PROBLEMS OF IMPLEMENTATION OF EUROPEAN PRINCIPLES OF DONATION INTO UKRAINIAN LEGISLATION

Oliinyk Roman Volodymyrovych - postgraduate student at the Department of Civil Law and Procedure of Faculty of Law of Ivan Franko National University of Lviv

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Статья посвящена проблемам имплементации европейских принципов донорства в украинское законодательство. Осуществлено четкое определение принципов гражданско-правового регулирования донорства.

Следует отметить, что принципы донорства - это руководящие принципы, основные положения, выражающие сущность гражданско-правового регулирования донорства, обеспечивают его внутреннее единство, определяют его общий смысл и направленность.

Перечень принципов донорства остается мало исследованным и законодательно не урегулированным в полном объеме. Все это порождает ряд противоречий на практике. В связи с этим сформулированы выводы и предложения по усовершенствованию национального законодательства.

Ключевые слова: донор, донорство, донорство крови и ее компонентов, трансплантация, принципы.

The article is devoted to the problems of implementation of European principles of donation into Ukrainian legislation. The principles of civil law regulation of donation were clearly defined.

It should be noted that the principles of donation are the guiding principles, the main regulations that express the essence of civil law regulation of donation, ensure its coherence and determine its general content and direction.

The list of principles of donation remains largely unexplored and not fully regulated by law. All this creates a number of controversies in practice. In this regard, conclusions and proposals for improving national legislation have been defined.

Key words: donor, donation, blood and its components donation, transplantation, principles.

Articolul este dedicat problemelor de implementare a principiilor europene de donație în legislația ucraineană. Principiile reglementării dreptului civil al donațiilor au fost clar definite.

Trebuie remarcat faptul că principiile donației sunt principiile directoare, principalele reglementări care exprimă esența reglementării dreptului civil al donației, asigură coerența acesteia și determină conținutul și direcția sa generală.

Lista principiilor donației rămâne în mare parte neexplorată și nu este reglementată în totalitate de lege. Toate acestea creează o serie de controverse în practică. În acest sens, au fost definite concluziile și propunerile pentru îmbunătățirea legislației naționale.

Cuvinte cheie: donator, donare, sânge și componentele sale donare, transplant, principii.

1. Introduction

Since its inception, donation and transplantation have raised many legal issues that had never had to be coped with in the process of society's development. The need for an absolute legal framework for transplantation is connected, first of all, with the special relationship between the donor and the recipient, the specifics of which lies in the fact that both have equal right to life. The guarantee of fundamental human and civil rights and

freedoms and, above all, the right to life is an indicator of the degree of civilization of a State [1, pp.33-48].

Transplantation as a method of treating some of the most serious human diseases is applied in the event that the elimination of the danger for life or recovery of the patient by other methods of treatment is impossible. Since 2018, there has been a decreasing tendency of number of transplantations in Ukraine. Thus, 119 kidney transplantations were performed in 2018 (incl. 6 cadaveric donations) and 10 liver transplantations, while in 2019 only 71 kidney transplantations (incl. 4 cadaveric donations) and 6 liver transplantations were performed. In the first half of 2020, only 46 kidney transplantations (incl. 6 cadaveric donations) and 3 liver transplantations were performed.

At the same time, according to the official statistics of the Ministry of Health of Ukraine as of August 4 of this year, the Ministry's Commission on refer for treatment abroad considers 32 cases of citizens (at different stages of preparation) in need of bone marrow transplantation, 46 – kidney transplantations, 6 – liver transplantations, 16 – heart transplantations, 7 – lung transplantations.

One of the reasons for the presence of citizens in need of transplantation abroad is the small number of people who wish to be organ donors after their death, as well as the imperfection of national legislation, primarily its inconsistency with European standards. Therefore, an effective solution to the issue of donation in Ukraine is impossible without the implementation of European standards for its regulation.

2. Results of research

The principles of donation and transplantation are defined in two national laws: On Blood and Its Components Donation and On Application of Transplantation of Anatomical Materials to Humans. A common principle for both laws is voluntary basis of donation. The presence of consent expressed in a voluntary form is the basis for further medical intervention. A comparative legal analysis of the legislation of countries that actively apply transplantation as a method of treating diseases and Ukraine indicates that the national legislation combines two principles: 'consent' and 'non-consent'.

This conclusion can be drawn from the content of Article 290 of the Civil Code of Ukraine, Part 3 of Article 47 of the Law of Ukraine Fundamentals of Health Care Law, Part 4 of Article 14 and Part 1 of Article 16 of the Law of Ukraine On Application of Transplantation of Anatomical Materials to Humans stipulating that every adult legally capable person may give written consent or non-consent to become a donor of anatomical materials. This provision must be considered misleading, as it creates a conflict in legal regulation.

