ORIENTATIONS OF LEGISLATION REGARDING ORGANS, TISSUES AND HUMAN CELLS TRANSPLANT

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Abstract

Law no. 95/2006 on healthcare reform regulated in Title VI the problem of organs, tissues and cells transplantation. This problem is of great interest for many reasons. First, there is a great need for transplant to save lives. Secondly there is an international cooperation, to facilitate patient-oriented allocation and cross-border exchange of deceased donor organs. National Transplant Agency Bucharest may conclude agreements with European organ exchange organizations, provided that such organizations ensure compliance with the requirements of Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety human organs intended for transplantation.

Unfortunately in our country there is not yet tradition or education to promote transplantation. So Romanians from abroad do not qualify for transplantation because the Romanian National Agency for Transplant can not fulfill his obligations. On the other hand, when the organ donor is alive, it must consider also his interests. He has the right to be properly informed about the risks the intervention presents for his health. This paper seeks to what extent the law promotes transplantation but also identifying weaknesses. It also values the experience of other states in the field.

Key words: *transplantation, donation, consent, traceability*

JEL Classification: [K36]

1. Introduction

The progress in medical science, especially in the field of transplantation of organs and tissues, is helping to save human lives or increase the quality of human life. The transplantation of organs and tissues is an integral part of health services provided to the population, there is an interest of a growing number of levies and transplants. The recent incident at a famous clinic from another country, when for a short period of time, Romanian patients were denied transplants because Romania has not fulfilled its obligations toward the Eurotransplant organization to provide human organs for carrying out transplants revealed an important truth, namely that the procurement and transplantation can not be done in isolation at the level of states, but its efficiency involves coordination at a European level.

The development of science and the increasing number of transplants generated numerous problems not only medical ones but also legal and ethical. Thus, the question of dignity and respect for the will of the person who could be jeopardized by improper use of biology and medicine; the need to respect the human being both as an individual and in his membership in the human species. On the other hand, there was the need to regulate the responsibility for the negative consequences of organs harvesting. In this context, the question of removal of unacceptable practices in organ

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donation and transplant of organs including trafficking in organs, sometimes linked to trafficking in human beings for the purposes of organs. These facts constitute a serious violation of fundamental rights and in particular of the human dignity and physical integrity. However, it required the international consecration of basic rules, some even elevated to the rank of principles that led to uniform national laws.

2. Highlights on the international legal framework

2.1. The European Convention of April 4th 1997

The European Convention of 4 April 1997 on the protection of human rights and dignity of the human being towards the applications of biology and medicine[1] has proposed to protect the dignity and identity of human beings and guarantee all persons, without discrimination, respect for integrity and other rights and fundamental freedoms in regards to the applications of biology and medicine. In order to achieve the aim pursued, the European Convention on the rule being dedicated to humans, holding that the interests and the good of the human being shall prevail over the sole interest of society or science. It also established the rule of equitable access to healthcare. In this regard, the parties are obligated to take into account the health needs and available resources, take all appropriate measures in order to ensure that, within their jurisdiction, there is an equitable access to health care of appropriate quality. In terms of the interventions that were done in the health field, including research, these had to be done with respect to the rules and obligations of professional conduct and rules of conduct applicable to the issue.

The Convention has established a series of rules, which were subsequently enshrined in the national legislation of the Member States. Thus, the Convention placed particular emphasis on establishing consent of person establishing in article 5 the rule that an intervention in the health field may be carried out only after the concerned person has given free and informed consent. In order to have a valid expression of will of the individual, The Convention established the right to receive appropriate information beforehand with regard to the purpose and nature of the intervention, as well as with regards to the consequences and risks. An important element which guarantees the rights of the person was the fact that the concerned person could at any time withdraw the consent freely.

The Convention allowed an indispensable intervention in terms of medical health service without the consent of the concerned person when this could not be obtained. It required taking into consideration the wishes expressed earlier regarding a medical intervention by a patient who at the time of the intervention is not in a state to express their will. As regards to the incapable persons art. 6 of the Convention dedicated a special rule, upon such person an intervention could be carried out only to the direct benefit of the person.

