

New Committee Stage Amendments added – Explanatory Note

Purpose

This note explains the new committee stage amendments added after the Bills Committee meeting of 14 June 2004.

The new S.(3)(2)

2. The Hon. Sophie LEUNG proposed at the Bills Committee meeting held on 14 June that the functions of the Human Organ Transplant Board should be clearly spelled out. The Administration agreed. This new subsection is added for the purpose of clearly stating the functions of the Human Organ Transplant Board.

The new S.7(H)(2)

3. We propose to add this new subsection to put it beyond doubt that the Director of Health has to take into consideration and address the reasons given by the Appeal Board for remitting the decision to him for reconsideration.

The new S.7(I)(1), (2) and (3)

4. We propose to state clearly in these subsections that the members of the Panel should not be public officers so that it is, and is seen to be, independent of the executive and the parties. This is in line with the spirit of Article 10 of the Hong Kong Bill of Rights. To avoid doubts

about the status of registered medical practitioners employed by the Hospital Authority who are employees of a publicly-funded subvented organization, we also propose to make it clear that this group can be appointed to be members of the Panel. We believe that this would enable a larger pool of registered medical practitioners who have expertise in various specialties to be appointed to the Panel and would in turn enable the Appeal Board to possess the requisite expertise when dealing with appeals.

Health, Welfare and Food Bureau

17 June 2004

**PROPOSED COMMITTEE STAGE AMENDMENTS
TO
HUMAN ORGAN TRANSPLANT (AMENDMENT) BILL 2001**

[Shown in revision mode on the Gazette version of the Bill]

A BILL

To

Amend the Human Organ Transplant Ordinance.

Enacted by the Legislative Council.

1. Short title and commencement

(1) This Ordinance may be cited as the Human Organ Transplant (Amendment) Ordinance 2001.

(2) This Ordinance shall come into operation on a day to be appointed by the Secretary for Health ~~and Welfare, Welfare and Food~~ by notice published in the Gazette.

2. Long title amended

The long title to the Human Organ Transplant Ordinance (Cap. 465) is amended by repealing "persons who are not genetically related, to regulate the importing of human organs intended for transplanting" and substituting "living persons and the transplanting of imported human organs,".

2A. Part heading added

The following is added immediately before section 1 -

"PART 1

PRELIMINARY".

3. Interpretation

Section 2 is amended -

- (a) by repealing the definition of "organ" and substituting -

"organ" (器官) -

- (a) means, except in relation to sections 5 to 7 -

- (i) any human bodily part which -

- (A) consists of a structured arrangement of tissues; and

- (B) if wholly removed, cannot be regenerated by the body;

- (ii) any human bodily part specified in the Schedule; or

- (iii) any structured arrangement of tissues forming part of any human bodily part mentioned in

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subparagraph (i) or
(ii);

(b) means, in relation to sections
5 to 7 -

(i) any human bodily part
mentioned in
paragraph (a)(i) and
not specified in the
Schedule; or

(ii) any structured
arrangement of
tissues forming part
of any human bodily
part mentioned in
subparagraph (i);"

(b) in the definition of "payment" -

(i) in paragraph (a), by repealing "; or" and
substituting a semicolon;

(ii) by adding -

"(aa) the administrative cost
incidental to the removal,
transportation or preservation
of the organ to be supplied;
or";

(c) by adding -

"Appeal Board" (上訴委員會) means the Appeal Board established by section 7G;

"Director" (署長) means the Director of Health;

"donor" (捐贈人), in relation to an organ, means the person from whom the organ is, or is intended to be, removed;

"function" (職能) includes a power and duty;

"perform" (執行), in relation to any function, includes exercise and discharge;

"recipient" (受贈人), in relation to a donor, means the person into whom an organ of the donor is, or is intended to be, transplanted;

"remove" (切除), in relation to an organ, includes take out by any method;

"restricted organ removal" (受規限器官切除) means the act of removing from a living person an organ for the purpose of transplanting it into another person;

"restricted organ transplant" (受規限器官移植) means the act of transplanting into a person an organ removed from another person who was living at the time of the removal-*i*

"Secretary" (局長) means the Secretary for Health, Welfare and Food."

3A. Part heading added

The following is added immediately before section 3 -

"PART 2

HUMAN ORGAN TRANSPLANT BOARD".

