Authority Paper

Paper Title	**Minutes of Authority meeting 5 March 2014**
Agenda Item	2
Paper Number	[HFEA (14/05/2014) 717]
Meeting Date	14 May 2014
Author	Charlotte Keen, Information Access and Policy Manager
For information or decision?	**Decision**
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.

Minutes of the Authority meeting on 5 March 2014 held at ETC Venues, Hatton Garden, 51-53 Hatton Garden, London, EC1N 8HN.

Members
There were 8 members at the meeting, 6 lay members and 2 professional members.

Members present
Sally Cheshire (Interim Chair)
Professor David Archard
Bishop Lee Rayfield
Sam Abdalla FRCOG
Rebekah Dundas
Dr Andy Greenfield
Dr Alan Thornhill
Jane Dibblin

Apologies
Gemma Hobcraft
Dr Susan Price
Debbie Barber

Observers
Ted Webb (DH)
Steve Pugh (DH)

Staff in attendance
Peter Thompson
Nick Jones
Juliet Tizzard
Sue Gallone
Catherine Drennan
Sam Hartley
Jessica Watkin
Paula Robinson
Joanne McAlpine
Charlotte Keen

1. Welcome, Apologies and Declaration of Interests

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the second meeting of 2014.

1.2. Apologies were received from Gemma Hobcraft, Dr Susan Price and Debbie Barber.

1.3. Declarations of interest were made by:

- Sam Abdalla (Person Responsible at a licensed centre).

2. Minutes of Authority meeting held on 22 January 2014

2.1. Members agreed the minutes of the meeting held on 22 January 2014 subject to some minor amendments. The Chair agreed to sign the minutes as amended.

3. Chair's Report

3.1. The Chair confirmed that the HFEA had decided to move to having all of the meetings of the full Authority in public. The meetings would continue to be audio-recorded and, from the next Authority meeting in May, the audio-recording would be made publicly available. At some point in the future, consideration may be given to videoing the meetings.

3.2. The Chair welcomed Sue Gallone to her first meeting as Shared Director of Finance and Resources for the HFEA and HTA.

3.3. The Chair advised members that she had chaired the Multiple Births Stakeholder Group on 29 January. It was a very positive meeting which highlighted the HFEA's commitment to its "One at a Time" policy and supporting the sector to get down to a multiple birth rate of 10%. The meeting took stock of progress towards the year 4 target and it also considered what new policies may be needed to maintain the momentum towards the 10% target rate.

3.4. The Chair and the Chief Executive had met Felicity Harvey, Director General at the Department of Health, on 4 February, to discuss the HFEA's strategic ambitions and how it could support the Department to achieve its priorities.

3.5. The HFEA Annual Conference took place on 26 February. This was a huge success with over 200 attendees from the sector. The HFEA had combined some headline work on its strategy with sessions which were particularly useful for those who worked in clinics. The Chair thanked staff and members for attending the Conference and for the various roles that they had played throughout the day. The Chair believed that the Conference marked an important turning point for the Authority in its relationship with the sector and in signalling its strategic concerns over the next three years.

3.6. Looking ahead, the Chair advised members that on 12 March she would be attending an ALB Chairs meeting, chaired by Earl Howe, to discuss key priorities for 2014/15.

3.7. On 7 May, the Chair would be attending the Department of Health and national Arm's Length Bodies Chairs and non-Executive Directors Conference. The Chair asked for any members who would be free to attend the meeting to let the Executive Assistant to the Chair and Chief Executive know, so that she could send them further details and confirm attendance.

4. Chief Executive's Report

4.1. The Chief Executive began by reiterating what a success the Annual Conference had been. He expressed his gratitude to members and staff and to all the delegates who had taken the time to attend the Conference. He also thanked staff and members who had helped to put the whole day together. The Chief Executive emphasised that the HFEA was determined to continue the conversation that had begun at the Conference and, to that end, all of the presentations had been put onto the HFEA's Conference microsite. Notes of the workshops would follow shortly. The Chief Executive advised members that he had also written a piece in Clinic Focus and in BioNews.

