

**THE HUMAN TISSUE (REMOVAL, PRESERVATION
AND TRANSPLANT) BILL**
(No.II of 2006)

Explanatory Memorandum

The object of this Bill is to provide the legal framework for carrying out the removal, preservation and transplant of human tissue, other than blood, under appropriate medical supervision.

2. There will be an Organ and Tissue Transplant Board which will –
 - (a) monitor all the activities governed by this Bill and ensure the appropriate follow-up action thereon;
 - (b) determine which persons and which health institutions will be permitted to perform those activities;
 - (c) keep an up-to-date Register containing such particulars as may be prescribed in relation to those activities; and
 - (d) advise the Minister on the framing of regulations to prescribe the specific requirements for the carrying out of those activities.

3. The Bill caters separately for donations of tissue to take effect after death and for donations effective during the lifetime of the donor, and for donations of regenerative and non-regenerative tissue. Donations by minors, or by adults who are unable to validly agree to make a donation, are permitted only in specific circumstances. While its provisions are mainly meant to regulate transplants for therapeutic purposes, the Bill also deals with donations of the human body or any tissue for scientific, educational or research purposes.

4. The Bill also addresses the Minister's duty to take all necessary measures to inform and educate the public about the essential features of this Bill.

5. Specific provisions are included for persons who, having previously made donations, die in health institutions or places, such as prisons, where they are lawfully detained.

17 March 2006

S. V. FAUGOO
Minister of Health and Quality of Life

THE HUMAN TISSUE (REMOVAL, PRESERVATION AND TRANSPLANT) BILL

(No. of 2006)

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A BILL

To provide for the legal framework for the donation, removal, preservation and transplant of human tissue for therapeutic and other purposes and for matters connected therewith

ENACTED by the Parliament of Mauritius, as follows -

1. Short title

This Act may be cited as the Human Tissue (Removal, Preservation and Transplant) Act 2006.

2. Interpretation

In this Act -

“approved health institution” means a health institution which has been prescribed for carrying out therein the removal, preservation and transplant of tissue;

“authorised consultant” means a medical practitioner holding a post not below the grade of consultant in the public service and authorised by the Board to issue certificates under section 8(3);

“authorised medical practitioner” means a medical practitioner who has been authorised by the Board, after consultation with the Minister, to effect, or assist in effecting, the removal or transplant of tissue;

“Board” means the Organ and Tissue Transplant Board constituted in accordance with section 16;

“Blood Transfusion Service” -

(a) means the Blood Transfusion Service of the Ministry responsible for the subject of health; and

(b) includes such other blood transfusion institution as may be prescribed;

“donation” means a donation of tissue made by a person in accordance with this Act for the purpose of the removal of the tissue from his body, or from that of a minor on whom he has parental authority;

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

“judicial officer” means a Judge or a Magistrate;

“medical consultant” means a medical practitioner holding the post of consultant in the public service;

“medical practitioner” means a person registered as general practitioner or specialist under the Medical Council Act;

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

“non-regenerative tissue” means any tissue other than regenerative tissue;

“prescribed institution” means such health institution or educational, research or scientific establishment which may be prescribed;

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

“relative” means spouse, son, daughter, father, mother, brother, sister, half brother, half-sister, first cousin, uncle, aunt, nephew, niece, grandparent, legally adopted child, person who has adopted another person, brother-in-law, sister-in-law, mother-in-law, father-in-law, son-in-law and daughter-in-law;

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

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

“tissue” -

- (a) means any human flesh, bone, circulating haemopoietic progenitor cells, or organ other than embryonic, foetal or reproductive organ or tissue;
- (b) does not include hair, nail or tooth;

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

3. Application of Act

(1) This Act shall -

- (a) bind the State;
- (b) not apply to -
 - (i) the removal of blood from a human body by or on behalf of a Blood Transfusion Service;
 - (ii) the transfusion of blood obtained from a Blood Transfusion Service into a human body;
 - (iii) the removal of blood from, or the donation of tissue by, living persons for scientific or research purposes, with their written informed consent and with the approval of such ethics committees as may be prescribed.

