

SECRETARIAT GENERAL

DIRECTORATE GENERAL
HUMAN RIGHTS AND RULE OF LAW

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

DGI(2018)09
14.11.2018

**Opinion of the Bioethics Unit,
Directorate General of Human Rights and Rule of Law**

**Prepared on the basis of the expertise by Ms Tesi Aschan,
Ms Ana M. Pires Silva and Mr Kristof Van Assche**

ON

Compliance of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” with the standards laid down in the Convention on Human Rights and Biomedicine and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin

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EXECUTIVE SUMMARY

This expert examination involves a legal assessment of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” (henceforth: Belarusian Transplant Law; the Transplant Law; or the Law) and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” (henceforth: Draft Law on Amendments to the Transplant Law; or Draft Law) vis-à-vis their compliance with the standards laid down in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (henceforth: Additional Protocol).

First, a legal assessment was made of the compliance of the general principles that govern the Belarusian Transplant Law with the general human rights principles enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol. On the basis of this assessment, it was concluded that the general principles that govern the Belarusian Transplant Law are in conformity with the general human rights principles enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol.

Second, a legal assessment was made of the compatibility of the provisions of the Belarusian Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol.

On the basis of this assessment, it was concluded that the Belarusian Transplant Law does not contain provisions that are clearly incompatible with the Convention on Human Rights and Biomedicine and its Additional Protocol.

The experts nevertheless considered it advisable to revise several of the provisions contained in the Belarusian Transplant Law so as to ensure their compliance with the Convention on Human Rights and Biomedicine and its Additional Protocol. Greater conformity with the Convention on Human Rights and Biomedicine and its Additional Protocol could be reached by re-examining some of the provisions contained in Articles 5, 8, 9, 11 and 12 of the Belarusian Transplant Law. More specifically, the following recommendations have been formulated:

1. The Belarusian authorities should consider amending Article 8 of the Law, so as to require that the removal of bone marrow and haematopoietic stem cells from minors unable to consent should only be authorised if, in addition to the requirements mentioned in Article 8, (1) there is no compatible donor available who has the capacity to consent; (2) the recipient is a brother or sister of the donor; and (3) the donation has the potential to be life-saving for the recipient.
2. The Belarusian authorities should consider making explicit in Article 8 of the Law that living organ removal is only allowed if, in addition to the requirements mentioned in Article 8, (1) there is a clear therapeutic benefit for the recipient; (2) there is no suitable organ or tissue available from a deceased person and no other alternative

therapeutic method of comparable effectiveness; and (3) there is no serious risk to the life or health of the donor.

3. The Belarusian authorities should consider amending Articles 8 and 9 of the Law to make explicit that the intended living donor: (1) should beforehand also be given appropriate information about the purpose and nature of the removal; (2) should be informed of the right to access to independent advice about the risks involved; (3) may freely withdraw consent at any time and without formal requirements; and (4) is not under any undue pressure to consent.
4. The Belarusian authorities should consider amending the Law to make explicit that surgical residues may only be used for transplant purposes if before the removal the patient had been informed about the storage and the intended use of the body parts.
5. The Belarusian authorities should consider amending Article 11 of the Law and Resolution No. 288 to the effect that the physicians involved in the certification of death should also not have any responsibilities for the care of potential organ or tissue recipients.
6. The Belarusian authorities should consider amending Article 12 of the Law to make explicit that the prospective recipients should beforehand also be given appropriate information about: (1) the purpose and nature of the implantation; (2) the consequences and risks of the implantation; and (3) the alternatives to the intervention.
7. To avoid the impression that the provisions on living donation are restricted to living organ donors, the Belarusian authorities should consider replacing in Article 1 of the Law the term “Organ retrieval” by “Organ and (or) tissue retrieval”, and, where in Articles 8 to 10 reference is made to “organ retrieval”, replacing this, where relevant, by “organ and (or) tissue retrieval”.
8. The Belarusian authorities should consider amending Article 5 of the Law to make more explicit: (1) the principle that donation of organs and tissues is free; and (2) the prohibition of transactions for financial gain and comparable advantage.
9. The Belarusian authorities should consider rephrasing the provision in Article 9 of the Law, so as to guarantee coverage of: (1) compensation of costs incurred by (potential) donors before donation; (2) compensation of all of the costs incurred by donors post-donation; (3) loss of income by (potential) donors linked to the donation; and (4) compensation in the event of complications resulting from the donation.
10. The Belarusian authorities should consider attaching clear sanctions to the infringements of the prohibitions of financial gain and advertisement, to the extent that this has not yet been properly addressed by other national legislation.

On the basis of this legal assessment, it was also concluded that several provisions of the Convention on Human Rights and Biomedicine and of its Additional Protocol have not yet been explicitly addressed in the Belarusian Transplant Law. The experts considered it advisable to revise some aspects of the Belarusian Transplant Law so as to give expression to these provisions and thereby ensure compliance with the Convention on Human Rights and

Biomedicine and its Additional Protocol. More specifically, the following recommendations have been formulated:

1. To the extent that no specific legislation governing the removal and transplantation of cells exists and to the extent that cells are currently excluded from the scope of the Transplant Law, the Belarussian authorities should consider including cells in the scope of that Law or adopting another legal instrument that specifies similar conditions for the removal and transplantation of cells than the ones that apply to the removal and transplantation of organs and tissues.
2. The Belarussian authorities should consider including in the Law a provision stipulating that appropriate medical follow-up shall be offered to living donors and recipients.
3. The Belarussian authorities should consider explicitly addressing in the Law the importance of the traceability of all organs and tissues removed, allocated, and transplanted in the Republic of Belarus.
4. The Belarussian authorities should consider directly addressing in the Law the principle of confidentiality and including in the Law a provision so as to guarantee the anonymity of donors and recipients who are not related.

The legal assessment also resulted in a number of suggestions for the implementation of certain provisions of the Belarussian Transplant Law in the light of the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol and in the light of practical proposals formulated in other relevant Council of Europe instruments. As compared to the recommendations outlined in the previous section, these suggestions concern aspects of the Belarussian Transplant Law that are clearly in accordance with the Convention on Human Rights and Biomedicine and its Additional Protocol but could nevertheless benefit from clarification or from elaboration with a view to further optimising the protection of the rights and freedoms of donors, potential donors and recipients.

Third, a legal assessment was made of the compatibility of the Draft Law on Amendments to the Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol. In this respect, it is concluded that, although the Draft Law does not directly address the recommendations formulated above, its adoption would significantly improve the further development of transplantation in the Republic of Belarus. The experts have taken the opportunity to formulate several suggestions for clarification or elaboration. They also encourage the Belarussian authorities to use the opportunity that the Law is currently under revision to ensure compliance with the Convention on Human Rights and Biomedicine and its Additional Protocol in the light of the recommendations contained in this report.

INTRODUCTION

This expert examination of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” is conducted in the framework of the Council of Europe Action Plan for Belarus under the request of the Belarusian Ministry of Health in cooperation with the Belarusian Ministry of Foreign Affairs. The expert examination is intended to contribute to the efforts of the Belarusian authorities’ to bring the regulatory framework on organ and tissue transplantation of the Republic of Belarus closer to the human rights standards of the Council of Europe in the field of transplantation.

The examination is conducted by the following experts. Ms Tesi Aschan is a senior legal adviser for the National Board of Health and Welfare in Sweden and a member of the Committee on Bioethics (DH-BIO) of the Council of Europe. Her main areas of expertise include transplant legislation. Ms Ana M. Pires Silva is a Legal and Ethical Adviser of the Portuguese Institute of Transplantation. She is also the Portuguese National Focal Point on Transplant-Related Crimes and an Expert of the European Committee on Organ Transplantation (CD-P-TO). Mr Kristof Van Assche is a Professor of health law and kinship studies at the University of Antwerp, Belgium. He is a member of the WHO Task Force on Donation and Transplantation of Human Organs and Tissues, of the Ethics Committee of The Transplantation Society and of the Custodian Group of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.

The expert examination involves a legal assessment of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” vis-à-vis their compliance with the standards laid down in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin.

EXPERT EXAMINATION OF THE TRANSPLANT LAW OF THE REPUBLIC OF BELARUS

1 STRUCTURE OF THE EXPERT EXAMINATION

The expert examination of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” was conducted as follows. First, a legal assessment was made of the compliance of the general principles that govern the Belarusian Transplant Law with the general human rights principles (e.g. equitable access; respect for autonomy; prohibition of financial gain) enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol.

Second, a legal assessment was made of the compliance of the provisions of the Belarusian Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol. This part examined whether the Belarusian Transplant Law contains provisions that are clearly incompatible with the Convention on Human Rights and Biomedicine and its Additional Protocol. In addition, attention was paid to provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol that have not been addressed in the Belarusian Transplant Law. Where appropriate, recommendations were formulated to ensure compliance. Finally, suggestions were made on the implementation of certain provisions, with a view to optimising the protection of the rights and freedoms of donors, potential donors and recipients in the light of the principles enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol.

Third, a legal assessment was made of the compatibility of the Draft Law on Amendments to the Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol. Where appropriate, suggestions were made on the implementation of certain provisions.

2 COMPLIANCE OF THE BELARUSIAN TRANSPLANT LAW WITH THE GENERAL HUMAN RIGHTS PRINCIPLES ENSHRINED IN THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE AND ITS ADDITIONAL PROTOCOL

Analysis

The human rights framework that should govern the removal and transplantation of organs and tissues is set out in Article 1 of the Convention on Human Rights and Biomedicine and Article 1 of its Additional Protocol. These provisions indicate that it is essential to “protect the dignity and identity of everyone and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms.” More specifically, the Convention on Human Rights and Biomedicine and its Additional Protocol aim to guarantee that the fundamental rights enshrined in the European Convention on Human Rights will be respected in the field of transplantation, most notably Article 2 (Right to life), Article 3 (Right not to be subjected to inhuman or degrading treatment), Article 8 (Right to respect for private and

family life), and Article 14 (Right not to be subjected to discrimination). As elaborated by the Convention on Human Rights and Biomedicine and its Additional Protocol, several general human rights principles will therefore need to be taken into account in the field of transplantation. These include:

- (1) equitable access to transplantation services for patients, as enshrined in Article 3 of the Convention on Human Rights and Biomedicine and in Article 3 of its Additional Protocol;
- (2) respect for autonomy, as enshrined in Articles 5 and 19 of the Convention on Human Rights and Biomedicine and in Articles 12, 13 and 17 of its Additional Protocol;
- (3) protection of persons unable to consent, as enshrined in Articles 6 and 20 of the Convention on Human Rights and Biomedicine and in Article 14 of its Additional Protocol;
- (4) minimisation of risks and maximisation of benefits, as enshrined in Articles 4 and 19 of the Convention on Human Rights and Biomedicine and in Articles 3, 4, 6, 7, 9 and 11 of its Additional Protocol;
- (5) dignified treatment of the deceased, as enshrined in Articles 16, 17 and 18 of the Additional Protocol;
- (6) confidentiality of personal data, as enshrined in Article 10 of the Convention on Human Rights and Biomedicine and in Article 23 of its Additional Protocol; and
- (7) prohibition of financial gain, as enshrined in Article 21 of the Convention on Human Rights and Biomedicine and in Articles 21 and 22 of its Additional Protocol.

As has also been confirmed by the Constitutional Court of the Republic of Belarus in its Decision No. R-757/2012 on the amendments proposed in 2012, the general principles that govern the Belarusian Transplant Law are in conformity with these human rights standards. First, the Law guarantees the rights of the citizens of the Republic of Belarus to the protection of their life and health by developing transplant resources and by providing equitable access to them. Second, it establishes an adequate balance of rights and legitimate interests among donors and recipients. Through the provisions on consent, donors (living or deceased) are protected against unwilling interference with their body. Special attention is also paid to the protection of persons who are not able to consent, and to the dignified treatment of the deceased. Moreover, a system of safety and quality assurance is established that minimises the risks for living donors and recipients. Third, it prohibits transplant practices that would be an affront to the dignity of the human person, such as the use of the human body and its parts, as such, for financial gain.

Conclusions

The general principles that govern the Belarusian Transplant Law are in conformity with the general human rights framework established by the Council of Europe in the Convention on Human Rights and Biomedicine and its Additional Protocol.

3 COMPLIANCE OF THE BELARUSIAN TRANSPLANT LAW WITH THE PROVISIONS OF THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE AND ITS ADDITIONAL PROTOCOL

A. Examination of potential incompatibilities

The expert examination did not bring to light clear incompatibilities between the provisions contained in the Belarusian Transplant Law and the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol.

Although no clear incompatibilities have been identified, the experts nevertheless consider it advisable to revise several of the provisions contained in the Belarusian Transplant Law so as to ensure their compliance with the Convention on Human Rights and Biomedicine and its Additional Protocol. In what follows, these provisions will be examined and recommendations will be formulated.