4. Establishment, ~~membership and procedure~~ of Human Organ Transplant Board and functions of the board

Section 3(2), (3) and (4) is repealed and the following substituted -

"(2) The board has the following functions -

- (a) to give approval to the carrying out of a restricted organ removal or a restricted organ transplant in accordance with the provisions in this Ordinance;
- (b) to receive any information and documents that by this Ordinance are required to be submitted or supplied to the board;
- (c) to require any information or documents that the board may require to be provided under this Ordinance;
- (d) to keep a record of information supplied to it in pursuance of the regulations made under section 6;

- (e) to receive and require information and documents in respect of imported organs in accordance with section 7;
- (f) to make regulation to provide for any matter that by this Ordinance is required or permitted to be prescribed by the board;
- (g) to perform any other functions that the board is required or permitted to perform under this Ordinance."

4A. Sections added

The following are added -

"3A. Constitution of the board

(21) The Secretary ~~for Health and Welfare~~ shall appoint 9 substantive members to the board as follows -

- (a) a chairman, who shall not be a registered medical practitioner;
- (b) a vice-chairman, who shall not be a registered medical practitioner;
- (c) 4 members from the medical sector, all of whom shall be registered medical practitioners;
- (d) 1 member from the social work sector, who shall be a registered social worker;
- (e) 1 member from the legal sector, who shall be a legally qualified person; and

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(f) 1 member from the non-medical sector, who shall not be a registered medical practitioner.

(~~32~~) The Secretary ~~for Health and Welfare~~ shall also appoint a panel consisting of -

- (a) 8 members from the medical sector, all of whom shall be registered medical practitioners;
- (b) 2 members from the social work sector, both of whom shall be registered social workers;
- (c) 2 members from the legal sector, both of whom shall be legally qualified persons; and
- (d) 2 members from the non-medical sector, neither of whom shall be a registered medical practitioner.

(~~43~~) The Secretary ~~for Health and Welfare~~ shall publish in the Gazette notice of every appointment made under subsection (~~21~~) or (~~32~~).

(~~54~~) The substantive members of the board and the panel members shall be appointed on such terms and for such period as the Secretary ~~for Health and Welfare~~ shall specify on appointing them.

(~~65~~) If a substantive member from a particular sector is unable to perform his functions during any period, the board may, according to its procedure, appoint a panel member from that sector to act as a substitute for that substantive member in the board during that period, except that the panel member shall not -

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- (a) be regarded as a substantive member mentioned in subsections (~~76~~), (~~87~~) and (~~98~~); or
- (b) participate in the making of any regulation by the board under this Ordinance.

(~~76~~) If the chairman of the board is unable to perform his functions during any period, the following person shall act as chairman during that period -

- (a) the vice-chairman of the board; or
- (b) if the vice-chairman is unable to act as chairman during that period, a person who complies with subsection (~~87~~) and who shall be -

- (i) appointed by the chairman or, if the chairman has failed to make the appointment, by the vice-chairman; or
- (ii) elected by the following persons among themselves if both the chairman and the vice-chairman have failed to make the appointment -
 - (A) all remaining substantive members in the board; and
 - (B) any panel member who is for the time being acting as a substitute in the board under subsection (~~65~~).

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(~~87~~) For the purpose of subsection (~~76~~)(b), a person who is to act as chairman of the board -

(a) shall not be a registered medical practitioner; and

(b) shall be a substantive member of the board unless all remaining substantive members in the board are registered medical practitioners, in which case that person may be a panel member who is for the time being acting as a substitute in the board under subsection (~~65~~).

(~~98~~) If a substantive member from a particular sector is acting as chairman of the board during any period, the board may, according to its procedure, appoint a panel member from that sector to act as a substitute for that substantive member in the board during that period.

(~~109~~) The Secretary ~~for Health and Welfare~~ shall appoint to the board a secretary and a legal adviser on such terms and for such period as the Secretary ~~for Health and Welfare~~ shall specify on appointing them.

3B. Procedure of the board

~~(11)~~—The board may determine its own procedure, whether to be followed in general situations or in a particular case, but the procedure shall not be inconsistent with any provision in this Ordinance or in any regulation made under this Ordinance.

3C. Application of Part VII of the Interpretation and General Clauses Ordinance to the board and panel

~~(12)~~—Part VII of the Interpretation and General Clauses Ordinance (Cap. 1) applies to the board and the panel, and to appointments to the board and the panel, except in so far as that Part is inconsistent with any provision in this Ordinance or in any regulation made under this Ordinance.”.

