

Statutory Approvals Committee – minutes

Item 8

Centre 0324 (City Fertility)

Special Directions application to Export & Import to Cyprus & Ukraine for patient couple's own use

Thursday, 29 November 2018

HFEA, 10 Spring Gardens, London, SW1A 2BU

Committee members Margaret Gilmore (Chair)
 Bobbie Farsides (Deputy Chair)
 Anne Lampe
 Anthony Rutherford
 Ruth Wilde
 Emma Cave

Members of the Executive	Dee Knoyle Catherine Burwood Paula Robinson Victoria Askew	Committee Secretary Senior Governance Manager (Observer) Head of Planning and Governance (Observer) Inspections & Logistics Officer (Observer)
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Specialist Adviser

Legal Adviser	Ros Foster	Browne Jacobson LLP
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Observers	Rachel Cutting (New Member Induction - Observer)
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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
- General Directions 0001 (2015)
- General Directions 0006 (2018)
- General Directions 0013 (2018)
- HFEA Standing Orders (2018)
- Special Directions Decision Tree (2018)

The following papers were considered by the committee:

- Executive summary.
- Application 6103 to **export 25 donor eggs** to ManorIVF operating from Pedieos IVF Clinic, **Cyprus**:
 - Application form 6103.
 - Letter from proposed receiving centre confirming acceptance of eggs.
 - Further information form.
- Application 6153 to **export 44 donor eggs** to ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine**:
 - Application form 6153.
 - Letter from proposed receiving centre confirming acceptance of eggs.
 - Further information form.
- Application 6101 to **export eight embryos** created with donor eggs originally imported from ManorIVF operating from Pedieos IVF Clinic, **Cyprus**:
 - Application form 6101.
 - Letter from proposed receiving centre confirming acceptance of embryos.
 - Further information form.
- Application 6150 to **import eight embryos** (referred to in application 6101) created with donor eggs originally imported from ManorIVF operating from Pedieos IVF Clinic, **Cyprus**:
 - Application form 6150.
 - Further information form.
- Application 6104 to **export nine embryos** created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine**:
 - Application form 6104.
 - Letter from proposed receiving centre confirming acceptance of embryos.
 - Further information form.
- Application 6107 to **export three embryos** created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine**:
 - Application form 6107.
 - Further information form.
 - Letter from proposed receiving centre confirming acceptance of embryos.
- Application 6152 to **export four embryos** created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine**:
 - Application form 6152.
 - Letter from proposed receiving centre confirming acceptance of embryos.
 - Further information form.

- Application 6148 to **import three embryos** (referred to in application 6107) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine:**
 - Application form 6148.
 - Further information form as provided in attachment 7 above.
- Application 6149 to **import nine embryos** (referred to in application 6104) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine:**
 - Application form 6149.
 - Further information form.
- Application 6151 to **import four embryos** (referred to in application 6152) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, **Ukraine:**
 - Application form 6151.
 - Further information form.
- Gamete provider details of the eggs to be exported, and embryos to be exported and re-imported, for the applications above.
- For the committee's reference: minutes of the Statutory Approvals Committee meeting of 22 March 2018 relating to centre 0338 (Reproductive Health Group) applications for Special Directions for the export of donor eggs to Ukraine and (virtual) export and re-import of embryos created with donor eggs from Ukraine.

1. Background

1.1. The Person Responsible (PR) at City Fertility, centre 0324 has applied for Special Directions for the following transactions:

Special Directions Application:

Cyprus:

Export donor eggs:

- Export (return) 25 donor eggs to ManorIVF operating from Pedieos IVF Clinic, Cyprus (Application form 6103)

Simultaneously Export & Import embryos:

- Export 8 embryos created with donor eggs originally imported from ManorIVF operating from Pedieos IVF Clinic, Cyprus (Application 6101)
- Re-Import 8 embryos (referred to in application 6101) created with donor eggs originally imported from ManorIVF operating from Pedieos IVF Clinic, Cyprus (Application 6150)

Ukraine:

Export donor eggs:

- Export (return) 44 donor eggs to ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine Application 6153

Simultaneously Export & Import embryos:

- Export 9 embryos created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine (Application 6104)
- Re-Import 9 embryos (referred to in application 6104) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine Application 6149)
- Export 3 embryos created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine (Application 6107)
- Re-Import 3 embryos (referred to in application 6107) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine Application 6148)
- Export 4 embryos created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine: Application 6152)
- Re-Import 4 embryos (referred to in application 6152) created with donor eggs originally imported from ManorIVF operating from Reproductive Genetics Clinic 'Victoria', Kiev, Ukraine Application 6151

- 1.2. The simultaneous export and re-import of the embryos mentioned above is a paper exercise that does not require the actual movement of the embryos but is necessary to ensure that they can continue to be stored and used on a lawful basis.

Imported Donor Eggs

Breach of Sections 4(1)(a) and (b) and 12(1)(e) of the HF&E Act and General Directions 0001 and 0006.

