

Law No. 22/2007 of the 29th of June

Partially transposes Directive No. 2004/23/EC, of the European Parliament and of the Council, of the 31st of March, to the national legal order, amending Law No. 12/93, of the 22nd of April, on harvesting and transplantation of organs and tissues of human origin.

The Assembly of the Republic decrees, under the terms of paragraph c) of article 161 of the Constitution, the following:

Article 1

Object

The present law partially transposes to the national legal order Directive no. 2004/23/EC, of the European Parliament and of the Council, of the 31st of March, concerning the establishment of quality and safety standards in relation to donation, collection, analysis, processing, preservation, storage and distribution of tissues and cells of human origin, with regards to the donation and collection of tissues and cells of human origin.

Article 2

Amendment to Law no. 12/93, of 22 April

Articles 1, 2, 3, 4, 5, 6, 8, 9, 11, 13, 15 and 15 of Law no. 12/93, of 22 April, on the collection and transplantation of organs and tissues of human origin, are replaced by the following:

«Article 1

[...]

1 - This law applies to acts that have the object of donating or harvesting organs, tissues and cells of human origin, for therapeutic or transplantation purposes, as well as to transplantation interventions themselves.

2-...

3-...

Article 2

[...]

1-...

2 - In relation to foreigners without permanent residence in Portugal, the legal regime of the acts provided for in paragraph 1 of article 1 is governed by their personal status.

Article 3

[...]

1-...

2-...

3 - Collection centers and transplant centers are authorized by the Minister of Health and are subject to periodic evaluation of their activities and results.

4 - The collection centers and transplantation centers already in operation do not require the authorization provided for in the preceding paragraph, but must, however, undergo such periodic evaluation.

Article 4

[...]

1 - (Previous body of the article.)

2 - The harvesting and transplantation centers guarantee the traceability of organs and tissues, in terms to be regulated.

Article 5

[...]

1 - The donation of organs, tissues and cells, for therapeutic or transplant purposes, may not, under any circumstances, be remunerated, and their commercialization is prohibited.

2 - (Repealed.)

3 - The agents of the acts referred to in paragraph 1 of article 1 and facilities authorized to perform organ, tissue and cell transplants may receive remuneration, solely and exclusively for the service provided, and the calculation of this remuneration may not attribute any value to organs, tissues or cells harvested or transplanted.

Article 6

[...]

1 - Without prejudice to the provisions of the following paragraphs, the donation and harvesting of organs, tissues and cells for therapeutic or transplant purposes are admissible.

2 - The harvesting of organs and tissues from a living person can only be done in the therapeutic interest of the recipient and provided that no suitable organ or tissue harvested from a post-mortem donor is available and there is no other alternative therapeutic method of comparable effectiveness.

3 - In the case of donation and harvesting of non-regenerable organs or tissues, the respective admissibility is dependent on a favorable opinion, issued by the Entity for the Verification of the Admissibility of the Harvest for Transplantation (EVA).

4 - The donation and procurement of organs or non-regenerable tissues when involving minors or other disabled persons is always prohibited.

5 - The donation and procurement of organs, tissues or regenerable cells involving minors or other disabled persons can only be carried out when the following cumulative requirements are met:

- a) Absence of compatible capable donors;
- b) The recipient is a brother or sister of the donor;
- c) The donation is necessary for the preservation of the recipient's life.

6 - The donation and harvesting of non-regenerable organs or tissues, which involve foreigners without permanent residence in Portugal, can only be done with judicial authorization.

7 - The donation and procurement of organs, tissues or cells is always prohibited when, with a high degree of probability, they involve a serious and permanent decrease in the physical integrity or health of the donor.

Article 8

[...]

1 - The consent of the donor and recipient must be free, informed and unequivocal and the donor can identify the beneficiary.

2 - The consent of the donor and of the recipient is given before:

- a) A doctor designated by the clinical director of the facility where the harvesting takes place, in the case of transplantation of organs, tissues and regenerable cells;
- b) A doctor designated by the clinical director of the facility where the harvesting takes place and who does not belong to the transplant team, in the case of transplantation of organs, tissues and non-regenerable cells.