[1] Published in Official Gazette number 103 dated February 28, 2001.

2.2. The Directive 2004/23/EC of March 31st 2004

The *Directive 2004/23/EC of March 31st 2004*[2] of the European Parliament and of the Council of the European Union considered as urgent the need to create a unified framework in order to ensure high standards of quality and safety for the obtaining, testing, processing, storage and distribution of tissues and cells in the Community and to facilitate exchanges of such tissues and cells between patients who follow this treatment each year. It was considered as essential to have provisions in place to ensure that the community human tissues and cells, irrespective of intended use, have a comparable level of quality and security. The establishment of such standards to contribute to ensuring the population with regard to the fact that human tissues and cells obtained in another Member State shall provide the same guarantees as those originating from their country. The aim was to setting standards for each step of the process for the use of human tissues and cells to ensure a high level of health protection in the Community.

Mainly, the program use of tissues and cells must be based on the principle of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States were urged to take steps to encourage the public and volunteers involvement in the provision of tissues and cells and in research and development of this sector. The rules established by the Directive 23/2004 / EC were not hindering the Member States from maintaining or introducing more stringent protective measures, insofar as they are in conformity with the treaty.

Art. 8 of Directive 2004/23 / EC ensures traceability from donor to recipient and vice versa for all tissues and cells procured, processed, stored or distributed on their territory. The traceability requirement applies to all relevant data relating to products and materials coming into contact with these tissues and cells. The notion of ' traceability' was going to be defined by Directive 2010/45 / EC.

2.3. The Directive 2010/45/UE of July 7th 2010

Subsequently, the establishment of standards of quality and safety of human organs intended for transplantation was adopted by the Directive 2010/45 / EC of 7th of July 2010[3] which requires common standards of quality and safety at EU level for the procurement, transport and use of organs. The purpose of establishing these standards was common, as in the case of tissues and cells, to facilitate the exchange

[2] The Directive 2004/23 / EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and human cells of the Parliament and the Council of the European Union was published in the Special Edition Official Journal number 0 on 1 January 2007.

[3] Published in the Official Journal number 207L of 6 August 6 2010.

of organs, which would benefit each year for thousands of European patients in need of this type of treatment.

Such standards would help to reassure the public that organs procured in another Member State have the same guarantees for quality and safety standards as those in their own country. Although the rules imposed by Directive 2010/45 / EC related to organ transplantation, from finding that frequently organ donors were also the tissue donors, it was considered that the requirements for quality and safety of organs should complete the system for tissues as under Directive 2004/23 / EC.

Reducing the organ transplant risks for the receiver was provided through national and international well-organized transplantation systems and applying the best available expertise, technology and innovative medical treatment. For the same purpose and to maximize the benefits of transplantation, it required that Member States would apply an effective framework for quality and safety. That framework should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover medical personnel and organization, premises, equipment, materials, documentation and record-keeping in question.

The Directive 2010/45 / EC has shown that in cases of transplantation of organs, the risk-benefit ratio is a fundamental approach. Because of the shortage of organs and the inherent life-threatening diseases that require organ transplants, the overall benefits of organ transplantation are high and more risk are accepted than in cases with blood or most treatments based on the use of tissues and cells.

The Directive sought to determine the information needed to achieve the risk-benefit assessment. The assessment of this report is made pursuant to potential donors prior to transplant evaluation by identifying and documenting risks and characteristics of the organ to allow allocation to a suitable recipient. In order to eliminate transmission of potentially serious diseases, the Directive emphasizes the importance of accurate, reliable and objective history of the potential donor achieved with by an interview with the living donor or, whenever necessary and appropriate with the family members of the deceased donor.

This approach to transplantation, in light of the risk benefits, allowed the increased number of transplants at European level. For example, although in France organ donors are subjected to tests in order to avoid transmission of infectious diseases through the transplantation, however there are certain conditions that constitute a barrier to transplantation. This is for instance the case of infection with cytomegalovirus (CMV). On the other hand, a decree of December 23rd 2010 authorized the taking from donors infected with hepatitis B or C (exemption subject to an assessment) to inform recipients (http://www.inserm.fr/thematiques/sante-publique/dossiers-d-information/transplantation-d-organes).

