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Paper for the House Committee meeting on 17 December 2010

Report of the Subcommittee on Human Organ Transplant (Amendment) Regulation 2010 and Human Organ Transplant (Appeal Board) Regulation

Purpose

This paper reports on the deliberations of the Subcommittee on Human Organ Transplant (Amendment) Regulation 2010 ("the Amendment Regulation") and Human Organ Transplant (Appeal Board) Regulation ("the Appeal Board Regulation").

Background

2. The Human Organ Transplant Ordinance (Cap. 465) ("HOTO") was 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. In recent years, advances in medical technology have resulted in the commercial production of certain products made from human tissues that are intended for transplant purposes. These products fall within the definition of "organ" in HOTO, the commercial dealings of which are prohibited by the original Ordinance. To allow the Hong Kong medical professions the opportunity to use these products for treatment subject to the condition that no payment has been made, or intended to be made, to the donor for supplying the tissues, the Human Organ Transplant (Amendment) Ordinance 2004 ("the Amendment Ordinance") was passed on 9 July 2004 to provide for a mechanism for exempting these products from HOTO, and put in place an associated appeal mechanism to handle appeals against decisions on exemptions.

3. Although the Amendment Ordinance was enacted in 2004, the relevant provisions relating to the exemption and the associated appeal mechanism have not come into operation pending the establishment of the appeal mechanism.

Human Organ Transplant (Amendment) Regulation 2010

4. Under section 6(1) of HOTO, the Human Organ Transplant Board may by regulation require prescribed persons to supply prescribed information to it with respect to transplants that have been or are proposed to be carried out using organs removed from dead or living persons. The relevant prescribed forms are provided in the Schedule to the Human Organ Transplant Regulation (Cap.465 sub.leg.A) ("HOTR").

5. There are three forms under the Schedule to HOTR, with one for supplying information on removal of organ(s) for transplant into another person, another for supplying information on transplant of organ(s) and the third form for supplying information on final disposal of organs removed or imported for transplant. The purpose of the Amendment Regulation is to make technical amendments to these forms so as to align with the provisions of HOTO as amended by the Amendment Ordinance.

Human Organ Transplant (Appeal Board) Regulation

6. Commercial dealings of human organs for transplant are prohibited under HOTO. The Amendment Ordinance provides that exemption may be granted to commercial products, which are made from human tissues supplied without payment, so that patients with genuine medical need could benefit from the use of these products.

7. Anyone who intends to make available these commercial products for transplant must apply for and obtain exemption from the Director of Health ("DoH"). The Amendment Ordinance provides for appeals to be made by those aggrieved by DoH's decisions on their applications for exemption. The Appeal Board Regulation seeks to provide for the rules and procedures of those appeals.

The Subcommittee

8. At the meeting of the House Committee on 5 November 2010, members agreed that a subcommittee should be formed to study the Regulations. To allow sufficient time for the Subcommittee to study the Regulations, a resolution was passed on 24 November 2010 to extend the scrutiny period to 5 January 2011.

9. The membership list of the Subcommittee is in **Appendix I**. Under the chairmanship of Hon Cyd HO, the Subcommittee has held two meetings, including one meeting to receive views from deputations. The list of organizations that have given views to the Subcommittee is in **Appendix II**.

Deliberations of the Subcommittee

Definition of "organ" and "regulated product"

10. The Subcommittee is concerned about the products that would be captured by the definition of "organ" or "regulated product" under HOTO. In particular, the Subcommittee is concerned that, if human sperm, egg and gamete fall within the definitions of "organ" and "regulated product", anyone who intends to make available these products may apply for and obtain exemption from DoH, this might create a loophole for commercial dealings in surrogacy arrangements.

11. The Administration has advised that by virtue of paragraph (a) of the interpretation of "organ" under section 2 of HOTO as amended by the Amendment Ordinance, the first test in determining what constitutes an "organ" is whether there is a "structured arrangement of tissues". Since human sperm, egg and gamete are not tissues, nor are they considered "structured arrangement of tissues", they will not fall within the definition of "organ". It follows that they and any product containing them will not fall within the definition of "regulated product" under section 7A(1) as added by the Amendment Ordinance. The Administration has further advised that the use of sperm, egg and gamete for any purpose in reproductive technology procedures, including their commercial dealings, is regulated separately under the Human Reproductive Technology Ordinance (Cap. 561) ("HRTO").