4.2. The Chief Executive advised members that he had met Ian Hudson, the new CEO of the Medicines and Healthcare Products Regulatory Agency (MHRA) on 30 January. This was both an introductory meeting and an opportunity to build on joint working, particularly over the patient safety issue of medical devices used in assisted reproduction, which were regulated by the MHRA.

4.3. Finally, the Chief Executive thanked members for their responses to the draft Framework Agreement between the HFEA and the Department of Health, which set out the broad constitutional relationship between the Department and the HFEA.

4.4. **Press Coverage:** the Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members.

4.5. Mitochondria replacement consultation: the Department of Health had launched its consultation on the mitochondria replacement regulations on 27 February which was picked up by the BBC, ITV, the Guardian, Telegraph, Independent and the Daily Mail. The consultation followed the HFEA's own public dialogue exercise – Medical Frontiers: debating mitochondria replacement.

4.6. Re-registering as an identifiable donor: There had been a piece in the Guardian at the beginning of February, written by a man who donated sperm some years ago and had since opted to re-register as identifiable in case any of the children he had fathered wanted to trace him. The article was largely positive and reflected on the process the donor went through to decide to re-register as an identifiable donor. The HFEA hoped that it had raised awareness about re-registration, and a link to re-registration information had been placed on the HFEA website on the same day.

4.7. Embryo incidents: a Sunday Times article on 2 February had reported on three incidents of embryos being destroyed by accident, following an alert issued to all PRs. The HFEA gave the following statement to the Times: "staff at HFEA licensed fertility clinics are required to report adverse incidents and near misses that happen at their clinic. The HFEA then investigates the causes and ensures the clinic involved puts measures in place to prevent the same error happening again. Though regrettable, we need to recognise that incidents will always happen in healthcare; the important point is to ensure that clinics learn from any mistakes. Punishing clinics for incidents only leads to a culture of secrecy. We need to encourage a culture where incidents are reported openly and quickly. The HFEA alert system is designed to share the lessons learned from incidents with the fertility sector and we are preparing a publication on incidents with the aim of encouraging public understanding and best practice. It is not our practice to name the centres involved."

4.8. Stem cell research: researchers in Sweden and Singapore had developed a method which allowed for large-scale generation of human embryonic stem cells of high clinical quality from a single cell taken from a human embryo.

4.9. Risks of IVF: a commentary article had been published in the British Medical Journal on the risks of IVF, which had used HFEA data. The article was picked up by both BBC and Sky news and the HFEA gave the following comment: "IVF has enabled thousands of women to have a much wanted family. Fertility clinics in the UK are required by law to provide patients with information about the risks involved before treatment. The HFEA regularly reviews the latest research regarding the outcomes of IVF and provides information for patients on its website. We always advise that patients should speak to their treating clinicians if they have concerns."

5. Governance Review and Standing Orders

5.1. The Head of Governance and Licensing introduced the paper and explained that it brought together different updates and recommendations related to the governance of the Authority, namely:

- Feedback from the annual review of Committee effectiveness;
- Initial feedback from the Internal Auditors' review of governance;
- An update on the governance arrangements following the Authority's recent decisions on transparency;
- The delegation of the Authority's licensing powers; and
- The annual review of (and other consequent changes to) Standing Orders.

5.2. **The annual review of Committee effectiveness**: The Head of Governance and Licensing explained that all Committees were required to conduct an annual review of their effectiveness and these reviews had been carried out between October 2013 and January 2014. Generally, the feedback had been positive and the first year of the new Committee structure had worked well, with appropriate powers for each Committee and with high quality paperwork being provided to members.

5.3. Trends for improvement that had emerged from the review were around:

- Ensuring quoracy with fewer members;
- Communication between Committees and between Committees and the Authority and external bodies;
- Ensuring Committees were supported well with expert (or other external) advisers; and
- Work plans for the non-licensing Committees in order to make sure there was a clear map of future things to consider.

5.4. The Head of Governance and Licensing advised members that, since the reviews had been conducted, the Executive had taken a number of steps to address these issues and continued to do so.

