

LEGAL REGULATION OF THE PROCEDURE OF TRANSPLANTATION OF HUMAN ORGANS AND TISSUES IN THE COUNTRIES OF EUROPE

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REGLEMENTAREA LEGALĂ A PROCEDURII DE TRANSPLANT DE ORGANE ȘI ȚESUTURI UMANE ÎN ȚĂRILE EUROPEI

Pe baza legislației interne și externe, autorul ia în considerare o serie de probleme problematice legate de reglementarea legală a procedurii de transplant de organe și țesuturi umane.

In many European countries, a person, his life, health and honor are integral social values. But, unfortunately, according to recent events, such phenomena as violence, aggression, terror, human trafficking, which provoke the commission of socially dangerous acts, including the illegal removal of human organs for the purpose of enrichment, have become increasingly common in the world. Increasingly, the UN is receiving reports of the illegal removal of human organs and tissues, which become the subject of trade, since they can be used during genetic research or for religious or magical rites. But most often they are used for the purpose of transplantation.

It should be noted that in most European countries it is quite difficult to assess the extent of illegal trafficking in human organs and tissues, since the criminal laws governing this area of activity are not clear enough. At the same time, all major international documents regulating the issues of transplantation of human organs and tissues provide for a ban on the commercialization of transplants. For example, paragraph 8 of the Declaration on Human Organ Transplantation (1987), art. 21 Regulations on trade in living organs (1985), Convention on Human Rights and Biomedicine (1996) contain the main provisions that the human body and its parts should not be a source of income. The Belgian Organ Removal and Transplantation Act establishes that the consent of the donor must be in writing and signed in the presence of a capable witness. The Greek Law on the

Removal and Transplantation of Human Organs and Tissues defines several alternative forms of donor consent: a written form with notarization, a written form with a police signature of the donor, and an oral form of consent in the presence of two witnesses with an entry in a special register. The legislation of Belgium and Turkey contains a requirement to obtain the consent of not only the donor himself, but even his spouse [1].

In Ukraine, transplantation of human organs and tissues is carried out in accordance with the Law of Ukraine “On Transplantation of Organs and Other Anatomical Materials to Humans” under certain conditions: the presence of a voluntary consent of the donor to take an organ, the conclusion of a council of doctors about the possibility of transplantation, after familiarizing the potential donor with possible difficulties in connection with a future operation, and if the harm to the health of the donor as a result of the operation is less than the danger to the life of the recipient [2]. In accordance with Art. 12 of the above Law, commercial donation is illegal, and only close relatives or one of the spouses can be legal donors in Ukraine.

In Spain, there is an absolute ban on intravital removal of grafts from incapacitated persons [3]. In Denmark, the use as donors of persons under the age of 21, but actually able to consent to the operation to remove the transplant, is allowed in exceptional cases, with the permission of the parents [4]. Norwegian legislation establishes a similar rule for minors under 18 years of age [5].

Some states allow the removal of regenerative grafts from minors, regardless of their actual ability to give informed consent to surgery. For example, the Finnish Law on the Removal of Human Organs and Tissues for Medical Purposes establishes that the removal of a regenerating graft from a person under the age of 18 is allowed in the absence of his objections, with the consent of his legal representatives and the sanction of the National Board of Health.

In the Republic of Moldova, organ and tissue transplantation relations are regulated by the Law „On Organ and Tissue Transplantation” No. 42 of 06.03.2008. [6]. In Art. 13 of the above law defines the presumption of consent to the posthumous removal of the object of transplantation from the corpse. According to Art. 15 intravital transplantation is performed with the written consent of the recipient, given by him after receiving information about the possible risks and consequences.

The legislation of most countries imposes strict restrictions on the use of organs and tissues from persons incompetent due to minority or mental illness. Thus, the legislation of Greece and France allows the removal of only bone marrow from minors exclusively for transplantation to their brothers or sisters [7].

According to the legislation of the Republic of Moldova on transplantation, the use of persons under the age of 18 as lifetime donors is not allowed, with the exception of bone marrow donation. Therefore, children can be bone marrow donors with the consent of their legal representatives. Similarly, the issue of donation of minors is resolved in the Convention on Human Rights and Biomedicine. Yes, Art. 20 of this international document, it is established that, as an exception, with the written consent of legal representatives, it is allowed to use incapable persons as donors of regenerating transplants in the absence of a capable donor and the recipient is a brother or sister; if transplantation can save the life of the recipient and the donor does not object to taking the transplant [8].

Under any circumstances, it is illegal to use minors as donors of non-regenerating organs. The legislation of some states allows, subject to certain conditions, the use as lifetime donors of persons declared incompetent due to mental illness or dementia. These conditions are the actual ability to consent to the operation (Turkey) [9], obtaining the sanction of the authorized state bodies in the absence of objections from the donor (Sweden).

A person who has consented to the removal of organs and tissues from him for transplantation during his lifetime may withdraw it at any time and in any form. To ensure this right, Spanish law stipulates that the transplant removal operation cannot be carried out earlier than 24 hours after the consent of the donor has been obtained.

With the posthumous removal of organs and tissues for transplantation, it must be carried out in compliance with a number of legal conditions: as a rule, with the consent of the donor, expressed during his lifetime, or with the consent of his next of kin.

In the legislation of various countries, there are two main approaches to determining the legality of transplant removal from a deceased person. In a number of countries, there is a presumption of the consent of the deceased to the removal of his organs and tissues for transplantation purposes. The removal is not carried out if it became known that the deceased during his lifetime expressed his negative attitude towards the posthumous use of his

organs and tissues for transplantation, or in case of disagreement of his relatives. According to this model, in particular, the legislation in this area of France, Italy, and Turkey is built.

