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**Paper for the House Committee meeting
on 25 June 2004**

**Report of the Bills Committee on
Human Organ Transplant (Amendment) Bill 2001**

Purpose

This paper reports on the deliberations of the Bills Committee on Human Organ Transplant (Amendment) Bill 2001.

Background

2. The Human Organ Transplant Ordinance (Cap. 465)(the Ordinance) was first enacted in 1995 to prohibit commercial dealings in human organs intended for transplant, restrict the transplant of human organs between living persons, and regulate the importing of human organs intended for transplant.

3. The Human Organ Transplant (Amendment) Ordinance 1999 (the Amendment Ordinance) was enacted on 10 February 1999. It specifies, amongst other things, the circumstances in which an organ transplant involving a live donor may still be carried out in cases where the recipient is incapable of understanding the explanation required to be given to him under the Ordinance. During this last legislative amendment exercise, it was agreed that a comprehensive review of the Ordinance should be conducted following the enactment of the Amendment Ordinance and where appropriate, further amendments should be introduced as Stage II amendments to the Ordinance.

4. On the basis of the comments collected in the subsequent review and in the light of the operating experience of the Ordinance, the Health, Welfare and Food Bureau has identified some elements that may prevent the Human Organ Transplant Board (the Board) from discharging its duties effectively. These elements are mainly related to the definitions of "organ" and "payment", the appointment of temporary members to the Board, handling of transplant related to organs previously removed for therapeutic purposes and the handling of imported organs.

The Bill

5. The Bill seeks to -

- (a) amend the definitions of "organ" and "payment" and add some new definitions;
- (b) provide for a vice-chairman of the Board and a panel which provides substitute members to the Board to stand in for substantive members who are unable to perform their duties for a period;
- (c) state explicitly that a secretary and a legal adviser shall be appointed to the Board;
- (d) enable the transplant of organs previously removed for therapeutic purposes without going through the procedures prescribed in section 5 of the Ordinance;
- (e) enable the donor and recipient of an organ to be interviewed by different interviewers or medical practitioners;
- (f) refine the drafting of the existing section 5 of the Ordinance;
- (g) create offences for various contraventions;
- (h) require an organ imported for transplant to be accompanied by a certificate, which shall be supplied to the Board by the relevant medical practitioner who transplanted the imported organ into a recipient in Hong Kong within seven days after the transplant; and
- (i) provide for immunity for members and officers of the Board against personal liability.

The Bills Committee

6. At the House Committee meeting on 22 June 2001, Members agreed to form a Bills Committee to study the Bill. The membership list of the Bills Committee is in **Appendix I**.

7. Under the chairmanship of Dr Hon LO Wing-lok, the Bills Committee has held six meetings with the Administration. It has also met with

representatives of the Department of Surgery of The University of Hong Kong, the Hong Kong Burns Society, the Hong Kong College of Cardiology, the Hong Kong Society of Transplantation and the Hong Kong Chinese Medical Association and considered the views of 10 written submissions.

8. In October 2002, the Administration proposed, and the Bills Committee agreed, to put the scrutiny of the Bill on hold, pending further research by the Administration to work out a system for granting exemptions to individual products for transplantation that fall within the definition of "organ" and yet their commercial dealings should not be prohibited, amongst others. A report on the Bills Committee's decision to hold in abeyance the consideration of the Bill was made to the House Committee meeting on 1 November 2002.

9. On 1 June 2004, the Administration wrote to the Chairman of the Bills Committee to express its wish to resume meetings of the Bills Committee. At the House Committee meeting on 4 June 2004, Members agreed that the Bills Committee could be re-activated.

Deliberations of the Bills Committee

Definition of "organ"

10. Members note that the existing definition of "organ" is not entirely satisfactory as there are different views as to whether certain tissues like blood and bone marrow would fall within the definition. The Administration considers it desirable to clarify that commercial dealings in those human bodily parts are prohibited by the Ordinance but transplants of them are not restricted for the purposes of sections 5 to 7 of the Ordinance.

11. The revised definition of "organ" is set out in section 2 in clause 3(a) of the Bill. Those bodily parts referred to in paragraph 8 above are set out in the Schedule to the Ordinance.

12. The Administration has pointed out that in view of the rapid pace of technology advancement in the medical field, some tissues that cannot be transplanted at present may be transplantable in the future. To allow flexibility in catering for such changes, the Administration proposes that the Secretary for Health, Welfare and Food (SHWF) be empowered, after consultation with the Board, to amend the Schedule by notice in the Gazette. Such notice would be subsidiary legislation subject to negative vetting by the Legislative Council (LegCo). Members consider that amendments to the Schedule should be subject to positive vetting by LegCo. The Administration has accepted members' suggestion.