5.5. **Internal Audit review of governance**: the Head of Governance and Licensing explained that the Authority's internal auditors looked at different aspects of the way the Authority runs and assures itself every year. Currently they were concluding their review of governance and would report formally to the Audit and Governance Committee (AGC) on 19 March 2014. The internal audit team had worked in close collaboration with the Executive and the initial feedback

suggested that there was little of significant concern, although there were a number of minor actions to be taken. Many of these were already being addressed by the Executive, such as minor omissions in paperwork relating to appointments and adviser details. Others would be actioned following consideration of the final report by AGC.

5.6. **Transparency:** the Head of Governance and Licensing reminded members that, at the Authority meeting in January, they had agreed to opening all full Authority meetings to the public, subject to retaining the ability to meet in private session. Members had asked the Executive to consider some further questions in relation to live streaming and/or audio publication (which the Communications team were considering and hoping to progress quickly), the conduct of the meetings and items to be considered in private. The Executive had considered this and the proposed changes to the Standing Orders outlined suggested items to be taken in private, such as the risk register, the legal update and any commercially sensitive matters, with the discretion of the Chair to consider any other additional items as appropriate.

5.7. Every three years, the Authority was required to review its publication policy. The Information Access and Policy Manager, together with the Head of Governance and Licensing, had therefore reviewed the policy in order to bring it into line with the new Committee structure and the proposed changes to the delegation of licensing functions in the Standing Orders.

5.8. **Delegation of licensing functions**: since the Authority's Executive Licensing Panel (ELP) was established in 2009, the Panel had been successful in considering any 'routine' items in relation to licensing, thus taking the pressure off the Authority's licensing Committees. The protocol worked very well and the Executive's proposal was therefore for a 'Licensing Officer' role to be established, building on the success of ELP. The Licensing Officer would consider more administrative decisions, for example the change of Licence Holder or address for which there was no statutory test or obligation on the centre, or voluntary revocations where a centre had ceased activity. Delegation to a Licensing Officer role would enable such straightforward administrative decisions to be taken more quickly, and with fewer resources. Changes would be made to the Standing Orders to allow this proposal to be implemented and the Executive would fully develop and evaluate the proposal, with a view to implementation within six months. The Executive would keep the appropriate delegation of licensing functions under review.

5.9. **Annual Review of Standing Orders**: the Head of Governance and Licensing advised members that, in addition to the changes necessary to the schedule of delegation, the Executive had also conducted an annual review of the Standing Orders, which governed the way the Authority exercised its statutory functions. The proposed changes could be put into one of the following categories:

- Delegation of licensing functions;
- Authority's decisions on transparency, and the conduct of ordinary Authority meetings;
- The appointment of advisers or advisory groups;
- The way in which the role and powers of the Statutory Approvals Committee was described, better matching the statute and to reflect the recent discussion on HLA testing for non-heritable conditions;
- Minor changes to terminology or typographical corrections.

Decision

5.10. Following a discussion, Authority members:

- Noted the feedback from the annual review of Committee effectiveness, and progress made to date on addressing issues;
- Noted the update on the Internal Auditors' review of governance;
- Noted the arrangements for transparency and approved the revised Publication Policy;
- Approved the proposal to establish the role of Licensing Officer and associated revisions to the delegation of licensing functions.

5.11. Following a discussion, members voted to approve the revised Standing Orders. The vote was passed unanimously (8 members in favour). The Authority specifically noted and agreed the proposal for the Chair of the Statutory Approvals Committee to have a casting vote. Paragraph 3.10 in the Standing Orders relating to the Statutory Approvals Committee should therefore read "the Committee Chair shall have a casting vote."

6. Improving the Sharing, Quality and Disclosure of Donor Information

6.1. The Policy Manager introduced this paper and reminded members that at the Authority meeting on 3 July 2013, they had agreed that the Executive should scope out various models for establishing counselling and intermediary services for Opening the Register (OTR) applicants and to explore what specialist support could be provided for other people affected by donation.

6.2. This work had been identified as a high priority by a group of key stakeholders at an earlier meeting, organised by the HFEA, in June 2013. The purpose of this meeting had been to discuss and prioritise donation related work identified by the Executive following the review of donation policies carried out in 2011.

6.3. The importance of this work was also recognised in the McCracken review of the HFEA in 2013. Recommendation 7 of the review stated that the HFEA should "identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART."