1. Living donation of bone marrow and haematopoietic stem cells by minors

Analysis

The Belarusian Transplant Law restricts the legally acceptable categories of living donors of bone marrow and haematopoietic stem cells to competent adults and to minors (unless they are orphans or are deprived of parental care). However, the conditions that govern this type of living donation by minors, stipulated in Articles 7 and 8 of the Law, are currently not completely in accordance with the requirements as set out in Article 20 of the Convention on Human Rights and Biomedicine and in Article 14 of its Additional Protocol.¹ The five requirements listed in these Council of Europe instruments are: (1) there is no compatible donor available who has the capacity to consent; (2) the recipient is a brother or sister of the donor; (3) the donation has the potential to be life-saving for the recipient; (4) the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body; and (5) the potential donor concerned does not object.² In comparison, Article 8 of the Belarusian Transplant Law only explicitly mentions the fourth (written authorisation given by the minor's representative and approved by the competent body, in this case a notary) and the fifth (absence of objection) requirement.

In this regard, it should also be noted that, as explained in paragraph 64 of the Explanatory Report to the Additional Protocol, where living donation is allowed by a person who does not

¹ It should be noted that Article 15 of the Additional Protocol indicates that the conditions on organ and tissue removal from persons unable to consent, as mentioned in Article 14 of the Protocol, should also apply to cells in cases in which the removal of the cells implies more than minimal risk and burden for the donor. Since the removal of bone marrow is performed in operating theatres and requires general anaesthesia and hospitalisation, and since the removal of cells from peripheral blood involves the need to administer growth factors, it can be argued that in both situations the procedure implies more than minimal risk and more than minimal burden for the donor. Consequently, the conditions set in Article 14 of the Additional Protocol apply.

² In this regard, it should be noted that, where it concerns living donation of bone marrow and haematopoietic stem cells by minors, the information should also be provided to the minors themselves and their opinion should be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity. This is in accordance with Article 6 of the Convention on Human Rights and Biomedicine and Article 12 of the Additional Protocol.

have a close personal relationship with the recipient, the independent body that is responsible for ensuring that the conditions for living donation have been fulfilled should also ensure that the other conditions required by law have been met, and that, for example, no coercion or inducement is involved.

Recommendations

To ensure compliance with Article 20 of the Convention on Human Rights and Biomedicine and Article 14 of the Additional Protocol, the Belarusian authorities should consider amending Article 8 of the Transplant Law, so as to require that, at least for non-emancipated minors, the removal of bone marrow and haematopoietic stem cells should only be authorised if, in addition to the two requirements already mentioned in Articles 7 and 8, (1) there is no compatible donor available who has the capacity to consent; (2) the recipient is a brother or sister of the donor; and (3) the donation has the potential to be life-saving for the recipient.

2. Acceptability of living donation

Analysis

As to the question of the acceptability of living donation, Article 8 of the Belarusian Transplant Law is in conformity with the general principle, recognised in the Convention on Human Rights and Biomedicine and its Additional Protocol, that organ or tissue removal from a living person may only exceptionally be carried out and is subject to prior medical examination and approval by an expert committee.

However, it should be noted that the Convention on Human Rights and Biomedicine and its Additional Protocol state additional conditions concerning the appropriateness of the procedure and the health and compatibility of the donor. For instance, Article 19 of the Convention on Human Rights and Biomedicine and Article 9 of the Additional Protocol specify that living donation “may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness”.³

Moreover, Article 11 of the Additional Protocol stipulates that organ or tissue removal “may not be carried out if there is a serious risk to the life or health of the donor” and requires that, before organ or tissue removal, “appropriate medical investigations and interventions shall be carried out to evaluate and reduce physical and psychological risks to the health of the donor”. As explained by paragraph 67 of the Explanatory Report to this Protocol, this implies, on the one hand, that a medical evaluation should be carried out to evaluate the state of health of the intended donor and therefore the physical and the short and long-term psychological risks of donation and, on the other hand, that all reasonable measures should be taken to limit the risks to the donor without compromising the quality or viability of organ or tissues. This explanation indicates that the admissibility of the living donor includes appropriate medical investigations to evaluate and reduce physical risks to the health of the donor, but also a specific psychological evaluation to determine and reduce psychological risks to the donor.

³ In this regard, paragraph 60 of the Explanatory Report to the Additional Protocol explains that haemodialysis or peritoneal dialysis treatment are not considered to provide results in terms of the patient’s quality of life comparable with those obtained by a kidney transplant.

Donors whose donation may pose unacceptable health or psychological risks should be excluded.

Finally, it should be noted that the Transplant Law allows living donation of haematopoietic stem cells by persons who do not have a close personal relationship with the recipient. As indicated above, paragraph 64 of the Explanatory Report to the Additional Protocol indicates in this context that, where living donation is allowed by a person who does not have a close personal relationship with the recipient, the independent body that is responsible for ensuring that the conditions for living donation have been fulfilled should also ensure that the other conditions required by law have been met, and that, for example, no coercion or inducement is involved.

Recommendations

The Belarusian authorities should consider making more explicit (for instance in Article 8 of the Transplant Law) that living organ removal is only allowed if, in addition to the conditions already listed: (1) there is a clear therapeutic benefit for the recipient; (2) there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness; and (3) there is no serious risk to the life or health of the donor.

In addition, the Belarusian authorities should consider making explicit that the prior examination of the living donor also involves a psychological examination.

3. Free and informed consent for living donation

Analysis

Article 8 of the Belarusian Transplant Law indicates that a living organ donor should be informed about the potential deterioration of his or her health due to the organ removal and that this information should be provided in writing by a doctor in charge from the state healthcare institution. Similarly, Article 9 stipulates that a living organ donor has a right to obtain full and objective information on his or her state of health and on the consequences that may occur due to organ removal. Moreover, Article 8 also mentions that coercion of an individual to give his or her consent is prohibited.

Although the provisions on free and informed consent are in conformity with the Convention on Human Rights and Biomedicine and its Additional Protocol, the Additional Protocol also contains additional provisions that are relevant. For instance, Article 12 of the Additional Protocol stipulates that a living organ or tissue donor should beforehand also be given appropriate information as to the purpose and nature of the removal. Whereas this information will normally be required under the general health legislation of the Republic of Belarus, it may be useful to make this explicit in the Transplant Law itself.

In addition, in order to guarantee that the information that is provided is objective, Article 12 of the Additional Protocol requires that the donor should also be informed of the right to access to independent advice about the risks involved. This advice, when requested, should be provided by a health professional with appropriate experience, who is not involved in the organ or tissue removal or transplantation.

Furthermore, Article 13 of the Additional Protocol indicates that the intended living donor may freely withdraw consent at any time. As explained in paragraph 77 of the Explanatory Report to the Additional Protocol, there is no requirement for withdrawal of consent to be in writing or to follow any particular form. Moreover, as explained in paragraph 73 of the Explanatory Report, the person concerned should beforehand also be informed of the right to withdraw consent at any time.

Moreover, it should be noted that, as explained in paragraph 35 of the Explanatory Report to the Convention on Human Rights and Biomedicine and in paragraph 63 of the Explanatory Report to the Additional Protocol, free consent as defined in Article 5 of the Convention on Human Rights and Biomedicine and in Article 13 of the Additional Protocol means that consent is given in the absence of any undue pressure from anyone. Undue pressure is a concept that is considerably more broad than coercion.

Finally, Article 22 of the Convention on Human Rights and Biomedicine and Article 20 of the Additional Protocol stipulate that body parts removed in the course of an intervention may only be stored and used for a purpose other than that for which it was removed, if this is done in conformity with appropriate information and consent procedures. This would mean that surgical residues, such as amniotic membrane, femoral heads and heart valves, may only be used for transplant purposes if before the removal the patient had been informed about the storage and the intended use of the body parts.

Recommendations

To ensure compliance with Articles 12 and 13 of the Additional Protocol, the Belarusian authorities should consider amending, where relevant, Articles 8 and 9 of the Transplant Law to make explicit that the intended living donor: (1) should beforehand also be given appropriate information about the purpose and nature of the removal; (2) should be informed of the right to access to independent advice about the risks involved; (3) may freely withdraw consent at any time and without formal requirements (and should beforehand be informed about this right); and (4) is not under any undue pressure to consent.

In addition, to ensure compliance with Article 22 of the Convention on Human Rights and Biomedicine and Article 20 of the Additional Protocol, the Belarusian authorities should consider amending the Transplant Law to make explicit that surgical residues may only be used for transplant purposes if before the removal the patient had been informed about the storage and the intended use of the body parts.

4. Procedure of certification of death

Analysis

Article 11 of the Belarusian Transplant Law indicates that organ removal from a deceased person is only permitted after the pronouncement of death (more accurately: certification of death). The procedure for the certification of death is regulated in detail in Resolution No. 228 on Approval of the Instruction on the Procedure of Pronouncement of Death. This procedure guarantees that a person's death has been established before organs or tissues are removed. This is in accordance with Article 16 of the Additional Protocol, which states that "organs or tissues shall not be removed from the body of a deceased person unless that person has been

certified dead in accordance with the law”. Importantly, Resolution No. 288 also stipulates that the certification of death is issued by a multidisciplinary council of physicians, who have at least 5 years of practical expertise in the field. As indicated in Article 11 of the Transplant Law and in Resolution No. 288, these physicians should not be involved in the removal of organs or tissue from the deceased person, or in the transplantation of these organs or tissues.

In this regard, it should be noted that Article 16 of the Additional Protocol requires that the physicians who certify the death of a person: (1) should not participate directly in the removal of organs or tissues from the deceased person; (2) should not participate directly in the subsequent transplantation procedures; and (3) should not have any responsibilities for the care of potential organ or tissue recipients.

Recommendations

To ensure compliance with Article 16 of the Additional Protocol, the Belarusian authorities should consider amending Article 11 of the Transplant Law and Resolution No. 288 to the effect that the physicians involved in the certification of death should also not have any responsibilities for the care of potential organ or tissue recipients.

5. Informed consent of the recipient

Analysis

Article 12 of the Belarusian Transplant Law regulates the consent of the recipient and states that transplantation shall be carried out upon the written consent of the prospective recipient, who should before have been informed in writing about the potential deterioration of his or her health that may result from the forthcoming medical intervention.

Although the provisions on consent of the recipient are in conformity with the Additional Protocol, the Additional Protocol also contains additional provisions that are relevant. More specifically, Article 5 of the Additional Protocol stipulates that the prospective recipient (or, where applicable, the person providing authorisation) should receive “appropriate information as to the purpose and nature of the implantation, its consequences and risks, as well as on the alternatives to the intervention”.

Recommendations

To ensure compliance with Article 5 of the Additional Protocol, the Belarusian authorities should consider amending Article 12 of the Transplant Law to make explicit that the prospective recipients should beforehand also be given appropriate information about: (1) the purpose and nature of the implantation; (2) the consequences and risks of the implantation (which will include information on the potential deterioration of health); and (3) the alternatives to the intervention.

6. Living donation of tissues

Analysis

It should be noted that, in the current wording of the Belarusian Transplant Law, the impression may arise that almost all provisions on living donation are restricted to living organ donors, and that living tissue donors are not explicitly addressed. More specifically,

Article 8 (laying down the conditions for removal), Article 9 (stipulating the rights of the living donor), and Article 10 (establishing the liability of the living donor) all apply to “organ retrieval”. Consequently, it may at first sight seem that the Transplant Law for instance does not contain provisions on the procedure of consent for living tissue donation (with the exception of consent for the removal of bone marrow and haematopoietic stem cells from non-emancipated minors). This misunderstanding results from the definition of “organ retrieval” in Article 1 of the Transplant Law, stating that “Organ retrieval shall mean a medical intervention to recover organs and (or) tissues from a living or deceased donor.” On the basis of that definition, it becomes clear that all provisions where reference is made to “organ retrieval” also apply to tissues and that, as a consequence, Articles 8 to 10 also cover living tissue donors. However, to avoid confusion it may be advisable to change the wording of the definition in Article 1 and of the references in Articles 8 to 10.

Recommendations

In order to improve the accuracy of the definitions used in the Transplant Law and to avoid the impression that the provisions on living donation are restricted to living organ donors, Belarusian authorities should consider replacing in Article 1 the term “Organ retrieval” by “Organ and (or) tissue retrieval”. Similarly, where in Articles 8 to 10 reference is made to “organ retrieval”, it would be advisable to replace this, where relevant, by “organ and (or) tissue retrieval”.

7. Prohibition of financial gain

Analysis

The Belarusian Transplant Law stipulates in its Article 5 that organs and tissues “shall not be objects of civil transactions except for unrequited ones” and that “compensated transactioning and advertising of an offer and/or a demand for human organs and/or tissues shall be banned”. Moreover, Article 9 contains a list of expenses and damages eligible for compensation.

The prohibition of financial gain – the principle that organs and tissues should not be bought or sold or give rise to direct financial gain or comparable advantage for the person from whom they have been removed or for a third party – is well-established and can be found in Article 21 of the Convention on Human Rights and Biomedicine and in Articles 21 and 22 of its Additional Protocol.⁴ Importantly, as stipulated in Article 21 of the Additional Protocol, the prohibition does not prevent: (1) compensation of living donors for loss of earnings and other justifiable expenses caused by the removal or by the related medical examination; (2) payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation; and (3) compensation in case of undue damage resulting from the removal of organs or tissues from living persons.

Closely connected to the principle of prohibition of financial gain is the principle of prohibition of advertisement – the prohibition to advertise the need for, or the availability of,

⁴ See for more guidance, the Guide for the Implementation of the Principle of the Prohibition of Financial Gain with Respect to the Human Body and its Parts from Living or Deceased Donors, adopted by the Committee on Bioethics of the Council of Europe at its 12th meeting on 26-27 October 2017.

organs or tissues, with a view to offering or seeking financial gain or comparable advantage. That principle is also laid down in Article 21 of the Additional Protocol.