Granting exemptions to individual products for transplantation that fall within the definition of "organ" and yet their commercial dealings should not be prohibited

13. Members have asked the Administration to consider creating an additional Schedule to the Ordinance for setting out materials containing human parts, the transplant of which would not be restricted for the purposes of sections 5 to 7 of the Ordinance and in which commercial dealings would be allowed. The Administration is of the view that such products should be considered and examined individually before their trading is permitted with a view to ensuring that no illegal transactions are involved. It would therefore not be appropriate to set them out in a Schedule where items are usually described in generic terms only.

14. As an alternative, the Administration has proposed to add new provisions empowering the Director of Health (the Director) to grant exemption, upon application, for an organ/product to be exempted from the prohibition against commercial dealings. As an exemption authority, the Director -

- (a) may prescribe the manner and form in which the application must be made as well as the particulars and documents that should be submitted by the applicant;
- (b) upon receipt of an application made in the prescribed form and of all particulars and documents required from the applicant, may approve the application and grant the exemption or reject the application;
- (c) shall take into consideration the following factors in assessing the application -
 - (i) whether the harvesting and subsequent processing of the organ comply with the relevant laws of the jurisdiction(s) in which the harvesting and subsequent processing take place;
 - (ii) whether the organ product for transplant purposes is safe and has any adverse impact on the public health;
 - (iii) whether the manner in which is obtained is consistent with the principles enshrined in the Ordinance, for instance, prior consent of the donor has been given voluntarily and no payment of any form is involved in the supply of the organ; and

- (iv) any other factors that the Director deems fit;
- (d) will have the flexibility to limit the validity of the exemption as he sees fit; and
- (e) shall keep a register of his decisions at his office, where it will be made available to the public for information.

15. As the effect of an exemption granted by the Director would exempt the organ product under application from the prohibition against commercial dealings stipulated in section 4 of the Ordinance, the Administration has further proposed that the transplant of organ products exempted by the Director to a person in Hong Kong should also not be subject to the restrictions/requirements in sections 5 to 7 of the Ordinance.

Appeal mechanism

16. Members have asked the Administration to consider an appeal mechanism in 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. The Administration initially considered that the appeal mechanism provided by the Administrative Appeals Board Ordinance would be a feasible channel for the lodging of appeal applications against decisions made regarding the granting of the relevant exemption. However, the Administrative Appeals Board (AAB) has since pointed out that it deals mainly with appeals of a relatively general and minor nature. Given the nature of the administrative decision and the need for possession of the relevant medical knowledge by the appeal body, AAB is of the view that it is not a suitable or desirable appeal channel for the purpose.

17. In the light of the views of AAB, the Administration has explored with the Judiciary whether the court would be willing to hear these appeals. The Judiciary's view was that it might not be appropriate for the courts to act as the appeal channel for administrative decisions made by the Government, which were usually heard by statutory tribunals and appeal bodies.

18. The Administration has subsequently proposed to make Committee Stage amendments (CSAs) to make provisions under the Ordinance for the establishment of an Appeal Board with members selected from a Panel to handle appeals pertaining to the granting of exemption of individual organ products. The Appeal Panel shall be appointed by SHWF and the names of members published in the Gazette. It should comprise members of the following categories, namely, registered medical practitioners, legally qualified persons and other persons such as academics, social workers and other professionals. The appointment to the Appeal Panel shall be for a period not exceeding three years, and shall be determined by SHWF at the time of

appointment. The Appeal Board may uphold the Director's decision or remit the decision to the Director for reconsideration.

19. The Administration has advised that it plans to submit the proposals on the rules of appeal by regulation to LegCo in the next legislative session. The relevant provisions of the Bill, such as the provisions pertaining to the exemption and appeal mechanisms, will commence at the same time as the new regulation on the rules of appeal.

Definition of "payment"

20. Clause 3(b) of the Bill proposes to amend the definition of "payment" so that payment for the administrative cost incidental to the removal, transportation or preservation of the organ to be supplied will not be prohibited by the Ordinance.

21. Members have asked the Administration to clarify the types of payment falling within the meaning of "administrative cost incidental to the removal, transportation or preservation of the organ to be supplied" and to whom the payments would be made. In response, the Administration has explained that it is difficult to isolate the "administrative cost incidental to the removal, transportation or preservation of the organ" from the cost for removal, transportation or preservation of the organs, as these costs are usually associated.

22. The Administration has informed members that in practice, the payments are usually made to organ/tissue banks. As regards the calculation of the cost, it is usually based on the costs of procurement (mainly salaries of staff providing administrative support), cost of laboratory tests and transport medium and expenditure on transportation for processing and delivery of tissues.

23. As to which party is responsible for payment of such administrative cost, the Administration has pointed out that for living donors, the practice in the Hospital Authority (HA) is that the donor will pay for his/her own hospitalisation. Generally speaking, recipients in public hospitals will not be asked to pay for the harvesting cost on the part of the donor if the organ is supplied in Hong Kong.