6.4. The HFEA was currently consulting on elements of its future strategy and one of the three strategic statements in the published engagement document was to 'improve the lifelong experience for donors, donor conceived people, patients using donor conception and their wider families'. If this became a formal strategic focus for the Authority, this planned work would be a good strategic fit.

6.5. In the light of the Authority's previous decisions and the rationale for carrying out this work, the Policy Manager explained that the paper set out various models for establishing a support and intermediary service for those affected by donation.

6.6. The Policy Manager explained that the HFEA held both identifying and non-identifying information about donors on its Register. Non-identifying information could be accessed by donor conceived people on reaching 16. At present, identifying information about donors was only accessible to donor-conceived people if their donors had re-registered as identifiable. This would remain the case until 2024. At present under 130 donors had re-registered (under 1% of the total number of registered donors).

6.7. Despite these relatively small numbers, the HFEA had already received a small number of requests from donor conceived people for identifying information about

re-registered donors. The Authority, when it considered the 'Opening the Register' policy back in 2009, had recognised that it owed a duty of care to all those involved. This duty derived from the fact that the HFEA was the custodian of highly sensitive information, disclosure of which could have a significant impact on the lives of all those affected by it. It was therefore of vital importance that disclosure took place with the greatest of care and in accordance with good practice. It was also clear that it was time to consider longer term solutions. The HFEA expected further requests and demand would rise over time.

6.8. The Policy Manager advised members that, at present, the HFEA provided some basic advice to donors and donor conceived people on its website and signposted them to various organisations including the British Infertility Counselling Association (BICA) and the Donor Conception Network (DCN). In addition, when people contacted the HFEA, staff provided a considerable amount of advice and information (both in writing and over the phone). These enquiries came from a variety of different people affected by donation and could range from simple queries to more complex discussions, sometimes including the provision of a certain level of emotional support.

6.9. At present, the HFEA had received just three enquiries from donor conceived people whose donors had re-registered as identifiable and where contact had been considered. The HFEA, aware of its duty of care to all the people involved, had dealt with these cases very carefully and on an ad-hoc basis, including organising suitable opportunities for counselling and drawing up one-off contracts with counsellors. These had, however, been resource intensive exercises and would not be a sustainable long term model without additional resources, particularly since the number of applications would increase.

6.10. The Executive had therefore been exploring what a support and intermediary service might look like with key stakeholders from the British Medical Association (BMA), BICA and the Project Group on Assisted Reproduction (PROGAR). Discussions had also taken place with a large post adoption agency that provided support and intermediary services for those affected by adoption.

6.11. Following these discussions, it was proposed that the key components of the service should be:

- open to a broad range of people affected by donation
- able to provide advice, support and intermediary services
- provided by workers with experience in post adoption support.

6.12. The Policy Manager advised members that it was also proposed that donors and donor conceived people should have access to funded services. This would apply in cases where:

- A donor was considering re-registration
- Donors were aware that donor conceived offspring had applied for their identifying information
- Donor conceived offspring had applied for identifying or non-identifying information
- Intermediary services were needed, because contact was sought.

6.13. The rationale for providing funded services to donors and the donor conceived was that it recognised the donor's generosity and that this should be encouraged. It also acknowledged that donor conceived people were not responsible for the

circumstances of their conception and should have no financial obstacles in the way of accessing the information in a supported way.

6.14. It was proposed that up to five funded sessions per case, with support and an intermediary worker, would be made available and – for re-registration and people seeking non-identifying information - up to two sessions per individual of counselling in relation to implications.

6.15. The Policy Manager advised members that it was difficult to assess with any accuracy what the level of demand for the service would be. The Executive acknowledged that the number of applicants to date was small and was unlikely to grow significantly over the proposed three year pilot.

6.16. The Policy Manager outlined three service models on the level of service for members to consider:

- Option 1: service fully provided in-house
- Option 2: the HFEA to have contracts with external providers (post adoption sector)
- Option 3: the HFEA to have a contract with post adoption agency(ies). Payment on a 'per case' basis.

6.17. The paper asked the Authority to approve the proposal that the HFEA fund a three-year pilot, using option 3 as the model for that service.