(2) This Act shall not apply to cases where, in the course of or as a result of a Police enquiry, tissue is removed for the purposes of forensic examination, upon an order of a Magistrate or Judge, or upon the consent of a person from whom the tissue is to be removed.

4. Permitted donations by living persons

Subject to section 6, any person may make a donation, to take effect forthwith, for the purpose of a transplant to the body of a relative -

- (a) any regenerative tissue from his body;
- (b) any non-regenerative tissue from his body,

where it is certified by 2 medical practitioners that the removal of the tissue is not likely to endanger his health.

5. Permitted donations by deceased persons

(1) (a) Any person may make a donation, effective after his death, of any tissue from his body for therapeutic purposes to an approved health institution, or for research purposes to a prescribed institution.

(b) Where a person dies without having made a donation pursuant to paragraph (a) and without having expressed a contrary intention during his lifetime -

- (i) his spouse; or
- (ii) if he leaves no spouse or his spouse is unable to do so because of mental impairment or is abroad, his eldest adult child; or
- (iii) if he leaves no such child or the child is unable to do so because of mental impairment or is abroad, one of his heirs or legal representatives,

may make a donation of any tissue from his body for therapeutic purposes to an approved health institution or for research purposes to a prescribed institution.

(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 a donation of any tissue from the body of the minor to an approved health institution for therapeutic purposes, or to a prescribed institution for research purposes.

(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 for which it was intended,

the Board shall determine the purpose for which or the institution to which the donation will be deemed to have been made or intended.

6. Donation by minor or by adult incapable of agreeing to make donation

(1) Subject to subsection (2), no person shall, for the purpose of transplant to an intended recipient, remove any tissue from the body of a donor who is -

- (a) a minor; or
- (b) an adult certified by a specialist to be incapable by reason of mental or other impairment to agree to make a donation.

(2) Notwithstanding subsection (1), a donation by the minor or adult, or a removal as specified in that subsection, may be effected if -

- (a) the donation is of regenerative tissue only;
- (b) the intended recipient of the tissue is a relative of the minor or the adult;
- (c) there is no compatible donor available who has the capacity to consent to the donation;
- (d) the donation has the potential to be life-saving for the recipient;
- (e) no opposition to the removal has been signified by the minor or adult donor; and
- (f) the agreement to the donation was -
 - (i) in the case of a living minor, given in accordance with this Act, especially subsection (3);
 - (ii) in the case of a living adult, given by the person having legal authority, whether as legal or dative guardian or otherwise, to enter into an agreement on behalf of the adult.

(3) (a) Subject to paragraph (b), the person who lawfully exercises parental authority over a minor or, if there is more than one such person, those persons, if they so agree, may make a donation referred to in subsection (2).

(b) Where more than one person lawfully exercises parental authority over the 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 the making of the donation, the Judge in Chambers may, on application made to him by one of those persons, and after having sought the opinion of 2 authorised medical practitioners, authorise that person to make the donation.

(4) In every case where the donor was incapable of agreeing to make a donation, the intended recipient shall be told that the donor was so incapable.

7. Essential requirements for transplants

(1) Every person who is in any manner concerned with the removal of any tissue from the body for the purpose of a transplant shall take all reasonable steps to ensure -

- (a) where the person from whose body the tissue is to be removed is a minor, that the consent to the donation was given in accordance with this Act;
- (b) where the person from whose body the tissue is to be removed is an adult, that the adult has consented to the donation and has not subsequently signified his opposition to the removal, or that consent to the donation was given in accordance with this Act; and
- (c) that the donation has not been revoked.

(2) Every person who is in any manner concerned with the removal of any tissue for the purpose of a transplant shall take all reasonable steps -

- (a) to ensure that in the case of a cadaveric donor, no relative of the donor shall know the identity of the person who receives the transplant; and
- (b) to comply with such health safety measures as may be prescribed.