Chairman and vice-chairman of the Board

24. The Chairman of the Bills Committee has asked the Administration to explain the reason for providing in clause 4 (proposed section 3(2)) of the Bill that the chairman and vice-chairman of the Board shall not be registered medical practitioners. The Administration has pointed out that out of the nine members of the Board, four of them are from the medical sector. This strong

representation of medical practitioners has been a testimony to their value and importance to the Board. Nevertheless, to avoid potential conflict between the professional interest of a medical practitioner and the interest of the patient which is of utmost importance, the Administration considers it reasonable to preclude medical practitioners from being appointed as chairman and vice-chairman of the Board.

Function of the Board

25. Hon Mrs Sophie LEUNG has proposed to add a new provision to the Bill stipulating the Board's functions and purview clearly to avoid misunderstanding of what the Board is empowered to do. The Administration has accepted Mrs LEUNG's suggestion.

Transplant of organs previously removed for therapeutic purposes

26. The proposed section 5B(1) (clause 5 of the Bill) provides that a registered medical practitioner may carry out a restricted organ transplant if at the time when the organ concerned was removed from the donor, it was intended to be removed for the therapy of the donor and not for transplanting it into any specific person. The registered medical practitioner concerned is required under the proposed subsection(2) to make a declaration in writing that to the best of his knowledge -

- (a) he is not aware that any payment prohibited by the Ordinance has been made or is intended to be; and
- (b) at the time when the organ concerned was removed from its donor, it was intended to be removed for the therapy of the donor and not for transplanting it into any specific recipient.

27. Hon Audrey EU considers that 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.

28. The Administration has 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 intended for the therapy of the donor. Nevertheless, the Administration maintains its views that it is necessary to require the medical practitioner, who is to transplant organ 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.

29. The Chairman of the Bills Committee has asked the Administration to consider stating in the proposed section 5B(2)(a)(ii) that a medical practitioner would be considered to have satisfied the requirement that to his best knowledge, the organ/tissue he intends to transplant into his patient was previously removed for therapeutic purposes, if he declares that he has read the declaration made by the medical practitioner who removed the organ/tissue for therapeutic purposes.

30. In response, the Administration has proposed amending the provision 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 in connection with the organs therapeutically removed. This includes the documents prepared by the medical practitioner who previously removed the organ for the therapeutic purpose of the patient. In addition, the Administration will also set out clear instructions in the future Administrative Guidelines so that medical practitioners can refer to such documents as a means of verifying the origin of the organ.

Interview of donor and recipient

31. The proposed section 5C(5)(b) provides that the interviewer who interviews the donor under subsection (2)(b) may but need not be the same interviewer who interviews the recipient under the proposed subsection (3)(b).

32. Members have raised questions about the relative merits and demerits of requiring the same person to interview both the donor and the recipient or having two separate interviewers for the purpose. The Administration has pointed out that an interviewer could make a more consistent and accurate assessment if he could interview both the donor and the recipient. As the interviewer is an independent third party not involved in the transplant, it is unlikely that this arrangement will cause bias in the assessment results towards either the donor or recipient. Notwithstanding these merits, at the operational level, there might be situations where the interviewer is not able to conduct interviews for both the donor and recipient. In order to cater for this practical difficulty, the Administration considers it necessary to provide an element of flexibility by amending the existing provision to allow the donor and recipient to be interviewed by either the same or two different interviewers as in the proposed section 5C(5)(b).

DNA testing as a means to establish genetic relationship for organ transplant

33. Members have suggested that DNA testing should be used as a means of establishing genetic relationship for transplant of an organ from a living donor,

in the event that the means of establishing the same as stipulated in section 2 of the Human Organ Transplant Regulation should fail.

34. In response to the suggestion, the Administration has pointed out that there are certain limitations in utilising DNA testing as a means of establishing genetic relationships. DNA sequencing can only give a mathematical theory or probability that two persons are related. Although the degree of certainty for verification of close genetic relationships, such as natural parents and children, is high, it is low for half blood relationships. Therefore, even if DNA tests were to be allowed, they could only be used for establishing relationships specified in section 5(2)(a) (natural parents and children) and possibly (b) (brothers and sisters of the whole or half blood) of the Ordinance, but would have little use for establishing relationships specified in section 5(2)(c) (brothers and sisters of the whole or half blood of either of the natural parents) and (d) (natural children of the brothers and sisters of whole or half blood of either of the natural parents) of the Ordinance.

35. The Administration has also pointed out that it is difficult to estimate the time required for DNA tests as different relationships require different number of tests and techniques. Generally, it takes about a week for establishing relationships between natural parents and children which requires a relatively simple technique. Thus, DNA tests will not be useful for urgent cases.

Restrictions on transplant of imported organs

36. Under the proposed section 7(5)(a), a registered medical practitioner who has transplanted an imported organ into a recipient is required to ensure that the original of the certificate which accompanied the organ when it was imported into Hong Kong is supplied to the Board within "7 days" of the transplant, if only a copy of the certificate has been provided to the Board before the transplant.

