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Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act)

of 8 October 2004 (Status as of 1 February 2021)

The Federal Assembly of the Swiss Confederation,

based on Article 119a paragraphs 1 and 2 of the Federal Constitution¹, and having considered the Dispatch of the Federal Council of 12 September 2001²,

decrees:

Chapter 1 General Provisions

Art. 1 Aim

¹ This Act sets out the requirements for the use of organs, tissues or cells for transplantation purposes.

² It is intended to contribute to the availability of human organs, tissues and cells for transplantation purposes.

³ It is intended to prevent the improper handling of organs, tissues or cells in the context of human transplantation medicine, in particular commercial activities involving organs, and to protect human dignity, privacy and health.

Art. 2 Scope

¹ This Act applies to the handling of organs, tissues or cells of human or animal origin and products obtained from them (transplant products) intended for transplantation into humans.

² It does not apply to the handling of:

- a. artificial or devitalised organs, tissues or cells;
- b. blood, with the exception of blood stem cells;
- c. blood products;
- d. germ cells, impregnated egg cells and embryos in the context of medically assisted human reproduction.

AS 2007 1935

¹ SR 101

² BBl 2002 29

³ Articles 36 and 50 to 71 apply to the handling of organs, tissues or cells for autogenic transplantation. The Federal Council may issue regulations on the quality and safety of organs, tissues or cells for autogenic transplantation which are prepared prior to transplantation. Articles 4, 7 paragraph 2 letter b, 49 and 63-65 apply to transplant products for autogenic transplantation.

Art. 3 Definitions

In this Act:

- a. *organ* means any part of the body whose cells and tissues together comprise a unit with a specific function; organ parts whose function is similar to that of an organ and parts of the body that consist of different types of tissue and which have a specific function are regarded as equivalent to organs;
- b. *tissue* means a structured association of cells, consisting of the same or different types of cells, that has a common function in the body;
- c. *cell* means an individual cell, an unstructured cell mass or a cell suspension that consists exclusively of the same type of cell;
- d.³ ...

Art. 4 General duty of care

Any person who handles organs, tissues, cells or transplant products must take any measures that may be required in accordance with the current state of scientific and technical knowledge in order not to endanger human health.

Art. 5 Removal for purposes other than transplantation

¹ If organs, tissues or cells have been removed for purposes other than transplantation, they may only be stored, transplanted or used to obtain transplant products if the regulations concerning information and consent contained in Articles 8, 12 letter b, 13 paragraph 2 letter f and g, 39 paragraph 2 and 40 paragraph 2 have been complied with.

² The regulations concerning information and consent in paragraph 1 also apply to the handling of blood stems obtained from umbilical cord blood.

³ Repealed by No I of the FA of 19 June 2015, with effect from 1 May 2016 (AS 2016 1163; BBl 2013 2317).

Chapter 2 Human Organs, Tissues and Cells

Section 1 Non-Commercialism and Prohibition of Trade

Art. 6 Non-commercialism of donation

¹ It is prohibited to offer, grant, request or accept a financial gain or a comparable advantage for a donation of human organs, tissues or cells.⁴

² The following are not regarded as a financial gain or a comparable advantage:

- a. reimbursement of loss of earnings and expenses incurred directly by the donor;
- b. compensation for damage incurred by the donor as a result of organs, tissues or cells being removed;
- c. a subsequent symbolic gesture of gratitude;
- d. a crossover living donation.

Art. 7 Prohibition of trade

¹ It is prohibited:

- a. to trade in human organs, tissues or cells;
- b. to remove organs, tissues or cells from a living or deceased person or to transplant such human organs, tissues or cells if a financial gain or a comparable advantage has been offered, granted, requested or accepted for such organs, tissues or cells.⁵

² This prohibition does not apply to:

- a. the reimbursement of expenses incurred in the context of transplantation, and in particular costs for removal, transport, preparation, storage and transplantation;
- b. transplant products in accordance with Article 49.

Section 2 Removal of Organs, Tissues or Cells from Deceased Persons

Art. 8 Preconditions for removal

¹ Organs, tissues or cells may be removed from a deceased person if:

- a. the person has consented before their death to the removal;
- b. death has been determined.

