

立法會
Legislative Council

Ref : CB2/SS/1/10

LC Paper No. CB(2)633/10-11
(These minutes have been seen
by the Administration)

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

**Minutes of first meeting
held on Tuesday, 16 November 2010, at 8:30 am
in Conference Room A of the Legislative Council Building**

Members present : Hon Cyd HO Sau-lan (Chairman)
Hon CHEUNG Man-kwong
Hon Audrey EU Yuet-mee, SC, JP
Dr Hon LEUNG Ka-lau

Member absent : Hon CHAN Hak-kan

Public Officers attending : Item II

Mr Thomas CHAN Chung-ching, JP
Deputy Secretary for Food & Health (Health)2

Mr Jackson SIN Hey-long
Assistant Secretary for Food & Health (Health) 7

Dr Heston KWONG Kwok-wai
Assistant Director of Health (Special Health Services)

Dr Jaime SIN Tan
Principal Medical & Health Officer (3)
Department of Health

Miss Betty CHEUNG Yuet-wah
Senior Assistant Law Draftsman
Department of Justice

Clerk in attendance : Ms Elyssa WONG
Chief Council Secretary (2)5 (Des)

Staff in attendance : Miss Kitty CHENG
Assistant Legal Adviser 5

Ms Maisie LAM
Senior Council Secretary (2)6

Ms Sandy HAU
Legislative Assistant (2)5

Action

I. Election of Chairman

Ms Cyd HO was elected Chairman of the Subcommittee. Members agreed that election of a deputy chairman of the Subcommittee was not necessary.

II. Meeting with the Administration

(File Ref : HWF CR 1/3231/98, L.N. 143 of 2010 and L.N. 144 of 2010, LC Paper Nos.LS5/10-11 and CB(2)280/10-11(02) and (03))

2. The Subcommittee deliberated (index of proceedings attached at **Annex**).

Definitions of "organ" and "regulated product"

3. Members were concerned about the products that would be captured by the definition of "organ" in the Human Organ Transplant Ordinance (Cap. 465) ("HOTO"). They enquired whether human sperm, egg and gamete fell within the definition of "organ".

4. The Administration responded that by virtue of paragraph (a) of the interpretation of "organ" under section 2 of HOTO as amended by the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004)

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("the Amendment Ordinance"), the definition of "organ" had been revised to mean, except in relation to sections 5 to 7 of HOTO as amended by the Amendment Ordinance, (i) any human bodily part which consisted of a structured arrangement of tissues; and if wholly removed, could not 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 (i) and (ii). Since human sperm, egg and gamete were not tissues, nor were they considered structured arrangement of tissues, they did not fall within the definition of "organ" under the Amendment Ordinance. It followed that any product containing them would not fall within the definition of "regulated product" under the Amendment Ordinance. "Regulated product" was defined under section 7A(1) as added by the Amendment Ordinance as a product containing any structured arrangement of tissues that (i) fell within paragraph (a)(iii) of the definition of "organ" in section 2; and (ii) had been subjected to processing.

5. The Administration further advised that at present the use of sperm, egg and gamete for the purpose of reproductive technology, including their commercial dealings, was regulated separately under the Human Reproductive Technology Ordinance (Cap. 561) ("HRTO").

Admin

6. At the request of members, the Administration agreed to provide a detailed explanation in writing on why human sperm, egg and gamete did not fall within the definitions of "organ" and "regulated product" under the Amendment Ordinance.

Prohibition of commercial dealings in human organs

7. Ms Audrey EU noted that sections 16 and 17 of HRTO stipulated that commercial dealings in prescribed substance and surrogacy arrangements on commercial basis were prohibited whether in Hong Kong or elsewhere. She asked for the explanations as to why the prohibition of commercial dealings in human organs under section 4 of HOTO applied to acts committed in Hong Kong only. The Administration agreed to provide a response in writing.

Admin

Exemption of regulated products and the appeal mechanism

8. Ms Audrey EU noted that the relevant provisions relating to the exemption and appeal (new sections 7A to 7J as added by the Amendment Ordinance) had not yet come into operation pending the establishment of the appeal mechanism. She expressed dissatisfaction that it took six years for the Administration to draw up the appeal mechanism and asked

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whether the interest of patients in need of the regulated products for transplantation had been adversely affected due to the delay in the introduction of the subsidiary legislation.