6.18. The Policy Manager informed members that option 3 was the one favoured by stakeholders. Based on discussions with a major post adoption agency, it was estimated that, if option 3 was taken forward, each case involving a donor conceived individual and a donor, where contact and a meeting was envisaged, would cost up to £600-£700. For donors considering re-registering and those seeking non-identifying information from the register, it was estimated that those cases would cost up to £200 each.

6.19. The Policy Manager explained that the best estimate of demand during the pilot phase was around 60 intermediary cases which would require an allocation of £40,000. In addition, there would be modest funds required for training and therefore a ceiling of £50,000 would be prudent. The Executive would also need to get Government approval to fund the pilot from its reserve funds.

6.20. If members approved the recommendations, the Executive would firm up the service model and explore procurement options.

Decision

6.21. Although members were unanimous in recognising the ethical need for such a service and were supportive of the proposals, concerns were raised over the sustainability of such a service and the need to ensure the HFEA managed expectations and retained control over the quality of service provided. Members therefore emphasised the need to closely evaluate the service and explore long term funding options during the course of the pilot.

6.22. Following a discussion, Authority members agreed:

- That the current level of service should be increased, as per stakeholders' recommendations
- That the HFEA should apply for permission to fund a three year pilot, with that pilot subject to certain caveats, including suitable break-points for regular evaluations of the pilot, using option 3 as the service model.

7. Directorates Report

7.1. The interim Director of Strategy informed members that the number of visits to the HFEA website was moving towards 100,000 each month, following a dip before Christmas.

7.2. Reporting on the Annual Conference, the interim Director of Strategy said that it had been a key chance for the HFEA to have face to face discussions with members of the sector about our future strategy, following the engagement materials and questionnaire which had been launched in advance of the conference. It was evident on the day that people who had attended the workshops wanted to be involved on an ongoing basis. There had been some very helpful discussions, particularly around publishing patient experience information alongside outcome data on Choose a Fertility Clinic and there had been a clear steer that the HFEA should go in that direction.

7.3. The interim Director of Strategy advised members that the conference had not been the only point at which the future strategy would be discussed. The consultation would continue until the end of March and the market research company Opinion Leader had also been commissioned to carry out a series of patient focus groups and in-depth interviews with patients, donors and donor-conceived people in order to understand what the HFEA's priorities should be from their perspective. Opinion Leader would be carrying out an online survey of both patients' and stakeholders' perceptions of the HFEA.

7.4. In relation to mitochondria replacement, the interim Director of Strategy informed members that the Department of Health had launched their consultation on the regulations, and that this would close on 21 May. The Department of Health had also commissioned the HFEA to carry out a third review of the scientific research in this area. The first review had been carried out in spring 2011 and an updated review of the science was published in early 2013, alongside the HFEA's public dialogue report. Dr Andy Greenfield would be chairing on this occasion and a call for evidence would be issued towards the end of the week. This would close on 21 March. People would be invited to submit published research and would also have the opportunity to discuss research that was in progress. The outcome of that review would be submitted to the Department of Health towards the end of May.

7.5. The Director of Compliance and Information advised members that the Directorates Report revealed good performance all round in terms of processes and timeliness, although it did not reflect that this year there had been a particularly heavy workload for the team, with more inspections, and vacancies carried within the team for most of the year. There had also been a large number of PGD applications, which the team continued to handle professionally with high quality paperwork. It had been noted that there had been a general improvement in clinic performance across the board although there were exceptions which subsequently involved difficult inspection reports and equally difficult litigation along-side.

7.6. The Director of Compliance and Information explained that the information team had been extremely busy dealing with the cases referred to under item 6 of the agenda, together with supporting the Information for Quality Programme.

7.7. The Director of Finance and Resources provided members with the HFEA's 2014/15 budget overview. It was important to note that the changes made recently in relation to the HFEA's finance systems and team were still bedding down. Although the 2014/15 funding had not yet been confirmed by the

Department of Health, the headline budget was £6m, slightly less than the budget for the current financial year. The reduction was achieved through restructuring and efficiencies in finance, facilities, legal services contracts and office rates.

