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**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. Hon Cyd HO will move CSAs as mentioned in paragraph 46 above. The CSAs to be moved by the Administration include the amendments mentioned in paragraphs 12, 14, 15, 18, 25, 28, 30, 37, 39 and 42 above, as well as a number of technical and textual amendments.

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).

Consultation with the House Committee

49. The Bills Committee consulted the House Committee on 25 June 2004 and obtained its support for the Second Reading debate of the Bill to be resumed on 7 July 2004.

Appendix I

Bills Committee on Human Organ Transplant (Amendment) Bill 2001

Membership List

| | |
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| 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 | 31 October 2003 |