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Articles

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The Concept of a Donor under the Act of 1 July 2005 on the Procurement, Storage and Transplantation of Cells, Tissues and Organs: Remarks De Lege Lata and De Lege Ferenda

Pojęcie dawcy w świetle ustawy z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Uwagi de lege lata i de lege ferenda

ABSTRACT

This article is of a scientific and research character and focuses on concepts related to the subjective aspect of donation, as employed by the Polish legislator in the Act on the Procurement, Storage and Transplantation of Cells, Tissues and Organs, as well as in the relevant legal instruments of the European Union, namely a regulation and directives. The key concepts of "donor" and "living donor" are legally defined, whereas a number of other concepts, equally significant to the transplantation process, are not explained in any of the legal acts analysed. Nonetheless, legislators frequently employ terms such as "bone marrow donor", "organ donor", "potential donor", and "donor candidate",

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as well as the titles "Transplant Donor" and "Distinguished Transplant Donor". The purpose of this paper is therefore to examine these terms and attempt to determine their meaning. It is argued that the multiplicity of terms relating to the subjective aspect of donation and its various stages, as well as the multiplicity of their legal definitions, prevents a clear determination of their meaning and of the precise relationship between them. The problems associated with interpreting the concept of a donor and related terms are not merely theoretical. They are of considerable practical significance, as the different stages of the transplantation procedure entail distinct rights and obligations for healthcare providers, medical professionals, donors themselves, potential donors, and donor candidates. Given that this issue has rarely been the subject of in-depth scholarly analysis, it is anticipated that research in this area, and the dissemination of its findings, may contribute to the development of new legislative solutions.

Keywords: donor; potential donor; donor candidate; subjective side of donation; cell, tissue and organ donation

INTRODUCTION

Transplantation treatment is unique in that it essentially involves two individuals – the recipient and the donor – of whom only one, the recipient, derives a health benefit in the form of restoration or improvement of health.[1] Although transplantation procedures do not pursue a therapeutic aim with respect to the donor, the donor's role is indispensable; indeed, the life of the recipient may often depend on the availability of a compatible donor.

In Polish law, the admissibility of donation and the rules governing its conduct are set out in the Act of 1 July 2005 on the procurement, storage and transplantation of cells, tissues and organs.[2] This Act distinguishes between and separately regulates the conditions for the procurement of cells, tissues or organs from living donors and from deceased persons, as well as their transplantation or, in the case of cells and tissues, their application. It also permits the transplantation or application of cells or tissues of animal origin in humans. It is worth noting, however, that the legislator often uses various terms throughout the PSTO Act, which may appear to be legally equivalent or at least similar in meaning. These include the terms "donor", "living donor", "marrow donor", "organ donor", "potential donor", "candidate donor", as well as the titles "Transplant Donor" and "Distinguished Transplant Donor". Some of these terms are defined by statute, while others regrettably are not. It should also be emphasised that certain terms are defined in binding legal instruments of the European Union, namely a regulation and directives, which are applicable in Poland.

[1] M. Gałązka, *Transplantologia*, [in:] *System Prawa Medycznego*, vol. 2: *Szczególne świadczenia zdrowotne*, eds. L. Bosek, A. Wnukiewicz-Kozłowska, Warszawa 2018, p. 355.

[2] Consolidated text, Journal of Laws 2023, item 1185, as amended, hereinafter: the PSTO Act.

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Yet, the definitions laid down in those instruments do not invariably coincide with those adopted by the domestic legislator.

Accordingly, the aim of this article is to analyse the term "donor" and related notions under the PSTO Act, and to determine whether these correspond to the terminology adopted in EU legislation. At the outset, the following hypothesis was formulated: The multiplicity of terms relating to the subjective dimension of donation and its individual stages, as well as the plurality of their legal definitions, significantly hinders the determination of their precise meaning and the delineation of clear relationships between them. Verification of this hypothesis will, in consequence, require an analysis of the legal framework governing transplantation from the perspective of the possibility or necessity of its amendment. As Z. Ziembiński observes, "research into the real aspects of law must of necessity refer to research into the formal aspects of law, and the theories – constructed, in a certain sense, in parallel – concerning law in its various aspects must be interconnected in many respects".[3]

It should be emphasised that due to the aforementioned multiplicity of terms and definitions, the research area is very broad and, given the editorial limitations of this study, must be clearly narrowed to only part of it. Therefore, the analysis focuses exclusively on the interpretation of the term "donor" and related terms, and on determining the meaning of these terms both in the PSTO Act and within the relevant legal instruments of the European Union, namely a regulation and directives. Issues related to the admissibility of donation, including the conditions for expressing consent or objection, as well as fundamental principles of contemporary donation – such as non-remuneration and anonymity – fall outside the scope of this discussion.

The nature of the subject matter has led to the distinction of three main parts of this paper: the introduction, the research section, and the conclusion. The introduction outlines the background of the analysed problem and formulates the research hypothesis. The main part is divided into three sections: the first is devoted to an analysis of the definitions of the terms "donor" and "living donor" as formulated by the Polish legislator in the PSTO Act; the second identifies terms directly related to the donor used by the legislator in the PSTO Act but not defined therein; and the third addresses the concept of the donor in EU law. The final part consists of the conclusion, which summarises the analysis and includes the verification of the initial hypothesis, as well as *de lege ferenda* recommendations.

The research method adopted in this paper is the formal-dogmatic method, which allows for the analysis of binding legal provisions. Additionally, the views of legal doctrine have been taken into account. The considerations presented in

[3] Z. Ziembiński, *Charakterystyka teorii prawa jako dyscypliny prawoznawstwa*, [in:] *Zarys teorii prawa*, ed. S. Wronkowska, Poznań 2001, p. 16.

