Minutes of the Authority meeting on 20 November 2024

Members present	Julia Chain (Chair) Tim Child Frances Flinter Tom Fowler Zeynep Gurtin Graham James Alex Kafetz	Alison McTavish Catharine Seddon Christine Watson Geeta Nargund Rosamund Scott Anya Sizer Stephen Troup
Apologies	Steve Pugh, Department of Health and Social Care (DHSC)	
Observers	Adrian Thompson, Board Apprentice Farhia Yusuf (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) Rebecca Taylor (Scientific Policy Manager) Anna Coundley (Policy Manager) Anna Wilkinson (Policy Manager) Shabbir Qureshi (Risk and Business Planning Manager) Alison Margrave (Board Governance Manager)	

Members

There were 14 members at the meeting – 9 lay and 5 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and HFEA staff, A warm welcome was extended to the four new members, who commenced their appointment with the HFEA in October.

1.2. The Chair informed the meeting that apologies had been received from Steve Pugh from the Department of Health and Social Care.

1.3. The Chair also welcomed observers and stated that the meeting was being recorded in line with previous meetings and for reasons of transparency. The recording would be made available on the HFEA website to allow members of the public to view it.

1.4. Declarations of interest were made by:

- Tim Child (Clinician working at IVF company and consultant to a fertility company)
- Geeta Nargund (Clinician at a licensed clinic and licence holder)
- Anya Sizer (Fertility consultant and trustee of The Fertility Alliance)
- Stephen Troup (Consultancy work within the fertility sector)

2. Minutes of the last meeting and matters arising

2.1. The minutes of the meeting held on 25 September 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 item regarding communicating licensing, regulatory activity and incident information had been actioned as detailed in the Committee Chairs' reports paper presented to the meeting.

2.3. Members noted the matters arising report.

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. She informed members that she had chaired a meeting of the remuneration committee which had agreed to recommend a pay increase for staff in line with Government recommendations. The Chair said that this recommendation had been agreed by DHSC.

3.2. The Chair informed members that, together with the Chief Executive, she had attended the DHSC ALB Senior Leaders meeting where DHSC had shared the government's health mission and proposed plans.

3.3. The Chair spoke about the Conference hosted at Girton College, Cambridge, to mark the 100th anniversary of the birth of Mary Warnock, and expressed her thanks to the team at Girton College for hosting this event. The Chair outlined the programme with its focus on past, present and future developments and the range of speakers on this topic.

3.4. The Chair informed members that she would be attending and speaking at the Fertility Conference 2025 in January.

3.5. The Chief Executive spoke about the meeting held in early November with the Regulatory Innovation Office and the recently published Government innovation white paper.

3.6. The Chief Executive stated that he will be speaking at the Progress Educational Trust (PET) Conference held in early December.

3.7. Members were informed that the Director of Finance & Resources, Tom Skrinar, will be employed full time by the HFEA in the New Year. Currently this position is shared with the Human Tissue Authority (HTA) but following discussions with DHSC and HTA it was agreed to end this shared agreement. The Chief Executive stated that Tom's remit will be expanded to include IT and Planning and Governance and the relevant staff teams had been informed of the impending changes.

Decision

3.8. Members noted the Chair and Chief Executive's report.

Effective Governance

3.9. The Chief Executive introduced the paper and spoke to the proposal to amend article 1.6 of Annex D of the standing orders to allow for seven members of the Licence Committee, rather than six.

3.10. Members were reminded that they had received the required notice of motion in advance of this meeting, regarding the intention to amend the standing orders by a formal vote.

Decision

3.11. The members unanimously voted in favour of the changes to the standing orders.

Action

3.12. The Board Governance Manager to publish the revised standing orders.

4. Committee Chairs' reports

4.1. The Chair introduced the report in its new format, following the decisions made by the Authority in September regarding communicating licensing, regulatory activity and incident information. The Chair invited Committee Chairs to add any other comments to the presented report.

