

## **NOTE ON THE AMENDMENTS PROPOSED IN THE TRANSPLANTATION OF HUMAN ORGANS ACT**

The Union Parliament had enacted the Transplantation of Human Organs Act (THOA) in 1994 and the Act came into force in February, 1995. The main purpose of the Act is to regulate the removal, storage and transplantation of human organs for therapeutic purposes and to prevent commercial dealings in human organs. Despite having put into place a regulatory mechanism for transplantation of human organs, there is a wide disparity between demand and supply of organs in India. It is estimated that about 1,50,000 people are diagnosed with kidney failure in India every year, for whom the only way out is an organ transplant. However, it is believed that the number of transplants have fallen from 3600 in 2002 to a little more than 2000 in the year 2004. On the other hand, there has been a spate of reports in the print and electronic media about a thriving human organ trade in India and the consequential exploitation of economically weaker sections of the society. There has, therefore, been an increasing perception in civil society that while the Act has not been effective in curbing commercial transactions in organ transplant, it has thwarted genuine cases due to the complicated and long drawn process involving organ donation.

2. The Hon'ble High Court of Delhi had in September, 2004 constituted a Review Committee to examine various provisions of the Act and the Rules made there under. The Report of the Committee was put in the public domain by this Ministry and a National Consultation was held in the year 2007 to finalise inputs received from amending the Act and Rules.

3. Based on the feedback received, this Ministry has drafted the Transplantation of Human Organs and Tissues (Amendment) Bill, 2008. The logic for the amendments proposed in the Bill has been explained in the paragraphs below:-

### **The Act to cover both organs & tissues**

4. Currently, the Act deals only with human organs. During the national consultation, a view had emerged that with advancement in medical technology, apart from human organs, even tissues and cells were being transplanted. While a separate law would be required for regulating cell transplantation and therapy, the THO Act could be amended to include tissues also with the exception of blood. Accordingly, it is proposed to amend the THO Act by changing its name from 'Transplantation of Human Organs Act' to 'Transplantation of Human Organs & Tissues Act' by amending Section 1. Additionally, a definition of the term 'tissue' would be inserted in Section 2 (r). Further, throughout the Act, wherever, the term human organs appears, it shall be amended to read as 'human organs and tissues'

### **Expansion of the term "Near Relatives"**

5. The Act currently in Section 2 sub section (i) defines the term "near relative" to mean spouse, son, daughter, father, mother, brother or sister. As the law stands today, any individual who wishes to donate his or her organs for a recipient, who comes in the category of "near relatives" of the donor, can do so without the case being routed through the Authorization Committee.

6. A suggestion has been made that the definition of the term 'near relative' should be expanded to include grand parents, grand children, uncles and aunts all of whom are related by blood to the recipient. The view of the experts, however, is that it might not be desirable

to keep the definition of near relative so very wide that the relationship cannot be established even through genetic testing. It is also felt that it might expose the maternal side of the family for undue pressure for donating the organs to the recipient in the groom family. Therefore, it is proposed to modify the definition of ‘near relative’ in Section 2, only to the extent of including grand parents and grand children. All other cases of donation even from donors related by blood to the recipient would necessarily be routed through the Authorization Committee.

### **Required Request**

7. The Review Committee set up by the Delhi High Court has recommended that every hospital should make it mandatory for the ICU/ Treating Medical Staff to request relatives of brain dead patients for organ donation. A record of all brain dead patients and that of the next of kin who are approached should be kept.

8. In the United States of America, the Uniform Anatomical Gift Act, 1987 requires every hospital to ask each patient on or before admission to a hospital as soon as thereafter as to whether the person has pledged a donation of organ or tissue. It is believed that after this law was put into force in the USA, the awareness about organ donation and the number of organ donors went up considerably. By making such a provision in the Transplantation of Human Organs Act, 1994, this requirement can be enforced in respect of hospitals registered as Centres for Retrieval or Transplant of Organs. However, mostly hospitals with or without ICUs are registered under respective State laws for the regulation of clinical establishments. The Government of India has already introduced in Parliament the Clinical Establishment (Registration and Regulation) Bill that is currently pending with the Parliamentary Standing Committee. Once such a Law is enacted, it will be possible to prescribe standards and norms for hospitals with ICUs and the condition of ‘required request’ can be prescribed as a condition of registration. However, an enabling provision is proposed to be inserted in the Act that would vest the Central Government with the power to require hospitals with ICUs to make a request to the patient as explained above. It is proposed in the first instance to introduce this requirement of required request in the case of Corneas. To incorporate this provision, a new sub clause (A) shall be inserted in Section 3 sub section (1).

