

**THE HUMAN TISSUE
(REMOVAL, PRESERVATION AND TRANSPLANT) BILL**

Bill No. 05 of 2018

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The following Bills which are set out for introduction into the National Assembly are published for general information.

**THE HUMAN TISSUE
(REMOVAL, PRESERVATION AND TRANSPLANT) BILL
(No. V of 2018)**

Explanatory Memorandum

The object of this Bill is to repeal the Human Tissue (Removal, Preservation and Transplant) Act and the Human Tissue (Removal, Preservation and Transplant) (Amendment) Act 2013 and to replace them by a new and revised legislation which provides a better legal framework for the removal, preservation and transplant of human tissue, other than blood, under appropriate medical supervision.

2. The new legislation, inter alia –

(a) provides that–

- (i) no person shall donate any tissue, whether belonging to himself or to any other person, unless he obtains the approval of the Tissue Donation, Removal and Transplant Board;
- (ii) no person, other than an authorised specialist, shall remove any tissue, or cause or permit any tissue to be removed from, the body of a person unless conditions are satisfied;

- (iii) no person, other than an authorised specialist, shall perform a transplant;
- (b) removes the current restriction applicable in the case of donation of tissue by living or deceased persons for the purpose of a transplant to the body of any other person; and
- (c) provides that no removal of tissue, for the purpose of a transplant to an intended recipient, shall be allowed from the body of a person who is incapable, by reason of mental impairment, of agreeing to make a donation.

DR. M. A. HUSNOO

Minister of Health and Quality of Life

20 April 2018

THE HUMAN TISSUE

(REMOVAL, PRESERVATION AND TRANSPLANT) BILL

(No.V of 2018)

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A BILL

To establish a legal framework for the removal, preservation and transplant of human tissue under appropriate medical supervision, and for matters related thereto

ENACTED by the Parliament of Mauritius, as follows –

PART I – PRELIMINARY

1. Short title

This Act may be cited as the Human Tissue (Removal, Preservation and Transplant) Act 2018.

2. Interpretation

In this Act –

“approved health institution” means such health institution as may be prescribed to carry out the removal, preservation and transplant of tissue;

“authorised specialist” means a specialist in surgery having at least 5 years’ experience in the field of transplant surgery and authorised by the Board to –

(a) issue certificates under this Act; or

(b) effect, or assist in effecting, the removal or transplant of tissue;

“Board” means the Tissue Donation, Removal and Transplant Board referred to in section 4;

“Chairperson” means the Chairperson of the Board;

“donated tissue” means a tissue donated in accordance with this Act;

“donation” means a donation of tissue made by a person in accordance with this Act;

“donor” means a person making a donation;

“health institution” means a hospital, a clinic, a laboratory or any other health centre;

“judicial officer” means a Judge or Magistrate;

“medical consultant” means a specialist holding the post of consultant in the Ministry;

“member” –

(a) means a member of the Board; and

(b) includes the Chairperson;

“Minister” means the Minister to whom responsibility for the subject of health is assigned;

“Ministry” means the Ministry responsible for the subject of health;

“non-regenerative tissue” means a tissue other than a regenerative tissue; “prescribed institution” means such health institution or educational, research or scientific establishment as may be prescribed;

“recipient” means the recipient of a donated tissue;

“regenerative tissue” means a tissue which, after injury or removal, is regenerated in the body of a living person by natural growth or repair;

“Registrar” means the Registrar designated under section 7;

“removal” means the removal of a donated tissue from a living or dead human body;

“specialist” means a person registered as such under the Medical Council Act;

“supervising officer” means the supervising officer of the Ministry;

“tissue” –

(a) means any human flesh, bone, circulating haemopoietic progenitor cells, or organ other than an embryonic, foetal or reproductive organ or tissue; but

(b) does not include blood, hair, nail or tooth;

“transplant” means the transplant of donated tissue into a living human body.

3. Application of Act

(1) This Act shall bind the State.

(2) This Act shall apply only in cases of donated tissue.

(3) This Act shall be in addition to, and not in derogation from, any other enactment which applies to cases where, in the course, or as a result, of a police enquiry, tissue is removed for the purpose of forensic examination, upon an order made by a judicial officer, or with the consent of a person from whom the tissue is to be removed.

