

ASSEMBLY OF THE REPUBLIC

Law no. 22/2007

of 29 June

Partially transposes to the Portuguese legal framework, Directive no. 2004/23/CE, of the European Parliament and of the Council, of 31 March, that alters Law no. 12/93, of 22 April, on the procurement and transplant of human organs and tissues.

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 Portuguese legal framework Directive no. 2004/23/CE, of the European Parliament and of the Council, of 31 of March, on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, in the parte related to the donation and procurement of human tissues and cells.

Article 2

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

Articles 1, 2, 3, 4, 5, 6, 8, 9, 11, 13 and 15 of the Law no. 12/93, of 22 April, in relation to the procurement and transplant of human organs and tissues shall now have the following wording:

«Article 1

[. . .]

1 — The present law applies to acts aimed at the donation or procurement of human organs, tissues and cells, for therapeutic or transplant purposes, as well as transplant interventions.

2 —
3 —

Article 2

[. . .]

1 —
2 — For foreigners who are not permanently resident in Portugal, the legal regime of the acts specified in no. 1 of article 1 is governed by the latter's personal status.

Article 3

[. . .]

1 —
2 —
3 — Procurement centres and transplant centres are authorised by the Minister of Health and are subject to periodic evaluation of their activities and results.
4 — Procurement centres and transplant centres already in operation do not require the authorisation specified in the previous number, but should however submit themselves to the aforementioned periodic evaluation.

Article 4

[. . .]

1 — *(Previous main body of the article.)*
2 — Procurement centres and transplant centres shall guarantee the traceability of organs and tissues, under terms to be regulated.

Article 5

[. . .]

1 — The donation of organs, tissues and cells, for therapeutic or transplant purposes cannot, under any circumstances, be remunerated, and the respective commercialisation is prohibited.

2 — *(Revoked.)*

3 — The agents of the acts specified in no. 1 of the Article 1 and the establishments authorised to carry out transplants of organs, tissues and cells may receive remuneration, solely and exclusively for the service provided, wherein calculation of this remuneration cannot attribute any amount to the organs, tissues or cells that have been removed or transplanted.

Article 6

[. . .]

1 — Without prejudice to the provisions established in the following numbers, donation and procurement from a living donor of organs, tissues and cells is permitted for therapeutic or transplant purposes.

2 — Removal of organs and tissues from a living donor may only be performed, if it is performed exclusively for therapeutic purposes for the recipient and at the time of removal there is no suitable tissue or organ from a deceased donor available, and if there exists no other therapeutic method of comparable effectiveness.

3 — In the event of donation and removal of non-regenerative organs or tissues, the respective admissibility requires a favourable opinion, issued by the Entity for Verification of Transplant Procurement Admissibility (EVA).

4 — Donation and procurement of non-regenerative organs or tissues from minors or other incapacitated persons are always prohibited.

5 — Donation and procurement of regenerative organs, of tissues or of cells that involve minors or other incapacitated persons can only be carried out when the following cumulative requirements are fulfilled:

a) There is no other suitable donor available ;
b) The recipient is the donor's brother or sister;
c) The donation represents a possibility of saving the recipient's life.

6 — Donation and procurement of non-regenerative organs or tissues, that involve foreigners who are not permanently resident in Portugal, may only be carried out by means of judicial authorisation.

7 — Donation and procurement of organs, tissues or cells which is highly likely to lead to a serious and permanent reduction of the donor's physical integrity or health are always prohibited.

Article 8

[. . .]

1 — The consent of the donor and recipient must be free, clarified, informed and unequivocal and the donor may choose to identify the beneficiary.

2 — The consent of the donor and recipient is provided before:

a) A doctor designated by the clinical director of the establishment where the procurement is carried out, in the case of transplants of regenerative organs, tissues and cells;

b) A doctor designated by the clinical director of the establishment where the procurement is carried out and who does not pertain to the transplant team, in the case of transplants of non-regenerative organs, tissues and cells.

3 — In the case of donors who are minors, consent must be provided by the parents, provided that they have not been inhibited from exercising their paternal power, or, in the event of such inhibition or the absence of both parents, by the court.

4 — Donation of tissues or cells from minors who have the capacity to understand and express their own wishes also requires their agreement.

5 —

6 — The consent of the donor or the latter's legal representative must always be provided in writing, and is freely revocable.

Article 9

[. . .]

1 — The donor is entitled to medical assistance until full recovery.