### **Special Provision for removal of Corneas**

9. The THO Act in section 3, currently provides that organs shall be removed by a registered medical practitioner only. During the national consultation, it was pointed out that this stipulation was actually hampering the eye donation programme. It is generally difficult to keep available an eye surgeon for the removal of corneas. It was, therefore, suggested that for the removal of corneas, a trained eye technician could easily do the job. This would also have a positive impact on the number of corneas collected in the country. This suggestion has been accepted and it is proposed that in Section 3, after sub section (4), a new sub section 4-A shall be inserted to provide that a technician possessing such qualifications and experience as may be prescribed, may enucleate a cornea.

### **Certification of Brain Death**

10. Section 3 of the THO Act details the authorities competent to remove organs and tissues. In the case of removal of organs from a person who has been declared as brain dead, sub section 6 provides for a medical board to certify such death. This board is to comprise of among others by a neuro surgeon and a neurologist. The Review Committee had suggested that due to the shortage of neuro-surgeons and neurologists brain death certification had not

taken off in the country. A similar suggestion was also made in the national consultation. Further, as recommended by the Review Committee, it was to be made mandatory for all hospitals with ICUs to report brain death, then certification procedures had to be made feasible. It has, therefore, been recommended that in the event of the non-availability of a neurosurgeon/ neurologist, a surgeon/ physician and an anesthetist/ intensivist could be nominated from a panel already approved by the Appropriate Authority. Such surgeons/ physicians Anaesthetist / Intensivist shall, however, not associate with the removal of the organs from the donors or its transplantation into the recipients in any time before the members of the transplant team arrive. The recommendation is proposed to be given effect to by introducing a new sub clause (a) after sub-section (6)(iii) of Section 3.

### **Foreign Nationals**

11. There have been reports often carried by the media that India is heading towards becoming the hub of transplant tourism. The Gurgaon Kidney scam has lent credibility to such reports. To protect our vulnerable sections of society from exploitation through organ trade it is proposed to introduce two new provisions in the Act.

- i. Inserting in Section 9 a new sub section 3-A to prohibit grant of permission by the authorization committee for organ transplantation where the recipient is a foreign national and the donor is an Indian national.
- ii. Inserting in Section 9 a new subsection 1-A to provide that where the donor and/ or the recipient being near relatives are foreign nationals prior approval of the authorization committee would be required before removing and/ or transplanting organs in all such cases. As the law stands today, cases of near relatives are not required to be processed through the Authorisation Committees.

### **Minors**

12. Guiding Principle of the WHO, on Transplantation of Human Organs inter-alia provides, “No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor’s assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.” It is proposed to give effect to this guiding principle by inserting a new section 17 C in the Act to provide that no human organs or tissues should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions as may be prescribed.

The major exceptions that may be authorized are familial donation of regenerative cells (when a therapeutically comparable adult donor is not available) and kidney transplants between identical twins (where avoiding immunosuppression represents a benefit to the recipient adequate to justify the exception, in the absence of a genetic disorder that could adversely affect the donor in the future).

### **Swap donations**

13. Currently, the law permits donation of an organ by an individual, who falls in the category of near relative of the recipient without going through the Authorization Committee as indicated above. All other cases have to be routed through the Authorization Committee. The Committee set up by the Delhi High Court has, however, recommended that swap donations should be allowed. The Committee has recommended that two different willing

but incompatible ‘near relative’ donors (vis-à-vis their intended related recipient) should be permitted to donate their organs in exchange without any commercial interest and only due to the reason that despite willingness, their organ was not found medically compatible for their intended recipients. This would greatly help patients who have ‘near relatives’ willing to donate but incompatible for their recipient. Swap operations may be considered by authorization committee on case-to-case basis and as per the existing THO Act and Rules.

14. This recommendation has been accepted by the Ministry and an amendment is proposed to be made in section 9 by inserting a new subsection 3(a) to allow a swap donation.

### **Transplant Coordinators**

15. The Review Committee appointed by the Delhi High Court has recommended that hospitals/ centres in transplantation activity be advised to have a post of a coordinator in the ICU (who may be a doctor or a senior nursing staff member) independent of the Transplant team, who is trained in the communications skills and who can liaison between the treating physician and the potential brain-death donor and ORBO. Such coordinators should possess skills to communicate with the relatives and friends of the patient with a view to explain to them the merits of cadaver donation and who possesses adequate knowledge to remove their doubts and answer their queries with regard to the procedures involved in transplantation activities. Donor transplant coordinators are generally responsible for the care of the person who has died, speaking to their family and organising the organ donation procedure. They support families before, during and after donation and are there to answer any questions they might have. Part of their role is to ensure that the donor's family is told in general terms about the eventual use of the donated organs. Recipient transplant coordinators help to assess patients' suitability to go on the transplant waiting list and organise the transplant operation as well as follow-up consultations for those patients who have been lucky enough to receive a donated organ. Some coordinators work with both recipients and donor families.