Although Articles 5 and 9 of the Transplant Law are in accordance with the Convention on Human Rights and Biomedicine and its Additional Protocol, several elements have been identified that could be addressed to ensure conformity. First, the principle of unpaid and voluntary donation could be made clearer in this context. Even if “compensated transactioning” and required “civil transactions” are banned, altruistic and voluntary donation should be made clear as the fundamental underlying principle. The present wording of the ban does not contain a clear statement of this principle with reference to human rights and dignity, and does not seem to include a clear ban for compensation in other kind than money (i.e. comparable advantage).

Second, to the extent that Article 9 of the Transplant Law does currently not cover: (1) compensation of costs incurred by (potential) donors before donation (e.g. pre-operative screening costs); (2) compensation of all of the costs incurred by donors post-donation (e.g. expenses related to the medical follow-up); (3) loss of income by (potential) donors linked to the donation; and (4) compensation in the event of complications resulting from the donation, these elements could be included. Where appropriate, it may for instance be useful to rephrase the provision in Article 9 of the Transplant Law in the light of the wording used in Article 21 of the Additional Protocol.

Third, it should be pointed out that, whereas Article 26 of the Additional Protocol requires that appropriate sanctions should be applied in the event of infringement of the provision prohibiting financial gain, no sanctions are provided in the Transplant Law itself. To the extent that other legislation – for instance Articles 164 and 348 of the Criminal Code – do not attach sanctions to the infringements of the prohibitions of financial gain and advertisement, this may need to be addressed.⁵

Recommendations

To ensure compliance with Article 21 of the Convention on Human Rights and Biomedicine and Articles 21 and 22 of its Additional Protocol, the Belarusian authorities should consider amending Article 5 of the Transplant Law to make more explicit: (1) the principle that donation of organs and tissues is free; and (2) the prohibition of transactions for financial gain and comparable advantage.

In addition, it may be useful for the Belarusian authorities to consider rephrasing the provision in Article 9 of the Transplant Law, so as to guarantee coverage of: (1) compensation of costs incurred by (potential) donors before donation; (2) compensation of all of the costs incurred by donors post-donation; (3) loss of income by (potential) donors linked to the donation; and (4) compensation in the event of complications resulting from the donation.

To ensure compliance with Article 26 of the Additional Protocol, the Belarusian authorities should consider attaching clear sanctions to the infringements of the prohibitions of financial

⁵ Where appropriate, attention could also be paid to the Council of Europe Convention against Trafficking in Human Organs, which requires that a whole range of offences relating to illicit organ removal (including where an organ is removed for financial gain or comparable advantage) are established as a criminal offence under domestic law.

gain and advertisement, to the extent that this has not yet been properly addressed by other national legislation.

B. Examination of potential gaps

The expert examination has brought to light that several provisions of the Convention on Human Rights and Biomedicine and of its Additional Protocol have not been explicitly addressed in the Belarusian Transplant Law. The experts consider it advisable to revise some aspects of the Belarusian Transplant Law so as to give expression to these provisions and thereby ensure the compliance of the Transplant Law with the Convention on Human Rights and Biomedicine and its Additional Protocol. In what follows, these gaps will be examined and recommendations will be formulated.

1. Removal and transplantation of cells

Analysis

Article 2 of the Belarusian Transplant Law restricts the field of application of the Law to the field of transplantation of human organs and tissues, and does not include human cells intended for transplantation, with the exception of haematopoietic stem cells.

The field of the application of the Belarusian Transplant Law resembles the field of application of the Additional Protocol, as indicated in its Article 2. However, it should be noted that Article 2 of the Additional Protocol states that the provisions of the Protocol that are applicable to tissues also apply to cells. Therefore, the removal and transplantation of any kind of cells are subject to the same conditions. As indicated in paragraph 20 of the Explanatory Report to the Protocol, the transplantation of human cells generally poses problems similar to those related to the transplantation of organs and tissues, particularly the consequences of testing and traceability. Moreover, the provisions concerning informed consent or authorisation by or on behalf of the donor, confidentiality, health and safety, and the prohibition of financial gain also apply to cells as they do for tissues.

From the information provided to the experts by the designated state authorities for the purpose of the current expert examination, they have not been able to determine whether in the Republic of Belarus the removal and transplantation of cells, other than haematopoietic stem cells, is governed by specific legislation. To the extent that this would not be the case and to the extent that cells are currently excluded from the scope of the Transplant Law, it should, in the light of the explanation provided in the Explanatory Report to the Protocol, be considered to explicitly include cells within the field of application of the Transplant Law. Having in mind other possibilities of human application (e.g. cells from cord blood), the inclusion of cells in the scope of the Law would also avoid the need to amend the Law in the future if that possibility would become reality in the Republic of Belarus.

If no specific legislation exists and the Belarussian authorities would decide not to include cells in the scope of the Transplant Law, it may be advisable that another legal instrument or guidelines or codes of practice are adopted that regulate the removal and transplantation of the cells and that specify, where relevant, similar conditions than the ones that apply to the removal and transplantation of organs and tissues.

Recommendations

To the extent that no specific legislation governing the removal and transplantation of cells currently exists and to the extent that cells are currently excluded from the scope of the Transplant Law, the Belarussian authorities should consider including cells in the scope of the Transplant Law or adopting another legal instrument or guidelines or codes of practice that specify, where relevant, similar conditions for the removal and transplantation of cells than the ones that apply to the removal and transplantation of organs and tissues.

2. Medical follow-up of the living donor and the recipient

Analysis

The Belarussian Transplant Law does not contain any provisions on the issue of the medical follow-up of the living donor and the recipient, with a view to monitoring and guaranteeing their long-term health.

However, Article 7 of the Additional Protocol requires that “appropriate medical follow-up shall be offered to living donors and recipients after transplantation”. Medical follow-up is a condition for the eligibility of living donors because they have a greater potential for developing medical and psychosocial complications in the short and the longer term without adequate follow-up. Living donors should beforehand be informed about the medical-follow that will be provided and the expenses related to the medical follow-up should be covered. Furthermore, paragraph 56 of the Explanatory Report to the Additional Protocol explains that the nature and duration of such follow-up depend on the nature of the intervention and its potential health impact, but that life-long follow-up is essential for recipients requiring immunosuppressive therapy and is also desirable for living organ donors to enable any long-term effects of the donation to be identified.⁶

The information provided to the experts by the designated state authorities for the purpose of the current expert examination indicate that follow-up of living donors is conducted in the transplantation center in Minsk. However, the experts have not been able to determine for how long this follow-up is provided and whether there is a systematic follow-up of recipients.

Recommendations

To ensure compliance with Article 7 of the Additional Protocol, the Belarussian authorities should consider including in the Transplant Law a specific provision stipulating that appropriate medical follow-up shall be offered to living donors and recipients after transplantation.

3. Traceability of organs and tissues

Analysis

⁶ The need to provide appropriate follow-up is also advocated in other Council of Europe instruments, including in Resolution CM/Res(2008)4 and Resolution CM/Res(2013)56. In addition, as indicated in Resolution CM/Res(2015)11, collecting data on medical follow-up of living donors in a living donor registry, would allow to document and report risks, to document living donor prognoses, to investigate causal relationships between pre-donation risk factors and future prospects, and to improve follow-up of living donors.

The Belarusian Transplant Law does not contain any provisions on traceability⁷ of organs and tissues.

In this regard, it should be noted that Article 3 of the Additional Protocol indicates that it is necessary to “ensure the collection and recording of the information required to ensure traceability of organs and tissues”. As explained in paragraph 39 of the Explanatory Report to this Protocol, in view of the risk of transmission of disease through transplantation, traceability is essential both for public health reasons and to inform donors or recipients of potential problems.

There is a measure of traceability as far as the organs and tissues removed from deceased persons are concerned, in that, as indicated in Resolution No. 2 on Approval of Instructions for Procedure of Tissue and/or Organ Retrieval from Deceased Donor, one copy of all relevant information is kept in the medical record and another follows the graft to the centre of organ transplantation. In the light of Council of Europe proposals and international best practice, Belarusian authorities may, when useful in the context of the Belarusian transplant system, consider establishing a centralised system, preferably a registry, for the traceability of all organs and tissues removed, allocated, and transplanted in the Republic of Belarus. Where relevant, the responsibility for this registry should be entrusted to a dedicated authority (National Transplant Authority).

Recommendations

Belarusian authorities should consider explicitly addressing in the Transplant Law the importance of the traceability of all organs and tissues removed, allocated, and transplanted in the Republic of Belarus.

When useful in the context of the Belarusian transplant system, Belarusian authorities may consider establishing a centralised registry of traceability and entrusting responsibility for this registry to a dedicated authority.

4. Confidentiality and anonymity

Analysis

The Belarusian Transplant Law does not pay specific attention to the issues of confidentiality and anonymity.

However, it should be noted that the principle of confidentiality in the field of tissue and organ transplantation is emphasised in Article 23 of the Additional Protocol. More specifically, it is required that all personal data relating to the donor and the recipient have to be considered to be confidential and that these may only be collected, processed and communicated according to the rules of professional confidentiality and data protection. For legally justified purposes, such as for traceability and checking of the Transplantation Register, appropriate access can

⁷ Traceability is defined as “Ability to locate and identify an organ at each stage in the chain from donation to transplantation/disposal, including the ability to identify the donor, the donor hospital and the recipient(s) at the transplant centre(s), and to locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.” See European Committee on Organ Transplantation, *Guide to the Quality and Safety of Organs for Transplantation*, 2016, 305, available for downloading at <https://register.edqm.eu/freepub>.

be granted to healthcare professionals authorised to that aim. The protection of the anonymity of the donor and the recipient is also covered by the general provisions of confidentiality enshrined in Article 23 of the Additional Protocol. Similarly, Guiding Principle 11 of the WHO Guiding Principles stipulates that the anonymity and privacy of donors and recipients should always be protected. More specifically, except where the donor and the recipient know each other in the context of living donation, the identity of the donor should not be disclosed to the recipient and the identity of the recipient should not be disclosed to (the family of) the donor.

As to the protection of confidentiality in the field of tissue and organ transplantation in the Republic of Belarus, the information provided to the experts by the designated state authorities for the purpose of the current expert examination indicate that personal data as well as the information about the waiting list can only be accessed by the relevant medical staff and the persons involved. It is furthermore indicated that data protection in this field will more generally be covered by the Law No. 455-3 on Information, Informatization and Data Protection. This Law stipulates that personal data are protected, that the safety and security of these data are ensured when using information and information technologies, and that personal data can only be collected, processed and stored with the written consent of the individual concerned or on the basis of other grounds stipulated in the legislative acts of the Republic of Belarus (which would include transplant purposes).

Although it can be concluded that Belarusian legislation is in conformity with the standards set out in Article 23 of the Additional Protocol, it should be noted that, as highlighted above, the Law does not contain provisions on traceability. When the establishment of a system of traceability of organs and tissues would be considered, the confidentiality of personal data should also be guaranteed in this context.

In addition, it should be noted that in many countries (e.g. Belgium, Germany, Portugal) the issue of confidentiality is directly addressed in the transplant legislation itself. Where this is the case, the security measures in place to prevent unauthorised access and disclosure, and the conditions for granting authorisation are often described in considerable detail, and dissuasive sanctions are included. Similarly, although the requirement of anonymity might already be sufficiently protected by the Law No. 455-3 on Information, Informatization and Data Protection, it should be noted that in many countries (e.g. Belgium, Portugal, Romania) this issue is directly addressed in the transplant legislation itself.

Recommendations

To ensure compliance with Article 23 of the Additional Protocol, the Belarusian authorities should consider directly addressing in the Transplant Law the principle of confidentiality.

Furthermore, the Belarusian authorities should consider including in the Transplant Law a provision so as to guarantee the anonymity of donors and recipients who are not related.

C. Suggestions for implementation

Apart from the recommendations contained in the previous section, the expert examination has also resulted in a number of suggestions for the implementation of certain provisions of the Belarusian Transplant Law in the light of the provisions of the Convention on Human

Rights and Biomedicine and its Additional Protocol and in the light of practical proposals formulated in other relevant Council of Europe instruments (see attached the list of relevant instruments in the Appendix).

1. Transplant centres and healthcare personnel

Analysis

Article 6 of the Belarusian Transplant Law indicates that, unless otherwise provided for by law, “organ retrieval and transplantation shall be carried out only by state health care institutions”. Similarly, it is apparent from Article 5 of the Belarusian Transplant Law, Decree No. 134 on Certain Issues in Transplanting Human Organs and Tissue, and Resolution No. 2 on Approval of Instructions for Procedure of Tissue and/or Organ Retrieval from Deceased Donor that the medical opinion on the necessity of transplantation, the removal of organs from (deceased) donors, and the performance of transplantation are the exclusive prerogative of medical specialists affiliated with these accredited institutions.

