LAW 160(I)/2017

LAW AMENDING THE LAWS ON REMOVALS AND TRANSPLANTS OF ORGANS OF HUMAN ORIGIN OF 2012 AND 201

	The House of Representatives votes as follows:
Brief title. 127(I) of 2012 102(I) of 2014.	1. This Law shall be referred to as the Law on Deductions and and Transplantation of Organs of Human Origin (Amendment) Act, 2017 and shall be read together with the provisions of the Removal and Transplantation of Organs of Human Origin Human Organs of Human Origin Acts, 2012 and 2014 (hereinafter referred to as «the Main Act») and the principal Act and this Act shall together be referred to as the Removal and Transplantation of Organs of Human Origin Laws of 2012 to 2017.
Amendment of Article 20 of the Main Act.	2. Article 20 of the Main Act is amended as follows:
	(a) By replacing from paragraph (2) thereof the words « With the consent of the newly appointed representative of the potential cadaveric donor » (first and second lines), with the phrase « Subject to the provisions of subparagraph (3) and (5), »; and
	(b) By adding, immediately after subsection (4) thereof, the following new subsection (5) and by renumbering the existing subsections (5), (6), (7), (8) and (9) thereof into subsections (6), (7), (8), (9) and (10), respectively:
	« (5) If there is a living will expressed by a potential deceased donor for the removal of organs for the purpose of transplant, as documented in the National Register of Potential Donors, it may not be revoked by any of the of his/her newly appointed representatives listed in subsection (3).

102(I)/2014

AMENDMENT TO THE ACT OF 2012 ON THE REMOVAL AND TRANSPLANTATION OF ORGANS OF HUMAN ORIGIN

The House of Representatives shall vote as follows:

Short title.
127(I) of 2012.

1. This Act shall be referred to as the Removal and Transplantation of Organs of Human Origin (Amendment) Act, 2014 and shall be read together with the Law of 2012 on the removal and transplantation of organs of human origin (hereinafter referred to as "the principal Act"). The principal Act and this Act shall be referred to together as the Removal and Transplantation of Organs of Human Origin Act, 2012 and 2014.

Amendment of Article 28 of the basic Regulation law.

2. Paragraph (m) of subsection (1) of section 28 of the principal Act is amended by deleting therein the words 'in living donors' (second line).

Amendment of Article 37 of the basic Regulation law.

3. Article 37 of the basic law is amended as follows:

(a) By converting the existing text of this subsection into subsection (1), and

(b) by adding immediately thereafter the following new subsection (2):

"(2) Without prejudice to the generality of the provisions of subsection (1), these Regulations may provide for all or any of the matters relating to information concerning the procedures of the exchange of organs of human origin intended for transplantation and, in particular, procedures for

(i) the transmission of information on organ and donor characteristics,

(ii) the transmission of the information necessary to ensure the traceability of the instruments; and

(iii) ensure the reporting of serious adverse events and reactions.".

No. 4349, 27.7.2012

127(I)/2012

THE LAW OF 2012 ON THE REMOVAL AND TRANSPLANTATION OF ORGANS OF HUMAN ORIGIN

Article

38. Repeal.

THE LAW OF 2012 ON THE REMOVAL AND TRANSPLANTATION OF ORGANS OF HUMAN ORIGIN

Preamble. Official Journal of the EU: L 207, 6.8.2010, p. 140; L 243, 16.9.2010, σ. 68.

For the purposes of harmonisation with the act of the European Union entitled 'Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation',

The House of Representatives shall vote as follows:

1. Short title.

This Act shall be referred to as the Removal and Transplantation of Organs of Human Origin Act/2012.

PART I - INTRODUCTORY PROVISIONS

2. Interpretation.

In this Law, unless otherwise follows from the text -

'authorisation' means approval, accreditation, registration, designation or licensing by the competent authority;

‘competent authority’ means the Secretary of State for Health or any other person or group of people authorised by the Secretary of State for Health;

‘miscarriage’ means the final destination of an organ when it is not used for transplantation;

‘removal’ means the process by which the donated the organ becomes available for transplantation;

‘advertising’ means any written or oral indication or statement in any medium or manner by which the public may be informed or may be led to believe that any human organ is being sold or exchanged;

‘donor’ means any person who donates one or more organs, whether the donation is made during his or her lifetime or posthumously;

‘donation’ means the donation of a human organ for transplantation;

‘medical specialist’ means a registered doctor who has is recognised as holding a specific qualification in accordance with the Article 23 of the Law on the Registration of Doctors;

Chap. 250.

30 of 1959

30 of 1961

53 of 1961

79 of 1968

114 of 1968

14 of 1974

18 of 1979

72 of 1991

66(I) of 1995

112(I) of 1996

102(I) of 2004

24(I) of 2009

162(I) of 2011.

