ASSEMBLY OF THE REPUBLIC

Law 12/2009

of 26 March

Establishes the legal status for the quality and safety standards for the donation, procurement, testing, processing, preservation, storage, distribution and use of tissues and cells of human origin by transposing into domestic law Directives 2004/23/EC of the European Parliament and of the Council of 31 March, 2006/17/EC of the Commission of 8 February, and 2006/86/CE of the Commission of 24 October.

The Assembly of the Republic hereby decrees the following, pursuant to Article 161(*c*) of the Constitution:

CHAPTER I

General provisions

Article 1

Object

1 – This Law lays down the legal status for the quality and safety standards for the donation, procurement, testing, processing, preservation, storage, distribution and use of tissues and cells of human origin.

2 — This Law transposes into the domestic legal system Directives 2004/23/EC of the European Parliament and of the Council of 31 March, 2006/17/EC of the Commission of 8 February, and 2006/86/EC, of the Commission of 24 October.

Article 2

Scope of application

1 – The provisions in this law apply to:

a) the donation, procurement, testing, processing, preservation, storage, distribution and use of tissues and cells of human origin intended for use in human beings, including haematopoietic peripheral blood, umbilical cord blood and bone marrow stem cells, surgical waste and reproductive cells, foetal tissues and embryonic stem cells, without prejudice to provisions in specific legislation;

b) the donation, procurement, testing, processing, preservation, storage and distribution of manufactured products derived from tissues and cells of human origin intended for use in human beings;

c) tissues and cells of human origin where these are to be used in human beings in the context of clinical trials.

2 – This Law does not apply to:

a) tissues and cells used in autologous grafts within the same surgical procedure;

b) blood, its components and derivatives, within the meaning of Decree-Law 267/2007 of 24 July;

c) organs or parts of organs which may be used for the same purpose as the whole organ within the human body;

d) tissues and cells of human origin not intended for use in the human body, such as in research in animal models or *in vitro*.

3 – The procurement, testing, processing, storage, distribution and use of haematopoietic progenitor cells are excepted from the provision in paragraph *b*) of the preceding clause.

4 – This Law applies to tissues and cells intended to be used for industrially manufactured products, including medical devices only as far as donation, procurement and testing are concerned, and the processing, preservation, storage and distribution are regulated by separate legislation.

Article 3

Definitions

For the purposes of this law the technical terms used have the meanings set forth in Annex I of this law, whereof it is an integral part.

CHAPTER II

Duties of the competent authorities

Article 4

Competent authorities

1 – The competent authorities responsible for ensuring compliance with the technical requirements laid down in this Law are the Authority for Blood and Transplantation Services, known by the abbreviation ASST, and the National Council for Medically Assisted Reproduction, known by the abbreviation CNPMA.

2 – The ASST is the authority responsible for transplantation services. Its mission is to ensure standards of quality and safety for the donation, procurement and testing of tissues and cells of human origin intended for any purpose whatsoever, and for the processing, storage and distribution, including import and export operations, of tissues and cells when they are intended for transplantation, except for reproductive cells and embryonic stem cells and when these operations comply with the use of medically assisted reproduction techniques.

3 – The CNPMA is the competent authority with powers to ensure standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of reproductive cells and human embryonic stem cells in accordance with Article 30(2)(*a*,*b*,*c*,*e*) of Law 32/2006 of 26 July.

4 – Under the action specified in (2) the ASST is responsible for coordinating, guiding, regulating and inspecting the procurement, testing, processing, storage, distribution and transplantation of tissues and cells of human origin within Portugal.

5 – Under the action specified in (3) the CNPMA is responsible for monitoring the operations of the centres in which medically assisted reproduction is carried out where human gametes or embryos are preserved and for checking compliance with the law, in cooperation with the competent public bodies, pursuant to

Article 30(2) *c*) of Law 32/2006 of 26 July.

Article 5

Authorisation

1 — The activities specified in (2) and (3) of the preceding Article may only be carried out by establishments which have been authorised by the ASST pursuant to Article 5(1) of Law 32/2006 of 26 July.

2 – No activity related to the procurement of human reproductive cells and embryonic stem cells in the context of the application of medically assisted reproduction techniques can be undertaken anywhere except in the authorised centres in accordance with the conditions established by the CPNMA under Article 5 and in Article 30(2) *b*) of Law 32/2006 of 26 July.