4B. Part heading added

The following is added immediately before section 4 -

“PART 3

PROHIBITION OF COMMERCIAL DEALINGS
IN HUMAN ORGANS”.

5. Sections substituted

Section 5 is repealed and the following substituted -

“PART 4

RESTRICTIONS ON ORGAN TRANSPLANTS
BETWEEN LIVING PERSONS

~~5.~~ **Restriction on Offences in relation to organ transplants between living persons**

(1) Except as provided in section 5A(1), 5B(1) or 5C(1), no person shall carry out a restricted organ removal or a restricted organ transplant.

(2) A person who contravenes subsection (1) commits an offence and is liable -

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- (a) on a first conviction, to a fine at level 5 and to imprisonment for 3 months; and
- (b) on a subsequent conviction, to a fine at level 6 and to imprisonment for 1 year.

5A. Organ transplants between spouses or genetically related persons

(1) A registered medical practitioner may carry out a restricted organ removal or a restricted organ transplant or both if he is satisfied that -

- (a) the recipient of the organ concerned -
 - (i) is genetically related to its donor; or
 - (ii) is, at the time of the transplant, the spouse of the donor and their marriage has subsisted for not less than 3 years; and
- (b) either -
 - (i) all the requirements in section 5D are complied with; or
 - (ii) all the requirements in section 5D are complied with except that the requirement in section 5D(1)(d) is waived in accordance with section 5E.

(2) For the purpose of this section, a person is regarded as genetically related only to -

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- (a) his natural parents and natural children;
- (b) his siblings of the whole or half blood;
- (c) the siblings of the whole or half blood of either of his natural parents; and
- (d) the natural children of any of the siblings mentioned in paragraphs (b) and (c).

(3) Two persons shall not be regarded as genetically related in any of the ways described in subsection (2) unless the fact of that relationship has been established by such means as may be prescribed by the board by regulation.

(4) For the purpose of this section, two persons shall not be regarded as spouses whose marriage has subsisted for not less than 3 years unless the fact of that relationship has been established by such means as may be prescribed by the board by regulation.

(5) If a registered medical practitioner who intends to carry out a restricted organ transplant under subsection (1) is satisfied that the requirement in section 5D(1)(d) is waived in accordance with section 5E, he shall -

- (a) ensure that he has received a copy each of the certificates mentioned in section 5E(1)(a) and (b) before he carries out that transplant;
- (b) within 30 days after the transplant, or within such longer period as the board on application may allow, submit to the board -

- (i) a copy each of those certificates;

and

- (ii) a copy of the medical report mentioned in section 5E(1)(c); and
- (c) provide the board with any further information that it may reasonably require.

(6) Any person who, in purported compliance with any regulation made for the purpose of subsection (3) or (4), supplies information that he knows to be false or misleading in a material respect, or recklessly supplies information that is false or misleading in a material respect, commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months.

(7) A registered medical practitioner who, without reasonable excuse, fails to comply with subsection (5) commits an offence and is liable on conviction to a fine at level 5.

5B. Transplants involving organs removed for donors' therapy

~~(1) A registered medical practitioner may carry out a restricted organ transplant if at the time when the organ concerned was removed from its donor, it was intended to be removed for the therapy of the donor and not for transplanting it into any specific recipient.~~

(1) A registered medical practitioner may carry out a restricted organ transplant if he is satisfied that at the time the organ concerned was removed from its donor, it was

removed for the therapy of the donor and not for transplant into any specific recipient.

(2) Subject to subsection (2A), a registered medical practitioner who carries out a restricted organ transplant under subsection (1) shall -

~~(a) make a declaration in writing that, to his best knowledge—~~

~~— (i) he is not aware that any payment prohibited by this Ordinance has been made or is intended to be made; and~~

~~— (ii) at the time when the organ concerned was removed from its donor, it was intended to be removed for the therapy of the donor and not for transplanting it into any specific recipient;~~

(a) make a declaration in writing to the effect that -

(i) he has checked the related documents before he carried out that transplant;

(ii) he is satisfied that at the time the organ concerned was removed from its donor, it was removed for the therapy of the donor and not for

transplant into any specific recipient; and

(iii) to the best of his knowledge and belief, no payment prohibited by this Ordinance has been made or is intended to be made;

- (b) submit that declaration to the board within 30 days after the transplant, or within such longer period as the board may on application allow; and
- (c) provide the board with any further information that it may reasonably require.