3 - In the case of minor donors, consent must be given by the parents, provided that they are not inhibited from exercising parental authority, or, in the event of inhibition or lack of both, by the court.

4 - The donation and harvesting of organs, tissues and cells from minors of sound mind also need their agreement.

5-...

6 - The consent of the donor or whoever legally represents him is always given in writing, being freely revocable.

Article 9

[...]

1 - The donor is entitled to medical assistance until complete recovery.

2 - Without prejudice to the provisions of paragraph 1 of article 5, the donor has the right to be compensated for the damages suffered during the donation and harvesting process, regardless of fault, namely for the expenses resulting from the donation.

3 - The facilities referred to in paragraph 1 of article 3 are responsible for ensuring the rights referred to in paragraphs 1 and 2 of this article.

4 - The facilities mentioned in paragraph 1 of article 3 must conclude an insurance contract in favor of the donor and bear the respective charges.

Article 11

[...]

1-...

2 – The Government is authorized, following the opinion of the National Data Protection Commission, to regulate the organization and functioning of RENNDA and the issuance of an individual card, which will mention the status of non-donor.

3-...

Article 13

[...]

1-...

2-...

3-...

4-...

5 - One of the copies of the record is filed in the facilities where the harvest takes place and the other is sent, for statistical purposes, to the competent service of the Ministry of Health.

6-...

Article 15

[...]

1 - The Government must promote information campaigns on the meaning, in terms of solidarity, health policy and therapeutic means, of the harvesting of organs, tissues and cells and of transplants operations.

2 - ...”

Addition to Law no. 12/93, of the 22nd of April

Articles 1-A and 6-A are added to Law no.

12/93, of the 22nd of April, with the following wording:

“Article 1a

Definitions

For the purposes of this law, the following definitions apply:

- a) «Organ» is a differentiated and vital part of the human body, made up of various tissues, which maintains its structure, vascularization and ability to develop physiological functions in a largely autonomous way;
- b) «Tissue» means all the constituent parts of the human body formed by cells;
- c) «Cells» means individual cells or a set of cells of human origin, not linked together by any type of connective tissue;
- d) «Donor» means any human source, living or dead, of organs, tissues and cells of human origin;
- e) «Gift» any donation of organs, tissues and cells of human origin, intended for applications in the human body;
- f) «Harvesting» is a process in which organs, tissues and cells of human origin are made available.

Article 6a

Entity for the Verification of the Admissibility of the Harvest for Transplantation

1 - The Entity for the Verification of the Admissibility of the Harvest for Transplantation (EVA) is the organism that is responsible for issuing a binding opinion in the case of donation and living harvest of organs, tissues or cells for therapeutic or transplant purposes.

2 - EVA is created in each hospital where the harvest takes place, by order of the Minister of Health, under a joint proposal by the respective board of directors and the Portuguese Transplantation Organization.

3 - EVA works on the premises and as a section of the Health Ethics Committee of the hospital where the harvesting takes place. »

Article 4

Transitional provisions

Until the entry into operation of the EVA in each hospital where the harvesting takes place, article 6 of Law no. 12/93, of the 22nd of April, in its original wording, remains in force.

Article 5

Repealing rule

Paragraph 2 of article 5 of Law no. 12/93, of the 22nd of April, is revoked, in its original wording.

Article 6

Republication

It is republished, in annex, which is an integral part of this law, Law No. 12/93, of the 22nd of April, with the current wording.

Approved on April 26, 2007.

The President of the Assembly of the Republic, Jaime Gama.

Enacted on June 8, 2007.

Publish yourself.

The President of the Republic, ANÍBAL CAVACO SILVA.

Countersigned on June 12, 2007.