3 – In exceptional circumstances the procurement of tissues and cells mentioned in (2) of the preceding Article may take place in hospitals not authorised as procurement units provided that the tissues and cells are procured by professionals from authorised procurement units.

4 – For the purposes of the provision in the preceding point the authorised procurement units must ensure that all the conditions are in place for procurement to be carried out in accordance with the provisions established in this Law, including traceability of the donor and donation.

5 — The ASST must be informed of the procurement of tissues and cells undertaken in the circumstances described in (3) and (4).

6 – The ASST may:

a) authorise tissue and cell banks in relation to the procurement, testing, storage and distribution laid down under this Law;

b) authorise procurement units in relation to procurement practices;

c) authorise establishments responsible for using human tissues and cells in human beings;

d) Authorise procedures for the preparation of tissues and cells which the tissue and cell bank can carry out in compliance with the requirements set forth in Annex III of this law, whereof it is an integral part.

7 — For the purpose of the authorisation stipulated in the preceding point the ASST must be informed about the requirements to which Annexes II and III of this Law refer and whereof they are an integral part.

8 – The agreements signed by a bank and third parties, including procurement units, as set forth in Article 21, must be examined prior to consideration of the process leading to the granting of the authorisation.

9 – The request for authorisation must be submitted by the competent body of the organisation in which the establishment functions via an application sent to the ASST. This application must contain the following details:

a) Name of person or persons in charge of the activities and their *curricula vitae;*

b) The processes for which authorisation is sought;

c) qualifications of the staff involved or to be involved in the activities;

d) identification of the facilities, equipment interdisciplinary or inter-institutional relations, if applicable, relevant to the process;

e) Annual schedule of activities;

f) explanatory memorandum stating the nature of the use, the resources available to the establishment for carrying out the activity requested and the type of tissues or cells for which the authorisation is sought.

10 – After confirming that the establishment satisfies all the requirements laid down in this Law the ASST shall grant the authorisation and indicate which activities and preparation processes for tissues and cells are authorised and in what conditions, all of which shall be specified in a certificate issued for the purpose.

11 – The establishments shall not undertake any substantial changes to their activities and preparation processes for tissues and cells without the prior written approval of the ASST.

12 – The ASST may suspend or revoke the authorisation granted pursuant to (10) if inspections or control measures implemented pursuant to the next article demonstrate that the establishment is failing to comply with the requirements set forth in this Law.

13 — With respect to reproductive and embryonic stem cells, whenever such acts are undertaken within the context of medically assisted reproduction techniques, the CNPMA shall exercise the powers specified in (6) (7), (8) and (11).

14 – For the purposes of adopting the measures set forth in (12) the ASST must hear from the interested party, whenever possible, pursuant to Articles 100 ff of the Code of Administrative Procedure.

15 – The circumstances in which the authorisation of a centre where medically assisted reproduction techniques are carried out can be suspended or revoked are laid down in separate legislation.

Article 6

Inspection and control measures

1 – The ASST shall, in matters within its jurisdiction, undertake periodic inspections or other appropriate control measures on procurement units, tissue and cell banks and establishments responsible for tissue and cell application, in order to ensure compliance with the requirements of this Law. The period between such inspections shall not exceed two years.

2 - For the purposes of the provision in the preceding point the ASST has the following powers:

a) to inspect the procurement units, tissue and cell banks and establishments responsible for using them, and the facilities of third parties empowered by the holder of the authorisation to undertake any part of the procedures;

b) to assess and check the procedures and activities in the procurement units, tissue and cell banks, establishments responsible for using them and the facilities of third parties;

c) To collect samples for examination and tests;

d) to examine any documents or other records relation to the purpose of the inspection.

3 – The ASST must send a written report on the outcome of the inspections carried out pursuant to the preceding points to the heads of the establishments.

4 – The ASST shall establish the guidelines for the conditions for inspections and control measures, and for the training and qualification of the officials involved in order to ensure a high level of competence and performance.

5 – In the event of any adverse reaction or serious adverse event or the suspicion thereof, the ASST shall organise inspections or other control measures as deemed appropriate.

6 – The ASST shall also undertake an inspection or another control measure at the duly justified request of the competent authorities in another Member State in the event of an incident or serious adverse reaction.

7 — With respect to reproductive and embryonic stem cells and when these acts are undertaken within the context of medically assisted reproductive techniques, the CNPMA shall cooperate with the General Inspectorate of Health-related Activities, known by the abbreviation IGAS, in exercising the powers specified in (1), (2), (3), (4), (5) and (6).