4.2. The Licence Committee Chair (Graham James) stated that the newly appointed Authority members observed the recent Licence Committee meeting as part of their induction process. The committee had completed its committee effectiveness review. He welcomed the new format of the Committee Chair's report which reflected the decisions made at the last meeting regarding transparency of information.

4.3. The Statutory Approvals Committee (SAC) Deputy Chair (Geeta Nargund) provided further information about the PGT-M applications and special directions considered by the committee and stated that one PGT-M application had been refused due to insufficient data being available. The SAC Deputy Chair congratulated the committee staff for the excellent papers submitted to the committee.

4.4. The Audit and Governance Committee (AGC) Chair (Catharine Seddon) gave a brief overview of the remit of the committee for the benefit of the new members. Further context on the Data Security and Protection Toolkit (DSPT) 'limited assurance' audit was provided to members, noting that DSPT was designed for NHS Trusts and is not proportionate for small ALBs. The committee has asked the executive to review outstanding audit recommendations and propose those that they intend to accept at risk. Further information was provided on digital projects including the intention to publish Choose a Fertility Clinic (CaFC) data in 2025, governmental functional standards and the deep dive discussion on internal incidents and near misses. Members were reminded that they had received an invitation to the assurance mapping training being held on 6 December.

4.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) informed the authority that SCAAC had met on 7 October and had received an update from the Newcastle Fertility Centre on their mitochondrial donation work. The committee had also discussed stem-cell based embryo models (SCBEMs), in vitro derived gametes and scientific considerations relevant to the 14-day rule. The committee chair also gave SCAAC a brief overview of the annual horizon scanning meeting which was held at the European Society of Human Reproductive Medicine (ESHRE) Conference.

4.6. The Chair thanked all Committee Chairs for the reports and stated that committee papers and minutes are published on the HFEA website.

Decision

4.7. Members noted the Committee Chairs' reports.

5. Performance report

5.1. The Chief Executive introduced the performance report and for the benefit of the new Authority members stated that the Key Performance Indicators (KPIs) which had been agreed previously with the Authority measure various operational aspects of the business conducted by the HFEA.

5.2. The Chief Executive informed members that the report includes data up to the end of October. Performance continues to be good across the KPI indicators with ten green, two amber, one red and four neutral indicators.

5.3. The Chief Executive referred to the HR KPIs contained in the paper and informed members that staff turnover remains green, staying below the 15% target and is continuing its downwards trend. The Chief Executive spoke of the small size of the organisation, lack of promotion and public pay constraints which can affect staff turnover.

5.4. Whilst staff sickness slightly exceeds the 2.5% target, the Chief Executive remarked that this was due to seasonal viruses common at this time of the year.

5.5. The Chief Executive informed members that the staff survey had closed a couple of weeks ago and a response rate of 87% had been achieved. The question regarding whether staff members were happy working for the HFEA had received a positive response of nearly 90%. He expressed his thanks and gratitude to all staff for their work and contribution to the HFEA.

5.6. The Chair, on behalf of the Authority, expressed thanks to the Chief Executive and other member of the Senior Management Team for the happy and positive working culture they have created at the HFEA.

Compliance and Information

5.7. The Director of Compliance and Information stated that the new members of the inspection team are continuing to integrate well into the team and that there has been a significant, sustained improvement in the KPIs. Thanks were expressed to the whole team for this work.

5.8. Members were informed that the DSPT is now aligned to the cyber assessment framework (CAF) which has increased demands on the staff involved. A scoping exercise has been finalised and roles and responsibilities have been assigned. It was noted that the audit support documentation has not yet been published.

5.9. The Director of Compliance and Information informed members that the scoping of the application pen testing requirements is being undertaken with the supplier and is likely to start in the New Year.

5.10. The new Business Continuity plan has been finalised and disseminated amongst HFEA staff and plans are being made for the next business continuity exercise.

