

# Minutes of Authority meeting 18 March 2020

| Details:                                   |  |   |                          |
|--|--|---|--------------------------|
| Area(s) of strategy this paper relates to: | Safe, ethical effect standards through | ive treatment/Consistent outcom<br>intelligence | es and support/Improving |
| Agenda item                                | 1                                      |   |                          |
| Meeting date                               |  |   |                          |
| Author                                     | Debbie Okutubo, C                      | Sovernance Manager                              |                          |
| Output:                                    |  |   |                          |
| For information or decision?               | For decision                           |   |                          |
| Recommendation                             | Members are aske                       | d to confirm the minutes as a tru               | e record of the meeting  |
| Resource implications                      |  |   |                          |
| Implementation date                        |  |   |                          |
| Communication(s)                           |  |   |                          |
| Organisational risk                        | 🔀 Low                                  | Medium  | 🗌 High                   |
| Annexes                                    |  |   |                          |

# Minutes of the extraordinary Authority meeting on 18 March 2020

| Members present     | Sally Cheshire<br>Margaret Gilmore<br>Anita Bharucha<br>Anthony Rutherford<br>Emma Cave<br>Kate Brian | Jonathan Herring<br>Gudrun Moore<br>Ruth Wilde<br>Yacoub Khalaf<br>Ermal Kirby<br>Anne Lampe |  |
|---------------------|---|--|--|
| Apologies           | None  |  |  |
| Observers           | None  |  |  |
| Staff in attendance | Peter Thompson<br>Clare Ettinghausen<br>Richard Sydee<br>Rachel Cutting                               | Paula Robinson<br>Debbie Okutubo   |  |

#### Members

There were 12 members at the meeting – eight lay members and four professional members.

# 1. Welcome and apologies

- 1.1. The meeting was held on-line and with no members of the public present in light of the restrictions imposed as a result of the developing coronavirus outbreak and replaced the planned HFEA Authority meeting scheduled for the same day. This meeting would be considered an extraordinary meeting as allowed by HFEA standing orders.
- **1.2.** The Chair noted that the purpose of the meeting was to provide members with an opportunity to understand and support steps that have been taken by the Executive to address the implications for the regulatory activities and functioning of the organisation as a result of the coronavirus pandemic.

# 2. Minutes of 29 January 2020 Authority meeting

**2.1.** Members agreed that the minutes of the meeting held on 29 January 2020 be signed by the Chair.

#### 3. Chair's report

**3.1.** The Chair noted that for the foreseeable future due to the Coronavirus pandemic, Authority meetings will be held virtually.

#### DHSC Gametes storage consultation

**3.2.** It was agreed that the Executive would email or phone Authority members to gather any detailed comments in response to the DHSC gamete storage consultation.

#### Member appointment

- **3.3.** The Chair advised members that she had been appointed for a further term as Chair, which would end on 31 March 2021.
- 3.4. The terms of office of a number of members will be coming to an end later in 2020 and early 2021. This includes, in 2020, the Chair of Licence Committee and in 2021, the Authority Chair, Deputy Chair, Audit and Governance and Statutory Approval committee chairs. Conversations were ongoing with the DHSC to try and manage that risk.
- **3.5.** Members commented that this was an ongoing risk that was very difficult to manage.

#### PRISM

3.6. The Chief Executive outlined progress on PRISM. Members commented that, given the Coronavirus outbreak, contingency may need to be added to the completion plan in case key staff became unwell which could affect the project completion and launch date.

#### HFEA at 30

**3.7.** The 30th anniversary of the HFE Act was later in 2020 and of the establishment of the HFEA in 2021. Further discussions would take place in due course to mark these milestones.

# 4. Coronavirus (Covid-19)

- **4.1.** The Chief Executive outlined the position as of the date of the meeting relating to the impact of Coronavirus on licensed centres
- **4.2.** Coronavirus was having a profound effect on fertility patients and clinics. Clinics were considering their capacity to provide treatment due to staff becoming ill or being redirected to front line care. The Executive were in touch with licenced clinics about whether any fertility treatment could continue. Given the speed at which the pandemic was developing, future regulatory action may need to be taken at short notice.
- **4.3.** It was noted that patients were understandably worried, some were putting off treatment, while others were worried about the safety of becoming pregnant.
- **4.4.** Members were advised that a letter had been sent out to all persons responsible (PR) to establish what contingency plans clinics had in place. Further regulatory actions may be needed as and when the UK situation changed. To date, the HFEA had been guided by UK professional guidance (BFS and ARCS). Members agreed that this was the right approach. It was noted that further advice from the BFS and ARCS was expected.
- **4.5.** The Authority noted that HFEA inspections had been paused until 31 August 2020 because of the current situation. Systems would be put in place to ensure that all clinics remained licensed and that inspectors would monitor those licenced centres where concerns had been identified.
- **4.6.** It was also agreed that the scheduled ELP, Licence Committee and SAC meetings would go ahead online for the foreseeable future.
- **4.7.** Public events had been cancelled and communications activity had been refocused on providing advice to patients and clinics on the impact of coronavirus on fertility treatment.

