

Executive Licensing Panel - minutes

Centre 0157 (Assisted Reproduction and Gynaecology Centre)

Executive Update – Application to Vary and Revoke a Licence

Tuesday, 9 April 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen Chair) Richard Sydee Niamh Marren	Director of Strategy and Corporate Affairs Director of Finance and Resources Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Dina Halai Danielle Vincent	Licensing Manager Scientific Policy Manager Communications Manager

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. Background

- 1.1.** The panel noted the application made under s18A(2)(a) of the Act, to bring forward the start date of the licence that was issued to the Assisted Reproduction and Gynaecology Centre in 2018, but which has yet to come into effect. This would be done in order to align the centre's start date with two other centres in the same group. If this variation is agreed, an application is made to revoke the extant licence to ensure this administrative process can take place.
- 1.2.** The panel noted that there is one Person Responsible (PR) for three HFEA licenced fertility centres, London Fertility Centre (centre 0088), Assisted Reproduction and Gynaecology Centre (ARGC) (centre 0157) and Reproductive Genetics Institute (centre 0206). The start and end dates for the licences are provided below –
- Centre 0088 London Fertility Centre:
L-0088-19-a commenced on 01/09/2018 and expires on 31/08/2022
 - Centre 0206 Reproductive Genetics Institute:
L-0206-12-a commenced on 04/05/2018 and expires on 03/05/2022
 - Centre 0157 Assisted Reproduction and Gynaecology Centre:
L-0157-27-a commenced on 01/07/2016 and expires on 30/06/2019. A new licence, L0157-28-a, was granted in 2018 to commence on 01/07/2019 and expire on 30/06/2023
- 1.3.** The panel noted that the centres were inspected on 23, 24 and 25 January 2018 following which a recommendation was made for all three licences to be renewed. However, when the new licences were granted by the Executive Licensing Panel (ELP), the usual practice was followed of issuing the new licence with a valid from date following on from the expiry date of the old one.
- 1.4.** The panel noted the implications for this. Firstly, following the previous renewal in 2016, ARGC was granted a three-year licence which is only due to expire on 30 June 2019. Although the ELP took a decision in July 2018 to grant the clinic a four-year licence, that licence is only due to come into effect in July 2019 when the extant licence expires meaning that until then, the clinic has, in its view, a less than ideal four-star rating on the centre's entry on the Choose a Fertility Clinic page on the HFEA website.
- 1.5.** Secondly, as the end date of each licence to a large degree determines each clinic's inspection schedule it puts the requirement to inspect centre 0157 on a different inspection cycle to centres 0206 and 0088. As such, whilst the next inspections could be carried out together (at the interim stage – in early 2020), full (renewal) inspections to support an application for the renewal of licences of centre 0088 and 0206 must be carried out in early 2022, together with a further interim inspection of centre 0157 at the same time (to meet the HFEA statutory obligation to inspect at intervals of no more than two years). A further, full renewal, inspection would have to be carried out in early 2023 to support the renewal of the licence for centre 0157. This obviates the benefits of the arrangements agreed with the PR in 2018 to reduce the inspection burden.
- 1.6.** The panel noted that in order to align all three licences, the steps below are proposed:
- Licence of centre 0157 ARGC L-0157-28-a which was granted to run from 01/07/2019 to 30/06/2023 is varied under section 18A(2)(a) to bring forward its start date. It is recommended that the licence commences as soon as possible and expires on 31 August 2022, that is in line with the licence of centre 0088 (London Fertility Centre). This would vary the licence to a term less than four years, for the purpose simply of aligning this licence term with the other two.

- If ELP grants the licence in line with the above recommendation, to avoid there being two licences running at the same time for centre 0157, the PR makes application under section 18(1)(a) for the revocation of the current licence (L- 0157-27-a).

2. Consideration of application

- 2.1.** The panel considered the papers, which included an executive update and licensing minutes for the last three years.
- 2.2.** The panel noted that the executive recommended the following actions:
- To vary the new licence of centre 0157, L-0157-28-a, to commence as soon as possible and align with the expiry of licence L-0088-19-a, ending on 31 August 2022.
 - On the basis that the recommendation above is accepted by the Panel for it to then revoke licence L-0157-27-a.
 - To confirm that detailed consideration of the centre's application and inspection report was undertaken in July 2018 by the ELP, and a licence with a term of four years was granted. As such the star rating attached to centre 0157 (in the HFEA Choose a Fertility Clinic site) can be amended to a '5 star rating'.
 - The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence, Centre 0157 has an ITE import certificate. The inspectorate recommends the renewal of this centre's ITE import certificate in line with the centre's licence.