5.11. Members were informed that 20 bids for the Epicentre and CM (document management system) replacement had been received and these were now being independently reviewed by the bid assessment panel. It is anticipated that the tender will be awarded in late December with the project starting in the new calendar year.

5.12. The Director of Compliance and Information stated that the new Opening the Register (OTR) systems are now providing real benefit with 138 cases closed in September and 185 in October. Over the past six months 936 applications had been processed.

5.13. OTR applications remain steady with approximately 100 received each month, meaning that inroads have been made to the waiting list which has been reduced by 30% since its peak.

5.14. For applications closed in the last 6 months the wait time was 8.6 months and for those closed in the past month the average wait time had been reduced to 5.4 months.

5.15. Members were informed that OTR applications relating to post 2005 identifiable donors remain low with an average of 3 a month. In addition, there is a steady and small number of pre 2005 donors removing their anonymity and post 2005 updating their details.

5.16. A member questioned whether it was possible to develop a KPI to monitor special direction applications. The Director of Compliance and Information undertook to discuss this suggestion with the relevant teams.

5.17. A member congratulated the inspection team for the work and the positive results which are being achieved.

5.18. The Chair asked whether it would be possible to develop a KPI for OTR applications now that a good inroad had been made to the waiting list. The Director of Compliance and Information stated that this would be possible in the future as the Dynamics case manager system allows staff to split and differentiate applications, but further work is first required to reduce the waiting list, especially with regard to complex applications.

Strategy and Corporate Affairs

5.19. The Director of Strategy and Corporate Affairs spoke about the recent changes in law relating to screening in fertility treatment meaning that enhanced screening is no longer necessary for couples having reciprocal IVF, and people who are HIV+ with an undetectable viral load can now donate their gametes for use in treatment as 'known donors'.

5.20. Members were informed of the very good response rate across all groups, for the national patient survey which closed recently. Recruitment is now underway for new members for the Patient Engagement Forum (PEF).

5.21. The Director of Strategy and Corporate Affairs informed members that the annual State of the fertility sector report was published in October and the Family formations in fertility treatment report is due to be published shortly.

5.22. Members were informed that both stakeholder group meetings were held in October and groups discussed the HFEA's proposed new strategy and were able to feed ideas into this process.

5.23. The Governance Team and wider HFEA team had been involved in the induction process of the four new Authority members and thanks were given to all who had organised this.

5.24. The Director of Strategy and Corporate Affairs spoke of applications to the Register Research Panel (RRP); in response to a question, she explained the process for reviewing such applications and the strict criteria they must meet. Members were reminded that the HFEA now publishes a Data Research newsletter and an annual update on the will come to the Authority during 2025.

5.25. Members were updated on activities around National Fertility Awareness Week including webinars run for civil servants.

5.26. The Director of Strategy and Corporate Affairs informed members that the Head of Planning and Governance, Paula Robinson, will retire next year and explained how the team will be structured in the future. Members expressed their sincere thanks to the Head of Planning and Governance for all her work, especially in developing the new strategy.

Finance

5.27. The Director of Finance and Resources informed members that a detailed review of the forecasting for the remaining period had been completed and that a small underspend of £60,000 is being forecast, before taking into account any accounting adjustments such as potential provisions reversals.

5.28. Members were informed that due to the procurement process for the Epicentre replacement taking longer than first anticipated it will be necessary to return a proportion of the Grant-in-Aid (GIA) to the department and reapply for the same funds next year (and that there were no guarantees currently that this request would be agreed by the Department).

5.29. Members were informed of the work that is being undertaken by the Finance Team to reduce the historic debt.

5.30. A member questioned whether the budget would be out of step due to income being 8% down but treatment fees being higher for the same period. The Director of Finance and Resources responded that discussions are currently taking place with the National Audit Office (NAO) with regard to the level of provision required for duplicate invoices.

