

# Minutes of Authority meeting 14 November 2018

## Strategic delivery:

Safe, ethical  
effective  
treatment

Consistent  
outcomes and  
support

Improving standards  
through intelligence

## Details:

Meeting

Authority

Agenda item

2

Paper number

HFEA (30/01/19) 900

Meeting date

30 January 2019

Author

Catherine Burwood, Senior Governance Manager

## Output:

For information or  
decision?

For decision

Recommendation

Members are asked to confirm the minutes as a true and accurate record of the meeting.

Resource implications

Implementation date

Communication(s)

Organisational risk

Low

Medium

High

Annexes

## Minutes of the Authority meeting on 14 November 2018 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Andy Greenfield Anthony Rutherford Bobbie Farsides Emma Cave	Gudrun Moore Kate Brian Rachel Cutting Ruth Wilde Yacoub Khalaf
Apologies	Anne Lampe Anita Bharucha Jonathan Herring	
Observers	Steve Pugh (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Nick Jones Richard Sydee Catherine Drennan	Helen Crutcher Joanne Anton Laura Riley Lisa Whiting
Other attendees	Gavin Ellison (YouGov) Melanie Nicholls (YouGov)	

### Members

There were 11 members at the meeting; seven lay members and four professional members.

## 1. Welcome, apologies and declarations of interest

- 1.1. The Deputy Chair opened the meeting by welcoming Authority members and members of the public to the sixth meeting of 2018. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.
- 1.2. Apologies were received from Anne Lampe, Anita Bharucha and Jonathan Herring.
- 1.3. Declarations of interest were made by:
  - Anthony Rutherford (Clinician at a licensed centre)
  - Rachel Cutting (Clinician at a licensed centre)
  - Yacoub Khalaf (Clinician at a licensed centre)

## 2. Minutes of Authority meeting held on 12 September 2018

- 2.1. Members agreed the minutes of the meeting held on 12 September 2018 for signature by the Chair of the meeting.

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### 3. Chair's report

- 3.1. The Chair welcomed new Authority member, Professor Emma Cave, who joined the HFEA on 1 October 2018. The Chair explained that recruitment for a member from a faith background was being undertaken and it was hoped there would be an appointment agreed early in the new year. As usual the appointment process was being led by the Department of Health and Social Care (DHSC).
- 3.2. The Chair reminded members that this was the last Authority meeting for Dr Andy Greenfield, who joined the Authority in 2009 and whose term of appointment would end on 31 December 2018. The Chair thanked Dr Greenfield for his contributions to the Authority, the Licence Committee, which he chaired, and the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 3.3. On 19 September the Chair attended the first Royal Institution Trustee Supper Club to participate in an event on establishment of new technologies.
- 3.4. On 31 October the Chair attended a networking lunch with members of the Association of Fertility Patient Organisations (AFPO) and the Professional Organisations Stakeholder Group (PSG).
- 3.5. The Chair advised members that on 7 November the HFEA held the first of two leadership event for PRs, in London. Another event would take place in Manchester next week. Over 60 PRs attended and feedback suggests that the event was a great success.

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### 4. Chief Executive's report

- 4.1. The Chief Executive and Senior Management team attended the Department of Health and Social CARE (DHSC) and HFEA quarterly accountability meeting on 21 September.
- 4.2. On 1 October, together with the Director of Strategy and Corporate Affairs, the Chief Executive met the joint chairs of the Fertility Fairness campaign, Sarah Norcross and Aileen Feeney.
- 4.3. On 3 October the Chief Executive met representatives from other non-economic regulators to discuss whether there would be merit in working more closely together on common issues, such as good regulatory practice or talent management.
- 4.4. The Chief Executive attended the London leadership event for PRs on 7 November.

#### Press Coverage

- 4.5. The Chief Executive covered some of the main topics of enquiry and interest for this period:  
**Daily Mail reporting of some clinics offering sex selection**
- 4.6. Following a report by the Daily Mail the HFEA were looking into this matter. The Director of Compliance would provide an update on the progress of investigations into the allegations later in the meeting.

### Treatment add-ons

- 4.7.** The Chief Executive provided information about an article in the Guardian which had been written about the draft consensus statement on treatment add-ons.