In accordance with the provisions of the Law of Ukraine On Application of Transplantation of Anatomical Materials to Humans, a person may give consent to the removal of anatomical materials after death while alive. After the death of a potential donor, one of his spouses or close relatives (children, parents, siblings), in the absence of such consent, but also in the absence of non-consent to the removal of organs, expressed while alive, may consent to such removal. In the absence of a spouse or close relatives, consent to the removal of anatomical materials for transplantation and/or the manufacture of bioimplants from the body of the deceased is requested by the transplant coordinator from the person who undertook to bury the deceased.

Thus, from the content of Part 11 of this Article it is unclear who should first be asked for consent to receive human anatomical materials in the absence of consent to donation and appointed authorized representative by the deceased while alive – the other spouse or one of the close relatives of this person (children, parents, siblings), whether the transplant coordinator should request the consent of one or both parents. Given the above, there may be cases when one of the spouses will give consent to the removal of organs, and one of the close relatives will object, or vice versa. In order to avoid such situations, a clear hierarchy of giving such consent should be established. It is appropriate that the consent of one of the spouses has greater legal force. In case of receiving neither consent nor non-consent from the other spouse, consent should be requested from the parents of the potential donor. After that, according to a similar principle, consent should be requested from children, and then from a sibling.

However, non-consent to donation received from one of the spouses should stop further seeking views of other relatives. We believe that it is impossible to make a donation in case of consent from one of the equal representatives of a potential donor, while the other objects to the donation. This option is possible if the potential donor has a father or mother, or a brother and sister, one of whom has given consent, and the other objects.

It should be noted that the 'mixing' concepts of 'presumed consent' and 'presumed non-consent' hinders the development of domestic transplantology in Ukraine. However, it is necessary to take into account the level of awareness of the Ukrainian population about the problem of posthumous organ donation, which is currently extremely low. Ukrainian society is not prepared for an adequate perception of the idea of transplantation and a positive solution to the problem of shortage of donor material. Analysis of publications in the media shows that public opinion on transplantation in Ukraine is either not formed or is negative [2, pp.141-145].

The next principle of civil law regulation of donation is the principle of humanity, which is an integral part of medical care. According to this principle, the removal of anatomical materials for transplantation and/or manufacture of bioimplants from deceased persons belonging to the category of orphans and children deprived of parental care, persons declared legally incapable, persons whose identity has not been established (unidentified persons), as well as from persons who died as a result of the anti-terrorist operation and other hostilities during direct participation in the implementation of measures to ensure national security and defense, repel and deter armed aggression of the Russian Federation in Donetsk and Luhansk regions, being directly in the areas and during the implementation of these measures, and other hostilities is prohibited.

We believe that the inclusion in this list of persons who died as a result of the anti-terrorist operation and other hostilities during direct participation in the implementation of measures to ensure national security and defense, repel and deter armed aggression of the Russian Federation, is inappropriate. In this case, these individuals are deprived of the right to consciously choose to become donors. The criteria according to which the legislator included them in the list of persons who cannot be donors after their death are unclear. This may be due to the dishonesty of doctors who will state the death of soldiers. However, other individuals who have expressed a desire to be a donor after their death are exposed to the same risks.

The provision of anatomical materials exclusively on a gratuitous basis without any monetary or other remuneration regulates the principle of gratuitous of transplantation for the donor and recipient. The purchase or sale or offer of sale of anatomical materials for transplantation, sale by a living donor or a close relative of the deceased is prohibited by national law. Exceptions to this rule are established in relation to the removal of hematopoietic stem cells (bone marrow cells) from a donor, which can be carried out either free of charge (at the request of the donor) or on the basis of financial compensation at the expense of budgetary funds to the donor of hematopoietic stem cells for the costs associated with donation (except for the costs associated with the removal of anatomical material). The procedure and amount of reimbursement related to the donation of hematopoietic stem cells are established by the Cabinet of Ministers of Ukraine. Currently, there is no regulatory document that would regulate this issue, which indicates the need for its immediate development and adoption.

International instruments on transplantation, using the principle of prohibiting the commercial use of organs as one of the main in the field of donation and transplantation, aim to achieve several results. Thus, the 37th World Medical Assembly in 1985 condemned the "purchase and sale of human organs for transplantation", urging governments of all countries to take effective measures to prevent the commercial use of human organs [7]. At the same time, in order to prevent trafficking in human material in this way, international law notes a special merit, which consists in the voluntary donation of human material to save and prolong life [5].

