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Legal regulations regarding transplantation – in Poland, Germany and Switzerland

Abstract

Introduction. Transplantation surgery, involving transplantation of cells, tissues and organs, constitutes a common medical practice that saves the lives of a great number of patients.

Aim. The purpose of the present paper is to provide a comparative analysis of the legal regulations regarding transplantation that are in practice inside three European countries: Poland and Germany – EU Member States - and Switzerland – a non-EU state. The considerations made herein are meant to find an answer to the question whether the provisions of law regarding transplantation in the specified European countries regulate the legal situation of the donor and the recipient in a similar manner.

Material and methods. The paper is based on the following source documents: The Cell, Tissue and Organ Recovery, Storage and Transplantation Act of July 1, 2005; The Act on Donation, Recovery and Transplantation of Organs and Tissues of November 5, 1997 (Transplantation Act – TPG); Federal Act on Transplantation of Organs, Tissues and Cells of October 8, 2004. In our work, we applied two methods, the first being comparative, and the second being dogmatic-legal. The latter consists of analyzing the provisions regarding transplantation as found within the three selected European countries.

Results and Discussion. Under Polish, German and Swiss law alike, the recovery of cells, tissues and organs is allowed from an adult, who, under the Polish and German Acts, has full capacity to enter into legal transactions, and who, under the Swiss Act – is an adult who is *mentally competent*. Of note is that a minor might only be a donor in *ex vivo* transplantation provided that precisely specified requirements are met. Of additional note is that, under the German and Swiss Acts, recovery of tissues and organs from a human cadaver donor is allowed only if this person gave consent for such recovery prior to their death; under the Polish Act, this is allowed unless the deceased person expressed their objection when alive.

Conclusion. As far as *ex vivo* transplantation is concerned, the legal solutions regarding transplantation in Poland, Germany and Switzerland regulate the legal situation of the donor and the recipient of a transplant in a similar way, although there are a few significant differences. As for *ex mortuo* transplantations – the legal solutions applied in each country greatly differ.

Keywords: transplantation, legal regulations, donor, medical law.

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INTRODUCTION

In Europe, transplantation surgery constitutes a common medical practice that saves the lives of a great number of patients. It must be considered, however, that before cells, tissues or organs may be transplanted into the recipient's body, the recovery of transplant items must be performed. The transplant might be recovered either from a human corpse – in the case of *ex mortuo* transplantation – or from a living donor – in case of *ex vivo* transplantation. As regards the donor, the procedure of recovering a transplant in *ex vivo* transplantation has no medicinal purpose. What is more, it is not neutral to the donor's health. Therefore, the conditions under which transplantation surgery can be carried out need to be regulated by law.

The present paper contains an overview of legal regulations regarding transplantation *ex vivo* and *ex mortuo*, that are in force in three European countries: Poland and Germany (EU Member States), and in Switzerland (a non-EU state). The study does not contain an analysis of all legal regulations regarding transplantation in the aforementioned countries, since such an approach would extend the scope of research to excess.

AIM

The purpose of this study is an analysis and comparison of the legal regulations mentioned above. The considerations made herein are meant to find an answer to the question whether the provisions of law regarding transplantation

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in the specified European countries regulate the legal situation of the donor and the recipient of a transplant in a similar way.

MATERIAL AND METHODS

The paper is based on the following source documents: The Cell, Tissue and Organ Recovery, Storage and Transplantation Act of July 1, 2005 [1], hereinafter referred as the Polish Act; The Act on Donation, Recovery and Transplantation of Organs and Tissues of November 5, 1997 (Transplantation Act – TPG) [2], hereinafter referred as the German Act; Federal Act on Transplantation of Organs, Tissues and Cells of October 8, 2004 [3], hereinafter referred as the Swiss Act. The research methods applied herein are a comparative method and a dogmatic-legal approach. The latter consists of analyzing the provisions of law regarding transplantation in the three selected European countries, i.e. Poland, Germany and Switzerland.