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this paper are based primarily on the provisions of the PSTO Act, as well as on the relevant EU legal instruments pertinent to the analysis conducted. The literature cited relates in particular to the subjective aspect of donation of cells, tissues and organs. It should be noted that discussions on these issues are undertaken mainly in medical literature, whereas legal literature addressing the legal status of the donor and related concepts remains limited. This in itself provides justification for a more in-depth legal analysis of the issue.

DONOR AND LIVING DONOR UNDER THE ACT ON THE PROCUREMENT, STORAGE AND TRANSPLANTATION OF CELLS, TISSUES AND ORGANS

The statutory definitions of the terms used in the PSTO Act are contained in Article 2. Within this provision, the legislator has introduced legal definitions – in the sense of § 146 of the Regulation of 20 June 2002 on the "Rules of Legislative Drafting"[4] – which take the form of regulatory nominal definitions[5] essential for further analysis, namely donor and living donor. The first of these has been defined by the legislator as a living donor, human remains, or another type of living or deceased source from which cells, tissues or organs are procured (Article 2 (1) (7) of the PSTO Act). The second term – living donor – is defined as "a person from whom cells, tissues or organs are procured" (Article 2 (1) (53) of the PSTO Act).

With respect to the first of these terms – donor – it should be noted that its analysis allows for the distinction between two scopes of meaning: subjective and objective. Under the current legal framework, the subjective scope includes a living donor, human remains, and other types of living or deceased sources from which cells, tissues or organs are procured.[6] Among the terms used in the definiens of Article 2 (1) (7) of the PSTO Act, only the term "living donor" – as previously noted – has been further defined for the purposes of the Act. Given that a living donor is defined simply as a "person" from whom cells, tissues or organs are procured, without further specification, it must be assumed that the term refers to

[4] Consolidated text, Journal of Laws 2016, item 283, as amended.

[5] See Z. Ziembiński, *Logika praktyczna*, Warszawa 2001, pp. 44–55, 273. Cf. A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2*, [in:] *Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Komentarz*, ed. D. Tykwińska-Rutkowska, Warszawa 2025, p. 24.

[6] This wording is the result of the amendment introduced by the Act of 23 March 2017 amending the Act on the procurement, storage and transplantation of cells, tissues and organs (Journal of Laws 2017, item 798). As a consequence of this amendment, the original wording of the definition contained in Article 2 (2) of the PSTO Act was extended to include other living or deceased sources from which cells, tissues or organs are collected.

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a natural person.[7] A linguistic interpretation of the term "natural person" leads to the conclusion that a donor is a human being from the moment of live birth until death. The determination of these two moments – the beginning and the end of human life – requires, in the first case, recourse to Annex 1 to the Regulation of 6 April 2020 on the types, scope and templates of medical documentation and the manner of its processing,[8] which stipulates that "live birth shall be understood as the complete expulsion or extraction from the mother's body of a newborn, irrespective of the duration of the pregnancy, which, after such expulsion or extraction, breathes or exhibits any other signs of life, such as a heartbeat, pulsation of the umbilical cord, or definite movements of voluntary muscles, regardless of whether the umbilical cord has been cut or the placenta has been detached". In the second case, reference should be made to Article 43 (7) of the Act of 5 December 1996 on the professions of physician and dentist,[9] which provides that "the determination of permanent and irreversible cessation of brain function (brain death) or irreversible cessation of circulation is equivalent to the determination of death". This final moment is thus decisive in qualifying a donor as a living person and in establishing the appropriate legal rules governing the procurement of cells, tissues or organs.[10]

Although the statutory definition of a living donor does not include any subjective limitations, it must be emphasised that such limitations arise from other provisions of the PSTO Act. Pursuant to Article 12 (1) (7) of the PSTO Act, a candidate for donation must possess full legal capacity. In accordance with Article 11 of the Act of 23 April 1964 – Civil Code,[11] full legal capacity is acquired upon attaining the age of majority. Consequently, a donor cannot be a minor or a person who is partially or fully legally incapacitated. An exception applies in cases of bone marrow or peripheral blood stem cell donation by a minor to a sibling, where there is a direct risk to the recipient's life that cannot be averted by any other means, and where the collection does not pose any foreseeable risk of impairment to the donor's health or functioning (Article 12 (2) of the PSTO Act). Moreover, a pregnant woman's eligibility to act as a donor is also subject to limitation. According to Article 12 (1) (6) of the PSTO Act, she may only donate cells or tissues, provided that the risks associated with the procurement procedure are assessed not only in relation to the woman but also in relation to the unborn child. At the same time, it must be emphasised that obtaining the status of a living donor is conditional upon meeting

[7] Cf. I. Uhrynowska-Tyszkiewicz, *Komentarz do art. 2*, [in:] J. Haberko, I. Uhrynowska-Tyszkiewicz, *Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Komentarz*, Warszawa 2014, p. 31.

[8] Consolidated text, Journal of Laws 2024, item 798, as amended.

[9] Consolidated text, Journal of Laws 2024, item 1287, as amended, hereinafter: the APMD Act.

[10] Cf. A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 53*, [in:] *Ustawa o pobieraniu…*, p. 109.

[11] Consolidated text, Journal of Laws 2024, item 1061, as amended.

