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Sindh Ordinance No.V of 2012

THE SINDH TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ORDINANCE, 2012.

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Sindh Ordinance No.V of 2012

THE SINDH TRANSPLANTATION OF HUMAN ORGANS AND TISSUES ORDINANCE, 2012.

[28th August, 2012]

An Ordinance to provide for removal, storage and transplantation of human organs and tissues for therapeutic purposes.

Preamble.

WHEREAS it is expedient to provide for the regulation, removal, storage and transplantation of human organs and tissues for therapeutic purposes and for matters connected therewith or ancillary thereto;

AND WHEREAS the Provincial Assembly is not in session and the Governor is satisfied that circumstances exist which render it necessary to take immediate action;

NOW, THEREFORE, in exercise of the powers conferred by clause (1) of Article 128 of the Constitution of the Islamic Republic of Pakistan, 1973, the Governor is pleased to make and promulgate the following Ordinance: -

Short title extent and commencement.

1. (1) This Ordinance may be called the Sindh Transplantation of Human Organs and Tissues Ordinance, 2012.

(2) It shall come into force at once.

Definitions.

2. In this Act, unless there is anything repugnant in the subject or context-

(a) "brain dead" means irreversible loss of brain and brain stem functions simultaneously;

(b) "death" means an irreversible cessation of the entire function of brainstem;

(c) "donor" means a person who donates any part of his body, organ, tissue or cell;

(d) "Evaluation Committee" means a Committee appointed under section 5;

(e) "Government" means the Government of Sindh;

(f) "human organ" means any part of a human body, organ or tissue;

(g) "Monitoring Authority" means an authority constituted under section 8 to monitor the process of transplantation of Human organs or tissues and matters relating thereto;

(h) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing,-

(i) the cost of removing, transporting or preserving the human organ to be supplied; or

(ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any organ from his body;

(i) "prescribed" means prescribed by rules made under this Act;

(j) "recognized institution" means a medical institution or hospital for practice of operative surgery in transplantation of human organs or tissues to be recognized by the Monitoring Authority;

(k) "recognized transplant surgeon or physician" means Surgeon or Physician possessing appropriate qualifications, experience, and trained in the relevant field, to investigate, examine and carry out transplantation surgery of human organs or tissues; and

(l) "transplantation" means the grafting of any human organ or tissue of any living or deceased person to some other living person for therapeutic purposes.

Donation of organ or tissue by a living person.

3. (1) Notwithstanding anything contained in any other law for the time being in force, a living donor who is not less than eighteen years of age, may during his lifetime voluntarily donate any organ or tissue of his body to any other living person genetically and legally related, who is a close blood relative and the donation of organ or part or tissue by such person for therapeutic purpose shall be regulated in the manner as may be prescribed. In the case of regenerative tissue, i.e. stem cells, there is no restriction of age between siblings.

Explanation:- For the purpose of this section, the expression "close blood relative" means parent, son, daughter, sister, brother and includes spouse:

Provided that transplantation shall be voluntary, genuinely motivated and without any duress or coercion.

(2) In case of non availability of a donor as explained under sub-section (1), the Evaluation Committee may allow donation by a non-close blood relative, after satisfying itself that such donation is voluntary.

Donation of human organs or tissues after death.

4. (1) Any person may before his death, in writing duly signed and verified by the respective Evaluation Committee, donate any of his organ or tissue for transplantation. Where no such declaration was made but the person has been declared brain dead, either of the surviving spouse or parent or adult child of such person may authorize the removal of any organ for transplantation in any medical institution or hospital duly recognized by the Monitoring Authority. The cases of unclaimed brain dead hospitalized patients shall be presented to an Evaluation Committee for transplantation after an intense search for their relatives within twenty four hours.

(2) On the death of a donor referred to in sub-section (1), any close relative of the deceased shall inform the Evaluation Committee about the deceased and cause the removal of the human organ or tissue in accordance with the authorization.

(3) A donation under this section may be executed in such form and manner as may be prescribed and may be revoked at any time during the lifetime of the donor in the presence of two witnesses.

Evaluation Committee.

