Minutes of Authority meeting 11 September 2019

Strategic delivery:	☐ Safe, ethical, effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	2		
Paper number	HFEA (13/11/19) 929		
Meeting date	13 November 2019		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 11 September 2019 held at ETC.venues Victoria, 1 Drummond Gate SW1V 2QQ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Rachel Cutting Anne Lampe	Bobbie Farsides Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian Jonathan Herring
Apologies	None	
Observers	Steve Pugh (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Dina Halai	Laura Riley Paula Robinson Debbie Okutubo Anna Coundley

Members

There were 14 members at the meeting – 10 lay members and 4 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present. She stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not at the meeting to listen to deliberations.

1.2. There were no apologies for absence.

1.3. Declarations of interest were made by;

- Rachel Cutting (Person Responsible (PR) at a licensed centre)
- Yacoub Khalaf (PR at a licensed clinic)
- Anthony Rutherford (Clinician at a licensed clinic).

2. Minutes of Authority meeting held on 3 July 2019

2.1. Members agreed that the minutes of the meeting held on 3 July 2019 be signed by the Chair subject to an amendment in Minute 8.6 to read:

'… *an overview of treatment income issues* ….'

3. Chair's report

3.1. The Chair thanked staff for holding the fort in the absence of the third director, especially with the HFEA being a small organisation. She formally announced that Rachel Cutting had been appointed as the new Director of Compliance and Information from early November 2019, which meant that this would be her last meeting as an Authority member.

3.2. The Chair advised that on 9 July, she chaired a Remuneration Committee meeting.

3.3. Later that day, the Chair and Chief Executive (CE) had the annual accountability meeting with the Department of Health and Social Care (DHSC). The Chair described it as a positive meeting and explained that the DHSC recognised our achievements and gave positive feedback.

3.4. On 17 July, the Chair and Director of Strategy and Corporate Affairs met Helen Stokes-Lampard, the Chair of the Royal College of General Practioners (GPs). The discussion centered around the current links with primary care staff; feedback from the patient survey and actions to be taken; and future opportunities to work together.

3.5. On 25 July, the Chair and CE along with the CE of the Human Tissue Authority and HFEA Head of Human Resources held the interviews for the Director of Compliance and Information post at which Rachel Cutting was appointed.

4. Chief Executive's report

4.1. The CE also welcomed Rachel Cutting as the new Director and commented that her unique experience placed her as the best person for the role at this time.

4.2. On 5 July, the CE went to Manchester to visit Daniel Brison and Raj Mathur.

4.3. On 9 July, he attended the Remuneration Committee meeting. Later that day he met with Shaun Rodgers, the PR of City Fertility.

4.4. On 15 July, he had a meeting with James Duffy, NHS England and they discussed how to improve the identification of fertility research priorities.

4.5. On 31 July, he had an EU Exit telephone conference meeting and later that day he attended the Healthcare Leaders Senior Talent board meeting.

4.6. On 6 August, he met with James Nicopoullos, PR at the Lister Fertility clinic to discuss treatment add-ons.

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee reported that the committee met on 11 July and considered six items: two renewal research, two renewals for treatment and storage, one interim treatment and storage and one additional inspection for treatment and storage, all of which were granted.

5.2. The Committee also met on 5 September and considered four items: one renewal for treatment and storage, two interim treatment and storage and one executive update. The minutes were still in draft.

5.3. The Chair and Deputy Chair of the Committee commented on the accuracy of clinic websites. It was noted that the websites were increasingly becoming an issue for the Committee and that the Deputy Chair had written to the CE about their concerns.

Decision

5.4. Members noted their concerns and that the CE would discuss this matter with the inspectorate.

Statutory Approvals Committee

5.5. The Chair of Statutory Approvals Committee (SAC) noted that the items considered at the 27 June 2019 meeting, two PGD applications and two Special Directions, were all approved.

5.6. It was further reported that the Committee met on 25 July and considered four PGD applications which were all approved.

5.7. They also met on 29 August and considered four items: one mitochondrial donation, two PGD applications and one special direction. The minutes from the meeting were still in draft.

Executive Licensing Panel

5.8. The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met five times since the last Authority meeting on 9 July, 23 July, 6 August, 20 August and 3 September. The Panel considered 26 items: six renewals, 12 interims and eight variations. All items were approved except one renewal which was deferred.

5.9. The Chair of ELP also reported that 16 Licensing Officer considerations were approved: 13 for EU certificates, one for changes of Licence Holder and two for a change of centre name.