These provisions are in accordance with the standards of the Council of Europe on the quality and safety requirements for transplantation centres and healthcare personnel. The importance of quality and safety assurance concerning procurement and transplant centres and concerning healthcare personnel is emphasised in several provisions of the Additional Protocol, most notably by Articles 3, 4 and 6. It is proposed in Recommendation Rec(2006)15 of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation to practically implement these quality and safety standards by: (1) accrediting and monitoring procurement and transplantation centres; and (2) accrediting healthcare personnel and developing training programmes, and to entrust these tasks to the transplant regulatory body. In this view, it may be advisable for the Belarusian authorities to more explicitly and comprehensively regulate the quality and safety requirements for procurement and transplant centres and for healthcare personnel.

Suggestions

To the extent that this would not yet be the case, the Belarusian authorities might consider emphasising in the Transplant Law or in a supplementing decree or other regulatory instrument the importance of the following aspects: (1) removal and transplantation of organs and tissues can only be performed in centres licensed for the purpose of those activities; (2) removal and transplantation of organs and tissues can only be carried out by suitably qualified healthcare personnel; (3) removal and transplantation of organs and tissues can only take place in appropriately constructed, maintained and operated facilities which are properly equipped. It is advisable that the responsibility for supervision and control is entrusted to a dedicated authority (National Transplant Authority).

2. System of vigilance

Analysis

The Belarusian Transplant Law does not contain specific provisions on the establishment of a system of vigilance.

In this regard, and as outlined above both in the context of traceability and in the context of requirements for transplantation centres and healthcare personnel, it should be noted that the importance of quality and safety assurance is emphasised in several provisions of the Additional Protocol, most notably by Articles 3, 4 and 6. Apart from focusing on the establishment of a system of traceability, Council of Europe instruments propose to practically implement the quality and safety standards for organs and tissues by the establishment of reporting systems and registries.

More specifically, Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes, Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing, and Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors recommend the development of a national registry where information is collected on living donation and on the outcomes after donation, such as data on the donor and the recipient, the hospital(s) involved, the surgical procedure, including major donation-related complications, and the follow-up of the donor. Similarly, the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, in particular Guiding Principles 10 and 11, call on health authorities to implement a quality system that monitors the results of living donation and transplantation and that allows reporting and management of serious adverse events and reactions.⁸

The establishment of a national registry of living donors and of a central reporting and management system for serious adverse events and reactions would allow transplant authorities to identify, report and manage any serious adverse event relating to the quality and safety of the donated organ, with consequences for the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.⁹ In addition, it would guarantee and improve the long-term follow-up of the living donor. In this regard, it should be noted that it is international best practice to establish an integrated system of vigilance. Such an integrated system of vigilance, which for instance is in place in all Member States of the European Union, consists of: (1) a centralised system for traceability of organs and tissues; (2) a national living organ donor registry; and (3) a central reporting and management system for serious adverse events and reactions. In this way, quality and safety is maximally ensured at all levels and clinical practice is benefiting maximally.

Currently, as indicated in Article 10² of the Transplant Law, the Uniform Registry of Transplantation only includes information on the persons who underwent transplantation,

⁸ A serious adverse event is defined as “Any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation of an organ or associated with the procurement, testing, processing, storage and distribution of tissues and cells, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.” A serious adverse reaction is defined as “An unintended response – including a communicable disease, in the donor or in the recipient that might be associated with any stage of the chain from donation to transplantation of an organ or associated with the procurement or human application of tissues and cells – that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.” See European Committee on Organ Transplantation, *Guide to the Quality and Safety of Organs for Transplantation*, 2016, 303.

⁹ Such a registry would need to include the parameters listed in Resolution CM/Res (2015)11 and its Explanatory Memorandum.

those who declared objection to post-mortem removal, and, subject to the adoption of the Draft Law, on persons from whom organs have been removed. Where Belarusian authorities would also consider the establishment of an integrated system of vigilance, consisting of the three components outlined in the previous paragraph, it would be advisable to opt for two separate registries. One registry would include information on persons who declared objection to post-mortem removal; and the other registry would include information on: (1) persons who have undergone transplantation; (2) persons from whom organs and tissues have been removed; (3) living donation and the outcomes after donation; (4) traceability of organs and tissues; and (5) serious adverse events and reactions. Both registries have different purposes and the access to the personal data contained in them should be in conformity with those purposes so as to avoid unauthorised access.

Suggestions

In order to improve the quality and safety of the donation and transplantation process, the Belarusian authorities might consider establishing an integrated system of vigilance, consisting of: (1) a centralised system for traceability of organs and tissues; (2) a national living organ donor registry; and (3) a central reporting and management system for serious adverse events and reactions.

3. Transplant waiting list

Analysis

The issue of transplant waiting lists and, more generally, of equitable access to transplantation, is not directly addressed in the Belarusian Transplant Law. In this regard, the information provided to the experts by the designated state authorities for the purpose of the current expert examination indicate that specific waiting lists are in place for liver, heart and lung transplantation, which are managed by concilium of doctors, and that the waiting list for kidney transplantation is determined by computer software in accordance with multiple criteria. It can therefore be concluded that the decision on the necessity for transplantation and the allocation criteria are defined by an expert committee and guided by medical considerations.

The right to equitable access to transplantation is stipulated in Article 3 of the Additional Protocol. In addition, a general prohibition of discrimination in this field can be found in Article 1 of the Convention on Human Rights and Biomedicine and in Article 1 of its Additional Protocol. More specifically, as explained in paragraph 36 of the Explanatory Report to the Additional Protocol, equitable access implies that all citizens must be equally able to make use of available transplant services, including to be put on the transplant waiting list. In addition, Article 3 of the Additional Protocol and Recommendation No(2001)5 of the Committee of Ministers to member states on the management of organ transplant waiting lists state that organs removed from deceased persons should only be allocated to patients registered on an official waiting list and that allocation should happen in conformity with transparent, objective and duly justified rules according to medical criteria.

Suggestions

Although it can be presumed that, as regards transplant waiting lists, Belarusian transplant practice is in accordance with Article 3 of the Additional Protocol and Recommendation No(2001)5 of the Committee of Ministers to member states on the management of organ transplant waiting lists, it may nevertheless be advisable to more explicitly address both the organisation and maintenance of transplant waiting lists (e.g. through special registries) and the rules of allocation either directly in the Transplant Law or in its supplementing decrees.

4. Supervision of national transplant activities

Analysis

As indicated in its Article 3, the Belarusian Transplant Law provides a legal framework for the Belarusian transplantation system, that operates under the general control of the Ministry of Health of the Republic of Belarus.

This is in conformity with Article 3 of the Additional Protocol, which contains provisions on the establishment of a transplantation system. In this regard, it should be noted that it is recommended in Recommendation No(2006)15 of the Committee of Ministers to member states on the background, functions and responsibilities of a National Transplant Organisation to clearly set out the structure of the transplant system, its powers and responsibilities, and to entrust overall responsibility preferably to a single public body (i.e. a national transplant organisation (NTO)). Although the Republic of Belarus has entrusted some responsibilities to the Unified Transplantation Register department, the Belarusian Transplant Law does not designate a dedicated National Transplant Organisation responsible for the supervision of transplantation activities. From the information provided to the experts by the designated state authorities for the purpose of the current expert examination, the experts have not been able to determine whether there exists a dedicated national transplant organisation or whether control resides with the Ministry of Health or has partially been assigned to specific institutions, such as the Minsk Scientific-Practical Centre of Surgery, Transplantology and Haematology (former Republican Scientific and Practical Center for Organ and Tissue Transplants).

However, to the extent that no National Transplant Organisation has been established at this moment, it may be useful to consider doing so, with a view to improving the coordination and supervision of the Belarusian transplant system. More specifically, a National Transplant Organisation could be entrusted with the tasks highlighted in the recommendations and suggestions outlined above: (1) establishing and monitoring the quality and safety requirements for procurement and transplant centres and for healthcare personnel; (2) operating the Uniform Registry of Transplantation; (3) establishing and operating an integrated and centralised system of vigilance; and (4) guaranteeing equitable access to transplantation services for patients, including by managing the waiting list and ensuring fair allocation of organs and tissues.

Suggestions

To the extent that this would not yet be the case, the Belarusian authorities might consider establishing a National Transplant Organisation entrusted with the coordination of the Belarusian transplant system and the operation and monitoring of: (1) the quality and safety requirements for procurement and transplant centres and for healthcare personnel; (2) the

Uniform Registry of Transplantation; (3) a centralised system of vigilance; and (4) equitable access to transplantation services for patients.

5. International cooperation and organ exchange

Analysis

Article 4 of the Belarusian Transplant Law establishes the basis for international cooperation in transplantation. As indicated in the information provided to the experts by the designated state authorities for the purpose of the current expert examination, there currently are no official international treaties in place and exchange programmes will only start in 2019 after the expected adoption of the amendments to the Transplant Law.

In this regard, it should be noted that, to be in conformity with Article 3 of the Additional Protocol, the procedures for distribution of organs should take into account the principle of solidarity within each country. Moreover, appropriate safeguards would need to be provided to ensure adequate data protection and quality and safety of organs and tissues. From the information provided for this assessment, the experts have not been able to determine whether legislation or supplementing decrees governing the requirements for future organ exchange have already been issued. Where this would not be the case, it would be advisable for the Belarusian authorities to consider adopting regulation that incorporates specific provisions intended to ensure that the imported organs comply with the same standards as the ones that apply to organs removed and transplanted in the Republic of Belarus, in terms of quality and safety assurance.

Moreover, to the extent that the international organ exchange program would possibly also involve international exchange of kidneys from living donors, it is important to first implement an effective national kidney exchange program, so as to prevent organ trafficking (see also below in the examination of the proposed provisions on cross-transplantation).

Suggestions

To the extent that this would not yet be the case, the Belarusian authorities might consider: (1) adopting regulations on international cooperation, incorporating provisions ensuring that imported organs comply with the same quality and safety standards that apply to organs removed and transplanted in the Republic of Belarus; and (2) putting in place first an effective national kidney exchange program so as to prevent organ trafficking.

6. Donation after death

Analysis

The consent regime for post-mortem removal is laid down in Article 11 of the Belarusian Transplant Law. The Law operates a presumed consent system, in that it regards the absence of a statement indicating objection against organ removal after death as presumed consent to become a deceased donor. At the same time, in case a person had not expressed objection, organs can only be removed if the individual's close relatives or legal representatives do themselves not object to the removal. The right to express objection and the procedure for exercising this right are regulated by Articles 10¹ and 11 of the Law. Moreover, Article 10²

establishes a Uniform Registry of Transplantation where Belarusian citizens can register objections to post-mortem organ removal.

The Belarusian regime of consent for post-mortem removal of organs and tissues is in accordance with Article 17 of the Additional Protocol, which indicates that “organs and tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained” and that “removal shall not be carried out if the deceased person had objected to it”. In this regard, it is interesting to note that paragraphs 98 to 102 of the Explanatory Report to the Additional Protocol specify that, if persons have made known their wishes during their lifetime, these wishes should be respected after their death, and that, if the wishes of the deceased are not sufficiently established, efforts should be made to obtain testimony from close relatives. Moreover, it is stated that, unless national law provides otherwise, such authorisation should not depend on the close relatives’ own preferences regarding donation.

In the light of the explanations provided in the Explanatory Report to the Additional Protocol, it may be advisable for the Belarusian authorities to consider, to the extent that this possibility is not yet offered, to implement an easily accessible system of binding declarations of willingness regarding post-mortem organ removal for transplantation.¹⁰

Similarly, the explanations provided in the Explanatory Report indicate that the Additional Protocol has a strong preference that, if upon death of a person testimony is obtained from close relatives, these close relatives should be asked about the deceased person’s expressed or presumed wishes. This principle is also apparent from the central importance of the right to self-determination in the Convention on Human Rights and Biomedicine and its Additional Protocol. Although national law may provide otherwise and may make the authorisation dependent upon the close relatives’ own preferences regarding donation, it may be advisable for the Belarusian authorities to consider amending the Transplant Law to emphasise that the spouse, the close relatives or lawful guardians of the deceased person should primarily decide on the basis of the deceased person’s expressed or presumed wishes.

Suggestions

To the extent that this would not yet be the case, the Belarusian authorities might consider implementing an easily accessible system of binding declarations of willingness regarding post-mortem organ removal for transplantation.

In addition, the Belarusian authorities might consider amending Article 11 of the Transplant Law to the effect that a possible declaration of objection on the part of the spouse, the close relatives or lawful guardians should be primarily based on the deceased person’s expressed or presumed wishes.

7. Information for health professionals and the public

Analysis

¹⁰ As has been introduced in some other countries, it may for instance be considered to also include in the Unified Transplantation Register information on persons who have declared their willingness regarding post-mortem organ removal for transplantation.

The Belarusian Transplant Law does not contain any provisions on providing health professionals and the general public with relevant information about organ and tissue transplantation.

In this regard, it should be noted that Article 8 of the Additional Protocol requires the provision of information for health professionals and for the public on the need for organs and tissues, as well as on the conditions relating to removal and transplantation. The first type of information should emphasise the significance, in terms of solidarity, health policy and therapeutic means, of organ and tissue transplantation. Relatedly, Article 19 of the Additional Protocol stipulates that all appropriate measures should be taken to promote the donation of organs and tissues.

The second type of information mentioned in Article 8 of the Additional Protocol includes information about the regime of consent or authorisation, in particular where it concerns removal from deceased persons. Along the same lines, the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, in particular in the commentary to Guiding Principles 1, state that, given the ethical importance of consent, a presumed consent system of opting-out should ensure that people are fully informed about the policy and are provided with an easy means to opt out.