8 – The ASST and CNPMA shall, upon the request of another Member State or the European Commission, provide information on the results of inspections and control measures related to the requirements of this Law.

CHAPTER III

National tissue and cells network

Article 7

Network

1 – The national tissue and cells network, hereinafter called the network, consists of the procurement units, tissue and cell banks and establishments responsible for their use, regardless of their legal nature, duly authorised by the ASST and operating in Portugal.

2 – The procurement units, tissue and cell banks and establishments responsible for their use may jointly form coordination offices for the procurement of cells and tissues for transplantation, under terms to be regulated by ministerial order and approved by the government minister responsible for health.

3 – The network shall include histocompatibility establishments in accordance with their legally established powers,

4 – The provisions laid down in the preceding points do not apply to reproductive cells, embryonic stem cells and other cells or tissues procured in the context of medically assisted reproduction techniques.

Article 8

Traceability

1 – The tissues and cells procured, processed, stored, distributed and used in national territory must be traceable from the donor to the recipient and from the latter to former. All the relevant data relating to the products and materials coming into contact with these tissues and cells shall likewise be traceable.

2 – For the purposes of the provision in the preceding point the procurement units, tissue and cell banks and the establishments responsible for their use shall implement a donor identification system which assigns a unique code to each donation and each product associated with it in accordance with the provision in Article 12 and with the terms to be defined by the ASST and the CNPMA.

3 — All tissues and cells must be identified with a label that contains the information or references that allow a link to the information referred to in Annex VIII of this Law, whereof it is an integral part.

4 – The data necessary to ensure full traceability, specified in Annex X of this Law, shall be kept for at least 30 years after clinical use, regardless of the form of storage. Full confidentiality must be ensured.

Article 9

Import and export of tissues and cells of human origin

1 – Tissues and cells intended for use in human beings may only be imported from another country if:

a) they come from tissue and cell banks authorised for these activities and meet all the requirements for quality standards laid down in this Law;

b) they fulfil all the traceability requirements laid down in this Law;

c) they comply with a notification system for serious adverse reactions and events equivalent to that prescribed in this Law.

2 – The import of tissues or cells from third countries and their export to third countries can only be undertaken by tissue and cell banks that have been duly authorised for such activities, in compliance with this Law and on authorisation, in accordance with their respective sphere of competence, by the ASST and CNOMA, pursuant to
(4) and (5) below.

3 – All the measures necessary must be adopted to ensure that the export of tissues and cells to third countries is accomplished through tissue and cell banks duly authorised for these activities.

4 – Requests to import tissues and cells must specify the originating institution and they shall only be authorised by the ASST or the CNPMA, depending on the sphere of competence, when:

a) there is proven benefit to using the tissues or cells for which it is intended to apply;

b) the purpose of the tissues or cells is for human use;

c) Such tissues or cells are not available in a Portuguese bank;

d) there are reasons of medically justified compatibility.

5 – Applications to export tissues and cells must specify the destination institution and they shall only be authorised by the ASST or the CNPMA, depending on the sphere of competence, when a sufficient amount of tissues and cells are available in domestic tissue banks or for duly justified reasons of compatibility.

6 – In the event of an emergency the import or export of tissues and cells may be authorised directly by the ASST or the CNPMA, depending on the sphere of competence, provided that the supplier is

duly accredited, designated, licensed or authorised as established in this Law or in equivalent quality and safety standard norms.

7 – The provisions in the preceding points shall apply to the circulation of tissues and cells from third countries and from the European Union.

Article 10

Record keeping

1 – Tissue and cell banks and procurement units shall keep up-to-date records of their activities, access to which is restricted and confidential. These shall include the types and quantities of tissues and cells procured, tested, processed, preserved, stored and distributed or used in another way, along with the origin and destination of tissues and cells intended for use in human beings, pursuant to Annexes II and VIII of this Law, whereof they are an integral part.

2 – With respect to the establishments responsible for using the tissues and cells, the register referred to in the preceding point shall include the clinical applications involved, the data necessary for the identification of the recipients of the tissues and cells transplanted and their origin in order to ensure traceability as set forth in Annex X of this Law, whereof it is an integral part.

3 – The records specified in the preceding points must be kept for at least 30 years and destroyed when they are no longer needed for traceability purposes.

