立法會
Legislative Council

LC Paper No. CB(2)1740/08-09(07)

Ref : CB2/PL/HS

Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 8 June 2009

Licensing under the Human Reproductive Technology Ordinance

Purpose

This paper gives an account of the past discussions by the Panel on Health Services (the Panel) on licensing under the Human Reproductive Technology Ordinance (Cap. 561) (HRTO).

Background

2. HRTO was enacted in 2000 to, inter alia, regulate reproductive technology (RT) procedures and confine their application to infertile couples, and to regulate the use of embryos and gametes for research and other purposes. HRTO also prohibits certain activities and the use of RT in certain circumstances, for example, commercial dealings in gametes or embryos, and using donated gametes in surrogacy arrangement. The use of RT in other permitted circumstances is regulated, inter alia, through a system of licensing which includes a mechanism for handling complaints.

3. The Council on Human Reproductive Technology (CHRT) was established in accordance with HRTO in 2001 with a view to regulating RT procedures through a licensing system with detailed requirements to be formulated.

Deliberations of the Panel

4. At the meeting on 13 November 2006, the Administration briefed the Panel on the regulations proposed to be made by CHRT under HRTO to provide for the

licensing of and complaint handling procedures against RT service providers and embryo researchers. Major views/concerns expressed by members and responses from the Chairman of CHRT and the Administration are set out in the ensuing paragraphs.

Roles of CHRT

5. Members noted that CHRT proposed to issue four types of licences for different categories of RT activities, namely, (a) treatment licence; (b) artificial insemination by husband (AIH) licence; (c) storage licence; and (d) research licence. An Inspection Committee formed under CHRT comprising CHRT members and professionals in different medical and social fields would carry out inspection to ascertain whether the conditions of the premises under an application were suitable for performing the relevant RT procedures or embryo researches, and make recommendations to CHRT on the licensing application. Taking into consideration the recommendations of the Inspection Committee and other factors such as the qualifications and experience of the person responsible, CHRT would decide whether to grant a licence, subject to the applicable conditions.

6. Members also noted that under the proposed complaint handling procedures, any complaint against a licence applicant would be taken into consideration in the course of determination of the relevant licence application. For complaints against a licensee and/or a person responsible under a licence which had already been granted, an Investigation Committee established under CHRT, comprising CHRT members and professionals in legal, medical and social fields, might carry out investigation into the matter, convene an inquiry to hear representations from the licensee/person responsible. On the basis of the findings and recommendations of the Investigation Committee, CHRT would decide whether the complaint against alleged breach of licence conditions was valid and material and whether the licence in question should be varied or revoked as a result.

7. Concern was raised about the conflicting roles to be played by CHRT, as not only would CHRT make regulations under HRTO to provide for the licensing of and complaint handling procedures against RT service providers and embryo researchers, but it would also vet applications for licence to carry out RT activities and investigate complaint lodged against an applicant for a licence, a person responsible under a licence or a licensee.

8. The Administration responded that there was no cause for such concern as the functions and powers of CHRT were clearly defined in HRTO, which included keeping under review information about RT activities and advising the then Secretary for Health, Welfare and Food about those matters, making regulations to provide for the licensing and complaint handling procedures against RT service providers and embryo researchers, carrying out research into the social consequence of RT procedures and promoting research into the causes of human infertility. Although the Council was empowered to vet applications for licence to

carry out RT activities, any person aggrieved by the Council's decision in respect of a licence application, suspension, variation or revocation, or a complaint might appeal to the independent Administrative Appeals Board (AAB). If the Council's decision was reversed by AAB, the Council would be required to take all necessary actions to give effect of such reversal.

