S. Satel, G. R. Schutt, E. Sheehy, Y. Shimazono, D. Sipes, R. Titmuss, J. L. Verheijde and others. While some analysis has been undertaken on the empirical determinants of effective organ procurement rates, evidence on the underlying behavioral explanations of such decisions and the extent to which they are influenced by the particular legislative setting to which individuals are subject has been more limited [1].

Special contribution to the development of the doctrinal basis for conferring the status of legal norms to ethical, management and social norms in the area of transplantology was made by J. R. Chapman, M. Deierhoi, C. Wight, H. H. Kaufman, C. D. Keyes, D. Lamb, P. Lauritzen, F. T. Rapaport, W. E. Wiest.

In June 2006, the European Commission issued a consultation document concerning the state of organ donation and transplant policy at the European level [2]. The discussion over the EU policy on organ donation and transplantation highlights not only the heterogeneity of the latter throughout Europe but also the importance and the scope of successful policies to be potentially enacted [3]. A clearer picture of the decision-making process behind organ donation rates should inform this policy process.

Transplantation not only provides the possibility of saving lives but also yields the best results in terms of quality of life for patients and the reduction of long-term health care costs. It has higher measurable quality indicators than other replacement therapies such as dialysis. Nonetheless, the severe shortage of donors across all organ categories remains a major constraint the Member States in the European Union are facing. Efforts to expand the available organ supply have become more crucial for meeting transplant demand. However, often available organ transplants might well depend on institutional frameworks rather than on individual demand, namely the specific regulations in each country as well as individuals' awareness of this legislation. Therefore, at the moment when Ukraine is tending at European integration this article is aiming at increasing the awareness of the local officials and scholars of the new amendments in the approached legislation across Europe.

Following the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007 and entering into force on 1 December 2009, articles, sections, chapters, titles and parts of the Treaty on European Union and of the Treaty on the Functioning of the European Union (TFEU) [4] are renumbered (Treaty of Lisbon article 5 and Annex), new articles were added and some of them reviewed and modified. Within the scope of this article, the part of the TFEU presenting interest to us is the Title XIV (ex-Title XIII in TEC) «Public Health», Article 168 (ex Article 152 of TEC).

Aside from the word «Community» being replaced by «Union» in the entire Document, the changes made to this part are as follows: «The Union shall encourage cooperation between the Member States in the areas referred to in this Article

(Article 168) and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas» [5]. These additional provisions, along with other amendments are formally securing the need for an active cooperation between Member States, continuous exchange of experience, positive achievements. The role of an efficient monitoring and evaluation with a consequent reporting to the European Parliament is emphasized.

The vast majority of related legal documents supports the statement contained in 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, that «...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» [6]. The international society is also in favor of this statement and undertakes all the steps to encourage its further development. 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.» 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 [7].

The Directive was elaborated having regard to the TFEU, Article 168(4) thereof [8], 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 main reason of elaborating it 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 organized 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. They cover the process of «donation, testing, characterization, procurement, preservation, transport and transplantation of organs intended for

transplantation» at the EU level. Compliance to their provision should be supervised by competent authorities with a proper organization, suitably qualified personnel and adequate facilities and material.

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 [11].

The main requirements for the procurement of organs and the organizations performing it include that the procurement of organs is performed only in authorized medical institutions, in proper conditions, and following the decision of qualified medical doctors. 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 characterization» 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» [12].

The minimal amount of information to be collected during the pre-transplant evaluation of a donor before transplantation is defined. Still, 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 are available. This statement depicts one of the main principles 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 [13].

The information must accompany the organ be it within one transplantation center or throughout an organ exchange process among Member States. Rules for transportation in relation with timeframes, labeling and accompanying documentation are provided to reduce organ damage and to maintain confidentiality. Article 10 addresses the important aspect of traceability of organs in order to safeguard the health of donors and recipients. Again it should be done without affecting the confidentiality and data security, and requires from the Member States to ensure the implementation of a donor and recipient identification system. 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 shall be allowed only where the organs can be traced from the donor to the recipient

and vice versa. Following the requirements detailed in Article 10 for the Member States of the EU 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 [14].

The Directive includes the goals set for the development of specific training programs for the personnel involved in transplantation. It is necessary to create the position of a donor-coordinator, which is currently absent in Ukraine for instance, but actively requested by the transplantation centers of the Member States. The preamble of the Directive clearly states that 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 recognized 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. The experience of some EU Member States in promoting organ donation should be taken into consideration by the authorities of other countries and implemented in the legal framework of transplantation at the national level. It is important to note, that in the EU the TFEU 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» [15].

The use of tissues and cells to some extent raises the same issues as the use of organs, though there are serious differences, and it was decided at the European Community level that the two subjects should not be covered by one directive.

