For information on
8 March 2010

Legislative Council Panel on Health Services
Human Organ Transplant (Appeal) Regulation

Purpose

This paper informs Members of the Human Organ Transplant (Appeal) Regulation (the Regulation) proposed to be made by the Secretary for Food and Health (SFH) under the Human Organ Transplant Ordinance (Cap. 465) (the Ordinance) to provide for rules and procedures for appealing against a decision made by the Director of Health (the Director) in respect of an application for exemption of organ products from the Ordinance.

Background

2. The Ordinance was first enacted in 1995 to prohibit commercial dealings in human organs for transplant, restrict transplant between living persons, regulate the import of human organs for transplant purposes, etc.

3. In recent years, advances in medical technology have resulted in the commercial production of certain products made from human tissues for transplant purposes, such as skin substitutes and derived bone products. These products fall within the definition of "organ" in the Ordinance[1], and the commercial dealings of which are prohibited under the original Ordinance. However, these products are gradually becoming more widely used by medical professions in foreign jurisdictions for treatment. To provide the Hong Kong medical profession with the opportunity to use these products for treatment, the Legislative Council passed the Human Organ Transplant (Amendment) Ordinance 2004 (the Amendment Ordinance) on 9 July 2004 to revise the definition of "organ", provide for a mechanism for exempting these products from the Ordinance, and put in place an associated appeal mechanism to handle appeals against decisions on exemptions.[2]

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[1] Under Section 2 of the Ordinance, "organ" means any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be regenerated by the body, and includes part of an organ.

[2] By virtue of the Amendment Ordinance, amendments were made to the original Ordinance to (a) revise the definition of "organ" and amend and add the definitions of several other terms; (b) change the constitution of the Human Organ Transplant Board (the Board); (c) allow the transplant of organs previously removed for therapeutic purposes to be exempted from the procedures relating to restrictions on organ transplants between living persons under the Ordinance; (d) improve the drafting of section 5 of the Ordinance on restrictions on organ transplants between living persons; (e) specify the role of the Board with respect to imported organs; (f) provide for an exemption mechanism for exempting organ products from the Ordinance

4. Under the exemption mechanism, the Director may exempt, on a case-by-case basis, an organ product from the application of the Ordinance, including the prohibition against commercial dealings, provided that the Director is satisfied (i) that using the product for transplant purposes is safe and has no adverse impact on public health; (ii) either that the donor of the tissues concerned has 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 are removed for the therapy of the donor; (iii) that no payment has been made, or is 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 have been complied with in obtaining and processing the tissues; and (v) that the circumstances and manner in which the tissues are obtained and processed are not affected by any matter that the Director may consider to be objectionable.

5. The Director may grant an exemption subject to conditions that 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 the exemption may appeal to an Appeal Board to be constituted under the Amendment Ordinance. SFH is empowered under the Amendment Ordinance to make regulations to provide for the rules and procedures for the making, processing and determination of such appeals.

Appeal Board

6. In accordance with the Amendment Ordinance, SFH shall appoint an Appeal Board Panel (the Panel) comprising members in the following three categories: (a) registered medical practitioners; (b) legally qualified persons; and (c) persons who are neither a registered medical practitioner nor a legally qualified person. Whenever an appeal is made, SFH shall appoint three members, one from each of the three categories, to serve as members on an Appeal Board for the purpose of hearing and determining the appeal. One of the three members will be appointed as the Chairman of the Appeal Board (the Chairman). 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.

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and an associated appeal mechanism; and (g) include a provision for protection of members and officers of the Board against personal liability. 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.

Appeal Procedures

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

(a) Any person aggrieved by the Director's decision 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 a specified form to the secretary to the Appeal Board Panel with a copy of the same to the Director.

(b) When giving notice of appeal, the appellant may request for an oral hearing; otherwise, the appeal will be determined by the Appeal Board based on written submissions, which include the written representation of appeal by the appellant, comments by the Director on the representation, and response to the Director's comments by the appellant.

(c) The Appeal Board may, at any time, direct the appellant or the Director in writing 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.

(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 and send a copy of the same to the Appeal Board.

(e) If no oral hearing is to be conducted, the Director shall submit to the secretary to the Appeal Board (to be served by the secretary to the Panel) his/her comments on the appellant's written submissions within 15 days after the appellant made his/her submissions, and serve a copy of the same to the appellant. If the appellant wishes to make further response to the Director's comments, he/she may furnish his/her response to the secretary to the Appeal Board within 15 days after receipt of the comments and serve a copy of the same to the Director.

(f) If an oral hearing is to be conducted, the secretary to the Appeal Board shall give the appellant and the Director notice as to the date, time and place of the hearing at least 14 days before the hearing. The hearing will be held in public, but the Chairman may decide on his/her own or on the request of any party to the appeal to exclude certain persons from the hearing.

(g) In an oral hearing, any party to the appeal may make submissions in respect of the appeal either in person or by an authorised representative (including any legal representative) as he/she deems necessary or desirable, or as directed by the Chairman.

(h) If any party to the appeal fails to attend the oral hearing either in person or by an authorised representative, the Appeal Board may postpone the hearing if there are reasonable grounds for the party's failure to attend, or proceed to hear or dismiss the appeal.

(i) The Chairman may, on application by any party to the appeal, issue a witness summons requiring a person to appear before the Appeal Board at a hearing and to produce any document or other material in his/her possession, to answer any question and to give evidence relating to the appeal. Such a person will have the same liability, protection and immunity as a witness before the District Court.

(j) The Chairman may, at any stage of the hearing of an appeal, adjourn the hearing as he/she deems necessary. The appellant may also abandon the whole or any parts of the appeal at any time by notice in writing to the secretary to the Appeal Board.

(k) The Appeal Board will make its decision on the appeal and its reasons known to the appellant and the Director in writing.

(l) The secretary to 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 of the Appeal Board.

(m) The Appeal Board may determine its operational procedures not prescribed under the proposed Regulation, including the proceedings of oral hearings.

Consultation

8. Most organ transplant surgical operations take place in public hospitals. We thus expect that the Hospital Authority (HA) 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 HA and taken into consideration their views in formulating the above 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 (the 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). These statutory forms are prescribed for the purpose of obtaining information required by law to be supplied to the Board with respect to organ transplants that are proposed to be or have been carried out. The amendments are proposed by the Board after consultation with the Department of Health, HA and other private practitioners who are involved in

activities relating to organ transplants. The Ordinance empowers the Board to make changes to these forms through subsidiary legislation.

Timetable

10. The Administration is preparing the draft subsidiary legislation for the proposed rules and procedures for appeal as well as the proposed amendments to existing statutory forms. The Administration intends to table the subsidiary legislation at the Legislative Council within the current legislative session. After approval of the subsidiary legislation by way of negative vetting, SFH will appoint the commencement date of the subsidiary legislation and at the same time put into force all those provisions of the Amendment Ordinance that have not yet come into operation.

Food and Health Bureau
February 2010