Although the Directive aimed primarily the safety and quality of organs, its purpose was indirectly to combating organ trafficking through the establishment of competent authorities, the authorization of transplantation centers, the establishment of conditions of procurement and systems of traceability.

By the term 'traceability', used also by Directive 2004/23 / EC in the context of

tissues and cells, art. 3 point s of the Directive designates 'the ability to locate and identify the organ at any stage of the chain from donation to transplantation or disposal, including the ability to identify the donor and the procurement organization, identify the recipient (s) and the center (centers) of transplant and to locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ '. The Directive's definition will then be taken over by Law no. 95/2006 on healthcare reform in art. 142 letter v.

Member States shall ensure traceability from donor to recipient and vice versa of all organs procured, allocated and transplanted on their territory in order to protect the health of donors and recipients and provide for a system of identification of the donor and recipient that can identify each donation and each of the organs and recipients associated with it.

Regarding this system, Member States shall ensure that measures concerning privacy and security, in accordance with the Union's dispositions and the national ones. Another stated aim of the Directive was to raise awareness about organ donation and in particular to develop mechanisms to facilitate the identification of organ donors across Europe. In Romania there is a legal framework that allows participation in the international network of transplant. According to art. 148 paragraph 3 of Law no. 95/2006, while in the national territory there is no compatible recipient organs, available tissues and cells of human origin, can be assigned in international transplant network, under an authorization issued by the National Transplant Agency.

The benchmarks set by Directive 2004/23 / EC and the definitions of Directive 2010/45 / EC were transposed into Romanian law by Law no. 95 of April 14th 2006 on health reform.

2.4. Additional Protocol of February 20th 2015 to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin

By the Additional Protocol of February 20th 2015[4] to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Member States of the Council of Europe, other States and the European Community signatories to this Additional Protocol to the Convention for the Protection of Human Rights and human dignity applications to biology and medicine (hereinafter Convention on human rights and Biomedicine), was intended to take appropriate measures in the field of transplantation of organs and tissues to ensure human dignity and fundamental human rights and freedoms.

By the term 'transplant' the Protocol designates 'the entire procedure that includes removal of an organ or tissue from one person and the registry of this body or the tissues from another person, including the entire process of preparation, storage and preservation' while the term 'levy' denotes the harvesting for the purpose of the

[4] Published in the Official Gazette number 62 dated January 28, 2016.

implant. Exception is the case when an organ or an implant tissue is collected for purposes other than donation for an implant in which case Article 20 of the Protocol requires to explain to that person the possible consequences and risks, and obtain expressed informed consent.

In order to achieve its goal – to guarantee human dignity and fundamental human rights and freedoms – the Protocol establishes a series of important safeguards. Thus, it ensures the existence of a system enabling patients' fair access to transplant services by awarding bodies and, where appropriate, tissues only to registered patients on an official waiting list, according to some transparent rules, objective and duly justified in terms of medical criteria.

In terms of donor, the protocol requires compliance with important requirements: assessing risks to living donors (Article 11), informing him by a healthcare professional with appropriate experience and who does not participate in the work of procurement, transplantation or the following stages (Article 12), freely expressed and revocable consent of the living donor (Article 13), the removal of organs or tissue from the body of a deceased person only if consent or authorization by law required is obtained (Article 17) prohibition of financial gain (Article 21) and confidentiality.

3. The reflection of European law into national law

3.1. Introductive considerations

European standards in Romania were included in the Provisions of Title VI of Law no. 95/2006 on health reform [5]. Coordination, supervision, approval and implementation of any provisions for transplantation activity is incumbent to the National Transplant Agency and the organs, tissues and cells harvesting of human origin is performed in public or private accredited hospitals. The Law enshrines European principles. Law no. 95/2006 requires explicit informed consent requirement, the requirement of free access and confidentiality.

