

**Letterhead of HOSPITAL AUTHORITY
Quality Patient-Centred Care Through Tesmwol**

BY FAX (2840 0467)

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Secretary for Health & Welfare
(Attn: Mr Gregory Leung)
19-20/F Murray Building
Garden Road, HK

Dear Mr Leung,

Human Organ Transplant Ordinance (“HOT Ordinance”)

We would like to make the following comments in relation to the Human Organ Transplant Ordinance (HOTO):

1. Purpose of HOT Ordinance

The purpose of the HOT Ordinance is to prohibit organ trading whilst seeking to save lives. A balancing act is required.

2. Assumptions

From the presentation in the HOT Ordinance, it appears to be assumed that organ trading is less likely to occur in genetic or marriage relationships; hence, no prior approval of the HOT Board is required for living donor organ transplantation in such cases.

Prior approval of the HOT Board is required where the intended donor and recipient are not genetically or marriage related.

3. Safeguards

Medical practitioners

In respect of living donor transplants, there are criminal sanctions against the doctors for organ trading and for transplantation involving genetically unrelated persons, as follows:

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- Section 4(5) : a person is guilty of an offence if, in Hong Kong, he transplants an organ into a person and he knew or ought, after reasonable enquiry, to have known that a payment was or was to be made for supplying the organ, regardless of where the payment was made and, where payment was not made in Hong Kong, regardless of whether or not such payment was prohibited under the laws of the country where the payment was made. There is a similar offence for removal of an organ from the donor in section 4(7).
- Section 5(1) : a person is guilty of an offence if he removes or transplants an organ from or into a living person unless the recipient or intended recipient is genetically related OR is the spouse of the donor and the marriage has subsisted for not less than 3 years OR he has the approval of the HOT Board.
- First conviction : fine at level 5 and imprisonment for 3 months
Subsequent conviction : fine at level 6 and imprisonment for 1 year

Donor/recipient/third party

There are criminal sanctions against the donor/recipient/third party for commercial dealings in human organs, as follows:

- Section 4(1) : a person is guilty of an offence if in Hong Kong he (a) makes or receives any payment for the supply of or for an offer to supply, (b) seeks to find a person willing to supply for payment or offers to supply for payment, or (c) initiates or negotiates any arrangement involving the making of a payment for the supply of or for an offer to supply, an organ which has been or is to be removed from a person and is intended to be transplanted to another person.
- Section 4(2) : a person is guilty of an offence if he takes part in the management or control of a body of persons whose activities consist of or include the initiation or negotiation of any arrangements referred to in section 4(1)(c) above.
- Section 4(3) : a person is guilty of an offence if he causes to be published or distributed or knowingly publishes or distributes an advertisement (a) inviting persons to supply for payment an organ which has been or is removed from a person and is intended to be transplanted to another person or offering to supply such an organ for payment, or (b) indicating that the advertiser is willing to initiate or negotiate an arrangement referred to in section 4(1)(c) above.
- First conviction : fine at level 5 and imprisonment for 3 months
Subsequent conviction : fine at level 6 and imprisonment for 1 year

The HOT Board

The HOT Board is empowered to approve organ removal and transplantation between genetically unrelated donor/recipient.

4. The difficulties

In cases where difficulties in establishing the existence of genetic/marriage relationship through registration documents are encountered, approval from the HOT Board should be required. However, the HOT Board, a tier removed from the donor/recipient, may have problems in determining whether approval should be granted.

In cases which fall short of the requirements for locally issued registration documents (such as overseas or doubtful documents), the issues are :

- how should genetic/marriage relationship be established?
- by whom should such relationship be ascertained?
- how should emotional ties be established?
- who should approve the removal/transplantation of organs in such cases?

5. Genetic/marriage relationship

Establishment of genetic/marriage relationship

Under the present legislation, genetic and marriage (ie married and subsistence of marriage of not less than 3 years) relationships are to be established by registration documents prescribed in the HOT Regulations :

1. Hong Kong issued birth certificates, marriage certificates and identity documents;
2. birth certificates, marriage certificates and identity documents issued by the relevant overseas authorities.

The HOT Regulations are currently silent on the means of establishing the subsistence of marriage for not less than 3 years.

Difficulties in the establishment of genetic/marriage relationships

There are inherent difficulties in ascertaining the subsistence of marriage and the authenticity of overseas documents.

If an attempt is made to overcome such inherent difficulties by the use of statutory declarations by the intended donor/recipient to verify the statutory criteria for establishing genetic/marriage relationship, it is open to possible abuse by the declarants as front line medical personnel are not qualified to investigate and verify the assertions of the declarants.

In relation to criminal sanctions against the doctors, the current legislation focuses on the establishment of facts rather than on procedural compliance. Front line medical personnel are not necessarily in the best position or qualified to investigate and verify the factual matters, eg organ trading, genetic relationship or marriage relationship. In fact, we consider that their responsibilities should only be in exercising due diligence in verifying these factual matters.

Options

In light of the above background and difficulties, we put forward several options for establishing genetic and marriage relationships for consideration.

Option 1

Genetic or marriage relationship is to be established by registration documents alone.

In such circumstances,

- the requirement of "the subsistence of marriage for not less than 3 years" has to be deleted since the marriage certificate cannot by itself amount to proof of subsistence of marriage; and
- proof which falls short of the registration documents (eg inability to ascertain the authenticity of overseas registration documents) will have to be approved by the HOT Board.