Remuneration Committee

5.10. The Chair of the Authority, who was also the Chair of the Remuneration Committee, stated that the Committee met on 9 July 2019 and considered a new pay structure for staff and this year's pay award.

Decision

5.11. Members noted the Committee chairs' reports and the licensing activity report.

6. Performance report

6.1. A report summarising performance data up to the end of July 2019 was presented to the Authority.

6.2. Overall performance was considered to be good.

6.3. The Director of Strategy and Corporate Affairs reported back on a range of initiatives and events that were in progress including two workshops for clinic staff on improving patient support; developing the HFEA response to the Law Commission's consultation on surrogacy and drafting the State of the Sector report.

6.4. The HFEA was highly commended at the recent British Medical Association (BMA) patient information awards for our work on treatment add-ons.

6.5. The Director of Finance and Resources noted that an overspend was forecast against the budget, however the position could change if income remained on its current trajectory. Income

was above budget but below the levels seen in the previous financial year. Expenditure for the first quarter was showing an underspend against the budget.

6.6. There were no additional pressures on the budget at this time and work would be taking place during October to review the activity modelling that underpinned income forecasts, which would likely be completed for November.

6.7. In response to a question, it was noted that clinics were seeing a slight decrease in activity this year. NHS activity had declined but private patients had remained constant. There was a suggestion that any fall in the overall number of cycles funded by the NHS could have been masked in the short term by the transfer of already frozen embryos – but overall numbers might now be falling.

6.8. The CE (in the absence of a Director of Compliance and Information) commented that on the Inspection front we were on schedule. Regarding PGD applications performance varied depending on how complex each application was.

6.9. It was noted that with the development of the new strategy, this key performance indicator (KPI) would be reviewed and benchmarked as it needed to be managed effectively.

6.10. Members commented that the time PGD applications were taking was justified and would help future patients. Also, that peer reviewers were experts in their fields so any delay was a necessary one.

6.11. On another note, Members commented that even though staff turnover remained red on the RAG status it was not overly concerning at present as the position was being kept under review at Audit and Governance Committee meetings (AGC), through the strategic risk register.

Decision

6.12. Authority members noted the performance report.

7. EU Exit

7.1. The CE noted that we regularly assessed our operational readiness and that was reported to the DHSC and they agreed with our green RAG status.

7.2. To prepare for EU exit changes may need to be made to General Directions and decision trees and this may need to be implemented within a short time frame outside of the Authority meeting cycle.

Decision

7.3 Members agreed to delegate responsibility to the Chair and the CE under standing orders paragraph 5.2 with a report back to the Board at the November meeting.

8. Business Planning for 2020 - 2023

8.1. The Head of Business Planning and Governance presented the draft outline of the 2020/2021 business plan to the Authority.

8.2. The paper was a draft outline of a three-year delivery plan and proposed work to be done in the 2020/21 business year.

8.3. It was noted that the process was made more complex as we were simultaneously in the process of developing our new strategy for 2020-2023. However, the feedback received in the course of the strategy consultation indicated strong support, providing a reasonable basis for planning.

8.4. Members were invited to comment. There was a request that in future versions, the objectives should be listed in priority order.

8.5. Regarding being future ready, members suggested that we should be pro-active with meeting the sector and raising awareness on our priorities.

8.6. It was also noted that scoping work had already begun to assess future operational requirements for the Opening the Register (OTR) and Counselling service.

8.7. Members were advised that in November they would receive feedback on the strategy consultation and receive a full draft of the strategy for approval, as well as the first draft of the business plan for 2020/21.

Decision

8.8. Members approved in principle the draft outline business plan activities for 2020/21, as the basis for developing a full draft for the November Authority meeting.

9. Treatment add-ons

9.1. The Scientific Policy Manager presented the proposed aims for the add-ons work, the proposed criteria for an add-on and the proposed direction going forward for this work. It was noted that treatment add-ons were optional extras which claimed to improve patients' chances of having a baby, however the evidence base for many add-ons was either weak or absent.

9.2. Members proposed positive messaging to patients about success rates for core treatments (for example IVF or IUI) alone and that add-ons were not mandatory and not having an add-on would not put them at a disadvantage. The Executive agreed that it was important to have an agreed definition of what we meant by 'core treatment'. Members also considered it important to investigate what treatments clinics included within packages.