4 – The tissue and cell banks and the establishments responsible for their use shall submit to the ASST or the CNPMA, depending on the sphere of competence, an annual report on their activities which shall be an integral part of the assessment necessary to retain the authorisation to engage in the activity.

5 – Within their spheres of competence, the ASST and the CNPMA shall establish and keep updated a public register of authorised establishments and their activities.

Article 11

Notification of serious adverse events and reactions

1 – Tissue and cell banks and procurement units, plus the establishments responsible for using them, shall put in place a system for report, investigate, register and transmit information about serious adverse reactions and events that may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

2 – The person responsible specified in Article 14 shall ensure that the competent authority, the ASST or the CNPMA, depending on the sphere of competence, is notified of any serious adverse reactions or events referred to in the preceding point and that it is presented with a report analysing the causes and consequences, including measures taken.

3 – Any person or institution using tissues or cells of human origin pursuant to this Law shall report any relevant information to the procurement units and tissue and cell banks engaged in the donation, procurement, testing, processing, storage and distribution of tissues and cells of human origin in order to facilitate traceability and ensure quality and safety control.

4 – The tissue and cell banks and procurement units and establishments responsible for their use shall ensure that an accurate, rapid and verifiable procedure is in place that will enable them to recall from distribution any products which may be related to a serious adverse reaction or event.

5 – In the case of assisted reproduction, any kind of incorrect identification or exchange of gametes or embryos is held to be a serious adverse event, and everyone and every procurement establishment responsible for tissue and cell application in human beings which undertakes assisted reproduction shall report any such event to the CNPMA.

6 – The forms contained in Annex IX of this Law shall be used for the purposes of report serious adverse reactions and events, and this annex is considered to be an integral part of this Law.

CHAPTER IV

Procurement requirements

Article 12

Procurement of tissues and cells of human origin

1 – Tissue and cell banks and procurement units shall have written agreements with the staff or clinical teams responsible for donor selection unless they are employed by the same organisation or establishment, specifying the procedures to be followed in accordance with Annex V of this Law, whereof it is an integral part, the types of tissues and cells and the samples to be procured for testing and the protocols to be followed.

2 – Tissue and cell banks and procurement units shall utilise standard operating procedures (SOPs) for the verification of:

a) donor identity;

b) details of the donor or donor family consent, as established by law;

c) assessment of the selection criteria for donors, as detailed in Article 25(1);

d) assessment of the laboratory texts required for donors, as set forth in Annexes VI and VII of this Law, whereof they are an integral part.

3 – There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue bank or, in the case of direct distribution of tissues and cells, to the clinical team responsible for tissue and cell application or, in the case of tissue and cell samples, to the laboratory for testing, in accordance with Annex VIII of this Law, whereof it is an integral part.

4 - Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Annex VIII of this Law, whereof it is an integral part.

5 - Procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in Annex VIII, section 1.3, of this Law, whereof it is an integral part, and with due regard for domestic and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices.

6 – For the purposes of the preceding point, approved, sterile instruments and procurement devices shall be used for tissue and cell procurement.

7 – The procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy.

8 — The procurement of tissues and cells from deceased donors shall be carried out with respect for the dignity of the deceased persons, with special reference to the reconstruction of the body so that it shall resemble the original anatomical form as far as possible.

9 – The staff and equipment necessary for body reconstruction of the deceased donor shall be provided by cell and tissue banks and procurement units, for the purposes of the previous point.

10 - A unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue and cell bank, to ensure proper identification of the donor and the traceability of all donated material.

11 — For the purposes of the preceding point a national donor identification system is to be created which assigns a unique code to each donation and each product associated with it, in accordance wtih Annex II of this Law, whereof it is an integral part, without prejudice to the single European coding system which has been approved.

12 — The codified data shall be entered on a national register organised by the ASST or CNPMA, depending on the sphere of competence.

13 — Donor documentation shall be kept in accordance with section 1.4 of Annex VIII of this Law, whereof it is an integral part.

CHAPTER V

Provisions on the quality and safety of tissues and cells

Article 13

Quality management

1 – Procurement units, tissue and cell banks and the establishments responsible for their use shall put in place an update a quality system and quality management system based on principles of good practice which shall include at least the following documentation:

a) standard operating procedures of authorised activities and critical processes;

b) training and reference manuals;

c) reporting forms;

d) donor records;

e) information on the final destination of tissues or cells;

f) system to detect and report adverse reactions.