PART II – TISSUE DONATION, REMOVAL AND TRANSPLANT BOARD

4. Tissue Donation, Removal and Transplant Board

(1) There shall be, for the purposes of this Act, a Tissue Donation, Removal and Transplant Board which shall consist of –

- (a) the Director-General Health Services who shall be the Chairperson;
- (b) a representative of the Attorney-General's Office;
- (c) not more than 3 specialists, one of whom shall be a medical consultant, to be appointed by the Minister;
- (d) not more than 3 other members to represent civil society, to be appointed by the Minister;
- (e) where appropriate, one other member appointed pursuant to subsection (2).

(2) The Minister may, where it is necessary for the Board to take a decision regarding the removal or transplant of any tissue which requires specialised knowledge or experience in a medical field which the members of the Board do not have, appoint one medical

consultant or specialist who has the required knowledge or experience to take part in the decision.

(3) Every member referred to in subsection (1)(c) and (d) shall –

(a) be appointed by the Minister on such terms and conditions as he may determine; and

(b) hold office for a period of 2 years and be eligible for reappointment.

(4) Every member shall be paid such fees or allowances as the Board may, with the approval of the Minister, determine.

(5) (a) The Board may appoint such subcommittee as may be necessary to assist it in the discharge of its functions under this Act.

(b) The Board may co-opt such persons possessing appropriate qualifications, knowledge and experience as may be necessary on any subcommittee.

(c) Any person co-opted under paragraph (b) shall have no right to vote on any matter before the Board.

5. Functions and powers of Board

The Board shall –

(a) grant or refuse applications for the donation of tissue;

(b) determine, in the case of a donor who does not specify the recipient of a donated tissue, who the recipient shall be, in accordance with section 19(5);

(c) keep, for the purpose of paragraph (b), such recipient waiting list as may be necessary;

- (d) pursuant to section 11(2) and (3), determine the purpose for which a donation is made or the institution for which it is intended;
- (e) ensure that the removal, preservation and transplant of tissue is done in approved health institutions;
- (f) be responsible for granting authorisation –
 - (i) to authorised specialists to –
 - (A) issue certificates under this Act;
 - (B) effect, or assist in effecting, the removal or transplant of tissue for the purposes of this Act;
 - (ii) for the importation of any tissue under section 22;
- (g) establish such tissue banks as may be necessary for the purpose of storing and preserving donated tissues;
- (h) have the power to call for such information as it may require from any person for the purpose of discharging its functions under this Act;
- (i) keep a record of all its proceedings and decisions;
- (j) keep such registers as it may determine for the purpose of recording such information as may be necessary;
- (k) advise the Minister on any matter governed by this Act or any matter connected with, or incidental to, it; and
- (l) have and exercise the powers and functions which are attributed to it under this Act.

6. Meetings of Board

(1) The Board shall meet –

(a) at least once every month; and

(b) whenever required in case of an emergency.

(2) Where the Chairperson is absent from any meeting, the members present shall elect from amongst themselves a member to chair that meeting.

(3) At any meeting of the Board, 3 members shall constitute a quorum, of whom one shall be a specialist.

(4) A decision of the Board shall be by simple majority of the members present and voting.

7. Registrar and other officers of Board

(1) The supervising officer shall designate a public officer to be known as the Registrar to act as secretary to the Board.

(2) The Registrar shall –

(a) be responsible for the proper administration of the Board;

(b) execute all decisions of the Board;

(c) make necessary entries in registers kept by the Board;

(d) discharge such functions as the Board may assign to him;

- (e) in the discharge of his functions, act in accordance with such directions as he may receive from the Board.

(3) The supervising officer shall designate such number of public officers as the Board may require to assist it in the discharge of its functions and in the exercise of its powers.

(4) Every public officer designated under subsection (3) shall be under the administrative control of the Registrar.

PART III – DONATION

8. Application for donation of tissue

(1) No person shall donate any tissue under this Part, whether belonging to himself or to any other person, unless he obtains the written approval of the Board.

(2) Any person who wishes to donate any tissue under this Part shall make an application to the Board for approval in such form and manner as may be prescribed.

(3) An application made under subsection (2) shall be accompanied by such documents as the Board may require.

(4) Where the Board receives an application under subsection (2), it may –

- (a) grant the application and issue its approval on such terms and conditions as it considers appropriate; or
- (b) refuse the application and inform the applicant in writing of the reasons for its decision.

9. Donation of tissue by living person

Subject to section 10, where a living person makes an application to the Board for a donation, for the purpose of a transplant to the body of another person, of –

- (a) any tissue from his body, whether regenerative or non-regenerative, the application shall be accompanied by a certificate from 2 specialists stating that the removal of the tissue is not likely to endanger his health;
- (b) a non-regenerative tissue, the application shall also be accompanied by a certificate issued by an authorised specialist stating that he has explained to the donor the effect of the removal of the tissue.