In Belgium, the presumption of consent to the posthumous use of the body for transplantation applies to Belgian citizens and residents of the country, and the basis for the posthumous removal of organs or tissues from other persons can only be their consent given during life. Many foreign experts in medical ethics and healthcare law believe that the legally established presumption of consent plays only a deterrent role, causing distrust in people and encouraging them to look for ways to fix their objection to the posthumous use of their organs [10].

In Sweden, until 1988, a presumption of consent was applied, but the new transplant law replaced it with a presumption of disagreement, however, retaining exceptions for “minor interventions”: the removal of small organs and glands, for example, the cornea, pituitary gland, which are permissible without any restrictions, even against the will of relatives or the will of the deceased expressed in his lifetime. The Royal Committee has put forward a proposal to abandon this exception by extending a single legal regime to procedures for the post-mortem removal of any human organs and tissues.

Legal regulation of posthumous donation is associated with the establishment of a criterion for the death of a person. Since life does not stop simultaneously in all organs of the human body, it is important to determine which of the cessation of activity means the death of a person and makes it possible to remove organs and tissues from him for transplantation.

For a long time, the death of a person was determined by ascertaining the cessation of cardiac and respiratory activity. However, modern medicine allows you to maintain such an activity of the body artificially for a long time. In recent decades, the criterion for cardiac cessation has been replaced by the criterion of brain death (Swedish Transplant Act 1988) [11].

In most states, the legislation on transplantation contains norms designed to ensure the independence of the professional judgment of doctors when ascertaining the death of a person, to prevent the occurrence of a conflict of interest. For example, Belgian law prohibits doctors participating in the treatment of a potential recipient from certifying the death of a potential donor. Norwegian law prohibits the transplantation of posthumously harvested organs by a doctor who treated the donor immediately before death.

The relevant question is whether a person has the right to sell his organs, which can be removed *ex vivo*, for the needs of transplantation? A few supporters of a positive answer to this question believe that the sale of one's organs is the realization of individual freedom, and organ donation should be financially stimulated, like blood and sperm donation.

However, public opinion is generally negative about the commercialization of organ and tissue donation, especially non-regenerating ones. There are legitimate fears that this will lead to the exploitation of low-income individuals who will be forced to sell the non-renewable resources of their body. The legislation of most states contains a ban on the sale and purchase of donor organs under pain of criminal prosecution. At the same time, it seems acceptable and fair that a donor who, due to the loss of an organ, had to bear the costs of treatment or lost his ability to work, should receive compensation for losses.

The principle of no financial gain from the human body is also very important, since the altruistic donation system itself is threatened. Given that it is difficult to convince a person who is not a relative of the patient on moral grounds to donate their organ, there is a need to develop organ donation and increase the number of organs available for transplantation. In addition, in order to preserve the health of people, it is necessary to develop as much as possible legal and medical principles that will allow giving preference to donation from deceased donors.

Many countries in the world do not pay enough attention to the illegal imposition of various services and offers to receive illegal financial benefits from the sale of human organs. Preparation, storage, transportation, transfer, receipt, import and export of illegally harvested human organs should also be punishable by law. Taking into account the results of the studies carried out in different countries of the world, it became necessary to develop a new international legal act in this area.

The history of the creation of such a document began in 2008, when the Council of Europe and the United Nations decided to prepare a joint study on the topic: "Trafficking in organs, tissues and cells, as well as human trafficking for the purpose of organ removal". The report was published in October 2009. Along with other issues, it focused on the need to develop an international document that would contain a legal definition of the concept of "trafficking in organs, tissues and cells of human origin" and would fix a list of measures that countries should take to combating organ

trafficking, protecting victims, and criminalizing such acts.

Guided by the above opinion, in July 2011 the Committee of Ministers of the Council of Europe decided to establish a Committee of Experts on Combating Trafficking in Human Organs, Tissues and Cells (PC-TO), entrusting it with the development of a Council of Europe convention in this area. The mandate of the Committee of Experts included the development of a draft criminal law convention on combating trafficking in human organs, as well as, if necessary, a draft additional protocol to the said Convention on combating trafficking in tissues and cells of human origin. The Committee brought together the efforts of recognized experts in this field, thus showing that these projects enjoy the support of the expert community and reflect the achievements of advanced scientific thought and practice.

The final version of the draft Council of Europe Convention against Trafficking in Human Organs was approved at the 63rd meeting of the European Committee on Criminal Law in December 2012 and further developed by the relevant bodies of the Council of Europe in September 2013.

If the Committee of Ministers of the Council of Europe adopts the Convention against Trafficking in Human Organs, it will become the first international legally binding instrument that will regulate the issues of combating trafficking in human organs in Europe and may become the next step to join efforts in the fight against this evil at the global level.

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ACTUALITĂȚI PRIVIND NOTIFICAREA DATELOR STATISTICE LA COMISIA EUROPEANĂ, CE PRIVESC ETICA FOLOSIRII ANIMALELOR ÎN PROCEDURI EXPERIMENTALE

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NEWS REGARDING THE NOTIFICATION OF STATISTICAL DATA TO THE EUROPEAN COMMISSION, REGARDING THE ETHICS OF THE USE OF ANIMALS IN EXPERIMENTAL PROCEDURES

Starting with 2010 in the member states of the European Union, and ending with 2014 in Romania (also an EU member state), Directive 63/2010/EU regarding the use of animals in experimental procedures, was adopted and implemented. The Directive fundamentally changed this concept. Having a deeply ethical character, aimed mainly at the protection and welfare of animals, it led once it was adopted to the drastic reduction of animal experiments and the loss of authorisation, only in Romania, of at least one third of the experimental units.

Plecând de la dorința cercetătorilor, dar și a societății civile, de a reduce experimentarea pe animale, dar și pentru a avea un cadru legal unic, în anul