

## Minutes of the Authority meeting on 3 July 2024

Members present	Julia Chain Tim Child Frances Flinter Zeynep Gurtin Alex Kafetz Graham James	Alison McTavish Gudrun Moore Catharine Seddon Christine Watson
Apologies	Jonathan Herring Geeta Nargund	
Advisers	Jason Kasraie, Special Adviser	
Observers	Adrian Thompson, Board Apprentice Steve Pugh (DHSC)	
Staff in attendance	Peter Thompson (Chief Executive) Clare Ettinghausen (Director of Strategy & Corporate Affairs) Rachel Cutting (Director of Compliance & Information) Tom Skrinar (Director of Finance & Resources) Paula Robinson (Head of Planning and Governance) Alison Margrave (Board Governance Manager)	

### Members

There were 10 members at the meeting – 7 lay and 3 professional members.

## 1. Welcome and declarations of interest

- 1.1. The Chair opened the meeting by welcoming Authority members and HFEA staff to the Authority Meeting.
- 1.2. The Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. She stated that the recording would be made available on the HFEA website to allow members of the public to hear it.
- 1.3. Declarations of interest were made by:
  - Tim Child (part-time consultant to a fertility company)
  - Jason Kasraie (PR at a licensed clinic)

## 2. Minutes of the last meeting and matters arising

- 2.1. The minutes of the meeting held on 15 May 2024 were agreed as a true record of the meeting and could be signed by the Chair.

### Matters arising

- 2.2. Members were advised that the matters arising items had been actioned as detailed in the paper presented to the meeting.
- 2.3. Members noted the matters arising report.

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### 3. Chair and Chief Executive's report

- 3.1. The Chair gave an overview of her engagement with key stakeholders and her attendance at decision-making committees of the Authority.
- 3.2. The Chair informed members that in early June she had attended the Scientific and Clinical Advances Advisory Committee (SCAAC) meeting and in late June the Audit and Governance Committee (AGC) meeting and further information about these meetings would be given by the relevant Committee Chair under agenda item 4.
- 3.3. The Chair, together with the Chief Executive, had attended the annual accountability meeting with the HFEA's sponsor team at the DHSC to review the HFEA's achievements over the past year. This was a very positive meeting with DHSC recognising the work which the HFEA had completed including delivering on the business plan commitments, completion of work on treatment add-ons, processing OTR applications, making proposals for law reform and the positive Public Bodies Review. The Chair thanked the HFEA staff for all their hard work during the past year.
- 3.4. The Chair reminded members that the DHSC recruitment process for four new Authority members had started earlier in the year, and it is hoped that appointments will be announced in the next few weeks after the General Election. Due to the delay in appointing the new members, Ministers had agreed to extend the terms of Gudrun Moore and Johnathan Herring for an additional 6 months. The Chair thanked colleagues from DHSC for their assistance in this matter.
- 3.5. The Chief Executive provided an update on the key external activities contained in the paper. He provided further details about the Ethics and Policy Symposium on In Vitro Gametogenesis (IVG) he and Frances Flinter had spoken at. He stated that SCAAC had been tracking the development of IVG for a number of years and this work has now gathered pace and it could transfer to clinical practice within the next 5-10 years. Currently IVG is lawful in research but unlawful in treatment and the HFEA would need to take a policy decision on this in the future. SCAAC would continue to monitor IVG through its work.
- 3.6. Frances Flinter commented that IVG would be of interest for same sex couples as the child would be genetically related to both parties.
- 3.7. The Chief Executive spoke of the purpose of the Health and Care Regulators Forum which the HFEA had just joined in sharing policy thinking and common issues. Continuing, he spoke of the overlap in regulation between some organisations, so a forum such as this is useful in bringing the different parties together.
- 3.8. The Chair spoke of the speed of change in the fertility sector and the need to ensure that the HFEA's regulatory framework keeps pace with such changes.

#### Decision

- 3.9. Members noted the Chair and Chief Executive's report.

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### 4. Committee Chairs' reports

- 4.1. The Chair invited Committee Chairs to add any other comments to the presented report.