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the requirements set out in the Regulation of the Minister of Health of 25 April 2006 on the requirements for a candidate donor of cells, tissues or organs,[12] which allow for a determination that the procurement and transplantation of cells, tissues or an organ will not result in consequences endangering the life or health of either the donor or the recipient – that is, that the candidate is deemed eligible for the procurement procedure (§ 2 of this Regulation).[13] Furthermore, the procedure requires a determination of the justification and appropriateness of the procurement and transplantation of cells, tissues or organs, or the application of cells or tissues from a specific donor in human beings, as well as the provision of consent for the procurement of the transplant following prior detailed and written information (see in detail Article 12 (1) of the PSTO Act).[14]

With regard to the next concept falling within the personal scope of the term "donor" – namely, "human cadaver" – it should be noted that, due to the lack of a statutory definition in the PSTO Act, its meaning must be determined based on other applicable legal acts and the opinions presented in the legal literature. A legal definition of a human cadaver is provided in § 2 of the Regulation of the Minister of Health of 7 December 2001 on the handling of human cadaver and human remains,[15] under which a human cadaver is defined as "the bodies of deceased persons and stillborn children, regardless of the duration of the pregnancy". Although legal scholars differ in their views regarding the legal status of human remains understood in this way – some arguing that they constitute objects excluded from civil law commerce, or alternatively, inanimate objects subject to a separate legal regime – it appears, on ethical grounds, including the respect owed to human remains, that they should not be regarded as things within the meaning of civil law. Despite their tangible nature, they ought to be excluded from legal circulation, along with any cells, tissues or organs removed from them.[16] Considering that the above-mentioned definition introduced by

[12] Journals of Laws 2006, no. 79, item 566.

[13] As K. Miaskowska-Daszkiewicz (*Prawne instrumenty wspierające bezpieczeństwo epidemiczne biorców ludzkich komórek, tkanek i narządów*, "Studia Prawnicze KUL" 2017, no. 3, p. 82) aptly observes, "the qualification (and disqualification) of donors of human cells, tissues and organs constitutes an element of the so-called coordination of procurement and transplantation in humans, or procurement and application in humans, and is based on medical premises which find no reflection in the normative text".

[14] Cf. D. Tykwińska-Rutkowska, *Transplantacja. Studium z nauki prawa administracyjnego*, Warszawa 2013, pp. 126, 151–152, 155–163.

[15] Consolidated text, Journals of Laws 2021, item 1910, as amended.

[16] See P. Nazaruk, *Komentarz do art. 45*, [in:] *Kodeks cywilny. Komentarz aktualizowany*, ed. J. Ciszewski, LEX/el. 2023; T. Sokołowski, K. Żok, *Komentarz do art. 45*, [in:] *Kodeks cywilny*, vol. 1: *Komentarz do art. 1–352*, ed. M. Gutowski, Legalis 2021; P. Księżak, W. Robaczyński, *Dysponowanie zwłokami ludzkimi dla celów naukowych i medycznych*, "Państwo i Prawo" 2015, no. 1, pp. 59–60; R. Świrgoń-Skok, *Komentarz do art. 45*, [in:] *Kodeks cywilny. Komentarz*, ed. M. Załucki, Legalis 2023; I. Sierpowska, *Śmierć w ujęciu prawa administracyjnego*, Warszawa 2020, p. 163;

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the Regulation is not systemic in nature, it must be emphasised that "not all human cadavers, within the meaning of that Regulation's definition, may serve as sources for the procurement of cells, tissues or organs for the purposes set out in the PSTO Act".[17] It is important to note that, pursuant to Article 1 (2) of the PSTO Act, the Act does not apply, i.a., to the procurement and transplantation of embryonic and foetal tissues.[18] Furthermore, the procurement from a human cadavers is subject to the conditions set out in Chapter 2 of the PSTO Act, titled "Procurement of cells, tissues or organs from human cadavers". These include, in particular:

1) the crucial condition of no objection having been expressed during the donor's lifetime to post-mortem procurement of cells, tissues or organs for the purpose of transplantation or of cells and tissues for the purpose of application (the so-called presumed consent); and
2) in the case of death resulting from an act prohibited by law and constituting an offence – provided that the public prosecutor does not raise an objection and, in proceedings concerning a minor, the family court does not take a position on the intended procurement of cells, tissues or organs; and
3) the medical justification for the procurement, established by ruling out absolute and relative contraindications to donation, as well as by performing all necessary tests excluding risks associated with the procurement and transplantation procedure.[19]

The status of the donor within the meaning of Article 2 (1) (7) of the PSTO Act also covers another type of living or deceased source from which cells, tissues or organs are procured. While this term is general and imprecise, when analysed in conjunction with Article 20 of the PSTO Act, it may be concluded that it refers to "a non-human source that is either currently living or has previously lived",[20] such as cells, tissues or organs derived from animals (so-called xenotransplants), the use of which – pursuant to Article 20 (3) of the PSTO Act – is governed by the provisions of the APMD Act concerning medical experimentation, both scientific and therapeutic.[21] At present, due to the lack of a precise statutory definition or examples of other living or deceased sources that could be regarded as donors, it

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Ł. Żelechowski, *Komentarz do art. 43*, [in:] *Kodeks cywilny. Komentarz. Część ogólna. Przepisy wprowadzające KC. Prawo o notariacie*, vol. 1: *Komentarze prawa prywatnego*, ed. W. Borysiak, Legalis 2017.

[17] A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7*, [in:] *Ustawa o pobieraniu…*, p. 47.

[18] This matter is governed by the Act of 25 June 2015 on the treatment of infertility (consolidated text, Journal of Laws 2020, item 442, as amended).

[19] Cf. D. Tykwińska-Rutkowska, *Transplantacja…*, pp. 129–130, 134.

[20] A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7…*, p. 48.

[21] J. Haberko, *Komentarz do art. 20*, [in:] J. Haberko, I. Uhrynowska-Tyszkiewicz, *op. cit.*, pp. 219–220; M. Gałązka, *Transplantologia…*, p. 388.