16. The Ministry has accepted this recommendation. It is, therefore, proposed to define the term ‘transplant coordinator’ by inserting a new clause (s) in Section 2. Further, to provide that no hospital shall be registered under this Act, unless the appropriate authority is satisfied that such hospital has created the position of a Transplant Coordinator with such qualifications and experience as may be prescribed in the Rules and has also appointed the Transplant Coordinator accordingly, a new sub-section (4) shall be inserted after sub-section 3 in Section.

### **Powers of the Appropriate Authority**

17. The Act provides for an ‘Appropriate Authority’ to be set up in each State/ Union Territory to perform the following functions:-

- (i) To grant registration to a hospital for the removal, storage and transplantation of any human organ.
- (ii) To suspend or cancel such registration.
- (iii) To enforce standards for hospitals engaged in the removal/ storage or transplantation of human organs.
- (iv) To investigate any complaint or breach of any provision of the Act or the Rules made thereunder.
- (v) To inspect hospitals periodically for examination of the quality of transplantation and follow up medical care to the recipients as well as donors.

18. Such appropriate authorities are constituted by the Central Government in the case of Union Territories and by the State Government in the case of States. All States/ Union Territories have constituted such an appropriate authority. These are generally single member bodies comprising of Secretary (Health) or the Director of Health Services of the State Government concerned. In the case of Union Territories, Director General of Health Services , Government of India has been notified as the ‘appropriate authority’.

19. To improve the effectiveness of Appropriate Authorities, it is proposed to vest in them the powers to summon any person, seek production of a document and issue a warrant for the search of any place suspected to be indulging in unauthorized transactions in human organs. A new section 16 A is proposed to be introduced accordingly.

### **Setting up of an Advisory Committee for aiding and assisting Appropriate Authority in the discharge of its functions**

20. In the wake of the various media reports about commercial transactions in organs transplantation and the recent Gurgaon kidney scam, it has been felt that the Appropriate Authorities function rather mechanically. It has often been said that the poor conviction rate under the Act is mainly due to the fact that the officer of the Department of Health, who is designated as the appropriate authority in most States takes on this responsibility in addition to other administrative functions. He/ She is unable to find time for a methodical and systematic discharge of the duties assigned to the Appropriate Authority under the Act.

21. In view of the above, it is proposed to provide for the setting up of an Advisory Committee for the Appropriate Authority by inserting a new section 16 B.

22. The Advisory Committee shall function on a reference to be made by the Appropriate Authority and payment of remuneration shall be on per sitting basis. A similar set up has already been created under the PNDT Act.

### **Authorisation Committees**

23. The Review Committee set up by the Delhi High Court has observed that in Metropolitan Cities, for different hospitals, providing facilities of transplantation surgery, there are distinct and independent Authorization Committees. In the considered view of the committee, this practice of hospital based Authorization Committees is workable and practical in Metropolitan Cities and large capital cities of States where within the city, large distances need to be traveled and it may not be possible for the medical practitioners and other members of the committee to leave hospital and go to another place for attending the meeting. The increasing vehicular traffic in such cities restricts the mobility. But, in non-metropolitan cities and smaller capital cities of states, a single Authorization Committee for the entire district or a Division comprising of several Districts, depending upon the factors like size of population; number of transplantation centers available within the territory and other administrative exigencies, would serve the purpose.

24. This recommendation has been examined by the Committee and suitable modifications have been proposed in the rules. In so far as the Act itself is concerned, only two changes are being proposed in sub section 4 of Section 9:

- (a) Vesting in the Central Government the power to prescribe the composition of the Authorisation Committees though the actual appointments would be made by the concerned State Governments. Presently, this power is vested in the Central Government only in respect of Union Territories. It is considered desirable to have

uniformity in the composition of the Authorisation Committees. There would, therefore, be consequential changes in Section 9 of the Act.

- (b) Currently, the Central Government appoints the Authorisation Committees for Union Territories. It is proposed that this power be delegated to the respective Union Territories.

### **National Registry:**

25. The Central Government shall provide for the development and maintenance of a scientific registry of the recipients of organ transplants. The registry shall include such information in respect of patients and transplant procedures as the Central Government may prescribe as necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. A new section 17-A shall be inserted.

### **National Organ Retrieval, Banking and Transplantation Network:**

26. An efficient network that links organ retrieval and transplant centres to facilitate exchange information about availability of organs and data base of recipients holds the key to the success of any transplant programme. Organ Procurement & Transplant Networks have been set up in the USA, UK, Spain and in few other countries as well. While the structure of the networks may vary from country to country, their objectives are generally similar.