RESULTS AND DISCUSSION

1. General remarks on the legal regulations regarding transplantation

The legal regulations regarding transplantation being effective in Poland are contained in The Cell, Tissue and Organ Recovery, Storage and Transplantation Act of July 1, 2005 [1], in Germany – in The Act on Donation, Recovery and Transplantation of Organs and Tissues of November 5, 1997 (Transplantation Act – TPG) [2], and in Switzerland – in the Federal Act on Transplantation of Organs, Tissues and Cells of October 8, 2004 [3].

Under the Polish Act [1], qualified personnel are allowed to recover and transplant cells, including bone-marrow haematopoietic cells, peripheral blood and umbilical cord blood cells, as well as tissues and organs. The regulations of the present Act shall not, pursuant to Art. 1 Clause 2 [1], apply to a recovery and transplantation of gametes, gonads, embryonal and fetal tissues, and reproductive organs or parts of these. Neither does the Act apply to a recovery, storage and distribution of blood for transfusion purposes, or to blood component separation or to processing blood and blood products into medicines.

While transplanting organs and tissues is allowed under the German Act [2], it must be explained that, according to the legal definition set forth in § 1a of the German Act [2], the term ‘tissue’ includes any part of the human body built of cells other than that which is an organ as defined by the Act, including individual cells. Pursuant to § 1a of the German Act [2], it is allowed to donate the following organs: heart, lungs, liver, kidneys, pancreas and intestines. The regulations set forth in the German Act do not apply to autograft transplantation and the issues regarding recovery of blood or its components.

Under the Swiss Act [3], it is allowed to transplant organs, tissues, human or animal cells and products obtained thereof (so called transplantation products). The Swiss Act [3] does not apply to: artificial or lifeless organs, tissues or cells; blood, except for blood stem cells; blood products, gametes;

fertilized egg cells and embryos as far as medically assisted procreation of humans is concerned.

Under the provisions that are in force in Poland, Germany and Switzerland, it is allowed to carry out both *ex mortuo* and *ex vivo* transplantations provided that the requirements set forth respectively in the Polish [1], German [2] and Swiss [3] Acts are fulfilled.

It needs to be emphasized that in Poland, Germany and Switzerland, there has been passed an absolute prohibition of trafficking of human organs and tissues. Moreover, it is not allowed to give or accept financial benefits or derive any other profits from donation of human organs, tissues and cells.

2. Legal regulations concerning *ex vivo* transplantations

a) recovering a transplant from an adult donor

Pursuant to Art 12 item 1 of the Polish Act [1], the recovery of cells, tissues and organs from a living donor is admissible, in principle, if the recovery shall take place for the benefit of a linear relative, of brothers and sisters, of an adopted person or a spouse, and with the reservation of Article 13 of the Polish Act [1], for the benefit of another person ‘in the event of special personal reasons giving grounds for such conduct’. Art. 13 of the Polish Act [1], expresses the additional requirement to obtain court approval. This is issued after taking cognizance of an opinion put forward by the Committee of Ethics of the National Transplantation Council. The court decides whether between the potential donor and recipient there exist special personal concerns, i.e. an emotional attachment that justifies altruistic donation of a transplant in order to save the recipient’s life or health. Much less rigorous regulations are applied to the recovery from a living donor of bone marrow or other regenerating cells or tissues. In this respect, the legislator does not provide for either a personal limitation, nor a requirement to obtain court approval. Moreover, pursuant to Art. 12 Clause 1 item 7 of the Polish Act [1], it is required that the person who desires to become a donor of *ex vivo* transplantation should have full legal capacity. This requirement also must be met by a person wishing to donate both non-regenerating tissues or organs, as well as bone marrow and other regenerating cells or tissues. What is more, the risk involved in the procedure must not exceed the expected level that is acceptable for such kind of procedures, and cannot impair in a substantial degree, the health state of a donor. Furthermore, the procedure of recovering and transplanting cells, tissues or an organ, pursuant to Art. 12 Clause 3 of the Polish Act [1], should be justifiable and useful on the basis of up-to-date medical knowledge. In each case, “the relation between an individual donor and an individual recipient (as opposed to viewing the relation in abstract terms, as a whole class of such transplantations)” must be taken into consideration [4]. In addition, the justification and usefulness of the procedure shall be assessed on the basis of a previously conducted medical examination of the candidates who are to become the recipient and donor.