3.2. Explicit consent for the donation of organs or tissues or cells

Organ harvesting is carried out only after compliance with all consent or authorization requirements or absence of any objection in force in the Member State (Art. 14 of Directive 2010/45 / EU). Civil doctrine defines consent as 'externalization decision to conclude a legal act (Boroi and Anghelescu, 2012:131) or 'willingness in the legal sense' (Reghini, Diaconescu and Vasilescu, 2013:479) Consent is the

[5] Republished in the Official Gazette number 652 of August 28, 2015 pursuant to art.VI of Law no. 184/2015 approving Government Emergency Ordinance no. 77/2011 on the establishment of contributions to fund health spending and amending and supplementing Law no. 95/2006 on healthcare reform, published in the Official Gazette of Romania, Part I, no. 490 of 3 July 2015 texts shall be renumbered.

essential condition for harvesting organs, cells or tissues since without this, the levy may not take place, any discussion regarding other conditions is excluded. Romanian law requires both the consent of the donor and of the recipient.

In respect of the donor's consent to organ or tissue levy, he must be free of any constraints. Thus, art. 144 para. 1 letter d, prohibits taking and transplantation of organs, tissues and cells of human origin as a result of a physical or moral constraints on a person. In case the organ donation constraints would be cancelled the donor has a legal action based on tort liability for harm. If invalidity is based on constraint, the cause action in tort is the wrongful act causing injury (Guelfucci-Thibierge, 1992:313). If the conditions torts, the donor has an action, whether the removal of organs or not performed. Regarding the one who committed the threat, he acts criminally responsible for the act a criminal offense.

As noted in the introduction of Directive 2010/45 / EU of 7th of July 2010 (point 21) in the Union there are several models of consent to donation including explicit informed consent systems for organ donation *(opting- in),* where the consent must be obtained explicitly and presumed consent system *(opting out),* in which donation can take place only if there is no evidence of objection to donation. To allow individuals to express their donation intentions, some Member States have developed specific registries where citizens record these intentions. The Directive does not affect very different the systems of consent in the Member States. In some states, where applicable, the rule of presumed consent doctor is obliged to seek further consent from families.

In the network states that represent the Eurotransplant Foundation in Germany and the Netherlands is applicable the system of informed consent while Austria, Belgium, Croatia, Hungary, Luxembourg and Slovenia have adopted presumed consent system (http://ww.eurotransplant.org/cms/index.php?page=legislation1). The rule of presumed consent but can be found also in other European countries.

In Spain, the presumed consent rule was implemented in 1979 by Law 30 of October 27th 1979 on the removal or transplantation of organs. Article 5 paragraph 3 of Law no. 30/1979 presumed consent of the deceased if there had not been previously expressed its express opposition.

France introduced presumed consent in 1976 by the Law Caillavet. It was reaffirmed by the 1994 law on bioethics updated on the 6th of August 2004 and amended on 7th of July 2011 (Law no. 2011-814). The law establishes three principles: presumed consent, gratuity donation and anonymity between donor and recipient. So that law provides that all persons are presumed to have consented to donating a part of their body after their death for transplantation if they haven't expressed their opposition during life. The law provides opposition in two ways: by refusing entry in the national register and / or communicating the position to relatives will confirm this fact. People who oppose the removal of their organs after their death are entered in a national register kept by the Biomedicine Agency. In 2012, they were entered in the register of refusals around 8727 people (http://www.dondorganes.fr/049-le-consentement-presume) under conditions where

every year approximately 500,000 people die. When there is a possibility for an organ levy, the law requires a medical team to check in systematic and mandatory manner if the deceased is recorded in the register of refusals. If not, they address immediately after the death to relatives for them to express opposition that eventually was expressed by the deceased during life.

