

Minutes of Authority meeting 13 March 2019

Strategic delivery:

Safe, ethical
effective
treatment

Consistent
outcomes and
support

Improving standards
through intelligence

Details:

Meeting Authority

Agenda item 2

Paper number HFEA (08/05/19) 913

Meeting date 8 May 2019

Author Catherine Burwood, Licensing 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 13 March 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Kate Brian Emma Cave Rachel Cutting	Bobbie Farsides Jonathan Herring Anne Lampe Gudrun Moore Ruth Wilde
Apologies	Yacoub Khalaf Anthony Rutherford	
Observers	Dafni Moschidou (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Helen Crutcher Dina Halai Dan Howard Paula Robinson

Members

There were 11 members at the meeting; eight lay members and three professional members.

1. Welcome, apologies and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the second meeting of 2019. 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 Yacoub Khalaf and Anthony Rutherford.
- 1.3. Declarations of interest were made by:
 - Rachel Cutting (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 30 January 2019

- 2.1. Members agreed the minutes of the meeting held on 30 January 2019 for signature by the Chair of the meeting.

3. Chair's report

- 3.1. The Chair welcomed member Jonathan Herring back, following a short illness.
- 3.2. The Chair announced that the Authority had recruited a new member, Reverend Ermal Kirby, whose term of office would start on 1 May 2019.

- 3.3.** On 31 January, the Chair and Chief Executive met Jackie Doyle-Price MP, Minister in the Department of Health and Social Care, to discuss the provision of IVF in the NHS in England, including commissioning guidance and benchmark pricing.
- 3.4.** On 27 February, the Chair, Chief Executive and Authority member Yacoub Khalaf met Siobhain McDonagh MP to discuss a private members Bill. The Chair reported that the Bill's second reading in Parliament was scheduled for late March.
- 3.5.** On 4 March, the Chair and Chief Executive met Lord Lindsay, Chair of the United Kingdom Accreditation Service (UKAS). They discussed how to continue to build on their close working relationship and the creation of a memorandum of understanding between the HFEA and UKAS.
- 3.6.** On 8 March, the Chair led a Remuneration Committee.

4. Chief Executive's report

- 4.1.** On 4 February, the Chief Executive attended the Scientific and Clinical Advances Advisory Committee (SCAAC).
- 4.2.** On 8 March, the Chief Executive attended the Remuneration Committee.
- 4.3.** The Chief Executive reported that, along with the Chair and Head of Human Resources, he had interviewed candidates for the role of Director of Compliance and Information. Members would be updated about the outcome of this in due course.
- 4.4.** On 13 February, the Chief Executive attended a leadership development day along with the rest of the Corporate Management Group. This was followed up with an away day on 6 March.
- 4.5.** On 14 February, the Chief Executive spoke at a graduation event for the Health and Care Leaders Scheme for Aspiring Directors programme.
- 4.6.** The Chief Executive advised members that much of his time had been spent on activity related to the UK's planned exit from the EU. The Chief Executive would update members on EU exit later in the meeting.
- 4.7.** The Chief Executive finally reminded members of the new date for the HFEA's annual conference: 13 June 2019.

5. Committee Chairs' reports

Licence Committee

- 5.1.** The Chair of the Licence Committee provided an update regarding the 10 January meeting, the minutes of which were now approved. The committee approved two licence renewal applications; noted an Executive update regarding a previous grade A incident; approved the continuation of one licence following an interim inspection and served final notices with regards to the revocation of a licence.
- 5.2.** The Chair reported that the committee had also met on 7 March 2019 and considered five items: two licence renewal applications; one interim inspection report; one licence variation application and one grade A incident report.

- 5.3.** The Chair advised the other members that the minutes were still being drafted.