The Prime Minister, José Sócrates Carvalho Pinto de Sousa

Law No. 12/93 of the 22nd of April

Collection and transplantation of organs and tissues of human origin

The Assembly of the Republic decrees, under the terms of articles 164, paragraph e), 168, paragraph 1, paragraph f), and 169, paragraph 3, of the Constitution, the following:

CHAPTER I

General provisions

Article 1

Material scope of application

- 1 - This law applies to acts that have the object of donating or harvesting tissues or organs of human origin, for diagnostic purposes or for therapeutic and transplantation purposes, as well as to transplantation interventions themselves.
- 2 - Blood transfusion, egg and sperm donation and embryo transfer and manipulation are subject to special legislation.
- 3 - The donation and procurement of organs for the purpose of scientific research are also subject to special legislation.

Article 2

Personal scope of application

- 1 - This law applies to national citizens, and stateless persons and foreigners residing in Portugal.
- 2 - In relation to foreigners without permanent residence in Portugal, the legal regime of the acts provided for in paragraph 1 of article 1 is governed by their personal status.

Article 3

Authorized establishments and qualified persons

1 - The acts referred to in article 1, paragraph 1, may only be carried out under direct medical responsibility and surveillance, in accordance with the respective *leges artis* and in public or private hospital facilities.

2 - Tissue samples may also be harvested for therapeutic purposes during the autopsy at the institutes of forensic medicine.

3 - Transplant centers are authorized by the Ministry of Health and subject to periodic evaluation of their activities and results by the same Ministry.

4 - Transplant centers already in operation do not require the authorization provided for in the previous paragraph, but must, however, undergo the periodic evaluation referred to in the same paragraph.

Article 4

Confidentiality

Unless the rightful party consents, it is forbidden to reveal the identity of the organ or tissue donor or recipient.

Article 5

Free of charge

1 - The donation of tissues or organs for therapeutic purposes of transplantation cannot, under any circumstances, be remunerated, being its commercialization prohibited.

2 - It is unlawful to reimburse expenses incurred or losses immediately resulting from or which had as a direct cause the acts referred to in article 1, paragraph 1.

3 - The agents of the acts referred to in article 1, paragraph 1, and the establishments authorized to perform tissue or organ transplants may receive a fee for the service provided, but in calculating this fee, no value can be attributed to the tissues or transplanted organs.

CHAPTER II

Living harvest of organs

Article 6

Admissibility

1 - Without prejudice to the provisions of the following paragraph, only harvesting of regenerable substances is authorized in live organ procurement.

2 - The donation of organs or non-regenerable substances can be admitted when there is a relationship between the donor and the recipient up to the 3rd degree.

3 - Donations of non-regenerable substances made by minors or disabled persons are always prohibited.

4 - The donation is never admitted when, with a high degree of probability, it involves a serious and permanent decrease in the physical integrity and health of the donor.

Article 7

Information

The physician must inform the donor and recipient of the possible risks, the consequences of donation and the treatment and its side effects, in a fair, appropriate and clear manner, as well as the follow-up care.

Article 8

Consent

- 1 - The consent of the donor and of the recipient must be free, clear and unambiguous and the donor can identify the beneficiary.
- 2 - Consent is given to a doctor designated by the clinical director of the establishment where the collection takes place and who does not belong to the transplant team.
- 3 - In the case of minor donors, consent must be given by the parents, provided that they are not inhibited from exercising parental authority, or, in the event of inhibition or lack of both, by the court.
- 4 - The donation of tissues or organs by minors of sound mind also needs their agreement.
- 5 - Harvesting from psychic disabled adults can only be done with judicial authorization.
- 6 - The consent of the donor or whoever legally represents him is freely revocable.

Article 9

Right to assistance and compensation

- 1 - The donor is entitled to medical assistance until complete recovery and to be compensated for the damages suffered, regardless of fault.
- 2 - For the purposes of the preceding paragraph, mandatory donor insurance must be created, supported by the establishments referred to in paragraph 1 of article 3.