9. The Administration advised that so far it had not received any enquiry concerning applications for exemption of a regulated product. It was the Administration's plan for all those provisions of the Amendment Ordinance concerning regulated products that had not yet come into operation to commence in the 4th quarter of 2011 through a commencement notice to be made by the Secretary for Food and Health. The Administration further advised that at present, the Human Organ Transplant Board established under section 3 of HOTO were already empowered to consider applications made under section 5 of HOTO to determine whether approval should be granted for transplants between living persons, and these applications were not affected by the appeal mechanism for regulated products or its absence.

Admin

10. Dr LEUNG Ka-lau urged the Administration to expedite the commencement of the relevant provisions relating to the exemption and appeal as there was a strong demand from patients for commercial products made from human tissues for the purpose of transplant. The Administration agreed to consider whether it could expedite the work and advance the timetable for commencing the relevant provisions.

Admin

11. Members were not sure about the scope of “regulated products” for which commercial dealings may be exempted under the new Part 7 added by the Amendment Ordinance. Given the rapid pace of technology advancement in the medical field and the need to give members a full picture in considering the appeal mechanism, members requested the Administration to provide in writing a list setting out possible products for which applications for exemption from prohibition of commercial dealings might be made when the relevant provisions came into operation.

12. Mr CHEUNG Man-kwong considered that the items to be supplied by Form 3, which included (i) the particulars of the donor; (ii) the description of the disposed organ and the reason and manner of disposal; and (iii) the personal particulars of the person submitting the Form, were insufficient to enable the Director of Health (“the Director”) to assess an application for exemption from prohibition of commercial dealings under HOTO.

13. The Administration clarified that Form 3 was to be completed by the person who made the decision to dispose of the organ but not for the purpose of applying for an exemption from prohibition of commercial

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dealings under HOTO. Under section 7B(1) as added by the Amendment Ordinance, a person applying for an exemption in respect of a regulated product should submit an application to the Director in a form specified by the Director. Mr CHEUNG requested the Administration to provide the document or information required to be supplied in an application for exemption to enable the Director to determine the application.

14. In response to the Chairman's request for speeding up the processing of appeals in respect of applications for exemption of regulated products so that patients with genuine medical need for transplant could benefit from the use of these products, the Administration advised that suppliers of products derived from human tissues intended for transplant purpose were the potential applicants for exemption of organ products from HOTO as amended by the Amendment Ordinance. Once an exemption had been granted and remained in force, it was not necessary for individual patients to apply for the use of these products on a case-by-case basis.

III. Any other business

Invitation of public views and date of next meeting

15. Members agreed to invite the respective Faculty of Medicine of The Chinese University of Hong Kong and The University of Hong Kong, and the Hong Kong Academy of Medicine as well as the relevant colleges set up under the Academy, to give views on the availability of commercial products for transplant purpose under the Amendment Ordinance, as well as the appeal procedures against a decision of the Director on an application for exemption. The Chairman asked members to inform the Secretariat if they would like to invite any other organizations to give views on the subject. Members further agreed that the next meeting would be held on 26 November 2010 at 10:45 am to receive views from deputations and continue discussion with the Administration.

Extension of scrutiny period

16. Members agreed that the Chairman would move a motion on behalf of the Subcommittee at the Council meeting on 24 November 2010 to extend the scrutiny period of the two sets of Regulation to 5 January 2011.

Action

17. There being no other business, the meeting ended at 10:03 am.

Council Business Division 2
Legislative Council Secretariat
17 December 2010

**Proceedings of the meeting of the
Subcommittee on Human Organ Transplant (Amendment) Regulation 2010 and
Human Organ Transplant (Appeal Board) Regulation
on Tuesday, 16 November 2010, at 8:30 am
in Conference Room A of the Legislative Council Building**

