

Minutes of Authority meeting 20 January 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 9 March 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 20 January 2016 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN

Members present	Sally Cheshire (Chair) Dr Susan Price Professor David Archard Dr Andy Greenfield Kate Brian	Yacoub Khalaf Margaret Gilmore Anita Bharucha Ruth Wilde
Apologies	Anthony Rutherford Bishop Lee Rayfield	
Observers	Ted Webb (Department of Health)	
Staff in attendance	Peter Thompson Nick Jones Juliet Tizzard Sue Gallone Catherine Drennan	Suzanne Hodgson Anjeli Kara Joanne McAlpine Charlotte Keen

Members

There were 9 members at the meeting, 6 lay members and 3 professional members

1. Welcome, apologies and declarations of interest

- 1.1.** The Chair opened the meeting by welcoming Authority members and members of the public to the first 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 Bishop Lee Rayfield.
- 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 11 November 2015

- 2.1.** Members agreed the minutes of the meeting held on 11 November, subject to one minor amendment, for signature by the Chair of the meeting.

3. Chair's report

- 3.1.** The Chair welcomed two new Authority members, Ruth Wilde – a senior fertility counsellor - and Dr Anne Lampe – a clinical geneticist who had previously provided expert advice to the Statutory Approvals Committee (SAC) – to the meeting. Ruth Wilde's appointment commenced on 1 January 2016 and Dr Anne Lampe, who was observing the meeting, would formally become a member on 1 February 2016.
- 3.2.** The Chair informed members that this was Dr Sue Price's last board meeting for the HFEA, as her term of office would come to an end on 31 January 2016. The Chair thanked Dr Price on behalf of all the Authority members for her invaluable contribution to the work of the HFEA over many years, including her role as Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC), and wished her well for the future.
- 3.3.** The Chair provided members with a summary of events that she had attended with organisations in the IVF sector and the wider health and care system since the last Authority meeting.
- 3.4.** On 19 November, the Chair attended the annual dinner for the Royal College of Obstetricians and Gynaecologists (RCOG). On 2 December the Chair, together with the Chief Executive, attended a productive meeting with Lord Winston to discuss some of the issues that both Lord Winston and the HFEA were concerned about in the sector and in clinics.
- 3.5.** The Chair and the Chief Executive continued with their programme of visits to clinics outside of the regular inspection schedule, in order to hear what clinics felt about their performance and where they thought improvement was needed. The visits would then enable the HFEA, as the regulator, to consider how to help improve the quality of care. On 4 December, they visited the Newcastle Centre for Life where the research centre for mitochondrial donation was located. Future visits included the Bourn Hall clinic in Cambridge on 21 January.
- 3.6.** On 8 December, the Chair attended the Department of Health's arm's length bodies (ALBs) Ministerial round table with Jane Ellison, the Minister for Public Health. The main focus of the meeting was the comprehensive spending review.
- 3.7.** On 9 December, the Chair advised members that she had spoken at the Progress Educational Trust Conference on mitochondrial donation, where much of the day had focused on genome editing. The Chair joined a panel together with Professor Doug Turnbull from the University of Newcastle, and Viscount Matt Ridley from the House of Lords.
- 3.8.** On 12 January the Chair, together with an Authority member, attended the Department of Health's ALBs Corporate Leadership seminar on regulation.

4. Chief Executive's report

- 4.1.** The Chief Executive advised members that, on 24 November, he had participated in a seminar run by the Committee on Standards in Public Life as part of their investigation into ethical standards for regulators.
- 4.2.** On 8 December, the Chief Executive attended the National Information Board (NIB) Leadership meeting. The Chief Executive reminded members that the NIB was an initiative led

by the Department of Health involving all of the health sector's ALBs to make significant changes to the way in which information was used within the health and care system. The HFEA's role was limited given its specialist remit although it was appropriate that it was involved.