Prohibition of commercial dealings in human organs

12. Hon Audrey EU notes that the prohibition of commercial dealings in human organs under HOTO pertains to activities in Hong Kong only whereas commercial dealings in prescribed substance and surrogacy arrangements are prohibited under HRTO whether in Hong Kong or elsewhere. She enquires about the reason for the different treatments in the prohibition of commercial dealings in these two Ordinances.

13. The Administration has advised that HOTO regulates organ transplants whereas HRTO regulates reproductive technology procedures. HRTO does not relate to HOTO, nor does it relate to or affect the Amendment Regulation

or the Appeal Board Regulation. As regards Hon Audrey EU's concern about the different treatments under HOTO and HRTO in the prohibition of commercial dealings, the Administration has added that the intention of HOTO, similar to that of HRTO, is to make it an offence if there is an element of commercial dealings and any part of the act or event takes place in Hong Kong.

14. In response to Hon Cyd HO's enquiry on whether HOTO would extend to persons who have committed any part of the prohibited act in Hong Kong regardless of their nationality, the Administration has replied in the affirmative.

Domino transplantation

15. Members note from the example of domino transplantation as cited by the Hong Kong Academy of Medicine that advances in medical technology have made it possible to match a group of incompatible donor-recipient pairs (persons who are not compatible by blood or tissue) who are in a similar predicament to have transplants of organs that otherwise would not have taken place. Members are concerned whether such transplantation of organs from one person to another specific recipient would be regarded as a kind of commercial dealings in organs under HOTO.

16. The Administration has advised that under HOTO, applications have to be made to the Human Organ Transplant Board for approval of such kind of transplants. The Human Organ Transplant Board may give its approval if it is satisfied that conditions set out in section 5(4) of HOTO have been met, in particular, no payment prohibited by HOTO has been, or is intended to be, made. In addition, section 5(5) of HOTO stipulates that before giving its approval, the Human Organ Transplant Board shall ensure that the donor and the recipient have each been interviewed separately by a person whom the Human Organ Transplant Board considers to be suitably qualified to conduct such an interview, and the person has reported to the Human Organ Transplant Board on the donor's and recipient's understanding of, among other things, the conditions that the donor's consent to the removal of the organ is given without coercion or the offer of inducement and the donor's consent has not been subsequently withdrawn.

17. The Administration has added that under sections 7(1) and 7(2) of HOTO as amended by the Amendment Ordinance, any organ imported for the purpose of transplant must be accompanied by a certificate stating that, among other things, no person in the country of origin has made or received a payment for supplying the organ. This certificate has to be submitted to the

Human Organ Transplant Board by a registered medical practitioner performing the transplant or a person acceptable to the Board. Failure to submit the certificate will constitute an offence. In short, the key element to determine commercial dealings is whether any prohibited payment has been or is intended to be made.

Definition of "payment"

18. In the light of the views made by deputations regarding the surgery fee for transplantation and the payment for administrative cost incidental to the removal, transportation or preservation of an imported organ, some members asked about the definition of "payment" and whether any mechanism is in place to regulate the surgery and the administrative fee level.

19. The Administration has advised that the definition of "payment" under section 2 of HOTO has been revised so that it excludes payment for defraying or reimbursing –

> "(a) the cost of removing, transporting or preserving the organ to be supplied; or
>
> (aa) administrative cost incidental to the removal, transportation or preservation of an organ to be supplied; or
>
> (b) any expenses or loss of earnings incurred by a person and attributable to his supplying an organ from his body."
>
> (The new paragraph (aa) is to be added by the Amendment Ordinance.)

Hence, the payment for the surgery cost incurred in removing an organ for transplant and its associated administrative cost is not regarded as "payment" under HOTO as amended by the Amendment Ordinance.

Donor's consent to the removal of the organ

20. Members are concerned about how the Administration could ensure that in the case of imported organs, the donors have given their consent to the removal of the organs without coercion or the offer of inducement. In particular, some members are concerned about the trustworthiness or accuracy of the documents accompanying the imported organs for the purpose of transplant given that there are large variations in the legal, social and economic circumstances of different overseas jurisdictions.