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

8. Form of donation and revocation

(1) Consent for donation -

- (a) shall be recorded before a judicial officer in such form and manner as may be prescribed;
- (b) may, at any time before it is acted upon and in such form and manner as may be prescribed, be revoked before a judicial officer by the person who made it.

(2) Every judicial officer before whom a donation or a revocation is made shall forthwith cause a copy thereof to be filed with the Board.

(3) A donation of non-regenerative tissue made pursuant to section 4(1)(b) shall be of no effect unless there is also filed with the Board a certificate issued by an authorised consultant stating that he had, before the donation was made, explained to the person making the donation the effect of the removal of the tissue from his body.

9. Persons dying in certain institutions

(1) Where a person dies in an institution other than a health institution, or has been removed thereto after his death, or dies in any other place where he was lawfully detained, the public officer or other person in charge thereof may, subject to subsection (3), with the approval of the Chairperson of the Board and before the body is remitted to his heirs or personal representatives, but subject to subsection (2), give effect to a donation made by that person which has not been revoked.

(2) No effect may be given, pursuant to subsection (1), to a donation for therapeutic purposes unless the removal takes place not more than 6 hours after the person's death.

(3) 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 that such donation should be given effect to.

10. Removal of tissue

(1) No person shall remove any tissue, or cause or permit any tissue to be removed, from the body of a deceased person unless 2 medical practitioners not below the status of a specialist have certified in writing that the donor is clinically dead in accordance with the procedures set out in the Schedule to this Act.

(2) Except where it is otherwise prescribed in relation to any tissue other than a human organ, no person other than an authorised medical practitioner shall remove any tissue from a human body.

(3) A medical practitioner who has issued a certificate under section 8(3) or under subsection (1) shall not participate in the removal of any tissue from the body of a person to whom the certificate relates.

(4) The removal of any tissue shall not take place anywhere other than in an approved health institution.

(5) Every medical practitioner shall, before removing any tissue to be used for therapeutic purposes, take all the 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 contra-indications to the use of the tissue for those purposes.

(6) Notwithstanding subsections (1), (2) and (4), where the removal of tissue concerns the harvesting of eyes -

- (a) one medical practitioner may certify death in the case of a person dying at home;
- (b) harvesting of the eyes may be carried out by health personnel trained for enucleation;
- (c) the harvesting may be done at the deceased person's home.

11. Preservation of tissue

Except where an authorised medical practitioner 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 immediately ensure that it is taken to, and preserved in, such a place and under such conditions as may be prescribed.

12. Transplant of tissue

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

(2) No person, other than an authorised medical practitioner, shall perform a transplant.

(3) No medical practitioner who has issued a certificate under section 8(3) or 10(1) shall participate in the transplant of any tissue removed from the body of a person to whom the certificate relates.

(4) No medical practitioner or health professional shall engage in transplant procedure where he has reason to believe that the transplant concerned has been the subject of a commercial transaction.

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

13. 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 a person where that body is lawfully required to be examined for the purpose of determining the cause or circumstances of the person's death.

(2) Any tissue may, in accordance with this Act and with the authority of a Magistrate or Judge, 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 medical practitioner, after consultation with the police medical officer designated to carry out the examination, certifies that he has reason to believe that the tissue will not be required for the purpose for such an examination.

14. 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) Subject to section 15, 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).

15. Duty to inform and educate

The Minister shall take all reasonable steps to ensure that the essential features of this Act are adequately made known and explained to the public.

16. The Board

(1) There shall, for the purposes of this Act, be an Organ and Tissue Transplant Board which shall consist of -

- (a) the Chief Medical Officer of the Ministry responsible for the subject of Health, who shall be the Chairperson;
- (b) a representative of the Attorney General's Office;
- (c) not more than 3 medical practitioners not below the status of specialist, one of whom shall be a medical consultant, to be appointed by the Minister;
- (d) such other persons, not exceeding 3, as the Minister thinks fit;
- (e) where appropriate, one other person appointed pursuant to subsection (2).

