



Minutes of Authority meeting 9 March 2016

Strategic delivery: Setting standards Increasing and informing choice Demonstrating efficiency economy and value

Details:

Meeting Authority

Agenda item 2

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Meeting date 11 May 2016

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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 9 March 2016 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

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|---------------------|--|--|
| Members present | Sally Cheshire (Chair) Professor David Archard Dr Andy Greenfield Bishop Lee Rayfield Kate Brian | Rebekah Dundas Yacoub Khalaf Margaret Gilmore Ruth Wilde Dr Anne Lampe |
| Apologies | Anthony Rutherford Anita Bharucha | |
| Observers | Ted Webb (Department of Health) | Steve Pugh (Department of Health) |
| Staff in attendance | Peter Thompson Nick Jones Juliet Tizzard | Paula Robinson Joanne McAlpine Charlotte Keen |

Members

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

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair welcomed Authority members and observers to the second meeting of 2016. As with previous meetings, it was being audio-recorded and the recording would be made available on the HFEA website to enable interested members of the public who were not able to attend the meeting to listen to the HFEA's deliberations. This was part of the HFEA's drive to increase transparency about how the Authority goes about its business.
- 1.2.** Apologies were received from Anthony Rutherford and Anita Bharucha.
- 1.3.** Declarations of interest were made by:
- Kate Brian (Regional organiser for London and the South East for Infertility Network UK)
 - Yacoub Khalaf (Person Responsible at a licensed centre)
 - Ruth Wilde (Senior Fertility Counsellor at a licensed centre).

2. Minutes of Authority meeting held on 20 January 2016

- 2.1.** Members agreed the minutes of the meeting held on 20 January, subject to one minor amendment, for signature by the Chair.

3. Chair's report

- 3.1.** The Chair began by welcoming Dr Anne Lampe to her first meeting as a new Authority member.
- 3.2.** The Chair informed members that, since the last Authority meeting, she had been recovering from an operation and had therefore not attended as many engagements as usual with organisations in the IVF sector and the wider health and care system.
- 3.3.** However, the Chair advised members that, on 21 January, she and the Chief Executive had visited Bourn Hall Clinic in Cambridge as part of the continuing programme of visits to clinics outside of the regular inspection schedule.

4. Chief Executive's report

- 4.1.** The Chief Executive advised members that, on 26 January, he attended the second meeting of the Health and Social Care Leaders' Scheme which brought together the Department of Health and all of the Chief Executives of the health arm's length bodies (ALBs) to identify senior talent within the system. Both the Director of Compliance and Information and the Director of Strategy and Corporate Affairs had been selected onto the programme, which was testament to their abilities and the stretching roles at the HFEA.
- 4.2.** On 27 January, the Chief Executive attended the Health and Care Partnership Conference and, on 29 January, met with members of the Committee on Standards in Public Life who were conducting an investigation into ethical standards within regulators.
- 4.3.** On 3 February, the Chief Executive advised members that he attended the Scientific and Clinical Advances Advisory Committee (SCAAC) and on 3 March, he spoke at a conference organised by Healthcare UK at Wilton Park on genomics. The event showcased UK expertise in genomics to representatives of government and health systems in the Gulf States, India, the Far East and South America. It was part of a broader initiative to promote UK healthcare overseas. The Chief Executive, together with the Director of Compliance and Information, had met representatives from the United Arab Emirates some weeks earlier and advised members that they were both attending an event later in the day showcasing UK expertise in patient safety.
- 4.4.** The Chief Executive reminded members that, at the last Authority meeting in January, there was a paper setting out a range of activities on better regulation that the Government was promoting. As part of this work, Departments were required to publish innovation plans by spring 2016 and ALBs were now required to follow suit. This work was underway and it was possible it would need to be published before the next Authority meeting. The Executive believed that the regulatory scheme in place managed to support innovation in a way which also assured public confidence; indeed it was evident that regulation in bio-sciences had actually promoted innovation rather than hindered it. It was noteworthy that it was the UK, with its robust regulation, that had led to world firsts like regulated mitochondrial donation and the recent decision to allow genome editing in research. The HFEA's innovation plan would set out those achievements and seek views on where the organisation could improve still further.

