The Administration's Responses to Submissions on Human Organ Transplant (Amendment) Bill 2001

A. Definitions of "organ" and "payment"

1. *The term "human bodily parts" is used in the definition of "organ". However, liver and kidney are "organs", a piece of femoral head is "bodily part", bone marrow, stem cell etc. are "tissues". All these terms with common examples should be discussed. [Wai Poon]*

   "Human bodily part" refers to any part of a human body. In the Bill, "organs" mean only those human bodily parts that fall within the qualifying descriptions set out in the proposed new definition. We do not consider it necessary to further classify different human bodily parts into specific categories.

2. *Which party (the donor or the recipient) is responsible for the 'administrative cost' incidental to the removal, transportation or preservation of the organ to be supplied? [Wai Poon]*

   For living donors, the practice in the Hospital Authority is that the donor will pay for his/her own hospitalization. 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. For corneal transplantations, the Eye Bank charges private practitioners for supply of corneal tissues. The existing practice in public hospitals for harvesting organs/tissues outside Hong Kong is that the Hospital Authority will only absorb the harvesting cost for special programmes for which there are no specific designated recipients at the time of donation (e.g. procurement of corneal tissues from the Lyons Eye Bank, Florida).

B. Prohibition of commercial dealings in human organs

3. Human tendon and bone are commercially available as "allografts". As tendon and bone are likely to fall within the definition of "organ", the trading of which under the existing Ordinance would violate the prohibition of commercial dealings in human organs. They should be exempted from such prohibition. [S.H. Yeung]

The Administration will work out a system to administratively grant exemptions to individual products for transplantation that fall within the definition of "organ" and yet their commercial dealings should not be prohibited. Manufacturers could apply for exemptions but the granting of which will be subject to factors including their composition, requisition of raw materials, manufacturing processes, etc.

C. Human Organ Transplant Board membership

4. At least one member from the medical sector should come from the field of transplantation. [Albert Chui]

Although the Bill does not specifies that at least one member from the medical sector should come from the field of transplantation, it has all along been a preferred criterion for identifying potential Board members. In fact, at present, medical practitioners with relevant experience in organ transplant are appointed to serve on the Board.

D. Transplants involving organs previously removed for donors' therapy

*5. Flexibility should be given to transplants which involve organs removed for the donor's therapy and that they, at the time of removal, do have **specific** recipients who are willing to accept such organs and whose medical conditions are considered by the transplant teams as appropriate to receive the organs. An example of it is "domino liver transplantation". [C.H. Leong, S.T. Fan]*

In order to avoid this section of the Bill from being abused to trade human organs, we remain the view that the proposed Section 5B in the Bill should only be applicable to cases where the organ involved in the transplant was previously removed for therapeutic purpose of the donor, and at the time of removal, it was not for transplanting it into any specific recipient.

In transplant cases such as "domino liver transplantation" which involves organs removed for donors' therapy and the organs will be transplanted into specific recipients, it may be treated as organ transplant between living persons who are neither genetically related nor spouse, and applications can be made to the Board for approval of such transplants.

6. *Since some transplant operations such as bone graft are done quite frequently, requiring medical practitioners who are to transplant organs previously removed for donor's therapy to make declarations is unnecessary and could be too cumbersome, and it also imposes additional paper work to both medical practitioners and the Human Organ Transplant Board. [C.H. Leong, S.H. Yeung]*

We are prepared to request the medical practitioner, who has removed the organ from his patient and it was subsequently stored in the organ/tissue bank, to declare that the organ/tissue, at the time when it was removed from the patient, was intended for the patient's therapy and was not for transplanting it into any specific recipient.

Notwithstanding the above, we hold the view that it is still necessary for the medical practitioner, who is to transplant into a recipient an organ previously removed for therapeutic purpose of the donor, to check all the relevant documents in connection with the organ therapeutically removed. This is to serve as a safeguard against the possibility of commercial dealings and a means of verifying the origin of the organ.

7. *The health status of the donor tissue should be documented. Some form of stringent archive or audit system to safeguard the risk of infection or cancer cells transmission through transplant of organs should be required. [Albert Chui, Wai Poon]*

   We agree that the there should be some form of archive or audit system to safeguard the risk of infection or cancer cells from transmission through transplant of organs. In fact, such systems are in place in the tissue banks of the Hospital Authority. Also, we regard that this is also a responsibility of the medical practitioner who should be satisfied that the organ is in a state suitable to be transplanted into a recipient before he/she carries out the transplant operation.