5.31. The Chief Executive reminded members that 95% of the HFEA's income comes from billable activities and stated that the duplicate invoices arose from the change from the old system to the new PRISM system and a few centres entering duplicate data. Members were reminded that the new system has a number of checks and balances which ensures that this issue should not arise again.

5.32. A member questioned whether there was any concern from PRs about the lack of stakeholder events this year. The Chief Executive responded that when events are held there needs to be real value for all attendees and given pressures on both the sector and the HFEA this year it was not deemed viable to arrange PR events.

5.33. A member suggested that due to changes in PRs and licence holders it may be worth canvassing what events would be welcomed. The Director of Strategy and Corporate Affairs commented that there are now fewer PRs but that they often manage multiple clinics.

5.34. The Director of Compliance and Information reminded members of the various speaker engagements that HFEA staff had undertaken during the year and the range of different groups engaged with during the year.

5.35. The Chair drew the discussion to a conclusion stating that it had been an incredibly busy year for the HFEA and on behalf of the Authority expressed thanks to all staff for their efforts.

Decision

5.36. Members noted the performance report.

6. Strategy and Planning

6.1. The Chair introduced the agenda item reminding the Authority that they previously decided to extend the current strategy for an additional year, to the end of 2024.

6.2. The Head of Planning and Governance introduced the paper and spoke about how the proposed strategy was developed using input from various Authority workshops, staff members and stakeholder meetings and members of the patient engagement forum. The timeline for preparation and publication of the final strategy and corresponding business plan was explained.

6.3. The Head of Planning and Governance stated that a priority identified early in the planning phase was that the strategy should recognise the increasing complexity of the UK fertility landscape, and the challenges that presents, both for patients making difficult treatment choices, and for clinics and the HFEA.

6.4. The vision is to ensure a well-regulated fertility sector, which is trusted by patients and the wider public, with the information which the HFEA provides being useful and accessible and that biosciences that lead to innovations in treatment can flourish, within an ethical framework. This is encapsulated in the following vision statement:

Regulating for confidence:

- Safe treatment
- Right information
- Supported innovation

6.5. The Head of Planning and Governance spoke of the discussions around future challenges and priorities and how these helped to populate the columns in the tables contained in the strategy headed ‘we want’ and ‘we will’. These show the changes that the HFEA wants to see and explains at a high level how the HFEA will drive those changes. The corresponding business plans for each year of the strategy would set out the actions in more detail.

6.6. The proposed strategy has two main pillars of ‘regulating a changing environment’ and ‘supporting scientific and medical innovation’. The Head of Planning and Governance provided further information on proposed activities under both of these pillars.

6.7. The Head of Planning and Governance highlighted the range of stakeholder feedback received on the draft strategy and that overall, the feedback was very positive and supportive.

6.8. The Head of Planning and Governance spoke of how the strategy feeds into the business plans and for 2025/26 this is likely to include law reform; CaFC; the fees review; the Epicentre, content manager and portal project; patient survey outcomes and implementation; and supporting the Government’s ten-year health plan, once published.

6.9. The Head of Planning and Governance stated that the business plan for the coming year, and possibly beyond, would need to be flexible to allow for any reprioritisation which might be required for law reform discussions.

6.10. Members discussed the proposed strategy, noting that it had captured all their previous workshop discussions and articulated these into the vision and two main pillars of the strategy.

6.11. Members discussed how the HFEA can use its voice to not only highlight issues relating to the fertility sector but the wider women's health policy and 10-year health plan (once published). The HFEA's continued transparency and the visibility of its work was noted as very important.

6.12. Members discussed the issue raised regarding whether the Authority potentially has a role in regulating pricing, noting how complex this work could be. It was felt that the HFEA did not have the resources to consider this for the 2025-2028 strategy, but that it might be possible for the next period. Members discussed the generational change in attitude in spending money and behaviour of consumers and how this would affect pricing of goods and services.

6.13. Members discussed the importance of continuing to speak up for patients and highlighting the less represented groups, to ensure that all voices are heard.