(2A) A registered medical practitioner who carries out a restricted organ transplant under subsection (1) is not required to comply with subsection (2) if the organ concerned was removed from its donor before the commencement of this section.

(2B) In this section, "related documents" (相關文件), in relation to a restricted organ transplant, means -

- (a) a certificate issued by the registered medical practitioner who removes the organ concerned from its donor, certifying that the organ is removed for the therapy of the donor and not for transplant into any specific recipient; and

(b) a declaration made by that practitioner in writing to the effect that to the best of his knowledge and belief, no payment prohibited by this Ordinance has been made or is intended to be made.

(3) Despite section 13 of the Oaths and Declarations Ordinance (Cap. 11), the declaration mentioned in subsection (2) of this section is not required to be made and signed in the manner provided by section 14 of that Ordinance.

(4) A registered medical practitioner who, without reasonable excuse, fails to comply with subsection (2) commits an offence and is liable on conviction to a fine at level 5.

(5) A registered medical practitioner who, in purported compliance with subsection (2), makes a declaration that he knows to be false or misleading in a material respect, or recklessly makes a declaration that is false or misleading in a material respect, commits an offence and is liable on a conviction to a fine at level 5 and to imprisonment for 3 months.

5C. Organ transplants with prior approval of board

(1) A registered medical practitioner may carry out a restricted organ removal or a restricted organ transplant or both if the board has given its approval in writing.

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(2) The board may give its approval under subsection (1) only if it is satisfied that -

- (a) the proposed operation is referred to the board for its approval by a registered medical practitioner who has clinical responsibility for the donor concerned;
- (b) the donor has been interviewed, in the absence of his recipient, by an interviewer, and the interviewer has reported to the board that the donor has understood all aspects of the proposed organ removal listed under section 5D(1)(b) and that the donor has given his consent as described in section 5D(1)(c); and
- (c) subsection (3) or (4) is applicable.

(3) For the purpose of subsection (2)(c), this subsection is applicable only if -

- (a) all the requirements in section 5D are complied with; and
- (b) the recipient has been interviewed, in the absence of the donor, by an interviewer, and the interviewer has reported to the board that the recipient has understood all aspects of the proposed organ transplant listed under section 5D(1)(d).

(4) For the purpose of subsection (2)(c), this subsection is applicable only if -

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- (a) all the requirements in section 5D (except section 5D(1)(d)) are complied with;
 - (b) the requirements in subsection (3)(b) and in section 5D(1)(d) are waived in accordance with section 5E; and
 - (c) the following documents and information have been submitted to the board -
 - (i) a copy each of the certificates mentioned in section 5E(1)(a) and (b);
 - (ii) a copy of the medical report mentioned in section 5E(1)(c); and
 - (iii) any further information that the board may reasonably require.
- (5) For the purposes of subsections (2)(b) and (3)(b) -
- (a) an interviewer shall be a person whom the board considers to be suitably qualified to conduct an interview under those subsections but shall not be the registered medical practitioner who makes the explanation under section 5D(1)(b) or (d); and
 - (b) the interviewer who interviews the donor under subsection (2)(b) may but need not be the same interviewer who interviews the recipient under subsection (3)(b).

5D. General requirements to be satisfied for purposes of sections 5A and 5C

(1) For the purposes of sections 5A and 5C, the requirements in this section are as follows -

(a) the donor concerned ~~has reached the age of 18 years;~~

~~(i) has reached the age of 18 years; or~~

~~(ii) has reached the age of 16 years and is married;~~

(b) a registered medical practitioner has, in the absence of the recipient concerned, explained to the donor, and the donor has understood, the following aspects of the proposed organ removal -

(i) the procedure;

(ii) the risk involved; and

(iii) the donor's entitlement to withdraw consent to that removal at any time;

(c) the donor has given his consent to the proposed organ removal without coercion or the offer of inducement and has not subsequently withdrawn his consent;

(d) a registered medical practitioner has, in the absence of the donor, explained to the recipient, and the recipient has understood, the following aspects of the proposed organ transplant -

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- (i) the procedure;
- (ii) the risk involved; and
- (iii) the recipient's entitlement to withdraw consent to that transplant at any time;

(e) no payment prohibited by this Ordinance has been made, or is intended to be made.

