

**Summary of Matters discussed and agreed at the first four meetings of the Bills Committee
on the Human Organ Transplant (Amendment) Bill 2001**

Issues Raised by Members	Administration's Response
Issues raised at the first Bills Committee meeting on 14 December 2001	
1. DNA Testing should be used as a means of establishing genetic relationship for transplant of organ from a live donor, in the event that the means of establishing the same as stipulated in section 2 of the Human Organ Transplant Regulation should fail.	- Although the degree of certainty for verification of close genetic relationships is high, it is low for half blood relationships. In addition, the time required for DNA testing (minimum one week) would render the tool not useful in urgent cases.
2. Donor should be required to make a declaration that there is no commercial dealings in donating his organ for transplanting into another person.	- At present, for organ transplants between living persons, who are not genetically related or whose marriage has subsisted for less than 3 years, the donor has to declare to the best of his knowledge that no payment prohibited by the Ordinance have been or is intended to be made. In addition, the medical practitioner who removes an organ from a donor, whether living or dead, for the purpose of its transplanting into another person is required to declare in a form to the Human Organ Transplant Board that no payment prohibited by the Ordinance is made or intended to be made. Thus, the principle of prohibiting commercial dealings in human organs intended for transplants is upheld in all transplant cases.

Issues Raised by Members	Administration's Response
3. Amendment to the proposed Schedule setting out organs not to be covered by the Human Organ Transplant Ordinance should be subjected to positive vetting by the Legislative Council.	- The suggestion was accepted by the Administration. This has been incorporated in the proposed committee stage amendments.
4. Two persons from the non-medical sector should be retained as members of the Board.	- The proposed composition in the Bill will not diminish the representation of members in the "other person" category. There will be a Vice Chairman, who shall not be a registered medical practitioner, and a member from the non-medical sector.

Issues Raised by Members	Administration's Response
<p>5. Registered medical practitioners who are to transplant organs previously removed for therapeutic purposes should not be required to make a statement that no payment prohibited by the Ordinance has been or is intended to be made, and that the organs were removed for the therapy of the donors, having regard to the fact that the registered medical practitioners concerned do not have direct knowledge of the matter.</p>	<ul style="list-style-type: none">- The Administration proposed to require the medical practitioner who removed the organ which was subsequently stored in the organ/tissue bank to declare that the organ/tissue, at the time when it was removed from the donor, was originally intended for the therapy of the donor.- Nevertheless, the Administration remains of the view that it is necessary to require the medical practitioner, who is to transplant organs previously removed for therapeutic purpose, to declare, to his best knowledge that no payment prohibited by the Ordinance has been or is intended to be made and that the organ was originally removed for therapeutic purpose and not for transplanting into any specific recipient. To safeguard against the possibility of commercial dealings, it is necessary to require the medical practitioner, who is to carry out the transplant, to satisfy himself that the source of the organ/tissue is legitimate.- This has been incorporated in the proposed committee stage amendments.

Issues Raised by Members	Administration's Response
<p>6. Legal liability of the registered medical practitioner for performing an organ transplant on a patient without first obtaining the latter's consent under section 5D of the Bill because of his illness or impaired state of consciousness or his being a minor, a mentally disordered or handicapped person; whether relatives of a patient who cannot give consent may give consent on behalf of the patient; and what would happen if the relatives have no consensus on whether to give consent.</p>	<ul style="list-style-type: none">- If a patient has expressly indicated his unwillingness for organ transplant before he has become unconscious, the medical practitioner cannot act against his wish. If the patient has not made any advance directives regarding his wish, and since no one can give proxy consent on behalf of a competent adult who is rendered incompetent through illness or impaired consciousness, then the medical practitioner can act in accordance with his clinical judgement of what is in the patient's best interest.- For mentally incapacitated adults within the meaning of the Mental Health Ordinance who do not have a guardian, the medical practitioner can also act in accordance with his clinical judgement of what is in the best interest of the patients. However, where guardians have been appointed and vested with the power to consent to medical treatment on behalf of the mentally incapacitated adults, consent can be obtained from the guardians to the extent that the mentally incapacitated adults are incapable of consent. Applications may be made to the court to override the guardian's refusal.- Minors can consent to medical treatment if they understand the nature and consequences of the operation. For children who do not so understand, the power of consent is vested with the parents who must exercise such powers reasonably failing which an application can be made to the court to override their decision.