Therapies based on tissue and cell transplants are becoming ever more numerous and varied thanks to progress in cellular and molecular biotechnology. But tissues and cells carry potential risks for disease transmission. The European Parliament and the Council have already adopted Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [16]. The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use. It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'. The aim of these campaigns should be to help European citizens decide to become donors during their lifetime and let their families or legal representatives know their wishes. As there is a need to ensure the availability of tissues and cells

for medical treatments, the Directive provides for that the Member States should promote the donation of tissues and cells, including haematopoietic progenitors, of high quality and safety, thereby also increasing self-sufficiency in the Community [17].

It is essential that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, was aimed at helping to reassure the public that human tissues and cells that are procured in another Member State nonetheless carry the same guarantees as those in their own country.

In regards to tissues and cells intended to be used for industrially manufactured products, including medical devices, they are covered by this Directive only as far as donation, procurement and testing are concerned, whereas the processing, preservation, storage and distribution are regulated by other Community legislation. Specifically, the further manufacturing steps are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [18].

Directive 2004/23/EC applies to tissues and cells including haematopoietic peripheral blood, umbilical-cord blood and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells. This Directive excludes blood and blood products (other than haematopoietic progenitor cells) and human organs, as well as organs, tissues, or cells of animal origin. Blood and blood products are currently regulated by Directives 2001/83/EC and 2000/70/EC [19], Recommendation 98/463/EC [20] and Directive 2002/98/EC [21]. Tissues and cells used as an autologous graft (tissues removed and transplanted back to the same individual), within the same surgical procedure and without being subjected to any banking process, are also excluded from this Directive. The quality and safety considerations associated with this process are completely different. The tissue and cells Directive does not cover research using human tissues and cells, such as when used for purposes other than application to the human body, e.g. *in vitro* research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive. Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. In order to ensure that the health status of a living donor is not affected by the donation, a prior medical examination should be required. The dignity of the deceased donor should be respected, notably through the reconstruction of the donor's body, so that it is as similar as possible to its original anatomical shape.

There are wide differences in the organ donor rate if we compare the European countries. In 2004 they have varied widely [22]: 34.6 donors per million of population (ppm) in Spain, 13.8 ppm in UK; 6 ppm in Greece, and 0.5 ppm in Romania. Maintaining adequately high organ donation rates proves essential to offering patients all appropriate and available treatment options [23].There is an important positive correlation between having discussed the issue of donation

within the family and the willingness to actually donate organs. Since public awareness and opinion play a very important role in increasing organ donation rates, continuing education should form an essential part of all Member States' communication strategies on the issue. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens seem to have discussed organ donation within their families. The role of social interactions in influencing individuals' willingness to donate their organs or those of a relative is significant [24]. These differences cannot be explained exclusively by the differences in public attitude or mortality rates [25]. Comparison of other causes especially in the legal field between EU Member States offers some insight into the differences. To increase the supply of transplantable organs, some EU countries have begun implementing and enforcing presumed consent policies for organ donation [26; 27].

Every year organs are exchanged between Member States. The exchange of organs is an important way of increasing the number of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplantation. This is particularly important for the optimal treatment of specific patients such as patients requiring urgent treatment, hypersensitized or pediatric patients. Available organs should be able to cross borders without unnecessary problems and delays. There are already areas covered by international agreements where the interchange of organs between countries accounts for up to 20% of total organ transplants. This exchange of human organs is carried out within recognized quality and safety standards. Eurotransplant is the largest such organ exchange organization and includes Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands and Slovenia as members. Eurotransplant also exchanges with other national and international organizations. Scandiatransplant is a Nordic organ exchange organization and covers a population of 24,5 million inhabitants in five countries: Denmark, Finland, Iceland, Norway and Sweden [28].

Most of the Member States have legislation to protect the donor in respect of anonymity, confidentiality and non remuneration for the donation. There are laws in place covering the therapeutic use of organs in majority of countries, where they are legally binding and in two where they are as technical guidelines. In many of the states, there are also legally binding requirements when the final use of the organs is for research purposes.

The consent for living donations to genetically-related recipients is regulated by law in almost all EU states. In two it is included in guidelines or recommendations that professionals should follow, but this requirement is not enforceable by law. In all twenty six Member States where there are legal requirements, informed consent is imperative. Legally binding written consent is required in sixteen countries. In ten countries a witnessed official 'body' is required and in 3 of them this witnessed body has to be the court.

