

C040-E

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 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,".

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 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---

""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 a 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."

#### 4. Establishment, membership and procedure of Human Organ Transplant Board

Section 3(2), (3) and (4) is repealed and the following substituted---

"(2) 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

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

(3) 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.

(4) The Secretary for Health and Welfare shall publish in the Gazette notice of every appointment made under subsection (2) or (3).

(5) 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.

(6) 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---

(a) be regarded as a substantive member mentioned in subsections (7), (8) and (9); or

(b) participate in the making of any regulation by the board under this Ordinance.

(7) 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 (8) 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 (6).

(8) For the purpose of subsection (7)(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 (6).

(9) 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.

(10) 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.

(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.

(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."

5. Sections substituted

Section 5 is repealed and the following substituted---

"5. Restriction on 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---

(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---

(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.

(2) 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;

(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.

(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 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.

(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---

(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---

(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---

(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--

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

(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."

6. Section substituted

Section 7 is repealed and the following substituted---

"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---

(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---

- (a) ensure that the original of the certificate mentioned in subsection (1)(b) is supplied to the board within 7 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.

(6) A person who, without reasonable excuse, contravenes subsection (1) or (5) commits an offence and is liable on 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."

#### 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;
- (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

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

#### 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 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";

(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".

Explanatory Memorandum

This Bill amends the Human Organ Transplant Ordinance (Cap. 465) ("the principal Ordinance") for the following purposes---

(a) to revise the definition of "organ" so as to make it clear that commercial dealings in the human bodily parts listed in the proposed Schedule are prohibited but transplants of them are not subject to regulation by the Human Organ Transplant Board ("the board") (see clauses 3(a) and 8), and to empower the Secretary for Health and Welfare, after consultation with the board, to amend the Schedule by notice published in the Gazette (see proposed section 10 added by clause 7);

(b) to exclude certain incidental administrative costs from the definition of "payment" as prohibited by the principal Ordinance (see clause 3(b));

(c) to add the definitions of "donor", "functions", "perform", "recipient", "remove", "restricted organ removal" and "restricted organ transplant" (see clause 3(c));

(d) to make provisions for the Secretary for Health and Welfare to appoint for the board a vice-chairman, a panel of members from different sectors who can substitute for the substantive members of the board, a secretary and a legal adviser, to provide for various procedural matters (see clause 4), and to provide for the cessation of the offices of existing board members on the commencement of clause 4 (see clause 10);

(e) to permit registered medical practitioners to carry out transplants involving organs removed for the therapy of donors, to require the practitioners to submit related declarations and further information to the board, and to create offences for default and for making false or misleading declarations (see proposed section 5B added by clause 5);

(f) to allow the required explanation for an intended organ donor and his recipient to be made by two different registered medical practitioners (see proposed section 5D(3) added by clause 5), and to allow the required interview of the donor and the recipient to be conducted by two different qualified interviewers (see proposed section 5C(5)(b) added by clause 5);

(g) to create an offence for the failure to satisfy certain general requirements in the case of organ transplants between related persons (see proposed sections 5 and 5A(1)(b) added by clause 5);

(h) to create an offence for supplying false or misleading information for the establishment of genetic relationship (see proposed section 5A(6) added by clause 5);

(i) to restructure the existing provisions in section 5 of the principal Ordinance so that different restrictions on organ transplants between living persons are set out under more distinct categories (see proposed sections 5, 5A, 5C, 5D and 5E added by clause 5);

(j) to empower the board to waive certain requirements and require further information in relation to the transplants of imported organs (see clause 6);

(k) to protect members and officers serving the board from personal liability if they are acting in good faith in the performance of their statutory functions (see proposed section 9 added by clause 7);

(l) to make transitional provisions on the requirements applicable to proposed operations pending approval by the board and operations already approved or carried out before the commencement of the amendments (see clause 11); and

(m) to make minor, ancillary changes to existing provisions in the principal Ordinance, and to make consequential amendments to the long title and the Human Organ

Transplant Regulation (Cap. 465 sub. leg.) (see clauses 2 and 12 to 16) and to the cross-reference contained in the Mental Health Ordinance (Cap. 136) (see clause 17).