21. The Administration has advised that under sections 7(1) and 7(2) of HOTO as amended by the Amendment Ordinance, any imported organ has to be accompanied by a certificate which has been signed by a person in the country of origin who is acceptable to the Human Organ Transplant Board and contains, among other things, a statement that, in obtaining the organ, all applicable laws of the country of origin have been complied with; and another statement that no person in the country of origin has made or received a payment for supplying the organ. Since the certificate has to be signed by a person acceptable to the Human Organ Transplant Board, this will give the Human Organ Transplant Board the power to assess whether or not the certificate should be accepted.

Commencement of the Regulations

22. The Subcommittee notes that the relevant provisions relating to exemption and appeal (new sections 7A to 7J as added by the Amendment Ordinance in 2004) have not yet come into operation pending the establishment of the appeal mechanism. Some members have expressed dissatisfaction at the time taken to establish the appeal mechanism. They are concerned that the interests of patients who are in need of the regulated products for transplantation might have been adversely affected due to the delay in the introduction of the Regulations. They urge the Administration to expedite the commencement of the relevant provisions.

23. The Administration has advised that it has not received any enquiry concerning applications for exemption of a regulated product since the enactment of the Amendment Ordinance in 2004. In addition, the Human Organ Transplant Board is empowered by HOTO to consider applications and determine whether approval should be granted for transplants between living persons. These applications will not be affected by the appeal mechanism for regulated products or its absence. In the light of the above, the Administration has assured members that the delay in making the Regulations has not hindered or obstructed any life saving procedure.

24. As regards the commencement of the relevant provisions, the Administration has agreed to try to advance the timetable for those provisions of the Amendment Ordinance concerning regulated products that have not come into operation and in turn the Amendment Regulation and the Appeal Board Regulation from the 4th quarter to the 3rd quarter of 2011.

Form 3 under the Amendment Regulation

25. Hon CHEUNG Man-kwong notes that Form 3 under the Amendment

Regulation for final disposal of organs removed or imported for transplant requires the supply of the following information: (i) the particulars of the donor; (ii) the description of the disposed organ and the reason and manner of disposal; and (iii) the personal particulars of the person submitting the Form. He considers that the above information is insufficient to enable DoH to assess an application for exemption from prohibition of commercial dealings under HOTO.

26. The Administration has clarified that Form 3 is to be completed by the person who makes the decision to dispose of an organ for the purpose of supplying information to the Human Organ Transplant Board but not for the purpose of applying for an exemption of a "regulated product" from prohibition of commercial dealings under HOTO. Under section 7B(1) as added by the Amendment Ordinance, a person applying for an exemption in respect of a regulated product should submit an application to DoH in a form specified by DoH.

Operation and decision of the Appeal Board

27. The Subcommittee considers it important to make available information on the operation and decision of the Appeal Board. The Administration has agreed that the administrative guidelines for the operation of the Appeal Board would provide that the date, time and venue of each appeal shall be publicized by the Appeal Board through means such as the Internet. The Administration has also agreed to provide in a written response to the Subcommittee's request that the administrative guidelines for the operation of the Appeal Board should provide that the records of proceedings as well as the decisions of the Appeal Board should be made available for public inspection as a norm.

28. At the request of Hon Cyd HO, the Administration has undertaken to provide a copy of the administrative guidelines of the Appeal Board to the Panel on Health Services for information once the guidelines are ready.

Advice sought

29. Members are invited to note the deliberations of the Subcommittee.

Council Business Division 2
Legislative Council Secretariat
16 December 2010

Appendix I

Subcommittee on
Human Organ Transplant (Amendment) Regulation 2010 and
Human Organ Transplant (Appeal Board) Regulation

Membership list

Chairman	Hon Cyd Ho Sau-lan
Members	Hon CHEUNG Man-kwong Hon Audrey EU Yuet-mee, SC, JP Hon CHAN Hak-kan Dr Hon LEUNG Ka-lau (Total: 5 Members)
Clerk	Ms Elyssa WONG
Legal adviser	Miss Kitty CHENG
Date	16 November 2010

Appendix II

Subcommittee on
Human Organ Transplant (Amendment) Regulation 2010 and
Human Organ Transplant (Appeal Board) Regulation

List of organizations that have provided views to the Subcommittee

1. Hong Kong Academy of Medicine

2. The College of Surgeons of Hong Kong