37. Members have pointed out that taking into consideration that there may be public holidays in between, seven days is too short a period. The Administration has accepted members' suggestion to amend "7 days" to "7 working days" and will move an amendment to that effect.

Certification of the copy of the "import certificate" of an imported organ

38. The proposed subsection 7(5) of the Bill provides that a registered medical practitioner who has in Hong Kong transplanted an imported organ into a recipient shall ensure that the original of the certificate mentioned in the proposed subsection 7(1)(b) is supplied to the Board within 7 days after the transplant if a copy of that certificate has been supplied to the board under the proposed subsection 7(1)(c).

39. The Administration has proposed to amend the proposed subsection 7(5) to the effect that apart from the original of the certificate, the medical practitioner transplanting the imported organ may also be allowed to submit a copy of the certificate to the Board, provided that the copy is (i) certified to be a true copy of the original by the registered medical practitioner who imported the organ; and (ii) certified by the medical practitioner transplanting the organ that the registered medical practitioner who certified the copy is the person who imported the organ. This will enable medical practitioners to overcome the difficulty where there is only one original certificate accompanying several imported organs as well as provide better guarantee against the use of imported organs for transplant purposes.

Minimum age of donor

40. The proposed section 5D(1)(a) in clause 5 of the Bill provides that a living donor is required to be either at least 18 years of age or at least 16 years of age and married. Some members have asked the Administration to provide justifications for such a provision and explain whether the provision contravenes the Family Status Discrimination Ordinance (Cap. 527).

41. The Administration has pointed out that the provision is not a new requirement but a re-enactment of the existing section 5(4)(b)(i) and (ii) of the Ordinance. It does not contravene Cap. 527 by virtue of an exemption in that Ordinance for "existing statutory provisions". The original Human Organ Transplant Bill proposed the minimum age requirement of the donor to be 18 years old. However, the LegCo ad hoc group formed in 1992 to study the Bill proposed and the Administration agreed to lower the minimum age of living donors to 16 for married persons based mainly on the consideration that persons aged between 16 and 18 could get married with their parents' consent. The proposal was accepted by the Administration.

42. On review of the minimum age of donor, the Administration believes that a person who is 16 and married is not necessarily as mature as a person who is 18. Furthermore, a person who is not yet 18 but wishes to be a donor may circumvent the requirement by entering into a marriage, and it is very difficult to disprove the bona fides of a marriage. It has therefore proposed to delete the proposed section 5D(1)(a)(ii) from the Bill, as suggested by members. The effect of such a deletion would be that all persons must reach the age of 18, regardless of their marital status, to become an organ donor.

Transplant applications involving homosexual couples

43. Hon Cyd HO has asked the Administration to put it beyond doubt in the Ordinance that same sex 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 domestic partnerships registered overseas should

be treated on an equal footing with the marital relationship referred to in the proposed section 5A(1)(a)(ii).

44. The Administration has advised that the means for establishing the fact of a marriage are provided in section 2A of the Human Organ Transplant Regulation. The section provides that the fact of a marriage shall be established by means of any document or documents -

- (a) issued under the Marriage Ordinance (Cap. 181) or the Marriage Reform Ordinance (Cap. 178) which shows or show that the two persons are the parties to (i) a marriage celebrated or contracted in accordance with the provisions of the Marriage Ordinance; (ii) a modern marriage validated by the Marriage Reform Ordinance; or (iii) a customary marriage declared to be valid by the Marriage Reform Ordinance; or
- (b) equivalent to any document or documents issued under the Marriage Ordinance or the Marriage Reform Ordinance which shows or show that the two persons 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.

As section 2A of the Human Organ Transplant Regulation makes no distinction between opposite sex marriages and same sex marriages, it is therefore not necessary to expressly provide for same sex marriages recognised by law or by court outside Hong Kong in the proposed 5A of the Bill. SHWF is prepared, however, to put on record in his speech during the resumption of Second Reading debate of the Bill the proper interpretation of section 2A of the Human Organ Transplant Regulation in respect of same sex marriages celebrated outside Hong Kong. The Administration has also undertaken to liaise with the doctors' associations and HA on ways to ensure that medical practitioners would be well informed of the proper interpretation of the section.

45. Ms HO has also proposed to expand the coverage of the proposed section 5A(1)(a)(ii) beyond married persons to persons in "partnership" recognised by law or by a court outside Hong Kong. The Administration has indicated that persons in domestic partnership would not be treated in the same manner as married persons for the purpose of the proposed section 5A(1)(a)(ii). Under section 2A of the Human Organ Transplant Regulation, the fact of a marriage has to be established by valid marriage document(s) issued by the relevant authorities. Other types of documents, such as those for registered domestic partnerships, would not be accepted for the purpose of the proposed section 5A(1)(a)(ii). A proposed organ transplant between two persons in a registered domestic partnership would therefore require the prior written approval of the Board.

