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

Background brief prepared by the Legislative Council Secretariat

Purpose

1. This paper gives an account of the past discussions by the Panel on Health Services ("the Panel") on the appeal mechanism for exemptions of organ products under the Human Organ Transplant Ordinance (Cap. 465) ("HOTO").

Background

2. HOTO 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 imported 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, such as skin substitutes and derived bone products. These products fall within the definition of "organ" in HOTO, the commercial dealings of which are prohibited by the original Ordinance. However, these products are gradually becoming more widely used by medical professions in foreign jurisdictions for treatment. To allow the Hong Kong medical profession the opportunity to use these products for treatment, the Human Organ Transplant (Amendment) Ordinance 2004 ("the Amendment Ordinance") was passed on 9 July 2004 to revise the definition of "organ", 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. At present, except for the amended/new definitions of certain terms (excluding "organ"), the provision to make changes to the constitution of the Board and several miscellaneous provisions, all other provisions of the Amendment Ordinance have not yet come into operation.

Past discussions

3. The Panel held two meetings on 11 December 2006 and 8 March 2010 respectively to discuss the proposed regulation to be made under HOTO to provide for the rules and procedures for appeal against a decision by the Director of Health ("the Director") in respect of an application for exemptions of organ products from the application of HOTO. The deliberations and concerns of members are summarized below.

Definition of "organ" in HOTO

4. Members noted that under section 2 of HOTO, "organ" meant any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, could not be regenerated by the body, and included part of an organ. Question was raised as to whether products made from stem cells fell within the definition of "organ" in HOTO.

5. The Administration advised that using stem cells to produce tissues for transplant were currently being tested on animals only and had not yet advanced to testing on humans.

Exemption mechanism of organ products from HOTO

6. Members sought information on whether it was lawful to pay the donor for supplying the tissues from his/her for transplant purpose.

7. The Administration replied in the negative. Under the exemption mechanism, the Director might exempt an organ product from the application of HOTO including the prohibition against commercial dealings on a case-by-case basis, provided that the Director was satisfied (i) that using the product for transplant purpose was safe and had no adverse effects on public health; (ii) either that the donor of the tissues concerned had given his/her 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 were removed for the therapy of the donor; (iii) that no payment had been made, or was intended to be made to that donor for his/her supplying the tissues from his/her body; (iv) that all applicable laws of the place where the tissues were obtained or processed had been complied with in obtaining and processing the tissues; and (v) that the circumstances and manner in which the tissues were obtained and processed were not affected by any matter that the Director might consider to be objectionable. The Director was required to give reasons for rejecting an application for exemption. On the breach of any condition for exemption or at any time after an exemption had been granted, the Director might suspend, vary or revoke the exemption with written notice setting out the reasons for the decision. Any person who was

aggrieved by the Director's decisions in relation to exemption might appeal to an Appeal Board to be constituted under the Amendment Ordinance.

8. Members were further advised that the Secretary for Food and Health would appoint members to serve on an Appeal Board whenever an appeal was made. The Appeal Board would comprise three members, i.e. a registered medical practitioner, a legally qualified person, and a person in neither category, one of whom was to be appointed as Chairman of the Appeal Board. These members would be appointed from a standing Appeal Board Panel comprising members in the three mentioned categories. No person having a financial or other personal interest in the matter involved in an appeal was to serve as a member on the Appeal Board. The task of the Appeal Board was to hear and determine the appeal by deciding whether the appeal should be dismissed or remitted to the Director for reconsideration.

9. Question was raised as to how the Director would deal with an application for exemption of organ product from the application of HOTO, if the product concerned came from a place where there was no law in place to regulate how such products could be obtained or processed. The Administration advised that this should not compromise the consideration for exemption by the Director, as the HOTO had provisions to prohibit commercial dealings in human organs for transplant and to regulate the import of such, among others.

10. In response to members' queries about whether applications for exemption of organ products from HOTO were patient-based, the Administration advised that suppliers of products derived from human tissues intended for transplant purpose were the potential applicants for exemption of organ products from HOTO. Hence, it would not be necessary for an individual patient or his/her attending doctor to apply for exemption under HOTO.

Appeal procedures

11. Members raised concern about the limited time which the appellant might have to appeal against the decision of the Director arising from the implementation of five-day week in the civil service, if the deadlines prescribed for the appeal procedures were counted in working days.

12. The Administration advised that the deadlines prescribed for the appeal procedures were counted in calendar days. The Appeal Board would accept and process an appeal from an applicant even though the deadline for lodging the appeal fell outside a working day.

Consultation

13. Members noted that according to the Administration, most organ transplant surgical operations took place in public hospitals and it was expected that the Hospital Authority would be the main potential user of organ products and potential applicant for exemption for the use of specific organ products in organ transplant operations. In this regard, the Administration had consulted the Hospital Authority and taken into consideration its views in formulating the proposals. Some members were of the view that due to the time limit for the Legislative Council Members to scrutinize the proposed rules and procedures for appeal under the negative vetting procedure, the Administration should fully consult all stakeholders before tabling the subsidiary legislation.

Relevant papers

14. Members are invited to access the Legislative Council website (http://www.legco.gov.hk) for details of the relevant paper and minutes of the meetings.

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