- 4.2.** The Licence Committee Chair (Graham James) gave an overview of recent meetings and informed members that the Director of Compliance and Information had attended a recent committee meeting to explain how the Executive responds to critical incidents.
- 4.3.** The Statutory Approvals Committee (SAC) Deputy Chair (Gudrun Moore) provided a brief overview of recent meetings, noting that the last set of minutes have not yet been approved.
- 4.4.** The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed members that the committee had concluded that PGT-P (PGT for polygenic disorders or polygenic risk scores) is not yet able to accurately predict future health and appropriate patient information will be developed for the PGT pages of the HFEA website. With regard to artificial wombs for early or whole gestation and alternative methods to derive embryonic and embryonic-like stem cells, the committee will continue to monitor clinical and scientific advancements. The committee had also considered the application for androgen supplementation as a treatment add-on. And they welcomed the three newly appointed external advisers. The SCAAC Chair informed members that the HFEA annual horizon scanning meeting will be held during the European Society for Human Reproduction and Embryology (ESHRE) Conference in July.
- 4.5.** The Audit and Governance Committee (AGC) Chair (Catharine Seddon) informed members that the AGC had considered the draft Annual Report and Accounts and had made a provisional recommendation for the Accounting Officers to sign these, pending completion of a number of actions by the NAO. The committee had delegated authority to the AGC Chair or Deputy Chair to approve any amendments proposed by the NAO to the Annual Reports and Accounts and to authorise the Accounting Officer to sign said documents. Members were informed that the annual audit rating was 'moderate', noting good progress in a number of areas. The committee also received reports on the Strategic Risk Register, PRISM and HR.
- 4.6.** The Chair commented that it had been a very busy time for committee work and she thanked members of all the committees for their work in supporting the HFEA.

## Decision

- 4.7.** Members noted the Committee Chairs' reports.

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## 5. Performance report

- 5.1.** The Chief Executive introduced the performance report and stated that several KPIs had been recast to better provide clarity of what is being measured and why. He stated that performance has been good across the KPI indicators with nine green, three amber, two red and three neutral indicators.
- 5.2.** The Chief Executive referred to the HR KPIs and informed members that staff sickness rates have improved and when long-term sick leave is excluded this KPI is under the target range.
- 5.3.** Turnover rate continues to be higher than our ideal range, but the HFEA is a small organisation with limited opportunities for promotion and further constrained by pay rates set by Government. Staff surveys show high morale and HR processes to fill vacancies, when they arise, are efficient to minimise gaps and ease pressure on remaining staff.
- 5.4.** The Chair agreed with the Chief Executive's assessment, but added that HR have implemented several initiatives which make the HFEA a good place to work. She questioned whether the HFEA keeps in touch with former staff to inform them when vacancies arise.

- 5.5.** The Chief Executive responded that informal channels of communication are kept with former staff. The Chief Executive said that news of the anticipated staff pay award had been delayed by the Government until Autumn.
- 5.6.** A member congratulated the HFEA on its work and commitment under Equality, Diversity & Inclusion (EDI) which was reported to the AGC meeting via the HR bi-annual report.

### Compliance and Information

- 5.7.** The Director of Compliance and Information thanked the inspection team for their hard work in improving the inspection KPIs, whilst the team is still affected by one long term absence and the need to train new members. The KPIs for 'inspection reports to PR' and 'inspection report to committee' are both in green and the 'end to end licensing' KPI is achieving 90% of target completion. It was stressed that there would always be genuine reasons why a KPI may be breached, especially regarding challenging and complex inspections.
- 5.8.** Members were informed that OTR applications remain steady with approximately 80 per month, although there are increased spikes in applications around media interest. The new case management system and register tools allowed the OTR team to close 175 cases in May and 144 in June, which has started to make an inroad into the waiting list. Members were informed that the new tools will allow the team to process applications by type and monitor individual waiting times going forward.
- 5.9.** Members were informed that this year's Data Security and Protection Toolkit (DSPT) submission had been completed and thanks were given to the staff involved. The Director of Compliance and Information stated that whilst the HFEA's compliance is improving year-on-year, the set of requirements also increase year-on-year which increases significantly the documentation required.
- 5.10.** The Director of Compliance and Information informed members that the IT infrastructure Pen Test had been completed and the team were now working through the recommendations.
- 5.11.** Members were informed that the team were working with DHSC procurement colleagues to progress the Epicentre replacement.