46. As the Administration does not agree to her request to put it beyond doubt that same sex 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 should be treated in the same manner as marital relationship referred to in the proposed section 5A(1)(a)(ii), Hon Cyd HO has indicated her intent to move CSAs to that effect.

Committee Stage amendments

47. The proposed CSAs to be moved by SHWF and Hon Cyd HO are in **Appendices II and III**.

Issue to be mentioned by the Administration during resumption of Second Reading debate

48. The Administration has agreed that SHWF would mention in his speech during the resumption of Second Reading debate of the Bill that same sex marriages recognised by law or by a court outside Hong Kong are treated in the same manner as opposite sex marriages for the purposes of the proposed section 5A (paragraph 44 above refers).

Recommendation

49. Subject to the CSAs to be moved by the Administration, the Bills Committee supports the Bill and the resumption of Second Reading debate of the Bill at the Council meeting on 7 July 2004.

Advice sought

50. Members are invited to note the recommendation of the Bills Committee in paragraph 49 above.

Bills Committee on Human Organ Transplant (Amendment) Bill 2001

Membership List

| | |
|----------------------|---|
| Chairman | Dr Hon LO Wing-lok, JP |
| Members | Hon Cyd HO Sau-lan |
| | Hon CHAN Yuen-han, JP |
| | Hon Mrs Sophie LEUNG LAU Yau-fun, SBS, JP |
| | Dr Hon LAW Chi-kwong, JP |
| | Dr Hon TANG Siu-tong, JP |
| | Hon Michael MAK Kwok-fung |
| | Hon Audrey EU Yuet-mee, SC, JP |
| | (Total : 8 Members) |
| Clerk | Miss Mary SO |
| Legal Adviser | Mr LEE Yu-sung |
| Date | 14 December 2001 |

HUMAN ORGAN TRANSPLANT (AMENDMENT) BILL 2001

COMMITTEE STAGE

Amendments to be moved by the Secretary for Health,
Welfare and Food

| <u>Clause</u> | <u>Amendment Proposed</u> |
|---------------|--|
| 1(2) | By deleting "and Welfare" and substituting ", Welfare and Food". |
| New | By adding - "2A. Part heading added The following is added immediately before section 1 - "PART 1 PRELIMINARY".". |
| 3(c) | (a) In the proposed definition of "restricted organ transplant", by deleting the full stop and substituting a semicolon. (b) By adding - "Appeal Board" (上訴委員會) means the Appeal Board established by section 7G; "Director" (署長) means the Director of |

Health;

"Secretary" (局長) means the Secretary for Health, Welfare and Food."

New By adding -

"3A. Part heading added

The following is added immediately before section 3 -

"PART 2

HUMAN ORGAN TRANSPLANT BOARD".

- 4 (a) By deleting the heading and substituting
"Establishment and functions of the board".
- (b) By deleting the proposed section 3(2) to (12) and substituting -

"(2) The board has the following functions -

- (a) to give approval to the carrying out of a restricted organ removal or a restricted organ transplant in accordance with the provisions in this Ordinance;
- (b) to receive any information and documents that by this

Ordinance are required to be submitted or supplied to the board;

- (c) to require any information or documents that the board may require to be provided under this Ordinance;
- (d) to keep a record of information supplied to the board in pursuance of the regulations made under section 6;
- (e) to receive and require information and documents in respect of imported organs in accordance with section 7;
- (f) to make regulation to provide for any matter that by this Ordinance is required or permitted to be prescribed by the board;
- (g) to perform any other functions that the board is required or permitted

to perform under this
Ordinance.”.

New By adding -

“4A. Sections and Part heading added

The following are added -

“3A. Constitution of the board

(1) The Secretary shall appoint 9
substantive members to the board as
follows -

- (a) a chairman, who shall not
be a registered medical
practitioner;
- (b) a vice-chairman, who shall
not be a registered
medical practitioner;
- (c) 4 members from the medical
sector, all of whom shall
be registered medical
practitioners;
- (d) 1 member from the social
work sector, who shall be
a registered social
worker;
- (e) 1 member from the legal
sector, who shall be a
legally qualified person;

and

- (f) 1 member from the non-medical sector, who shall not be a registered medical practitioner.

(2) The Secretary shall also appoint a panel consisting of -

- (a) 8 members from the medical sector, all of whom shall be registered medical practitioners;
- (b) 2 members from the social work sector, both of whom shall be registered social workers;
- (c) 2 members from the legal sector, both of whom shall be legally qualified persons; and
- (d) 2 members from the non-medical sector, neither of whom shall be a registered medical practitioner.

(3) The Secretary shall publish in the Gazette notice of every appointment made under subsection (1) or (2).

(4) The substantive members of the

board and the panel members shall be appointed on such terms and for such period as the Secretary shall specify on appointing them.

(5) If a substantive member from a particular sector is unable to perform his functions during any period, the board may, according to its procedure, appoint a panel member from that sector to act as a substitute for that substantive member in the board during that period, except that the panel member shall not -

- (a) be regarded as a substantive member mentioned in subsections (6), (7) and (8); or
- (b) participate in the making of any regulation by the board under this Ordinance.