In order to respect the rights provided for in Article 8 of the Additional Protocol, the consent regime in place in the Republic of Belarus would require extensive efforts in informing the public about the existence of the Unified Transplantation Register and the consequence (presumed consent) of not registering their possible objection to the removal of organs and tissues after their death. This information should be made accessible and be understandable for all people concerned. It is not clear from the information provided for this assessment to what extent and how health professionals and the public are informed about the consent regime in place in the Republic of Belarus, the right to state their objection to organ and tissue removal after death, and the existence of, and access procedure to, the Unified Transplantation Register. In this regard, it may be pointed out that the Constitutional Court Decision No. R-757/2012 on the amendments proposed in 2012, calls upon the authorities to “define a clear mechanism for informing citizens about the current presumption of their consent for organ harvesting for transplantation in the absence of the relevant expression of a lack of consent from a citizen or his/her close relatives or legal representatives”.

It is similarly not clear from the information provided for this assessment to what extent and how health professionals and the public are informed on the need for organs and tissues and to what extent and how organ and tissue donation is promoted. If this would not yet be the case, information campaigns and promotion activities would need to be considered. In accordance with the Guide for the Implementation of the Principle of the Prohibition of Financial Gain, adopted by the Committee on Bioethics (DH-BIO) and the European Committee on Organ Transplantation (CD-P-TO), these could consist of awareness-raising campaigns (e.g. European Day for Organ Donation and Transplantation), or information on governmental websites or websites of donation centres.

Suggestions

The Belarusian authorities might consider explicitly addressing in the Transplant Law the importance of informing health professionals and the public about the need for organs and tissues, as well as about the conditions relating to removal and transplantation, including the regime of consent or authorisation for donation after death.

To the extent that comprehensive information and awareness-raising campaigns are currently not yet being conducted, the Belarusian authorities might consider initiating such campaigns.

4 COMPLIANCE OF THE DRAFT LAW ON AMENDMENTS TO THE BELARUSIAN TRANSPLANT LAW WITH THE PROVISIONS OF THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE AND ITS ADDITIONAL PROTOCOL

Apart from the recommendations and suggestions contained in the previous sections, the expert examination has also resulted in a number of suggestions for the implementation of certain provisions of the Draft Law on Amendments to the Transplant Law, in the light of the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol and in the light of practical proposals formulated in other relevant Council of Europe instruments (see attached the list of relevant instruments in the Appendix).

1. International cooperation and organ exchange

Analysis

The Draft Law on Amendments to the Transplant Law proposes to supplement Article 4 of the Belarusian Transplant Law, which establishes the basis for international cooperation in transplantation, with two additional provisions. According to the first provision, the Ministry of Health shall decide on the need to import and export organs and/or human tissue to/from the Republic of Belarus at no charge in order to select optimal donor-recipient pairs. According to the second provision, human organs and tissue shall be imported to and exported from the Republic of Belarus for transplantation taking into account the requirements established by the legislation of the Republic of Belarus, international treaties of the Republic of Belarus, and acts constituting the law of the Eurasian Economic Union. International cooperation and, more specifically, organ exchange with the FOEDUS International Organ Exchange Organisation, is expected to contribute to the further development of transplantation in the Republic of Belarus. As indicated in the information provided to the experts by the designated state authorities for the purpose of the current expert examination, official international treaties on organ exchange are expected to be signed in the near future and exchange programmes will start in 2019, subject to the adoption of the amendments to the Transplant Law.

It should be emphasised that initiating international organ exchange is important in the light of Articles 3 and 27 of the Additional Protocol. More specifically, as explained in paragraph 135 of the Explanatory Report to the Additional Protocol, “difficulties of tissue matching or the urgency of the clinical condition may require access to a large or very large population if the transplant is to be successful”. It is therefore recommended to put arrangements in place to allow an organ that becomes available in a country which has no suitable patient on its waiting list, to be offered rapidly to patients on other transplant waiting lists if the organ is not to be wasted. Countries are expected to set up transborder links so as to facilitate the exchange of

information and the transportation of organs and tissues between states. The proposed amendment to Article 4 of the Belarusian Transplant Law is completely in line with these recommendations.

As already discussed above, it should be noted that, to be in conformity with Articles 3 and 27 of the Additional Protocol, the procedures for distribution of organs should take into account the principle of solidarity within each country and appropriate safeguards would need to be provided to ensure adequate data protection and quality and safety of organs and tissues.¹¹ From the information provided for this assessment, the experts have not been able to determine whether legislation or supplementing decrees governing the requirements for future organ exchange have already been issued. Where this would not be the case, it would be advisable for the Belarusian authorities to consider adopting regulation that incorporates specific provisions intended to ensure that the imported organs comply with the same standards as the ones that apply to organs removed and transplanted in the Republic of Belarus, in terms of quality and safety assurance.

Suggestions

As already outlined above, the experts suggest that, to the extent that this would not yet be the case, the Belarusian authorities might consider adopting regulations on international cooperation, incorporating provisions ensuring that imported organs comply with the same quality and safety standards that apply to organs removed and transplanted in the Republic of Belarus.

2. Acceptable living organ donor categories

Analysis

In its Article 7, the Belarusian Transplant Law lists who could not legally qualify as a living donor. The list of legally acceptable categories of living organ donors is currently restricted to competent adults who are “close relatives”, defined as parents, adoptive parents, children, including adopted ones, siblings, grandparents and grandchildren. As proposed in the Draft Law on Amendments to the Transplant Law, the acceptable categories of living organ donors will be expanded to include competent adults who are “relatives”, defined as spouses, blood relatives up to the third degree, adoptive parents, adopted children, stepsons, or stepdaughters. In addition, cross-transplantation of an organ will become possible (see below for a legal analysis), in which case there are no restrictions to relatives since the living donor will be the intended living donor of the other pair. The Explanatory Note on the necessity of adoption of the Draft Law makes clear that the purpose of this proposed amendment is to expand, in a legally and ethically appropriate way, the categories of individuals who could be considered living related organ donors, so as to increase the number of organs that would become available from living donors.

¹¹ In this regard, it should be noted that the FOEDUS international organ requires the collection and recording of the information required to ensure traceability of organs and tissues, characterisation of the donor and organs, follow-up data of the recipient, and reporting of occurrence of serious incidents and adverse reactions to the competent authorities with no delay.

This expansion is in line with the recommendation contained in Resolution CM/Res(2013)56 to “optimise programmes for kidney donation from live donors based on recognised ethical and professional standards as a better way to pursue self-sufficiency in transplantation” and to “consider more extensive use of live kidney donors through the removal of technical barriers”.

In this regard, it should also be pointed out that, as explained in paragraphs 63 and 64 of the Explanatory Report to the Additional Protocol, Article 10 of the Additional Protocol requires a cautious approach “to prevent undue pressure to donate being brought to bear on people without a strong emotional relationship with the recipient.” Where living organ donation is considered by persons who are not in a close relationship with the recipient, the Explanatory Report states that additional conditions may be necessary, such as involving an appropriate independent body responsible for ensuring that, for example, no coercion or financial inducement is involved. Such conditions would act as an important safeguard against potential organ trafficking.

In this respect, it is interesting to note that this concern is addressed in the proposition in the Draft Law to supplement Article 8 of the Transplant Law to the effect that organ removal from a living donor who is not a close relative of the recipient would only be allowed after the state healthcare organisation, in coordination with the internal affairs authorities, has issued a decision on the feasibility of organ removal. The decision on the feasibility of organ removal is based on an assessment that ascertains the conditions specified in Article 5, paragraph 4 of the Transplant Law, including the absence of financial transactions or advertisement.

It should be noted that one expert engaged in the legal examination was of the opinion that, for all cases of living donation, the fulfilment of the conditions – including free and informed consent and the absence of financial transactions or advertisement – would best be assessed by a specific and multidisciplinary ethics committee at the level of the state healthcare organisation.

Conclusions

It is concluded that the proposal in the Draft Law on Amendments to the Transplant Law to expand the acceptable categories of living organ donors is in conformity with the provisions of the Additional Protocol and other relevant instruments of the Council of Europe.

3. Cross-transplantation

Analysis

As indicated above, the Draft Law on Amendments to the Transplant Law also offers the possibility that, at national level or within the framework of international cooperation, a system of cross-transplantation (more accurately defined as “paired exchange” or “cross-over transplantation”) will be established. As stated in the Explanatory Note on the necessity of adoption of the Draft Law, cross-transplantation “makes it possible to solve problems that arise in the event of genetic incompatibility between the donor and the recipient”. If such problems would arise, they could be solved by involving another incompatible pair, where the donor from the first pair is genetically compatible with the recipient from the second pair, and the donor from the second pair is compatible with the recipient from the first pair.

Where neither of the donors receive any kind of financial benefit, except for reimbursements of costs related to the donation, cross-transplantation may be fully compatible with Article 21 of the Convention on Human Rights and Biomedicine and Article 21 of the Additional Protocol. As indicated above, the proposal in the Draft Law to introduce an additional protective measure in Article 8 of the Transplant Law, requiring that organ removal from a living donor who is not a close relative of the recipient would only be allowed after the state healthcare organisation, in coordination with the internal affairs authorities, has issued a decision on the feasibility of organ removal, is sufficient to ascertain appropriate consent and the absence of financial transactions or advertisement.

In this regard, it should be noted that, if through the system of cross-transplantation the international exchange of kidneys from living donors would be allowed, including with non-resident pairs from the Eurasian Economic Union, it would be especially important for the state healthcare organisation, in coordination with the internal affairs authorities, to pay attention to the prevention of organ trafficking. Specific attention may even need to be given to new forms of organ trafficking that would not involve direct financial inducements, and that have recently been discussed within the context of the so-called “global kidney exchange programme”.¹²

Suggestions

The Draft Law on Amendments to the Transplant Law has introduced an additional protective measure that is sufficient to ascertain appropriate consent and the absence of financial transactions or advertisement, where organ removal is concerned from a living donor who is not a close relative of the recipient. Acknowledging the exemplary nature of this legal measure, the experts would nevertheless like to encourage the state healthcare organisation and the internal affairs authorities involved to pay specific attention to the conditions specified in Article 5, paragraph 4 of the Transplant Law, when non-resident living donors would present themselves.

4. Free and informed consent for living donation by a close relative of the recipient

Analysis

Articles 5, 7, 8 and 9 of the Belarusian Transplant Law require that living organ donation should only be allowed if the intended living donor has given free and informed consent and if it has been ascertained that no financial transactions or advertisement had been involved. As

¹² Moreover, in the context of international paired exchange, sometimes there are other incentives that may be regarded as comparable advantages to financial gain, from which one should refrain. These incentives may include the prospect of receiving a transplant only if one is able to find a donor who is compatible with a recipient in a high-income country. In this regard, it should be noted that the Council of Europe European Committee on Organ Transplantation, with the support of the Committee on Bioethics, recently adopted a statement declining a proposal on a global kidney exchange programme matching donor pairs from low/middle-income countries with pairs in high income countries, which would give access to treatment in high income countries for the donor and recipient from the low/middle-income country. The statement concluded that the proposal gave rise to concerns of exploitation of the vulnerable patient and donor from a low/middle-income country, and that the access criteria were inconsistent with the principle on prohibition of financial gain. The statement is available at https://www.edqm.eu/sites/default/files/statement_cd_p_to_global_kidney_exchange_concept_april_2018.pdf.

discussed above, the Draft Law on Amendments to the Transplant Law proposes to supplement Article 8 of the Transplant Law to the effect that organ removal from a living donor who is not a close relative of the recipient would only be allowed after the state healthcare organisation, in coordination with the internal affairs authorities, has issued a decision on the feasibility of organ removal. This decision is based on an assessment that ascertains the conditions specified in Article 5, paragraph 4 of the Transplant Law, including the absence of financial transactions or advertisement.

However, from this provision in the Draft Law – which is sufficient to ascertain appropriate consent and the absence of financial gain on the part of a living donor who is not a close relative of the recipient – it is unclear whether, and, if so, how the conditions specified in Article 5, paragraph 4 of the Transplant Law are also ascertained in cases where the living donor is a close relative of the recipient. More specifically, from the information provided to the experts by the designated state authorities for the purpose of the current expert examination, they have not been able to determine whether a decision on the feasibility of organ removal is also necessary in case of a living donor who is a close relative of the recipient, or whether the conditions specified in Article 5, paragraph 4 of the Transplant Law are ascertained in another way. The experts wish to emphasise that the conditions specified in Article 5, paragraph 4 of the Transplant Law should not be considered any differently, depending on whether the donor is a close relative or not. These conditions are in place to protect all vulnerable persons from exploitation, and these persons may include close relatives of the recipients.

In this respect, and as already indicated above, it should be noted that one of the experts was of the opinion that, for all cases of living donation, the fulfilment of the conditions would best be assessed by a specific and multidisciplinary ethics committee at the level of the state healthcare organisation.

Suggestions

To the extent that the conditions specified in Article 5, paragraph 4 of the Transplant Law would not yet be specifically ascertained for living donors who are close relatives of the recipients, the Belarusian authorities might consider amending the provisions of the Draft Law on Article 8, so as to ensure that also organ removal from a living donor who is a close relative of the recipient is dependent upon such a decision on the feasibility of organ removal.