Statutory Approvals Committee

- 5.4.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 31 January and 28 February.
- 5.5.** On 31 January the committee considered eight items: two mitochondrial donation applications; two pre-implantation genetic diagnosis (PGD) applications; three Special Directions applications and one human leukocyte antigen testing application which had previously been adjourned.
- 5.6.** All applications were approved with the exception of one Special Directions application which was adjourned. The Chair noted that all PGD applications related to multi-type conditions.
- 5.7.** On 28 February the committee considered five PGD applications and received a briefing from the external legal advisor on the Authority's policy position in relation to patient choice in mitochondrial donation applications.
- 5.8.** The Chair advised the other members that the minutes were still being drafted and provided an outline of the briefing received on patient choice in mitochondrial donation applications.

Executive Licensing Panel

- 5.9.** The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met twice since the last Authority meeting, on 12 February and 26 February.
- 5.10.** The panel considered seven items in total: two licence renewal applications; three interim inspection reports; one licence variation application and one application for Special Directions.
- 5.11.** All applications were granted with exception of one licence renewal application, which was adjourned.
- 5.12.** The Chair of ELP also reported that 11 Licensing Officer considerations had been completed. All were for the approval of Importing Tissue Establishment certificates.

Audit and Governance Committee

- 5.13.** The Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 5 March 2019.
- 5.14.** Aside from the usual standing items and updates from internal and external audit, the committee received reports on: register and regulatory management; the digital programme; finance; EU exit and the anti-fraud and whistleblowing policy, an update of which was approved.

Scientific and Clinical Advances Advisory Committee

- 5.15.** The Deputy Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) reported that the committee had met on 4 February 2019.
- 5.16.** The committee considered items on horizon scanning and high priority standing items such as mitochondrial donation and genome editing.

6. Performance report

- 6.1.** The Director of Strategy and Corporate Affairs provided members with information about the following areas: two private members bills currently going through Parliament; the HFEA annual conference; the Licensing Review Implementation project; EU exit; the Fertility Show; the Fertility Forum held at the Royal College of Obstetricians and Gynaecologists (RCOG); a joint British Fertility Society (BFS) study week programme on leadership; implementing the changes from the new Code Of Practice regarding treatment add-ons and patient support; and work being completed in relation to HFEA data and research support.
- 6.2.** The Director of Finance and Resources corrected errors in the projected year end variance for IT costs which was 332K, rather than 310K, over budget, presented in the Performance Report document and then went on to provide an update on the HFEA's financial position.
- 6.3.** The Chief Executive provided members with an update regarding the Compliance team, following the departure of the Director of Compliance and Information, and in the absence of the Chief Inspector who had been on long term sick leave. The Chief Executive thanked the team and Senior Inspectors for keeping work to a high standard.
- 6.4.** The Chief Executive invited the Chief Information Officer to provide an update on the digital programme. Members heard that progress was good regarding to the introduction of PRISM, the new data submission system, with a completion date expected at the end of March.
- 6.5.** Members heard that progress with data migration was slower, due to an issue relating to the tracking of data over time in the Register. Options to resolve the issue would be brought to AGC at the end of April.

Decision

- 6.6.** The members noted the latest performance report.
- 6.7.** The members discussed the current format of the performance report and whether it represented the risks the Authority should focus on. It was agreed that developing a performance report that could combine strategic and patient risks would be considered as part of the development of the next strategy.

7. Effective governance

- 7.1.** The Head of Planning and Governance explained that the Authority is committed to an annual review of governance arrangements, consisting of a self-review of each committee's effectiveness, and a review of standing orders.
- 7.2.** As minor changes to several committee terms of reference in the Standing Orders were agreed at the last Authority meeting, the Head of Planning and Governance presented a paper about the annual reviews of committee effectiveness.
- 7.3.** Members heard that this exercise was recently conducted by the Licence Committee, SAC, ELP and SCAAC.

7.4. The Head of Planning and Governance summarised the feedback received from committees, most of which was positive. Some improvement points were raised.

7.5. Positive feedback included:

- That roles and scope were clear
- The skills and knowledge in place
- Effective decision making at meetings
- Good committee support and papers
- Good quality Chairing
- The ability to have open discussions
- That a large and varied amount of business was handled well.