- 4.3.** On 9 December, the Chief Executive advised members that he attended the Audit and Governance Committee (AGC) and the Progress Educational Trust (PET) Conference to which the Chair had already referred.
- 4.4.** On 8 January, the Chief Executive attended the British Fertility Society (BFS) Annual Conference where the Director of Strategy and Corporate Affairs presented a talk about consent which was well received.
- 4.5.** On 19 January, the Chief Executive, together with the Director of Compliance and Information, had spoken to visitors from the Government of the United Arab Emirates, who were keen to learn about the regulation of assisted reproduction in the UK.
- 4.6.** The Chief Executive advised members that, on 15 December, HFEA staff had participated in an all staff away day. This had been an opportunity to reflect on a very busy year, the progress made in terms of delivering the business plan, and a forward look to the future. A large part of the day had been spent on preparing for the forthcoming office move which would be discussed in more detail later in the meeting.
- 4.7.** On 11 January, the Chief Executive, with the Director of Compliance and Information, sat on an interview panel to appoint a new Chief Inspector. The calibre of the candidates was very high and the appointment of the successful candidate would be formally announced shortly.
- 4.8.** 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.
- 4.9.** Press Coverage: the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.
- 4.10.** Genome Editing: the Chief Executive advised members that there had been considerable press coverage of the fact that HFEA had received a research application which involved the use of the genome editing technique Crispr-Cas9. The HFEA Licence Committee met to consider the application, although the decision would not be made public until the minutes of the meeting have been agreed. The Chief Executive reminded members that the genetic modification of embryos had been legal in a research context in the UK since 2009, although it remained illegal in treatment.
- 4.11.** Unregulated sperm donation: an unregulated sperm donor, claiming to have fathered 800 children, had been interviewed on the Victoria Derbyshire programme. The Chief Executive, together with the Chief Executive of the National Gamete Donation Trust (NGDT) had also taken part in the discussion. The HFEA planned to provide more information on the new website as to the dangers of using such services. There had been a lot of press coverage both before and after the show.

- 4.12.** London Sperm Bank: the Chief Executive advised members that it had been brought to the HFEA's attention by a national newspaper that the promotional material for the London Sperm Bank stated that it screened potential sperm donors for dyslexia, attention deficit hyperactivity disorder (ADHD), attention deficit disorder (ADD) and other conditions. When questioned, the clinic claimed that HFEA guidelines permitted such screening. The HFEA had made it clear to both the newspaper and the clinic that the HFEA did not, or ever had, endorsed or guided clinics to screen for such conditions. Following discussions with their HFEA inspector, the clinic's management had removed the claims from their promotional materials and would be producing updated guidance for clinic staff.

5. Committee chairs' updates

- 5.1.** The Chair of the Statutory Approvals Committee (SAC) reported that the committee had met on 26 November and 17 December. There had been five preimplantation genetic diagnosis (PGD) applications in November, all of which were approved, and one request for Special Directions which was granted. At the December meeting, two PGD applications had been considered, one of which was approved and one rejected.
- 5.2.** The Chair of the Licence Committee advised members that the committee had met on 14 January. The minutes had not yet been published. The committee had considered one research renewal application, an initial research licence application and a research project interim inspection.
- 5.3.** The Chair of AGC advised members that the committee had met on 9 December, and had received reports on:
- The spending review, the HFEA's office move and resilience and business continuity management, from the Director of Finance and Resources
 - Register and Compliance risks and an update on the IfQ Programme, from the Director of Compliance and Information
 - Strategic risks, from the Head of Business Planning
 - Updates from the Internal and External Audit teams
 - The implementation of audit recommendations, from the Finance and Accounting Manager
 - Licensing appeals, from the Chief Executive
 - An annual review of AGC activities and effectiveness.
- 5.4.** The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the last Authority meeting. At the first three meetings, the panel had considered four treatment and storage renewal applications, all of which were approved; three licence variations, all of which were approved; three interim inspection reports, where the licences had been continued; and two Special Directions, both of which were granted. At the meeting on 15 January, the minutes of which had not yet been published, the panel had considered three interim inspections, two licence variations, three treatment and storage renewal applications, and one progress report.