2 — Without prejudice to the provisions established in no. 1 of article 5, the donor is entitled to be indemnified for any damages suffered during the course of the donation and procurement process, independently of the liability in particular for expenses arising from the donation.

3 — The establishments specified in no. 1 of article 3 are responsible for guaranteeing the rights specified in nos. 1 and 2 of this article.

4 — The establishments mentioned in no. 1 of Article 3 must sign an insurance contract issued to the credit of the donor and bear the respective expenses.

Article 11

[. . .]

1 —

2 — The Government is authorised, following a prior opinion from the National Data Privacy Commission (CNPD), to regulate the organization and operation of RENNDA and the issuance of an individual card, which will include mention of the non-donor status.

3 —

Article 13

[. . .]

1 —

2 —

3 —

4 —

5 — One of the copies of the record will be archived in the establishment that carried out the procurement and the other is submitted, for statistical purposes, to the competent service of the Ministry of Health.

6 —

Article 15

[. . .]

1 — The Government must foster information campaigns concerning the significance, in terms of solidarity, health policy and therapeutic means, of the procurement of organs, tissues and cells and of implementation of transplants.

2 —

Article 3

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

Articles 1-A and 6-A are added to Law no. 12/93, of 22 April, with the following wording:

«Article 1-A

Definitions

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

a) «Organ» a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

b) «Tissue» all constituent parts of the human body formed by cells;

c) «Cells» individual human cells or a procurement of human cells when not bound by any form of connective tissue;

d) «Donor» every human source, whether living or deceased, of human cells or tissues;

e) «Donation» any donation of organs, tissues and cells of human origin, intended a applications in the human body;

f) «Procurement» a process by which tissue or cells are made available.

Article 6-A

Entity for Verification of Transplant Procurement Admissibility

1 — The Entity for Verification of Transplant Procurement Admissibility (EVA) is the organisation responsible for issuing a binding opinion in the event of donation and procurement from living donors of organs, tissues or cells for therapeutic or transplant purposes.

2 — The EVA is created, in each hospital establishment where procurement is carried out, by a ministerial order issued by the Minister of Health, on the basis of a joint proposal issued by the respective board of directors and the Portuguese Transplantation Organisation.

3 — The EVA reports to, and operates as a section of the Health Ethics Commission of the hospital establishment where the procurement is carried out.»

Article 4

Transitional provisions

Until the entry into operation of the EVA in each hospital establishment where procurement is carried out, article 6 of Law no. 12/93, of 22 April, in its original wording, will remain in force.

Article 5

Revocatory norm

Article 5 (2) of Law no. 12/93, of 22 April, in its original wording, is revoked.

Article 6

Republication

Law no. 12/93, of 22 April, with its current wording, that forms an integral part of this law, is republished, in the annex.

Approved on 26 April, 2007.

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

Proclaimed on 8 June, 2007.

Let this be published

President of the Republic, ANÍBAL CAVACO SILVA.

Countersigned on 12 June, 2007.

Prime-Minister, *José Sócrates Carvalho Pinto de Sousa*.

ANNEX

**Republication of the Law no. 12/93, of 22 April —
Procurement and transplant of organs, tissues and
cells of human origin**

CHAPTER I

General provisions

Article 1

Material framework of application

1 — The present law applies to acts aimed at the donation or procurement of human organs, tissues and cells, for therapeutic or transplant purposes, as well as transplant interventions.

2 — Blood transfusion, egg and sperm donation and transfer and manipulation of embryos will be subject to special legislation.

3 — Donation and procurement of organs for scientific research purposes will also be subject to special legislation.

Article 1-A

Definitions

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

a) «Organ» a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

b) «Tissue» all constituent parts of the human body formed by cells;

c) «Cells» individual human cells or a procurement of human cells when not bound by any form of connective tissue;

d) «Donor» every human source, whether living or deceased, of human cells or tissues;

e) «Donation» any donation of organs, tissues and cells of human origin, intended a applications in the human body;

f) «Procurement» a process by which tissue or cells are made available.

Article 2

Personal framework of application

1 — This law applies to national citizens and stateless persons and foreigners resident in Portugal.

2 — For foreigners who are not permanently resident in Portugal, the legal regime of the acts specified in no. 1 of article 1 is governed by the latter's personal status.

Article 3

Authorised establishments and qualified persons

1 — The acts specified in article 1, no. 1, can only be performed under medical direct supervision and responsibility, in accordance with the respective *leges artis* and in public or private hospital establishments.