Living donations to other relatives (not genetically related) is not authorized in three countries. There is missing information for two countries and in 23 it is

regulated by law. In 22 of them written consent is necessary, in 9 a witnessed official body is required and in 3 of them this witnessed body has to be the court. Living donors unable to consent legally (minors or others who are incapacitated) are excluded from donation by law in 18 countries. Three countries give legal authorization for these types of donors if permission is given by parents or guardians. Three other countries give this authorization only if in addition to such consent it is an emergency situation. In a remaining four countries, it is only authorized under specific circumstances and with the previous authorization of a court.

Medical examination to evaluate the suitability of the donor is required by law in 21 of the countries and in another seven it is indicated in the technical guidelines. Nine countries include psychological evaluation as binding criteria for the assessment of the donor. It is included in technical guidelines in ten more countries. Eighteen countries include a legal provision indicating that the living donor is able to withdraw the consent at any time. In 28 countries the consent for a donation from the deceased donor is embedded in a binding law. Only in one is it organized through guidelines.

Generally four forms of consent exist among European Union countries. Most of the countries have a donor register in place; in 16 the existence of these registers is compulsory by law. There are different types of registers: dedicated registers of donors, non-donors, combined and other types such as a register of inhabitants that incorporates also the information about the willingness — or not — to donate or other kind of registers such as driving license or donor cards. Most of states have binding legislation in place establishing a definition of brain death; three more have technical guidelines with definitions [29].

In the UK, the law regarding removal of organs from people after their death is set out in the Human Tissue Act 2004, covering England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act 2006.

These laws repealed the 1961 Human Tissue Act, which was introduced when transplantation was in its infancy. The new legislation, which was announced in the Queen's speech in 2003, takes a modern approach to the issues and was widely consulted on. The Department of Health consultation document entitled *Human bodies, human choices* was published in July 2002 followed by a Summary of responses to the consultation in April 2003 [30].

The UK regulates transplant and reproductive issues separately. Transplant medicine is regulated under the Human Tissue Act of 2004, while embryos and live gametes are regulated under the Human Fertilisation and Embryology Act (HFEA) of 1990 [31].

Both Human Tissue Acts state that if a person has, while alive and competent, given consent for some or all of their organs or tissue to be donated following his or her death, then that consent is sufficient for the donation to go ahead. Once consent is established, relatives or other relevant people should be advised of the fact and encouraged to respect the deceased's wishes. They will be treated with the utmost sensitively but advised that they have no legal right to veto or overrule

them. In some cases, however, there still may be circumstances where donation may not be appropriate.

If there is no record of the deceased's wishes, the medical staff will approach the relatives or other relevant people to establish any known wishes of the deceased. If these are not known, and the deceased has nominated a person to deal with the use of their body after death, then consent can be given by that person.

If neither of the above apply, consent to donate can be given by someone in a «qualifying relationship» immediately before the death of the deceased person. Those in qualifying relationships differ slightly for Scotland but both lists, which are set out in a strict order of priority, include family members and close friends [32].

The Human Tissue Authority has been selected as the body that will set standards for the quality and safety of transplant organs across the European Union. The Authority has been named as the competent organization for England and Wales for the European Union Organ Directive and has taken the lead on developing a regulatory framework and implementation into legislation by August 2012. It is the first time a formal regulatory framework has been developed for the donation and transplant of organs. The aim was to standardize the systems and processes used by member states. It should also help facilitate the more effective exchange of organs between member states. The ultimate goal is to ensure common high quality and safe standards for the donation, procurement, transportation, traceability and follow up of donated organs for transplant across the European Union.

The Department of Health works with the Human Tissue Authority, other health administrations, NHS Blood and Transplant and transplant community to create an overall framework that will ensure the all organizations involved in organ donation and transplantation comply with the Directive; develop a system to license procurement and transplantation; confirm arrangements for reporting serious adverse events and reactions; issue guidance to healthcare providers involved in all stages of the transplant chain; and supervise organ exchange with other member states. The Department of Health considered a number of possible organizations but the Human Tissue Authority was chosen because it best demonstrates the necessary expertise and has established a reputation in ensuring that its regulation is proportionate, effective and efficient. It already regulates the procurement, storage and transport of tissue and cells under the Human Tissue Act of 2004 and is responsible for licensing all tissue establishments [33].

The EU has established an Action Plan on Organ Donation and Transplantation from 2009–2015 for Strengthened Co-operation between member states. In April 2008, MEPs voted overwhelmingly to create an EU-wide donor card to tackle the transplants shortage. There is also a vision for a common 'organ pool', with cross-border organ donation and a single transplantation hotline. In recent years, the Commission has put considerable effort, under different Community programs, into supporting initiatives in the area of organ transplantation. A large number of projects have been co-funded, the results of which have generated a considerable

amount of information and knowledge. It is very important that further work under the existing programs should be continued involving not only the Member States but also other relevant stakeholders.