‘European organ exchange organisation’ means a non-profit organisation, whether public or private, engaged in domestic and cross-border organ exchange, whose member are, in the majority of cases, EU Member States.

‘Living donor’ means a blood relative up to the third degree of consanguinity of the recipient or a person who has a close personal relationship with the recipient.

‘Able to give informed consent to become a living donor’ means a person who understands and freely consents to become a donor and has been properly informed about the purpose and nature of the operation and its consequences and risks.

‘Traceability’ means the ability of the competent authority to locate and identify the organ at each stage of the procedure from donation to transplantation or discard of the organ.

‘Recipient’ means the person who receives an organ transplant.

‘Transplantation’ means the process by which an attempt is made to restore certain functions of the human body by transferring an organ from a donor to a recipient.

‘Transplantation centre’ means a hospital, hospital team or unit or other organisation that undertakes organ transplantation and is authorised to do so by the competent authority on the recommendation of the Transplantation Council.

‘Designated representative of a potential dead donor’ means one of the persons specified in subsection (3) of Article 20 who, in the event of the death of a potential donor, gives consent to the removal of an organ when the potential donor did not express his or her refusal to donate an organ while he or she was alive;

‘Procurement organisation’ means a healthcare institution, a hospital team or unit, a legal person or any other entity that undertakes or supervises or coordinates the procurement of organs and is authorised to do so by the competent authority on the recommendation of the Council.

Transplantation:

‘organ’ means the differentiated part of the human body, formed by various tissues, which retains its structure, its vascularity and its ability to develop physiological functions with a significant level of autonomy. Organ parts are also considered to fall within this definition if they are intended for the same purpose as the complete organ in the human body and fulfil the requirements of structure and vascularity;

‘dead donor’ means a donor who has been diagnosed as dead in accordance with the provisions of this Law;

‘serious adverse reaction’ means an unanticipated response, including a communicable disease, of the living donor or recipient, which is associated with any stage of the transplantation procedure from donation to transplantation and which is fatal or life-threatening or causes disability or incapacity or results in or prolongs hospitalisation or morbidity;

‘serious adverse event’ means any unexpected occurrence associated with any stage of the transplantation procedure from donation to transplantation which could lead to the transmission of a communicable disease or be fatal or life-threatening or cause disability or incapacity of patients or result in or prolong hospitalisation or morbidity;

‘close personal relationship’ means a relationship that is determined by the Transplantation Council to exist between donor and recipient that justifies the altruistic donor's selfless donation to the recipient;

‘family relationship’ means a relationship of blood relationship up to the third degree;

‘Transplantation Council’ means the Council established under Article 26;

‘preservation’ means the use of chemical agents, changes in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of human organs from removal until transplantation;

‘transplant coordinator’ means the specially trained person appointed by the Minister of Health;

‘standardised procedures’ means the written instructions describing the stages of a particular process, including the materials and methods to be used and the expected ended result.

‘Minister’ means the Minister of Health;

‘Donor characterisation’ means the collection of appropriate data on donor characteristics necessary to assess the suitability of the donor for organ donation in order to perform an appropriate risk assessment and to minimise the risks to the recipient and to optimise organ allocation;

‘Organ characterisation’ means the collection of appropriate data on the characteristics of an organ, which is necessary to assess its suitability in order to make an appropriate risk assessment and to minimise the risks to the recipient and to optimise the allocation of organs.

3. Scope.

(1) This Law applies to the characterisation, donation, removal, preservation, transport, transplantation and control of an organ intended for transplantation and aims to ensure standards of quality and safety of the human organ in order to ensure a high level of protection of human health.

(2) This Law does not apply to:

(a) receiving or transfusing blood;

(b) in embryo transplantation;

(c) the removal and transplantation of human reproductive organs;

(d) the use of eggs and sperm;

(e) in autotransplants;

(f) in the reception and transplantation of tissues;

(g) transplantation of an organ of animal origin.

PART II - QUALITY AND SAFETY OF ORGANS

4. Quality and safety framework.

(1) The competent authority shall ensure that a quality and safety framework is established to cover all stages of the procedure from donation to transplantation or organ removal.

(2) The competent authority shall ensure the adoption and implementation of operational procedures by transplant coordinators in accordance with Article 29.

(3) The competent authority shall ensure that the nursing staff involved in all stages of the procedure from donation to transplantation or organ removal are appropriately qualified, trained and competent.

(4) The competent authority shall ensure the continuous professional training of the medical personnel involved in all stages of the procedure from donation to transplantation or organ removal by ensuring their participation in specific training and education programmes.