Manpower of CHRT

9. Concern was also raised as to whether CHRT had adequate manpower to implement the licensing under HRTO. Chairman of CHRT admitted that the Council might face some difficulties if all of the about 50 treatment centres and research centres engaging in RT activities in Hong Kong applied for licence at the same time. However, not all applications would take the same time for processing, having regard to the varied requirements for different types of licences. For instance, the granting of an AIH licence should take less time than that of a storage licence. In view of the lack of professionals in Hong Kong experienced in carrying out inspections to ascertain whether the conditions of the premises under an application were suitable for performing the relevant RT procedures or embryo researches for the purpose of licensing, arrangements had been made for members of the Council to learn how this was being done in overseas places, such as Australia and the United Kingdom, which had ample experience in this regard. To ensure smooth implementation of the licensing system, the Council planned to invite overseas experts as well as local professionals in different medical and social fields to assist in its initial rounds of inspection.

Compliance with the Code of Practice on Reproductive Technology & Embryo Research

10. Members noted that CHRT had, in consultation with RT practitioners, drawn up a Code of Practice on Reproductive Technology & Embryo Research (CoP) to provide guidance for practitioners in the field with a view to promoting the adoption of safe and quality practices. However, failure to comply with the CoP would not in itself result in liabilities to any proceedings.

11. The Administration advised that HRTO had explicit and specific provisions on what would constitute criminal offences. On the other hand, CoP was intended to provide guidance for practitioners and researchers in the field on the proper conduct of any relevant activity. Although non-compliance with CoP would not in itself result in liabilities to any proceedings, CHRT would take into account of such when considering renewal, variation, suspension or revocation of licences.

12. Hon Audrey EU asked whether an act, in contravention of CoP, committed by an applicant or a licensee/person responsible outside Hong Kong would constitute a ground for CHRT to turn down, suspend or revoke the licence. The Administration advised that CHRT was not in a position to do so.

Commercial surrogacy

13. On amending the HRTO to allow commercial surrogacy which was practised in many overseas developed countries, the Administration responded that prohibiting surrogacy arrangements on commercial basis was the result of extensive deliberations by the Legislative Council (LegCo) prior to the enactment of HRTO. In view of the complex social, moral, ethical and legal issues involved in RT activities, a multi-disciplinary approach was adopted by CHRT to ensure the RT service providers and researchers paid due respect to human life, the role of the family, the rights of service users and the welfare of the children born as a result of the use of the technology. For instance, the suitability of a woman to be a surrogate mother needed to be assessed by doctor(s) and the commissioning couple needed to undergo first counselling by lawyers, clinical psychologists and social workers. The Administration would closely monitor public opinions on surrogacy and would conduct a review on allowing commercial surrogacy if warranted.

Recent developments

14. CHRT made the Human Reproductive Technology (Licensing) Regulation (Cap. 561A) in 2007 to provide for the detailed licensing requirements and procedures. The Secretary for Financial Services and the Treasury (as Financial Secretary by virtues of section 3 of Interpretation and General Clauses Ordinance (Cap. 1)) also made the Human Reproductive Technology (Fees) Regulation (Cap. 561B) in the same year to prescribe the fees to be paid to CHRT in respect of any licence application and for other related services. Under section 47 of HRTO, existing RT service providers and embryo researchers have a transitional period of six months after commencement of the relevant provisions for applying for a licence. According to the transitional arrangement, existing RT service providers and embryo researchers who gave notice to CHRT by 31 August 2007 and submitted application for licence by 31 January 2008 would be permitted to carry on the relevant activities under HRTO until determination of application by CHRT.

15. The Administration informed the Panel in June 2008 that as at 31 August 2007, CHRT received a total of 63 notices from existing service providers and embryo researchers. Amongst them, 61 have submitted applications for licence by 31 January 2008 (four applications were subsequently withdrawn by the applicants). As at 31 May 2008, CRHT received a total of 58 licence applications (including 57 from existing service providers and embryo researchers) with breakdown as follows -

Type of Licence Applied	Number of Licence Applied
AIH Licence	42
Treatment Licence	13
Research Licence	3
Total	**58**

Relevant papers

16. Members are invited to access LegCo website (http://www.legco.gov.hk) for details of the relevant papers and minutes of the meeting.

Council Business Division 2
Legislative Council Secretariat
3 June 2009