2 – The procurement units, tissue and cell banks and establishments responsible for their use shall take all necessary measures to ensure that this documentation is available for inspection by the competent authority, i.e. the ASST or IGAS in conjunction with the CNPMA.

Article 14

Responsible person

1 – The responsible person designated by procurement units, tissue and cell banks and by the establishments responsible for tissue and cell application shall be a medical doctor or a graduate in pharmaceutical or biological sciences and have at least two years' experience in the field.

2 – The above provision shall not apply to centres carrying out medically assisted reproduction techniques.

3 – The person designated in point 1 shall be responsible for:

a) ensuring that human tissues and cells intended for application in human beings are procured, tested, processed, stored, distributed and applied in accordance with this Law;

b) providing all necessary information to the ASST pursuant to this Law;

c) ensuring compliance with requirements in terms of staff training, the quality system, documentation, record keeping, traceability, reporting, data protection and confidentiality;

d) ensuring that medical activities, in particular the selection of donors, analysis of laboratory results, the tissues and cells to be applied and their application are carried out under medical responsibility and direct medical supervision.

4 – The functions specified in the preceding point can be delegated provided that the delegated person has the qualifications stipulated in (1).

5 – Procurement units, tissue and cell banks and establishments responsible for tissue and cell application shall inform the ASST or the CNPMA, depending on the sphere of competence, of the name of the responsible person and of their replacement, in the event of temporary or definitive absence.

Article 15

Person nel

Personnel working in procurement units, tissue and cell banks and in establishments responsible for tissue and cell application shall be appropriately qualified to perform such tasks and be provided with suitable, timely and regular training.

Article 16

Tissue and cell reception

1 – Tissue and cell banks shall ensure that:

a) all human tissue and cell donors are subjected to tests in accordance with the

requirements set forth in Annexes VI and VII of this Law, whereof they are an integral part;

b) tissue and cell selection and acceptance shall take place in accordance with the requirements set forth in Annexes V to VII of this Law, whereof they are an integral part;

c) human tissues and cells and their associated documentation comply with the requirements set forth in Annexes II to VIII of this Law and of any regulations which may be approved pursuant to Article 33(c);

d) the packaging of human tissues and cells received complies with the requirements set forth in Annex III of this Law, whereof it is an integral part.

2 – All tissues or cells received that do not comply with the provisions laid down in the preceding points shall be discarded.

3 – The acceptance or rejection of tissues or cells received shall be documented.

4 — The tissue and cell banks shall ensure that the human tissues and cells are correctly identified at all times during any processing stage. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with Article 12(10,11).

5 — Tissues and cells shall be held in quarantine until requirements relating to donor testing and information have been met in accordance with Annex VIII of this Law, whereof it is an integral part.

Article 17

Tissue and cell processing

1 – Tissue and cell banks shall include in their SOPs all the processes that may affect quality and safety and shall ensure that they are carried out under controlled conditions.

2 — Tissue and cell banks shall ensure that the equipment used, the working environment and process design, validation and control conditions are compliance with the requirements set forth in Annex II of this Law, whereof it is an integral part.

3 – Tissue and cell banks shall include in their SOPs special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues and cells, the processing environment or personnel.

4 – Any change to the processes used in the preparation of tissues and cells shall obey the provisions in (1).

Article 18

Tissue and cell storage conditions.

1 — Tissue and cell banks shall ensure that all procedures linked to the storage of tissues and cells are documented in the SOPs and that the storage procedures meet the requirements established in Annex II of this Law, whereof it is an integral part.

2 — Tissue and cell banks shall establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might affect the proper functioning of the tissues and cells in light of their intended purpose.

3 — Processed tissues or cells may not be distributed until all the requirements set forth in this Law have been met.

4 — Should the tissue and cell bank terminate its activities the stored tissues and cells shall be transferred to other establishments duly authorised by the ASST.

5 — The termination of activity of an embryonic stem cell bank or any bank holding tissues or cells procured in the context of medically assisted reproduction techniques is regulated by separate legislation.

Article 19

Labelling, documentation and packaging

Tissue and cell banks shall ensure that labelling, documentation and packaging of tissues and cells meet the requirements set forth in Annexes III and VIII of this Law, whereof it is an integral part.