- 1.3. The HFEA Executive undertook a review of activities across the sector in relation to the importation of eggs, in particular donor eggs, for use in treatment in the UK. This review across the sector was in response to a non-compliance identified at another HFEA licensed centre where the import of donor eggs from Ukraine was not compliant with HFEA General Direction 0006 because the amount of compensation given to the egg donors in Ukraine was not compliant with General Direction 0001.
- 1.4. In March 2018, the Person Responsible (PR) of centre 0324 confirmed that his centre had imported donor eggs from Ukraine, and he was made aware of the Executive's concerns regarding the level of compensation provided to donors overseas. The PR has fully engaged with the Executive in providing any requested information such as copies of the centre's records of evidence of compliance with General Direction 0006 and 0001. In accordance with the HFEA's Compliance and Enforcement Policy, the Executive held a number of management review meetings to review and evaluate the information provided by the centre. Having reviewed all the information provided, the Executive concluded that the centre's imports of the donor eggs from Ukraine, and additionally from Cyprus, were not compliant with General Direction 0006, because the amount of compensation given to the egg donors was not compliant with General Direction 0001.
- 1.5. In June 2018, the PR confirmed that centre 0324 would no longer advise patients to consider this source of egg donation for treatment and that no further donor eggs would be imported from these sources and no further treatment will be started using eggs already imported from those sources. The PR also confirmed that these imported donor eggs had not been supplied to any other centres in the UK by his centre.
- 1.6. The PR informed the Executive that he had halted the treatment of a patient planned for June 2018 and that he had taken the decision to export the donor eggs allocated for this patient back to Ukraine (where they had originally been imported from) so that the patient could complete her treatment there. This export was undertaken on 26 June 2018. Whilst the PR was aware that the import of the eggs was not compliant with General Directions 0001 and 0006, he later acknowledged that he had not realised that the export of these donor eggs could also not take place under General Directions, and that he would require Special Directions to do so. Following further communications with the Executive, the PR acknowledged this error and agreed that whilst he had been trying to do his best to support the patient and enable her to complete her treatment he should not have exported the donor eggs to Ukraine without having obtained the requisite authority. As requested by the Executive, the PR submitted an incident report regarding this issue to the HFEA on 5 July 2018.
- 1.7. A routine, unannounced interim inspection was conducted at the centre on 20 September 2018, during which time the non-compliant import of donor eggs from Cyprus and Ukraine and related incident were discussed in detail with the PR. Given that the PR had accepted this failing, engaged with the Executive, and taken immediate action to suspend any further imports of donor eggs from ManorIVF in Cyprus and Ukraine, the Executive considered that no further regulatory action was necessary.

- 1.8. The PR has now applied for Special Directions as the centre is unable to complete the above transactions under the auspices of General Direction 0006 because the following requirements are not satisfied:

Schedule 1 – Import of gametes and embryos from Gibraltar and the European Economic Area (EEA)

Cyprus

Part 1

(e) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits

Schedule 2 - Export of gametes and embryos to Gibraltar and the European Economic Area (EEA)

Cyprus

Part 1

(d) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits

(f) the gametes or embryos are not exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre; and

Schedule 3 – Import of gametes and embryos from outside of the European Economic Area (EEA)

Ukraine

Part 1

(h) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits

Schedule 4 - Export of gametes and embryos outside of the European Economic Area (EEA)

Part 1

Ukraine

(f) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving of money or other benefits

(h) the gametes or embryos are not exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre

2. Consideration of application

Application

- 2.1. The committee noted that the PR at centre 0324 has applied for Special Directions to export donor eggs back to ManorIVF located in Cyprus and Ukraine as they were not compliant with General Direction 0006, because the amount of compensation given to the egg donors was not compliant with General Direction 0001. Applications for embryos created using other donor eggs imported from the same source have also been submitted to export them to Cyprus and Ukraine and simultaneously re-import them back to the UK, the simultaneous export and re-import of the embryos being a paper exercise only.
- 2.2. The committee noted that suitably completed application forms and further information forms were received by the HFEA Executive, along with confirmation that the receiving centres, ManorIVF operating in Cyprus and Ukraine are willing to accept the return of the donor eggs they had originally provided to centre 0324.

Importing Tissue Establishment' (ITE) Certificate

- 2.3. The committee noted that the Human Fertilisation and Embryology Act 1990 (the 1990 Act) was amended as of 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations') to incorporate procedures for verifying the standards of quality and safety of imported gametes and embryos into the United Kingdom (UK) from tissue establishments outside of the European Union (EU), European Economic Area (EEA) or Gibraltar. Such establishments are classified as 'third country suppliers' (TCS). HFEA licensed centres wishing to import gametes or embryos from a clinic in a country located outside of the EU, EEA or Gibraltar are required to apply to the HFEA for a certificate to do so. For the purposes of the 2018 Regulations, any centre in the EU importing gametes or embryos from a TCS is referred to as an 'Importing Tissue Establishment' (ITE). The Executive has confirmed that centre 0324 holds a valid ITE certificate to complete the transactions applied for.