Time marker	Speaker	Subject	Action required
000000 - 000217	Mr CHEUNG Man-kwong Dr LEUNG Ka-lau Ms Audrey EU Ms Cyd HO	Election of Chairman	
000218 - 000457	Chairman Clerk	Opening remarks	
000458 - 001525	Admin	Briefing by the Administration on the Human Organ Transplant (Amendment) Regulation 2010 and the Human Organ Transplant (Appeal Board Regulation	
001526 - 001803	Chairman Mr CHEUNG Man-kwong Admin	Whether human sperm and egg fell within the definition of "organ" that their commercial dealings in the form of artificial insemination and surrogacy arrangement were prohibited by the Human Organ Transplant Ordinance (Cap. 465) ("HOTO")	
001804 - 003556	Ms Audrey EU Admin Chairman	<p>Reasons for the Administration having taken six years to come up with the appeal mechanism to handle appeals against decisions on applications for exemption after the enactment of the Human Organ Transplant (Amendment) Ordinance (29 of 2004) ("the Amendment Ordinance") in 2004</p> <p>The time required by the Appeal Board to handle appeals against decisions on applications for exemption</p> <p>The Administration was requested to provide a response in writing on why the prohibition of commercial dealings in human organs under section 4 of HOTO applied to acts committed in Hong Kong only, whereas commercial dealings in prescribed substance and surrogacy arrangements under sections 16 and 17 of the Human Reproductive Technology Ordinance (Cap. 561) were prohibited whether in Hong Kong or elsewhere</p>	Admin (para. 7 of the minutes refers)

Time marker	Speaker	Subject	Action required
003557 - 005017	Dr LEUNG Ka-lau Admin Chairman Ms Audrey EU Mr CHEUNG Man-kwong	Whether testicles and sperms which formed part of the testicles fell within the definition of "organ" under the Amendment Ordinance Definitions of "regulated product" and "processing" under section 7A(1)(a) and (b) as added by the Amendment Ordinance for the purpose of exempting regulated products from HOTO	
005018 - 010051	Ms Audrey EU Admin Chairman	The Administration was requested to provide the following information in writing – (a) detailed explanation on why human sperm, egg and gamete did not fall within the revised definition of "organ" and the new definition of "regulated product" under the Amendment Ordinance; and (b) a list setting out the possible products for which applications for exemption from prohibition of commercial dealings might be made when the relevant provisions came into operation Factors that the Director of Health ("the Director") would take into account in assessing applications for exempting a regulated product from prohibition against commercial dealings	Admin (para. 6 of the minutes refers) Admin (para. 11 of the minutes refers)
010052 - 010600	Dr LEUNG Ka-lau Admin	The Administration was requested to consider and revert whether it could advance the timetable for commencing the relevant provisions relating to exemption and appeal	Admin (para. 10 of the minutes refers)
010601 - 012113	Ms Audrey EU Chairman Mr CHEUNG Man-kwong Admin Dr LEUNG Ka-lau	Members' agreement to invite views from the respective Faculty of Medicine of The Chinese University of Hong Kong and The University of Hong Kong, the Hong Kong Academy of Medicine as well as its specialty colleges on the availability of commercial products for transplant purpose under the Amendment Ordinance, as well as the appeal procedures against a decision of the Director on an application for exemption	
012114 - 012442	Chairman Mr CHEUNG Man-kwong Admin	Whether there were regulated products, other than products made from human skin tissues and derived bone products, for which applications for exemption from HOTO might be made	
012443 - 012537	Chairman	The way to ensure that in the country from which an exempted regulated product was exported, no payment had been made, or was intended to be made to the donor for his supplying the tissues from his body for the purpose of producing the product in question; or the tissues were not supplied under coercion or the offer of inducement	

Time marker	Speaker	Subject	Action required
012538 - 012811	Chairman Mr CHEUNG Man-kwong Admin	The Administration was requested to provide information on the documents or particulars required from the applicant for an application for exemption	Admin (para. 13 of the minutes refers)
012812 - 012855	Chairman Clerk	Members' agreement that the Chairman would move a motion on behalf of the Subcommittee at the Council meeting on 24 November 2010 to extend the scrutiny period of the two sets of Regulation to 5 January 2011	
012856 - 013138	Chairman Ms Audrey EU Admin	Suggestion on inviting suppliers of the regulated products to give views on the subject	
013139 - 013507	Chairman Ms Audrey EU Mr CHEUNG Man-kwong Dr LEUNG Ka-lau	Date of next meeting	

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