5. Revocation of a declaration of objection to organ removal after death

Analysis

Articles 10¹ and 11 of the Belarusian Transplant Law enshrine the right to express a lack of consent for the removal of organs and tissues for transplantation after death and the procedure for exercising this right. The Draft Law on Amendments to the Transplant Law proposes to supplement Articles 10¹ and 11 with provisions introducing a procedure for revocation of a declaration of objection. As indicated in the Explanatory Note on the necessity of adoption of the Draft Law, these proposed amendments have been motivated by the observation that some citizens have expressed a desire to revoke their declarations of objection after a while.

In addition, the Draft Law proposes to supplement Article 10¹ by a provision stating that persons who submit a declaration of objection to the removal of organs and tissues for transplantation after death, should, upon their own request, provide an indication of the reasons for their refusal. In this way, relevant authorities would be able to study and analyse the causes and conditions that prompt citizens to express their refusal.

Amending the Transplant Law so as to provide a clear and efficient procedure to revoke a declaration of objection would ensure the complementarity of the Transplant Law with Article 17 of the Additional Protocol. More specifically, it would further increase the likelihood that persons are able to make their wishes known, including by revoking earlier wishes if they want to do so.

Moreover, requiring from persons who submit a declaration of objection to provide, upon their request, an indication of the reasons for their refusal, is commendable in the light of Articles 8 and 19 of the Additional Protocol. More specifically, the information collected in this way may allow the authorities to better inform the public and to take more appropriate measures to promote the donation of organs and tissues after death.

Conclusions

It is concluded that the proposal in the Draft Law on Amendments to the Transplant Law to introduce a procedure for revocation of a declaration of objection is in conformity with the provisions of the Additional Protocol.

6. Expansion of the Unified Transplantation Registry

Analysis

The Draft Law on Amendments to the Transplant Law proposes to supplement Article 10² of the Transplant Law so as to expand the information that is included in the Unified Transplantation Registry. In addition to the types of information that are already included – information about individuals who have undergone transplantation as well as about persons who have expressed a lack of consent to organ removal after death – it is proposed to also include information on individuals from whom organs and tissues have been removed.

As indicated above, it is in the light of Articles 3, 4 and 6 of the Additional Protocol and of Resolutions CM/Res(2013)56, CM/Res(2015)11 and CM/Res(2017)1 recommended to establish a system of traceability and reporting systems and registries. The expansion of the types of information included in the Unified Transplantation Registry is in line with these recommendations and, as stated in the Explanatory Note on the necessity of adoption of the Draft Law, it will help to make the Unified Transplantation Registry more informative.

However, as has also been outlined above, it may be useful for Belarusian authorities to consider the establishment of a more extensive and integrated system of vigilance. More specifically, it would in that case be advisable to opt for two separate registries. One registry would include information on persons who declared objection to post-mortem removal; and the other registry would include information on: (1) persons who have undergone transplantation; (2) persons from whom organs and tissues have been removed; (3) living donation and the outcomes after donation; (4) traceability of organs and tissues; and (5) serious adverse events and reactions.

Suggestions

In order to further improve the quality and safety of the donation and transplantation process, the Belarusian authorities might consider including additional types of information in the Unified Transplantation Registry, or in two separate registries. More specifically, and as has already been suggested above, this additional information might include information on living donation and the outcomes after donation; traceability of organs and tissues; and serious adverse events and reactions.

7. Obligation for living donors to provide information on risky behaviour

Analysis

Article 10 of the Belarusian Transplant Law emphasises the obligations of the intended living donor to inform the doctor in charge of organ retrieval about both previous or present diseases and social habits. The Draft Law on Amendments to the Transplant Law proposes to replace the concept “bad habits” that is currently used in Article 10 of the Transplant Law by the concept “risky behaviour”.

The provision to require that the intended living donor provides information on his or her exposure to relevant risks builds on Article 6 of the Additional Protocol, requiring all transplant professionals to take all reasonable measures to minimise the risks of transmission of any disease to the recipient. To ensure accurate information about the living donor and proper screening of the living donor, it may be expected that the living donor him or herself provides all relevant information.

As indicated in the Explanatory Note on the necessity of adoption of the Draft Law, the proposed change in wording to “risky behaviour” is motivated by concern that the concept of “bad habits” is judgment-based and a change in terminology would be more objective and neutral.

Conclusions

By proposing to change the concept of “bad habits” into “risky behaviour”, the Draft Law on Amendments to the Transplant Law will introduce terminology that is more objective and neutral with regard to the intended living donor’s possible exposure to relevant risks.

5 GENERAL CONCLUSION

The expert examination of the “Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” and of the “Draft Law of the Republic of Belarus on Amendments to the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on the Transplantation of Human Organs and Tissues” was conducted in three parts.

First, a legal assessment was made of the compliance of the general principles that govern the Belarusian Transplant Law with the general human rights principles (e.g. equitable access; respect for autonomy; prohibition of financial gain) enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol. On the basis of this assessment, it was concluded that the general principles that govern the Belarusian Transplant Law are in conformity with the general human rights principles enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol.

Second, a legal assessment was made of the compliance of the provisions of the Belarusian Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol. The purpose of this assessment was to determine: (1) whether the Law contains provisions that are clearly incompatible with the Convention on Human Rights and Biomedicine and its Additional Protocol; (2) whether some of the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol have not been addressed in the Law; and (3) whether certain provisions of the Law could be implemented in a way that optimises the protection of the rights and freedoms of donors, potential donors and recipients in the light of the principles enshrined in the Convention on Human Rights and Biomedicine and its Additional Protocol and in the light of practical proposals formulated in other relevant Council of Europe instruments.

On the basis of this legal assessment, it was concluded that the Belarusian Transplant Law does not contain provisions that are clearly incompatible with the Convention on Human Rights and Biomedicine and its Additional Protocol. It was nevertheless considered that there is room to ensure the compliance of the Belarusian Transplant Law with the Convention on Human Rights and Biomedicine and its Additional Protocol. Greater conformity with the Convention on Human Rights and Biomedicine and its Additional Protocol could be reached by re-examining some of the provisions contained in Articles 5, 8, 9, 11 and 12 of the Belarusian Transplant Law. More specifically, the following recommendations have been formulated:

1. The Belarusian authorities should consider amending Article 8 of the Law, so as to require that the removal of bone marrow and haematopoietic stem cells from minors unable to consent should only be authorised if, in addition to the requirements mentioned in Article 8, (1) there is no compatible donor available who has the capacity to consent; (2) the recipient is a brother or sister of the donor; and (3) the donation has the potential to be life-saving for the recipient.
2. The Belarusian authorities should consider making explicit in Article 8 of the Law that living organ removal is only allowed if, in addition to the requirements mentioned in Article 8, (1) there is a clear therapeutic benefit for the recipient; (2) there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness; and (3) there is no serious risk to the life or health of the donor.
3. The Belarusian authorities should consider amending Articles 8 and 9 of the Law to make explicit that the intended living donor: (1) should beforehand also be given appropriate information about the purpose and nature of the removal; (2) should be informed of the right to access to independent advice about the risks involved; (3) may freely withdraw consent at any time and without formal requirements; and (4) is not under any undue pressure to consent.
4. The Belarusian authorities should consider amending the Law to make explicit that surgical residues may only be used for transplant purposes if before the removal the patient had been informed about the storage and the intended use of the body parts.

5. The Belarusian authorities should consider amending Article 11 of the Law and Resolution No. 288 to the effect that the physicians involved in the certification of death should also not have any responsibilities for the care of potential organ or tissue recipients.
6. The Belarusian authorities should consider amending Article 12 of the Law to make explicit that the prospective recipients should beforehand also be given appropriate information about: (1) the purpose and nature of the implantation; (2) the consequences and risks of the implantation; and (3) the alternatives to the intervention.
7. To avoid the impression that the provisions on living donation are restricted to living organ donors, the Belarusian authorities should consider replacing in Article 1 of the Law the term “Organ retrieval” by “Organ and (or) tissue retrieval”, and, where in Articles 8 to 10 reference is made to “organ retrieval”, replacing this, where relevant, by “organ and (or) tissue retrieval”.
8. The Belarusian authorities should consider amending Article 5 of the Law to make more explicit: (1) the principle that donation of organs and tissues is free; and (2) the prohibition of transactions for financial gain and comparable advantage.
9. The Belarusian authorities should consider rephrasing the provision in Article 9 of the Law, so as to guarantee coverage of: (1) compensation of costs incurred by (potential) donors before donation; (2) compensation of all of the costs incurred by donors post-donation; (3) loss of income by (potential) donors linked to the donation; and (4) compensation in the event of complications resulting from the donation.
10. The Belarusian authorities should consider attaching clear sanctions to the infringements of the prohibitions of financial gain and advertisement, to the extent that this has not yet been properly addressed by other national legislation.

On the basis of this legal assessment, it was also concluded that several provisions of the Convention on Human Rights and Biomedicine and of its Additional Protocol have not yet been explicitly addressed in the Belarusian Transplant Law. The experts considered it advisable to revise some aspects of the Belarusian Transplant Law so as to give expression to these provisions and thereby ensure compliance with the Convention on Human Rights and Biomedicine and its Additional Protocol. More specifically, the following recommendations have been formulated:

1. To the extent that no specific legislation governing the removal and transplantation of cells exists and to the extent that cells are currently excluded from the scope of the Transplant Law, the Belarusian authorities should consider including cells in the scope of that Law or adopting another legal instrument that specifies similar conditions for the removal and transplantation of cells than the ones that apply to the removal and transplantation of organs and tissues.
2. The Belarusian authorities should consider including in the Law a provision stipulating that appropriate medical follow-up shall be offered to living donors and recipients.

3. The Belarusian authorities should consider explicitly addressing in the Law the importance of the traceability of all organs and tissues removed, allocated, and transplanted in the Republic of Belarus.
4. The Belarusian authorities should consider directly addressing in the Law the principle of confidentiality and including in the Law a provision so as to guarantee the anonymity of donors and recipients who are not related.

The legal assessment also resulted in a number of suggestions for the implementation of certain provisions of the Belarusian Transplant Law. As compared to the recommendations outlined in the previous section, these suggestions concern aspects of the Belarusian Transplant Law that are clearly in accordance with the Convention on Human Rights and Biomedicine and its Additional Protocol but could nevertheless benefit from clarification or from elaboration with a view to further optimising the protection of the rights and freedoms of donors, potential donors and recipients. More specifically, the following suggestions have been formulated:

1. To the extent that this would not yet be the case, the Belarusian authorities might consider emphasising in the Transplant Law or in a supplementing decree or other regulatory instrument the importance of the following aspects: (1) removal and transplantation of organs and tissues can only be performed in centres licensed for the purpose of those activities; (2) removal and transplantation of organs and tissues can only be carried out by suitably qualified healthcare personnel; (3) removal and transplantation of organs and tissues can only take place in appropriately constructed, maintained and operated facilities which are properly equipped. It is advisable that the responsibility for supervision and control is entrusted to a dedicated authority (National Transplant Authority).
2. In order to improve the quality and safety of the donation and transplantation process, the Belarusian authorities might consider establishing an integrated system of vigilance, consisting of: (1) a centralised registry for traceability of organs and tissues; (2) a national living organ donor registry; and (3) a central reporting and management system for serious adverse events and reactions.
3. The Belarusian authorities might consider more explicitly addressing both the organisation and maintenance of transplant waiting lists (e.g. through special registries) and the rules of allocation either directly in the Transplant Law or in its supplementing decrees.
4. To the extent that this would not yet be the case, the Belarusian authorities might consider establishing a National Transplant Organisation entrusted with the coordination of the Belarusian transplant system and the operation and monitoring of: (1) the quality and safety requirements for procurement and transplant centres and for healthcare personnel; (2) the Uniform Registry of Transplantation; (3) a centralised system of vigilance; and (4) equitable access to transplantation services for patients.
5. To the extent that this would not yet be the case, the Belarusian authorities might consider: (1) adopting regulations on international cooperation, incorporating provisions ensuring that imported organs comply with the same quality and safety

standards that apply to organs removed and transplanted in the Republic of Belarus; and (2) putting in place first an effective national kidney exchange program so as to prevent organ trafficking.

6. To the extent that this would not yet be the case, the Belarusian authorities might consider: (1) implementing an easily accessible system of binding declarations of willingness regarding post-mortem organ removal for transplantation; and (2) amending Article 11 of the Transplant Law to the effect that a possible declaration of objection on the part of the spouse, the close relatives or lawful guardians should be primarily based on the deceased person's expressed or presumed wishes.
7. The Belarusian authorities might consider explicitly addressing in the Transplant Law the importance of informing health professionals and the public about the need for organs and tissues, as well as about the conditions relating to removal and transplantation, including the regime of consent or authorisation for donation after death.
8. To the extent that comprehensive information and awareness-raising campaigns are currently not yet being conducted, the Belarusian authorities might consider initiating such campaigns.