- 4.5.** On 18 January, the Chief Executive attended the third Department of Health led project board meeting of the HFEA's triennial review. The Chief Executive reminded members it had long been Government policy that all public bodies should be subject to a periodic review. The review had looked at the functions of the organisation and whether those functions were carried out in the most efficient way possible. The report was nearing its conclusion and, subject to Ministerial sign-off, should be published in the spring.
- 4.6.** Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.
- 4.7.** Genome Editing: the Chief Executive advised members that there had been considerable press coverage, both in the UK and across the world, since the HFEA's Licence Committee had approved the Francis Crick Institute's research renewal application, part of which included a proposal to use the genome editing technique Crispr-Cas9. It was a significant decision, since it was the first time in the world in a regulated system that the technique had been allowed in research. Given the level of interest, the HFEA had issued a short press statement and, as usual, had published the inspection report and the minutes on the website. Outside the UK, there had been articles in Germany, France, Italy, the Czech Republic, Russia and elsewhere. The discussion was largely quite balanced, focusing on the risks and opportunities and the UK's stance on research more generally. The Chief Executive advised members that several countries were now preparing more in-depth responses to this research.
- 4.8.** The 'M' case: the Chief Executive reminded members of this case, where a woman tragically died with her eggs in storage and her mother had applied for special directions to have the eggs exported to the USA so that she could try to conceive with her daughter's eggs and donated sperm. The case was in court again recently and generated some press coverage. The HFEA's Statutory Approvals Committee (SAC) had considered the issue on three occasions and had concluded that the evidence required for consent was not in place. That decision was challenged in the High Court and the judge had agreed with the HFEA decision. However, a Court of Appeal judge had now decided that the case was arguable and had granted leave to appeal. The case would be heard in May.
- 4.9.** Delegated powers: the Chief Executive advised members that, as required by Standing Orders, he wanted to secure their approval to establish an ad hoc sub-committee to consider the lawfulness of a new technique called Augment which was being marketed by a US company, Ovascience. If it was decided that the technique was lawful by the ad hoc committee, Augment would then need to be considered by SCAAC and SAC to see whether it met the statutory tests for a novel process.
- 4.10.** Members were therefore asked to indicate whether they were content to establish a committee, consisting of three Authority members, in order to consider the question of lawfulness. The Chief Executive advised members that the statutory basis to establish a committee for such a purpose could be found in section 9A(2) of the HFE Act 1990 (as amended) and in paragraph two of Schedule one of the Act.
- 4.11.** Authority members unanimously expressed their agreement for the Executive to establish the ad-hoc committee.

5. Committee chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 28 January and 25 February. There had been four preimplantation genetic diagnosis (PGD) applications in January, all of which were approved, and two requests for Special Directions both of which were granted. At the February meeting, the minutes of which had not yet been published, seven PGD applications had been considered.
- 5.2.** The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) informed members that the committee had met on 3 February, and had received reports on:
- Culture media, with a representative from the Medicines and Healthcare Products Regulatory Agency (MHRA) discussing concerns raised on this topic at the October 2015 meeting
 - An IfQ update and website content review
 - Prioritisation of issues identified through the horizon scanning process, including endometrial receptivity assay as a treatment 'add-on', genome editing, in-vitro derived gametes, the use of ICSI and non-invasive methods of assessing embryo viability
 - A discussion on the remit of the committee and its work plan.
- 5.3.** The committee also welcomed Anne Lampe who joined both SAC and SCAAC as a new Authority member.
- 5.4.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met three times since the last Authority meeting, on 29 January, 12 February and 26 February. The panel had considered 20 items in total, all of which were approved and noted. There were five interim consideration of treatment licences, four interim consideration of research licences, two voluntary revocations of small treatment centres, seven licence variations and two progress reports.

6. Strategic performance report

- 6.1.** The Chair introduced this item, advising that the strategic performance report was a general summary of both the HFEA's performance measures, the progress towards implementation of the strategy, the HFEA's programmes and their status, and generally the wider performance of the Authority.
- 6.2.** The Director of Compliance and Information summarised the activities within his directorate. Three – out of four - main performance indicators showing as red status were in his directorate. Firstly, the number of working days from the day of inspection to the day the draft report was sent to the Person Responsible (PR) had a target of 90% in 20 working days. In December, performance was at 50%, with two out of four reports being sent at 27 working days, mainly due to unexpected additional workload. There was also one report outstanding from November, which was sent 39 days after inspection. This was due to practical issues in obtaining a suitable peer review.