(6) If the chairman of the board is unable to perform his functions during any period, the following person shall act as chairman during that period -

- (a) the vice-chairman of the board; or

(b) if the vice-chairman is unable to act as chairman during that period, a person who complies with subsection (7) and who shall be -

(i) appointed by the chairman or, if the chairman has failed to make the appointment, by the vice-chairman; or

(ii) elected by the following persons among themselves if both the chairman and the vice-chairman have failed to make the appointment -

(A) all remaining substantive members in

the board;

and

- (B) any panel member who is for the time being acting as a substitute in the board under subsection (5).

(7) For the purpose of subsection (6)(b), a person who is to act as chairman of the board -

- (a) shall not be a registered medical practitioner; and
- (b) shall be a substantive member of the board unless all remaining substantive members in the board are registered medical practitioners, in which case that person may be a panel member who is for the time being acting as a substitute in the board

under subsection (5).

(8) If a substantive member from a particular sector is acting as chairman of the board during any period, the board may, according to its procedure, appoint a panel member from that sector to act as a substitute for that substantive member in the board during that period.

(9) The Secretary shall appoint to the board a secretary and a legal adviser on such terms and for such period as the Secretary shall specify on appointing them.

3B. Procedure of the board

The board may determine its own procedure, whether to be followed in general situations or in a particular case, but the procedure shall not be inconsistent with any provision in this Ordinance or in any regulation made under this Ordinance.

3C. Application of Part VII of the Interpretation and General Clauses Ordinance to the board and panel

Part VII of the Interpretation and

General Clauses Ordinance (Cap. 1) applies to the board and the panel, and to appointments to the board and the panel, except in so far as that Part is inconsistent with any provision in this Ordinance or in any regulation made under this Ordinance.

PART 3

PROHIBITION OF COMMERCIAL
DEALINGS IN HUMAN
ORGANS".".

- 5 (a) By adding immediately before the proposed section 5 -

"PART 4

RESTRICTIONS ON ORGAN TRANSPLANTS
BETWEEN LIVING PERSONS".

- (b) In the proposed section 5, in the heading, by deleting "**Restriction on**" and substituting "**Offence in respect of**".
- (c) By deleting the proposed section 5B(1) and (2) and substituting -

"(1) A registered medical practitioner may carry out a restricted organ transplant if he is satisfied that at the time the organ concerned was

removed from its donor, it was removed for the therapy of the donor and not for transplant into any specific recipient.

(2) Subject to subsection (2A), a registered medical practitioner who carries out a restricted organ transplant under subsection (1) shall -

(a) make a declaration in writing to the effect that -

(i) he had checked the related documents as defined in subsection (2B) before he carried out that transplant;

(ii) he is satisfied that at the time the organ concerned was removed from its donor, it was removed for the therapy of the donor and not

for transplant
into any
specific
recipient; and

(iii) to the best of
his knowledge
and belief, no
payment
prohibited by
this Ordinance
has been made or
is intended to
be made;

(b) submit that declaration to
the board within 30 days
after the transplant, or
within such longer period
as the board may on
application allow; and

(c) provide the board with any
further information that
it may reasonably require.

(2A) A registered medical
practitioner who carries out a restricted
organ transplant under subsection (1) is
not required to comply with subsection

(2) if the organ concerned was removed from its donor before the commencement of this section.

(2B) In this subsection (2)(a)(i), "related documents" (相關文件), in relation to a restricted organ transplant, means -

(a) a certificate issued by the registered medical practitioner who removes the organ concerned from its donor, certifying that the organ is removed for the therapy of the donor and not for transplant into any specific recipient; and

(b) a declaration made by that practitioner in writing to the effect that to the best of his knowledge and belief, no payment prohibited by this Ordinance has been made or is intended to be made."

(d) By deleting the proposed section 5D(1)(a) and

substituting -

"(a) the donor concerned has reached the age of 18 years;".

New

By adding -

"5A. Part heading added

The following is added immediately before section 6 -

"PART 5

INFORMATION ON TRANSPLANTS USING
ORGANS FROM DEAD OR LIVING
PERSONS".

6

(a) By adding immediately before the proposed section 7 -

"PART 6

RESTRICTIONS ON TRANSPLANTS OF
IMPORTED ORGANS".

(b) By deleting the proposed section 7(5), (6) and (7) and substituting -

"(5) In subsection (2), "specified place" (指明地方), in relation to an imported organ, means the place outside Hong Kong where the organ was removed from its donor.

(6) A registered medical practitioner who, in Hong Kong,

transplants an imported organ into a recipient ("the transplanting practitioner") shall -

(a) ensure that the original or a certified true copy of the certificate mentioned in subsection (1)(b) is supplied to the board within 7 working days after the transplant if a copy of that certificate has been supplied to the board under subsection (1)(c); and

(b) provide the board with any further information that it may reasonably require.