2 — Tissues may also be procured for therapeutic purposes during an autopsy in legal medicine institutes.

3 — Procurement centres and transplant centres are authorised by the Minister of Health and are subject to periodic evaluation of their activities and results.

4 — Procurement centres and transplant centres already in operation do not require the authorisation specified in the previous number, but should however submit themselves to the aforementioned periodic evaluation.

Article 4

Confidentiality

1 — Unless the respective consent is provided by the person holding this right, revelation of the identity of the donor or of the recipient of organ or tissue is prohibited.

2 — Procurement centres and transplant centres shall guarantee the traceability of organs and tissues, under terms to be regulated.

Article 5

Gratuitousness

1 — Donation of organs, tissues and cells, for therapeutic or transplant purposes cannot, under any circumstances, be remunerated, and the respective commercialisation is prohibited.

2 — (*Revoked.*)

3 — The agents of the acts specified in no. 1 of the Article 1 and the establishments authorised to carry out transplants of organs, tissues and cells may receive remuneration, solely and exclusively for the service provided, wherein calculation of this remuneration cannot attribute any amount to the organs, tissues or cells that have been removed or transplanted.

CHAPTER II

Procurement from living donors

Article 6

Admissibility

1 — Without prejudice to the provisions established in the following numbers, donation and procurement from a living donor of organs, tissues and cells is permitted for therapeutic or transplant purposes.

2 — Removal of organs and tissues from a living donor may only be performed, if it is performed exclusively for therapeutic purposes for the recipient and at the time of removal there is no suitable tissue or organ from a deceased donor available, and if there exists no other therapeutic method of comparable effectiveness.

3 — In the event of donation and removal of non-regenerative organs or tissues, the respective admissibility requires a favourable opinion, issued by the Entity for Verification of Transplant Procurement Admissibility (EVA).

4 — Donation and procurement of non-regenerative organs or tissues from minors or other incapacitated persons are always prohibited.

5 — Donation and procurement of regenerative organs, of tissues or of cells that involve minors or other incapacitated persons can only be carried out when the following cumulative requirements are fulfilled:

- a) There is no other suitable donor available ;
- b) The recipient is the donor's brother or sister;
- c) The donation represents a possibility of saving the recipient's life.

6 — Donation and procurement of non-regenerative organs or tissues, that involve foreigners who are not permanently resident in Portugal, may only be carried out by means of judicial authorisation.

7 — Donation and procurement of organs, tissues or cells which is highly likely to lead to a serious and permanent reduction of the donor's physical integrity or health are always prohibited.

Article 6-A

Entity for Verification of Transplant Procurement Admissibility

1 — The Entity for Verification of Transplant Procurement Admissibility (EVA) is the organisation responsible for issuing a binding opinion in the event of donation and procurement from living donors of organs, tissues or cells for therapeutic or transplant purposes.

2 — The EVA is created, in each hospital establishment where procurement is carried out, by a ministerial order issued by the Minister of Health, on the basis of a joint proposal issued by the respective board of directors and the Portuguese Transplantation Organisation.

3 — The EVA reports to, and operates as a section of the Health Ethics Commission of the hospital establishment where the procurement is carried out.

Article 7

Information

The doctor must faithfully, suitably and intelligibly inform the donor and recipient of the possible risks, consequences of the donation and processing and its secondary effects, together with the subsequent care to be observed.

Article 8

Consent

1 — The consent of the donor and recipient must be free, clarified, informed and unequivocal and the donor may choose to identify the beneficiary.

2 — The consent of the donor and recipient is provided before:

a) A doctor designed by the clinical director of the establishment where the procurement is carried out, in the case of transplants of regenerative organs, tissues and cells;

b) A doctor designed by the clinical director of the establishment where the procurement is carried out and who does not pertain to the transplant team, in the case of transplants of non-regenerative organs, tissues and cells.

3 — In the case of donors who are minors, consent must be provided by the parents, provided that they have not been inhibited from exercising their paternal power, or, in the event of such inhibition or the absence of both parents, by the court.

4 — Donation of tissues or cells from minors who have the capacity to understand and express their own wishes also requires their agreement.

5 — Procurement in persons of majority age who are incapacitated due to a psychic anomaly may only be carried out subject to judicial authorisation.

6 — The consent of the donor or the latter's legal representative must always be provided in writing, and is freely revocable.