6.14. Members discussed the potential of combining efforts with other health bodies and regulators to help influence and inform policy.

6.15. Member discussed the duty of providing the right information and how to continue to raise the HFEA's visibility with patients, noting that the landscape of how people access information is changing with a greater emphasis on the internet and social media.

6.16. Members discussed the impact of the law reform work, noting that the timetable for any changes is for Government to decide.

Decision

6.17. The Authority welcomed the direction of travel outlined in the draft strategy presented to the meeting.

6.18. It was agreed that regulating pricing should not be included in the 2025-2028 strategy, but that it may be appropriate to consider this for the next strategy.

Action

6.19. Authority members to send their views on the positioning of the vision statement within the document to the Head of Planning and Governance by close of business next day.

6.20. Head of Planning and Governance to further develop the strategy and business plan for the January 2025 Authority meeting.

7. Law Reform – Scientific developments

7.1. The Chief Executive spoke about the suite of proposals on law reform which the HFEA had published last year. Within these proposals were several items which required further work and therefore these two agenda items are brought to the meeting today for debate and decision.

7.2. The Chair spoke about the Warnock Report published in 1984 which identified the need for principles and limits to govern fertility treatment and human embryo research and recommended the creation of the HFEA. The Chair spoke about the developments within the sector and how the HFEA and the sector are operating within an Act which is 30 years old. The Chair spoke about the considerable work the HFEA undertook to develop the proposals for law reform.

7.3. The Chair stated that as an expert regulatory body, it is expected that the HFEA advises the Government on proposed changes to the law. The Chair stressed that the issue of embryo

research is not being re-opened but that the Authority needs to consider whether to recommend amending the time limit permitted for research.

7.4. The Scientific Policy Manager introduced the paper and informed members that one of the areas identified under the theme future scientific developments in the proposals published last year was the 14-day rule for embryo research and the paper before the Authority considers this item in detail and makes recommendations for change.

7.5. The Scientific Policy Manager highlight to members that a number of countries are considering extension to 28 days, such as Netherlands, Sweden and Norway. Members were informed that the Health Council of Netherlands (an advisory body) had recommended the change to 28 days in a report published in October 2023.

7.6. Members were informed that the Scientific and Clinical Advances Advisory Committee (SCAAC) considered the scientific and technical case for and against extending the 14-day rule at their meeting held in early October. A summary of SCAAC's discussions is shown at section four of the paper presented to the Authority Meeting.

7.7. The Scientific Policy Manager spoke of the case to revisit the 14-day rule noting that advances in embryo culture makes it possible to sustain embryos for longer and that previous concerns about sentience have been clarified. The opportunity to be able to research what is called the "black box" of embryo development from 14 to 28 days during which time miscarriages occur and congenital conditions begin to develop was highlighted.

7.8. Members were informed that advances arising from better understanding of early embryo development could also enable validation of stem cell-based embryo models (SCBEMs).

7.9. The Scientific Policy Manager outlined the case for keeping the status quo and the case for extending the 14-day rule as detailed in the paper presented to the Authority; clearly explaining both to members.

7.10. The Scientific Policy Manager highlighted the surveys and public dialogue already conducted regarding the ethical and moral considerations and public opinion of extending the 14-day time limit for embryo research.

7.11. The Chair of SCAAC spoke of the process and options which patients are given when considering donating embryos for research. He took the opportunity to summarise the outcomes of the SCAAC's discussion on this item for the Authority:

- The committee had agreed there was a case for extending the limit beyond 14 days.
- The majority of the committee agreed that if the time limit were to be extended there should be a new upper limit agreed, and whilst the committee did not make a recommendation on a new time limit, 28 days was the most widely discussed time period.
- The majority of the committee felt that the justification for extending the time limit should be considered on a case-by-case basis.

7.12. A number of members spoke in favour of extending the time limit to 28 days for the benefit of research, although this view was not unanimous. The potential benefits and positive impact for patients was highlighted, especially research into early pregnancy loss. A few members spoke strongly in favour of advancing such research.