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is difficult to determine, for instance, whether certain technological advancements such as 3D bioprinting[22] – in which living components such as cells are embedded in specially created and patented bio-inks – could qualify as another type of living source from which materials are procured. However, in view of the material scope of the PSTO Act, it seems justified to exclude plant cells and tissues from the definitional scope of the term "donor".[23]

In addition to the personal (subjective) scope of the term "donor", it is also necessary to examine its material (objective) scope. This scope is defined not so much by the act of donation itself – or, as introduced by the 23 March 2017 amendment to the PSTO Act,[24] by the notion of donation – but by the act of procurement.[25] A donor is thus a source from which cells, tissues or organs are procured. In formulating the statutory definition of "donor", the legislator clearly emphasised the act or process by which donated cells, tissues or organs are obtained,[26] although *de facto*, in common language, a donor is understood as someone who gives or donates something, not someone from whom something is taken.[27] However, it must be stressed that, in the absence of the act of donation, understood as the voluntary giving, transferring or surrendering cells, tissues or organs intended for transplantation or use in humans – procurement would not be possible.[28]

TERMS RELATED TO THE CONCEPT OF "DONOR" USED IN THE PSTO ACT BUT NOT DEFINED THEREIN

As already indicated above, the term "donor" is one of the key concepts for the transplantation procedure as well as for the PSTO Act itself. It is therefore appropriate that the legislator has provided a statutory definition of this term. However, one may also identify other expressions that are similar in both their subjective and

[22] Cf. B. Sarecka-Hujar, A. Ostróżka-Cieślik, A. Banyś, *Innowacyjne technologie w medycynie i farmacji*, "Acta Bio-Optica et Informatica Medica / Inżynieria Biomedyczna" 2016, vol. 22(1), p. 10.

[23] See A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7…*, p. 48.

[24] Act of 23 March 2017 amending the Act on the procurement, storage and transplantation of cells, tissues and organs (Journal of Laws 2017, item 798).

[25] See A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7…*, p. 48.

[26] Cf. D. Tykwińska-Rutkowska, *Prawo do procedury medycznie wspomaganej prokreacji (studium z zakresu nauki prawa administracyjnego)*, Warszawa 2024, p. 36.

[27] See R. Łapa, *„Dawca" i „biorca" we współczesnych tekstach prawnych*, "Białostockie Archiwum Językowe" 2009, no. 9, pp. 171–185. Cf. A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7…*, p. 48.

[28] Cf. A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 2 ust. 1 pkt 7…*, p. 48.

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objective scope to the notion of donor and which are also used in the PSTO Act, yet have not been defined therein. As a result, it is difficult to establish their meaning with precision, and thus to clearly determine at what stage of the transplantation process such terms should be applied. Examples of such terms include potential donor and donor candidate.

The first of these – potential donor – appears in the PSTO Act as many as 29 times. Most frequently, the legislator refers to the potential donor in the context of the determination of the costs of transplantation procedures (Article 3 of the PSTO Act) and the functioning of bone marrow donor centres (Articles 16a and 16b of the PSTO Act). In Article 3, reference is made to the identification and qualification of the potential donor, hospitalisation of the potential donor, transport of the potential donor to the healthcare provider where procurement is to take place or to the provider where the transplantation will occur, as well as preparation of the living potential donor for procurement. In turn, in the provisions concerning bone marrow donor centres, the legislator refers to the terms "potential bone marrow donor" and "potential peripheral blood stem cell donor", indicating the tasks of such centres in acquiring, registering, testing, and storing documentation of potential donors. It should be noted that in all these instances, the term "potential donor" refers to a person who has not yet become a donor – in other words, no procurement of cells, tissues or organs has taken place.

The second term – donor candidate – is used less frequently in the PSTO Act, appearing only nine times. It is employed by the legislator in the context of regulating the conditions under which procurement of tissues, cells and organs from a living donor is permissible (Article 12 of the PSTO Act). In doing so, the PSTO Act refers to the requirement of providing the donor candidate with written information concerning the nature of the procedure, its associated risks, and any foreseeable consequences for their future health. It also refers to the requirement of obtaining the donor candidate's voluntarily given, written consent to the procurement of cells, tissues or organs for the purpose of their transplantation, or of cells or tissues for the purpose of their application in a known recipient. Furthermore, the donor candidate must have full legal capacity. As in the case of the potential donor, no procurement of cells, tissues or organs has yet occurred in relation to the donor candidate. Therefore, being a potential donor or a donor candidate precedes being a donor within the meaning of the PSTO Act. However, the Act does not clarify whether these two terms are legally equivalent. If the latter view is adopted, it remains unclear at which stage of the transplantation process each of these terms should be applied, and precisely when an individual becomes and ceases to be a potential donor or a donor candidate. It would therefore be desirable for the legislator to clarify this matter.

As the PSTO Act does not provide definitions of the terms "potential donor" or "donor candidate", medical literature may prove helpful in determining their

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meaning. These terms are also used by transplant physicians and other medical personnel involved in the transplantation process. It should be noted, however, that medical terminology includes further concepts not employed by the legislator in the PSTO Act. Within the process of post-mortem donation, the following terms are distinguished, in sequential order: "probable deceased donor" – that is, a person with severe, primary or secondary brain damage, on mechanical ventilation, and without any absolute medical contraindications to organ donation; "potential deceased donor" – that is, a person in whom brain death is suspected or confirmed, and in whom no absolute medical contraindications to donation have been identified; "eligible deceased donor" – that is, a person in whom brain death has been confirmed, in whom no absolute medical contraindications to organ donation are present, and for whom authorisation for procurement has been granted, including the completion of a family interview with the relatives of the potential donor.[29] Once at least one organ has been procured from a deceased individual for the purpose of transplantation, such a person becomes an actual deceased organ donor. If at least one organ has been transplanted, the person is referred to as a utilised deceased donor.[30]