27. A similar role had been expected of the Organ Retrieval & Banking Organisation (ORBO) set up at AIIMS in New Delhi. However, experience indicates that ORBO has got largely confined to AIIMS and Delhi. Therefore, the need has been felt for the establishment of a nation wide network on the lines of the Organ Procurement and Transplantation Network of USA or UK Transplant of UK. Such a network would include:

- a. All transplant centres
- b. All retrieval organizations
- c. All certified HLA testing labs
- d. In future – all trauma centres, all dialysis centres, all hospitals with ICUs

The network would maintain a waiting list of patients awaiting transplantation. Different lists would be maintained for different organs. The network would facilitate matching of organs through a computerized data base. It would establish a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs.

28. It is, therefore, proposed that the Central Government shall as soon as it may be possible, provide for the establishment and operation of an Organ Retrieval, Banking and Transplantation Network at one location or through multi-locations and/ or Regional Centres. For this purpose, a new section 17-B shall be introduced.

### **Review of Penal Provisions**

#### **Difficulty in proving that payments have been made for procuring organs**

29. The Review Committee of the High Court has observed that in most of the cases where complaints are made, alleging commercial dealing in organ donation, police

investigations cannot lead to any conclusive proof of commercial transaction. At best, the police may be able to gather evidence with regard to impersonation, false documentation or wrong affidavits. But evidence of the allegation that money has exchanged hands is extremely difficult to be collected. The factors like impersonation, forgery or swearing false affidavits are already covered as punishable offences under the Indian Penal Code. Section 19 of THO Act, except for defining the nature of activities requiring prosecution has no other substantial role to play. Accordingly, it is recommended that the Central Government may review Section 19 of THO Act. It is also suggested that the THO Act and Rules may be amended to introduce an element of presumption in cases where there has been impersonation and falsification of documents to establish relationship between donor and recipient when none exists. This can at least make law justifiable (effective).

30. It is, therefore, proposed to insert a new clause (g) in Section 19 to provide that whoever prepares or abets in the preparation and or submission or whoever, submits false documents including wrong affidavits to establish that the donor is making the donation of an organ as a near relative or out of love and affection for the recipient would also be punishable as a person who has offered or received payment for the organs.

### **Enhancement of Penalties**

31. The Review Committee has recommended significant enhancements in the penalties for offences committed under the Act. The consensus was that the fines and term of imprisonment should be enhanced in a way that these serve as effective deterrents. It is, therefore, proposed that minimum imprisonment for offences under the Act should not be less than five years and fine would not be less than Rs. Five lacs. The following amendments are therefore to be made:

#### **Section 18: Punishment for removal of human organ without authority**

- a. In Section 18 sub-section (i), the term “five years” shall be substituted by the term “ten years” and the term “ten thousand rupees” shall be substituted by term “five lakh rupees”.
- b. In sub-section (ii), the term “two years” shall be substituted by the term “three years”.

#### **Section 19: Punishment for commercial dealings in human organs**

- c. Section 19 – The term “two years” shall be substituted by the term “five years” and the term “seven years” shall be substituted by the term “ten years” and the term “ten thousand rupees” shall be substituted by “five lakh rupees” and the amount “twenty thousand rupees” shall be substituted by “twenty lakh rupees”.
- d. The proviso to Section 19 shall be deleted.

#### **Section 20: Punishment for contravention of any other provision of this Act**

- e. Section 20 – the term “three years” shall be substituted by the term “five years” and the amount of “five thousand rupees” shall be substituted by “five lakh rupees”.

### **Registration of NGOs**

32. It is also proposed to introduce a provision for the registration of Non Government Organizations that are engaged in transplantation of organs in any manner whatsoever, with the appropriate authority. This is being suggested with a view to be able to monitor the

activities of all organizations/ agencies including not for profit bodies that are engaged in or associated with the transplantation of human organs. A new section 17-D is being introduced accordingly.

### **Power to make rules**

33. It is also proposed to amend Section 24 to expand the rule making power of the Central Government to provide for the following:

- (i). the qualification and experience to be possessed by a technician to be eligible for enucleating a cornea.
- (ii). the conditions for an anesthetist/ intensivist and surgeon/ physician for being included on the medical board for certification of brain death.
- (iii). the qualifications and experience required for the position of transplant coordinator.
- (iv). the composition of authorization committees.
- (v). conduct of business by the authorization committees.
- (vi). narrow exceptions in which transplants from a minor are to be allowed.
- (vii). the form and manner in which the National Registry specified is to be maintained.
- (viii). the functions to be performed by the National Organs Retrieval Banking and Transplantation Network.
- (ix). the registration of NGOs.