At the same time, in our opinion, certain types of donation may be paid. Accordingly, on the day of donating blood and (or) its components, as well as on the day of the medical examination, an employee who is a donor or has expressed a desire

to become a donor is released from work at the enterprise, institution, organization, regardless of the form of ownership, with retaining his average earnings. He is also given an extra day of rest and improved nutrition. In fact, this is nothing more than payment to the donor for donated blood and its components.

In addition, breast milk donation may be paid for. Thus, despite the absence of a national regulatory framework, the donor breast milk is widely used and no restrictions, criteria nor other legislative requirements are set.

Ukraine has not recognized the breast milk as an object of donation at the legal level, although there is a relationship of providing breast milk to a non-biological child. In the legal scientific works of Ukraine, there is no mention of the right to donate breast milk, since there is an opinion in society that human breast milk is a food product and does not have medicinal properties.

The principle, which is closely related to the prohibition of commercial use of anatomical material, and actually follows from it, is the principle of adherence to priority (except for family and cross donation), the guarantee of which is a waiting list (list) – a list of recipients registered with a healthcare institution for the purpose of doing them transplantation.

One of the WHO Guiding Principles on Human Transplantation is formulated as follows: "in the light of the principles of fair and equitable distribution of organ transplants, they should be made available to patients only according to medical criteria and ethical reasons, instead of financial or other reasons" [5]. The implementation of this principle is reflected in Article 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning the Transplantation of Human Organs and Tissues, ETS No 186 of January 24, 2002, according to which organs and tissues are distributed only to patients from the official waiting list according to transparent, objective and duly confirmed rules and medical indicators [3].

The principle of a dignified attitude to the human body in case of posthumous donation implies respect for the body of a dead donor, depending on his philosophical or religious views during his lifetime, taking into account the cultural traditions of the country. This principle also assumes the maximum preservation of the lifetime appearance of a person. An example of the consequences of such unlawful behavior is the judgement of Kyiv-Sviatoshynskyi District Court of Kyiv region dated March 21, 2012 in case No 2-1090 / 12, which established an undignified attitude towards the body of a deceased person by the head of the pathological department of Kyiv-Sviatoshynskyi Central District Hospital, who, conducting an autopsy, without the consent of the relatives, surgically removed the eyeballs from the corpse of the plaintiff's mother [4].

3. Conclusions

The analysis of the legal regulation of donation, as well as national international legislation in this realm, makes it possible to single out a number of principles that should be consolidated at the legislative level.

Thus, earlier we considered the principle of voluntariness, which provides for the expression of voluntary consent to the removal of anatomical material. In international law, this principle is closely related to the awareness of the donor and recipient about the possible consequences of donation and further transplantation. By informing the donor, he should be warned about the prohibition of disclosing information about the health status of the recipient in case of family or cross donation. The donor should be provided in advance with all information about the purpose and nature of transplantation, its consequences and risks, as well as about the possibility of alternative intervention. He should also be provided with information about his rights and guarantees provided for by national legislation. In particular, he should be provided with information on the right to obtain independent advice on risks from medical specialists having relevant experience and who are not involved in the process of tissue or organ removal or their subsequent transplantation. We believe that this information should be brought to the attention of the recipient, thereby informing about the medical and social status of the donor, without revealing his identity.

Another principle, which must be necessarily enshrined in the current legislation, concerns the elimination of the conflict of interests of the do-

nor, recipient and doctors who treat the donor and remove the anatomical material from the donor's corpse.

It is appropriate to consolidate at the legislative level the principle of prohibiting the participation of doctors who have attested the death of a potential donor in the procedure of removal the anatomical material from him and in subsequent transplantation procedures. They also should not be the attending physicians of potential recipients of such cells, tissues or organs. I believe that the consolidation of such a principle can to some extent change the consciousness of people, including those who are afraid to be them after death, because they do not fully trust doctors who may be interested in the posthumous removal of anatomical material and therefore do not provide the entire spectrum of necessary medical assistance for a potential donor.

Legislative regulation requires the principle of prohibiting doctors, other health care professionals and persons involved in the delivery and transplantation of anatomical tissues from receiving remuneration that exceeds the reasonable amount of remuneration for the services provided.

Another principle of donation, which is considered in modern legal science, is the principle of integration into the international transplant communities. World practice clearly shows that the issues of transplantation know no boundaries. They are different in different countries, related to the regulatory framework of transplantation, financial capabilities, the level of legal culture of society, etc. However, there are common issues, and the main one is the constant shortage of donor organs. Not a single country in the world in which transplants are performed has yet been able to fully solve this problem [6].

Currently, Ukraine does not use such opportunities. The reason for this is that the Unified State Information System for Organ and Tissue Transplantation does not operate in our state.

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