3. Decision

- 3.1.** The panel endorsed the inspectorate's recommendations and agreed the below:
- To vary the new licence, L-0157-28-a, to commence as soon as possible and align with the expiry of licence L-0088-19-a and end on 31 August 2022.
 - To revoke licence L-0157-27-a at the same time that licence L-0157-28-a becomes active.
 - Confirmed that detailed consideration of the centre's application and inspection report was undertaken in July 2018 by the ELP, and a licence with a term of four years was granted. The panel agreed that the star rating attached to centre 0157 (in the HFEA Choose a Fertility Clinic site) can be amended to a '5 star rating'.
 - To renew the centre's ITE import certificate in line with the centre's licence.

4. Chair's signature

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

Signature



Clare Ettinghausen

Date

15 April 2019

**Executive Summary for Executive Licensing Panel
9 April 2019**

Centre number	0157
Centre name	Assisted Reproduction and Gynaecology Centre (ARGC)
Person Responsible	Mr Mohamed Taranissi

Application to vary, and revoke, a licence

Background

1. This is an application made under s18A(2)(a) of the Act, to bring forward the start date of the licence that was issued to the Assisted Reproduction and Gynaecology Centre in 2018 but which has yet to come into effect and if this variation is agreed, an application is made to revoke the extant licence. The background and reasons for these applications are set out in more detail below.
2. Mr Taranissi is the PR for three HFEA licenced fertility centres, 0088 London Fertility Centre; 0157 Assisted Reproduction and Gynaecology Centre (ARGC); and 0206 Reproductive Genetics Institute.

The start and end dates for each of the three licences are as follows:

- Centre 0088 London Fertility Centre:
L-0088-19-a commenced on 01/09/2018 and expires on 31/08/2022
 - Centre 0206 Reproductive Genetics Institute:
L-0206-12-a commenced on 04/05/2018 and expires on 03/05/2022
 - Centre 0157 Assisted Reproduction and Gynaecology Centre:
L-0157-27-a commenced on 01/07/2016 and expires on 30/06/2019
New licence L0157-28-a granted in 2018 (offer accepted) to commence on 01/07/2019 and expire on 30/06/2023
3. The centres were inspected on 23, 24 and 25 January 2018 following which a recommendation was made for all three licences to be renewed. The intention had been to use this as an opportunity to align all three licences ensuring that they were all valid from and expired on the same date, or at around the same time. This undertaking was given by Nick Jones following discussions with the PR in 2018. However, when the new licences were granted by ELP, the usual practice was followed of issuing the new licence with a valid from date which follows on from the expiry date of the old one.

4. The implications of this are several. Firstly, following the previous renewal in 2016, ARGC was granted a three-year licence which is only due to expire on 30 June 2019. Although the ELP took a decision in July 2018 to grant the clinic a four-year licence, that licence is only due to come into effect in July 2019 when the extant licence expires meaning that until then, the clinic has, in its view, a less than ideal three-star rating on the centre's entry on the Choose a Fertility Clinic page on the HFEA website.
5. Secondly, as the end date of each licence to a large degree determines each clinic's inspection schedule it puts the requirement to inspect centre 0157 on a different inspection cycle to centres 0206 and 0088. As such, whilst the next inspections could be carried out together (at the interim stage – in early 2020), full (renewal) inspections to support an application for the renewal of licences of centre 0088 and 0206 must be carried out in early 2022, together with a further interim inspection of centre 0157 at the same time (to meet the HFEA statutory obligation to inspect at intervals of no more than two years). A further, full renewal, inspection would have to be carried out in early 2023 to support the renewal of the licence for centre 0157. This obviates the benefits of the arrangements agreed with Mr Taranissi in 2018 to reduce the inspection burden.
6. In order to align all three licences, the following steps are proposed:
 - a. Licence of centre 0157 ARGC L-0157-28-a which was granted to run from 01/07/2019 to 30/06/2023 is varied under section 18A(2)(a) to bring forward its start date. It is recommended that the licence commences as soon as possible and expires on 31 August 2022, that is in line with the licence of centre 0088 (London Fertility Centre). This would vary the licence to a term less than four years, for the purpose simply of aligning this licence term with the other two.
 - b. If ELP grants the licence in line with the above recommendation, to avoid there being two licences running at the same time for centre 0157, the PR makes application under section 18(1)(a) for the revocation of the current licence (L-0157-27-a).

Recommendation

To put this into effect, the inspectorate recommends the following:

- a. To vary the new licence, L-0157-28-a, to commence as soon as possible and align with the expiry of licence L-0088-19-a and to end on 31 August 2022.
- b. On the basis that the recommendation above is accepted by the Panel for it to then revoke licence L-0157-27-a.
- c. To confirm, that detailed consideration of the centre's application and inspection report was undertaken in July 2018 by the Executive Licensing Panel of the HFEA, and a licence with a term of four years was granted. As such the star rating attached to centre 0157 (in the HFEA Choose a Fertility Clinic site) can be amended to a '5 star rating.'

- d. The HF&E Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018 (the '2018 Regulations'), to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence, Centre 0157 has an ITE import certificate. The inspectorate recommends the renewal of this centre's ITE import certificate in line with the centre's licence.

Polly Todd
Senior Inspector