- 6.3.** The Director of Compliance and Information advised members that the total number of data errors in the system, taking into account the eight weeks centres were given to resolve those errors, had risen by 16% in December to 2,240. This was, in part, due to important IfQ-related work taking higher priority and a number of clinics with high error rates.
- 6.4.** The Director of Compliance and Information advised members that the Fertility Trends Report project required data for analysis, some of which (on egg freezing) required cleansing before it could be used and had been on a red risk rating. This cleansing needed to be performed by the same staff who were currently cleansing the data for the IfQ-related data migration, and had had to be prioritised over that work. In addition, the report needed to be published at the HFEA Annual Conference on 24 March. Since December, the data cleansing required had progressed well and the risk rating had therefore been reduced to amber.
- 6.5.** The Office Move project was also on a red risk rating in December, pending the resolution of some technical issues in relation to the new internet connection. This had since been resolved and the risk rating had accordingly been reduced to amber.
- 6.6.** The Director of Compliance and Information provided an overview of the Directorate's contribution to the HFEA strategy. The Register team was preparing for a new Register which involved ensuring that all the existing data in the current Register was fit for purpose to be migrated. The team was also developing the new data dictionary. The IT team had been heavily involved in ensuring the technical infrastructure behind the new clinic portal and the website was robust, fit for purpose and met current best practice requirements. The IT team had also been busy ensuring that the organisation had all the necessary equipment to function well, with new hardware being issued to all staff.
- 6.7.** In relation to the inspection and compliance activities, members were advised that the 2015/16 inspection year had been a particularly busy one, with 98 inspections taking place in the financial year, 92 of which had already been carried out. This compared to 71 inspections in the previous financial year, a 35% increase in inspection workload year on year.
- 6.8.** The Director of Strategy and Corporate Affairs reminded members of the HFEA annual conference which was due to take place on 24 March. The theme of the conference was the 25th anniversary of the HFEA, which would be marked by a panel discussion where invited speakers had been invited to look back over the 25 years. The session would be chaired by Laurence McGinty, the Science and Medical Editor for ITV news.
- 6.9.** The Director of Strategy and Corporate Affairs advised members that two workshops would also be held at the conference, one on the movement of gametes and embryos across borders, which was the subject of a new EU Directive coming into force next April, and another on avoiding breaches of patient confidentiality in clinics. The annual fertility trends report would also be launched on the day, as mentioned earlier in the meeting. The Director of Compliance and Information would also be showcasing the new Clinic Portal and the Directorate of Strategy and Corporate Affairs the new HFEA website and Choose a Fertility Clinic (CaFC).
- 6.10.** In the absence of the Director of Finance and Resources, the Chief Executive provided an overview of financial performance and a summary of the position coming towards the end of the financial year. A surplus of around £200k was forecast for year-end which was partly due

to a lower spend on salaries and legal costs. The Finance team would now be preparing the end of year accounts which would be submitted to the Audit and Governance Committee.

- 6.11.** In relation to the HFEA's office move to Spring Gardens, the Chief Executive advised members that the HFEA, from 11 April, would be sharing office space with the National Institute of Clinical Excellence (NICE) and the British Council. This would mean developing more flexible ways of working for staff and a 'ways of working' group had been set up which would play a key part in this. Visits to the new office were also currently underway for all staff. The Executive would arrange for passes to be prepared for all Authority members on their first visit to the new office. It was hoped that the majority of meetings would be held at the new offices, subject to availability of meeting rooms. The Chief Executive confirmed that SAC on 28 April and the Authority meeting on 11 May would be held at Spring Gardens.
- 6.12.** Following the discussion, members noted the latest strategic performance report, in particular the 35% increase in inspections.

7. Information for Quality: update

- 7.1.** The Director of Compliance and Information explained that the IfQ programme was a comprehensive review of the information that the HFEA held, the systems that governed the submission of data, the uses to which it was put and the ways in which the information was published. It included:
- The redesign of the HFEA's website and Choose a Fertility Clinic (CaFC) function
 - The redesign of the 'Clinic Portal' used for interacting with clinics
 - Combining data submission functionality
 - A revised dataset and data dictionary which would be accredited
 - A revised Register of treatments, which would include the migration of historical data contained within the existing Register
 - The redesign of the HFEA's main internal systems that comprised the Authority's Register and supporting IT processes.
- 7.2.** The Director of Compliance and Information advised members that the purpose of this presentation was to update members on:
- The approvals process to proceed to 'beta' phase
 - The HFEA annual conference
 - Data migration
 - Programme timelines and budget implications
 - The data dictionary.
- 7.3.** The approvals process to proceed to 'beta' phase: the Director of Compliance and Information reminded members that the externally facing part of the programme could not formally proceed beyond 'alpha' proof of concept stage until approvals in line with Government Digital Standards (GDS) had been granted by the Department of Health. The first, alpha, stage assessment, undertaken by the Department of Health Digital Projects team