⁴ Amended by Annex No 1 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

⁵ Amended by Annex No 1 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

² If no documented consent or refusal by the deceased person is available, the next of kin must be asked whether they are aware of the person having declared an intention to donate.

³ If the next of kin are not aware of any such declaration, organs, tissues or cells may be removed if the next of kin give consent. The decision of the next of kin shall be guided by what they believe the deceased person would have wanted.

^{3bis} The request to the next of kin may be made and their consent obtained only once it has been decided to discontinue life support measures.⁶

⁴ If there are no next of kin, or they cannot be contacted, removal is not permitted.

⁵ The wishes of the deceased person take priority over those of the next of kin.

⁶ If the deceased person has demonstrably delegated the decision on the removal of organs, tissues or cells to a trusted person, this person shall be consulted instead of the next of kin.

⁷ Individuals who have reached the age of 16 may declare their intention to donate.

⁸ The next of kin shall be defined by the Federal Council.

Art. 9 Criteria for death and determination of death

¹ A person is dead if the functions of their brain, including the brain stem, have ceased irreversibly.

² The Federal Council shall issue regulations on the determination of death. In particular, it shall specify:

- a. which clinical signs must be present so that it can be concluded that the functions of the brain, including the brain stem, have ceased irreversibly;
- b. the requirements which must be fulfilled by the doctors who determine death.

Art. 10⁷ Preparatory medical measures

¹ Medical measures intended solely to preserve organs, tissues or cells may only be undertaken prior to the death of the donor if the donor has been informed comprehensively and has freely given their consent.

² If the donor is incapable of judgement and has not given their consent, measures in terms of paragraph 1 may only be carried out if the next of kin consent, and the measures meet the requirements of paragraph 3 letters a and b. The decision of the next of kin shall be guided by what they believe the deceased person would have wanted.

³ If they are uncertain as to what the donor would have wanted, the next of kin may consent to measures under paragraph 1 if these:

⁶ Inserted by No I of the FA of 19 June 2015, in force since 15 Nov. 2017 (AS 2016 1163, 2017 5629; BBl 2013 2317).

⁷ Amended by No I of the FA of 19 June 2015, in force since 15 Nov. 2017 (AS 2016 1163, 2017 5629; BBl 2013 2317).

- a. are essential for the successful transplantation of organs, tissue or cells; and
- b. any risk or harm to the donor is minimal.

⁴ The Federal Council shall specify which measures do not meet the requirements of paragraph 3 letters a and b. It shall consult interested groups beforehand.

⁵ The next of kin may consent to measures under paragraph 1 only when it has been decided to discontinue life support measures.

⁶ Measures under paragraph 1 are not permitted if the donor is incapable of judgement and there are no next of kin or no next of kin can be contacted.

⁷ Such measures are also prohibited if they:

- a. hasten the death of the donor;
- b. may lead to the donor entering a permanent vegetative state.

⁸ If a person has not declared their intention to donate, measures under paragraph 1 may be carried out after the death of the donor until the next of kin have reached a decision. The Federal Council shall specify the maximum length of time during which such measures may be carried out.

⁹ Article 8 paragraph 6 applies *mutatis mutandis*.

Art. 11 Independence of persons involved

¹ Doctors who determine the death of a person may not:

- a. participate either in the removal or the transplantation of organs, tissues or cells;
- b. be subject to orders from a medical professional who is involved in such activities.

² Doctors who remove or transplant organs, tissues or cells and associated medical personnel must not pressurise individuals who are caring for the dying person or who determine death or attempt to influence them in any other way.

Section 3 **Removal of Organs, Tissues and Cells from Living Persons**

Art. 12 Preconditions for removal

Organs, tissues and cells may be removed from a living person if:

- a. that person is capable of judgement and has reached the age of majority⁸;
- b. that person has been informed comprehensively and has freely given their consent in writing;

⁸ Expression in accordance with Annex No 21 para. 1 of the FA of 18 Dec. 2008 (Adult Protection, Law of Persons and Law of Children), in force since 1 Jan. 2013 (AS 2011 725; BBl 2006 7001). This amendment has been made throughout the text.