However, by promulgating administrative guidelines, the HOT Board can request for a report on emotional ties to assist them in their deliberation on whether approval should be granted or not. The hospital will produce the report and it will be up to the HOT Board to judge whether the report is adequate for consideration in granting approval.

Option 2

Genetic or marriage relationship is to be established by registration documents and a statutory declaration prescribed by the HOT Board in the HOT Regulations verifying the subsistence of marriage of not less than 3 years.

In such circumstances,

- the declarant will be subject to criminal sanction in section 36 of the Crimes Ordinance where he knowingly and wilfully makes a statement false in a material particular in a statutory declaration; and
- proof which falls short of the registration documents (eg inability to ascertain the authenticity of overseas registration documents) will have to be approved by the HOT Board.

Again, by promulgating administrative guidelines, the HOT Board can request for a report on emotional ties to assist them in their deliberation on whether approval should be granted or not. The hospital will produce the report and it will be up to the HOT Board to judge whether the report is adequate for consideration in granting approval.

Option 3

Where no registration documents are available, genetic or marriage relationship is to be established by a statutory declaration prescribed by the HOT Board in the HOT Regulations verifying the genetic or marriage relationship and the subsistence of marriage of not less than 3 years in the case of a marriage relationship.

In such circumstances,

- the declarant will be subject to criminal sanction in section 26 of the Crimes Ordinance where he knowingly and wilfully makes a statement false in a material particular in a statutory declaration; and
- proof which falls short of the statutory declarations (since registration documents are not available or doubtful) will have to be approved by the HOT Board.

Again, by promulgating administrative guidelines, the HOT Board can request for a report on emotional ties to assist them in their deliberation on whether approval should be granted or not.

The preferred option

Whilst option 1 gives the greatest certainty to front line medical personnel, we believe that option 2 is more practical approach given the recognised functions of medical personnel and the HOT Board intended under the HOT Ordinance. In respect of option 3, whilst it is the most easy to implement, we are concerned that the sole reliance on statutory declarations may lead to possible abuse that will be difficult to ascertain. Option 2 is therefore preferred.

Emotional ties

Emotional ties cannot establish the fact of a genetic or marriage relationship. It is merely information that will assist the HOT Board in determining whether approval ought to be granted.

It will be difficult to prescribe HOT Regulations for the determination or interpretation of emotional ties. We believe that the relevant procedural requirement (eg interviews etc) should be set out in the HOT Regulations as prescribed by the HOT Board or in their administrative guidelines. The different circumstances of each case will make it impossible for cut and dried interpretation of the evidence obtained from the emotional ties assessment.

If the obligation falls on the front line medical practitioner to assess whether there is a genetic or marriage relationship under options 2 and 3, then in

relation to the issue of emotional ties, the obligation of the doctor should be one of compliance of due process and not on interpretation of the evidence. Strong emotional ties may not speak of the fact of genetic or marriage relationship and, vice versa, uncertain emotional ties does not necessarily refute the existence of a genetic or marriage relationship. It is ultimate a matter of policy as to whether the obligation should fall on the doctors or an independent statutory body.

We submit that it is more appropriate for the obligation to fall on the HOT Board so that the evidence on emotional ties obtained after compliance of due process by the doctors is one of the factors to be considered by the HOT Board in exercising their discretion in determining whether approval should be given.

6. Criminal sanctions

HA would like to propose a statutory defence for section 5(1) so that a person is not guilty of an offence if he was on reasonable grounds of the opinion that the intended recipient or recipient is genetically related, "such opinion to be based on evidence submitted by virtue of the Regulations", or is at the time of the transplant the spouse of the donor and the marriage has subsisted for not less than 3 years. We would also propose a similar statutory defence for the establishment of the subsistence of marriage.

If the burden of determining whether there is organ trading or whether there is a genetic or marriage relationship falls on the front line medical personnel, then, by reason of the inherent difficulties discussed above, the front line medical personnel should only be sanctioned for non-compliance of due process (similar to the proposed section 5(9) in Human Organ Transplant (Amendment) Bill 1999) and the sanctions should not turn on whether the fact of the genetic or marriage relationship is shown as prescribed.

7. Definition of Organ in Section 2

'Organ' is defined under Section 2 as 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'.

The definition is very wide. Whether dead tissues or tissues removed for therapeutic reasons that is otherwise of no use should be regarded as 'organ' is subjected to debate. Furthermore, the phrases 'structured arrangement of tissues' and 'cannot be regenerated by the body' should be better defined by the medical profession based on consensus. Perhaps the power to determine whether any "tissue" constitutes an "organ" should be vested with the Board, following consultation with HA, HKMA or the Professional Colleges.

8. Section 5(8) of the Human Organ Transplant (Amendment) Bill - criminal sanctions in relation to Section 5(6A).

In respect to Section 5(8) of the Human Organ Transplant (Amendment) Bill, we noted that Section 36 of the Crimes Ordinance already provides for an offence to statutory declarations and other statements without oath where the person making the same knowingly and wilfully makes the statements false in a material particular. We do not see the necessity of creating an overlapping offence. Furthermore as declarations required under Section 5(6A) of the HOT (Amendment) Bill deals with matters related to clinical judgment, there may be a possibility of a doctor committing offence as a result of his clinical judgement out of his intention.

We should be grateful if our concerns and comments could be brought to the attention of the Subcommittee on Human Organ Transplant Ordinance of the Legislative Council.

Thank you for your attention.

Yours sincerely,

(Dr Beatrice CHENG)
for Chief Executive
Hospital Authority

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