Third, a legal assessment was made of the compatibility of the Draft Law on Amendments to the Transplant Law with the provisions of the Convention on Human Rights and Biomedicine and its Additional Protocol. In this respect, it was concluded that, although the Draft Law does not directly address the recommendations formulated above, its adoption would significantly improve the further development of transplantation in the Republic of Belarus. As was the case with the legal assessment of the Belarusian Transplant Law itself, the expert examination also resulted in a number of suggestions for the implementation of certain provisions of the Draft Law on Amendments to the Transplant Law. More specifically, the following suggestions have been formulated:

1. The Belarusian authorities might consider encouraging the state healthcare organisation and the internal affairs authorities involved in the decision on the feasibility of organ removal from a living donor who is not a close relative of the recipient to pay specific attention to the conditions specified in Article 5, paragraph 4 of the Transplant Law, when, for example through the system of cross-transplantation, non-resident living donors would present themselves.
2. To the extent that the conditions specified in Article 5, paragraph 4 of the Transplant Law would not yet be specifically ascertained for living donors who are close relatives of the recipients, the Belarusian authorities might consider amending the provisions of the Draft Law on Article 8, so as to ensure that also organ removal from a living donor who is a close relative of the recipient is dependent upon such a decision on the feasibility of organ removal.

The experts would also like to encourage the Belarusian authorities to use the opportunity that the Transplant Law is currently under revision to ensure compliance with the Convention on Human Rights and Biomedicine and its Additional Protocol in the light of the recommendations contained in this report.

APPENDIX

1 LEGAL DOCUMENTS OF THE REPUBLIC OF BELARUS

A. Subject of the expert examination

- Law of the Republic of Belarus No. 28-3 of 4 March 1997 on Transplantation of Human Organs and Tissues (as amended by the Laws of the Republic of Belarus No. 207-3 of 9 January 2007, No. 407-3 of 13 July 2012, No. 232-3 of 1 January 2015);
- Draft Law of 2018, amending the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on Transplantation of Human Organs and Tissues, with the Explanatory note on the necessity of the adoption of the Draft Law, amending the Law of the Republic of Belarus No. 28-3 of 4 March 1997 on Transplantation of Human Organs and Tissues

B. Relevant national legal background

- Decree No. 134 of the Ministry of Health of the Republic of Belarus of 29 August 2012 “On Certain Issues in Transplanting Human Organs and Tissues” (as amended by Decree No. 124 of the Ministry of Public Health of the Republic of Belarus of 16 December 2015 and Decree No. 111 of the Ministry of Health of the Republic of Belarus of 18 October 2016);
- Decree No. 19 of the Ministry of Healthcare and Ministry of Justice of the Republic of Belarus of 18 March 2013 “On Approval of the Instructions for Creating and Maintaining the Unified Transplantation Register”;
- Decree No. 1216 of the Council of Ministers of the Republic of Belarus of 27 December 2012 “On the Procedure for Creating and Maintaining the Unified Transplantation Register”;
- Resolution of the Ministry of Health of the Republic of Belarus No. 2 of 4 January 2010 “On Approval of Instructions for Procedure of Tissue and (or) Organ Retrieval from Deceased Donor after Death Pronouncement” (as amended by the Resolutions of the Ministry of Health No. 209 of 28 December 2012, and No. 37 of 10 April 2015);
- Resolution of the Ministry of Health of the Republic of Belarus No. 228 of 20 December 2008 “On Approval of the Instruction on the Procedure of Pronouncement of Death and Revocation of the Resolution of the Ministry of Health of the Republic of Belarus No.47 of 2 July 2002” (as amended by the Resolution of the Ministry of Health No. 210 of 28 December 2012);
- Order of the Ministry of Health of the Republic of Belarus No. 578 of 6 May 2013 “On Creating the Unified Transplantation Register”;
- Decision No. R-757/2012 of the Constitutional Court of the Republic of Belarus of 9 July 2012 “On Compliance of the Law of the Republic of Belarus ‘On Amendment of

Certain Laws of the Republic of Belarus on the Matters of Human Organ and Tissue Transplantation’ with the Constitution of the Republic of Belarus”;

- Law of the Republic of Belarus No. 55-3 of 12 November 2001 “On Burial and Funeral Business” (as amended and supplemented by Law No. 407-3 of 13 July 2012);
- Law of the Republic of Belarus No. 455-3 of 10 November 2008 “On Information, Informatisation and Data Protection of Information’ (as amended by the Law of the Republic of Belarus No. 102-Z of 4 January 2014 and Law of the Republic of Belarus No. 362-Z of 11 May 2016);
- Criminal Code of the Republic of Belarus No. 275-3 of 9 July 1999 (last edition from 18 July 2017)

2 REFERENCE DOCUMENTS AND OTHER RELEVANT DOCUMENTS

A. *Reference documents*

- Oviedo Convention: Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (and its Explanatory Report)
- Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin (and its Explanatory Report)
- Convention for the Protection of Human Rights and Fundamental Freedoms

B. *Other documents*

- The Convention against Trafficking in Human Organs and its Explanatory Report
- The Convention on action against trafficking in human beings and its Explanatory Report
- Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors, adopted by the DH-BIO on 4 December 2017, adopted by the CD-P-TO on 11 January 2018
- Relevant cases of the European Court of Human Rights: *Petrova v. Latvia*, no. 4605/05, judgment of 24 June 2014 and *Elberte v. Latvia*, no. 61243/08, judgment of 13 January 2015
- Recommendation No (2006) 16 of the Committee of Ministers to member states on quality improvement programmes for organ donation
- Recommendation No (2006) 15 of the Committee of Ministers to member states on the background, functions and responsibilities of a National Transplant Organisation (NTO)
- Recommendation No (2005) 11 of the Committee of Ministers to member states on the role and training of professionals responsible for organ donation (transplant “donor coordinators”)

- Recommendation No (2004) 7 of the Committee of Ministers to member states on organ trafficking
- Recommendation No (2003) 12 of the Committee of Ministers to member states on organ donor registers
- Recommendation No (2001) 5 of the Committee of Ministers to member states on the management of organ transplant waiting lists
- Recommendation No (98) 2 of the Committee of Ministers to member states on provision of haematopoietic progenitor cells
- Recommendation No (97) 16 of the Committee of Ministers to member states on liver transplantation from living related donors
- Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care
- Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors
- Resolution CM/Res(2015)11 on establishing harmonised national living donor registries with a view to facilitating international data sharing and its Explanatory Memorandum
- Resolution CM/Res(2015)10 on the role and training of critical care professionals in deceased donation
- Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes and its Explanatory memorandum
- Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system
- Resolution CM/Res(2008)6 on transplantation of kidneys from living donors who are not genetically related to the recipient
- Resolution CM/Res(2008)4 on adult-to-adult living donor liver transplantation
- Resolution CM/Res(78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances
- Guide of the European Committee on Transplantation of Organs (CD-P-TO) to the quality and safety of tissues and cells for human application
- Guide of the European Committee on Transplantation of Organs (CD-P-TO) to the quality and safety of organs for transplantation
- WHO guiding principles on human cell, tissue and organ transplantation, as endorsed by the 63rd WHA, May 2010, Resolution WHA63.22

3 LAW OF THE REPUBLIC OF BELARUS NO. 28-3 OF 4 MARCH 1997 ON THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES

Registered in the National Register of Legal Acts
of the Republic of Belarus on 20 May 2001, No. 2/576

LAW OF THE REPUBLIC OF BELARUS No. 28-3 of 4 March 1997

ON THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES

Adopted by the House of Representatives on 30 January 1997

Approved by the Council of Ministers on 18 February 1997

(as amended by the Laws of the Republic of Belarus [No. 207-3](#) of 09.01.2007,
[No. 407-3](#) of 13.07.2012, [No. 232-3](#) of 01.01.2015)

This Law is intended to provide for the legal and institutional framework for state regulation in the sphere of transplantation of human organs and (or) tissues for the purpose of realisation of the right of the citizens of the Republic of Belarus to life and health protection.

Article 1. Key terms, used in this Law, and their definitions

(as amended by the Law of the Republic of Belarus [No. 407-3](#) of 13.07.2012)

For the purposes of this Law the following terms shall have the following definitions:

Close relatives shall mean parents, adoptive parents, children, including adopted ones, siblings, grandparents and grandchildren;

Hematopoietic stem cells shall mean a combination of cells derived from bone marrow or peripheral blood, including umbilical cord blood, and capable to regenerate hematopoietic system when it is damaged due to a disease;

Living donor shall mean a person who gave his voluntary consent in line with the established procedure to donation of human organs and (or) tissues (hereinafter referred to as organs retrieval) for transplantation of human organs and tissues (hereinafter referred to as transplantation) to a recipient;

Organ retrieval shall mean medical intervention to recover organs and (or) tissues from a living or deceased donor;

Human organs and (or) tissues shall mean anatomical structures (whole organs, parts of organs, combination of cells) that do not determine distinctive features of personal identity;

Recipient shall mean a patient receiving a transplant;

Death shall mean irreversible cessation of human brain function (brain death) upon which a patient's cardiac and pulmonary functions can be temporarily artificially maintained with the help of medicinal products

and medical equipment;

Transplantation shall mean a medical intervention to replace a recipient's missing or injured organs and (or) tissues that fail to perform their vital functions by human organs and (or) tissues obtained as a result of organ donation;

Deceased donor shall mean a body of a human after the death of whom organs are retrieved for the purposes of transplantation to a recipient.

Article 2. Scope of this Law

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

This Law regulates relations arising in the situation of transplantation except for relations pertaining to the process of human reproduction (ova, semen, ovaries, testicles or embryos), blood and its components, tissue components used for manufacturing of medicinal and medical products, and preparation of transplantation materials.

Article 3. Laws of the Republic of Belarus on transplantation

The legal framework of the Republic of Belarus in the sphere of transplantation is based on the Constitution of the Republic of Belarus and comprises this Law, other legal acts of the Republic of Belarus and international agreements of the Republic of Belarus.

When international agreements of the Republic of Belarus establish rules different from ones specified by this Law, the rules provided for by the international agreements shall apply.

Article 4. International cooperation

State health care institutions practicing transplantation are entitled to maintain international cooperation in the sphere of exchange of human organs and (or) tissues free of charge for the purposes of the best possible matching of donor-recipient pairs according to the procedure established by the legislation of the Republic of Belarus.

Article 5. Conditions and procedure of transplantation

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Transplantation shall be carried out only when it is impossible to save a patient's life or restore his or her health with the help of other methods of treatment. It shall be performed in line with the medical opinion on the necessity of transplantation and on the basis of clinical protocols endorsed by the Ministry of Health of the Republic of Belarus.

Medical opinion on the necessity of transplantation is passed by a council of physicians of the state health care institution consisting of a doctor in charge of the patient, a transplant surgeon and (or) surgeon, intensivist and, if necessary, other medical specialists according to the procedure established by the Ministry of Health of the Republic of Belarus.

The list of human organs and tissues subject to transplantation is established by the Ministry of Health of the Republic of Belarus.

Human organs and (or) tissues shall not be objects of civil transactions except for unrequited ones. Compensated transactioning and advertising of offer and (or) demand for human organs and (or) tissues shall be banned.

Medical specialists may not carry out transplantation if the conditions established by this Law are not observed.

Article 6. Institutions carrying out organ recovery and (or) transplantation

(as amended by the Law of the Republic of Belarus No. 232-3 of 01.01.2015)

Organ retrieval and transplantation shall be carried out only by state health care institutions unless otherwise is provided for by this Law or other legal acts of the Republic of Belarus.

In case of cessation of circulatory and respiratory functions in deceased donor, organ retrieval can be also carried out by the State Committee of the Republic of Belarus on Forensic Expertise.

The procedure of organ retrieval and (or) transplantation is established by this Law and other legal acts of the Republic of Belarus.

Article 7. Restrictions concerning living donors

The following individuals cannot be living donors:

Persons who are neither spouses nor close relatives of the recipient (except for bone marrow and hematopoietic stem cells retrieval);

(the paragraph is introduced by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Under age individuals (except for bone marrow and hematopoietic stem cells retrieval);

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Persons, who were recognised as incapable according to the established procedure as well as persons suffering from a mental disorder (illness);

Persons, who were diagnosed with conditions threatening life and health of a recipient;

Pregnant women;

Orphaned children and children deprived of parental care.

Article 8. Living donor organ retrieval conditions

In case of a living donor, organ retrieval for transplantation shall be allowed if the following conditions are observed:

A doctor in charge from the state health care institution shall issue a written warning for this living donor about potential deterioration of his or her health due to organ retrieval for transplantation;

The living donor shall give his or her notarised voluntary written consent to organ retrieval (except for case provided for in the part 2 of this Article);

The living donor shall undergo medical examination and obtain the opinion of a medical consultation commission of the state health care institution on the possibility of organ retrieval for transplantation. The procedure of medical examination of living donors is established by the Ministry of Health of the Republic of Belarus.

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Bone marrow and hematopoietic stem cells retrieval from under aged individuals that are not entirely sui juris is carried out upon the notarised written consent of their lawful guardians and custody and guardianship authority. In case of explicit written or oral objection of under aged individuals bone marrow or hematopoietic

stem cells retrieval shall not be permitted.

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

For the purpose of transplantation a living donor can donate only one of paired organs, a part of azygos organ or a tissue, deficit of which won't lead to irreversible processes in human body.

Coercion of an individual to give his or her consent to organ retrieval shall be banned.

Article 9. Rights of living donor

Prior to organ retrieval a living donor has a right to obtain full and objective information on his or her state of health and consequences that may occur due to organ retrieval.