### Strategy and Corporate Affairs

- 5.12.** The Director of Strategy and Corporate Affairs remarked that as Co-Chair of the Executive Licensing Panel she had seen an increase in Person Responsible (PR) comments on inspection reports coming to the committee and that these were positive about working with the inspection team.
- 5.13.** Members were informed about the internal audit on the Register Research Panel (RRP) noting that it had achieved a 'substantial rating' with just one recommendation.
- 5.14.** Due to the General Election communication activities have been quieter than normal, although media requests are still coming through. Members were informed about the anticipated publication dates for various reports and the patient survey.
- 5.15.** The Director of Strategy and Corporate Affairs informed members that the progress of the Statutory Instrument on screening had been paused due to the General Election. At the previous meeting the Authority had delegated responsibility to the Chair to sign the updated documents relating to these changes. Given the delay in this work she sought assurance from the Authority

that they were content with their previous decision regarding delegated responsibility. Members confirmed satisfaction with their previous decision.

- 5.16.** In response to a question the Director of Strategy and Corporate Affairs stated that data on the webpages visited is collected but this did not vary much from one month to the next. However we could add to the commentary on significant changes in future.

## Finance

- 5.17.** The Director of Finance and Resources referred to the information contained in the paper and stated that whilst the first two months of the year are showing a small surplus it is too early to provide meaningful data.
- 5.18.** Members were informed that the Finance Team will begin its detailed forecasting of the first quarter and if required teams will amend their plans to reflect the forecasting.

## Decision

- 5.19.** Members noted the performance report.

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## 6. Strategic Risk Register

- 6.1.** The Chair introduced this agenda item by reminding the Authority that they receive the strategic risk register (SRR) twice a year for review; with the last review taking place in November 2023. Members were informed that the AGC had scrutinised the SRR in detail at their meeting on 26 June.
- 6.2.** The Head of Planning and Governance presented the SRR and stated that her commentary will include suggestions made by the AGC members at their meeting last week.
- 6.3.** Members were informed that the financial risk has been updated with the new fee regime and the impact from the reduction in Grant-in-Aid (GIA). The governance risk has been updated to reflect the growth in online services.
- 6.4.** Information had been updated to reflect the increase in media coverage and the work that will be required on the HFEA website once the Epicentre replacement is secured. Information 2 had been updated to reflect the changes in the OTR system.
- 6.5.** Members were informed that the operational risk commentary had been updated to reflect the risk position regarding Epicentre and a new sub-section for CaFC had been included.
- 6.6.** The People risk commentary text had been updated to reflect the single point of failure in small teams. For the People 2 risk the AGC had asked management to review the wording as the HFEA operates a robust and thorough induction process for Authority members. The issue that arises is the time needed to train and upskill new members before serving on our licensing committees, and the short lead in time from when appointments are announced.
- 6.7.** The Head of Planning and Governance stated that the AGC had agreed with the strengthened mitigations in security and had agreed to close the strategy risk as the Public Body Review had been concluded successfully.
- 6.8.** The AGC Chair informed members that the committee had held a discussion on whistleblowing by clinic staff and whether this should be captured within one of the risk categories due to the resource implication for dealing with such reports.

- 6.9.** The Director of Compliance and Information spoke of the work of the inspection team in encouraging whistleblowing and the fact that they meet with a range of clinic staff and not just the PR during an inspection. The compliance team have also encouraged whistleblowing by leaving contact cards in clinics. We have seen a positive response to this. She spoke about the experience of the clinical governance team and the Chief Inspector and the legislation around whistleblowing that the HFEA complies with. Members were reminded of the HFEA's remit and the legislation within which it operates and how some whistleblowing reports, such as clinic HR matters, are outside the remit of the HFEA. However, it was acknowledged that information received through whistle blowing was useful intelligence,
- 6.10.** A member suggested that existing members of the Licence Committee could assist in the induction of new members assigned to the Committee, as a source of sharing knowledge and upskilling new members quicker.
- 6.11.** The Chief Executive commented that one element of the risk associated with People 2 had decreased due to the extension of two existing members' term of office, but the risk associated with the lead time for new members' appointments, allowing for induction and training, was still live.

#### Decision

- 6.12.** The Authority noted the Strategic Risk Register.