5. Removal organisations.

(1) The removal of an organ for the purpose of transplantation is carried out in nursing homes which comply with the provisions of this Law and which are determined by a decree of the Minister published in the Official Gazette of the Republic.

(2) Removal organisations for which the competent authority has granted a licence shall provide the Transplantation Council with the necessary data for the control and evaluation of their activities and comply with the provisions of this Act.

6. Removal of organs.

The competent authority shall ensure that:

(a) the medical activities of the procurement organisations, such as donor selection and evaluation and the method of organ removal, are carried out in accordance with the recommendations and under the guidance of a responsible physician of the transplantation centre that will transplant the organ;
(b) the removal is carried out in an operating theatre which is designed, constructed, maintained and operated to appropriate standards and in accordance with best medical practice to ensure the quality and safety of the organ to be removed;
(c) organ removal is performed by a surgeon trained in organ removal, in cooperation with the transplant team that will transplant the organs in the Republic of Cyprus or in the European Union or in a third country, or in the case of a dead donor, by a designated or specialised forensic or pathological anatomist.

7. Organ and donor characterisation. Annex I, Annex II.

(1) The competent authority shall ensure that all organs that will be removed and all donors are identified prior to transplantation by collecting the information and data listed in Annexes I and II. Information specified in Annex I shall include the set of minimum data to be collected by transplant coordinators for each donation. The information specified in Annex II shall include the set of additional information to be collected in addition, on the basis of a decision by the transplantation team, taking into account the availability of this information and the specific circumstances of the case.

(2) Without prejudice to the provisions of subsection (1), if following the risk-benefit analysis for a specific case, including emergency cases where there is a threat to the patient's life in the judgment of the transplant team, and where the expected benefits outweigh the risks due to the existence of incomplete data, the organ transplantation is carried out, even if not all the minimum data specified in Annex I are available.

(3) The transplant team shall collect all necessary information from living donors and provide them with the information they need to understand the implications of the donation. In the case of post-mortem donation, the transplant coordinators shall ensure that information is collected from the newly appointed representative and/or the attending physician of the potential dead donor.

(4) The tests required for organ and donor characterisation shall be carried out by a laboratory with qualified or trained and competent personnel and appropriate facilities and equipment.

(5) The competent authority shall ensure that the organisation, institution and laboratory involved in organ and donor characterisation implement appropriate procedures to ensure that the organ and donor characterisation data are transmitted to the transplant centre in a timely manner.

(6) In the event of an exchange of organs between Member States or third countries, transplantation coordinators shall ensure that organ and donor characterisation information, as specified in Annexes I and II, are transmitted to the Member State or third country with which the organ is exchanged, in accordance with the procedures established by the Transplantation Council.

(7) The histocompatibility tests necessary for the identification of a histocompatible organ recipient for transplantation from a living or dead donor shall be carried out in a recognised immunogenetics and histocompatibility laboratory which is active and accredited by the European Federation of Immunogenetics.

8. Transport of instruments.

The competent authority shall ensure that the following requirements are met:

(a) The organisation, institution or company involved in organ transport shall implement appropriate procedures to ensure the integrity of the organ during transport and ensure that the time of transport is appropriate to the needs of the transplant team;
(b) the labelling of the packaging used for the transport of organs, completed by the transplant coordinators, shall bear the following information cumulatively:

(i) Identification of the removal organisation and the centre where the removal took place, including addresses and their phone numbers,

(ii) identification of the transplant centres the destination, including its address and telephone number,

(iii) an indication that the packaging contains a human organ, specifying the type of organ and its right or left position, if such clarification is required, and the indication "FLEXIBLE",

(iv) recommended conditions of transport, and instructions for keeping the packaging in the suitable temperature and position,

(v) the organs transferred are accompanied by the characterisation report of the organ and the donor:

Provided that the conditions set out in sub-paragraph (ii) of paragraph (b) shall not apply if the transfer takes place within the same building.

Transplant Centres. Annex I, Annex II

9.- (1) For reasons of public interest and following a positive recommendation of the Transplantation Council, the competent authority shall, exceptionally, authorize the operation of more than one transplantation centre.

(2) The transplantation centre shall ensure that the human body and its parts are not subject to commercial transactions and that the procurement of organs is carried out without any exchange or benefit.

(3) The competent authority shall ensure that the transplantation takes place in or from a transplantation center that complies with this Act.

(4) A transplantation center shall operate upon obtaining an operating license, which shall be valid for one year and shall be issued by the competent authority, upon application of the transplantation center to the Transplantation Council and a positive recommendation of the Transplantation Council to the competent authority. The authorization shall be issued once the Transplantation Council has established the adequacy of the facility and its ability to contribute to meeting transplantation needs.