was passed to a high standard. The second stage assessment, undertaken by the GDS (essentially a check on the first stage departmental process) had now also been passed. In early May 2016, both the website and clinic portal would again require assessment and, subject to the associated approvals from the Department of Health and GDS, both products would be released to 'public beta'.

- 7.4.** The Director of Compliance and Information advised members that the programme was currently halfway through the beta phase and significant progress had been made on the development of the new website, CaFC and the clinic portal. Despite some delays, which had previously been reported to members, the programme remained on track to meet reported deadlines and the beta assessment deadline.
- 7.5.** The HFEA conference: as mentioned earlier in the meeting, a centre-piece of the HFEA annual conference would be showcasing the progress made and generating a sense of anticipation for the roll-out of the beta version of the updated website, CaFC and the clinic portal. It was anticipated that the demonstration would include aspects of the search tool and the clinic portal 'knowledge base' and 'dashboard'.
- 7.6.** Data migration: as previously mentioned, the Director of Compliance and Information advised members that the Register team had finalised the extent to which data in the current Register needed to be cleansed in order to effect a smooth transfer to the new Register with a different data structure in line with the HFEA data dictionary.
- 7.7.** The Information and IT teams had been carrying out substantial cleansing activity and the burden placed on clinics to undertake this work had been minimalised. However, it was acknowledged that the quantum required by some clinics would be material. In order to form a clearer picture of the amount of time clinics would need to conduct cleansing, eight clinics had been selected to undertake a pilot of cleansing activity in April. The Executive had been communicating with clinics in order to prepare them for the requirement to cleanse data, and it was hoped that the prospective benefits offered by the new system would act as an incentive. However, it was acknowledged that this was a risk and may be unpopular.
- 7.8.** Timelines and budget implications: the Director of Compliance and Information advised members that a revised programme plan had been finalised and signed off by the IfQ Programme Board in January 2016, in line with the overall £1.134m agreed by the Authority. Members were reminded that the changes to the timeline meant that the public beta for the website and clinic portal were pushed back approximately three months and two months respectively, with both now expected to be launched for beta testing in July 2016 (subject to the required GDS approvals). Whilst the overall budget for IfQ remained unchanged at £1.134m, the revised timeline would extend work originally expected to be completed in the current financial year, into the next. This would result in approximately £450,000 within the IfQ budget being carried over into the next financial year.
- 7.9.** The data dictionary: the Director of Compliance and Information advised members that a significant part of the IfQ Programme related to restructuring the HFEA Register. Licensed fertility clinics submitted information about each cycle of treatment they carried out, such as patient and donor details, the treatment provided and its outcome. The requirement to keep a Register of Treatments stemmed from the HFE Act 1990 (as amended). At the January 2015

meeting, Authority members had agreed that data should only be collected if it met at least one of the following criteria:

- It was required by law, in particular to enable the HFEA to provide donors, donor-conceived people and their parents with information they were entitled to
- To provide prospective and current patients and donors with sufficient information to allow them to make informed decisions
- To enable the HFEA to assess compliance of individual clinics against agreed standards
- To provide information that enabled the HFEA to alert clinics of performance changes
- To obtain information about current practice that was useful and beneficial
- To provide identifying information that enabled linkage studies about children conceived as a result of licensed treatment
- To enable ethically and scientifically approved research.

7.10. The Director of Compliance and Information advised members that the Register was an extremely valuable asset to both the HFEA and its stakeholders. It was used to:

- Securely hold information about donors and their donations
- Ensure traceability of gametes and embryos
- Provide patient information on success rates
- Monitor clinic performance, and
- Facilitate research into the safety of treatments.

7.11. The Director of Compliance and Information provided members with a summary of progress made thus far on the data dictionary:

- A set of operational adjustments had been made, including additions, removals and amendments, taking into account various factors
- The adjustments were consistent with the determination of the stakeholder group
- HFEA staff had been working with the Standardisation Committee for Care Information (SCCI) staff in order to enable the HFEA Register Data submission to be awarded an official Information Standards Notice (ISN), with the approval process leading to a national dataset in July 2016.

