Urgent By Fax

Paper No. CB(2)2622/03-04(02)

Our ref: HWF CR/1/3231/98(01) Pt.10 ***Tel:*** (852) 2973 8107
Your ref: ***Fax:*** (852) 2840 0467

1 June 2004

Ms Mary So
Clerk to Bills Committee
Legislative Council Secretariat
3/F, Citibank Tower
3 Garden Road
Central, Hong Kong
(By Fax: 2509 9055)

Dear Ms So,

Resumption of Meetings of the Bills Committee on the Human Organ Transplant (Amendment) Bill 2001

We have written to Dr Hon LO Wing-lok, Chairman of the Bills Committee, today expressing our wish to resume meetings of the Bills Committee on the Human Organ Transplant (Amendment) Bill 2001. A copy of that letter has been copied to you.

In October 2002, the Administration proposed, and the Bills Committee agreed, to put on hold the scrutiny of the above Bill, pending further research and deliberation by the Administration of the most appropriate mechanisms for granting exemptions to individual organ products from the prohibition against commercial dealings and for hearing appeals from people/organisations aggrieved by the decisions made regarding their application for exemption. We have now formulated proposals on this issue. We have also a couple of straightforward amendments to the Bill to propose. Enclosed please find an information paper on the outstanding issues and I should be grateful if you would forward it to Members of the Bills Committee for their information. We hope that this information paper would pave the

way for the expeditious resolution of the outstanding issues, should our request for resuming the scrutiny of the Bill is approved by the House Committee.

Yours sincerely,

(Mrs Ingrid Yeung)
for Secretary for Health, Welfare and Food

Bills Committee on
Human Organ Transplant (Amendment) Bill 2001

A. Administration's Response to Issues Raised by Members

(a) *To consider creating an additional Schedule to the Human Organ Transplant Ordinance (the 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. (Raised by Members at the Bills Committee on 25 January 2002.)*

In the response issued to Members dated 21 February 2002, the Administration agreed with Members that there were individual products for transplantation which might fall within the definition of "organ" and yet their commercial dealings should not be prohibited. Nevertheless, we had reservations on Members' suggestion that we should set out these materials in a Schedule. Instead, we were of the view that these products should be considered and examined individually before their trading was permitted with a view to ensuring that no illegal transactions were involved. Thus, it would not be appropriate to set them out in a Schedule where items under which are usually described in generic terms only. As an alternative, we undertook to work out a system for granting exemptions administratively to individual products for transplantation that fall within the definition of "organ" and yet their commercial dealings should not be prohibited.

Director of Health to act as exemption authority

The Administration would like to propose that the Director of Health (the Director) should be empowered to grant exemption, upon application, for an organ, or type of organ of a certain description, to be exempted from the prohibition against commercial dealings. The Director 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.

It is envisaged that an application for exemption can be submitted by the manufacturer of an organ product, a potential importer, a potential local agent of the manufacturer, a registered medical practitioner or an institution such as private hospitals, universities or the Hospital Authority. Therefore, we not intend to restrict who the applicant should be.

The Administration also proposes that the Director shall have the power to require the applicant to provide additional information and documents as are reasonably necessary to enable the Director to determine the application. As and when the Director is satisfied that all the necessary information and documents have been submitted, he shall issue a written acknowledgement to the applicant confirming the receipt of all information and documents he requires for determining the application.

The Director shall within a reasonable period of time after the issue of the written acknowledgement make a decision in writing and send a written notice of his decision to the applicant by registered mail. If an application is refused, the reasons for the refusal should be explained in the written decision of the Director.

Exemption criteria

In assessing an application, the Director shall take into consideration the following factors, which will be stipulated in the Ordinance –

- 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;
- Whether the organ product is safe for transplant purposes;
- Whether the use of the organ product for transplant purposes has any adverse impact on public health;
- Whether the manner in which the organ is obtained is consistent with the principles enshrined in the Human Organ Transplant Ordinance, e.g. prior consent of the donor has been given voluntarily, no payment of any form is involved in the supply of the organ; and
- Any other factors that the Director deems relevant.

Director may attach conditions to the exemptions

In the case an application is granted, the Director shall have the flexibility to limit the validity of the exemption for a single occasion (i.e. the applicant may buy or sell the organ product for the purpose of transplanting in a specific patient), or for a specified period of time, or for an unlimited time period. The Director shall also have the flexibility of applying the exemption to the applicant only, or to a group of persons (e.g. surgeons in the Faulty of Medicine of a specified university), or to all persons (i.e. once granted, the exemption can be enjoyed by everyone wishing to buy or sell the organ product under application for the purpose of transplant). In addition, the Director may attach other conditions to his granting of an application. In short, we

propose to give the Director the flexibility to limit the validity of the exemption as he sees fit.

Effects of an exemption

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 proposes that the transplant of organ products exempted by the Director to a person in Hong Kong should also be not subjected to the restrictions/requirements in sections 5 to 7 of the Ordinance, i.e. the transplant of these exempted organs (the donor(s) and recipient(s) of which are most certainly non-genetically related) should not be required to have the approval of the Human Organ Transplant Board.