(5) The competent authority shall indicate in the operating license it the activities that the transplant center may undertake and the organs that the transplant center may transplant.

(6) The transplant center shall submit an annual report of its activities to the Transplant Council; and –

a. verify that the organ and donor characterization has been completed in accordance with the model set out in Annexes I and II and that all the registers provided for in this Law are kept;

b. provide all information necessary for the Transplant Council to maintain its records.

(7) The competent authority may suspend the license of a transplant center if it finds that the transplant center does not comply with the provisions of this Act.

Traceability. Annex I, Annex II

10.- (1) The competent authority shall ensure that all organs removed, disposed of and transplanted in the Republic of Cyprus can be traced from donor to recipient and vice versa, in order to safeguard the health of donors and recipients.

(2) The competent authority and other actors involved in the procedure from donation to transplantation or organ removal shall keep the data necessary to ensure traceability at each stage of the procedure from

donation to transplantation or organ removal and information on organ and donor characterization, as defined in Annexes I and II, in accordance with the quality and safety framework.

Implementation of the system of identification of donors and recipients

11.- (1) The competent authority shall ensure the implementation of an identification system for donors and recipients which can identify each donation and each organ and recipient linked to it.

(2) The data required for full traceability shall be kept by the Transplantation Council for at least thirty years after donation and may be stored in electronic form.

Management of serious adverse events and reactions.

Official Journal of the EU: L 207, 6.8.2010, p. 140; L 243, 16.9.2010, σ. 68.

12.- (1) The competent authority shall ensure that the transplantation center implements a system of reporting to the Transplantation Council for reporting, investigating, recording and transmitting relevant and necessary data on serious adverse events that may affect the quality and safety of organs and which may be related to the testing, characterization, removal, maintenance and transfer of organs, as well as any serious adverse reaction observed during or after transplantation that may be associated with these activities.

(2) The transplant center and transplant coordinators shall implement an operational process for the accurate, prompt and verifiable reporting of serious adverse events and reactions and their timely notification to the Transplant Council.

(3) The Transplant Council shall implement an operational procedure for the timely notification of any serious adverse event and reaction to the relevant affected transplant centers.

(4) The Transplantation Council shall ensure the interconnection between the reporting system referred to in subsection (1) and the reporting system established pursuant to paragraph 1 of Article 11(1) of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, as corrected.

PART III - PRINCIPLES GOVERNING THE DONATION OF ORGANS

Principles governing organ donation.

13.- (1) The removal of an organ from a living donor for the purpose of transplantation is permitted when it is carried out solely for the therapeutic benefit of the recipient, provided that it does not involve an obvious risk to the life or health of the living donor.

(2) The donation of a human organ from a cadaveric or living donor shall be voluntary, without conditions, remuneration or consideration.

(3) Compensation to the living donor by the State is permitted, provided that such compensation is strictly limited to compensating for the expenses and loss of income associated with the donation. The Transplantation Council, in cooperation with the competent authority, shall define the conditions under which compensation may be granted, while avoiding creating a financial incentive or benefit for the potential donor. The State may compensate living donors, upon their request to the Transplantation

Council, for the costs or losses they will incur (loss of salary or income due to inability to work for a period of up to three months) in order to donate an organ. Exceptionally, if complications from organ donation continue beyond three months, the Transplantation Council shall review the amount of compensation after obtaining an opinion from a specialized medical committee. The State shall provide free medical care to living donors for organ and donor characterization, as provided for in Article 7, or for needs that may arise as a result of organ donation.

(4) It is prohibited for any person to disclose the need or availability of a human organ:

it is understood that the competent authority may take steps to inform the public.

(5) The removal of an organ from a living donor shall be permitted only when the transplantation is to be performed on the donor's spouse or a relative up to the third degree of kinship or the donor has a close personal relationship with the recipient as determined by the Transplantation Council.

PART IV – REMOVAL OF ORGANS FROM A LIVING DONOR

Consent conditions.

14.- (1) Removal of an organ from a living donor is only permitted after the free, specific and written consent of the potential living donor who is capable of giving consent, and after having been informed of the purpose and nature, as well as the potential risks of the procedure. The consent of the living donor shall be freely revocable in any manner, until the start of the removal procedure.

(2) Intervention on a minor person or an adult who lacks the capacity to consent to an intervention due to mental incapacity or illness shall be permitted upon written authorization of his/her legal representative and with the approval of the Transplantation Council.

(3) Removal from a person who lacks capacity to consent under may be authorized by the Transplant Council provided that the following conditions are cumulatively met:

α. there is no other suitable donor available who has the capacity to consent;

β. the recipient is a blood relative up to the third degree;

γ. the potential donor does not object;

δ. the life of the donor is not endangered.

