For information on
13 November 2006

Legislative Council Panel on Health Services

Licensing and Complaint Procedures under the Human Reproductive Technology Ordinance

Purpose

This paper informs Members of the regulations proposed to be made by the Council on Human Reproductive Technology under the Human Reproductive Technology Ordinance (Cap. 561) (HRTO) to provide for the licensing of and complaint handling procedures against reproductive technology service providers and embryo researchers.

Background

2. The Human Reproductive Technology Ordinance was enacted in 2000. Some of its objectives are to regulate reproductive technology procedures and confine their application to infertile couples, and to regulate the use of embryos and gametes for research and other purposes. The HRTO also prohibits certain activities and the use of reproductive technology in certain circumstances, e.g. commercial dealings in gametes or embryos, and using donated gametes in surrogacy arrangement. The use of reproductive technology 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 to administer various regulatory functions under HRTO including the licensing system. CHRT takes a multi-disciplinary approach to ensure that reproductive technology service providers and researchers pay due respect to human life, the role of the family, the rights of service users and the welfare of children born as a

result of the use of the technology.

4. Currently, there are around 50 treatment centres and research centres engaging in reproductive technology activities.[1] In 2002, after consulting with the relevant professions, CHRT introduced the first draft of a Code of Practice on Reproductive Technology & Embryo Research ("CoP") to provide guidance for practitioners and researchers in the field, and has regularly updated the draft CoP. The last updating exercise was done in July 2006. Failure to comply with the CoP does not in itself result in liabilities to any proceedings, but will be considered when CHRT grants, renews, varies, suspends or revokes licences. In addition, the practitioners and researchers are also subject to the codes of practice and professional ethics of their respective disciplines.

5. The provisions in HRTO on prohibitions, licensing and enforcement, have not yet been put into operation, and the CoP has yet to be gazetted pending making of regulations to stipulate the detailed procedures for licensing applications and lodging complaints against malpractices of licence applicants, persons responsible under a licence or licensees. CHRT is empowered under HRTO to make such regulations.[2] After drawing reference from international practices and consultation with reproductive technology practitioners, social workers, legal practitioners, the academia and ethical groups, CHRT proposes to enact subsidiary legislation to put in place licensing and complaint procedures as detailed in paragraphs 6 to 10 below.

Licensing Procedures

6. Taking into consideration the types of activities involved, CHRT proposed to issue four types of licences for different categories of activities namely: (i) treatment licence, (ii) artificial insemination by husband (AIH) licence, (iii) storage licence, and (iv) research licence. Centres which administer reproductive technology procedures or conduct embryo researches are required to apply for (an) appropriate type(s) of licences in respect of premises conducting such activities. 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

[1] Statistics according to a survey conducted in 2004 by the Council on Human Reproductive Technology.
[2] Section 45(2) of HRTO.

responsible. The person responsible in turn should ensure that 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 the storage and disposal of gametes or embryos.

7. In accordance with HRTO[3], CHRT, before granting a licence must be 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[4] and records, performing reproductive technology procedures only at prescribed classes of premises[5], 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, an Inspection Committee formed under CHRT comprising CHRT members and professionals in different medical and social fields will carry out inspection to ascertain whether the conditions of the premises under an application are suitable for performing the relevant reproductive technology 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 will decide whether to grant a licence, subject to the applicable conditions.

Complaint Handling Mechanism

[3] Section 23(2) of HRTO.

[4] 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 procedure carried out at the licensed centre. Secrecy of and access to such information is protected under the HRTO.

[5] Under the proposed regulations, the activities to which the Ordinance 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.

9. Under HRTO, any person may file a complaint against an applicant for a licence, a person responsible under a licence, or a licensee. CHRT may, after receipt and investigation of a complaint, revoke or vary a licence if it is satisfied that any condition of a licence is not being satisfied, e.g. the premises under licence are no longer suitable for the relevant activities, or the person responsible has failed to discharge his duties. In exceptional situations where there are reasonable grounds to suspect a serious breach, CHRT may also temporarily suspend a licence by notice for a period not exceeding 3 months pending an investigation.

10. Under the proposed complaint handling procedures, any complaint against a licence applicant will 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 has already been granted, an Investigation Committee established under CHRT, comprising CHRT members and professionals in legal, medical and social fields, may carry out investigation into the matter and convene an inquiry to hear representations from the licensee/person responsible. On the basis of the findings and recommendations of the Investigation Committee, CHRT will decide whether the complaint against alleged breach of licence conditions is valid and material and whether the licence in question should be varied or revoked as a result.

Channel for Appeal

11. Under HRTO[6], any person aggrieved by the Council's decision in respect of a licence application, suspension, variation or revocation, or a complaint may appeal to the Administrative Appeals Board (AAB). If the Council's decision is reversed by AAB, the Council will be required to take all necessary actions to give effect of such reversal.

Consultation

12. In July 2006, the Council launched a consultation exercise with the relevant professions, existing reproductive technology service providers and

[6] Section 41 of the Ordinance

potential applicants on the licensing system as well as the latest version of the CoP. A total of 13 written responses were received and most of them were supportive in principle of the licensing system. The Council has taken into account the comments received in preparing the proposed licensing procedures and the CoP.

Timetable

13. The proposed regulations to give effect to the licensing and complaint handling procedures outlined above are currently under preparation. The Administration intends to table them at this Council as soon as possible with a view to putting in place the licensing system and effecting the commencement of the relevant parts of the HRTO by April 2007.

Conclusion

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

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