7.13. In discussing the proposed time extension members noted that for research post 28 days material can be used which is obtained through early pregnancy loss or terminations. Members discussed the importance of having a defined upper time limit, for public confidence and researcher clarity.

7.14. Members discussed the ethical aspects of extending the time limit, noting the debate and public engagement during the creation of the Warnock Report. Members were informed that the Nuffield Council on Bioethics plan to look at ethical issues and public engagement around extension of the 14-day rule.

7.15. In response to a question the Director of Compliance and Information stated that embryo research is regulated by the HFEA and the purposes embryos can be used for is clearly set out in law, as described in section 2.6 in the paper before the Authority. A research application is scrutinised by the HFEA, both by the inspectors, peer review and those considering the approval of a licence. Following a licence being granted research premises are inspected in a similar way to a fertility clinic.

7.16. Continuing, the Director of Compliance and Information said that the HFEA Code of Practice makes it clear that we would expect patients give fully informed consent when donating their embryos to research following receipt of appropriate information from a designated person who is independent to the patient's treatment. A patient in a clinic should also have access to counselling when making decisions. Members were informed that the provision of information, offer of counselling and consent is all inspected against.

7.17. A number of members were reassured by the explanation and existing stringent processes the HFEA has in place for reviewing research applications.

7.18. Members discussed the principles of extending the time limit for research projects and came to the view that it should not be a blanket increase for all research projects, but that applications must set out the reasons for the extension and meet strict criteria. Any such applications must be considered on a case-by-case basis and should state the specific time limit beyond 14 days their research requires, which must be the minimum needed for the purposes of the research.

7.19. Members discussed the special status of the embryo as defined in the Act and that any research undertaken could provide significant results which may assist future patients. The principles around the protection, treatment and respect for embryo research from the original Warnock report would still be maintained.

7.20. Members discussed the scientific material and information which had been presented to them and the advice received from SCAAC.

Decision

7.21. The Authority agreed with a clear majority that there is now a case for recommending that the law is changed to extend the time limit on embryo research.

7.22. The Authority agreed that 28 days would be an appropriate new fixed upper limit.

7.23. The Authority agreed that if the new time limit is established for embryo research, those projects seeking to extend beyond 14 days would need to meet specific criteria.

Action

7.24. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

8. Law Reform – Patient protection and safety

8.1. The Policy Manager introduced the paper and informed members that this paper contains more detailed recommendations relating to the following law reform proposals:

- Proposal 3: The HFEA should have a broader and more proportionate range of regulatory enforcement powers.
- Proposal 4: The HFFEA should have the power to impose financial penalties.
- Proposal 5: The Act should be revised to include an over-arching focus on patient protection.
- Proposal 6: The Act should be revised to accommodate developments in the way fertility services are provided.

8.2. The Policy Manager informed members that the proposals contained within the papers have been developed following discussions with a number of other regulatory bodies, both inside and outside of the healthcare sector and with the Institute of Regulation. The work was also discussed at the September meeting of the Licensed Centres Panel.

8.3. The Policy Manager introduced the recommendation to have an expanded ladder of regulatory sanctions and commented that the benefits of such would be:

- To provide greater flexibility to take earlier, more targeted and proportionate action.
- To enable targeted, regulatory action that would better protect the patient and reduce the complete (temporary or permanent) closure of clinics, which is unlikely to be in patients' best interests.
- To provide a more agile regulatory system incorporating sanctions that are quicker to agree and implement, in addition to the more severe sanctions that the HFEA have.

8.4. The Policy Manager explained that the expanded ladder of regulatory sanctions would allow for greater flexibility to vary or suspend licences.

8.5. Members were informed that if the HFEA was given the legal power to issue written warnings it would, effectively, put the HFEA's current process on a statutory footing and provide a stronger incentive for PRs to address non-compliances. The Policy Manager stated that many other regulators such as the CQC, Gambling Commission and Ofcom use formal written warnings to address non-compliance.

