

Statutory Approvals Committee - minutes

Centre 0293 Andrology Solutions – application for Special Directions to export gametes to Cape Fertility Clinic, South Africa

Thursday, 27 October 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margret Gilmore (Chair) Rebekah Dundas Anne Lampe	
Members of the Executive	Siobhain Kelly Trent Fisher	Interim Head of Corporate Governance Secretary
Legal Adviser	Graham Miles	Blake Morgan LLP
Observers	Eve Piffaretti	Blake Morgan LLP

Declarations of interest:

- members of the committee 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 summary
- application form
- further information form
- letter from receiving centre required by General Directions 0008 (section M)
- supporting letter from receiving centre
- evidence of accreditation submitted in support of application
- letter from patients to the Committee

1. Background

- 1.1.** The committee noted that this is an application for Special Directions (under section 24(4) of the Human Fertilisation and Embryology Act 1990, as amended ('the Act')) to export sperm of a patient (A) from Andrology Solutions, London to the Cape Fertility Clinic, South Africa to enable the gametes to be used in providing treatment services to A's partner (B) involving an anonymous egg donor.
- 1.2.** The application contained the following information and submissions:
- The treatment of A requires the use of an egg donor. A resides in Germany, where egg donation is illegal.
 - B resides in Ireland. The couple (A and B) are unable to have treatment in Ireland as there is a limited supply of egg donors and the waiting list is 'too long and too expensive'.
 - The couple are unable to have treatment in the UK as the waiting list is very long and, due to their ages, 'they do not have time to wait'.
 - The couple previously travelled to South Africa for treatment in April 2016, but the lengthy journey caused A stress and anxiety to the extent that he now feels unable to make a further trip to South Africa. A now wishes his sperm to be cryopreserved and transported to South Africa for treatment.
 - There is no clinic in Ireland which has a licence to export gametes to South Africa. If a clinic in Ireland should seek to apply for a licence it would be very costly for the couple and would extend the waiting time for them with no guaranteed positive outcome.
 - The gametes are not currently in storage at Centre 0293. If the application for Special Directions is granted, A's gametes will be harvested and placed in storage at the centre for the sole purpose of being exported to the Cape Fertility Clinic.
 - The couple have 'no choice but to attempt to export the sperm from the UK'. The couple consider this to be their last chance to have a child and found a family. If the application is not approved and the sperm cannot be exported this would mean that the couple would be unable to proceed with fertility treatment at their chosen clinic. It is submitted that this would be an unjustified interference with Article 8 of the ECHR (the right to respect for private and family life) and Article 12 (the right to marry and found a family).

1. Consideration of application

- 1.3.** The committee noted that section 24(4) of the Act permits the Authority to authorise the export of gametes or embryos outside of the United Kingdom. The Committee further noted that, in relation to the export of gametes outside the EEA, if the conditions in schedule 4 to General Directions 0006 are satisfied, export is permitted without the need for Special Directions.
- 1.4.** The committee noted that the application for Special Directions is being made as the centre is unable to export the gametes under General Directions 0006 because the requirements of paragraph (h) of Schedule 4 cannot be met.
- 1.5.** Paragraph (h) provides that gametes may not be exported under the General Directions if the gametes could not be used in the UK in the manner or circumstances in which it is proposed that they be used by the receiving centre. The proposed use of an anonymous egg donor would be unlawful in the UK as Standard Licence Condition T54 requires that identifiable donors be used in licensed treatment. This reflects the change in the law in 2005 that donors of gametes on or after 1 April 2005 will be identifiable to anyone born as a result of licensed treatment services in the UK once they are 18 years old. The anonymity of donors was removed as it was recognised that many

donor-conceived people have a desire and interest in obtaining information about their genetic origins.

1.6. The committee noted that Special Directions should not be granted routinely, nor where the purpose or dominant effect appears to be to circumvent the requirements of the Act.

1.7. The committee noted that no detailed information or supporting evidence has been provided as to:

- the availability of egg donors in Ireland
- the costs of treatment services in Ireland as compared with treatment in the UK or in South Africa
- the process, timescale or costs involved in obtaining a licence to export A's gametes from Ireland, where A currently resides.
- the lack of availability of an egg donor in the UK or the length of the waiting list for such a donor for the provision of treatment services at licensed centres in the UK.

1.6. The committee also noted that no medical evidence has been presented in relation to A's inability to undertake a long flight to South Africa. The committee further noted that no explanation has been provided as to why travel to another closer destination, perhaps in Europe, would not be possible or appropriate.