7.6. The main suggestions were:

- To consider for improvement the balance of business between the Licence Committee and ELP
- Scheduling and weighting of agendas
- Committee paper structures and consistency
- Enabling videoconferencing capability (which the members heard work was underway on).

7.7. The Authority was asked to note the feedback from the annual reviews of committee effectiveness.

Decision

7.8. Members noted and discussed the feedback from the annual reviews of committee effectiveness, and the action points for each committee.

7.9. The Chair gave thanks to the committees and the staff who support them, noting the variety of work that they are presented with.

8. Finance and business plan update 2019/20

8.1. The Director of Finance and Resources presented an update on the current financial and business plans for the 2019/20 business year.

Income forecasting

8.2. The Director of Finance and Resources provided an overview of the HFEA's funding streams, stating that 80% of funding comes from treatment fees.

8.3. The Director of Finance and Resources outlined the income forecast model assumptions, and members heard that the base assumption remained that the volume growth rate of 2% per annum would remain constant in the medium term.

8.4. The Director of Finance and Resources presented members with demographic data showing changes in conception rates and an increasing population of 35-45 year old

women. It was expected that demand for fertility treatment would remain static or to increase.

- 8.5.** Regarding economic factors, members heard that there were no directly observable economic trends that suggested a fall in demand for private IVF treatments over the next financial year.
- 8.6.** The Director of Finance and Resources outlined the choice between basing income planning on the trend of volume growth in treatment cycles, or to plan more prudently to ensure that, should we see a drop in treatment volumes, the HFEA will be able to meet it's financial commitments.
- 8.7.** Members heard that for planning purposes the budget was based on the lower 2018/19 assumption and that a conservative forecast had been developed.

2019/20 budget

- 8.8.** The Director of Finance and Resources went on to outline the 2019/20 budget and the assumptions that had fed into this: pay increases; maintaining a reserve against litigation of c£300k; IT system refreshes; and inflation in key external contracts and expenditure.
- 8.9.** Members heard that in budget planning the HFEA had chosen not to factor in a planned increase in employer pension contributions to the Civil Service Pension Scheme at this time, as this remained an area of ongoing negotiation between the Department of Health and Social Care (DHSC) and HM Treasury. However, the Director of Finance and Resources advised members that on the preceding Monday, it had been confirmed that HFEA contributions would increase by 2.5%, leaving a shortfall in budget of £70k.
- 8.10.** The Director of Finance and Resources presented members with the draft budget for 2019/20 which met all planned business delivery assumptions for the year and provided a buffer should treatment volumes drop.

Business plan 2019/20

- 8.11.** The Risk and Business Planning Manager explained that the content of the business plan for 2019/20, agreed in draft at the November 2018 meeting, had been further developed to add a looking back section, reviewing what had been achieved in 2018/19. In addition, year-end and EU exit content would also be added imminently.
- 8.12.** The Risk and Business Planning Manager noted that the activities related to our EU exit role would be reflected in the business plan, so that it was clear the HFEA would be maintaining the same standards and objectives following EU exit.
- 8.13.** Members heard how, due to wider uncertainties, the final business plan and budget was not brought to this Authority meeting for sign off. Confirmation was being sought from DHSC regarding the process for departmental sign-off.
- 8.14.** Given these circumstances, it was proposed that we await the remaining content, add year-end data, and circulate for Authority sign off via email.

8.15. The Authority was asked to:

- Note the assumptions behind the 2019/20 income and expenditure forecasts.
- Note the unusual circumstances around business plan sign-off this year and the imminent addition of further content related to EU exit and year-end.
- Agree to review and sign off further content via email, though any major revisions to previously agreed content will be brought before the Authority at its May meeting.
- Agree that DHSC sign-off of the business plan and the associated budget according to their timetable, after which the business plan will be published on our website.