Under the Swiss Act [3], recovery of organs, tissues or cells to be transplanted is admissible if all of the following conditions are met:

- 1) the person is an adult and is mentally competent;
- 2) there is no serious risk to the life and health of the donor;
- 3) no comparable therapeutic effect in the recipient's state of health may be achieved by way of the employment of any other available therapeutic method.

Under the German Act [2], an organ or tissue can be recovered from a living donor with the purpose of donating it to a recipient, if, in this particular case, there is no cadaver donor available, and, if according to medical judgment, donating the organ or tissue shall result in saving the recipient's life, or shall allow the recovery from serious illness, or prevent the recipient's health from further deterioration, or will alleviate the pain and trouble caused by serious illness. Yet another condition is the requirement that the donor should be an adult and have full legal capacity. The next indispensable condition which must be met before an explantation in *ex vivo* transplantation may be performed, is the obligation of determining whether the recovery of an organ or tissue does not pose a considerable threat to the donor's life and does not cause grievous bodily harm resulting in the donor necessitating an explantation procedure in turn. In the light of § 8 of the German Act [2], recovery of a kidney, part of a liver or another non-regenerating organ is admissible only with the purpose of donating it to a relative of first or second degree of consanguinity, or to a spouse, life partner (*der eingetragene Lebenspartner*), fiancé or fiancée, or to any other person who remains in a "particular personal link" with the donor. As stressed in the doctrine, the 'link' is not to be understood as 'economically motivated instrumental relationship'. It refers to a 'life bond' (*biographisch gewachsene*) – a reciprocal feeling of community and mutual responsibility 'due to the ups and downs of life', as well as to frequent close and personal contacts maintained over a considerably long time [5].

A vitally important notion that conditions the performance of the recovery of cells, tissues or an organ in *ex vivo* transplantation under the Polish, German and Swiss law is the donor's consent. This ought to be expressed in writing. Before giving consent, the donor should be provided with exhaustive information.

Under the Polish Act [1], the person who is to become a donor must be informed in detail as regards the type of procedure, the risk associated with the procedure, and the predictable consequences to the donor's own health state in the future, as well as the consequences of withdrawing the consent to a recovery of cells, tissues or an organ for the recipient, which are connected with the last phase of recipient preparation for transplantation of these. Such information shall be communicated by two physicians – by the physician who carries out the procedure, and by another physician who is not directly involved in the recovery of cells, tissues or an organ.

Under the German Act [2], the donor must be informed by a physician in a comprehensible way about the purpose and method by which the procedure shall be carried out, the medical examinations preceding it and the results thereof, the measures put in place to protect the donor, the course

of surgical intervention, possible direct and indirect consequences of purposeful recovery of an organ or tissue to the donor's health, the doctor's obligation to keep secret the donation and activity surrounding the donation, the estimated chances for a successful transplantation of an organ or tissue and its consequences for the recipient, as well as other circumstances which are related to the transplantation. Besides the aforementioned, there is an obligation to inform the involved persons about collecting and processing personal data. Furthermore, the doctor shall provide the donor with the relevant explanations in writing, in the presence of another doctor, or another competent person – should it be necessary.

With respect to the Swiss Act [3], this puts forward a requirement to comprehensively inform the donor. It does not specify, though, what kind of information and by whom this is to be given.

b) recovering a transplant from a donor who is a minor

As prescribed by the Polish Act [1], a minor can become a donor only of regenerating cells or tissues such as bone marrow and haematopoietic peripheral blood cells, if the procedure of recovering a transplant shall not cause foreseeable impairment of the donor's body efficiency. Furthermore, a transplant may be recovered only for the benefit of siblings, and only in the event of immediate danger to the recipient's life, and when such danger cannot be avoided by the means of any treatment other than transplantation. What is more, it is necessary to obtain the consent of the minor's statutory representative, and in case of a minor who is over 13, the minor's own consent, too. Moreover, the guardianship court must give approval.

