

Statutory Approvals Committee – minutes

Centre 0075 (London Women’s Clinic, Darlington)

Special Direction application to import sperm from Pivet Medical Centre, Australia for patient’s own use.

Thursday, 29 October 2020

HFEA, 10 Spring Gardens, London, SW1A 2BU via Teams Meeting

Committee members	Margaret Gilmore (Chair) Anne Lampe Tony Rutherford Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Legal Adviser	Eve Piffaretti	Blake Morgan - LLP
Observer	Bernice Ash Jane Darragh	Committee Officer Research Manager, Induction

Declarations of interest

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

Apologies:

- Apologies were received from Emma Cave

The committee had before it:

- 9th 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
- Special Direction Application Form
- Further Information Form

1. Background

- 1.1. The Person Responsible (PR) at London Women's Clinic, Darlington has applied for a Special Direction to import four straws of sperm from Pivet Medical Centre, Australia, for storage and use in treatment for a patient at the London Women's Clinic, Darlington, UK.
 - 1.2. The patient and his partner, due to personal circumstances, have relocated to the UK and now wish to import the frozen sperm from Australia to continue their treatment.
 - 1.3. The four straws of sperm to be imported were surgically retrieved and are vital for the patient and his partner's treatment in the UK.
-

2. Consideration of application

- 2.1. The committee considered the application, which included an executive summary, a Special Direction application form, and a Further Information form.
- 2.2. The committee noted that the Human Fertilisation and Embryology Act 1990 (as amended) permits the Authority to issue directions to allow imports of gametes or embryos from countries outside of the United Kingdom. Furthermore, the committee noted that, in relation to the import of gametes and embryos from countries outside of Gibraltar and the European Economic Area (EEA), this can be permitted without the need for a Special Direction if the conditions outlined in General Direction 0006 are satisfied.
- 2.3. The committee noted that this application for a Special Direction is being made as the centre is unable to import the sperm from Pivet Medical Centre under General Direction 0006, because the following requirements of Schedule 3, paragraph 3, are not met:
 - (j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice currently in force.
- 2.4. The committee noted the information that had been provided to support the Special Direction application.
- 2.5. In considering the application, the committee had regard to the principles (tests) derived from the decision of the Court of Appeal in *R v HFEA ex parte Blood* (1997) 2 All ER 687 and from rights arising under the Human Rights Act 1998.
- 2.6. **Principle 1**

The committee recognised that the centre is unable to import the sperm, for use in treatment, under General Direction 0006 because the following requirements cannot be complied with:

 - (j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice currently in force
- 2.7. The committee observed that, except for those cited at paragraph 3 (j) of Schedule 3, the other relevant requirements of General Direction 0006 were satisfied.
- 2.8. The committee noted that pre-screening of the patient was performed more than three months prior to the patient's sperm being frozen. This is in line with Australian screening regulations, but not those in the UK. However, the supplying centre has confirmed in writing, compliance with all other requirements, and the receiving centre has agreed to adhere to the non-compliant condition once the sperm have been imported.
- 2.9. **Principle 2**

The committee acknowledged the patient's wishes to import the sperm from a country outside of the EEA and considered whether a refusal would amount to an interference with the patient's rights.

2.10. Principle 3

The committee recognised that rights under the European Convention on Human Rights (ECHR) are separate and distinct from those arising under the Treaty on the Functioning of the European Union. Based on all of the patient's circumstances, the committee accepted that a refusal to allow the frozen sperm to be imported would amount to an interference with the patient's rights to respect for his private and family life under Article 8 and to found a family under Article 12 of the ECHR and that any refusal to grant the application would need to be justified and proportionate.

2.11. Principle 4 and 5

The committee considered whether interference with the patient's rights under the ECHR could be justified and whether a refusal to grant the application would be disproportionate. In doing so, the committee had regard to the patient's particular circumstances. The committee considered the effect of a refusal on the patient and whether his situation was likely to constitute an isolated example or whether granting the application would set an undesirable precedent.

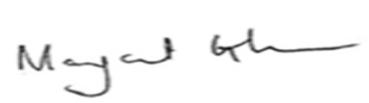
3. Decision

- 3.1.** The committee took into consideration the patient's change in life circumstances, noting that the patient had undergone surgical retrieval of his sperm in Australia, and that the sperm had been frozen and placed into storage.
- 3.2.** The committee noted the frozen sperm are essential to the patient and his partner's further fertility treatment, and as the couple have now relocated to the UK, the patient would have to travel back to Australia to use this sperm or undertake further sperm retrieval. It was also noted that a further procedure may not guarantee sufficient fresh sperm for use and would add both financial and emotional cost to the patient and his partner. In addition, the committee were cognizant of the fact that any travel abroad is now not a practical option given government advice to avoid non-essential travel due to the Covid-19 pandemic.
- 3.3.** With regard to the screening, the committee felt it was important to remind the centre that screening must be conducted ahead of treatment, and if required, appropriate procedures and subsequent actions are carried out in accordance with the HFEA Code of Practice.
- 3.4.** Taking all of these circumstances into account, the committee concluded that a refusal could not be justified and/or would amount to a disproportionate interference with the rights of the patient. The committee was satisfied that granting the application in the exceptional circumstances of this case would not set an undesirable precedent to import four straws of sperm for use in treatment from Pivet Medical Centre, 166-168 Cambridge St, Leederville, WA 6007, Australia to London Women's Clinic, Darlington, Woodlands Hospital, Morton Park, Darlington, Durham, DL1 4PL, United Kingdom.

4. Chair's signature

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

Signature

A handwritten signature in black ink, appearing to read "Margaret Gilmore", enclosed in a thin black rectangular border.

Name

Margaret Gilmore

Date

16 November 2020