The Commission has identified a detailed list of priority actions. In turn, the Action Plan divides each priority action into various actions, and each Member State will decide what action and measures need to be taken in order to achieve the desired objectives; these will be included in their Sets of National Priority Actions, which should serve as a platform for discussion, exchange of expertise, and identification of best practices in the framework of this Action Plan. The Sets of National Priority Actions should be country-specific and tailored to the specific situation of each Member State [34]. At a later stage the Commission and the Member States should aim to establish European or international accreditation schemes for transplant donor coordinators [35; 36].

Exchanging information and best practices will help countries with low organ availability to improve their availability rates. Implementation of elements of the Spanish Model in Italy, for example, has been very successful in increasing organ donation rates, which demonstrated that changes in the organization of organ donation and procurement can substantially increase and sustain organ donation rates [37].

Spain continues to lead the way in organ donation with the so-called Spanish Model approach. Spain attributes its success to its transplant co-ordination network with transplant co-ordinators based at the site of the donation. Spain has a theoretical presumed consent law but, from a practical point of view, family consent is always asked for and the wishes of the relatives are always respected. The Spanish Model is being applied in other states, particularly in Tuscany, Italy, with success. In the U.K., the debate on presumed consent for organ donation has been under way for a number of years [38].

The Directive and the Action Plan on organ donation and transplantation are mutually reinforcing. While the Directive lays down binding measures to be adopted by the Members States for the quality and safety of organs, the Action Plan, adopted in 2009, has a broader scope, covering also the availability of organs and efficiency of transplantation systems [39].

The European scenario in the field of donation and transplantation was very heterogeneous until a very few years ago, in which each country used different methodologies for data definition, collection and processing. As a result data was hardly comparable and not available for consultation in real time. Since that time, many of old European Union Member States reinforced their cooperation in the field of organ donation and transplantation and, in particular, on the issue of data collection. Measurable results were achieved, on the harmonization of definitions for organ-related processes and the creation of a data collection registry.

Nevertheless, new European developments such as the entrance of the ten new Member States and the approval of the Directive 2004/23 on tissues and cells, combined with further IT innovations, have opened new horizons and highlighted the growing needs in this field [40].

The broad range of regulatory documents and provisions existing in the European Union at the community level and the separate national legal frameworks regarding organ, tissue and cell transplantation and donation has been extensively studied by European officials and scholars, have been continuously amended in order to achieve an optimal level of freedom and regulation to ensure maximal efficiency and donation rate in the field of transplantation. Awareness of all these theoretical and practical changes is crucial for Ukrainian public health and legal authorities in generating a national EU-harmonized legislation.

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Summary

Voloc A. **Comparative legal analysis of the regulatory framework of transplantation in the European Union.** — Article.

The article focuses on the legal regulation of organ, tissue and cell transplantation as a challenging field of health care activity at the level of the European Union and its Member States. The main provisions of the Directives of the European Parliament and the Council regarding transplantation are analyzed and the particularities of corresponding national legislation of Member States are described aiming at increasing the awareness of interested Ukrainian stakeholders to be taken into account in amending the national legislation.

Keywords: transplantation of organs, tissue, cells, legal regulation of transplantation in European Union.

Анотація

Волок О. О. **Порівняльно-правовий аналіз нормативного регулювання трансплантації в Європейському Союзі.** — Стаття.

У статті розглядається законодавство Європейського Союзу та його держав-членів, що регламентує трансплантологію органів, тканин і клітин як одну з проблемних галузей охорони здоров'я. Аналізуються основні приписи відповідних Директив Європейського парламенту та Ради, що стосуються трансплантології. Описуються особливості відповідного внутрішнього права держав — членів ЄС з метою підвищення рівня інформованості учасників законотворчого процесу в Україні для належної адаптації національного законодавства.

Ключові слова: трансплантація органів, тканин, клітин, нормативне регулювання трансплантації в Європейському Союзі.

Аннотация

Волок А. А. **Сравнительно-правовой анализ нормативного регулирования трансплантации в Европейском Союзе.** — Статья.

В статье рассматривается законодательство Европейского Союза и его государств-членов, регламентирующее трансплантологию органов, тканей и клеток как одну из проблемных отраслей здравоохранения. Анализируются основные предписания соответствующих Директив Европейского парламента и Совета, касающиеся трансплантологии. Описываются особенности соответствующего внутреннего права государств — членов ЕС с целью повышения уровня информированности участников законотворческого процесса в Украине для надлежащей адаптации национального законодательства.

Ключевые слова: трансплантация органов, тканей, клеток, нормативное регулирование трансплантации в Европейском Союзе.