Article 9

Right to assistance and indemnification

1 — The donor is entitled to medical assistance until full recovery.

2 — Without prejudice to the provisions established in no. 1 of article 5, the donor is entitled to be indemnified for any damages suffered during the course of the donation and procurement process, independently of the liability in particular for expenses arising from the donation.

3 — The establishments specified in no. 1 of article 3 are responsible for guaranteeing the rights specified in nos. 1 and 2 of this article.

4 — The establishments mentioned in no. 1 of Article 3 must sign an insurance contract issued to the credit of the donor and bear the respective expenses.

CHAPTER III

Procurement from deceased donors

Article 10

Potential donors

1 — All national citizens, stateless persons and foreigners resident in Portugal that have not stated their capacity as non-donors to the Ministry of Health are considered to be potential *post mortem* donors.

2 — When the non-availability of donation is restricted to specific organs or tissues or to certain purposes, these restrictions must be expressly indicated in the respective records and card.

3 — The non-availability of donation for minors and incapacitated persons is expressed, for registration purposes, by the respective legal representatives and may also be expressed by minors who have the capacity for understanding and expressing their own intentions.

Article 11

National Register

1 — The computerised National Register of Non-Donors (RENNDNA) is created, in order to register all those who have stated their capacity as non-donors to the Ministry of Health.

2 — The Government is authorised, following a prior opinion from the National Data Privacy Commission (CNPD), to regulate the organization and operation of RENNDNA and the issuance of an individual card, which will include mention of the non-donor status.

3 — RENNDNA must be regulated and commence its activity up until 1 October 1993.

Article 12

Death Certification

1 — The Portuguese Medical Association (Ordem dos Médicos) after consulting the National Council of Ethics for Life Sciences is responsible for establishing and keeping updated, in accordance with scientific progress recorded over time, the set of idoneous medical-legal semiological rules for verification of cerebral death.

2 — The president (“bastonário”) of the Portuguese Medical Association must communicate to the Ministry of Health the text approved by this Association, setting the criteria and rules specified in the previous number, for publication in the 1st series of the *Diário da República*.

3 — The first publication must be made up until 1 October 1993.

Article 13

Certification formalities

1 — The doctors that have carried out the procurement must draw up a record, in duplicate, specifying the identity of the deceased person, the time and date of death, mention of having consulted RENNDNA and the individual card, if available, and of the absence of opposition to the procurement, the removed organs or tissues and the respective destination.

2 — No doctor pertaining to the transplant team may intervene in the verification of death.

3 — The procurement must be performed by a medical team authorised by the clinical director of the establishment where the procurement is carried out.

4 — The record specified in no. 1 must be signed by the intervening doctors and by the clinical director of the establishment.

5 — One of the copies of the record will be archived in the establishment that carried out the procurement and the other is submitted, for statistical purposes, to the competent service of the Ministry of Health.

6 — When it has not been possible to identify the corpse, it shall be presumed that there is no opposition to donation unless otherwise indicated by the circumstantial elements.

Article 14

Care to be observed in execution of the procurement

1 — During execution of the procurement it is necessary to avoid any form of mutilation or dissection other than that which is strictly necessary for removal and use of the tissues or organs and that which may hinder implementation of an autopsy, when this takes place.

2 — The fact that the death occurred in conditions that make the implementation of a medical-legal autopsy

necessary, does not impede implementation of the procurement, however the doctor must report in writing all and any observations that may be useful in order to complete the autopsy report.

CHAPTER IV

Complementary provisions

Article 15

Information campaign

1 — The Government must foster information campaigns concerning the significance, in terms of solidarity, health policy and therapeutic means, of the procurement of organs, tissues and cells and of implementation of transplants.

2 — The information campaign must also inform people of their right to state their non-availability for *post mortem* donation, the existence of the National Register of these decisions and issue and use of an individual card in which this mention is made.

Article 16

Responsibility

Any person infringing the provisions established in this law will incur civil, penal and disciplinary liability, under the general terms of the law.

Article 17

Revocatory norm

Decree-Law no. 553/76, of 13 July is revoked.

Article 18

Entry into force

1 — Articles 11 and 12 of this law enter into force in general terms.

2 — The other provisions of this law enter into force on the day after publication in the 1st series of the *Diário da República* of the criteria and rules specified in article 12 and the communication from the Minister of Health declaring the entry into operation of RENNDNA.