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## 7. Fees Review

- 7.1.** The Chair introduced this agenda item and stated that this will be a long piece of work, involving consultation and any proposed changes will need to be agreed by HM Treasury. She stressed that the Authority is not being asked to decide today, but rather to consider the options presented in the paper and give a steer on preferred options to the Chief Executive and Director of Finance and Resources.
- 7.2.** The Director of Finance and Resources introduced the paper stating that it had long been the policy of UK governments that regulated entities should bear the cost of regulation. He explained the HFEA's current fee model and the recent reduction in grant in aid (GIA).
- 7.3.** In January 2020 the Authority had agreed that the HFEA should undertake a review of its licence fee model for the 2021/22 financial year but the subsequent impact of COVID-19 on the sector prompted the Authority to delay the review to a future date.
- 7.4.** The Public Body Review that was conducted in 2023 had agreed that within the next 18 months the HFEA should establish plans to allow it to conduct a review of its fee model.
- 7.5.** The Director of Finance and Resources explained the basis of the current fee structure, noting that there are a range of activities, such as egg and embryo storage cycles, which require regulatory oversight but do not currently incur a fee.
- 7.6.** The Director of Finance and Resources stated that the principles for a review of the fee model should be to fairly and transparently recover the actual costs of regulation incurred by the HFEA; be logically and administratively simple; and provide budgetary certainty and stability to support financial planning and management for both the HFEA and clinics.

- 7.7.** The Director of Finance and Resources introduced the options contained in the paper and explained each one in detail.
- 7.8.** The Chair remarked that the fertility sector is one where activities have expanded quickly but the fee regime has not kept up with those changes.
- 7.9.** A member gave their view from a clinic's perspective stating that there is wide acceptance of how the current fee structure works but they acknowledged that activities, such as egg and embryo storage, are outside the current fee structure. Smaller clinics could be concerned about a flat annual fee and he questioned what the banded flat annual fee would be based on. The Director of Finance and Resources responded that the banding levels would be based on the level of clinic activities.
- 7.10.** In response to a question the Director of Compliance and Information informed members that a third party is a satellite clinic, such as a local regional hospital that may undertake consent work and initial paperwork while the licensed treatment activity takes place at the primary licensed centre.
- 7.11.** Several members agreed with the sentiment of decoupling the HFEA fee as a perceived 'treatment tax' which clinics levy on patients' overall bills. The banded flat annual fee could mean that clinics absorb this fee, as they do other overheads such as rent and utilities and pass on a percentage of this to their customers.
- 7.12.** A member commented that it could be helpful to have information and comparison with other regulators and what fee structure they have implemented.
- 7.13.** The Chief Executive commented that the proposals contained in the paper are set out to recover the costs of regulation and not designed to generate profit.
- 7.14.** Members discussed the benefits and advantages of the status quo plus option as presented in the paper and how this could be accepted by the sector.
- 7.15.** In response to a question the Director of Compliance and Information spoke of how intensive and time-consuming initial applications are for the inspection team and under the present fee model those costs are not recouped.
- 7.16.** A member questioned whether it was possible to incentivise clinics for compliance and perhaps implement a fining system for non-compliance.
- 7.17.** A member spoke about compliance for non-payment of bills and that the HFEA should be able to charge for non-payment.
- 7.18.** The Chair drew the discussion to a close noting that the principles for the review were agreed; that options B 'status quo plus (mixed activity driven)' and E 'banded flat annual fee' as presented in the paper were currently favoured by the Authority and warranted further development; and that if possible the decoupling of the HFEA's fee as a perceived 'treatment tax' levied on patients by clinics was welcomed.

## Decision

- 7.19.** The Authority agreed that the principles for a review of the fees should fairly and transparently recover the actual costs of regulation incurred by the HFEA; be logically and administratively simple; and provide budgetary certainty and stability to support financial planning and management for both the HFEA and clinics.

- 7.20.** The Authority noted the range of regulatory and clinic activities to be reviewed and the process and timing of the review.
- 7.21.** The Authority noted that out of the options presented in the paper, options B and E warranted further development.

#### Action

- 7.22.** The Director of Finance and Resources to commence work on the fee review.

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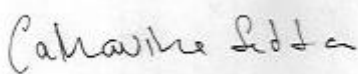
## 8. Any other business

- 8.1.** The Chair thanked all for their active participation in the meeting.
- 8.2.** The Chair reminded members of the dates of the September and November meetings and that an Authority away day will also be held in November. It is hoped that the new Authority members will be appointed by then.
- 8.3.** The Chair spoke about an event she had arranged for the 100<sup>th</sup> birthday celebration of the late Mary Warnock being held on 30 October and she would circulate details to members.
- 8.4.** There being no further items of any other business the Chair reminded members that the next meeting will be held on 25 September 2024.
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## Chair's signature

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

#### Signature



Deputy Chair: Catharine Seddon

Date: 25 September 2024