For discussion on
8 June 2009

Legislative Council Panel on Health Services

Progress of Licensing under the Human Reproductive Technology Ordinance

Purpose

This paper informs Members of the progress of licensing under the Human Reproductive Technology Ordinance ("HRTO") (Cap. 561) by the Council on Human Reproductive Technology ("CHRT"). We last reported to this Panel vide LC Paper No. CB(2)2224/07-08(01) in June 2008.

Background

2. HRTO was enacted in 2000, *inter alia*, to establish CHRT with a view to regulating reproductive technology procedures through a licensing system. After its establishment in 2001, CHRT made the Human Reproductive Technology (Licensing) Regulation ("the 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.

3. HRTO[1] and the two regulations as mentioned in paragraph 2 above came into full effect on 1 August 2007. Under section 47 of HRTO, existing

[1] Except section 33(4)(a). Section 33(4) provides that an adult may enquire with CHRT whether he was born out of reproductive technology procedures through donated gametes, and if so, may ask CHRT for certain prescribed information. Section 33(4)(a) provides that, apart from the information already prescribed in HRTO, the Secretary for Food and Health may also prescribe by regulation to be made by Secretary for Food and Health under section 45(1)(d) other information concerning the gamete donors that the adult may ask from CHRT. CHRT has advised that no information about the gamete donors other than those already prescribed in section 33(4) of HRTO should be disclosed to an adult making such request for information. There is thus no need to make any regulation under section 45(1)(d) and to bring into operation section 33(4)(a) at this juncture.

reproductive technology service providers and embryo researchers has a transitional period of six months after commencement of the relevant provisions for applying for a licence. According to the transitional arrangement, existing reproductive technology 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.

4. The Code of Practice on Reproductive Technology and Embryo Research ("CoP") also took effect on the same day with the commencement of the two regulations mentioned above. The CoP was prepared by CHRT to provide guidance for good practices for practitioners and researchers in the field. Failure to comply with the CoP does not in itself result in legal liabilities, but will be taken into consideration when CHRT grants, renews, varies, suspends or revokes licences.

5. CHRT has publicised to both the public and the providers on the coming into operation of the licensing system, both before and after its commencement. CHRT has set up a website to provide the public and providers with information on the licensing system. Reminder letters were issued to specialists in obstetrics & gynecology and in urology on 14 May 2009 to remind them to perform human reproductive technology procedures in licensed premises.

Licensing Procedures

6. According to the Licensing Regulation, the Council may issue four types of licences, namely (i) artificial insemination by husband (AIH) licence; (ii) treatment licence; (iii) research licence and (iv) storage licence. Under each type of licence, a licensee should appoint a "person responsible" for the activities under the licence and has the duty to secure proper discharge of obligations by the person responsible. The person responsible in turn should ensure the professional staff at the reproductive technology centres are well-qualified by training and experience and suitable to take part in the relevant procedures, adopt proper practices and use proper equipment, and make proper arrangements for storage and disposal of gametes or embryos.

7. In accordance with HRTO[2], CHRT, before granting a licence, must be

[2] Section 23(2) of HRTO

satisfied that, *inter alia*, the person responsible has the prescribed qualifications and experience, the premise under application is suitable for the activities concerned, and that the licensee and person responsible will discharge their obligations under HRTO and the licence. The grant of licences is subject to certain conditions, such as keeping and managing proper registers[3] and records, performing reproductive technology procedures only at prescribed classes of premises[4], and compliance with the CoP published by CHRT. In addition, CHRT must be satisfied that the person responsible has sufficient insight into the scientific, medical, legal and other aspects of the work of the treatment, AIH, storage or research centre in question to enable them to supervise the activities of the licensed premises properly.

8. For the purpose of licensing, CHRT has set up an Inspection Committee comprising CHRT members and professionals from different medical and social fields. The Inspection Committee has also set up various inspection teams to assist in the conducting of on-site inspections for the purpose of licensing, to ascertain whether the centres applying for licence comply with the requirements of HRTO and the Licensing Regulation, and that the practices are in line with the CoP. The inspection teams comprise members of CHRT and its Ethics Committee and/or Inspection Committee, and individuals from different medical and social fields. CHRT will consider the recommendations of the Committee in deciding whether to grant a licence, subject to the applicable conditions.

9. Since the licensing system is a new measure in Hong Kong, CHRT invited two overseas inspectors from the Human Fertilisation and Embryology Authority of the United Kingdom to Hong Kong in November 2007 for exchanges and conducting of a training workshop for the local inspectors with a view to assisting CHRT in performing the licensing work. Regular training for inspectors will be arranged on an annual basis.

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[3] The licensees are required to keep separate registers of information on (i) donors of gametes or embryos; (ii) women undergoing treatment procedures and their husbands; and (iii) children born as a result of treatment procedures carried out at the licensed centre. Secrecy of and access to such information are protected under HRTO.

[4] Under the Licensing Regulation, the activities to which HRTO is applicable can only be carried out in registered medical clinics, registered private hospitals, public hospitals, private consulting rooms used exclusively by registered medical practitioners or medical or research laboratories.

Latest Position

10. CHRT has started issuing licences since October 2008. As at 27 May 2009, CHRT has received 59 applications for new licences. 58 of them were submitted on or before 31 January 2008 (the last day to submit applications under the transitional arrangement explained in paragraph 3 above) and the remaining one was submitted in November 2008. So far 54 licences have been issued, one application is pending the decision of CHRT, and four applications were rejected. Of the rejected applications, two of them applied for research licence for activities that did not fall under the definition of "embryo research" under HRTO, one of them applied for an AIH licence but the inspection team was of the view that the person responsible did not have adequate knowledge of the CoP, and the remaining application was unsuccessful because the proposed premise did not have sufficient manpower to provide AIH services. The breakdown of the 54 licences that have been issued is as follows:

Type of Licence	**Number of Licences Issued**
AIH	40
Treatment	12
Research	2
Total	**54**

11. With the completion of the first round of licensing, CHRT is currently conducting a review of the licensing system covering the CoP, licence application forms and inspection checklists with a view to improving the licensing system.

12. Members are invited to take note of the content of this paper.

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