7.12. The Director of Compliance and Information advised members that the changes to the data collected should be seen alongside the planned improvements in the data collection method. The IfQ aim to reduce the burden for clinics had always been firmly based on changing the collection method. The changes in methods of data entry were being developed and would include:

- Improved accuracy of inputting information by using more on screen prompts and access to data descriptions whilst inputting data
- More incentives to improve the quality of information by the use of flagging, and more real-time error information so that issues could be readily understood and problems fixed on the spot

- Saving time and improving quality by having no opportunity for duplicate entries and consequent issues with identifying and deleting previous or copy records
- Minimising the burden of clinics undertaking periodic verification work by real-time confirmation when data is entered.

7.13. Following a discussion, members noted the progress made on the IfQ programme, specifically on the data dictionary.

8. Compliance and enforcement policy

8.1. The Director of Compliance and Information presented this item and advised members that the HFEA's compliance and enforcement policy, in force since 2009, set out the HFEA's general approach in ensuring compliance with regulatory requirements. The Director of Compliance and Information reminded members that the policy set out the routine actions by which the HFEA judged compliance, notably inspection and the licensing process; and, second, more importantly, the steps the HFEA would take to escalate and manage concerns about regulatory compliance.

8.2. At its September 2015 meeting, Authority members considered a proposed revised policy together with changes to two indicative guidance documents provided to licence committees; the first regarding the length of licences granted and the second regarding the potential sanctions that might be applied, where concerns relating to poor performance were evident. Authority members agreed that the proposed documents should be subject to focused consultation and piloting, which had now been undertaken. Members were now presented with the revised policy, and the paper before them proposed a new single guidance document on licensing drawing together the two documents referred to above.

8.3. The Director of Compliance and Information advised members that the revised policy followed better regulation principles and it was important to note that the main proposed changes to the policy did not place any new or additional requirements on licensed centres. The key features of the revised policy were:

- Clearer escalation protocols with more well-defined signalling on the move from routine activity towards enforcement
- Clearer signalling of the significance of the 'management review', carried out when the inspection team became aware of concerns about a clinic's compliance or performance
- Clarity and certainty around 'further investigation' in order to ensure that clinics were only subject to such scrutiny if concerns were suitably serious, whilst empowering the HFEA compliance team in what might otherwise be challenging circumstances
- Amendments to the process by which a warrant might be sought which, whilst very rare, required a particular escalation process.

8.4. The Director of Compliance and Information advised members that the guidance on licensing had been consolidated within a single document. The document provided improved clarity for clinics and others about licensing decisions and a framework for licensing committees and replaced:

- Guidance on periods for which new or renewed licences should be granted

- Indicative sanctions guidance for licence committees.

8.5. In relation to the length of a licence, the Director of Compliance and Information advised members that the Executive believed there were substantial advantages in better linking clinics' relative performance and the length of the licence granted – an evidence based judgement made by a licensing committee at the time the licence was granted. A range of options had been considered and it was proposed that in CaFC the inspectors' rating of a clinic would be based on the length of a licence. Considerations would incorporate:

- The clinic's history of compliance up to the last renewal of the licence
- Evidence of non-compliance with statutory requirements and the scale and impact
- The quality of the service to patients provided by the clinic.

8.6. The Director of Compliance and Information advised members that the purpose of applying sanctions was to:

- Promote compliance with the requirements of the Act and the Code of Practice issued by the Authority
- Protect those using, or affected by, the services offered at clinics licensed by the Authority; and
- To maintain public confidence in the conduct of licensed activities.

8.7. The Director of Compliance and Information explained that the changes in relation to sanctions retained the features of the current guidance, particularly regarding the statutory basis for applying sanctions, and sought to align the guidance more closely with the sections of the Act which set out when the Authority may suspend or revoke a licence. The guidance had also been revised to emphasise the factors that a licensing committee might consider in reaching a decision. The guidance sought to simplify and clarify the aggravating and mitigating features that a licensing committee could consider in relation to any matters of non-compliance reported to it.

Decision

8.8. Following a discussion, members approved the revised compliance and enforcement policy and the new guidance on licensing effective from 1 April 2016, subject to minor amendments for clarity on specific points, including paragraph 3.6 and 3.7 of the policy.