(7) For the purpose of subsection (6)(a), a certified true copy of a certificate accompanying an imported organ must be a copy certified by the registered medical practitioner who imported the organ ("the importing practitioner") to be a true copy of that certificate.

(8) If the transplanting

practitioner of an imported organ is not its importing practitioner and a certified true copy is supplied under subsection (6)(a), the transplanting practitioner shall -

(a) make a declaration in writing to the effect that to the best of his knowledge and belief, the certified true copy was certified by the importing practitioner of that organ; and

(b) submit that declaration to the board within 7 working days after the transplant.

(9) Despite section 13 of the Oaths and Declarations Ordinance (Cap. 11), the declaration mentioned in subsection (8) of this section is not required to be made and signed in the manner provided by section 14 of that Ordinance.

(10) A person who, without reasonable excuse, contravenes subsection (1), (6) or (8) commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months.

(11) A registered medical practitioner who, in purported compliance with subsection (8), makes a declaration that he knows to be false or misleading in a material respect, or recklessly makes a declaration that is false or misleading in a material respect, commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months."

New

By adding -

"6A. Parts and part heading added

The following are added -

"PART 7

EXEMPTION OF REGULATED PRODUCTS

7A. Exemption of regulated products from this Ordinance

(1) For the purposes of this Part -

(a) "regulated product" (受規管產品)

means a product containing any structured arrangement of tissues that -

(i) falls within paragraph (a)(iii) of the definition of

"organ" in section 2;

and

(ii) has been subjected to processing;

(b) "processing" (加工處理), in relation to any structured arrangement of tissues, means any activity performed on the tissues which alters the biological characteristics, function or integrity of the tissues, but does not include recovering or preparing the tissues, preserving the tissues for storage, or removing the tissues from storage.

(2) This Ordinance shall not apply to a regulated product to the extent that it is exempted by the Director under this Part.

(3) The Director may, on application, exempt a regulated product from the application of this Ordinance if he is satisfied -

(a) that using the product for transplant purposes is safe and has no adverse impact on public

health;

- (b) either that the donor of the tissues concerned has given his consent to the removal of the tissues for the purpose of producing the product without coercion or the offer of inducement, or that the tissues are removed for the therapy of the donor;
- (c) that no payment has been made, or is intended to be made to that donor for his supplying the tissues from his body;
- (d) that all applicable laws of the place where the tissues were obtained or processed have been complied with in obtaining and processing the tissues; and
- (e) that the circumstances and manner in which the tissues are obtained and processed are not affected by any matter that the Director may consider to be objectionable.

7B. How to apply for an exemption

(1) A person may apply for an exemption in respect of a regulated product under this Part by submitting an application to the Director in a form specified by the Director.

(2) A form specified for the purpose of subsection (1) may require that -

(a) it be completed in a specified way;

(b) specified information be included in or attached to it;
or

(c) it be submitted in a specified manner.

(3) If any requirement under subsection (2) is not complied with in relation to a form, the form is not properly completed.

(4) The Director may, by written notice, require an applicant to provide, within a reasonable period specified in the notice, additional information and documents as are reasonably necessary to enable the Director to determine the application.

(5) If such a requirement is not complied with, the Director may reject the application.

(6) When the Director is satisfied that the form of an application has been properly

completed and all the information and documents he requires for determining the application have been submitted, he shall issue a written acknowledgement to the applicant confirming the receipt of the application.

(7) Any person who, in purported compliance with this section, supplies information that he knows to be false or misleading in a material respect, or recklessly supplies information that is false or misleading in a material respect, commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months.

7C. Determination of applications for exemption

(1) After considering an application for exemption under this Part, the Director may decide to approve the application and grant the exemption, or to reject the application.

(2) The Director shall give the applicant written notice of the decision by registered post.

(3) In approving an application for exemption, the Director may -

- (a) limit the validity of the exemption to a specified period; or
- (b) grant the exemption only to the applicant, a specified person or a specified class of persons.

(4) The Director may grant the exemption subject to such conditions as the Director considers appropriate, including a condition limiting the exemption only for a particular occasion or for the purpose of a specified type of transplant.

(5) On the breach of a condition imposed under subsection (4), the Director may -

- (a) revoke the exemption concerned so that it shall have no effect either on the breach or from such date as the Director may determine;
- (b) vary that exemption in such manner as the Director may determine; or
- (c) suspend that exemption so that it shall have no effect for such period or until compliance with such other conditions as

the Director may determine.

(6) A determination under subsection (5)(a), (b) or (c) may be made at the time the condition concerned is imposed under subsection (4) or breached.

(7) If an exemption granted by the Director is subject to any condition imposed under subsection (4), he shall specify that condition and the applicable consequence of its breach under subsection (5) in the written notice given under subsection (2).

(8) The Director may specify different consequences for the breach of different conditions under subsection (5). The Director may specify that a consequence shall apply generally or to the person who breaches the condition.