Public access to Director's decisions

To facilitate public access to the decisions made by the Director, the Administration will stipulate in the Ordinance that the Director shall keep a register of his decisions at his office, where it will be made available to the public for information. In practice, the Director will also publish a copy of the register at the website of the Department of Health.

(b) *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, prepare proposed committee stage amendments accordingly. (Raised by Members at the Bills Committee meeting on 22 March 2002)*

The Administration has considered whether the Administrative Appeals Board (AAB) should include in its purview appeals against the Director's decision pertaining to the granting of exemptions to individual products for transplantation that fall within the definition of "organ" from prohibition of commercial dealings. We have concluded that the AAB would not be the appropriate body to handle such appeals. The AAB deals mainly with appeals of a relatively general and minor nature. However, given the technical nature of the decisions to be taken by the Director in exempting organ products and the need for the appeal body to possess the relevant medical knowledge, the appeal body needs to be able to understand the medical and other technical information submitted by the parties to the appeal, and AAB would not be a suitable appeal channel.

We have also 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.

<u>Establishment of an Appeal Panel</u>

In view of the above, the Administration proposes that provisions be made under the Human Organ Transplant 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 the Secretary for Health, Welfare and Food and the names of members published in the Gazette. It should comprise members of the following categories –

- Registered medical practitioners – to ensure that arguments forwarded by the parties to the appeal on medical grounds or containing medical knowledge are well understood and considered;
- Legally qualified persons – to ensure that the decisions of the Appeal Board are in line with both the spirit and letters of the Ordinance; and
- Other persons (e.g. academics, social workers and other

professionals).

The purpose of establishing an Appeal Panel is to ensure that there will be a sufficient pool of members to handle the appeals at any time. The appointment to the Appeal Panel shall be for a period not exceeding three years, which shall be determined by the Secretary for Health, Welfare and Food at the time of appointment. A member of the Appeal Panel may resign his office by giving notice in writing to the Secretary for Health, Welfare and Food. A person who ceases to be a member of the Appeal Panel shall be eligible for reappointment. The Secretary for Health, Welfare and Food shall also appoint a secretary to the Appeal Panel to assist the Panel in carrying out its duties.

Appointment of an Appeal Board upon receipt of notice of appeal

Applicants aggrieved by the decision of the Director, other than a decision made by the Director on the grounds of safety of the organ and public health, may appeal against the decision by giving notice to the secretary of the Appeal Panel within 30 working days from his receipt of the Director's decision. Where such a notice is given, the Secretary for Health, Welfare and Food shall appoint, from the Appeal Panel, an Appeal Board consisting of three members, one from each of the three categories mentioned above. The Secretary for Health, Welfare and Food shall also appoint one of the three appointed members as Chairman of the Appeal Board. In appointing the members of the appeal board, the Secretary for Health, Welfare and Food will ensure that no person having a financial or personal interest in an appeal would sit as a member of the Appeal Board.

The Appeal Board may uphold the Director's decision or require the Director to reconsider the application.

Rules of appeal

The appellant shall be entitled to request for an oral hearing, which will be held in public, unless the appeal board, after consulting the parties to the appeal, is satisfied that it is desirable to hold part or the whole of the hearing in private.

The Secretary for Health, Welfare and Food may determine the rules of appeal by regulation. We will submit our proposals in this regard to the Legislative Council in the next legislative year and the relevant provisions in the Amendment Bill (e.g. the new definition of "organ", the provisions pertaining to the exemption and appeal mechanisms, etc) will commence at the same time as the new regulation on the rules of appeal

does.

(c) *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. (Raised by Members at the Bills Committee meeting on 22 February 2002)*

In the response issued to Members on 20 March 2002, the Administration informed Members that in the original Human Organ Transplant Bill prepared by the Administration in 1992, the proposed minimum age requirement of an organ donor was 18 years old. It was in fact a proposal of the Legislative Council ad hoc group, which was set up to study the original Bill in 1999, to lower the minimum age requirement so that persons who have reached the age of 16 and married may also become a donor. The proposal was agreed by the Administration, which became section 5(4)(b)(i) and (ii) in the Human Organ Transplant Ordinance. The Administration also explained that such a provision was not a contravention against the Family Status Discrimination Ordinance (Cap 527) by virtue of an exemption in that Ordinance for "existing statutory provision".

The Administration has re-considered its position on the issue of minimum age. While the proposed section 5D(1)(a)(ii) does not contravene the Family Status Discrimination Ordinance, we would like to take this opportunity to amend the minimum age requirement in the Human Organ Ordinance. The purpose for setting a minimum age limit for organ donors is to ensure that donors are capable of understanding all the implications of donating an organ and of making the decision to donate an organ independently. On review, we believe 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. We, therefore, propose 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.

B. New Proposed Amendment by the Administration

(a) Certification of the copy of the "import certificate" of an imported organ

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 subsection 7(1)(b) is supplied to the Human Organ Transplant Board within 7 days after the transplant if a copy of that certificate has been supplied to the board under subsection 7(1)(c). We have reviewed this subsection and concluded that the proposed subsection may present practical difficulties in the case where a single certificate is covering more than one organ which are to be transplanted into multiple recipients. To resolve this problem, we propose 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 Human Organ Transplant 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.

Health, Welfare and Food Bureau
June 2004