Protection of living donors.

15.- (1) The competent authority shall take all necessary measures to ensure the maximum protection of living donors.

(2) The competent authority shall ensure that living donors are selected on the basis of their health and medical and psychological history by qualified or trained and competent professionals, based on a written protocol of procedures implemented by the Transplantation Center. The consideration of these elements may lead to the exclusion of people whose donation could pose an unacceptably high risk to their health.

Register of living donors.

16.- The competent authority shall ensure that the Transplantation Council maintains a register of living donors, after donation, of donation-related complications that may arise in the short, medium and long term, which shall be updated annually.

Monitorization of the Status of living donors.

17.- The competent authority shall ensure that the status of living donors is monitored at least once in a year in order to identify, report and manage any event that may be related to the quality and safety of the donated organ and, consequently, the safety of the recipient, as well as any serious adverse reaction that may occur in the donor as a result of the donation.

Compensation.

18.- In the event of disability or death of the donor or potential donor due to complications arising from the removal or the preliminary examinations involved, compensation shall be paid by the State, in addition to the benefits provided by the insurance institutions to the donor or the donor's dependents.

PART V - REMOVAL OF ORGANS FROM DECEASED DONOR

National register of potential donors.

19.- The competent authority shall ensure that a national register of potential donors is maintained for the post-mortem donation of their body or organs for transplantation and for scientific research or training.

Principles governing the organs removal after death.

20.- (1) In case the attending physician determines that the course of health of a patient who could be a potential donor leads or has led to brain death, he/she shall inform the competent transplant coordinator to initiate the procedure for the evaluation of the potential donor and the procedure for conducting brain death tests.

(2) With the consent of the newly appointed representative of the potential deceased donor, organs may be removed from a deceased donor for therapeutic purposes, which, if deemed unsuitable for transplantation, may be made available for scientific research or education:

it is understood that transplant coordinators shall consider prior consent for all of the above possibilities.

(3) If the potential deceased donor had not expressed his/her consent or refusal, the removal of organs shall be carried out with the consent of the newly appointed representative of a potential deceased donor, who shall be, in order of priority, one of the following persons:

α. husband/wife;

β. adult child;

γ. the parent or guardian or custodian;

δ. brother/sister;

ε. grandparent;

στ. grandchild;

ζ. stepfather/stepmother;

η. half-brother/half-sister;

θ. friend from a close personal relationship.

(4) Removal of organs is permitted after death, even if the functions of certain organs are artificially maintained.

(5) The removal of organs from a deceased donor is prohibited if there is a declared living will of the deceased against it.

(6) If there are reasons to suspect that a death investigation or autopsy may be required on the body, there must be consultation with the State pathologist-medical examiner on duty to determine whether he or she should be present at the organ removal procedure.

(7) Without prejudice to the provisions of subsection (4), the removal of a biological substance from a body is permitted if it is to assist in the decision to remove an organ for the purpose of transplantation.

(8) Any action on a person to remove a biological substance is permitted after it has been determined that the person is dead:

it is understood that in the case of screening for possible infectious diseases or for the evaluation of the function of the organs of the potential donor which may exclude the potential donor from donating organs, an operation on the deceased body to remove biological substance is allowed.

(9) After brain death is established and until the organs are removed for transplantation, any hospitalization costs shall be covered by the State.

Death determination criteria.

21.- (1) A person is considered dead if the protocol for the diagnosis of brain death establishes the existence of signs indicating the permanent and irreversible absence of all reflexes of the brain stem.

(2) Death shall be diagnosed by a protocol for the diagnosis of brain death based on the prevailing scientific evidence by two medical specialists (intensivist or pulmonologist or cardiologist or general practitioner or anesthesiologist or neurologist or neurosurgeon) who are not related to any scientific group interested or involved in transplantation therapy. The death shall be established at two different times and the date and time of death shall be recorded after the last series of clinical tests certifying brain death.

Procedures after death certification.22.- (1) After certification of brain death and if the functions of certain organs are artificially maintained, the transplant coordinator, in collaboration with the responsible medical practitioners who established the brain death and/or with a psychologist, shall inform the newly designated

potential deceased donor representative of the death, as well as and of the possibility of organ donation for the purpose of transplantation in order to obtain his/her consent or refusal, as provided for in paragraph (3) of Article 20. Only in case of transplantation, artificial support for the organs is continued in

order to ensure the quality of the organs and safety of transplants. If the transplantation will not be carried out organs are not taken for the purpose of transplantation, the artificial support shall be discontinued.

(2) A medical practitioner shall, when performing any operation on a cadaver for scientific purposes, follow a technique to minimize deformation of the external characteristics of the cadaver before handing it over to the newly appointed representative of a potential deceased donor.