6. Strategic performance report

- 6.1.** The Chair of the meeting 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 Strategy and Corporate Affairs provided members with a summary of activities within her Directorate in the last six months and an overview of the Directorate's contribution to the HFEA strategy.
- 6.3.** Setting standards – improving quality of care and the lifelong experience of donor conception: the Director of Strategy and Corporate Affairs reminded members that a new process for regulating mitochondrial donation had been launched following the regulations coming into force on 29 October 2015. Work also continued on redesigning the Choose a Fertility Clinic (CaFC) website as part of the IfQ programme. It was felt that CaFC and the information on each of the clinics which the HFEA licensed had an equally important role in driving up standards in clinics as the formal regulatory policies.
- 6.4.** Increasing and informing choice – using HFEA data to improve outcomes and ensuring patients have access to high quality information: the Director of Strategy and Corporate Affairs advised members that the HFEA had attended both the Fertility Show and the Alternative Parenting Show which was an opportunity to meet patients, prospective patients and donors. 600 copies of the HFEA's 'Getting Started' guide were handed out together with 100 donation and multiple births leaflets. Patient information on reproductive immunology on the HFEA's website had also been updated as a result of SCAAC having reviewed the evidence.
- 6.5.** Efficiency, economy and value - ensuring the HFEA remains demonstrably good value: the Director of Strategy and Corporate Affairs advised members that staff resources would be focused on work which would achieve the HFEA strategy, and saving money by implementing the refreshed brand which had been achieved by cutting expenditure on design and print.
- 6.6.** The Director of Strategy and Corporate Affairs provided members with an overview of the HFEA's website activity. The most popular device used to access the HFEA website was the mobile phone, with 48% of users, although these users were the ones spending the least amount of time on the website. This was followed by 41% using a desktop or laptop and 11% using a tablet. After the United Kingdom, at 48%, the most popular geographical location of website users was the United States at 16%, India at 13%, Australia at 3% and Canada at 2%. Popular pages on the HFEA website continued to be the intrauterine insemination (IUI), in vitro fertilisation (IVF) and Intracytoplasmic sperm injection (ICSI). However, surrogacy, although not regulated by the HFEA, was the second most visited page on the website.
- 6.7.** The Director of Strategy and Corporate Affairs reminded members that the annual conference, scheduled to take place on 24 March, was mainly for professionals working in licensed clinics and laboratories. Registration for the conference would be launched on 1 February and members were asked to let the Executive Assistant to the Chair and Chief Executive know if they wished to attend.
- 6.8.** The Director of Compliance and Information provided members with an update on legal parenthood since the last Authority meeting. From 6 April 2009, women, and the partners of

women treated with donor sperm, where the couple was neither married nor in a civil partnership, were required to give their consent in order to become the legal parent of any child born. Legal parenthood gave a lifelong connection between a parent and a child, and affected things like nationality, inheritance, contact and some aspects of financial responsibility.

- 6.9.** In 2009, the HFEA had issued a suite of guidance and specific new forms to enable the obligations on clinics to be discharged appropriately on behalf of patients. At the time, the HFEA also ran a series of workshops and inspectors also began looking in some depth on this subject at each clinic they visited.
- 6.10.** The Director of Compliance and Information advised members that in June 2013 two issues emerged. One related to an inspection where defects were found in a clinic in the documentation for 14 specific cases. In the same week, a judgement was made on a particular application made to the court by a separated couple, where the judge had to make a declaration in terms of parenthood. The HFEA felt that this was a significant development and there was a need to understand better the extent to which there might be a more widespread issue. Therefore, in autumn of the same year, the HFEA issued information to all clinics through Clinic Focus and asked a number of clinics to undertake a detailed audit, as part of a trial, in order to understand whether the problem was more extensive. The evidence subsequently suggested that it might be and the HFEA consequently required all clinics to undertake an audit which would then be checked at inspection. The Chief Executive issued a letter to all clinics reporting the results of that audit and intimating that there was more widespread poor practice.
- 6.11.** Between February and September 2015, the Family Division of the High Court gave consideration to a number of cases, the outcome of which made it clear that there were defects in the records affecting eight couples. A declaration was made on seven of the couples and the judge was able to grant parenthood.
- 6.12.** The Director of Compliance and Information advised members that the HFEA's approach was one of transparency and openness and clinics were expected to take the same approach. Regular reports had been provided both to Authority members and AGC. Throughout the process, there had been good cooperation from clinics, with most clinics being exemplary in terms of the communication with the HFEA. The HFEA wanted to seek assurance from clinics that their processes going forward were robust and that every step had been taken to minimise the potential for failures of consent taking place in the future. The responsibility for this was clearly placed on the Person Responsible (PR) of each clinic. It was emphasised that a clear expectation had been placed on the PR to support patients through the difficult process as far as possible.
- 6.13.** The Director of Compliance and Information emphasised that legal parenthood would continue to be a focus of the HFEA's inspection and monitoring activity. He noted that clinics had provided assurances to the HFEA about their current practice. Of the 92 clinics that had provided such treatment since the law changed in 2009, 28 clinics had one or more anomaly, and fewer than five clinics were subject to ongoing inquiries. It was expected that, on the basis of the evidence that the HFEA had seen, there would be around 90 patients with some level of parenthood doubt. However, a proportion of those patients were unlikely to pursue the matter any further. Some seven cases had already been determined at the High Court with a further