CHAPTER III

Corpses harvesting of organs

Article 10

Potential donors

- 1 - Potential post-mortem donors are considered to be all national citizens, and stateless persons and foreigners residing in Portugal who have not expressed their status as non-donors to the Ministry of Health.
- 2 - When the non-willingness to donate is limited to certain organs or tissues or for certain purposes, the restrictions must be expressly indicated in the respective records and card.
- 3 - The non-willingness to donate by minors and disabled persons is manifested, for the purposes of registration, by the respective legal representatives and can also be expressed by minors of sound mind.

Article 11

National Registry

- 1 - A computerized National Register of Non-Donors (RENNDA) is created to register all those who have expressed their status as non-donors to the Ministry of Health.
- 2 - The Government is authorized, following the opinion of the National Commission for the Protection of Computerized Personal Data, to regulate the organization and functioning of RENNDA and the issuance of an individual card, mentioning the status of non-donor.
- 3 - RENNDA must be regulated and operating by October 1, 1993.

Article 12

Death certification

- 1 - It is incumbent upon the Order of Doctors, after hearing the National Council of Ethics for the Life Sciences, to enunciate and keep updated, in accordance with the scientific progress that may be registered, the set of criteria and rules of suitable medico-legal semiology for the verification of brain death.
- 2 - The president shall communicate to the Ministry of Health the text approved by the Portuguese Medical Association, setting the criteria and rules referred to in the previous number, for publication in the 1st series of the Diário da República.
- 3 - The first publication must be made by October 1, 1993.

Article 13

Certification formalities

- 1 - Doctors who proceed with the harvesting must prepare, in duplicate copy, a record stating the identity of the deceased, the day and time of the death certification, a mention of the consultation with RENNDA and the personal card, if any, and the lack of opposition to the harvest, the organs or tissues collected and the respective destination.
- 2 – No doctor taking part in the transplant operation should intervene during the death certification process.
- 3 - The harvesting must be performed by a medical team authorized by the clinical director of the establishment where it is to be carried out.
- 4 - The report referred to in paragraph 1 must be signed by the intervening doctors and the clinical director of the establishment.
- 5 - One of the copies of the record is filed in the facility where the harvest takes place and the other is sent, for statistical purposes, to the Information Service of the Ministry of Health.
- 6 - When it has not been possible to identify the corpse, non-opposition to the donation is presumed if something else does not result from the circumstantial elements.

Article 14

Precautions to be taken when carrying out the harvest

- 1 - When carrying out the harvesting, mutilations or dissections that are not strictly indispensable for the collection and use of tissues or organs that may impair the performance of an autopsy, when it occurs, must be avoided.
- 2 - The fact that the death occurred in conditions that require the performance of a medico-legal autopsy does not prevent the harvesting from being carried out, however, the doctor must report any and all observations that may be useful in order to complete the autopsy.

CHAPTER IV

Complementary provisions

Article 15

Information campaign

- 1 - The Government must promote an information campaign on the meaning, in terms of social solidarity, health policy and therapeutic means, of the harvesting of organs and tissues and of the transplant operations.
- 2 - The information campaign should also elucidate the possibility of manifesting the non-willingness for post-mortem donation, the existence of the National Register of these decisions and the issue and use of the individual card on which this mention is made.

Article 16

Responsibility

Violators of the provisions of this law incur civil, criminal and disciplinary liability, under the general terms of law.

Article 17

Repealing rule

Decree-Law no. 553/76, of the 13th of June, is hereby revoked.

Article 18

Implementation

1 - Articles 11 and 12 of this law come into force in general terms.

2 - The remaining provisions of this law come into force on the day following the publication in the 1st series of the Diário da República of the criteria and rules referred to in article 12 and of the communication from the Minister of Health declaring the entry into operation from RENNDA.

Approved on February 9, 1993.

The President of the Assembly of the Republic, António Moreira Barbosa de Melo.

Enacted on March 24, 1993.

The President of the Republic, MÁRIO SOARES.

Countersigned on March 26, 1993.

The Prime Minister, Aníbal António Cavaco Silva.