5. (1) As soon as may be after the commencement of this Act Government may, by notification in the Official Gazette, appoint as many Evaluation Committees as may be necessary which shall consist of a surgical specialist, a medical specialist, a transplant specialist, a nephrologist, and a neuro-physician and an intensivist where available and two local notables having a good record of social service. The Evaluation Committee shall be established for every recognized medical institution and hospital where at least twenty-five transplants are being carried out annually.

(2) The Evaluation Committee shall–

(a) ensure that no organ or tissue is retrieved from non-related living donors without the prior approval of the Evaluation Committee;

(b) determine brain death of a person;

(c) determine propriety of removal of a human organ from any living person using brain death protocol to be formulated; and

(d) determine fitness or otherwise for transplantation of a human organ into any other body.

Transplantation to be carried out by the team of transplant surgeons and physicians, etc.

6. (1) The transplantation of human organ or tissue or removal of any part of human organ for the purpose of transplantation shall only be carried out by the recognized professionals who shall, before the removal of any human organ from the body of the deceased, ensure that written certification has been obtained from the Evaluation Committee that death has occurred.

(2) For the purpose of sub-section (1) a person shall be deemed to be medically and legally dead at the time when in the opinion of the Evaluation Committee, based upon acceptable medical standard there is–

(a) an absence of natural respiratory and cardiac functions and attempt at resuscitation are not successful in restoring those functions; or

(b) an irreversible and permanent cessation of all brainstem functions and future attempt of resuscitation or continued supportive maintenance would not be successful in restoring such natural functions.

(3) On the commencement of this Act Government shall on the recommendation of the Monitoring Authority, by notification in the official Gazette, publish the list of medical institutions and hospitals as recognized medical institutions and hospitals for act of operative surgery in transplantation of human organs and tissues. Government may revise the list from time to time.

(4) No hospital or medical institution shall carry out transplantation of human organs and tissues unless it is recognized as provided in sub-section (3).

Effects etc., to the donor and the recipient.

7. (1) No transplantation of a human organ and tissue from a donor other than defined in sub section (1) of section 3 shall be carried out without prior permission of the appropriate Evaluation Committee and only at such medical institutions and hospitals which have been notified under sub section (3) of section (6), provided that such donation by Pakistan citizen shall not be permissible to citizens of other countries.

(2) No human organ or tissue shall be removed from the body of a living person except for the purposes of section 3 and no transplantation team of a recognized medical institution or hospital shall undertake the removal or transplantation of any human organ or tissue from a living donor unless they have explained the effects, complications and hazards connected with the removal of organ or tissue for transplantation to the donor and its outcome in the recipient respectively in such manner as may be prescribed.

Monitoring Authority.

8. (1) Government shall, by notification in the official Gazette, constitute a Monitoring Authority consisting of the following namely:—

(i)	Minister for Health	Chairman
(ii)	Secretary Health Department	Member/ Secretary
(iii)	The Police Surgeon	Member
(iv)	President, Transplantation Society Of Sindh	Member
(v)	Executive Director, Pakistan Medical Research Council	Member
(vi)	President, Ophthalmological Society of Sindh	Member
(vii)	President, Pakistan Medical Association of Sindh	Member

(viii)	President, Society of Gastroenterology of Sindh	Member
(ix)	Surgical Transplant Specialist	Member
(x)	Any other outstanding Medical Specialist whom the Government may nominate	Member

(2) The Authority so constituted shall–

(a) monitor transplantation and enforce prescribed standards for recognized medical institutions and hospitals;

(b) investigate and hold inquiry into the allegations of breach of any provision of this Act;

(c) inspect recognized medical institutions and hospitals for examination of quality of transplantation, follow up medical care of donor and recipient and any other matter ancillary thereto and also periodically inspect institutions wishing to be recognized;

(d) cause establishment of a Provincial Registry and regional networks for evaluating quality and outcome of transplant centers and cause enhancement and promotion of transplantation; and

(e) due to shortage of available human organs for transplantation to meet lifesaving patient needs; the Monitoring Authority will explore and support the international collaboration of xeno transplantation in future, after considering all ethical and safety risks and also continue to examine and collect global data on the practice, safety, quality, efficacy and epidemiology of stem cell as well as non-human organ transplantation.