(3) The removal of organs from the deceased donor shall be carried out with respect to the body of the deceased and under appropriate conditions.

(4) The competent authority shall ensure that the operation to obtain an organ for transplantation precedes another operation that is not urgent.

Registry of deceased donors.

23.- With reference to Article 7, the competent authority is responsible for maintaining a register with information of deceased donors.

Preserving anonymity.

24.- The identity of the deceased donor must not be disclosed to the recipient and his/her family and the identity of the recipient must not be disclosed to the family of the deceased donor:

it is understood that the recipient may express his or her thanks to the deceased donor's family in an anonymous letter addressed to the Transplantation Council.

Donation to a certain person.

25.- The selection of a designated recipient by the newly appointed representative of a potential cadaveric donor is prohibited and the allocation of organs is carried out according to scientific criteria for the order of priority, which are determined by the Transplantation Council:

It is understood that the Transplantation Council shall establish specific criteria for the order of priority in the allocation of organs.

PART VI - TRANSPLANTATION COUNCIL

Establishment of Transplantation Council.

26.- (1) It has been established the Transplantation Council, that is composed of the following persons:

α. A representative of the Ministry of Health who performs the duties of the President;

β. the Director of the State Transplant Center;

γ. a transplant coordinator

δ. two representatives of representative patient organizations related to transplants;

ε. a doctor with a specialty related to transplants or organ donation;

στ. a representative of the Cyprus National Bioethics Commission;

ζ. a lawyer representing the Cyprus Bar Association;

η. a doctor who is a representative of the Pancyprian Medical Association, a well-known association, who does not deal with organ transplants

θ. one representative of a recognized laboratory of immunogenetics and histocompatibility.

(2) The members of the Transplantation Council shall be appointed by the Council of Ministers on the recommendation of the Minister of Health and shall receive a remuneration determined by the Council of Ministers.

(3) The Vice-Chairman of the Transplant Council shall be elected by the members of the Council.

(4) The term of office of the Transplant Council shall be three years and may be renewed for further periods.

(5) A quorum shall consist of five members, including the chairman, and in his absence, the vice-chairman shall preside.

(6) Valid decisions shall be taken by the affirmative vote of the members present, by a majority, provided there is a quorum, and in the case of a tie, the President shall have the casting vote:

it is understood that decisions of the Transplantation Council shall be adopted immediately.

(7) A report of the proceedings of each meeting shall be kept with full particulars of the decisions taken, the manner in which they were taken and the reasons for them, and shall be certified and signed by the chairman or vice-chairman.

(8) Subject to the provisions of this Act, no member of the Transplant Council shall be liable for anything said or done or omitted to be done in the good faith performance of his or her duties.

Privacy.

27.- All members of the Transplant Council shall treat as confidential any matter raised or discussed at any meeting or other work of the Council and any information, whether written or oral, which comes to their knowledge in the course of their duties concerning personal data contained in the records of the Council and shall not disclose or communicate any such matter or information.

Responsibilities.

28. (1) The Transplantation Council has the following responsibilities:

a) To supervise the criteria for establishing the national waiting list of patients for transplantation by organ and the operation of the computer program that ranks the order priority based on the register of potential transplant recipients of each organ donation from a cadaveric donor.

b) To supervise the conduct of transplants from a transplantation centre for the purpose of verifying the application of the principle of equal access for patients to the organs available for transplantation;

c) To seek to increase the number of organs for transplantation, by raising awareness, informing, and educating citizens and the medical and nursing staff on the subject of transplantation;

d) To cooperate with similar organisations abroad for the procurement and exchange of organs for donation.

e) To recommend to the competent authority methods to ensure the traceability of organs available for transplantation through a traceability process, as provided for in Articles 10 and 11.

f) To recommend a national quality control programme in all procedures from donation to transplantation or organ discard; it shall monitor and impose measures to ensure the quality of the organ;

g) To establish the close personal relationship between the donor and the recipient in the absence of a family or marital relationship between the living donor and the recipient;

h) To keep a register of cadaveric donors who have donated an organ for traceability purposes;

i) To keep a register of living donors who donated an organ for traceability purposes and for quality control purposes for long-term protection of their health;

j) To keep a register of transplants for traceability and quality control, to the purpose of a long-term evaluation of the results of the transplants;

k) To supervise the register of potential transplant recipients maintained by the transplant centre in cooperation with the histocompatibility laboratory designated by the competent authority; the right to be registered in it is open to permanent legal residents of the Republic of Cyprus who are Cypriot citizens, or citizens of the European Union;

l) To maintain a national register of potential donors where permanent legal residents of the Republic of Cyprus who are Cypriot citizens or citizens of the European Union may declare their willingness to post-mortem donation of their body or organs for transplant or scientific research;

m) To keep a register of adverse events and reactions in living donors;

n) To authorise the removal of organs from persons who are not fit for consent, in accordance with subsection (2) of Article 14;

o) To implement the intergovernmental agreements;

p) Without prejudice to subsection (5) of Article 13, to authorise the exchange of an organ for transplantation from one or more potential donor-recipient pairs to others for the purpose of achieving a compatible transplantation, if requested by the transplantation centre for clinical reasons, in which case the competent authority shall ensure that the removal of organs from living donors is carried out simultaneously.