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## 5. Committee Chairs' reports

### Licence Committee

- 5.1.** The Chair of the Licence Committee provided the members with an update on the 6 September meeting, now that the minutes were finalised.
- 5.2.** At this meeting the committee approved two research renewal applications and two treatment and storage licence renewal applications. The committee also considered and noted two executive updates and one grade A incident report.
- 5.3.** The Chair of the Licence Committee reported that the committee had last met on 8 November.
- 5.4.** The committee considered 11 items: six research renewal applications; one treatment and storage licence renewal application; one application to vary premises; one application to vary the PR; one application to vary the licence holder; and one executive update. The minutes were not signed yet so the Chair of the committee could not provide details of the decisions made.

### Statutory Approvals Committee

- 5.5.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 27 September and 25 October.
- 5.6.** In September the committee considered seven items: two mitochondrial donation applications and five pre-implantation genetic diagnosis (PGD) applications. All applications were approved.
- 5.7.** In October the committee considered eight items: three mitochondrial donation applications and five PGD applications. The minutes were not signed yet so the Chair of SAC could not provide details of the decisions made.
- 5.8.** At this meeting the committee also considered a paper regarding the outcome of the recently completed PGD review. The Chair of SAC provided the members with the background around this piece of work and the outcomes of it.

### Executive Licensing Panel

- 5.9.** The Chair of the Executive Licensing Panel (ELP) advised members that the Panel had met five times since the last Authority meeting, on: 11 September, 26 September, 10 October, 24 October and 8 November.
- 5.10.** The panel considered 21 items in total: two initial treatment and storage licence applications; four licence renewal applications; five interim inspection reports; eight licence variation application; one executive update; and one application for special directions. 20 applications were approved, and the executive update was noted.

- 5.11.** The Chair of ELP reported that the Licensing Officer had considered 68 items: 65 importing tissue establishment (ITE) certificate applications and three applications to change licence holder.

### **Audit and Governance Committee**

- 5.12.** The Deputy Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 9 October 2018.
- 5.13.** Aside from the usual standing items and updates from internal and external audit, the committee received reports on: General Data Protection Regulation; a Digital Programme update; resilience, business continuity management and cyber security; an estates update; the risk policy; the strategic risk register; Brexit; legal risks; whistle blowing and fraud; and contracts and procurement.
- 5.14.** The Chief Executive reported that more information about Brexit would be reported in January 2019.

### **Scientific and Clinical Advances Advisory Committee**

- 5.15.** The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) reported that the committee had met on 15 October 2018.
- 5.16.** The committee considered items on the following topics: intrauterine culture; treatment add-ons; and alternative methods to derive embryonic and embryonic-like stem cells.

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## **6. Performance report**

- 6.1.** The Chief Executive began by providing members with an update about staffing and resources, stating that the number of leavers was still higher than wished. The staff survey had recently been completed and the results would be considered at the upcoming staff away day in December.
- 6.2.** The Director of Compliance and Information provided the members with an update about the sex selection investigation being undertaken in response to a Daily Mail article. The members heard that it had been determined that there had been no breach of law in the UK, but that the HFEA was exploring UK clinics' and clinicians' associations with clinics abroad.
- 6.3.** The Director of Compliance and Information also provided an update about the data submission system (PRISM) and data migration to support this.
- 6.4.** The Director of Strategy and Corporate Affairs provided members with information about the implementation of the next version of the Code of Practice, which was still with the DHSC for approval from the Secretary of State.
- 6.5.** The Director of Strategy and Corporate Affairs also provided information about the State of the Sector report; two private members bills that were going through Parliament; and Fertility Awareness Week, which ran from 29 October to 4 November.
- 6.6.** In relation to Fertility Awareness Week, the Chair expressed concerns over some of the exhibitors present at the London Fertility Show. An alternative fertility day which would

be held at the Royal College of Obstetricians and Gynaecologists (RCOG) would take place in March 2019 and the Chair urged patients to take note of this.

- 6.7.** The Director of Finance and Resources provided members with information on the financial forecast. Members heard that the HFEA had a larger than anticipated surplus, and that we were also ahead of our full-year forecast. The members heard that the HFEA will look to utilise this emerging position in a practical way.
- 6.8.** The Director of Finance and Resources also reported that, following meetings with the DHSC in November, further news regarding estates should be available in the new year.