Under the German Act [2], recovering bone marrow from a minor donor is admissible only for the benefit of a minor's siblings or relatives of first degree consanguinity. Such recovery is acceptable when there is no suitable donor at that time and the bone marrow material is necessary to cure the recipient from a life-threatening disease. In order to recover and use bone marrow, one needs to obtain the consent of the minor's legal representative. The minor must also give their consent if he or she is capable of comprehending the nature, meaning and importance of bone marrow recovery, and if he or she can express their will. There is an additional requirement conditioning the performance of an explantation procedure from a minor's organism, namely – obtaining family court approval.

According to the Swiss Act [3], all that is allowed to be recovered from a minor are regenerating cells and tissues if a comparable therapeutic result in the recipient's health cannot be achieved by means of any other treatment alternative to transplantation, and this procedure alone is likely to save the recipient's life, and there is no suitable 'mentally competent' adult donor available. The next condition is that recovering a transplant is likely to cause only minimal risk for the donor and may merely constitute an insignificant burden for that individual. Furthermore, the transplant may be recovered solely with the purpose of transplanting it to the recipient being the donor's parent, child, brother or sister. Additionally, it is required that consent be given by the underage

donor's legal representative, and in case of 'a minor with mental capacity' – the minor's own consent as well. What is more, a relevant authorization issued by a competent independent institution must be obtained.

3. Legal regulations regarding *ex mortuo* transplantation

Pursuant to Art. 9 Clause 1 of the Polish Act [1], recovering cells, tissues or organs for transplantation is admissible after a permanent and irreversible cessation of brain activity has been determined (brain death), while pursuant to Art 9a Clause 1 [1] – after establishing a diagnosis of death due to irreversible cessation of blood circulation. Brain death shall be established unanimously by a body consisting of three physicians. A physician establishing the donor's death must not participate in the procedure involving the recovery and transplantation of cells, tissues or organs from this donor. In accordance with the provisions of Art. 5 Clause 1 of the Polish Act [1], the recovery of cells, tissues or organs from a human corpse for the purpose of transplantation is normally allowed, unless the deceased person has expressed his or her prior objection. This shall be stated in the form of:

- 1) an objection to recover cells, tissues and organs from one's own human cadaver that is registered in the Central Objection Register;
- 2) a written statement hand signed by the person to whom it concerns;
- 3) an oral statement made in the presence of at least two witnesses and confirmed by these witnesses in writing.

As prescribed by the German Act [2], recovery of organs or tissues from cadaver donors is allowed, provided that all of the following requirements are met:

- 1) the diagnosis of the donor's death has been established according to current medical knowledge and specific procedure;
- 2) the donor of an organ or tissue, when alive, gave his or her consent for the explantation to be performed after their death;
- 3) the procedure of recovering a transplant shall be carried out by a physician or, by way of an exception, a person who has other qualifications, but is following doctor's instructions and acting on the doctor's responsibility.

Pursuant to § 3 and 5 of the German Act [2], *ex mortuo* transplantation may be performed only in case when, prior to recovering organs or tissues, and according to current medical knowledge, an absolute and irreversible cessation of brain, cerebellum and brain stem activity has been established. The provision refers also to an absolute and irreversible cessation of blood circulation and to cardiac arrest. In addition, more than three hours must pass since the diagnosis was established. In accordance with § 5 of the aforesaid Act [2], as a general rule, the death is to be stated by two qualified physicians. These individuals must conduct the donor's examination independent of one another. What is more, the doctors that participate in establishing the donor's death must not take part in the procedure of recovering organs or be subordinate to the doctor who performs the said procedure.

Under the Swiss Act [3], it is allowed to recover organs, tissues or cells from a human cadaver donor if the death of the donor has been determined, and the donor, when alive, gave consent to recover a transplant from their corpse. Pursuant to Art. 9 of the Swiss Act [3], the death of a person shall be stated if irreversible cessation of brain activity (including brain stem activity) can be determined. Doctors who are to establish the diagnosis of death may not participate in recovering the organs, tissues or cells that are to be transplanted, or be obliged to follow the orders given by a person who participates in the explantation procedure.