(9) If the Director rejects an application for exemption, he shall include in the written notice given under subsection (2) a statement setting out the reasons for the decision.

7D. Director's power in relation to exemptions granted

(1) At any time after an exemption has been granted under this Part, the Director

may, on such grounds as he considers appropriate -

- (a) revoke the exemption so that it shall have no effect from such date as the Director may determine;
- (b) vary the exemption in such manner as the Director may determine; or
- (c) suspend the exemption so that it shall have no effect for such period or until compliance with such conditions as the Director may determine.

(2) The Director shall give the person to whom the exemption is granted a written notice of any decision under subsection (1) by registered post. The notice shall include a statement setting out the reasons for the decision.

7E. Register of exemptions

(1) The Director shall maintain a register in a form determined by him containing details of the exemptions granted, revoked, varied and suspended under this Part.

(2) The Director shall make the register

available for inspection by the public, free of charge, during ordinary business hours at his office.

PART 8

APPEAL BOARD

7F. Right of appeal to Appeal Board against Director's decision on application for exemption

A person aggrieved by a decision of the Director under section 7C or 7D may appeal to the Appeal Board by giving a notice of appeal in such manner and with in such period as the Secretary may prescribe by regulation.

7G. Constitution of Appeal Board

(1) There is established an Appeal Board for the purpose of hearing and determining an appeal under section 7F.

(2) The Appeal Board is to be constituted according to this section.

(3) Where a notice of appeal is given under section 7F, the Secretary shall appoint 3 members from the Appeal Board Panel constituted according to section 7I, one from each group of members described in section 7I(2)(a), (b) and (c), to serve as members on

the Appeal Board for the purpose of hearing and determining the appeal to which the notice relates.

(4) The Secretary shall appoint one of those 3 members to be the Chairman of the Appeal Board in the hearing of that appeal.

(5) The Secretary shall ensure that no person having a financial or other personal interest in the matter involved in an appeal is to serve as a member on the Appeal Board for hearing and determining that appeal.

7H. Determination of appeals

(1) In determining an appeal, the Appeal Board may either -

- (a) dismiss the appeal; or
- (b) remit to the Director the matter under appeal for his reconsideration.

(2) The Director shall reconsider the matter remitted under subsection (1)(b) and make a decision having regard to any reasons given by the Appeal Board for the determination.

(3) A decision under subsection (2) is regarded as a new decision under section 7C or

7D (as the case may be) and is subject to appeal to the Appeal Board.

7I. Constitution of Appeal Board Panel

(1) Subject to subsections (2) and (3), the Secretary shall appoint an Appeal Board Panel ("the Panel") consisting of such persons as he considers suitable to serve as members of the Appeal Board. None of those persons shall be a public officer.

(2) The Panel shall have the following members -

- (a) a group of members who are registered medical practitioners;
- (b) a group of members who are legally qualified persons; and
- (c) a group of members who are neither registered medical practitioners nor legally qualified persons.

(3) For the avoidance of doubt, a registered medical practitioner who is an employee of the Hospital Authority established by section 3 of the Hospital Authority Ordinance (Cap. 113) may be appointed as a member of the Panel.

(4) An appointment under subsection (1) shall be for a period which shall not exceed 3 years and which shall be determined by the Secretary at the time of the appointment.

(5) A member of the Panel may resign his office by giving notice in writing to the Secretary.

(6) A person who ceases to be a member of the Panel shall be eligible for reappointment to the Panel.

(7) The Secretary shall publish in the Gazette notice of every appointment under subsection (1).

(8) The Secretary shall also appoint a secretary to the Panel on such terms and for such period as the Secretary shall specify on appointing him.

7J. Power of Secretary to make regulations

The Secretary may by regulation provide for -

- (a) the procedures to be followed in making an appeal under this Part, including matters and information to be set out in or to accompany the notice of

- appeal;
- (b) the hearing and determination of such appeal;
- (c) the practice and procedure of the Appeal Board;
- (d) any matter that by this Part is required or permitted to be prescribed by the Secretary; and
- (e) any matter ancillary or incidental to those specified in paragraph (a), (b), (c) or (d).

PART 9

MISCELLANEOUS".".

- 7 (a) In the proposed section 10, by renumbering it as section 10(1).
 - (b) In subsection (1), by deleting "for Health and Welfare".
 - (c) By adding -
 - "(2) An amendment under subsection (1) is subject to the approval of the Legislative Council."
- 10(2) By deleting "and Welfare" and substituting ",

Welfare and Food".

Appendix III

HUMAN ORGAN TRANSPLANT (AMENDMENT) BILL 2001

COMMITTEE STAGE

Amendments to be moved by the Honourable Cyd HO Sau-lan

Clause

Amendment Proposed

5 In the proposed section 5A, by adding –

“(8) For the purpose of subsection (1)(a)(ii), marriage includes one in which the parties are of the same sex and which was 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.”.