(2) The registered medical practitioner who makes the explanation under subsection (1)(b) or (d) shall not be the registered medical practitioner who is to carry out the restricted organ removal or the restricted organ transplant.

(3) The registered medical practitioner who makes the explanation to the donor under subsection (1)(b) may but need not be the same registered medical practitioner who makes the explanation to the recipient under subsection (1)(d).

5E. Circumstances in which requirements in sections 5C(3)(b) and 5D(1)(d) are waived

(1) The requirement in section 5D(1)(d) is waived for the purpose of section 5A(1)(b)(ii), and the requirements in sections 5C(3)(b) and 5D(1)(d) are waived for the purpose of section 5C(4)(b), if -

(a) a registered medical practitioner has issued a certificate certifying that -

- (i) the recipient concerned is in fact incapable of understanding the

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explanation required under section 5D(1)(d); and

(ii) that fact is attributable to one or more of the following reasons -

(A) his suffering any illness;

(B) his being a minor;

(C) his being a mentally incapacitated person within the meaning of the Mental Health Ordinance (Cap. 136);

(D) his suffering an impaired state of consciousness;

(b) a registered medical practitioner has issued a certificate certifying that it would not be in the best interests of the recipient to wait until he is capable of understanding the explanation required under section 5D(1)(d); and

(c) the registered medical practitioner who is to carry out the restricted organ transplant has kept a medical report in writing stating the reason why the requirement in section 5D(1)(d) cannot be complied with.

(2) The registered medical practitioner who issues a certificate under subsection (1)(a) or (b) shall not be the registered medical practitioner who is to carry out the restricted organ removal or the restricted organ transplant.

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(3) The registered medical practitioner who issues a certificate under subsection (1)(a) in respect of a recipient may but need not be the same registered medical practitioner who issues a certificate under subsection (1)(b) in respect of the same recipient.

(4) A registered medical practitioner who -

- (a) in purported compliance with subsection (1)(a) or (b), issues a certificate that he knows to be false or misleading in a material respect, or recklessly issues a certificate that is false or misleading in a material respect; or
- (b) in purported compliance with subsection (1)(c), keeps a medical report that he knows to be false or misleading in a material respect, or recklessly keeps a medical report that is false or misleading in a material respect,

commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months."

5A. Part heading added

The following is added immediately before section 6 -

"PART 5

INFORMATION ON ORGAN TRANSPLANTS
REQUIRED BY THE BOARD".

6. Section substituted

Section 7 is repealed and the following substituted -

"PART 6

RESTRICTIONS ON TRANSPLANTS
OF IMPORTED ORGANS

7. Restrictions on transplants of imported organs

(1) No person shall in Hong Kong transplant an imported organ into a recipient unless -

- (a) the person who carries out the transplant is a registered medical practitioner;
- (b) that organ, when imported into Hong Kong, is accompanied by a certificate that complies with all the requirements in subsection (2) except those that have been waived by the board under subsection (4); and
- (c) that registered medical practitioner or another person who is acceptable to the board has supplied the original of that certificate or a copy of it to the board.

(2) The certificate for an imported organ mentioned in subsection (1)(b) must -

- (a) be signed in the specified place by a person who is acceptable to the board; and
- (b) contain the following -

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- (i) a statement that, in obtaining the organ, all applicable laws of the specified place were complied with;
- (ii) a statement that, at the time the donor of the organ was tested in the specified place, he was not shown to be infected with any disease that was known, at the time of the testing, to be transmissible to the recipient of the organ through transplanting;
- (iii) a statement that the organ was removed in a hospital in which the government of the specified place has authorized organs to be removed for transplanting;
- (iv) a statement that no person in the specified place made or received a payment for supplying the organ; and
- (v) such other information as the board may, by regulation, require to be supplied.

(3) For the purpose of subsection (2)(b)(v), the board may require different information to be supplied in relation to different organs.

(4) The board may, by notice in writing, waive any of the requirements in subsection (2) in any particular case if it considers it appropriate to do so in the circumstances.

~~(5) A registered medical practitioner who has in Hong Kong transplanted an imported organ into a recipient shall -~~

(5) A registered medical practitioner who, in Hong Kong, transplants an imported organ into a recipient ("the transplanting practitioner") shall -

- (a) ensure that the original or a certified true copy of the certificate mentioned in subsection (1)(b) is supplied to the board within 7 working days after the transplant if a copy of that certificate has been supplied to the board under subsection (1)(c); and
- (b) provide the board with any further information that it may reasonably require.