8. *Is there a definition for "therapeutic purposes"? It seems that all organ transplants are for therapeutic purposes. [C.C. Chi]*

   There is no need to define "therapeutic purposes" because it is not the term we use to express the statutory requirement in the proposed new section 5B. That section states clearly that a registered medical practitioner may carry out a restricted organ transplant if at the time when the organ concerned was removed from its donor, it was intended to be removed "for the therapy of the donor", not for the therapy of any specific recipient.

9. *The use of bone removed for donors' therapy is both environmental friendly and cost-effective. Medical practitioners should be encouraged to use such methods. It is suggested that bone removed for donors' therapy are exempted from the administrative requirements. [S.H. Yeung]*

   The Administration is of the view that the requirements the medical practitioners involved in the removal or transplant of such bones have to fulfill are necessary and should not be exempted. Notwithstanding the low commercial value of the bones, the requirements are still necessary to serve as a means to safeguard against the possibility of commercial dealings and to verify the legitimacy of the origin of the organ.

E. Interview of donor and recipient

10. Having the same medical practitioner or interviewer to interview both the donor and recipient would give a more consistent impression and information to the persons involved. [Stephen K.S. Foo]

An interviewer could have more consistent and accurate assessement if one could interview both the donor and recipient. Also, it is unlikely that this arrangement will cause bias in the assessment results towards either the donor or recipient, for the interviewer is an independent third party not involved in the transplant. 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, we consider it necessary to provide an element of flexibility by amending the provision to allow the donor and recipient to be interviewed by either the same or two different interviewers as proposed in Section 5C(5)(b) of the Bill.

F. Section 5 of the Ordinance

11. What are the types of transplants not subject to the requirements set out in Section 5 of the Ordinance? [C.C. Chi]

Human bodily parts that do not fall within the description in paragraph (a)(i) of the proposed new definition of "organ" as well as those that are listed in the proposed Schedule in the Bill will not be subject to the requirements set out in the proposed sections 5 to 7. At present, blood (including cord blood) and bone marrow have been included in the proposed Schedule. Although blood transfusion and bone marrow transplants will not be restricted for the purposes of the proposed sections 5 to 7, commercial dealings in them will still be prohibited.

*12. Minors should be allowed to be donors in the cases of **bone marrow**, **cord blood** and **peripheral stem harvest**. [Betty Young]*

Bone marrow and blood (including cord blood) have been included in the proposed Schedule in the Bill. Peripheral stem cell harvest refers to the process used to extract stem cells from the bloodstream. Stem cell, being a component of blood, is covered under the meaning of blood. As any human bodily part specified in the proposed Schedule is expressly excluded from the proposed new definition of "organ" in relation to the requirements set out in the proposed sections 5 to 7 in the Bill, the minimum age requirement stipulated in the proposed section 5D will not apply to donors of bone marrow, cord blood or donors undergoing peripheral stem cell harvest.

G. Legal responsibility of medical practitioners involved in transplant operations

13. The legal liability placed on medical practitioners involved in organ transplants is too heavy. Amendments should be made to protect medical practitioners insofar as they have acted to their best knowledge and in good faith. [C.H. Leong, Betty Young]

Although medical practitioners are required to submit documents, keep medical reports and make declarations and certifications in relation to organ transplant operations, they will not be liable unless they intentionally or recklessly provide false or misleading information. Neither will they be liable for non-compliance if they have a reasonable excuse. For example, if a donor falsifies a marriage certificate and supplies it to a medical practitioner to establish his marital relationship with a recipient, it is the donor who will be liable under the existing section 5(8) of the Ordinance (equivalent to the proposed section 5A(6) in the Bill). The medical practitioner will only be liable if he submits the marriage certificate to the Board even though he knows its falsity, or he recklessly submits that falsified certificate to the Board.

14. Transplant operations such as kidney transplants are very often team works involving transplant surgeons, physicians, nurses, etc. FORM 1 and FORM 2, which are prescribed in the Human Organ Transplant Regulation and have to be supplied to the Board for each organ removal or transplant, are signed by members of the team in a "representative" capacity. This "team spirit" is however not reflected in the forms. [Peter S.F. Chan]

We consider that instances of team operations are well-anticipated because the footnotes of the existing FORM 1 and FORM 2 have already specified that where more than one medical practitioner is involved in removing or transplanting an organ, any of the medical practitioners may submit the information in the forms but the medical practitioner who is in charge of the operation shall ensure that the form is submitted. This arrangement will avoid creating unnecessary paperwork because each member of the operation team is not required to submit an individual form.

