

Executive Licensing Panel - minutes

Centre 0077 (Regional Fertility Centre, Belfast)

Licence Extension application

Monday, 2 November 2020

HFEA Teleconference Meeting

Panel members	Clare Ettinghausen (Chair) Dina Halai Yvonne Akinmodun	Director of Strategy and Corporate Affairs Scientific Policy Manager Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers		

Declarations of interest

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

The panel had before it:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

1. Consideration of application

- 1.1. The panel considered the papers, which included a completed application form and Executive summary.
- 1.2. The panel noted that the Regional Fertility Centre, Belfast has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. Other licensed activities at the centre include storage of gametes and embryos.
- 1.3. In response to UK measures to contain and mitigate the spread of the Covid-19 coronavirus, a decision was taken by the HFEA to suspend all inspections of licensed premises until at least 1 November 2020.
- 1.4. The panel noted that HFEA licensed premises should be inspected every two years (Schedule 3B paragraph (4)(1)). The suspension of inspections impacts on the Authority's legal duties to carry out its regulatory functions. This action has been agreed with the Authority.
- 1.5. The panel noted that the HFEA normally issues licences for treatment and/or storage for a duration of up to four years but can issue a licence for five years (Schedule 2 paragraph 1(5) of the HF&E Act 1990).
- 1.6. In light of the current suspension of inspections, due to Covid-19, centre 0077 has applied to extend their licence by one year; the current licence expires on 31 March 2021.
- 1.7. The panel noted that the centre was last inspected on 19 February 2020 and recommendations were made in relation to three major and two 'other' areas of non-compliance. The Person Responsible (PR) has provided evidence that all the recommendations were implemented to the satisfaction of the inspection team. After a request from the executive, further evidence that the implementation of the recommendations remains effective, has recently been provided by the PR.
- 1.8. The panel noted that the executive is satisfied that;
 - the PR has discharged their responsibility under section 17 of the Act;
 - the centre has followed professional body guidance to suspend all non-essential activity in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services;
 - the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
 - there have been no serious (Grade A) incidents since the last inspection;
 - the centre has suitable procedures in place to continue to support patients.
- 1.9. The executive recommends the approval of the application to vary the centre's treatment and storage licence, extending the duration to 31 March 2022, without additional conditions.
- 1.10. The panel noted that centre 0077 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to section 24(4AD). Such certificates are generally synchronised to the centre's HFEA licence. The executive therefore recommends the extension of the centre's ITE import certificate in line with the centre's licence.

2. Decision

- 2.1. The panel was satisfied that;
 - the PR has discharged their responsibility under section 17 of the Act;
 - the centre has followed professional body guidance to suspend all non-essential activity in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services;

- the centre continues to manage the storage of gametes, embryos and patient records appropriately during this period;
- there have been no serious (Grade A) incidents since the last inspection;
- the centre has suitable procedures in place to continue to support patients.

2.2. The panel endorsed the executive's recommendation to vary the centre's treatment and storage licence, extending the duration to 31 March 2022, without additional conditions.

2.3. The panel endorsed the executive's recommendation to extend the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

6 November 2020