In the context of organ donation from living persons, the terms "potential donor" and "donor candidate" are also used in medical literature. However, it is worth noting that, in those provisions where the legislator applies the term "donor candidate" (e.g. Article 12 (1) (7) of the PSTO Act: "the donor candidate has full legal capacity…", and Article 12 (1) (8): "the donor candidate has been informed, prior to giving consent, of the consequences for the recipient resulting from the withdrawal of consent for the procurement of cells, tissues or organs"), the term is often replaced in medical sources with the term "potential donor", e.g. "The potential donor must have full legal capacity and must give informed and voluntary consent to the procurement of an organ for the purpose of transplantation to a specified recipient (…) the potential donor has been informed, prior to giving consent, of the consequences for the recipient arising from the withdrawal of consent at the final stage of preparation for transplantation".[31] This raises the question of whether, in practice, these terms should be regarded as legally equivalent. Once again, a *de lege ferenda* postulate must be reiterated: it would be desirable for the legislator to provide a precise definition of these terms and, should they be intended to bear the same meaning, this should also be expressly stated.

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[29] J. Czerwiński, A. Jakubowska-Winecka, T. Kubik, R. Becler, M. Trujnara, *Dawstwo i pobieranie narządów*, [in:] *Medycyna transplantacyjna dla pielęgniarek*, eds. J. Czerwiński, P. Małkowski, Warszawa 2017, p. 45; J. Czerwiński, R. Danielewicz, *Prawo i organizacja pobierania i przeszczepiania narządów w Polsce*, [in:] *Transplantologia kliniczna. Skrypt dla studentów i lekarzy*, eds. A. Kwiatkowski, M. Durlik, T. Bączkowska, A. Chmura, Warszawa 2015, pp. 9–38.

[30] *Ibidem*.

[31] J. Czerwiński, R. Danielewicz, *op. cit*., p. 15.

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Terminological ambiguity may also arise from the use of the terms "donor" and "potential donor" in the context of the organisation and operation of bone marrow donor centres. These matters are governed by Articles 16a and 16b of the PSTO Act. First, attention should be drawn to the name of the centre itself and the use of the term "bone marrow donor". Legal scholarship has pointed out that this name is not entirely appropriate, given that in most cases it is not bone marrow that is donated, but rather haematopoietic stem cells derived from peripheral blood.[32] Therefore, it has been proposed that the name of the institution should not be simplified, but instead should adopt a more accurate and precise form: "haematopoietic stem cell donor centre".[33] On the other hand, it is important to note that the term "donor" used in this context does not correspond to the statutory definition of donor under the PSTO Act. The term "bone marrow donor centre" may imply that donation has already taken place. In reality, however, the primary task of such centres is to recruit potential donors, i.e. persons who declare their willingness to donate bone marrow (or, more precisely, peripheral blood stem cells) in the future. If a recipient with a matching HLA profile is not identified, the donation may never occur, meaning that individuals registered in the centre may, in fact, never become actual donors.[34] Strictly speaking, therefore, these are not centres of donors, but rather centres of potential bone marrow donors – or, as postulated above, of haematopoietic stem cell.

In the practical operation of bone marrow donor centres, various terms are also used to describe the period between a person's registration with the centre and the actual procurement of haematopoietic cells, although such terminology is not employed by the legislator in the PSTO Act. I. Uhrynowska-Tyszkiewicz has even proposed the introduction and distinction of the following terms: "candidate for a potential haematopoietic stem cell donor", "potential haematopoietic stem cell donor", "candidate for a haematopoietic stem cell donor", and "haematopoietic stem cell donor".[35]

As indicated in the introduction, the PSTO Act also uses the titles "Transplant Donor" and "Distinguished Transplant Donor". Although these expressions are not defined in the glossary set out in Article 2 of the PSTO Act, the relevant regulation in Chapter 5 appears sufficiently precise, and it is not difficult to determine the criteria for conferring such titles. Pursuant to Article 22 (1) of the PSTO Act, the

[32] I. Uhrynowska-Tyszkiewicz, *Komentarz do art. 16a*, [in:] J. Haberko, I. Uhrynowska-Tyszkiewicz, *op. cit.*, p. 165.

[33] I. Uhrynowska-Tyszkiewicz, A. Kamiński, *Ośrodki dawców komórek krwiotwórczych*, [in:] *Transplantologia kliniczna. Przeszczepy komórkowe*, eds. W.W. Jędrzejczak, L. Cierpka, Poznań 2021, p. 173.

[34] A. Rabiega-Przyłęcka, D. Tykwińska-Rutkowska, A. Wołoszyn-Cichocka, *Komentarz do art. 16a*, [in:] *Ustawa o pobieraniu… i przeszczepianiu komórek, tkanek i narządów. Komentarz*, ed. D. Tykwińska-Rutkowska, Warszawa 2025, p. 240.

[35] I. Uhrynowska-Tyszkiewicz, *Komentarz do art. 16a…*, pp. 165–166.

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title of Transplant Donor is granted to persons who have donated bone marrow or other regenerating cells and tissues. In turn, Article 22 (3) provides that the title of Distinguished Transplant Donor is awarded to individuals who have donated bone marrow or other regenerating cells or tissues more than once. This honorary title is also granted to organ donors.

