Statutory Approvals Committee - minutes

Centre 0339 (CREATE, St Paul's London)

Executive Update - Application for Special Directions to Import Sperm from South Africa

Monday, 23 January 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Tony Rutherford	
Members of the Executive	Dee Knoyle Siobhain Kelly	Secretary Interim Head of Corporate Governance
External adviser		
Legal Adviser	Tom Rider	Field Fisher
Observers	Bobby Farsides Anjeli Kara Bernice Ash	Member (Induction) Regulatory Policy Manager Committee Secretary (induction)

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

The following papers were considered by the committee:

- Executive Update
- Minutes of Statutory Approvals Committee Meeting - initial consideration of application on 24 November 2016
- Further documents submitted in support of application following adjournment:
  - Further information form 2
  - Consent to store, transport and use of sperm
  - Certificate from supplying centre

Original application

- Executive summary
- Application form
- Special Directions further information form
- Documents submitted in support of the application
  - Summary report from receiving centre
  - Declaration from Managing Director of supplying centre
  - Export permit
  - Application for Authorisation
  - Follow up on request for Authorisation

1. Background

1.1. The Committee considered an application from CREATE, St Paul's, London centre 0339 for Special Directions to import sperm from Androcryos, a centre located in Johannesburg, South Africa.

1.2. The application had previously come before the committee at its meeting on 24 November 2016. On that occasion, the committee concluded that it did not have enough information to make a decision and therefore adjourned its consideration to enable the centre to provide the following information:

- why the patient needed treatment and the ages of both the patient and partner;
- whether the patient and partner intended to reside together and, if so, where;
- the nature of the restriction on the gamete provider's inability to obtain a permit for travel to the UK, including whether this was a permanent or temporary restriction;
- how CREATE (St Paul's London), the receiving centre, will conduct the welfare of the child assessment;
- why Special Directions were being applied for rather than the patient travelling to South Africa;
- how consent for use of the sperm would be taken.

1.3. The committee noted from the documents before it that the centre had now provided information in relation to each these matters.

2. Consideration of application

2.1. The committee noted that section 24(4) of the HFEA Act 1990 (as amended) permits the Authority to issue directions to allow the import of gametes or embryos from countries outside the United Kingdom.

2.2. The committee further noted that, in relation to the import of gametes from outside the European Economic Area and Gibraltar, import can be permitted without the need for directions if the conditions in schedule 3 to General Directions 0006 are satisfied.

2.3. The committee noted that the centre was unable to import the gametes under General Directions 0006 because it is unable to satisfy the following two conditions in schedule 3:

(a) The centre from which the gametes or embryos are to be imported (the supplying centre) is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated;

(b) The supplying centre has a quality management system in place which has been certified by an internationally recognised body.

2.4. The committee agreed that Special Directions should not be routinely granted and not where the purpose or dominant effect appears to be to circumvent the requirements of the Act and/ or those contained in General Directions 0006.

2.5. The committee noted that there is no established accreditation scheme for reproductive tissue banks in South Africa. A scheme is in the process of being implemented. Androcryos, the supplying centre, submitted an application for accreditation in November 2015 to the Department of Health of the Republic of South Africa but is still awaiting a response.

2.6. The committee noted that the supplying centre has a quality management system but it has not been accredited against an international standard.

2.7. The committee noted that the partner is aged 48 and is resident in Zimbabwe. The patient is a British citizen aged 42 who is resident in the UK. They married in 2011 and have been trying to start a family for 5 years. They want his sperm to be imported for use in her treatment and they want her to be treated at the centre.

2.8. The committee noted that the centre stated in the application that the partner would not be able to produce another sample in the UK as he had business interests in Zimbabwe that he could not leave at this time and he had caring responsibilities for his elderly mother. The centre also stated that it would be difficult for him to obtain a permit for air travel from Zimbabwe to the UK. Further clarification regarding travel to the UK has now been provided by the centre. It states that, as far as they are aware, there is no actual restriction on him travelling to the UK (for example a legal restriction) but it would cause him immense difficulties and excessive expense above and beyond the travel expenses to undertake this journey. Further, they have reported that the couple consider it would highly impractical for the patient to travel regularly to South Africa for treatment, which could result in a lengthy stay, since she has no family or friends there to support her.

2.9. The committee noted the centre reporting that if the treatment is successful the resulting offspring will reside with the mother in the UK, where she has family.

2.10. The committee also noted that the centre has provided assurances regarding the completion of the 'welfare of the child' assessment form.

3. Decision

3.1. The committee had regard to its decision tree. It agreed that the requirements of schedule 3 to General Directions 0006 could not be met.

3.2. The committee considered whether a refusal to make Special Directions would be an interference with the patient's rights under Articles 8 and/ or 12 of the ECHR. The committee agreed that it may amount to interference in that the couple wish to import the partner's sperm for the treatment of the patient in a UK centre and the gametes are essential for the patient's treatment.

3.3. The committee went on to consider whether such interference would be justified and proportionate. The Committee had regard to the Authority's statutory duty to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act. It recognised that, when setting the requirements in schedule 3 to General Directions 0006, the Authority attached considerable importance to the supplying centre being accredited and to it having a quality management system in place which has been certified by an internationally recognised body.

3.4. However, the committee decided that, on balance, refusal to make Special Directions would not be justified or proportionate in the exceptional circumstances of this case, where the gametes are essential to the treatment, and due to the location and particular personal circumstances of the partner, there is no realistic opportunity for the partner to travel to the UK to provide a new sample or for the patient to go to South Africa for the treatment. The committee also considered the age of the patient and partner.

3.5. The committee therefore agreed to grant Special Directions to CREATE, St Paul's London, centre 0339 to import sperm from Androcryos located in Johannesburg, South Africa.

3.6. The committee considered that granting Special Directions for this application would not set an undesirable precedent which would undermine the imperative requirements identified.

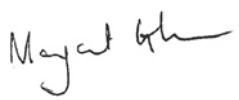
3.7. The committee reminded the centre of its duty to provide good patient information to support patient choice and that it must manage patient expectations with regards to the outcomes of treatment

3.8. The centre is also reminded of its duty to ensure that the welfare of a child requirements are satisfied at the appropriate time.

4. Chair's signature

4.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

10 February 2017