9. Governance and transparency

9.1. Annual review of committee effectiveness: the Director of Strategy and Corporate Affairs advised members that all committees had carried out the required annual review of their effectiveness. Generally the feedback was positive and the key findings were:

- New Authority members had been incorporated well
- Quoracy and succession planning were much improved
- SCAAC wished to strengthen the patient information role in its terms of reference.

9.2. Review of Standing Orders: the Director of Strategy and Corporate Affairs advised members that the Standing Orders had been amended to reflect changes of job titles and the names of guidance documents for licensing, as discussed in item 8 of the meeting. One further

amendment had been made to SCAAC's purpose to reflect its role relating to patient information and the safety and efficacy of treatments.

Decision

- 9.3.** Following a discussion, members noted the committees' annual reviews and unanimously voted to approve the changes to Standing Orders and SCAAC's remit.

10. Strategic risk register

- 10.1.** The Head of Business Planning presented this item to provide members with an overview of the risks, showing the relative risk tolerance positions and residual risk scores. Six of the thirteen risks remained high and were deemed above tolerance:
- Office move: remained above tolerance with tight timelines and practical risks. The residual risk of 16 was higher than tolerance (set at a medium level of 6)
 - Legal challenge: a relatively high risk tolerance of 12 was set for this particular risk due to the inevitability of some degree of resource diversion owing to the nature of the HFEA's work. The residual risk was currently higher than tolerance at 15
 - IfQ - improved information access: the residual risk of 12 was higher than tolerance (set at a medium level of 8) due to approval process delays at the first stage of the programme, and the risk to the quality of the final product that could be delivered if there were any further approval delays encountered.
 - IfQ - delivery of promised efficiencies: the residual risk of 12 was higher than tolerance (set at a medium level of 9) with further GDS approvals delays likely and two further full gateway reviews now likely to be required, contrary to earlier advice
 - Data – incorrect data being released: although good controls were in place for dealing with PQs and other externally generated requests, volumes could not be controlled and the HFEA had received extremely high volumes in the first half of the year. The residual risk of 12 was therefore higher than the tolerance threshold of 8
 - Capability – knowledge and capability: the residual risk of 9 was above the current tolerance level of 6. Staff turnover could lead to fluctuations in overall capability, and although the period of highest turnover appeared to be ending, two posts at Head level remained vacant pending start dates.
- 10.2.** The Head of Business Planning advised members that the new activity of risk assurance mapping had recently started up at the HFEA as part of the internal audit programme. The Department of Health internal audit team ran a half day workshop with managers on 10 February, focusing on the HFEA's highest risk operational area, capability and resourcing. The workshop approach was well received by staff and the Executive now had a report for consideration internally which made a number of suggestions for possible further risk mitigations in this area.
- 10.3.** Members noted the latest version of the strategic risk register.

11. Business plan 2016/17

- 11.1.** The Head of Business Planning introduced this item and reminded members that they had agreed a draft of the new business plan at the November meeting. The content had now been further developed and the business plan was at an advanced stage.
- 11.2.** Following submission of the earlier draft in December, the Department of Health had only minor comments and had indicated they were broadly content, with publication anticipated by mid-April. Budget confirmation had also been received.
- 11.3.** The Head of Business Planning advised members that some sections could not be incorporated until after the end of the business year on 31 March. These sections included:
- The 'facts and figures' table relating to the previous business year
 - Standard HR benchmarking information; and
 - The performance indicator section.
- 11.4.** The Head of Business Planning advised members that, since the earlier draft, the following items had been added or refined:
- Work relating to the Government-wide better regulation rules
 - More measurable and specific outcomes
 - Acknowledgement of the Department of Health's shared delivery plan
 - A full account of work on legal parenthood
 - Updated information about the HFEA office's post-move sustainability and facilities arrangements.

Decision

- 11.5.** Following a discussion, members noted the current position and formally approved the Business Plan for 2016/17, subject to the awaited approvals, the addition of year end information and formal sign-off by the Department of Health, and also subject to incorporating members' comments on the descriptive text prefacing the activities section.

12. Any other business

- 12.1.** The Chair of the meeting confirmed that the next meeting would be held on 11 May at 10 Spring Gardens, London, SW1A 2BU. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

13. Chair's signature

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

Signature

S Christie

11 May 2016

Chair

Date