Human Fertilisation and Embryology Act 1990 (as amended) Section 24

General Directions 0006

- 2.4. The committee noted that Section 24(4) of the 1990 Act provides a power to make Directions and confers a broad power on the Authority to permit the import and export of a person's gametes and embryos. Pursuant to this power the Authority has issued General Direction 0006 ('the General Direction'). However, these applications have arisen because not all of the requirements of the General Direction can be met and therefore the committee is asked to consider whether, in the particular circumstances of this case, there are grounds to exercise the power under section 24(4) to issue Special Directions so as to permit the transactions to which the applications before the committee relate.

General Direction 0001

2.5. The committee noted that General Direction 0001 sets out the requirements for giving and receiving money or other benefits in respect to any import of gametes or embryos from outside the UK. Parts 12 and 13 provide as follows:

Part 12

When considering whether to import gametes donated overseas, the centre should ensure the donor has not received compensation which exceeds:

- (a) *reasonable expenses incurred by the donor in connection with the donation of gametes provided to that centre; and*
- (b) *loss of earnings (but not for other costs or inconveniences) incurred by the donor up to a daily maximum of £61.28 but with an overall limit of £250 for each course or cycle of donation (local currency equivalent).*

Part 13

2.6. When receiving donated gametes from overseas, the centre must keep a record (provided by the overseas centre) of:

- (c) *the actual expenses incurred by the donor;*
- (d) *the amount reimbursed to the donor; and*
- (e) *the receipts produced by the donor, and/or the steps taken by the person responsible to satisfy themselves that the excess expenses claimed by the donor have in fact been incurred.*

2.7. The committee noted that the HFEA's requirements on donor compensation aim to balance the desire to treat donors fairly with the need to avoid a financial inducement to donate. The fundamental principle is that donation must be altruistic in nature. Donor compensation limits for UK donors are different from those that apply in respect of overseas donors. General Direction 0006 sets out the requirements that must be met before gametes can be imported into the UK.

3. Decision

3.1. The committee had regard to:

- HFEA General Directions 0001
- HFEA General Directions 0006
- The Human Rights Act 1998:
 - Article 8 - respect for private and family life
 - Article 12 - right to marry and found a family

3.2. 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. Section 4(1)(a) and (b) of the 1990 Act state that 'No person shall store any gametes, or – in the course of providing treatment services for any woman, use.... (iii) the eggs of any other woman.. except in pursuance of a licence'. The committee noted that the ongoing storage and use of these imported donor eggs and embryos created using these gametes to treat patients is currently not 'in pursuance of' the clinic's licence and as such cannot take place lawfully. Special Directions to enable the simultaneous import and export of the embryos was being sought in order to rectify the position.

Eggs donated from ManorIVF Cyprus and Ukraine

3.3. In relation to Special Directions for the export of the donor eggs originally received from Cyprus and Ukraine, the committee noted that the donors involved in producing these eggs for donation would have undergone an invasive procedure to extract these eggs and although the committee agreed that they could not be lawfully used in the UK, they could be used for patients elsewhere and this was a more favourable option rather than allowing them to perish.

Embryos created using donor eggs from ManorIVF Cyprus and Ukraine

3.4. The committee considered whether a refusal to make Special Directions for the export and simultaneous import of the embryos would be an interference with the patients' rights under Articles 8 and/or 12 of the European Convention on Human Rights and whether such interference would be justified and proportionate. The committee decided that refusal is likely to amount to interference which is not justified or proportionate for the following reasons:

Embryos created using donor eggs from ManorIVF Cyprus and Ukraine:

- patients have consented in good faith to treatment using donor eggs to create a family and it was presumably unknown to them that these eggs were imported unlawfully from ManorIVF located in Cyprus and Ukraine. These embryos are essential to the patients' treatment. The committee considered that a refusal to allow these embryos to be simultaneously (but notionally) exported to Cyprus and Ukraine and imported back to the UK for patients' use would not be proportionate in this case and would have a huge impact on the patients concerned. A refusal, which would impact on their rights to family life and to found a family, could not be justified in the circumstances.

3.5. The committee concluded that, taking all the factors into account, the current case involves a highly exceptional set of circumstances and agreed to issue Special Directions to allow the transaction of gametes and embryos listed at paragraph 1.1 (details of gamete providers listed in Annex 1).

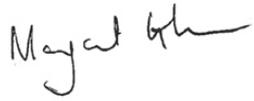
3.6. The committee noted the requirement to obtain written consent for the embryos being imported/exported. Given that this is a notional exercise and the embryos will not actually be leaving their current place of storage, the committee agreed that compliance with these conditions was not required.

3.7. The committee considered that granting Special Directions for these applications, would be in the best interests of the patients affected in this exceptional case and would not set an undesirable precedent which would undermine the imperative requirements identified.

4. Chairs 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".

Name

Margaret Gilmore

Date

19 December 2018