(5A) For the purpose of subsection (5)(a), a certified true copy of a certificate accompanying an imported organ shall be a copy certified by the registered medical practitioner who imported the organ ("the importing practitioner") to be a true copy of that certificate.

(5B) If the transplanting practitioner of an imported organ is not its importing practitioner and a certified true copy is supplied under subsection (5)(a), the transplanting practitioner shall -

- (a) make a declaration in writing to the effect that to the best of his knowledge and belief,

the certified true copy was certified by the importing practitioner; and

(b) submit that declaration to the board within 7 working days after the transplant.

(5C) Despite section 13 of the Oaths and Declarations Ordinance (Cap. 11), the declaration mentioned in subsection (5B) of this section is not required to be made and signed in the manner provided by section 14 of that Ordinance.

(6) A person who, without reasonable excuse, contravenes subsection (1)~~or~~, (5) or (5B) commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months.

(6A) A registered medical practitioner who, in purported compliance with subsection (5B), makes a declaration that he knows to be false or misleading in a material respect, or recklessly makes a declaration that is false or misleading in a material respect, commits an offence and is liable on a conviction to a fine at level 5 and to imprisonment for 3 months.

(7) In this section, "specified place" (指明地方), in relation to an imported organ, means the place outside Hong Kong where the organ was removed from its donor."

6A. Sections added

The following are added -

"PART 7

EXEMPTION OF REGULATED PRODUCTS
FROM THIS ORDINANCE

7A. Exemption of regulated products

(1) For the purposes of this section -

(a) "regulated product" means a product containing
any structured arrangement of tissues that -

(i) falls within paragraph (a)(iii) of
the definition of "organ" in section
2; and

(ii) has been subjected to processing;

(b) "processing", in relation to any structured
arrangement of tissues means any activity
performed on the tissues which alters the
biological characteristics, function or
integrity of the tissues, but does not include
recovering or preparing the tissues,
preserving the tissues for storage, or
removing the tissues from storage.

(2) This Ordinance shall not apply to a regulated
product to the extent that it is exempted by the Director
under this section.

(3) The Director may, on application, exempt a
regulated product from the application of this Ordinance if
he is satisfied -

- (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 regulated 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
- (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.

7B. How to apply for an exemption

(1) A person may apply for an exemption in respect of a regulated product under this section by submitting an application to the Director in a form specified by the Director.

(2) A form specified for the purposes of subsection (1) may require that -

(a) it be completed in a specified way;

(b) specified information be included in or attached to it; or

(c) it be submitted in a specified manner.

(3) If any requirement under subsection (2) is included in the form, the form is not properly completed unless such requirement is complied with.

(4) The Director may, by written notice, require an applicant to provide, within a reasonable period specified in the notice, additional information and documents as are reasonably necessary to enable the Director to determine the application.

(5) If such a requirement is not complied with, the Director may reject the application.

(6) When the Director is satisfied that all the information and documents he requires for determining the application have been submitted, he shall issue a written acknowledgement to the applicant confirming the receipt of the information and documents.

(7) Any person who, in purported compliance with this section, supplies information that he knows to be false or misleading in a material respect, or recklessly supplies information that is false or misleading in a material respect, commits an offence and is liable on conviction to a fine at level 5 and to imprisonment for 3 months.

7C. Determination of applications for exemption

(1) After considering an application for exemption under this Part, the Director may decide to approve the application and grant the exemption or to reject the application.

(2) The Director shall give the applicant written notice of the decision by registered post.

(3) In approving an application for exemption, the Director may -

(a) limit the validity of the exemption to a specified period; or

(b) grant the exemption only to the applicant, a specified person or a specified class of persons.

(4) The Director may grant the exemption subject to such conditions as the Director considers appropriate, including a condition limiting the exemption only for a particular occasion or for the purpose of a specified type of transplant.

(5) On the breach of a condition imposed under subsection (4), the Director may -

(a) revoke the exemption concerned so that it shall have no effect either on the breach or from such date as the Director may determine;

(b) vary that exemption in such manner as the Director may determine; or

(c) suspend that exemption so that it shall have no effect for such period or until compliance with such conditions as the Director may determine.

(6) A determination under subsection (5)(a), (b) or (c) may be made at the time the condition concerned is imposed or breached.