1.7. The committee considered Articles 8 and 12 of the European Convention on Human Rights (ECHR), which state as follows:

Article 8

(1) Everyone has the right to respect for his private and family life, his home and his correspondence.

(2) There shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in a democratic society in the interests of national security or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Article 12

Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.

1.8. The committee noted that in *Evans v United Kingdom* (2008) 43 EHRR 21 at 71, the European Court of Human Rights stated that 'private life' under Article 8 'is a broad term encompassing, inter alia, aspects of an individual's physical and social identity including the right to personal autonomy, personal development and to establish and develop relationships with other human beings and the outside world [and] incorporates the right to respect for both the decisions to become and not to become a parent'.

1.9. The committee accepted the legal advice that, if Article 8 is engaged, any interference must be in accordance with the law, necessary in a democratic society in order to pursue one of the legitimate aims under Article 8(2) and must be proportionate. The word 'necessary' implies that the legitimate aim that is pursued cannot be achieved by less restrictive measures. In practice, a court will consider whether there is a 'pressing social need' for the interference and whether the interference is reasonably proportionate to the fulfilment of that need.

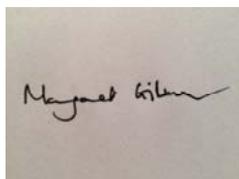
2. Decision

- 2.1. The committee had regard to its decision tree. It noted that this was an application to export A's sperm to a receiving centre in South Africa and that the centre is unable to export the gametes under General Directions 0006 because the gametes could not be lawfully used in the UK in the manner or circumstance in which it is proposed that the gametes be used by the receiving centre.
- 2.2. The committee concluded that a refusal to make Special Directions would not interfere with the patients' rights to obtain medical treatment services under EU law as the receiving centre is not within the EEA.
- 2.3. The committee considered whether a refusal to make Special Directions would be an interference with the patients' rights under Articles 8 and/or 12 of the ECHR. The Committee agreed that a decision which has the effect of preventing patients from obtaining treatment services for the purposes of becoming parents might amount to an interference with their Article 8 rights.
- 2.4. However, in the light of the lack of information and supporting evidence referred to in paragraphs 2.5 and 2.6 the committee was unable to accept the assertion made that the only choice available to the couple is the export of A's gametes to South Africa from a licensed centre in the UK. Given the other options available to the couple, the committee was not satisfied that a refusal to make Special Directions would amount to an interference with their rights under Articles 8 or 12.
- 2.5. Despite this conclusion, the Committee went on to consider the application on the basis that any limitation in the options available to the couple might be regarded as interfering with their rights under Articles 8 and/or 12. The Committee then considered whether such interference would be justified and proportionate.
- 2.6. The committee concluded that the interference would be in accordance with the law; section 24(4) of the Act.
- 2.7. Furthermore, in the view of the committee, a refusal to make Special Directions would pursue the legitimate aim of protecting the rights and freedoms of others. In this context, the committee had in mind the rights of donor-conceived people to obtain information about their genetic origins. The committee regarded the protection of the ability of such individuals to be able to obtain information about their genetic origins as a pressing social need.
- 2.8. The committee also had regard to the Authority's statutory duty under section 8(1)(cb) of the Act to promote, in relation to activities governed by the Act, compliance with requirements imposed by or under the Act.
- 2.9. The committee noted that this is not a case in which the couple are seeking to export gametes for the purpose of creating a child with the same genetic parents as an existing child. The committee recognised that, in such exceptional circumstances, a refusal to make Special Directions might represent a disproportionate interference that could not be justified. However, in the particular circumstances of this case, the committee concluded that a refusal to make Special Directions fulfils a pressing social need and is proportionate to the fulfilment of that need.
- 2.10. In reaching this conclusion, the committee also had regard to the fact that A's gametes are not currently stored at a centre licensed by the Authority. The gametes would not be harvested and stored unless Special Directions are made. The storage at the licensed centre would then only be for the purpose of exporting the gametes in accordance with those Special Directions. The committee was concerned that granting Special Directions in such circumstances might create an undesirable precedent and would not be in accordance with the Authority's statutory duty under section 8(1)(cb).
- 2.11. The committee agreed that the application for Special Directions should be refused.

3. Chair's signature

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

Signature

A photograph of a handwritten signature in black ink on a light-colored background. The signature is written in a cursive style and reads "Margaret Gilmore".

Name

Margaret Gilmore

Date

11 November 2016