(2) The competent authority shall provide financial, administrative, and secretarial support to the Transplantation Council.

Transplant coordinators.

29.- (1) The Minister shall appoint medical or nursing staff who are suitably and specially trained as transplant coordinators, who shall coordinate the procedures for the characterisation, removal, preservation and transport of organs and tissues for the purpose of transplant and shall have the following duties:

a) Searching for potential cadaveric donors and the verification of the donor's identity in cooperation with the treating physicians;

b) Cooperating with the responsible medical specialists who certify the death and informing the legal representative of the potential cadaveric donor of the death;

c) Providing full and independent information to legal representative of the potential cadaveric donor, in collaboration with the treating physician, on the possibility of donating the organs for transplant, for the purpose of obtaining written consent in the specified format;

d) Verifying the details of the consent, approval, or lack of objections of the donor or the donor's family before the donation and the removal of an organ takes place;

e) Verifying the completion of the characterisation of the organ and the donor and reporting all the above information to the transplant team before proceeding with the removal of organs;

f) Supporting the relatives of cadaveric donors;

g) Coordinating the process of removal, packaging, labelling, transport, and distribution of grafts;

h) Conservation, before and after the removal of the organs of the brain-dead person, following recommendations from the transplant centre;

i) Participating in informing, educating, and raising awareness among citizens and the medical and nursing staff on organ donation and transplantation;

j) Coordinating the characterisation of potential living donors and recipients following recommendations from the director of the State transplantation centre in question, in accordance with the provisions of Article 7.

(2) Transplant coordinators shall submit annual reports on their activities to the Transplantation Council.

PART VII - RESPONSIBILITIES OF THE COMPETENT AUTHORITY

Responsibilities of the competent authority.

30. The competent authority shall have the following additional responsibilities:

a) To check that the transplant centre submits annual reports on its activities to the Transplantation Council

b) To grant, suspend or withdraw, as appropriate, the authorisation to operate a transplant centre, if it is clear from the control measures that the centre in question does not comply with the requirements of this law;

c) To provide appropriate guidance to hospitals, professionals and other actors involved at every stage of the chain from donation to transplant or organ rejection;

d) To participate in the community network and coordinate participation in the activities of the network at national level;

e) To supervise exchanges of organs with other Member States and with third countries;

f) To ensure that the fundamental right to the protection of personal data is fully and effectively defended in all organ transplantation activities;

g) To provide the necessary support to the Transplantation Council for the maintenance of the registers provided for in Article 28;

h) To prepare and make public an annual report on activities in the field of organ transplantation;

i) To identify the donor and the procurement organisation;

j) To identify the recipient at the transplant centre;

k) To locate and identify all relevant non-personal data relating to the products; and materials in contact with the organ in question.

PART VII - EXCHANGES OF ORGANS WITH THIRD COUNTRIES AND EUROPEAN ORGAN EXCHANGE ORGANISATIONS

Framework for cooperation and exchange of organs with third countries.

31.- (1) The procedure for the exchange of organs with third countries shall be approved by the Transplantation Council in cooperation with the competent authority.

(2) The import and export of human organs to and from third countries shall be carried out through designated hospitals, accredited, designated or authorised in order to ensure the traceability of organs from the donor to the recipient and vice versa and that these organs meet the quality and safety requirements.

(3) The approval for an exchange of organs in accordance with subsection (1) shall be granted only if the institution –

a) can be traced from the donor to the recipient, and vice versa; and

b) meets the quality and safety requirements.

European institutions for the exchange of organs.

32.- (1) The procedure for the exchange of organs with the Member States shall be approved by the Transplantation Council in cooperation with the competent authority.

(2) The exchange of organs shall be carried out through designated medical establishments accredited, designated, or authorised in order to ensure traceability of the organs from the donor to the recipient and vice versa and that these organs meet quality and safety requirements.

(3) The competent authority may draw up written agreements with European organ exchange organisations or their counterparts in third countries, entrusting them with –

a) the performance of activities in the field of transplantation of solid organs of human origin;

b) the performance of specific tasks.