(7) If the Director's approval for an application for exemption under this section is made subject to any condition imposed under subsection (4), he shall specify the condition and the consequence of its breach under subsection (5) in the written notice given under subsection (2).

(8) The Director may specify different consequences for the breach of different conditions under subsection (5). The Director may specify that a consequence shall apply generally or to the person who breaches the condition.

(9) If the Director rejects an application for exemption under this section, he shall include in the written notice given under subsection (2) a statement setting out the reasons for his decision.

7D. Director's power in relation to exemptions granted

(1) At any time after an exemption has been granted under this Part, the Director may, on such grounds as he considers appropriate -

(a) revoke the exemption so that it shall have no effect from such date as the Director may determine;

(b) vary the exemption in such manner as the Director may determine; or

(c) suspend the exemption so that it shall have no effect for such period or until compliance with such conditions as the Director may determine.

(2) The Director shall give the person to whom the exemption is granted a written notice of any decision under subsection (1) by registered post. The notice shall include a statement setting out the reasons for the decision.

7E. Register of exemptions

(1) The Director shall maintain a register in a form determined by him containing details of the exemptions granted, revoked, varied and suspended under this Part.

(2) The Director shall make the register available for inspection by the public, free of charge, during ordinary business hours at his office.

PART 8

APPEAL BOARD

7F. Right of appeal to Appeal Board against Director's decision on application for exemption

A person aggrieved by a decision of the Director under section 7C or 7D may appeal to the Appeal Board by giving a notice of appeal in such manner and with such period as the Secretary may prescribe by regulation.

7G. Constitution of Appeal Board

(1) There is established an Appeal Board for the purpose of hearing and determining an appeal under section 7F.

(2) The Appeal Board is to be constituted according to this section.

(3) Where a notice of appeal is given under section 7F, the Secretary shall appoint 3 members from the Appeal Board Panel constituted under section 7I, one from each group of members described in section 7I(2)(a), (b) and (c), to serve as members on the Appeal Board for the purpose of hearing and determining the appeal to which the notice relates.

(4) The Secretary shall appoint one of those 3 members to be the Chairman of the Appeal Board in the hearing of that appeal.

(5) The Secretary shall ensure that 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 for hearing and determining that appeal.

7H. Determination of appeals

(1) In determining an appeal, the Appeal Board may either -

(a) dismiss the appeal; or

(b) remit to the Director the matter under appeal for his reconsideration.

(2) The Director shall reconsider the matter remitted under subsection (1)(b) and make a decision having regard to any reasons given by the Appeal Board for its decision on the matter.

(3) A decision under subsection (2) is regarded as a new decision under section 7C or 7D (as the case may be) and is subject to appeal to the Appeal Board.

7I. Constitution of Appeal Board Panel

(1) Subject to subsections (2) and (3), the Secretary shall appoint an Appeal Board Panel ("the Panel") consisting of such persons as he considers suitable to serve as members of the Appeal Board. None of those persons shall be a public officer.

(2) The Panel shall have the following members -

(a) a group of members who are registered medical practitioners;

(b) a group of members who are legally qualified persons; and

(c) a group of members who are neither registered medical practitioners nor legally qualified persons.

(3) For the avoidance of doubt, a registered medical practitioner who is an employee of the Hospital Authority established by section 3 of the Hospital Authority Ordinance (Cap. 113) may be appointed as a member of the Panel.

(4) An appointment under subsection (1) shall be for a period which shall not exceed 3 years and which shall be determined by the Secretary at the time of the appointment.

(5) A member of the Panel may resign his office by giving notice in writing to the Secretary.

(6) A person who ceases to be a member of the Panel shall be eligible for reappointment to the Panel.

(7) The Secretary shall publish in the Gazette a notice of every appointment under subsection (1).

(8) The Secretary shall also appoint a secretary to the Panel on such terms and for such period as the Secretary shall specify on appointing him.

7J. Regulations

The Secretary may by regulation provide for -

(a) the procedures to be followed in making an appeal under this Part, including matters to be set out in or to accompany the notice of appeal;

(b) the hearing and determination of an appeal made under this Part;

(c) the practice and procedure of the Appeal Board;

(d) any matter that by this Part is required or permitted to be prescribed by regulation; and

(e) any matter ancillary or incidental to those specified in paragraphs (a) to (d).

PART 9

MISCELLANEOUS".

