

For information on
11 December 2006

Legislative Council Panel on Health Services

Appeal Mechanism for Exemptions of Organ Products under the Human Organ Transplant Ordinance

Purpose

This paper informs Members of the regulations proposed to be made by the Secretary for Health, Welfare and Food (SHWF) under the Human Organ Transplant Ordinance (Cap. 465) (the Ordinance) to provide for 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 the Ordinance.

Background

2. The Ordinance was first enacted in 1995 to prohibit commercial dealings in human organs for transplant, regulate the import of such, and restrict transplant between living persons. 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 provided for, *inter alia*, an exemption mechanism for such products and an associated appeal mechanism to handle appeals against decisions on exemptions.

3. Under the exemption mechanism, the Director of Health (the Director) may exempt an organ product from the application of the Ordinance including the prohibition against commercial dealings on a case-by-case basis, provided that the Director is satisfied, *inter alia*, that: (i) the use of the product for transplant purpose is safe and has no adverse

effects on public health, (ii) either the donor has consented to the removal of the tissues for producing the product without coercion or financial inducement, or that the tissues are removed for the therapy of the donor, (iii) no payment has 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 have been complied with.

4. The Director may grant an exemption subject to conditions he considers appropriate, including a condition limiting the exemption only for a particular occasion or for the purpose of a specified type of transplant. If the Director rejects an application for exemption, he is required to give reasons for the decision. On the breach of any condition for exemption or at any time after an exemption has been granted, the Director may suspend, vary or revoke the exemption with written notice setting out the reasons for the decision. Any person who is aggrieved by the Director's decisions in relation to exemption may appeal to an Appeal Board to be constituted under the Ordinance. SHWF may make regulations by way of subsidiary legislation to provide for the rules and procedures for the making, processing and determination of such appeals.

5. The Amendment Ordinance will come into force together with the subsidiary legislation to provide for the rules and procedures for appeal.

The Appeal Board

6. In accordance with the Ordinance, whenever an appeal is made, SHWF shall appoint members to serve on an Appeal Board for the purpose of hearing and determining the appeal. The Appeal Board comprises three members: a registered medical practitioner, a legally qualified person, and a person in neither category, one of whom is to be appointed as the Chairman of the Appeal Board (the Chairman). These members are to 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 is to serve as a member on the Appeal Board. The task of the Appeal Board is to **hear** and **determine the appeal** by deciding whether the appeal should be dismissed or remitted to the Director for reconsideration.

The Appeal Procedures

7. The salient features of the proposed rules and procedures for the making and determination of appeals are summarised as follows –

- (a) An applicant aggrieved by the Director's decisions may appeal, within 30 days after the date on which the appellant was notified of the decision, by giving a notice of appeal in writing in specified form to the secretary to the Appeal Board Panel, copying to the Director.
- (b) When giving notice of appeal, the appellant may request for an oral hearing otherwise the appeal will be determined on written submissions, which include the written representation of appeal by the appellant, comments by the Director on the representations, and response to the Director's comments by the appellant.
- (c) The Appeal Board may, at any time, direct the appellant or the Director to furnish within a specified period of time any document or material in their possession which is considered by the Appeal Board to be relevant to the appeal. Such directions shall be given by notice in writing.
- (d) Either the appellant or the Director may, within 7 days after the notice of appeal was served (or such longer period as the Chairman may allow), request from each other further specific particulars relating to the appeal. The other party shall, within 7 days (or such longer period as the Chairman may allow), furnish such particulars to the other party copying to the Appeal Board.
- (e) If an oral hearing is to be conducted, the secretary to the Appeal Board shall give the appellant and the Director notice for the hearing at least 14 days before the hearing. The hearing would be held in public, but the Chairman may decide on his own or on the request of either party to exclude certain persons from the hearing.
- (f) In an oral hearing, the parties to the appeal may make submissions in respect of the appeal, either in person or by an authorized representative (including any legal representative), as they deem necessary or desirable, or as directed by the Chairman.
- (g) If the appellant fails to attend the hearing either in person or by an authorized representative, the Appeal Board may postpone the hearing if there are reasonable grounds for the appellant's absence, or proceed to hear or dismiss the appeal.
- (h) The Chairman may, on application by either party, issue a witness

summons requiring a person to appear before the Appeal Board at a hearing and to produce any document or other material, to answer any question and to give evidence relating to the appeal. Such a person will have the same liabilities, protection and immunity as a witness before the District Court.

- (i) If deemed necessary, the Chairman may, at any stage of the hearing of an appeal, adjourn the hearing to a later time or date. The appellant may also abandon the whole or any part of the appeal at any time by notice in writing to the secretary of the Appeal Board.
- (j) The Appeal Board will make its decision on the appeal and its reasons for the decision known to the appellant and the Director in writing.
- (k) The secretary of the Appeal Board will keep a written summary of the appeal proceedings, including the particulars and grounds of the appeal, the major findings from the evidence given by witnesses and the decisions and reasons for such of the Appeal Board.
- (l) The Appeal Board may also, subject to the provisions of the Ordinance and the rules and procedures of appeal prescribed under the proposed subsidiary legislation, regulate its own procedures including the proceedings of any oral hearing.

Consultation

8. Most organ transplant surgical operations take place in public hospitals. We thus expect 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, we have consulted the Hospital Authority and have taken into consideration their views in formulating the proposals.

Amendments to Existing Statutory Forms

9. Taking the opportunity of making subsidiary legislation to provide for the rules and procedures for appeal, the Human Organ Transplant Board proposes to make certain textual amendments to the three statutory forms in the Schedule to the Human Organ Transplant Regulation

(Cap. 465 sub. leg. A), an existing piece of subsidiary legislation under the Ordinance. These statutory forms are prescribed for the purpose of obtaining information with respect to organ transplants that are proposed to be or have been carried out, which are required by law to be supplied to the Board. The textual amendments are proposed after consultation with the Department of Health, Hospital Authority and other private practitioners who are involved in activities relating to organ transplant. In accordance with the Ordinance, the Board is empowered to make changes to these forms through subsidiary legislation.

Timetable

10. The draft subsidiary legislation for the proposed rules and procedures for appeal as well as the textual amendments to existing statutory forms are under preparation. The Administration intends to table them at this Council as soon as they are ready, within the first half of 2007. When the subsidiary legislation is ready for commencement, we will put the Human Organ Transplant (Amendment) Ordinance 2004 into force at the same time.

Conclusion

11. Members are invited to take note of the content of this paper.

Health, Welfare and Food Bureau
December 2006