nine cases currently under consideration. In most cases to date, the Department of Health had decided to intervene in the court proceedings, in order to try to ensure the determination was made in accordance with statute.

- 6.14.** The Director of Compliance and Information provided members with a summary of lessons learned. When the new rules came into force in 2009, it was felt that the HFEA acted in a thoughtful and consultative manner when setting the expectations of clinics. However, it was acknowledged that the difficulty of the task faced by them may have been under-estimated.
- 6.15.** In conclusion, the Director of Compliance and Information advised members that, going forward, it was fundamental there was a clear policy and a shared understanding of why adhering to a rigorous process was so important. The requirements were not just administrative in nature: they set out the basis of the legal relationship of the parent and child going forward. The use of multiple forms, the lack of checking, mistakes and quality assurance were suggestive of an absence of a clear understanding at all levels within a service.
- 6.16.** Following a discussion, members noted the update on legal parenthood and that further communication to the sector would be forthcoming as regards lessons learned.
- 6.17.** The Director of Finance and Resources provided an overview of financial performance and a summary of the position towards the end of the financial year. At the end of December, there was a surplus of £383k. The surplus was partly due to a lower spend on salaries and legal costs. The forecast for the end of the financial year was a surplus of just under £300k.
- 6.18.** Turning to the 2016/17 financial year, the Director of Finance and Resources advised members that the changes to fees, which had been agreed at the last Authority meeting, had been announced to clinics in Clinic Focus at the beginning of January, although it was made clear that those changes were still subject to Treasury approval. The Treasury had considered the changes and there were a few outstanding queries to clarify with them.
- 6.19.** The Director of Finance and Resources advised members that the Department of Health had confirmed the amount of grant-in aid for 2016-17, which was a small reduction from the current financial year.
- 6.20.** In relation to the HFEA's office move, the Director of Finance and Resources confirmed that the HFEA would be sharing office space with the National Institute of Clinical Excellence (NICE). 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 making sure that staff concerns were addressed. Visits to the new offices were also currently underway for all staff.
- 6.21.** Following the discussion, members noted the presentation and the latest strategic performance report.

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 and the data dictionary
- Revisions to the programme timeline
- Arrangements for the management of the IfQ programme.

7.3. As members had been previously advised, the externally facing part of the programme could not formally proceed beyond 'Alpha' (proof-of-concept) stage until approvals in line with Government Digital Service (GDS) Standards had been granted by the Department of Health. The Director of Compliance and Information advised members that the first stage assessment, undertaken by the Department of Health Digital Projects team on 12 November, was passed to a high standard. The second stage assessment – undertaken by the Government Digital Service itself – had also been approved.

7.4. The Director of Compliance and Information advised members that, building on the proof-of-concept work presented to Authority members at the last meeting, the teams had made good progress on a working website and clinic portal. The HFEA conference to be held in March 2016 would provide an opportunity to showcase the progress made, and to generate anticipation for the roll-out of the 'beta' version of the products. It would also introduce the proposed data dictionary (the data required to be submitted to the HFEA relating to treatments and other activity) together with the plans for the data submission part of the clinic portal. Members were advised the clinic portal was scheduled for release in October 2016.

7.5. The Director of Compliance and Information advised members that substantial cleansing activity of Register data was being undertaken by the Information and IT teams at the HFEA, in order to effect a smooth transfer to the new Register in line with the HFEA data dictionary. Whilst this work had minimised data cleansing burden on clinics, input from clinics was required and this work was expected to take place over the next three to four months. The HFEA had communicated with clinics in order to prepare them for this next step, although it was unlikely to be a popular move, and the Executive noted that further communication with clinics was vital in order to work most effectively with them in the coming months.