DONOR UNDER THE RELEVANT EU LEGAL INSTRUMENTS

The issue of transplantation is also regulated by binding EU law applicable in Poland. To date, the European Union has adopted seven directives relating to transplantation medicine.[36] Among them are instruments in which the term "donor" is explicitly defined. One such act is Directive 2004/23/EC of the European Parliament and of the Council 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 cells.[37] According to Article 2 (1) of the Directive, it applies to the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells intended for human application, as well as manufactured products derived from such tissues and cells intended for human application. The definitions it contains are therefore determined by the Directive's material scope. In the context of the present analysis, Article 3 (c) of Directive 2004/23/EC is particularly relevant, as it defines donor as any human source, whether living or deceased, of human cells or tissues. It should thus be emphasised that a donor, within the meaning of Directive 2004/23/EC, does not include living or deceased sources of organs, since the Directive does not apply to them. In contrast, the Polish PSTO Act does apply to organs – understood as distinct and essential parts of the human body, composed of various tissues, capable of maintaining their structure, vascularisation, and ability to perform autonomous physiological functions – as well as to their parts, provided these can be used in the human body for the same purpose as the entire organ (Article 2 (1) (30) of the PSTO Act). Consequently, under the PSTO Act, a donor may be a source of such organs.

Although Directive 2004/23/EC does not apply to the donation, procurement, testing, processing, preservation, storage, and distribution of organs, this does not mean that the area is left unregulated under EU law. This matter is addressed by Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010

[36] For a more detailed discussion of the material scope of individual EU directives, see R. Danielewicz, *Dawstwo komórek krwiotwórczych – prawo i organizacja*, [in:] *Transplantologia kliniczna…*, p. 151 ff.

[37] OJ L 102/48, 7.4.2004.

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on standards of quality and safety of human organs intended for transplantation.[38] The Directive applies to the donation, testing, characterisation, procurement, preservation, transport, and transplantation of organs intended for transplantation (Article 2 (1) of Directive 2010/53/EU). It is worth noting, however, that this Directive was not transposed into the Polish legal order within the prescribed timeframe, as the process was deemed unnecessary. According to representatives of the Ministry of Health, the provisions of the PSTO Act already regulate the matters covered by Directive 2010/53/EU, and therefore explicit transposition into the national legal system was considered unnecessary.[39] Indeed, during the legislative process, the explanatory memorandum to the draft PSTO Act stated that the Act extends EU requirements to cover the handling of organs, "with due regard for the wellbeing of recipients and the high quality of procedures related to organ procurement and transplantation".[40] It should nevertheless be observed that while the PSTO Act includes an explicit reference to Directive 2004/23/EC – indicating that the Act implements its provisions – no such reference was introduced with respect to Directive 2010/53/EU in subsequent years.

Given the applicability of Directive 2010/53/EU, and the assumption that the PSTO Act fully implements its provisions, the definition of donor set out therein warrants examination. Pursuant to Article 3 (d) of the Directive, a donor is defined as a person who donates one or several organs, whether donation occurs during lifetime or after death. Owing to the material scope of the Directive, this definition does not encompass the donation of cells or tissues, which marks a departure from the definition adopted by the Polish legislator in the PSTO Act.

Taking into account the material scope of Directives 2004/23/EC and 2010/53/EU, one may conclude that the definition of donor under the PSTO Act ought to reflect the combined meanings adopted in both instruments. On the one hand, it should be noted that both Directives refer exclusively to human sources and to human cells, tissues and organs, whereas the Polish legislator, in defining a donor, also includes other types of living or deceased sources from which cells, tissues or organs are procured. In this respect, the domestic definition may be regarded as broader than the combined scope of the definitions provided in the analysed

[38] OJ L 207/14, 6.8.2010.

[39] For a broader analysis of the concerns surrounding the necessity of implementing Directive 2010/53/EU, see D. Tykwińska-Rutkowska, *„Zbyteczność" implementacji dyrektywy Parlamentu Europejskiego i Rady 2010/53/UE z 7 lipca 2010 r. w sprawie norm jakości i bezpieczeństwa narządów ludzkich przeznaczonych do przeszczepienia (?)*, "Przegląd Prawa Publicznego" 2013, no. 2, pp. 26–39.

[40] Explanatory Memorandum to the Draft Act on the Procurement, Storage and Transplantation of Cells, Tissues and Organs, together with Draft Implementing Acts, Sejm Paper No. 3856, 31.3.2005, https://orka.sejm.gov.pl/proc4.nsf/0/7744ECA014D1A1B6C12570C70030360A?OpenDocument (access: 30.1.2025).

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Directives. On the other hand, however, the definition in Directive 2004/23/EC (in view of its material scope) extends beyond the notion of donor under the PSTO Act. Recital 7 of Directive 2004/23/EC states that the Directive applies to tissues and cells, including haematopoietic progenitor cells, umbilical cord blood and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells, as well as adult and embryonic stem cells. Accordingly, it must be acknowledged that under the Directive, a donor may be a source of such tissues and cells. By contrast, Article 1(2) of the PSTO Act explicitly excludes from its scope the procurement and transplantation of reproductive cells, gonads, embryonic and foetal tissues, as well as reproductive organs or their parts, and also the collection, storage, and distribution of human blood for the purposes of transfusion, separation of its components, or processing into medicinal products. These matters are governed by other legal acts, such as the Act of 25 June 2015 on the treatment of infertility and the Act of 22 August 1997 on the public blood service,[41] which respectively provide definitions of donor, embryo donors,[42] and blood donors.[43]

It should be noted, however, that in the near future the Polish legislature will have to review the existing legal framework concerning the procurement, storage and transplantation of cells, tissues and organs. This follows from the reform of EU law effected by Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application, repealing Directives 2002/98/EC and 2004/23/EC.[44] As stated in Recitals 6 and 7 of the SoHO Regulation, its purpose is to establish general principles common to blood, tissues and cells. Accordingly, it applies to blood and blood components regulated under Directive 2002/98/EC,[45] as well as to tissues and cells – such as haematopoietic stem cells from peripheral blood, umbilical cord blood, or bone marrow, reproductive cells, embryos, foetal tissues and cells, and both adult and embryonic stem cells – previously covered

[41] Consolidated text, Journal of Laws 2024, item 1782, as amended.