15. The responsibility of providing reliable information in relation to the transplants has somehow fallen on medical practitioners, who may not be able to verify the authenticity of the documents, and yet they have to bear the legal responsibility and consequences of any discrepancy. It is suggested that the Board could verify all such matters at the outset rather than at the end of the transplant procedure. The Board could also consider accepting those information, including overseas certificates and documents which cannot be verified, to be legal after declaration by the patients or parties concerned. [Peter S.F. Chan, Betty Young]

In case medical practitioners have difficulties verifying the authenticity of the documents, they could, before carrying out the organ removal or transplant, pass all the relevant documents in connection to this case to the Board for its consideration. The Board will then examine the case to decide whether approval should be given for such application. The acceptance of any certificate or document under question should be determined by the Board on a case-by-case basis.

H. Import of organs for transplants

16. Money payment is often involved in import of organs. This borders on commercialization and makes such imports liable to accusation of "organ trade" under the definition of "payment". [C.H. Leong, Albert Chui]

Despite that money payment is often involved in import of organ, as long as the payment is for defraying or reimbursing: (1) the cost of removal, transplantation or preserving the organ to be supplied; or (2) any expenses or loss of earnings incurred by a person and attributable to his supplying an organ from his body; or (3) the administrative cost incidental to the removal, transportation or preservation of the organ to be supplied, it will be excluded from the definition of "payment" as prohibited by the Ordinance. Any payment for purposes other than those stated above is regarded as contravention against the prohibition of commercial dealings in human organs.

17. Due to donor confidentiality, getting donor details to safeguard the tissue or organ quality could be difficult and may need more working out. [Albert Chui]

In order to ensure that imported organs are suitable for transplants, the Bill contains provisions to the effect that imported organs must be accompanied by a certificate which contains, among other things, a statement that, at the time the donor of the organ was tested in the specified place, he was not shown to be infected with any disease that was known, at the time of the testing, to be transmissible to the recipient of the organ through transplanting. At the same time, the Bill also provides flexibility by empowering the Board to waive certain requirements relating to the certificate in any particular case if the Board considers it appropriate to do so in the circumstances.

18. The need to supply to the Board all the information of an imported organ before transplantation can be done means that the Board will need to function frequently in order not to delay operations for which patients and organs cannot wait. [Betty Young]

The Bill requires that before the transplantation of an imported organ, a registered medical practitioner or a person who is acceptable to the Board must supply to the Board a certificate (or a copy of it) containing all the necessary information and statements. In fact, not only cases regarding transplants of imported organs, the Board processes promptly all applications including transplants involving living persons who are neither genetically related nor spouses in order not to delay any transplant operations especially the urgent ones.

19. Medical practitioners are required, as proposed in the Bill, to supply any other information the Board may require failing which is an offence. This bestows the Board unchallengeable power for it can demand any information which may not be able to be supplied with. Such information should be specific and stated beforehand in the Ordinance. [Betty Young]

Regarding transplants of imported organs, the existing Ordinance and the Bill both stipulate that the Board may, by regulation, require additional information be supplied in the certificate for an imported organ, and it may require different information to be supplied for different imported organs. In this case, the information required will be set out clearly in the Human Organ Transplant Regulation.

Furthermore, the Bill provides that a registered medical practitioner who has in Hong Kong transplanted an imported organ into a recipient should also provide the Board with "any further information that it may reasonably require". This provision will not have the effect of conferring power on the Board to make unreasonable demand for unobtainable information. As information required may be different subject to circumstances of individual cases, it is not always possible to prescribe by legislation all the information required in every single case. For example, in a case of dubious circumstances, the Board

may consider it necessary to request further details to verify the source of a particular imported organ. We trust that the Board will exercise this power reasonably and sensibly. If there is a reasonable excuse for the medical practitioner's failure to comply with the Board's request, he will not be liable under the proposed section 7(6) in the Bill.

I. Paperwork involved in human organ transplants

20. Procedural matters in relation to transplants should be simplified and medical practitioners should not be overloaded with paperwork. [Wai Poon, Betty Young]

While we agree that medical practitioners should not be overloaded with unnecessary paperwork, we are of the view that their filling in of forms and making of declarations in connection to organ transplant are crucial in safeguarding against commercial dealings in human organs. In spite of that, we shall, after the enactment of the Bill, review, streamline and as appropriate, amend the various forms and declarations that medical practitioners involved in organ transplants have to fill in or make.