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

The Administration's Response

Information required to be supplied in an application for exempting "regulated products" from the application of HOTO

At the meeting of the Subcommittee on 16 November 2010, Members enquired about the information required to be supplied in an application to the Director of Health ("the Director") for exempting a "regulated product"[1] from the application of the Human Organ Transplant Ordinance (Cap.465) ("HOTO")[2]. The Administration undertook to examine the issue and revert.

2. The Director may grant exemption to a regulated product when he is satisfied that it has fulfilled all statutory requirements listed under Section 7A(3) of the HOTO[3]. In seeking the Director's approval for exemption of a regulated product from the HOTO, the applicant should supply the information and supporting documents to the satisfaction of the Director –

(a) that using the product for transplant purposes is safe and has no adverse impact on public health;

(b) either that the donor of the tissues concerned has given his 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;

(c) that no payment has been made, or is intended to be made to that donor for his supplying the tissues from his body;

(d) 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

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[1] "Regulated product" is defined by Section 7A(1) of the HOTO, as added by the Human Organ Transplant (Amendment) Ordinance 2004, but the section has yet to commence operation.

[2] The exemption mechanism was added by the Human Organ Transplant (Amendment) Ordinance 2004, but has yet to commence operation.

[3] As added by the Human Organ Transplant (Amendment) Ordinance 2004, but has yet to commence operation.

(e) 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.

Administrative guidelines for the operation of the Appeal Board and the availability of relevant information for public inspection

3. At the meeting of the Subcommittee on 26 November 2010, Members enquired whether the administrative guidelines for the operation of the Appeal Board would provide that information concerning the date, time and venue of the hearing of each appeal would be publicized by the Appeal Board for public information, and records of proceedings and decisions of the Appeal Board should be made available for public inspection as a norm.

4. The Administration will, in preparing the administrative guidelines for the operation of the Appeal Board, include arrangements to make public the date, time and venue of the hearing of each appeal (including possible means such as through the Internet) for public information.

5. As regards the proceedings of the appeal, section 16 of the Human Organ Transplant (Appeal Board) Regulation ("HOT(AB)R") provides that a summary of the decision of the Appeal Board and the reasons for the decision must be made in respect of every appeal determined by the Appeal Board. While there is no requirement on the disclosure or publication of records of proceedings by the Appeal Board, we would consider including in the administrative guidelines a recommendation to the Appeal Board to make available for public inspection relevant information concerning each appeal where appropriate.

6. In accordance with section 15 of the HOT(AB)R, the Appeal Board may regulate its own procedure. Whether, what and how information may be disclosed or published is entirely and ultimately a matter for the Appeal Board to decide. In particular, the Appeal Board may, in accordance with sections 6 and 10 of the HOT(AB)R, give directions to prohibit or restrict the publication, disclosure or use of information including those given to the Appeal Board or produced at a hearing.

Food and Health Bureau
14 December 2010