(3) The Monitoring Authority shall appoint an Administrator, preferably from the medical profession, and also appoint such other officers as may be required, on terms and conditions, to be determined by it, to carry out the day-to-day business of the Authority, for which Government shall provide it reasonable annual grant.

(4) Government in consultation with the Monitoring Authority shall establish a fund consisting of grants by Government and contributions by NGOs, philanthropists and other individuals for the transplantation or indigent patients including post transplant care and medicines.

(5) The pool of voluntary donors and registry of potential recipients shall be established and regulated as may be prescribed.

Prohibition of removal or transplantation of human organs for any purpose other than therapeutic purpose.

9. No donor and no person empowered to give authority for removal of any human organ shall authorize the removal of any human organ for any purpose other than the therapeutic purposes.

Punishment for removal of human organ without authority.

10. (1) Whoever renders his services to or at any recognized medical institution or hospital and who for the purposes of transplantation, conducts, associates with or helps in any manner, in the removal of any human organ without authority, shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

(2) Where any person convicted under sub-section (1) is a registered medical Practitioner, his name shall also be reported to the Pakistan Medical and Dental Council for appropriate action including removal of his name from the register of Council for a period of three years for the first offence and permanently for subsequent offence.

Punishment for commercial dealings in human organ.

11. Whoever–

(a) makes or receives any payment for the supply of, or for an offer to supply, any human organ;

(b) seeks to find a person willing to supply for payment of any human organ;

(c) offers to supply any human organ for payment; or

(d) initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply any human organ,—

(i) takes part in the management or control of a body of persons, whether a society, firm, or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or

(ii) publishes or distributes or causes to be published or distributed any advertisement,–

(a) inviting persons to supply for payment of any human organ;

(b) offering to supply any human organ for payment; or

(c) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in clause (d), shall be punished with imprisonment for a term which may extend to ten years and with fine which may extend to one million rupees.

Punishment for contravention of any other provision of this Act.

12. Whoever contravenes any provision of this Act or any rule made, or any condition of the registration granted, thereunder for which no punishment is separately provided in this Act, shall be punished with imprisonment for a term which may extend to three years or with fine which may extend to three hundred thousand rupees or with both.

Offences by companies.

13. Where any offence, punishable under this Act has been committed by a company, its Chief Executive or Director or any other person who, at the time the offence was committed was Incharge of, and was responsible to, the company for the conduct of business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that a company shall be liable to pay fine only:

Provided further that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

Explanation.-for the purposes of this section,–

(a) "company" means any body corporate and includes a firm or other association of individuals; and

(b) "director", in relation to a firm, means its partner in the firm.

Cognizance offences.

14. (1) No Court inferior to that of the Magistrate of First Class empowered under section 30 of the Code of Criminal Procedure,1898 (Act V of 1898) shall try an offence punishable under this Act.

(2) No court shall take cognizance of an offence under this Act except on a complaint in writing made by,–

(a) the Monitoring Authority or its Secretary; or

(b) an aggrieved person who has given notice of not less than fifteen days, in such manner as may be prescribed, to the Monitoring Authority, of the alleged offence and of his intention to lodge a complaint.

(3) Notwithstanding anything in the Code of Criminal Procedure, 1898 (Act V of 1898) the offences punishable under this Act shall be non-bailable.

Savings.

15. Neither the grant of any facilities of any authority for removal of any human organ from the body of the donor deceased or alive in accordance with the provisions of this Act nor removal of any human organ or tissue from the body of a deceased person with due care in pursuance of such authority shall be deemed to be an offence punishable under section 297 of the Pakistan Penal Code (Act XLV of 1860).

Protection of actions taken in good faith.

16. (1) No suit, prosecution or other legal proceedings shall lie against any person for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or rules made there under.

(2) No suit or other legal proceedings shall lie against Government for any damage caused or likely to be caused for anything which is done with due care in good faith or intended to be done in pursuance of the provisions of this Act.

Power to make rules.

17. Government, may by notification in the official Gazette, make rules for carrying out the purposes of this Act.

Removal of difficulties

18. If any difficulty arises in giving effect to any provision of this Act, Government may make such order as it considers necessary or expedient for the purpose of removing the difficulty.