Of existing statistics, in 2014, there were harvested organs from 1,655 people who were brain dead, to which are added and 530 living donors and 40 in heart attack. With an average of three organs taken from each deceased it was possible to achieve a total of 5357 transplants (http://www.inserm.fr/thematiques/sante-publique/dossiers-d-information/transplantation-d-organes) According to a press release from the French Agency of Biomedicine, every year are performed approximately 2,500 kidney transplants, 900 for liver, 320 for a heart, 150 for lung, 20 of heart and lung transplants, 100 of pancreas and some of intestines. The tissue transplants, especially the corneal transplants are quite spread, about 4000 transplants yearly (http://www.allodocteurs.fr/se-soigner/greffes-don-d-organes/la-greffe-du-prelevement-a-la-transplantation_786.html)

Presumed consent system was established in Hungary. Rules on transplantation and removal of tissues or organs were provided by Law no. 154 (CLIV) from 1997 about health. Art. 203 of Act 203 of Law 154 establishes the rule that there must be used for transplantation organs or tissues taken mainly from dead people. According to art. 211 of Law no. 154/1997, the organs or tissues harvesting from deceased persons is allowed only if the deceased during his lifetime did not oppose this. The statement of opposition for a capable person may be written or, to an extent may not make a written statement or can be done only with considerable difficulty verbally.

The one with a limited legal capacity may make a statement of opposition, while for the incapable this statement is made by his legal representative. The attending physician within the time available for taking tissue or organ is obliged to verify if during the patient's life he brought a statement of opposition. In the absence of such a declaration, the treating physician must obtain the statement from the caregivers, expressly listed by the law, regarding the desire of the deceased on organ harvesting. As an exception, the collection of corneas can be done without this statement. If there is no possibility to obtain the declaration referred to in the time taken for transplantation, it is presumed the lack of statement of opposition.

Romania, along with Germany and the Netherlands, is among the states that devotes explicit informed consent system for organ donation. Regarding the removal of organs, tissues and cells from deceased persons, art. 81 of the New Romanian Civil Code, in force since 2011, provides that this shall be made only as provided by law, by written agreement, expressed during the life of the deceased or, if failing that, with the written consent freely expressed of the surviving spouse, parents, offspring or, finally by collateral relatives up to the fourth degree.

Law no. 95 of April 4th 2006 on healthcare reform devotes Title VI of Carrying out the removal and transplantation of organs, tissues and cells of human origin for therapeutic purposes. Regarding the removal of organs, tissues and / or cells from

deceased persons, according to art. 147, paragraph 4 this is only done with the written consent of at least one adult family member or relative in the following order: surviving spouse, parent, child, brother / sister, other relative in the collateral line up to including the fourth degree. Organ harvesting can be done without the consent of family members only if, during their lifetime, the person already opted for the donation, through an affidavit of consent for levy and is registered in the National Register of donors of organs, tissues and cells. It is considered that although not expressly regulated, the law allows organ harvesting not only from the deceased adults, but also the minor that died. If the donor is a minor, the levy can be made only with the written consent of parents or legal representative. In the case of a categorical refusal of organ or tissue, it would not be possible because 'the child, in relation to the adult, is not the owner of his body' (Ungureanu and Munteanu, 2013:33). Regarding the removal of organs, tissues and cells of human origin from donor who is alive, According to art. 144 para. 1 of Law no. 95/2006, this can be made with adults, in full legal capacity after obtaining the informed consent, in writing, freely expressed by them. It is prohibited the organs, tissues and cells harvesting from indiscriminate people. The removal of organs, tissues or cells will be done after the committee approved it, and will be made with the endorsement opinion of donations from living donors established by the hospital where the transplant is performed; this committee will assess motivation of donation and will monitor compliance with patient rights.

Although if the consent mainly given to the conclusion of a legal act is irrevocable, art. 68 para. 1 of the Civil Code allows the donor to reconsider the consent given prior harvesting time (so it is disposed in the same direction by art. 144 letter C of Law no. 95/2006). On major interest relating to the protection of the physical integrity of a person deviates from the rule of symmetry.

Law no. 95/2006 requires not only the consent requirement but donor and recipient. According to art. 150 of the Law, transplantation of organs, tissues and cells of human origin is carried out with the written consent of the recipient after he was informed about the risks and benefits of the procedure. If the recipient is unable to express the consent, this may be given in writing by one of the family member or legal representative. Transplantation can be done without the consent of the recipient if the recipient is unable to express consent, due to objective circumstances and can not get in touch in time with the family or the legal representative, and the delay would inevitably lead to death of patient.

3.3. Informed consent

Art. 144, paragraph 1, letter b of Law no. 95/2006 provides that consent is signed only after the donor was informed by the doctor, social worker or other skilled person on the possible risks and consequences on the physical, mental, family, professional and social plan, resulting from the act of extraction.