8.6. The Policy Manager spoke about the proposal for the HFEA to be able to issue fixed penalty notices (FPNs) noting that many regulators such as CQC, The Pension's Regulator and The Gambling Commission have powers to issue financial penalties as a means of incentivising compliance.

8.7. The Chair of the Licence Committee spoke in favour of having a greater variety of regulatory sanctions available to address breaches of licence conditions. He highlighted the possible benefits that this could bring.

8.8. Members discussed the proposed expanded ladder of regulatory sanctions, noting that financial penalties must be applied consistently to both the private and public sector. Some members expressed concerns that fines might be passed onto patients. Members agreed that any new suite of tools would carry resource implications for the HFEA and should not be overly onerous to use.

8.9. The Policy Manager referred to proposal 5, that the Act should be revised to include an over-arching focus on patient protection, and informed members that last month the Patient Safety Commissioner published a set of patient safety principles. She commented that the HFEA's jurisdiction is confined to areas specifically set out in the Act and in the absence of any specific reference to patients in the Act, it is difficult for the HFEA to create enforceable regulatory policies to address patient protection issues.

8.10. Members were very supportive of the proposed approach, as detailed in the paper presented to the Authority, to introducing a patient protection principle to the legislation. Members discussed the possibility of adding a set of principles to the Act, as with the Mental Capacity Act and a number of members offered their support to the Policy Team in developing this idea further.

8.11. The Policy Manager referred to proposal 6, that the Act should be revised to accommodate developments in the way fertility services are provided. The Policy Manager explained that a range of activities marketed as fertility treatments now take place outside of HFEA licensed clinics in a variety of settings and the challenges this can cause for patients

8.12. Members discussed how the patient pathway has changed since the Act was first introduced, noting that the Act currently reflects a model where treatment happens at a licensed centre. Members were supportive of the greater patient protection these proposals could bring.

8.13. The Policy Manager explained that the proposal is to bring more activity under the HFEA's regulatory oversight by expanding the list of activities that the HFEA currently regulates and to regulate entities which provide those activities.

8.14. Members spoke of not adding to the burden of regulation unnecessarily and that regulation should be proportionate for the services being offered at the facility, noting that the Authority could adopt a graduated approach to the regulation and oversight of these service providers, depending on the type of activity being offered.

8.15. Members spoke about possible unintended consequences of expanding regulatory oversight, including the impact on HFEA's resources and the possible movement of some services abroad to circumvent the UK regulations.

Decision

8.16. The Authority agreed to an expanded ladder of regulatory sanctions; lowering the thresholds for placing conditions on a licence or suspending a licence and that the addition of formal written warnings and fines would better support the HFEA's regulatory and compliance activities.

8.17. The Authority agreed the proposed approach, as outlined in the paper, to introducing a patient protection principle to the legislation.

8.18. The Authority agreed the proposed approach to bringing more activity under HFEA regulatory oversight by expanding the list of activities that it currently regulates.

8.19. The Authority agreed with the general direction of travel to bring into the regulatory scope some of the service providers which are not currently being regulated.

Action

8.20. The HFEA to continue to discuss with DHSC and Government the law reform proposals.

9. Any other business

9.1. The Chair thanked everyone for their active participation in the meeting which had considered a full and detailed agenda.

9.2. The Chair informed members that this would be Adrian Thompson's last meeting as his Boardroom Apprentice placement concludes at the end of December. On behalf of the Authority the Chair thanked Adrian for his time and hoped that he had found his placement useful.

9.3. Adrian Thompson thanked the HFEA for the opportunity to undertake his placement with the organisation and said that he had learnt a lot from his time with the Authority.

9.4. There being no further items of any other business the Chair extended season's greetings to all and reminded members that the next Authority meeting will be held on 22 January 2025.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 22 January 2025