7.8. Authority members noted the summarised Directorates Report.

8. Committee Chairs' Updates

8.1. The Chair of the Statutory Approvals Committee (SAC) reported that the Committee had met twice, on 30 January and 27 February. In each meeting, seven PGD applications were considered, together with two Special Directions applications. Of the fourteen PGD applications, one was refused (for autism spectrum disorder) after extensive discussion. One of the four Special Directions applications was adjourned. The Chair expressed his thanks to the Head of Governance and Licensing and the Committee Administrator for their work in supporting the Committee and for the excellent quality of the paperwork.

8.2. The Deputy Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) reported that the Committee had met on 5 February. Members had discussed embryo culture media, which was of ongoing interest to the Committee, together with the Horizon Scanning process, in order to prioritise certain areas for discussion and new technologies.

9. Progress on the McCracken Review

9.1. The Chief Executive provided members with an update on progress on the McCracken Review, which was "an independent review of the way in which the HFEA and HTA undertake their functions and operations, with a view to delivering greater efficiencies and giving serious consideration to a merger of the two bodies." The review followed a decision by the Government that the two regulators should remain as separate NDPBs. A paper was presented to the Authority at its meeting in September 2013 where members agreed what the Executive's actions should be against the McCracken recommendations and that the Chief Executive should come back to members periodically to report progress. This was the first of those progress reports.

9.2. The Chief Executive reminded members that McCracken was generally positive about the HFEA but had made ten specific recommendations where the HFEA ought to improve. Of those, six months on, the HFEA had completed four recommendations and the remainder were under way or planned. The Chief Executive provided a summary of the recommendations and progress made on each.

9.3. **Shared Services (recommendation 2)**: "the support services of the two bodies should be combined and managed by a single Director of Finance and Resources supporting both Chief Executives. This will facilitate the achievement of significant further efficiency savings, estimated at £2.8m over 10 years." This recommendation was complete, with the shared Director in post from March 2014, responsible for a wide range of functions including finance, procurement, audit, business continuity planning and facilities.

9.4. **Stakeholder Engagement (recommendation 13)**: "the HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months' time, the HFEA should undertake a structured and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan." This was being addressed in tandem with the next recommendation.

9.5. (**Recommendation 4**): "In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings." Both of these recommendations were in progress and the interim Director of Strategy had explained what was planned so as to engage with stakeholders, under item 7. The Annual Conference held on 26 February had represented a significant milestone in the reinvigoration of the HFEA's relationship with its stakeholders and suggested that real progress had been made over the past six months.

9.6. (**Recommendation 5**): "Both the HFEA and the HTA should establish and operate a (permanent) fees review group to improve accountability and facilitate dialogue with licence fee payers." The Chief Executive advised that the HFEA planned to establish such a group later in 2014, so that it could inform the budget setting process.

9.7. **Better use of Information (recommendation 6):** "to reduce the unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the BFS/ACE paper as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation Document for this work by July 2013 and then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1m." The Information for Quality (IfQ) work programme was well underway. An IfQ Advisory Group was established in October 2013, with four expert sub-groups. There would be an options appraisal presented to members at the Authority meeting in July and the programme of work would be delivered by the end of 2014/15 business year.

9.8. **(Recommendation 7):** "on completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART." The first part of this recommendation would follow from the IfQ programme of work. The second part formed the basis of the discussion of item 6 of the agenda and members had agreed to proceed with a pilot in relation to improving the sharing, quality and disclosure of donor information.

9.9. **Working with other Regulators (recommendation 8):** "in order to improve the approval process for research projects involving gametes and embryos the HFEA should commit to participating fully in the new IRAS system from its launch in 2014 (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it." This recommendation was complete. Agreement had been reached with the HRA in November 2013 and the HFEA would participate with the new IRAS system when it was launched in early 2015.

9.10. **(Recommendation 11):** "the HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter's regulatory oversight but which take place within premises regulated by the HFEA." This recommendation was complete, with an information sharing agreement reached with the MHRA, and guidance on CE marking of medical devices issued to clinics.