Issues Raised by Members	Administration's Response
Issues raised at the second Bills Committee meeting on 25 January 2002	
<p>7. To confirm whether these two skin substitutes, "AlloDerm" and "Apligraf", fell within the definition of organ in the Bill.</p>	<ul style="list-style-type: none"> - AlloDerm is technically a cellular human cadaveric dermis. It is considered as a structured arrangement of tissues and thus falling within the definition of organ. - Apligraf, on the contrary, is technically speaking a prefabricated structure comprising living human skin cells. It does not constitute structured tissue and therefore considered falling outside of the definition of organ.
<p>8. To consider creating an additional Schedule to the Human Organ Transplant Ordinance for the setting out of materials containing human bodily parts where transplant of such would not be restricted for the purposes of sections 5 to 7 of the Ordinance and where commercial dealings would be allowed.</p>	<ul style="list-style-type: none"> - The Administration was of the view that these products should be considered and examined individually before their trading is permitted. This is to ensure that no illegal transaction are involved. Therefore, it would not be appropriate to set them out in a Schedule where items are usually described in generic terms only. - The Administration suggested that a system should be worked out to grant exemptions administratively to individual organ products for transplantation where their commercial dealings should not be prohibited. The details of our proposal has been set out in a separate paper issued to Members on 1 June 2004 and incorporated in the proposed committee stage amendments.
<p>9. To give reasons for the view that medical members of the Human Organ Transplant Board might have conflict of interests if they were appointed Chairman or Vice Chairman of the Board.</p>	<ul style="list-style-type: none"> - The Administration explained that the intention was to avoid potential conflict between professional interest of a medical practitioner and the interest of a patient.

<p style="text-align: center;">Issues Raised by Members</p>	<p style="text-align: center;">Administration's Response</p>
<p>10. To provide plan on enhancing communication between frontline medical practitioners and the Board.</p>	<ul style="list-style-type: none"> - The Hospital Authority has sent a senior executive to attend all Board meetings to serve as a point of liaison and communication between the Board and the Hospital Authority. The Board has also participated in talks/seminars organised by transplant organisations. - We would encourage the Board to devise plans to foster a more established channel of communication and collaboration.
<p>11. To state in section 5B(2)(a)(ii) in clause 5 of the Bill that a medical practitioner would be considered to have satisfied the requirement that, to his best knowledge, the organ/tissue he intended to transplant into his patient was previously removed for therapeutic purposes if he declared that he had read the declaration made by the medical practitioner who removed the organ/tissue for therapeutic purposes.</p>	<ul style="list-style-type: none"> - The Administration suggested amending the Bill to the effect that the medical practitioner, who is to transplant the organ previously removed for therapeutic purpose, should have checked all the relevant documents prepared by the medical practitioner who previously removed the organ for the therapeutic purpose of the patient. This has been incorporate in the Proposed committee stage amendments. Furthermore, we would also set out clear instructions in the future Administrative Guideline that medical practitioners can refer to such documents as a means of verifying the origin of the organ.
<p>Issues raised at the third Bills Committee meeting on 22 February 2002</p>	
<p>12. To consider an appeal mechanism in the proposed administrative arrangement for granting exemptions to individual products for transplantation that fall within the definition of organ and yet their commercial dealings should not be prohibited.</p>	<ul style="list-style-type: none"> - The Administration proposed to set up an Appeal Panel under the Human Organ Transplant Ordinance to hear the appeals. The details of our proposal has been set out in a separate paper issued to Members on 1 June 2004 and incorporated in the proposed committee stage amendments.