Human organ trafficking.

33. The commercial transaction of a human organ for the purpose of transplant is prohibited.

Transmission of information in the event of organ exchanges.

34. In the event of an organ exchange between EU Member States and/or with third countries, the Member States concerned, and those third countries shall submit the necessary information to the Transplantation Council to ensure traceability of the organs pursuant to the provisions of this law.

PART IX - CRIMINAL PROVISIONS

Criminal offences and sanctions.

35.- (1) Any person –

a) acting on a corpse for the purpose of taking organs in violations of the provisions of Article 6-

b) achieving the consent of a living donor provided for in Article 14 through physical or psychological violence;

c) concealing or intentionally and materially underestimating the medical consequences of the removal of the organ in violation of Article 14;

d) giving or receiving compensation or consideration for the supply or offer to supply any human organs or tissues;

e) offering to supply a human organ for remuneration;

f) negotiating any agreement concerning the granting of remuneration for the supply or an offer to supply human organs;

g) participating or taking part in the management or control of a legal or natural person whose activities include any dealing mentioned in the above paragraphs;

h) who has caused the publication or distribution of advertisement or knowingly publishes or distributes advertisement inviting people to supply or offer to supply any human organ to transplant or indicates to be willing to negotiate any deal for this purpose

is guilty of a criminal offence and liable to a custodial sentence of not more than five years or a fine not exceeding one hundred thousand euros (€100,000) or both penalties.

(2) A member of the Transplant Council acting in violation of the provisions of Article 27 or failing to comply with them, is guilty of an offence and shall be liable to a fine not exceeding three thousand euros (€3.000).

PART X - MISCELLANEOUS PROVISIONS

Protection of personal data.

138(I) of 2001

37(I) of 2003.

36.- (1) The competent authority shall ensure that the fundamental right to the protection of personal data is fully and effectively preserved in any organ transplant activity.

(2) Without prejudice of the provisions of the acts regarding the processing of personal data (Protection of the Individual) of 2001 and of 2003, as amended or replaced, the disclosure of the identity of the recipient to the donor's family unless there is a family relationship, or a close personal relationship and the recipient gives their consent.

(3) The provisions of subsection (2) do not apply where the disclosure is made after the transplant has taken place and the person who discloses the information has been authorised to do so by the recipient or, in in the case of a minor recipient, by their legal guardian.

(4) It seems advisable to exploit the possibilities of using electronic encryption and personal password access for the electronic personal data list.

Issuing of regulations.

37. The Council of Ministers may issue regulations for the better application of this law and to determine any matter which by virtue of the provisions of this requires or is amenable to determination.

Repeal.

97 of 1987

5(I) of 1999. 38. Upon the entry into force of this law, the provisions on the removal and transplant of biological substances of human origin of the 1987 and 1999 acts are repealed.

Minimum data - information for organ and donor characterisation to be collected for each donation.

Minimum information package

Minimum data - information for organ and donor characterisation to be collected for each donation.

a) Centre where the removal is performed and other general data.
b) Type of donor.
c) Blood type.
d) Gender.
e) Cause of death.
f) Date of death
g) Date of birth or estimated age.
h) Weight.
i) Height.
j) History of intravenous drug abuse (past or present).
k) History of malignant neoplasia (past or present).
l) History of other transmissible diseases (present).
m) HIV/AIDS, hepatitis C virus and hepatitis B virus tests.
n) Basic information for the evaluation of the functioning of the donated organ.

Annex II
Additional information package
Supplementary data - information on organ and donor characterisation, collected in addition to the minimum information specified in Annex I, on the basis of a decision of the transplantation team, considering the availability of such information and the particular circumstances of the specific case.
a) General data
Contact details of the organisation/centre where the removal takes place, necessary for the coordination, allocation, and traceability of the organs from donors to recipients and vice versa.
b) Donor’s details

Demographic and anthrogeographical data required to ensure appropriate compatibility between the organ donor and the recipient.

c) Donor's medical history

Medical history of the donor, especially medical conditions that may affect the suitability of the organs for the transplant and may pose a risk of transmission of disease.

d) Histopathological and clinical data

Data from a clinical examination, necessary to assess the pathoanatomical condition of the potential donor as well as any findings indicative of conditions not detected in the examination of the donor's medical history, and which may affect the suitability of the organs for the transplant and pose a risk of disease transmission.

e) Laboratory parameters

Data needed to assess the functional characterisation of organs and to detect potentially transmissible diseases and possible contraindications to the organ donation.

f) Imaging test

Imaging investigations necessary for the assessment of anatomical condition of the organs to be transplanted.

g) Treatment

Therapies administered to the donor that are relevant to assess the functional status of the organs and their suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.