Likewise, it was disposed by the Protocol of February 20th 2015 to the Convention on Human Rights and Biomedicine, art. 12 donor and, where appropriate,

the person or body responsible for the authorization are informed in advance, adequately about the purpose and nature of the extraction and of the consequences and risks. They also are aware of the rights and safeguards prescribed by law for the protection of the donor. In particular, they are informed of the right to receive, from a healthcare professional with appropriate experience and who is not involved in taking organ or tissue in question and nor to later stages of transplantation, an independent information on risks levy. As we can see, it is essential that the information has to be made independent by a professional who is not involved in the organ or tissue levy and, accordingly, is not interested in making them.

3.4. Free donation of organs, tissue or cells

According to art. 66 of the Civil Code, any act to confer a human body value, its elements or products are null and void, unless expressly provided by law. Organ or tissue donation is a selfless act, incompatible with trade acts. In this respect, art. 144 paragraph 1 states that the donation and transplantation of organs, tissues and cells of human origin may not be the subject to legal documents or acts in order to obtain a material interest. As a precaution, the legal text provides that donor and the recipient will sign an authentic document stating that the donation is for humanitarian purposes, is a selfless act and not subject to legal documents in order to obtain material benefit. Art. 144 para 1 letter g of Law no. 95/2006 provides only payment exemption for hospitalization of donor/donation and related hospitalizations and associated costs for regular medical checks. Considering the altruism of the donor, the act of donation grafted onto two essential conditions complementary but different: donation should be voluntary and be free (Gicu, 2013).

An important goal of national rules is to eliminate the possibilities of trading on organs, tissues or cells that are donated. For example in Hungary, the removal of organs from the living people has a simple rule: usually it is based on genetic kinship. Regarding organ harvesting from people who are living, art. 206 paragraph 2 of Law no. 154 (CLIV) of 1997 on health, organ donation is allowed by people who are relative to the recipient, is the brother of a relative in a straight line or a relative in the straight line of a brother. Exceptionally, the legal text allows organ donation if between donor and recipient are no shown relationships. In this case the joint request of the donor and recipient is examined by the hospital ethics committee. The ethics commission authorizes the levy if convinced that in between the two parties there is a close emotional tie and donation takes place without consideration and free of coercion, threat or deception. If a case of prisoners or conscripts, they can donate only under the terms of art. 206 para. 2 of the Law.

Organ donation is only permitted free of charge, without payback. But the donor is entitled to reimbursement of costs incurred and compensation for transplantation and revenues as a result of transplantation.

3.5. Confidentiality, anonymity and advertising ban

Art. 148 para. 12 of Law no. 95/2006 prohibits the disclosure of any information regarding the identity of the donor's body, and the recipient, unless the donor family or recipient agree, and where the declaration of identity is required by law. Data on donor and the recipient, including genetic information to third parties who may have access shall be communicated anonymously, so that neither the donor nor the recipient can not be identified. Any unauthorized accessing of data or systems that makes identification of donors or recipients shall be sanctioned in accordance with legal regulations. Privacy is an important principle for international regulations also.

4. Conclusions

Reported to the previous settlement, the image of organ, tissue and cell transplantation Romanian law is characterized by numerous elements of novelty. Those few examples from other countries legislation had the purpose to show the convergence of the systems of law of the European countries and to unveil the signs of unification by inserting the European rules in their national legislation. We can observe thus on European level a clear tendency of unification of the norms of internal law having as objective, on long term, the elaboration of a common legislation.

On the other side, regarding the consent, we notice that the tendency in UE is to generalize the presumed consent as a result of the benefits that this rule has in the matter of organ donation. In order to change the Romanian legislation it needs a better information and education of citizens about the social benefits of donation. Also it should be considered intermediate option, the organ donation system which requires doctors to ask permission from relatives. Likewise increase legal 'vigilance' is required to maintain free nature of organ donation and eliminate the possibility that some people, particularly those who by reason of their job have contact with the donation and transplantation, turn transplantation into a source of income.

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