Issues Raised by Members	Administration's Response
13. To review the various declarations and forms required of the doctors who intended to carry out restricted organ transplants after the implementation of the Bill.	- The Administration would, in consultation with the Human Organ Transplant Board, review, streamline and, as appropriate, amend the various declarations and forms in relation to the Human Organ Transplant Ordinance after the enactment of the Bill.
14. To amend "7 days" in the proposed section 7(5)(a) to "7 working days" and to consider whether the time limit could be extended to 14 working days.	- The Administration accepted Members' suggestion to amend "7 days" in the proposed section 7(5)(a) to "7 working days". This has been incorporated in the Proposed committee stage amendments.
15. To simplify the completion of cause of death under item 1(b) of Form 1 in the Schedule to the Human Organ Transplant Ordinance.	- The Administration would review the various declarations and forms after the enactment of the Bill.
16. To consider whether "legally qualified person" referred to in the proposed section 3 should be required to be so qualified in Hong Kong.	- The Administration was of the view that the substantive member and panel members of the Board from the legal sector should be "legally qualified" but not necessarily be so qualified in Hong Kong. This would give the Administration greater flexibility in appointing the appropriate persons with expertise in the legal field. It should also be noted that the task of providing legal advice is to be undertaken by the legal advisor appointed to the Board rather than the substantive/panel members from the legal field.

Issues Raised by Members	Administration's Response
17. To review the proposed section 5C(5)(b) by weighing the pros and cons of requiring the same person to interview both the donor and the recipient or having two separate interviewers for the purpose.	- There might be practical difficulties at the operational level for the same person to interview both the donor and the recipient. The Administration considered it necessary to provide a certain degree of flexibility by amending the existing provision in the Ordinance to allow the donor and recipient to be interviewed by either the same or by two different interviewers, as proposed in section 5C(5)(b) of the Bill.
18. To consider deleting the proposed section 5D(1)(a)(ii) which stipulated that a donor must have reached the age of 16 and was married and if the suggestion could not be acceded to, to provide justifications for the provision and explain whether the existence of such a provision contravened the Family Status Discrimination Ordinance.	- The Administration explained that the existing section 5(4)(b)(ii) of the Human Organ Transplant Ordinance does not contravene the Family Status Discrimination Ordinance by virtue of an exemption in the latter Ordinance for "existing statutory provision". - Nevertheless, the Administration has reviewed its position on the issue and decided to accept Members' suggestion of deleting the proposed 5D(1)(a)(ii) in the Bill. The effect of this would be that a person must have reached the age of 18, regardless of his/her marital status, to become an organ donor. This has been explained to Members in a separate paper issued to Members on 1 June 2004 and incorporated in the proposed committee stage amendments.

Issues Raised by Members	Administration's Response
<p>19. To confirm whether a person who had married outside Hong Kong and reached the age of 16 (or 18 if the suggestion in 18 above was agreed) could donate his/her organ to his/her spouse so long as their marriage had subsisted for not less than three years.</p>	<p>- The Administration confirmed that a person who had married outside Hong Kong and reached the minimum age stipulated in the Human Organ Transplant Ordinance can donate his/her organ to his/her spouse, provided that their marital relationship could be established by means of (i) a document that is equivalent to the one issued under the Marriage Ordinance or the Marriage Reform Ordinance and that shows the donor and the recipient are the parties to a marriage celebrated or contracted outside Hong Kong in accordance with the law in force at the time and in the place where the marriage was performed; and (ii) a statutory declaration by either the donor or the recipient to the effect that the marriage has subsisted for not less than three years.</p>
Issues raised at the fourth Bills Committee meeting on 22 March 2002	
<p>20. To ascertain and report on whether the Administrative Appeals Board would agree to hear appeals pertaining to the granting of exemptions to individual products for transplantation that fall within the definition of organ and yet their commercial dealings should not be prohibited, and if so, to prepare proposed committee stage amendments accordingly.</p>	<p>- The Administration explained to Members in a separate paper issued on 1 June 2004 that the Administrative Appeals Board would not be a suitable channel for hearing the appeals.</p>

Issues Raised by Members	Administration's Response
21. To consider whether further amendment should be included in this Bill so that homosexual marriages/domestic partnerships registered overseas and having subsisted for not less than three years would be treated on an equal footing with the marital relationship referred to in the proposed section 5A(1)(a)(ii).	- Response issued to Bills Committee on 5 June 2002 is superseded by response issued on 10 June 2004.

Health, Welfare and Food Bureau
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