Article 20

Distribution

1 — Tissue and cell banks shall ensure that the distribution conditions for tissues and cells meet the requirements set forth in Annexes III and VIII of this Law, whereof they are an integral part, and of such regulations as may be approved pursuant to Article 33(*d*) and (*e*).

2 — Within its sphere of competence the ASST can authorise the direct distribution of certain tissues and cells from the procurement site to the healthcare establishment for immediate transplantation.

Article 21

Relations between the tissue and cell banks and third parties

1 — Tissue and cell banks shall establish agreements with a third party whenever an external activity takes place which influences the quality and safety of tissues and cells processed in the following circumstances, in particular:

a) where a tissue and cell bank entrusts one of the stages of tissue or cell procurement, processing or testing to a third party;

b) where a third party provides goods or services that may affect tissue or cell quality and safety, including their distribution;

c) where a tissue and cell bank provides services to another tissue and cell bank relating to a specific procedure for which it is not authorised;

d) where a tissue and cell bank distributes tissues or cells processed by third parties.

2 — third parties shall be assessed and selected in order to conclude the agreements referred to in the preceding point on the basis of their ability to meet the requirements laid down in this Law.

3 — the agreements referred to in this Article, in terms of their regulation by ministerial order to be issued by the government minister responsible for health shall specify the responsibilities of third parties and lay down the

procedures and protocols to be fulfilled by each in relation to the activity contracted, including the terms of the forwarding procedure referred to in the next point.

4 — If the contract is terminated the contracted party shall send the contracting party the documents, data, samples and all information that may influence the traceability, quality and safety of the tissues and cells.

5 — Tissue and cell banks shall keep a complete list of the agreements signed with third parties and provide copies thereof to the ASST or CNPMA, depending on the sphere of competence.

CHAPTER VI

Donor selection and evaluation

Article 22

Applicable principles

1 – The donation of cells and tissues is voluntary. altruistic and selfless, and there is no place whatsoever for any economic or pecuniary payment in relation to either the donor or to any other person or entity.

2 — Umbilical cord blood stored in public banks shall be at the disposal of any patient for whom its use is indicated, including the donor.

3 — Without prejudice to the provision in (1) living donors may receive a strictly limited payment to reimburse expenses incurred or losses directly arising from the donation, pursuant to Article 9 of the annex to Law 22/2007 of 29 June.

4 – The terms and conditions under which the assignment of compensation provided for in the preceding point shall be set by order of the Minister for Health.

5 — No payment may be requested of recipients for the tissues or cells received.

6 — The provision of services in the context of harvesting, procurement, testing, processing, preservation, storage, distribution and application of human tissues and cells meets the conditions of authorisation, safety, quality and publicity laid down in this Law.

7 – Donation shall be promoted and advertised only in general terms and shall at all times be transparent and obey principles of scientific rigour, trustworthiness and intelligibility of information and not seek benefits for specific individuals, demonstrating its voluntary, altruistic and impartial nature.

8 — Deceptive advertising is that which misleads with respect to the real usefulness of obtaining, processing, preserving and storing human cells and tissues, when it is not borne out scientifically according to the scientific criteria established or accepted by the ASST or the CNPMA.

Article 23

Data protection and confidentiality

1 — In strict compliance with the terms and conditions laid down in the Law on the Protection of Personal Data, approved by Law 67/98 of 26 October, personal data relating to donors and recipients, their processing and interlinking are subject to professional secrecy and to appropriate measures to ensure the safety and confidentiality of information.

2 — Donors and recipients are assured of confidentiality of all information related to their health, the results of tests on donations and the traceability of donations.

3 — The unauthorised addition, removal or amendment of data contained in donor records or exclusion entries is expressly forbidden, as is the unauthorised transfer of information which does not comply with Law 67/98 of 26 October (Law on the Protection of Personal Data), on this matter.

4 — The information systems of tissue and cell banks shall ensure the safety of data pursuant to this Article and the procedures required to resolve any discrepancy of data.

5 — Rights of access and opposition of holders of the data to the information kept in the donation and donor registration systems are exercised pursuant to the terms and conditions referred to in Articles 10 to 13 of Law 67/98 of 26 October, without prejudice to the provisions in legislation on the use and application of medically assisted reproduction techniques.