Consent to organ retrieval can be withdrawn at any time, except for cases when medical specialists have already initiated organ retrieval according to the procedure established by the legal acts of the Republic of Belarus and its cessation or reversion are impossible or may incur a threat to life or health of a living donor.

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Subsequent to organ retrieval a living donor has a right to:

Compensation of costs incurred by the necessity to restore his or her health due to organ retrieval. The procedure of reimbursement and its amount shall be established by the Council of Ministers of the Republic of Belarus;

Temporary incapacity allowance equal to 100 % of earnings for the period of incapacity resulting from organ retrieval.

Disability of a living donor resulting from organ retrieval shall be considered equal to disability resulting from industrial accident or occupational disease.

Article 10. Liability of living donor

A living donor shall be obliged to inform the doctor in charge representing a state health care institution carrying out organ retrieval about previous or present diseases and social habits.

Article 10¹. The right of citizens to object post-mortem organ retrieval for transplantation

(introduced by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Able citizens have a right to submit to a state health care institution at place of residence (temporary residence) or to any other state health care institution delivering medical support a written statement expressing objection to post-mortem organ retrieval for transplantation. In case of under aged citizens, except for those who were recognized sui juris in line with the established procedure, and individuals who were recognized as disabled according to the established procedure such a statement shall be submitted by their lawful guardians. In case of individuals who are not able to make a conscious decision due to state of their health such a statement is presented by a spouse of one of the close relatives.

Head of a state health care institution, head of a department of a state health care institution or persons performing their duties within six hours from the moment of receiving of the written statement expressing objection to post-mortem organ retrieval for transplantation shall duly inform the Ministry of Health of the Republic of Belarus for the purpose of registration in the Uniform Registry of Transplantation.

Article 10². Uniform Registry of Transplantation

(introduced by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

The Uniform Registry of Transplantation shall be established for the purposes of control over the use of human organ and (or) tissues and of delivery of prompt medical support to individuals in need of transplantation. The procedure of development and maintenance of the Uniform Registry of Transplantation shall be established by the Council of Ministers of the Republic of Belarus.

The Uniform Registry of transplantation shall include information on:

Persons who underwent transplantation;

Persons who declared their objection to post-mortem organ retrieval for transplantation in line with the procedures established by this Law.

Article 11. Conditions of organ retrieval from deceased donor

(as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

Organ retrieval from deceased donor shall be permitted upon the moment of pronouncement of death according to the procedure established by the Ministry of Health of the Republic of Belarus in coordination with the State Committee of the Republic of Belarus on Forensic Expertise.

(as amended by the Laws of the Republic of Belarus No. 407-3 of 13.07.2012 and No. 232-3 of 01.01.2015)

Organ retrieval from deceased donor shall not be permitted if this individual in his or her lifetime or individuals mentioned in part 1, Article 10¹, of this Law, prior to his or her death declared their objection to post-mortem organ retrieval for transplantation according to the procedure established by this Law. Organ retrieval from deceased donor shall not be permitted if heads of state health care institutions, heads of units of the State Committee of the Republic of Belarus on Forensic Expertise, heads of departments of state health care institutions, heads of departments of the State Committee of the Republic of Belarus on Forensic Expertise or persons performing their duties received a written statement expressing objection to organ retrieval for transplantation from a spouse or, in case of his or her absence, from one of the close relatives or lawful guardians of the deceased donor.

(as amended by the Laws of the Republic of Belarus No. 407-3 of 13.07.2012 and No. 232-3 of 01.01.2015)

Organ retrieval from deceased donor shall not be permitted if a state health care institution or a unit of the State Committee of the Republic of Belarus on Forensic Expertise were informed about the individual's objection to organ retrieval for transplantation prior to his or her death in written or oral form in presence of a medical specialist (medical specialists), other officials from a state health care institution or unit of the State Committee of the Republic of Belarus on Forensic Expertise, or other individuals that can witness such an objection.

(as amended by the Laws of the Republic of Belarus No. 407-3 of 13.07.2012 and No.232-3 of 01.01.2015)

Medical specialists that are to perform transplantation as well as members of teams carrying out organ retrieval shall not be permitted to take part in the pronouncement of death of the individual from whose body organs will be recovered.

(part 4, Article 11, as amended by the Law of the Republic of Belarus No.407-3 of 13.07.2012)

In case deceased donor is subject to forensic medical examination or post-mortem examination, a written consent to organ retrieval from deceased donor shall be given by a state coroner or pathologist present during the operation on organ retrieval.

(as amended by the Laws of the Republic of Belarus No. 407-3 of 13.07.2012 and No.232-3 of 01.01.2015)

Upon receiving a written consent to organ retrieval from deceased donor issued by a state coroner or pathologist correspondingly a state health care institution or a unit of the State Committee of the Republic of Belarus on Forensic Expertise shall immediately inform prosecution authorities about the forthcoming organ

retrieval from deceased donor subject to subsequent forensic medical examination or post-mortem examination.
(as amended by the Laws of the Republic of Belarus No. 407-3 of 13.07.2012 and No.232-3 of 01.01.2015)

Article 12. Consent of recipient to transplantation

Transplantation shall be carried out only upon written consent of a recipient. Herewith, a recipient must be warned in written form about potential deterioration of his or her health due to a forthcoming medical intervention. In case of an under aged recipient who is not fully sui juris or a recipient recognised as incapable according to the established procedure, transplantation is carried out upon written consent of their lawful guardians.

Transplantation to a recipient who is not able to make conscious decision due to the state of his or her health is carried out upon written consent of a spouse or one of the close relatives.

(part 2, Article 12, as amended by the Law of the Republic of Belarus No. 407-3 of 13.07.2012)

In extraordinary circumstances when delay of transplantation threatens the life of a patient and persons mentioned in part 1 and 2 of this Article are absent or impossible to locate, the decision on transplantation is taken by a council of physicians, and if latter is not available – by a medical specialist carrying out transplantation with due registration in medical documents and subsequent notification of administration of the state health care institution within 24 hours.

(as amended by the Law of the Republic of Belarus No.407-3 of 13.07.2012)

ConsultantPlus: note.

Responsibility for violation of transplantation procedure is established by Article 164 of the Criminal Code of the Republic of Belarus.

ConsultantPlus: note.

Responsibility for illegal organ or tissue retrieval from deceased donor is established by Article 348 of the Criminal Code of the Republic of Belarus.

Article 13. Responsibility for violation of laws of the Republic of Belarus on transplantation

Persons guilty of violation of the laws of the Republic of Belarus on transplantation bear responsibility as set forth by legal acts of the Republic of Belarus.

The President of the Republic of Belarus

A.Lukashenko

4 DRAFT LAW OF THE REPUBLIC OF BELARUS ON AMENDMENTS TO THE LAW OF THE REPUBLIC OF BELARUS ON THE TRANSPLANTATION OF HUMAN ORGANS AND TISSUES

Draft

LAW OF THE REPUBLIC OF BELARUS

On Amendments to the Law of the Republic of Belarus on the Transplantation of Human Organs and Tissues

Adopted by the House of Representatives
Approved by the Council of the Republic

Article 1. To make the following amendments and additions to the Law of the Republic of Belarus dated 4 March 1997 “On the Transplantation of Human Organs and Tissues” as amended by the Law of the Republic of Belarus dated 9 January 2007 (Bulletin of the National Assembly of the Republic of Belarus, 1997, No. 9, Article 196; National Register of Legal Acts Republic of Belarus, 2007, No. 15, 2/1304; National Legal Internet Portal of the Republic of Belarus, 19 July 2012, 2/1959):

1. In Article 1:

paragraph 2 shall be removed;

the article shall be supplemented with the following paragraph after paragraph 6:

“cross-transplantation – transplantation involving at least two pairs each of which consists of a living donor and a recipient who are relatives or spouses who are immunologically incompatible with each other, but in which a living donor from one pair is immunologically compatible with a recipient from another pair and vice versa;”;

the article shall be supplemented with the following paragraph after paragraph 7:

“relatives – individuals who have a shared bloodline and have common ancestors up to a great-grandfather and great-grandmother inclusive, adoptive parents, adopted children, stepchildren, and stepdaughters;”;

paragraphs 3–10 shall be regarded as paragraphs 2–11, respectively.

2. Article 4 shall be supplemented with Parts 2 and 3 as follows:

“The Ministry of Health of the Republic of Belarus shall decide on the need to import and export organs and/or human tissue to/from the Republic of Belarus at no charge in order to select optimal donor-recipient pairs.

Human organs and tissue shall be imported to and exported from the Republic of Belarus for transplantation taking into account the requirements established by the legislation of the Republic of Belarus, international treaties of the Republic of Belarus, and acts constituting the law of the Eurasian Economic Union”.

3. In paragraph 2 of Article 7:

the word “close” shall be deleted;

the paragraph shall be supplemented with the words “, cases of cross transplantation” after the word “cells”.

4. Part 1, Article 8 shall be supplemented with paragraph 5 as follows:

“the existence of a decision by a state healthcare organization that was adopted in coordination with the internal affairs authorities concerning the feasibility of organ harvesting from a living donor (hereinafter the decision on

the feasibility of organ harvesting). The decision on the feasibility of organ harvesting shall be adopted with respect to a living donor who is not a close relative of the recipient (parents, adoptive parents, children, including adopted children, siblings, grandfathers, grandmothers, and grandchildren). Establishing the absence of the conditions specified in Part 4, Article 5 of this Law shall constitute the basis for adopting a decision on the feasibility of organ harvesting. The procedure and conditions for interaction between state healthcare organizations and the internal affairs authorities when deciding on the feasibility of organ harvesting shall be determined by the Ministry of Health of the Republic of Belarus and the Ministry of Internal Affairs of the Republic of Belarus.”.

5. In Article 10, the words “and bad habits” shall be replaced by the words “, and also about the forms of risky behaviour, a list of which is established by the Ministry of Health of the Republic of Belarus.”

6. Article 10¹ shall read as follows:

“Article 10¹. Right of citizens to express a lack of consent to organ harvesting for transplantation after death. Revocation of a declaration on a lack of consent to organ harvesting for transplantation after death.

Legally capable citizens shall be entitled to submit a written declaration expressing a lack of consent to organ harvesting for transplantation after death to the state healthcare organization at their place of residence (place of stay) as well as to another state healthcare organization at which they receive medical care. With respect to minors, except for those who have acquired full legal capability in the prescribed manner, and individuals recognized as legally capable in the prescribed manner, such a declaration shall be submitted by their legal representatives. With respect to individuals who are not able to make an informed decision due to their health condition, this declaration shall be submitted by their spouse or a close relative (parents, adoptive parents, children, including adopted children, siblings, grandfathers, grandmothers, and grandchildren). A written declaration expressing a lack of consent to organ harvesting for transplantation after death shall indicate the reasons for the lack of consent to organ harvesting for transplantation after death at the request of the person submitting such a declaration.

The head of a state healthcare organization, the head of a structural unit of a state healthcare organization, or individuals performing their duties shall submit the relevant information to the Unified Transplantation Registry within six hours from the time a written declaration expressing a lack of consent to organ harvesting for transplantation after death is submitted to a state healthcare organization.

A written declaration expressing a lack of consent to organ harvesting for transplantation after death may be revoked by:

the citizen who submitted such a declaration;

the citizen with respect to whom such a declaration was submitted by his/her legal representative after the citizen reaches the age of majority or after the entry into legal force of a court decision recognizing the citizen as legally capable;

the citizen with respect to which such a declaration was submitted by his/her spouse or a close relative (parents, adoptive parents, children, including adopted children, siblings, grandfathers, grandmothers, and grandchildren), after the grounds for considering such a citizen to be in a state in which he/she is incapable of making an informed decision are no longer valid.

The revocation of a written declaration expressing a lack of consent to organ harvesting for transplantation after death shall take place in the manner prescribed by Part 1 of this article for the submission of a written declaration expressing a lack of consent to organ harvesting for transplantation after death.

The head of a state healthcare organization, the head of a structural unit of a state healthcare organization, or individuals performing their duties shall submit the relevant information to the Unified Transplantation Registry within six hours from the time a written declaration on the revocation of a declaration expressing a lack of consent to organ harvesting for transplantation after death is submitted to a state healthcare organization.”.

7. Part 2, Article 10² shall be supplemented with paragraph 4 as follows:

“about individuals from which organs are harvested.”

8. In Article 11:

Part 2 shall be supplemented with the words “(parents, adoptive parents, children, including adopted children, siblings, grandfathers, grandmothers, and grandchildren)” after the words “close relatives”;

the article shall be supplemented after Part 3 with a part as follows:

“The individuals specified in Parts 2 and 3 of this article who have expressed a lack of consent to organ harvesting from a deceased donor may revoke their declaration in the manner prescribed by Parts 2 and 3 of this article for the submission of such a declaration.”;

Parts 4–6 shall be regarded as Parts 5–7, respectively.

9. Part 2, Article 12 shall be supplemented with the words “(parents, adoptive parents, children, including adopted children, siblings, grandfathers, grandmothers, and grandchildren)” after the words “close relatives”.

Article 2. The Council of Ministers of the Republic of Belarus within six months shall:

ensure that legislative acts are brought into conformity with this Law;

take other measures to implement the provisions of this Law.

Article 3. This Law shall enter into force in the following sequence:

Article 1 – within six months after the official publication of this Law;

other provisions – following the official publication of this Law.

President of the Republic of Belarus