### Decision

- 6.9.** The members noted the latest performance report.

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## 7. National Patient Survey

- 7.1.** The Chair welcomed two representatives from YouGov, Gavin Ellison and Melanie Nicholls, to the meeting, following which the Director of Strategy and Corporate Affairs introduced this item regarding the recently completed National Fertility Patient Survey.
- 7.2.** The Research Manager provided the members with background about why the Executive decided to conduct this work and the subsequent approach that was taken.
- 7.3.** Following a competitive tender process, YouGov were appointed to conduct the survey. They delivered the project overseen by an internal working group, which included two Authority members.
- 7.4.** The YouGov representatives explained the methodology used for the survey. Qualitative research was conducted via focus groups and in-depth interviews, which fed in to the development of the quantitative survey. This was carried out between 3 September and 2 October 2018. 1,017 patients or partners responded.
- 7.5.** The YouGov representatives outlined the findings of the survey. This included information on the following topics: routes to finding treatment; the patient experience of treatment; treatment add-ons and transparency of costs; overall experience; and familiarity with the HFEA.
- 7.6.** The key findings found related to the following areas:
- The role of GPs
  - The detail of treatment planning
  - Feeling comfortable asking questions and the desire for doctors' notes/audio recording of consultations.
  - Interest shown to patients and partners "as a person"
  - The role of counselling in impacting overall experiences
  - Small changes that could positively impact dignity and respect for patients
  - The coordination of administration of treatment

**7.7.** The Research Manager outlined the next steps, including the publication of the report and using the findings to feed into future HFEA work.

**7.8.** The Authority was asked to:

- Note the results of the national patient survey
- Comment on the strategic implications for the Authority

### Decision

**7.9.** The members noted and discussed the results of the survey.

**7.10.** The members raised questions and discussed areas including assessing the quality of counselling and non-medical treatment add-ons, such as acupuncture. The members heard that it would be possible to interrogate the survey data further to determine areas the HFEA could look into and to drive future strategic planning.

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## 8. Business plan 2019/20 – full draft

**8.1.** The Risk and Business Planning Manager introduced this item and reminded members that the Authority approved an outline of the business plan for 2019-2020 in September.

**8.2.** Members were presented with the full draft of the business plan, in readiness for submission to the DHSC.

**8.3.** The draft business plan set out key activities for 2019/20, which would take the HFEA to the end of its current strategy period. The Risk and Business Planning Manager explained that some sections of the business plan would be written later in the business year for practical reasons, so the document would continue to be a work in progress.

**8.4.** The members were asked to approve the draft business plan for 2019/20, for submission to the DHSC and for further development.

**8.5.** The members were also advised that a near-final version of the business plan would be presented at the March 2019 Authority for sign-off, prior to publication.

### Decision

**8.6.** The members agreed to approve the current draft of the 2019/20 business plan.

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## 9. Donor conceived register

**9.1.** The Chief Executive introduced this item which outlined several deliverable options that had been identified to provide a new service for the donor conceived register (DCR) and new counselling/support services in relation to opening the register (OTR) requests. The Chief Executive advised the members that the options presented did not indicate the limit of possibilities available for this work.

**9.2.** The Policy Manager explained that four distinct approaches had been identified and provided details of the key considerations that had been taken into account when doing so.

**9.3.** The Policy Manager described the possible options, stating that option 3 had received the highest score when assessing the service qualities of each possible approach.

- 9.4.** The Authority was asked to consider the four approaches and agree a preferred approach, to be implemented by March 2019 when the current service would end.

### Option 1

- 9.5.** Option 1 was to work with direct to consumer DNA testing and matching websites, with counselling provision delivered by the HFEA.
- 9.6.** This option presented the greatest likelihood of donors and donor conceived people finding genetic matches and was the lowest resource option for the HFEA.
- 9.7.** However, this option would risk disclosing the identity of a donor or donor conceived person without consent.

### Option 2

- 9.8.** Option 2 was for the DCR and counselling provision to be delivered by the HFEA.
- 9.9.** This option was favoured by some DCR registrants who trust the HFEA to provide a high quality service. However, we do not have the necessary skill set or structure in place to deliver this. Similarly, the HFEA has no experience in dealing with genetic test results.
- 9.10.** This was also the most expensive option.