7.6. Progress on exposing the data dictionary to stakeholders, and for accreditation by the Health and Social Care Information Centre (HSCIC), had been slower than hoped. Consequently, this part of the programme was becoming a risk to delivery. Members noted they would be asked to 'sign off' the data dictionary at the Authority meeting in March.

- 7.7.** Principally as a consequence of the first stage approval delay, the Director of Compliance and Information advised members that there had been subsequent revisions to the programme timeline. The public beta for the website and clinic portal had now been pushed back approximately three months and two months respectively – with both now expected to be launched (for beta testing) in July 2016. The revised timeline had been discussed with stakeholders and, from feedback, it was clear that it was best to ensure complete confidence in the accuracy of the products before release, even if this resulted in a slight delay.
- 7.8.** The Director of Compliance and Information advised members that the IfQ programme oversight had now been absorbed by the HFEA's Programme Management Office (PMO), further to the departure of the dedicated Programme Manager. Whilst in its early days, the arrangement was working well with the programme helped by having well-established project boards with continuing oversight of each of the projects making up the Programme.
- 7.9.** Following a discussion, members noted the progress made on the IfQ programme and the slippage on timescales.

8. Applications to use Register data for epidemiology studies

- 8.1.** The Researcher in Statistics and Epidemiology presented this item and advised members that the HFEA Register Research Panel (RRP) had been set up in 2010 after the law changed to allow the disclosure to external researchers of patients' identifying information. The Authority remained the statutory Oversight Committee and therefore had a duty to exercise oversight of the work of the RRP.
- 8.2.** Since 2010, a total of eight studies had been approved, with three published papers and two presentations at international conferences (the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM)).
- 8.3.** Since the last report to Authority members in January 2015, the panel had received and approved one new application, with three other grant applications, one of which had already been approved. The number of new applications was disappointing. However, the excellent quality of work performed demonstrated the value of the Register and allowing researchers access to it. The studies helped to answer questions of significant patient and scientific interest, including the long term health of women and their babies, development of prognostic tools, and the effect of culture media.
- 8.4.** The Researcher in Statistics and Epidemiology provided members with an update on ongoing studies. The HFEA was currently preparing data for two studies:
- Mortality and morbidity in children born after IVF (University College London) – the HFEA was in the process of extracting data for linkage at the HSCIC
 - A culture media linkage study (University of Manchester) aiming to identify the impact of different culture media on subsequent live birth rates and birth weights – the HFEA was extracting data for linkage onsite.
- 8.5.** The Researcher in Statistics and Epidemiology advised members of three studies, previously reported to them and due to be published later in the year:

- The Epihealth Outcomes Project (University of Manchester) in relation to the effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health – researchers were still working on their analysis of the data that the HFEA had provided and planned to start writing up their findings in the coming months
- The development and validation of statistical models to predict pregnancy outcomes following IVF (University of Aberdeen) – researchers had completed their analysis, with one paper already published and one planned for publication later in the year
- The cancer risk and mortality in women after IVF (UCL) – the principal investigator, Professor Alastair Sutcliffe, presented the ovarian cancer results at the ASRM in October 2015. The remainder of the analysis should be published soon.

8.6. Following a discussion, Authority members noted the report provided to them by the RRP.

9. Embryo testing: testing for more than one condition at a time

- 9.1.** The Regulatory Policy Manager provided members with a background to embryo testing technologies. Preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) had been available for many years. Technologies used in PGD were used to identify embryos at risk of being affected by an inherited genetic or chromosomal condition. PGS was used to screen embryos for common chromosomal abnormalities that could cause miscarriage or IVF failure.
- 9.2.** The requirements for PGD and PGS were as follows. A centre was only permitted to carry out PGS in order to establish whether an embryo may have an abnormality that ‘may affect its capacity to result in a live birth.’ Centres were required to validate the use of PGS for each group of patients to whom they offered it. To carry out PGD, two requirements must be met: there must be a ‘particular’ risk (an existing known risk of a genetic disease in the family) and a ‘significant’ risk (the disease must be sufficiently serious and on the list of conditions authorised by the Authority for PGD).
- 9.3.** The Regulatory Policy Manager advised members that, in recent years, significant advances had occurred in embryo testing technologies. The latest developments meant that it was now possible to simultaneously screen embryos under PGD and PGS at the same time. New technologies had also presented the ability to generate additional genetic information about conditions/abnormalities not being specifically tested for.
- 9.4.** The Regulatory Policy Manager reminded members of two potential scenarios which had arisen from the latest developments in embryo testing technologies, and the legal advice which had been sought by the Executive for both scenarios:
- Patients may wish to have both PGS and PGD at the same time – legal advice concluded that PGS and PGD should be considered separately and the requirements for each must be satisfied before testing was carried out. If a patient satisfied the requirements for PGD and PGS, both forms of embryo testing could be carried out at the same time.
 - Patients may wish to use PGD to test for more than one genetic condition at a time - legal advice concluded that it was possible for an embryo that had satisfied the particular and significant risk requirements for PGD for one genetic condition, to be