(2) Where it is necessary for the Board to make a decision regarding the removal or transplant of any tissue which requires specialised knowledge or experience in a field of medicine which the members of the Board do not have, the Minister shall appoint one other medical consultant who has the required knowledge or experience to take part in the decision.

(3) Subject to subsection (4), the Board shall -

- (a) sit at such time and place as the Chairperson shall determine;
- (b) make its decision by a majority of the members present and voting, the Chairperson having a second and casting vote in case of an equality of votes;
- (c) subject to subsection (2), be properly constituted where 3 members are present.

(4) Where owing to the urgency of any matter, it is not practicable to convene a meeting of the Board, the Chairperson may decide the matter himself and seek the covering approval of the Board at a subsequent meeting.

(5) The Board shall -

- (a) have and exercise the powers and functions which are attributed to it under this Act or which may be prescribed;

- (b) keep such registers or confidential registers as may be prescribed or determined by the Board for the purpose of recording such information as may be necessary -
 - (i) in relation to donations and any revocation thereof, to oppositions to the removal of tissue and to transplants; and
 - (ii) to allow the traceability of transplant from donor to recipient;
- (c) have power to call for such information as it may require from any person for the purpose of exercising its functions under this Act;
- (d) advise the Minister on any other matter relating to the removal, preservation or transplant of tissue.

17. Donations for scientific or other purposes

(1) Any person may, 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.

(2) Every donation referred to in subsection (1) shall be subject to the provisions of section 8(1) and (2) and to such other requirements or conditions as may be prescribed.

18. 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.

19. Misuse of tissue

- (1) (a) No person shall, except with the authorisation of the Board, import any tissue.
- (b) The Board may, on granting an authorisation under paragraph (a), impose such conditions as it thinks fit, and every person 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;
- (b) the purpose for which an authorisation was granted under subsection (1); or
- (c) in any other case, a therapeutic, scientific, educational or research purpose.

20. Offences and jurisdiction

(1) Any person who contravenes sections 6, 7, 9(2) and (3), 10, 11, 12, 13, 14, 18 or 19 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, impose any penalty provided by this Act.

21. Regulations

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

(2) Any regulation made pursuant to this section 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 therein the removal, preservation and transplant of tissue;
- (d) the designation of health institutions as Blood Transfusion Services;
- (e) the designation of health institutions or educational, research or scientific establishments for the purposes of scientific, educational or research purposes;
- (f) the setting up of such ethics committee as may be required for the purposes of this Act;
- (g) the issue of guidelines in respect of donation, removal, preservation and transplant of human tissue.

(3) Regulations made under this section may provide that any person who contravenes them shall commit an offence and shall, on conviction, be liable to a fine not exceeding 10,000 rupees and to imprisonment for a term not exceeding 2 years.

22. Commencement

(1) This Act shall come into operation on a day to be fixed by Proclamation.

(2) Different days may be fixed for the coming into force of different provisions of this Act.

SCHEDULE
(section 10(1))

Procedure for certifying death of a donor

1. Death is diagnosed by the irreversible cessation of brain-stem function (brain death).
2.
 - (a) Death should be diagnosed by at least 2 medical practitioners not below the status of specialist.
 - (b) One of the medical practitioners should preferably be the one who was in charge of the patient and the other one, as far as practicable, a neuro-surgeon, neurologist, physician or an anaesthetist.
 - (c) Each medical practitioner shall make his diagnosis independently of the other after ensuring that the preconditions, as stipulated in the Act, have been met.
 - (d) Each medical practitioner shall record the result of his examinations and diagnosis separately and independently of each other.
 - (e) Test to ascertain brain death in a patient shall be performed twice before pronouncement of death.
 - (f) A patient shall be presumed to be alive unless and until it is conclusively established that the patient is brain-dead.
 - (g) The time of death shall not be the time at which artificial ventilation has been withdrawn or when the heart-beat ceases, but shall be the time at which the patient has been conclusively certified as brain-dead.
 - (h) 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.