10. Donation of tissue by living minor

(1) No person shall make an application to the Board for the donation of any tissue from the body of a living minor unless –

- (a) the donation is of a regenerative tissue only and the application is accompanied by a certificate from 2 specialists stating that the removal of the tissue is not likely to endanger the living minor's health;
- (b) there is no compatible adult donor available;
- (c) the donation has the potential to be lifesaving for the recipient; and
- (d) the application for the donation is made in accordance with subsection (2).

(2) (a) Subject to paragraph (b), the person who lawfully exercises parental authority over a living minor or, where more than one person lawfully exercises parental authority over the living minor, those persons, if they so agree, may make an application for the donation of a regenerative tissue from the body of that living minor.

(b) Where more than one person lawfully exercises parental authority over the living minor, and one of them is, for any of the reasons specified in article 373 of the Code Civil Mauricien unable or, without reasonable cause, unwilling, to agree to make the

application for the donation, one of those persons may make an application to the Judge in Chambers to authorise him to make an application to the Board for the donation.

(c) An application made to the Honourable Judge in Chambers under paragraph (b) shall be –

(i) accompanied by an affidavit sworn or solemnly affirmed by the applicant setting out the reasons for applying to the Board for the donation of a regenerative tissue from the body of the living minor; and

(ii) supported by affidavits from 2 specialists stating that –

(A) the removal of the tissue is not likely to endanger the living minor's health; and

(B) the applicant has been explained the effect of the removal of the tissue.

(d) Where the Judge in Chambers is satisfied, on the basis of the affidavit evidence before him, that the application for the donation is justified, he shall authorise the applicant to make the application to the Board.

11. Donation of tissue by deceased person

(1) (a) A person may make an application to the Board for a donation, effective after his death, of any tissue from his body under this Part.

(b) Where a person, other than a minor, dies without having made an application for a donation under paragraph (a) and without, during his lifetime, having expressed a contrary intention to the Board in such form as the Board may prescribe –

(i) his spouse;

(ii) if he leaves no spouse or his spouse is unable to do so

because of mental impairment or because he is abroad, his child, or if he has more than one child, all his children jointly, acting through the legal administrator or guardian in the case of a minor child; or

(iii) his living parents or, in their absence, his living heirs,

may make an application to the Board for a donation of any tissue from his body under this Part.

(c) Where a minor dies, the person who lawfully exercises parental authority over him or, if there is more than one such person, those persons, if they so agree, may make an application to the Board for a donation of any tissue from the body of the minor under this Part.

(2) Where a person referred to in subsection (1)(a), (b) or (c) has not, in the donation, specified –

(a) the purpose for which it was made; or

(b) the institution or recipient for which it was intended,

the Board shall determine the purpose for, or the institution or recipient to, which the donation shall be made.

(3) Where –

(a) a person, other than a minor, dies without having made an application for a donation under subsection (1)(a) and without, during his lifetime, having expressed a contrary intention to the Board in such form as the Board may prescribe; and

(b) no application is made for a donation under subsection (1)(b),

the deceased person shall be presumed to be a donor and the Board may –

- (i) determine the purpose for, or the institution or recipient to, which the donation shall be made; and
- (ii) authorise a removal under this Act.

12. Donation for scientific or other purposes

(1) No person shall, for scientific, educational or research purposes, make a donation of his body or of any tissue thereof to a prescribed institution, to take effect after his death, unless he obtains the written approval of the Board in the manner specified in section 8.

(2) Every donation referred to in subsection (1) shall be subject to such other requirements or conditions as may be prescribed.

13. Revocation of donation

(1) A donation may, at any time before it is acted upon, be revoked by the person who consented to the donation, on the condition that such revocation is forthwith signified in writing to the Board in such form and manner as may be prescribed.

(2) On being informed of a revocation under subsection (1), the Board shall cancel the approval granted for the donation.

14. Persons dying in certain institutions

- (1) Where a person –
 - (a) dies in an institution other than a health institution;
 - (b) has been removed to an institution other than a health institution after his death; or

- (c) dies in any other place where he was lawfully detained,

the person in charge thereof may, before the body is remitted to the heirs or personal representatives of the deceased person, subject to subsection (2) and with the written approval of the Board, give effect to a donation made by that person which has not been revoked.

- (2) No effect shall be given to a donation made by a deceased person while he was in lawful custody unless the personal representative of that person agrees, in writing, that such donation should be given effect to.