tested for additional conditions at the same time, provided it satisfied the significant risk test.

- 9.5.** Members had last considered this issue at its meeting in May 2015. At that meeting, members had expressed misgivings about the type of patients currently being offered PGS by clinics and how complex test results could be interpreted. It was therefore agreed that these comments should be further considered before a decision is made. The paper now presented to members addressed the Authority's comments before asking for a decision on whether it was appropriate to test for more than one condition or abnormality at a time. The Authority's choice would come down to where members wished to strike the balance between maximising patient choice and being concerned about the implications of handling and interpreting additional genetic information.
- 9.6.** In line with the Authority's recommendations in May 2015, SCAAC considered the Code of Practice guidance note on PGS at their June meeting, and made the following recommendations:
- Based on the current level of evidence, the Authority should not recommend PGS for particular patient groups
 - Guidance around information for patients should be updated to reflect the use of the latest embryo testing technologies
 - Genetic information generated through embryo testing technologies should be interpreted by experts in genetics and embryo testing
 - Patients should be offered access to both genetic and infertility counsellors, and given guidance on questions they should ask.
- 9.7.** The Regulatory Policy Manager provided members with a summary of stakeholder views. In relation to handling and sharing information:
- Patients would want access to any information generated through embryo testing, however ambiguous the finding may be
 - Patients should see an expert in interpreting genetic information and discuss their options in the light of the information generated
 - Patients should be able to opt out of receiving any additional genetic information that embryo testing might find
 - Genetic information which could not help select an optimal embryo for transfer should not be tested for.
- 9.8.** In relation to counselling requirements and recording consent, stakeholder views were that:
- Any additional genetic information that could be obtained via embryo testing should be explained to the patient
 - Patients should be offered access to both a genetic and infertility counsellor, before and after embryo testing
 - Consent should be recorded for what is being tested for, and whether any additional information should be disclosed to the patient.
- 9.9.** Taking into account the legal advice, the views of SCAAC and stakeholders, the Regulatory Policy Manager asked members to consider two possible policy options and for members to decide on the most appropriate approach:

- Option one: to prohibit the use of PGD to test for more than one genetic condition (where there is only a known risk of one condition)
- Option two: to allow testing of more than one genetic condition, making sure that patients consent to receive (or not receive) the information generated.

Decision

- 9.10.** Following a discussion, members agreed that option two was the most appropriate because it best reflected the legal position and they could see no evidence for being more stringent than the law allowed. Members were reassured that this would not result in people requesting PGD for non-serious reasons. This was because in order to allow testing for a second genetic condition, patients would already have qualified for PGD and met the two requirements: that there must be a ‘particular’ risk (an existing known risk of a genetic disease in the family) and a ‘significant’ risk (the disease must be serious enough and on the list of conditions authorised by the Authority for PGD). The second disease must also be serious enough to be on the same list.
- 9.11.** The Executive agreed to consider how to communicate the new guidance to clinics, and how best to let patients know about the options available to them and their implications.

10. Government initiatives around better regulation

- 10.1.** Authority members accepted the following recommendations in relation to the Government initiatives around better regulation, subject only to comments and questions from members:
- The emerging proposals from Government
 - The forthcoming consultation on bodies having a duty under the terms of the Enterprise Bill, and that the HFEA does not make a case for exemption
 - The Executive’s proposed approach to fulfilling these duties (when enacted)
 - The Executive’s proposed approach to continue to resist any duty to appoint a Small Business Appeals Champion.

11. Any other business

- 11.1.** The Chair of the meeting confirmed that the next meeting would be held on 9 March at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

12. Chair’s signature

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

Signature

Chair

Date