7. Sections added

The following are added -

"9. Protection of members and officers of board against personal liability

(1) No person to whom this subsection applies, acting in good faith, shall be personally liable for any civil liability or any claim in respect of any act done or default made in the performance or purported performance of any function under this Ordinance.

(2) The protection given to a person by subsection (1) in respect of an act or default does not affect any liability of the board for that act or default.

(3) The persons to whom subsection (1) applies are -

(a) any substantive member of the board;

Clause

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- (b) any member of the panel while acting as a substitute in the board under section 3(6);
- (c) the secretary of the board; and
- (d) any public officer assisting the board in the performance or purported performance of any function under this Ordinance.

10. Amendment of Schedule

(1) The Secretary ~~for Health and Welfare~~ may, after consultation with the board, amend the Schedule by notice published in the Gazette."

(2) An amendment under subsection (1) is subject to the approval of the Legislative Council."

8. Schedule added

The following is added -

"SCHEDULE [ss. 2 & 10]
HUMAN BODILY PARTS

1. Blood (including cord blood)
2. Bone marrow".

9. Interpretation of sections 10 and 11

If an expression defined in section 2 of the principal Ordinance as amended by this Ordinance is used in sections 10 and 11, its meaning in sections 10 and 11 is the same as in that section 2.

10. Cessation of offices of existing board members

(1) A person who holds office as the chairman or a member of the board immediately before the commencement of section 4 ceases to hold that office on that commencement.

(2) Nothing in this section shall be construed as preventing the Secretary for Health ~~and Welfare, Welfare and Food~~ from appointing a person mentioned in subsection (1) as a substantive member of the board, or a member of the panel, under section 3 of the principal Ordinance as amended by this Ordinance.

11. Transitional provisions

(1) In this section -

"commencement date" (生效日期) means the date on which section 5 comes into operation;

"former section 5" (原有第5條) means section 5 of the principal Ordinance as in force immediately before the commencement date.

(2) If a person has referred a proposed operation to the board for its approval under the former section 5 but the board has not given its approval, or has declined to give its approval, before the commencement date, the board may only give its approval in respect of that operation in accordance with the principal Ordinance as amended by section 5.

(3) If the board has given its approval under the former section 5 in respect of a proposed operation but that operation has not been carried out before the commencement date, that approval shall be deemed to be an approval given by the board in accordance with the principal Ordinance as amended by section 5.

(4) If a person, on or after the commencement date, supplies information in accordance with section 3 of the Human Organ Transplant Regulation (Cap. 465 sub. leg.) in respect of -

(a) an organ removal that has been carried out before the commencement date, the information shall be supplied in Form 1 in the Schedule to that Regulation as in force immediately before the commencement date; or

(b) an organ transplant that has been carried out before the commencement date, the information shall

be supplied in Form 2 in the Schedule to that Regulation as in force immediately before the commencement date.

Consequential Amendments

Human Organ Transplant Regulation

12. Empowering section amended

The empowering section to the Human Organ Transplant Regulation (Cap. 465 sub. leg.) is amended by repealing "sections 5(2), 6(1) and 7(1)(e)" and substituting "sections 5A, 6 and 7".

13. Sections amended

Sections 2 and 2A are amended by repealing "section 5" and substituting "section 5A".

14. Information that must be supplied to the board and the persons who must supply it

Section 3(5) is amended -

- (a) by repealing "section 5(3)" and substituting "section 5C";
- (b) in paragraph (a), by repealing "caused the matter to be referred" and substituting "referred the proposed operation".

15. Additional information for imported organs

Section 4 is amended by repealing "section 7(1)" and substituting "section 7(2)".

16. Schedule amended

The Schedule is amended -

(a) in Form 1 -

(i) in paragraph (a)(i) and (ii) of Part I, by repealing everything after "satisfied" and substituting -

"that -

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with.

[OR]

* all the requirements in section 5D of the Human Organ Transplant Ordinance have been complied with except that the requirement in section 5D(1)(d) has been waived in accordance with section 5E of that Ordinance." ;

(ii) in Note 1, by repealing "caused the matter to be referred" and substituting "referred the proposed operation" ;

Clause

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(b) in Form 2, in Part II, by repealing "Section 7(1)" and substituting "section 7".

Mental Health Ordinance

17. Prohibition against organ transplant

Section 59ZBA(2) of the Mental Health Ordinance (Cap. 136) is amended by adding "contained in subparagraphs (i), (ii) and (iii) under paragraph (a) of the definition of "organ"" after "as".