[42] Pursuant to Article 2 (1) (5) of the Infertility Treatment Act, a donor is defined as a living person from whom reproductive cells are procured for the purpose of use in humans. In turn, Article 2 (1) (6) of this Act defines embryo donors as living persons who have donated the reproductive cells from which the embryo was created.

[43] According to Article 5 (3) of the Public Blood Service Act, a blood donor is understood as a person who has donated blood or its components for purposes other than diagnostic testing. It is also worth noting that Article 5 (5) of this Act sets out a definition of a candidate blood donor, understood as a person who, for the first time, presents themself to an organisational unit of the public blood service, as referred to in Article 4 (3) (2) to (4) of the Act, with the intention of donating blood or its components for purposes other than diagnostic testing or autologous transfusion.

[44] OJ L 2024/1938, 17.7.2024, hereinafter: the SoHO Regulation.

[45] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33/30, 8.2.2003).

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by Directive 2004/23/EC. As a result, both Directives are repealed.[46] Given the increasing prevalence of donation and clinical use of substances of human origin not previously covered by the above Directives, the scope of the SoHO Regulation has been extended to include such materials. The SoHO Regulation will therefore also apply to human breast milk (unless used exclusively to feed the donor's own child without any processing), intestinal microbiota, blood-derived preparations not used for transfusion, and any other substances of human origin that may in future be applied in medical treatment.

A central concept under the SoHO Regulation is that of a substance of human origin (SoHO), which is defined in Article 3 (1) of the SoHO Regulation as "any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such substance". This definition is exceptionally broad and, as a rule, brings within the material scope of the Regulation all SoHO intended for human application. However, Recital 26 of the SoHO Regulation expressly excludes solid organs from the notion of SoHO, thereby leaving the regulation of their donation and transplantation within the scope of Directive 2010/53/EU. Nonetheless, where organs are removed from a SoHO donor for the purpose of separating tissues or cells for human application – such as the extraction of heart valves from a heart or pancreatic islets from a pancreas – the provisions of the SoHO Regulation shall apply.

A living SoHO donor, as defined in Article 3 (7) of the SoHO Regulation, means "a living person who has volunteered to a SoHO entity, or has been presented by a person granting consent on their behalf, in accordance with national legislation, with a view to making a donation of SoHO, for the purpose of use in a person other than themselves, and other than in situations of within-relationship use". It should be emphasised that this definition is considerably broader than the corresponding definition of a living donor under the PSTO Act. Leaving aside the differences in the material scope of the SoHO Regulation and the PSTO Act – particularly with regard to the object of donation – it is important to note that, under the PSTO Act, an individual qualifies as a living donor only once the procurement of cells, tissues or organs has actually taken place.[47] In contrast, under the SoHO Regulation, a person

[46] It is worth noting, following K. Mełgieś, K. Miaskowska-Daszkiewicz and M. Sjeničić (*On the Need to Change the Model of Supervision over Substances of Human Origin from the Perspective of Regulation (EU) 2024/1938: Polish and Serbian Examples*, "Bialystok Legal Studies 2025, vol. 30(2), p. 204), "that the Regulation performs a material defragmentation of the regulatory scope of the previous directives".

[47] In the case of a living donor within the meaning of the PSTO Act, the subject of donation may also include organs, which, by contrast, do not fall within the scope of the concept of SoHO. Accordingly, a living SoHO donor will not donate organs. On the other hand, due to the very broad definition of SoHO, not everything that may be donated under the SoHO Regulation qualifies as such

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is considered a living SoHO donor as soon as they have presented themselves with the intention to donate, even if the donation has not yet occurred. Consequently, this category appears to also cover what the PSTO Act refers to as a "potential donor" or "donor candidate".

According to Article 3 (8) of the SoHO Regulation, a deceased SoHO donor is defined as "a deceased person who has been referred to a SoHO entity with a view to SoHO collection, and from whom consent has been granted in the respect or from whom SoHO collection is permitted in accordance with national legislation". This term has no direct equivalent in the PSTO Act, although the Act does permit the procurement of cells, tissues and organs from deceased human bodies. Similarly, none of the previously discussed EU directives contain a corresponding definition. It is worth highlighting that in defining a deceased SoHO donor, the EU legislator grants a certain margin of discretion to Member States with regard to regulating the conditions under which SoHO may be collected from deceased persons. On the one hand, the SoHO Regulation acknowledges the donor's will expressed during their lifetime, referring explicitly to prior consent. On the other hand, it permits alternative legal bases for collection from the deceased, provided such mechanisms are recognised under national law. This approach corresponds to the opt-out (presumed consent) model adopted by the Polish legislator.

The SoHO Regulation entered into force on the twentieth day following its publication in the Official Journal of the European Union, namely on 6 August 2024. However, as a rule, it shall only apply from 7 August 2027. This interim period is intended to allow Member States to adapt their national legal frameworks to the provisions of the SoHO Regulation. It is important to note the change in the legal form adopted by the EU legislator. Previously, the regulation of matters broadly related to transplantation was effected through directives, which required transposition into domestic legal orders. In contrast, a regulation is binding in its entirety and directly applicable in all Member States. Due to the large number of new and previously unknown legal solutions, as well as the introduction of a new terminological framework, amendments to the Polish legislation governing the relevant subject matter will be required, in particular to the PSTO Act. Such amendments could consist in excluding from the scope of application of the PSTO Act – in matters concerning donation (and thus the concept of the donor) – substances of human origin. In this respect, the provisions of the SoHO Regulation will apply. However, organ donation, which does not fall within the scope of the SoHO Regulation, will continue to be regulated at the statutory level.