PART IV – REMOVAL, PRESERVATION AND TRANSPLANT

15. Removal of tissue

(1) No person other than an authorised specialist shall, except where it is otherwise prescribed in relation to any tissue other than a human organ, remove any tissue from the body of a living or deceased person for the purpose of giving effect to a donation.

(2) No authorised specialist shall remove any tissue, or cause or permit any tissue to be removed, from the body of a person unless –

- (a) the Board has approved the donation of such tissue under section 8;
- (b) the removal takes place –
 - (i) in an approved health institution; and
 - (ii) in such form and manner and within such timeframe as may be prescribed; and
- (c) in the case of a deceased person, 2 specialists certify in writing that the donor is clinically dead in accordance with the procedures set out in the Schedule.

(3) Subject to section 10 and the Board's approval under section 8, no person shall, for the purpose of a transplant to an intended recipient, remove any tissue, or cause or permit any tissue to be removed, from the body of a living minor.

(4) Any specialist or authorised specialist who issues a certificate under this Act shall not participate in the removal of any tissue from the body of a person to whom the certificate relates.

(5) Every authorised specialist shall, before removing any tissue –

(a) ensure that the donation has not been revoked; and

(b) take all necessary measures to ensure, as far as is medically possible, that on the basis of the person's medical or surgical antecedents, there are no contraindications to the use of the tissue for those purposes.

16. Person with mental impairment

No person shall, for the purpose of transplant to an intended recipient, remove any tissue from the body of a person who is incapable, by reason of mental impairment, of agreeing to make a donation.

17. Post-mortem examinations

(1) No person shall, except for histopathological purposes, remove any tissue, or cause or permit it to be removed, from the body of another person where that body is lawfully required to be examined for the purpose of determining the cause or circumstances of the other person's death.

(2) Any tissue may, in accordance with this Act and with the authority of a judicial officer, be removed from the body of a person after the conclusion of an examination referred to in subsection (1).

(3) Subsections (1) and (2) shall not preclude the removal, in accordance with this Act, of any tissue before carrying out the examination referred to in subsection (1) where an authorised specialist, after consultation with the police medical officer designated to carry out the examination, certifies that he has reason to believe that the tissue shall not be required for the purpose of such an examination.

18. Preservation of tissue

Except where an authorised specialist certifies in writing that it is necessary to perform a transplant forthwith of any tissue which has been removed, the person who has removed the tissue shall forthwith ensure that it is taken to, and preserved in, such place and under such conditions as may be prescribed.

19. Transplant of tissue

(1) No person, other than an authorised specialist, shall perform a transplant.

(2) No authorised specialist shall transplant any tissue, or cause or permit it to be transplanted, at any place other than in an approved health institution.

(3) No authorised specialist or specialist who issues a certificate under this Act shall participate in the transplant of any tissue removed from the body of a person to whom the certificate relates.

(4) No authorised specialist shall engage in, and no person shall assist in, a transplant procedure where he has reason to believe that the transplant has been the subject of a commercial transaction.

(5) The allocation of a donated tissue to a recipient shall be made in accordance with the best match and in the order of priority warranted by the recipient waiting list.

20. Essential requirements for transplant

(1) Every person who is concerned with the removal of any tissue for the purpose of a transplant shall take all reasonable steps—

- (a) to ensure that the Board's written approval has been obtained for the donation of such tissue;
- (b) to ensure that the donation has not been revoked; and
- (c) to comply with such health and safety measures as may be prescribed.

(2) No tissue shall be used in a transplant where it is infected with any known virus or bacteria or with incompetent vascular system or presenting visible anomalies, except in cases where the donor and recipient share the same viruses.

PART V – FURTHER PROHIBITIONS

21. Commercial dealings in tissue

(1) Subject to subsection (2), no person shall –

- (a) make or receive any payment for the supply of, or for an offer to supply, any tissue;
- (b) seek to find a person willing to supply any tissue for payment;
- (c) initiate or negotiate any arrangement involving the making of any payment for the supply of, or for an offer to supply, any tissue;
- (d) take part in the management or control of any association or combination of persons, the activities of which consist of, or include, the initiation or the negotiation of any arrangement referred to in paragraph (c).

(2) No person shall publish or distribute, or cause or permit to be published or distributed, any form of advertisement –

- (a) inviting persons to supply tissue against payment;
- (b) offering to supply tissue for payment; or
- (c) indicating that the advertiser is willing to initiate or negotiate an arrangement referred to in subsection (1)(c).