Article 24

Consent

1 — The procurement of human tissues and cells and their application in human beings shall only be carried out after all the mandatory informed consent requirements laid down in Article 8 of the annex to Law 22/2007 of 29 June and in Annex IV of this Law, whereof it is an integral part, have been met, without prejudice to the provisions in the legislation which governs the use and application of medically assisted reproduction techniques.

2 — Donor informed consent shall be obtained for the procurement of surgical waste and the same principles as those for living donors shall apply.

Article 25

Selection, evaluation, procurement and reception

1 — Donors shall meet the selection criteria laid down in Annex V of this Law, whereof it is an integral part, and, in the case of donors of reproductive cells, in Annex VII of this Law, whereof it is an integral part.

2 — Donors of tissues and cells, except for donors of reproductive cells, shall undergo the biological tests specified in (1) of Annex VI of this Law, whereof it is an integral part.

3 — Donors of reproductive cells shall undergo the biological tests specified in (2) and (3) of Annex VII of this Law, whereof it is an integral part.

4 — The tests referred to in (2) shall be carried out in compliance with the general requirements laid down in (2) of Annex VI of this Law, whereof it is an integral part.

5 — The tests referred to in (3) shall be carried out in compliance with the general requirements laid down in (4) of Annex VII of this Law, whereof it is an integral part.

6 — In the case of autologous donation the criteria established in (2.1) of Annex V of this Law, whereof it is an integral part, shall be observed.

7 —The results of the donor evaluation and testing procedures shall be documented and any major anomalies shall be reported in accordance with the requirements referred to in Annex V of this Law, whereof it is an integral part.

8 — Tests carried out on donors shall be carried out by a laboratory that has been certified or accredited and authorised by the ASST for this purpose and which has a contract with the tissue and cell bank.

9 — The donation and procurement of tissues and cells and their reception in the tissue and cell bank must meet the requirements established in Annex VIII of this Law, whereof it is an integral part.

10 – The provision laid down in (8) does not apply to reproductive cells, embryonic stem cells and other cells or tissues harvested in the context of medically assisted reproduction techniques.

CHAPTER VII

Exchange of information and reports

Article 26

Reports

Depending on the sphere of competence, the ASST and the CNPMA shall send to the European Commission before 7 April 2009, and every three years thereafter, a report on the activities developed under the implementation of this Law, including a report on the measures adopted as regards inspection and monitoring.

CHAPTER VIII

Infringement and penalties

Article 27

Administrative offences

1 — Without prejudice to any civil or criminal liability, the provisions in Articles 44 and 45 of Law 32/2006 of 26 July and the administrative measures to which they give rise, any infraction of the norms laid down in this Law constitute an administrative offence as set forth in the points below.

2 — Minor administrative offences are:

a) Non-compliance with Article 14(5);
a) Non-compliance with Article 21(5).

3 — Serious administrative offences are:

a) Failure to observe the provisions in Article 5 (1-5)(7)
(9) and (11);
a) Non-compliance with Article 10(3,4);
c) Non-compliance with Article 14(1,3,4);
d) Non-compliance with Article 15;
e) Non-compliance with Article 13(2);
f) Non-compliance with Article 22(7);
g) Non-compliance with Article 21(1-4);
h) Failure to observe the decisions and instructions of the
ASST or the CNPMA;
i) Intransigence in supplying information requested by the ASST or the CNPMA and any conduct that may be interpreted as failure to cooperate with these bodies;
j) Infringements that facilitate or conceal minor infringements;
l) Repetition of minor infringements committed in the past six months;
m) Issuing misleading advertising as defined in Article 22(8).

4 — Extremely serious administrative offences are:

a) Engaging in activities not authorised by the ASST or the CNPMA in continuing disregard for Article 5 (1-5,7,9,11);
b) Non-compliance with Article 10(1,2);
c) Non-compliance with Article 9;
d) Non-compliance with Article 16;
e) Non-compliance with Article 17;
f) Non-compliance with Article 18;
g) Non-compliance with Article 19;
h) Non-compliance with Article 20(1);
i) Non-compliance with Article 12;
j) Non-compliance with Article 25;
l) Non-compliance with Article 8;
m) Non-compliance with Article 13(1);
n) Non-compliance with Article 11(1-5);
o) Non-compliance with Article 22(1,3,5,6);
p) Persistent misleading advertising as defined in Article 22(8).
q) Non-compliance with Article 23;
r) Non-compliance with Article 24;
s) The use of the licence for purposes other than those established therein;
t) Infringements which influence the quality and safety of tissues and cells and thus give rise to serious hazard or damage to individual or public health;
u) Infringements that facilitate or conceal serious or extremely serious infringements;
v) Repeated non-compliance with the decisions and instructions of the ASST or the CNPMA;
x) Refusal to provide information requested by the ASST or the CNPMA and any conduct that may be interpreted as refusal to cooperate with these bodies;
z) Non-compliance with Article 34(3);
aa) Repeated perpetration of serious infringements in the past five years.

