

# 立法會 *Legislative Council*

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## **Panel on Health Services**

### **Background brief prepared by the Legislative Council Secretariat for the meeting on 8 March 2010**

#### **Appeal mechanism for exemptions of organ products under the Human Organ Transplant Ordinance**

#### **Purpose**

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 has resulted in the commercial production of certain products made from human tissues that were intended for transplant purposes, such as skin substitutes and derived bone products. These products fall within the definition of "organ" in the Ordinance, 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, which mainly deals with the application and grant of exemption and the establishment of an Appeal Board to handle appeals against decisions on exemption, was enacted on 9 July 2004. 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. On 11 December 2006, the Administration briefed the Panel on 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 Administration intended to table the subsidiary legislation at the Legislative Council (LegCo) within the first half of 2007.

4. Members were advised that 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 he was satisfied, inter alia, that (i) the use of the product for transplant purpose was safe and had no adverse effects on public health; (ii) either the donor had consented to the removal of the tissues for producing the product without coercion or financial inducement, or that the tissues were removed for the therapy of the donor; (iii) no payment had been or intended to be made to the donor for supplying the tissue; and (iv) all applicable laws of the place where the tissues were obtained or processed had been complied with. If the Director rejected an application for exemption, he was required to give reasons for the decision. 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.

5. 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 the 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.

6. 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 place where the product made from human tissues that were intended for transplant purposes came from did not have laws regulating 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.

7. On whether products made from stem cells fell within the definition of "organ" in HOTO, 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.

8. Concern was raised that the appellant might have less time 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. 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.

### **Relevant papers**

9. Members are invited to access LegCo website (<http://www.legco.gov.hk>) for details of the relevant paper and minutes of the meeting.

Council Business Division 2  
Legislative Council Secretariat  
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