CONCLUSIONS

1. In Poland, Germany and Switzerland alike, there is a specific Act regulating in a comprehensive way, the issue of performing transplantation surgery.
2. Transplantation in Poland, Germany and Switzerland may refer to procedures and practices involving cells, tissues and organs.
3. In accordance with the law that is effective in Poland, Germany and Switzerland, the performance of both *ex mortuo* and *ex vivo* transplantations is allowed if the conditions specified in, respectively, the Polish, German and Swiss Acts, are fulfilled.
4. In all three countries, there is an absolute ban on the trading of organs and tissues. Moreover, it is prohibited to give and obtain financial benefits or derive any other profits from donating human organs, tissues and cells.
5. The informed consent of the donor, expressed in writing is a condition for recovery of cells, tissues or organs under the Polish, German and Swiss law alike.
6. Inside Polish as well as German and Swiss regulations, there is a rule that cells, tissues and organs may be recovered from an adult, who, under the Polish and German Acts, has full legal capacity, whereas under the Swiss Act, is mentally competent. What is more, under the legislation of all three countries, a minor may become a donor in *ex vivo* transplantation only by way of exception and on condition that a number of precisely specified requirements are fulfilled.
7. Under the German Act, an organ or tissue can be recovered from a living donor with the purpose of donating it to another person only if in this particular case, there is no possibility of finding a cadaver donor. Neither the Polish nor the Swiss Act provides for such a requirement.
8. According to Polish, German and Swiss regulations, a minor may become a donor only of regenerating cells and tissues. With respect to the Polish Act, bone marrow and haematopoietic peripheral blood cells made be recovered from a minor donor. With regard to the German Act, bone marrow alone is recoverable. Of note, the Swiss Act does not specify which regenerating cells and tissues might be recovered from a minor.
9. Pertinent to the Polish Act, a transplant may be recovered from a minor only for the benefit of the donor's siblings. Under the German Act, this is allowed if it is for the benefit of a relative of first degree of consanguinity or siblings. Pursuant to the Swiss Act, recovery is permitted for the

benefit of a parent, a child or the siblings of the underage donor.

10. A transplant may be recovered from a minor only exceptionally:
 - when, subject of the Polish Act, there is an immediate risk of the recipient's death and such danger cannot be avoided in any way other than performing a transplantation surgery;
 - when, subject to the German Act, there is no suitable donor at that time, and the recovered bone marrow is necessary to cure the recipient of a life-threatening illness;
 - when a comparable therapeutic effect in the recipient's health cannot be achieved by applying any therapeutic procedure other than transplantation, and this practice is likely to save the recipient's life, and there is no suitable adult donor who is mentally competent.
11. The condition for an explantation from a minor's organism in *ex vivo* transplantation is obtaining, in Poland and Germany – court approval, whereas in Switzerland – obtaining an authorization issued by an independent institution.
12. To recover a transplant, it is required that authorized personnel obtain, apart from a legal representative's consent, a minor's own consent if he or she is over 13 years old (the Polish Act), if a minor is capable of comprehending the nature, meaning and importance of bone recovery and can express his or her will (the German Act); if a minor has full mental capacity (the Swiss Act). The obligation to obtain the underage donor's consent in Poland depends on the donor's age, whereas in Ger-

many and Switzerland, this depends on whether the minor is fully aware of the facts.

13. *Ex mortuo* transplantation is admissible provided that the following has been established: permanent and irreversible cessation of brain activity (brain death) or death due to irreversible cessation of blood circulation (under the Polish Act); absolute and irreversible discontinuation of brain, cerebellum and brain stem activity or death due to absolute and irreversible cessation of blood circulation and cardiac arrest, and that at least three hours has passed since these facts were established (under the German Act); irreversible cessation of brain functions, including brain stem functions, has come about (under the Swiss Act).
14. Subject to the Polish, German and Swiss Acts likewise, the physicians who establish a diagnosis of death may not participate in recovering organs, tissues or cells for transplantation.
15. In the light of the German and Swiss Acts, the recovery of tissues and organs is allowed from a cadaver donor if the person gave their consent for recovery of a transplant prior to death, whereas, pursuant to the Polish Act, this is allowed if the deceased did not express his or her objection when alive.

To sum up, as far as *ex vivo* transplantation is concerned, the legal solutions regarding transplantation in Poland, Germany and Switzerland regulate the legal situation of the donor and the recipient of a transplant in a similar way (although there are a few significant differences). As for *ex mortuo* transplantations, the legal solutions applied in each country vastly differ.

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