### Option 3

- 9.11.** Option 3 was for the end-to-end service to be provided by an external provider (GeneHealthUK; The National Fertility Service; the Hewitt Fertility Centre's counselling team; or Rafan House).
- 9.12.** Most of these providers would have infrastructure already in place and were open to recruiting additional staff where necessary. Some also have relationships with genetic laboratories, and experience of providing test results or telephone helplines.

### Option 4

- 9.13.** Option 4 was a mixed model, with the DCR run by an external provider and counselling provision overseen by the HFEA.
- 9.14.** Whilst this option would overcome the challenge of using an agency without direct experience of specialist counselling, the Policy Manager explained that it may not be as user friendly, as it would require people to potentially contact two organisations for support.

### Decision

- 9.15.** Members noted the importance of these services, but recognised that the counselling service would potentially only be required for very small numbers of people.
- 9.16.** Members also noted concern about the March 2019 deadline, although it was not possible to extend this.
- 9.17.** It was agreed that the executive should explore all options further, taking note of the suggestions and points raised by members.



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## 10. Strategic risk register

- 10.1.** The Risk and Business Planning Manager presented the latest edition of the strategic risk register.
- 10.2.** The strategic risk register was last reviewed by AGC on 9 October and by the Senior Management Team (SMT) on 29 October.
- 10.3.** The Risk and Business Planning Manager reported that currently one risk was rated as high (capability), and one risk (cyber security) was above tolerance.
- 10.4.** The Risk and Business Planning Manager explained that the HFEA defines risk appetite as the general level of risk that we are willing to accept, as opposed to risk tolerance, which is the particular level we are willing to accept in relation to specific risks. The members heard that the statement on risk appetite had not been reviewed by the Authority for some time. It was good practice to confirm this periodically.
- 10.5.** The Authority was asked to:
- Note and comment on the latest edition of the strategic risk register.
  - Discuss and agree the current appetite of the Authority to risk, as outlined at section 2.3 of the risk policy.

### Decision

- 10.6.** Following discussion, the members confirmed the current low appetite of the Authority to risk as outlined at section 2.3 of the risk policy.

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## 11. Consensus statement on treatment add-ons

- 11.1.** The Head of Regulatory Policy presented a paper on innovative treatments used in fertility, explaining that the responsible use of such treatment add-ons had been an issue of concern to the HFEA and many in the fertility sector for some time.
- 11.2.** In September 2017 it was agreed that a working group composed mainly of professional and patient organisations would be set up to develop a consensus statement on the responsible use of treatment add-ons.
- 11.3.** The working group met for the first time in March 2018, and agreed that the HFEA should put together a first draft of the statement.
- 11.4.** The first draft was circulated in August 2018 and, based on feedback, a second draft was developed. The second draft was discussed at a further working group meeting in October 2018. No substantive changes were made and final comments were agreed via email.
- 11.5.** The Head of Regulatory Policy provided information about plans for dissemination and publication of the final statement, as agreed at the October working group meeting. This included publication on all signatories' websites, conveying necessary messages at the HFEA's Leadership events in November 2018 and discussion at the HFEA's 2019 annual conference.

- 11.6.** Future HFEA inspections will also include a checklist seeking information from clinics about what add-ons they offer and how these are presented to patients. This will be supported by workshops for clinics, being held in 2019, around the key consensus statement principles.
- 11.7.** The Head of Regulatory Policy explained that it was hoped that agreement on the final text of the consensus statement would be reached by the end of November 2018. Members had received a draft version of the text in their papers.
- 11.8.** The Authority was asked to note:
- that the consensus statement aims to support partnership working by signatories towards the responsible use of treatment add-ons in fertility services.
  - that the HFEA will continue to monitor the use of add-ons in use in clinics via inspection and other methods and that the consensus statement is likely to inform future work by the HFEA towards supporting the aims of the statement.
  - the plans for dissemination and publication of the consensus statement.

#### Decision

- 11.9.** The members noted the above points, and positively acknowledged the progress that had been made to date.

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## 12. Any other business

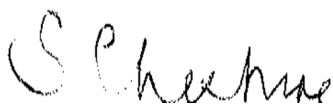
- 12.1.** There was no further business discussed.

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## 13. Chair's signature

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

### Signature



**Chair: Sally Cheshire**