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under the provisions of the Polish Act. This includes, i.a., reproductive cells, gonads, embryonic and foetal tissues, blood and blood components, as well as human breast milk and intestinal microbiota.

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CONCLUSIONS

In light of the foregoing analysis, the hypothesis set out at the beginning of this paper must be confirmed. It must therefore be acknowledged that the multiplicity of terms relating to the subjective aspect of donation and its various stages, as well as the variety of legal definitions applied, precludes a clear determination of their precise meaning and the relationships between them.

The issue under examination appears to be particularly complex. Although the concept of the donor constitutes the overarching term within the framework of the PSTO Act – and a statutory definition of this term has been provided therein – the existence of numerous definitions employed by the national legislator in the aforementioned Act, as well as by the EU legislator in legal instruments governing the field of transplantation, significantly hinders interpretative clarity. It creates uncertainty as to the exact scope of application of specific provisions and the identification of the individuals to whom they relate.

The analysis of the statutory terms, as well as those introduced by the relevant EU legal instruments central to the field of transplant medicine, leads to the fundamental conclusion that determining the meaning of individual terms requires specialist knowledge – encompassing organisational, technical, and medical norms – as the law inevitably reaches its limits within any institutional structure.[48] Research conducted to date within the field of law proves insufficient in this regard, rendering recourse to the views of representatives of the medical sciences essential. Current medical knowledge, however, is neither readily accessible to a broader audience nor constant in nature – it is influenced not only by continuous technological advancement in medicine, but also by the need to develop a praxis, as its contemporaneity is determined not solely by scientific theories produced within institutional medical science, but equally by clinical practice.[49] Often, under the influence of such developments, medical practice adopts terminology unfamiliar to the legislator or uses statutory terms interchangeably – as evidenced by the medical publications referenced in this paper. While the inherent indeterminacy of legal concepts allows for a desirable degree of flexibility, particularly in the context of a rapidly developing branch of medicine, legal uncertainty arises the moment doubts appear concerning the rights and obligations of individuals subject to a given regulation – as is clearly the case here – and such ambiguity calls for legislative clarification. It must be emphasised that the interpretative challenges concerning the notion of a donor in the PSTO Act are not merely theoretical in nature. The problem diagnosed herein

[48] W. Dawidowicz, *Zagadnienia teorii organizacji i kierownictwa w administracji państwowej*, Warszawa 1972, p. 43.

[49] T. Widłak, *Interpretacja klauzuli „aktualna wiedza medyczna" w polskim prawie – zarys zagadnień episemologicznych i metodologicznych*, "Gdańskie Studia Prawnicze" 2017, vol. 2, p. 613.

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is of significant practical relevance and directly affects the functioning of the law. This is because different rights and obligations apply to different stages of the transplantation process – affecting healthcare providers, medical professionals, donors, potential donors, and donor candidates alike. Accordingly, a *de lege ferenda* postulate must be advanced, calling for the precise clarification of the terminology used by the legislator in the PSTO Act, namely "donor", "living donor", "potential donor", "donor candidate", and "bone marrow donor", with due consideration of their practical application. In light of the approaching date of application of the SoHO Regulation, such clarification appears not only inevitable but also legally achievable – particularly given that the EU legislator has now opted for a regulation, which precludes Member States from introducing a wide range of domestic variations in the legal framework governing the use of substances of human origin.

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ABSTRAKT

Artykuł ma charakter naukowo-badawczy, a rozważania w nim prowadzone koncentrują się wokół pojęć związanych ze stroną podmiotową donacji, użytych przez polskiego prawodawcę w ustawie o pobieraniu, przechowywaniu, przeszczepianiu komórek, tkanek i narządów, a także przez prawodawcę unijnego w relewantnych aktach: rozporządzeniu i dyrektywach. Kluczowe pojęcia dawcy oraz żywego dawcy posiadają definicje legalne, natomiast inne pojęcia, równie istotne dla procesu przeszczepiania, nie zostały wyjaśnione w żadnym z poddanych analizie aktów prawnych. Tymczasem równie często prawodawcy używają takich określeń jak: dawca szpiku, dawca narządu, potencjalny dawca, kandydat na dawcę, a także tytułów Dawca Przeszczepu oraz Zasłużony Dawca Przeszczepu. W związku z tym celem opracowania jest analiza wskazanych pojęć i próba ustalenia ich znaczenia. Uznano przy tym, że mnogość terminów związanych ze stroną podmiotową donacji oraz jej poszczególnymi etapami, jak również wielość ich definicji legalnych nie pozwalają jednoznacznie ustalić ich znaczenia oraz wyznaczyć wyraźnej relacji między nimi. Problemy interpretacyjne pojęcia dawcy oraz pojęć do niego zbliżonych nie są przy tym rozważaniami wyłącznie teoretycznymi.

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Są one niezwykle istotne, gdyż poszczególne etapy procedury przeszczepiania wiążą się z różnymi uprawnieniami i obowiązkami zarówno po stronie podmiotów leczniczych, osób wykonujących zawody medyczne, jak i samych dawców czy też potencjalnych dawców albo kandydatów na dawców. Jako że zagadnienie będące przedmiotem rozważań niezwykle rzadko jest poddawane pogłębionym analizom naukowym, w założeniu przeprowadzenie badań w tym zakresie i upowszechnienie ich wyników może okazać się pomocne w wypracowaniu nowych rozwiązań legislacyjnych.

Słowa kluczowe: dawca; potencjalny dawca; kandydat na dawcę; podmiotowa strona dawstwa; dawstwo komórek, tkanek, narządów

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