9.11. **(Recommendation 12):** "the HFEA should implement their agreement with the CQC, which was approved by the HFEA during my review, to eliminate duplication of regulatory activity between them." This recommendation was complete, with an HFEA/CQC agreement effective from April 2013, resulting in no duplication in England between the clinics the CQC regulated and the clinics the HFEA regulated.

9.12. **Regulatory Focus (recommendation 10):** "the HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different activities that it oversees. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity." This recommendation was much wider and in progress. The new 3 year Strategy would address issues of regulatory focus around quality of care and patients. A consultation was issued online on 10 February and would close on 28 March with a finalised Strategy in place by summer 2014.

9.13. Authority members noted the progress made over the past six months in meeting the McCracken recommendations. The Chief Executive advised members that he would return to the Authority in six months to report on further progress.

10. Business Plan 2014/15

10.1. The Head of Business Planning presented this item, advising members that the business plan for 2014/15 was now at an advanced stage. At a meeting on 6 February, the HFEA's Department of Health sponsors had suggested only a few minor additions to the text, and had indicated that they were broadly content. As mentioned earlier in the meeting, budget confirmation was expected shortly.

10.2. Since members had last considered the business plan in draft, the Head of Business Planning advised that some of the activities listed in the objectives section had been re-ordered so as to better signal the HFEA's future strategic intentions. Text throughout the document had also been written or edited to the same end.

10.3. In addition to adding a Preface, the Looking Back section had now been completed, and the Corporate Enablers and Finance sections had been edited to clarify a number of points raised by the Department of Health.

10.4. The Head of Business Planning advised members that some figures could not be calculated until the end of the business year on 31 March and these would be added to the business plan then. These figures included the 'facts and figures' table at the end of the Looking Back section, the HR benchmarking information in the Corporate Enablers sections, and the performance indicator outcomes for 2013/14.

10.5. The Head of Business Planning informed members that the intention was to review the performance indicators in the business plan, and the way the HFEA monitored and reported performance information in general, once the new strategy had been agreed. For this reason, the performance indicators for 2014/15 would not be included in the first edition of the business plan this year.

10.6. The likely publication date for the business plan was around mid-April and the Head of Business Planning advised that any delays or other unexpected developments would be communicated via email.

Decision

10.7. Authority members approved the Business Plan for 2014/15, subject to the addition of year end information, Department of Health confirmation of the budget and final Department of Health approval.

11. Information for Quality

11.1. The Director of Compliance and Information provided members with a brief summary of progress in relation to Information for Quality (IfQ), which was a large programme of work to transform the way in which the HFEA defined the data requirements collected primarily from clinics, the way in which clinics presented and provided that information to the HFEA and the uses to which the organisation put it, both in terms of the products and the medium by which that information was accessed. This encompassed everything from the dataset to the website and every point inbetween.

11.2. The Director of Compliance and Information explained that the IfQ Advisory Group, chaired by Dr Alan Thornhill, was established in order to guide and define the work within the programme. To support the projects within the programme, expert groups were also being established where people from clinics, patients and other stakeholders, including from the research community, were actively involved.

11.3. In particular, the Data Dictionary Project, established to identify what data the HFEA required, what use it was being put to and what cost was involved in collecting that information, currently had about ten proposed expert group members. This expert group would be chaired by Professor Alison Murdoch, author of the paper which Justin McCracken had referenced as being a piece of evidence and research that the HFEA should have regard to.

11.4. The Director of Compliance and Information advised members that he, together with the interim Director of Strategy, would update the Authority on 14 May on the stakeholder engagement element of the programme. In the meantime, however, running alongside that was a technical evaluation by a third party agency which would be selected shortly (using the Crown Commercial Service, as per central Government requirements) and would work over a compressed period of six to eight weeks to look at the HFEA's processes and the technological options so that proposals could be put to members in the summer.

11.5. Authority members noted the progress report on the IfQ Programme. The Chair thanked the team and the Advisory Group for all the work undertaken so far and emphasised the importance of engaging closely with stakeholders to keep them informed of progress within the programme.

12. Any Other Business

12.1. The Chair confirmed that the next meeting would be held on Wednesday, 14 May 2014 at ETC Venues, Bonhill House, 103, Bonhill Street, London, EC2A 4BX.

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

Chair 

Date **15/05/2014**