5 — In the administrative offences specified in the preceding points negligence and attempt are punishable,

with the amounts of the fines specified in the next Article being reduced by half.

Article 28

Fines

The administrative offences established in the preceding Article are punishable with fines, as follows:

a) Minor administrative offences are punished with fines up to € 500;
b) Serious administrative offences are punished with fines from € 500 to € 1500, for individuals, and up to € 15 000 for legal persons;
c) Extremely serious administrative offences are punished with fines from € 1500 to € 3500, for individuals, and from € 15 000 to € 44 000, for legal persons.

Article 29

Additional penalties

Depending on the seriousness of the infringement and the degree of misconduct of the agent, the following penalties may be imposed in addition to a fine:

a) Suspension or partial revocation of the authorisation granted to engage in the activity or in the preparation of tissues and cells;
b) Closure of the establishment.

Article 30

Inspection, inquiry and imposition of fines

1 — The ASST shall organise inspections of compliance with the provisions laid down in this Law and the imposition of the penalties established in this Chapter, except for reproduction cells, embryonic stem cells and other cells or tissues harvested in the context of the application of medically assisted reproduction techniques, for which the CNPMA is the competent authority.
2 — IGAS is the competent body for holding inquiries into administrative offence proceedings launched by the ASST or the CNPMA.

Article 31

Destination of fines

The monies yielded by the fines established in this Law revert to:

a) 60 % to the state;
b) 30 % to the ASST or the CNPMA, depending on the sphere of competence;
c) 10 % to IGAS.

CHAPTER IX

Final and temporary provisions

Article 32

Charges

1 — The consideration of applications for authorisation submitted under this Law shall be subject to charges which shall be fixed, paid and collected under the terms and conditions to be established by a ministerial order from the Ministry of Health.
2 — The ministerial order referred to in the preceding Article may also fix the charges payable for services rendered under this Law by private entities duly authorised for the purpose, viz. procurement units, tissue and cell banks and establishments responsible for tissue and cell application.
3 — The destination of and forms of allocating the revenue yielded by such charges are established by the ministerial order referred to in this Article, with at least 50% going to fund the public tissue and cell banks which are to be set up.

Article 33

Technical requirements and their adaptation to scientific and technical advances

The following technical requirements and their adaptation to scientific advances shall be regulated by ministerial order and approved by the government minister responsible for health:

a) requirements related to the authorisation of procurement units, tissue and cell banks and establishments responsible for tissue and cell application;
b) quality system;
c) requirements relating to tissue and cell preparation procedures;
d) processing, storage and distribution of tissues and cells;
e) requirements for the direct distribution of specific tissues and cells to recipients;
f) biovigilance.

Article 34

Temporary norm

1 — Procurement units, tissue and cell banks and establishments responsible for tissue and cell application that are currently in operation must adapt to comply with the requirements laid down in this Law within 12 months of its publication.
2 — Once the period referred to in the preceding point has elapsed the procurement units, tissue and cell banks and the establishments responsible for their use must request the ASST to renew their authorisation in accordance with this Law within 30 business days.
3 — Non-compliance with the previous point will result in the immediate suspension of operations until an inspection has been conducted for the purposes of authorisation.
4 — The provisions laid down in (2) and (3) shall not apply to centres in which medically assisted reproduction techniques are administered.

Article 35

Revocation

1 — Articles 7 and 8 of Ministerial Order 31/2002 of 8 January are hereby repealed in the part which relates to tissues and cells.
2 — Article 3(3,4) of the annex to Law 22/2007 of 29 June are hereby repealed in the part which relates to tissues and cells.

Article 36

Entry into force

This Law shall enter into force on the day following its publication.

Approved on 5 February 2009.

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

Promulgated on 11 March 2009. Let it

be published.

The President of the Republic, ANÍBAL CAVACO

SILVA. Ratified on 12 March 2009

The Prime Minister, *José Sócrates Carvalho Pinto de Sousa*