9.3. Members highlighted that the current definition for a red traffic light rated add-on was '**there is no evidence that this add-on is effective and safe**' and therefore that the Executive should consider including the commonly opted for holistic therapies (for example massage, acupuncture and nutritional therapy) in the add-ons list.

9.4. Members agreed that there needed to be evidence before any treatment add-on was used in a clinical setting. Also that a meaningful discussion with the sector about offering interventions without evidence needed to happen. They also discussed what could be done to encourage research in this field and agreed that the Scientific and Clinical Advances Advisory Committee (SCAAC) should discuss the evidence base required for a green traffic light rating and to what extent other methods could be used.

9.5. Members had concerns that as we were not routinely aware of the messaging from clinics to patients it was difficult to be fully in control on what information was being provided to patients. A

member highlighted the Montgomery case as a landmark for informed consent. The member added that, as a result of this ruling, the law now required that patients should only be offered 'reasonable' treatment options for which there was a good medical reason and this legal basis could be used in communication with the sector around responsibly offering add-ons. It was therefore imperative to be clear on what was standard treatment and what was an add-on.

9.6. Members suggested adding a tick box into the HFEA's register (PRISM) for clinics to record which treatment add-on a patient had during their fertility treatment and that this data could then be used to look at the success rates when add-ons were used.

Decision

9.7. The Authority agreed that the aims of the add-ons work will be:

9.7.1. to raise awareness of treatment add-ons and the issues therein

9.7.2. to encourage responsible supply and only when a treatment is indicated

9.7.3. to prevent patients from being misled (in terms of potentially exploiting unfounded expectations) by ensuring, through inspections and our own published information, that patients are provided with information that is clear and reliable

9.7.4. to ensure informed consent is obtained

9.7.5. to enhance patient safety by investigating how outcomes and follow ups can be best assessed

9.7.6. to encourage research to assess whether any current or future add-ons increase success rates

9.7.7. to require clinics to provide costed/itemised treatment plans where the costs of treatments and add-ons are clear and to avoid costs being lost in package prices

9.8. The Authority agreed that the criteria for an add-on to be included in the executives list will be:

9.8.1. additional treatments (to the core treatment e.g. IVF or IUI), that patients need unbiased information about effectiveness and risks, that are being offered in fertility clinics;

9.8.2. where evidence on efficacy or safety for the use of the treatment in a clinical setting is lacking or absent.

9.9. The Authority agreed with the way forward for the add-ons work and the Executive will reconvene the Working Group made up of the 11 signatories of the Consensus Statement and involve the General Medical Council (GMC) as appropriate.

10. DNA based matching websites

10.1. The paper reminded members of the September 2018 meeting where the Authority was briefed on the wide-ranging impact of direct-to-consumer genetic testing services offering opt-in matching services on donor anonymity and the managed sharing of information around donor conception, and at which a number of activities including developing new Code guidance were proposed.

10.2. Many DNA testing websites for family history or ancestral ethnicity purposes, or for generalised health information, also offer optional additional services to help identify genetic relatedness between their users, by 'matching' them with other users in their database. The results of this matching, if combined with other information, could also make it possible to infer genetic relatedness with other people who were not on the website database themselves, but who were closely related to those who had been matched.

10.3. Members were reminded that the DNA matching sites were not within the regulatory remit of the HFEA but had important implications for our work.

10.4. We had spoken to three major web-based companies and in response they would be enhancing the information relevant to donor conception on their websites, if they had not already done so. New resources for clinics were being developed for the HFEA website, including podcasts, to support new Code requirements for prospective donors and recipients to be informed by clinics about the implications of such services for the anonymity of donors and donor conceived people and their close genetic relatives.

10.5. A member noted that podcasts were very important and a different way of communicating.

Decision

10.6. Members noted that significant progress has been made and that this would continue as part of business as usual.

11. Update on other strategic priorities

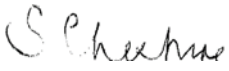
11.1. The Head of Regulatory Policy gave an update to the Authority on the progress made on leadership and patient support, two key strategic priorities resulting in additional guidance in the new edition of the Code of Practice (9.0) published in January 2019.

11.2. Members were advised that these areas would both become part of our inspection regime from 1 October 2019 for the first time, and that clinics' preparation for this had been supported by the provision of workshop events and practical resources placed on the website.

11.3. Members noted and welcomed the update on these two areas.

12. Chair's signature

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

Signature 

Chair: **Sally Cheshire**

Date: 13 November 2019