Decision

8.16. Members noted the assumptions behind the 2019/20 income and expenditure forecasts but expressed concerns that too cautious an approach was being taken. Members discussed the possibility that any underspend be used to fund patient focused projects and to recruit a limited amount of new staff to help with capacity issues. The Chief Executive would discuss resources with the DHSC in the immediate term.

8.17. The members noted the unusual circumstances around business plan sign-off and the imminent addition of further content related to EU exit and year-end, and agreed to approve the draft business plan via email, or to consider further information in May if there were any further developments.

8.18. Members also agreed to DHSC sign-off of the business plan and the associated budget according to their timetable, after which the business plan would be published on the HFEA website.

9. EU Exit

9.1. The Chief Executive presented members with a verbal update regarding the UK's exit from the EU, providing an overview of activity to date and the different legal and operational preparations taking place.

Decision

9.2. Members noted the update on EU exit.

10. Strategy development

10.1. The Head of Planning and Governance presented a paper about the emerging shape of the 2020-2023 strategy, due to be launched in April 2020, and proposals for consultation and engagement during 2019.

10.2. Members heard that being ambitious and working with others to achieve results were key aims. The Head of Planning and Governance also summarised the operating landscape which would influence the strategy.

10.3. The Head of Planning and Governance went on to talk about the proposed strategic themes of the strategy.

- 10.4.** The theme of ethical and effective care would include work on treatment add-ons; consent; treatment of partners; research and intelligence.
- 10.5.** The theme of reaching people before treatment would include work with GPs and practice nurses; educating GPs and prospective patients; looking at access to treatment options and supporting initial choices.
- 10.6.** The theme of being future ready would include work on legislative reviews; Opening the Register requests and the impact of the first donor conceived people turning 16 and 18 during the strategy period and considering developments in genetics.
- 10.7.** The Head of Planning and Governance then outlined the overall strategic approach, including proposals on who the HFEA would work with and how, as well as possible consultation channels.
- 10.8.** The Authority was asked to comment on the:
- Context and themes set out in this paper, with a view to further shaping our aims and the broad tactics we should adopt to achieve those aims.
 - Broad approach outlined for consulting stakeholders and the general public.

Decision

- 10.9.** Members agreed with the overall proposed themes of the strategy and approach to consultation.
- 10.10.** Members discussed the use of the word 'ethical' and the proposal to specifically reach people before treatment. Members proposed wording suggestions that the Head of Planning and Governance would take away in order to prepare the strategy for consultation in such a way that would be appropriate for the remit of the HFEA.

11. The use of electronic consent

- 11.1.** The Scientific Policy Manager presented a paper on the use of electronic consent in clinics, explaining that recent interest in the sector required the HFEA to consider whether to provide explicit Code of Practice guidance on the use of new technology.
- 11.2.** Members heard that current guidance for centres only envisaged paper-based consenting using HFEA consent forms, and that it was therefore not explicitly applicable to the various methods of electronic consenting.
- 11.3.** The Scientific Policy Manager talked about legal advice that had been sought. This included whether, for the purposes of Schedule 3 of the HFE Act 1990 which relates to consent, a consent form completed electronically and with an electronic signature would satisfy the requirement for consent to be "in writing". Legal advisers confirmed that electronic signature capture would be lawful. Additionally, advice was sought on practical and operational issues that research had uncovered.
- 11.4.** If the Authority approved the recommendation to develop guidance on electronic consent, the Scientific Policy Manager confirmed that draft wording would be brought to the Authority for approval.

11.5. The Authority was asked to consider:

- current practice and use of electronic consent and
- the need for the HFEA to provide guidance on the safe and effective use of electronic consent.

Decision

11.6. Members expressed interest in this topic, and the area of consent in general. Concerns were expressed about electronic consenting, including ensuring that consent is always informed and provided by the person in question.

11.7. It was agreed that the executive would continue to look into ways to provide guidance in this area and report back to the Authority for consideration.

12. Any other business

12.1. There was no further business to discuss.

13. Chair's signature

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

Signature



Chair: Sally Cheshire

Date: 8 May 2019