22. Importation and use of tissue

(1) (a) No person shall, except with the written authorisation of the Board, import any tissue.

(b) The Board may, on granting an authorisation under paragraph (a), impose such conditions as it may determine, and every person who has obtained such authorisation shall comply with any such condition.

(2) No person shall use any tissue, or cause or permit it to be used, for a purpose other than –

- (a) the purpose, if any, which the person making the donation had specified in the donation; or
- (b) the purpose for which an authorisation was granted under subsection (1).

23. Disclosure of information

Subject to section 300 of the Criminal Code, no person shall give or disclose to another person any information, oral or written, whereby the identity of any person who has –

- (a) made or revoked a donation;
- (b) received any tissue from the body of another person,

is, or may be, disclosed.

PART VI – OFFENCES AND JURISDICTION

24. Offences and jurisdiction

(1) Any person who contravenes section 8(1), 10(1), 12(1), 15, 16, 17, 18, 19, 20, 21, 22 or 23 shall commit an offence and shall, on conviction, be liable to a fine not exceeding 500,000 rupees and to imprisonment for a term not exceeding 15 years.

(2) The Intermediate Court shall have jurisdiction to try any offence under this Act and, notwithstanding section 113(2) of the Courts Act, may impose any penalty provided under this Act.

PART VII – MISCELLANEOUS

25. Annual report

(1) The Board shall submit to the Minister an annual report on its activities.

(2) The Board shall, in respect of its activities, furnish to the Minister such information in such manner and at such time as the Minister may require.

26. Powers of Minister

The Minister may give such directions to the Board, not inconsistent with this Act, as he considers necessary in the public interest and the Board shall comply with those directions.

27. Protection from liability

(1) No liability, civil or criminal, shall be incurred by the Minister, the supervising officer, the Board or any of its members or officers, a member of any subcommittee appointed under this Act or any other person or body, in respect of any act done or omitted in good faith in the discharge of his or its functions or exercise of his or its powers under this Act.

(2) This section shall be in addition to, and not in derogation from, the Public Officers' Protection Act.

28. Regulations

(1) Subject to subsection (2), the Minister may, on the advice of the Board, make such regulations as he thinks fit for the purposes of this Act.

(2) Any regulation made under this Act may provide for –

- (a) the amendment of the Schedule;
- (b) the levying of fees and the payment of charges;
- (c) the designation of health institutions for carrying out the removal, preservation and transplant of tissue;
- (d) the designation of health institutions or educational, research or scientific establishments for the purposes of scientific, educational or research;
- (e) the procedures to be followed in respect of donation, removal, preservation and transplant of tissue; and
- (f) any matter necessary for, or consequential to, the implementation of this Act.

(3) Any regulations made under this Act may provide that any person who contravenes them shall commit an offence and shall, on conviction, be liable to a fine not exceeding 200,000 rupees and to imprisonment for a term not exceeding 10 years.

29. Repeal

The Human Tissue (Removal, Preservation and Transplant) Act and the Human Tissue (Removal, Preservation and Transplant) (Amendment) Act 2013 are repealed.

30. Commencement

(1) Subject to subsection (2), this Act shall come into operation on a date to be fixed by Proclamation.

(2) Different dates may be fixed for the coming into operation of different sections of this Act.

SCHEDULE

[Section 15(2)]

PROCEDURE FOR CERTIFYING DEATH OF A DONOR

- 1.** Death shall be diagnosed by the irreversible cessation of brain stem function (brain death).
 - 2.** (1) Death shall be diagnosed by at least 2 specialists.

(2) One of the specialists shall preferably be the one who was in charge of the patient and the other one, as far as practicable, a neurosurgeon, neurologist, physician or an anaesthetist.
 - 3.** (1) Each specialist shall make his diagnosis independently of the other after ensuring that the preconditions, as specified in this Act, have been met.

(2) Each specialist shall record the result of his examinations and diagnosis separately and independently of each other.
 - 4.** A test to ascertain brain death in a patient shall be performed twice before the pronouncement of death.
 - 5.** A patient shall be presumed to be alive unless and until it is conclusively established that the patient is brain dead.
 - 6.** The time of death shall not be the time at which artificial ventilation has been withdrawn or when the heartbeat ceases, but shall be the time at which the patient has been conclusively certified as brain dead.
 - 7.** A diagnosis of brain death shall normally not be considered until the expiry of at least 6 hours after the onset of a coma, or, where a cardiac arrest is the cause of the coma, until 24 hours after the circulation has been restored.
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