- **4.8.** The Business Plan for 2020-21 would be reviewed to ensure that it was re-focused given the coronavirus pandemic.
- **4.9.** Members were advised that all staff were now working from home as part of the government's advice.
- **4.10.** Members discussed the impact on ongoing organisational activity and the well-being of HFEA staff in the circumstances.

### 5. Any other business

- **5.1.** Members were advised that the next ordinary Authority meeting was scheduled for 13 May. An extraordinary Authority meeting would be held in April.
- **5.2.** Authority members to be canvassed for their availability.

# 6. Chair's signature

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

#### Signature

Scheeping

Chair: Sally Cheshire
Date: 21 April 2020



# Resuming fertility treatment: what criteria should we use in deciding whether to vary or revoke General Direction 0014?

# Details about this paper

| Area(s) of strategy this paper relates to: |   |
|--|---|
| Meeting:                                   | Authority   |
| Agenda item:                               | 3   |
| Meeting date:                              | 21 April 2020 (Extraordinary meeting by teleconference) |
| Author:                                    | Peter Thompson, Chief Executive                         |
| Annexes                                    | N/a   |

# **Output from this paper**

| For information or decision? | For decision  |
|------------------------------|---|
| Recommendation:              | That members consider the criteria set out in section 3 |
| Resource implications:       | N/a   |
| Implementation date:         | N/a   |
| Communication(s):            | Letter to all PRs (see 5.1 below)                       |
| Organisational risk:         | High  |

#### 1. Introduction

**1.1.** General Direction 0014 came into force on 23 March 2020. It requires all licensed centres to have in place a Covid-19 Treatment Strategy. GD 0014 states that:

"The Treatment Strategy must confirm that:

(a) that the PR has read and intends to comply with advice issued by the British Fertility Society and the Association of Reproductive and Clinical Scientists;

(b) that the centre has closed or will be closing (on what date) in respect of all physical attendance by those seeking treatment services (other than those patients referred to at (d) below);

(c) that the centre will have ceased all treatment services by 15 April 2020 at the latest;

(d) that after 15 April 2020, the clinic will only offer non-elective fertility preservation to patients who are, in the written opinion of a registered medical practitioner, likely to become prematurely infertile;

(e) that when the centre has closed for treatment services it has a skeleton staff available to ensure stored gametes and embryos are not put at risk;

(f) that the centre has put measures in place to keep patients informed of any changes to their treatment plans and the reason for these, as well as have adequate cover to support patients remotely who have concerns or require support."

- **1.2.** Licensed centres were required to report to their HFEA inspector by 5pm on 25 March 2020 that they had in place a Covid-19 Treatment Strategy. All centres confirmed that they did so by that date.
- 1.3. GD0014 is not time limited; it remains in force until it is varied or revoked. While a decision to vary or revoke GD0014 is not imminent and, crucially, will depend on wider Government decisions on lifting or liberalising the lockdown it is important that we begin to flesh out an 'exit strategy'. This paper represents the first step in that process; considerable detail will need to follow. It has been produced to facilitate discussion within the HFEA; it does not represent an agreed policy position. It is assumed that we will need to revisit the issue as the situation changes.
- 1.4. The aim is to enable agreement on the criteria against which the decision to vary or revoke GD0014 should be assessed (see section 3). Section 4 of the paper sets out three key issues which should guide that consideration. Next steps are briefly outlined in section 5.

# 2. Why we introduced GD0014

**2.1.** In considering this question it is helpful to begin with a summary of why we introduced GD0014 in the first place; that way we can better understand whether those conditions have so changed that it would be appropriate to revoke the original decision.

- 2.2. GD0014 was introduced in response to guidance on the appropriate provision of fertility services from the relevant professional societies (BFS/ARCS<sup>1</sup>, 18 March and a subsequent Open Letter, 23 March); the decision (in a letter of 17 March) to cease all non-urgent elective surgery in the NHS in England by 15 April; and more general guidance from the Government<sup>2</sup> (developing throughout March) designed to slow the spread of Covid-19.
- **2.3.** Taken together, that suite of guidance can be summarised under four headings:
  - Patient health: the impact of Covid-19 on the health of pregnant women is not known and a
    precautionary approach is therefore reasonable. The BFS/ARCS guidance stated that at the time
    of writing (18 March) "it is not thought that the infection causes miscarriage or fetal abnormality,
    and pregnant women do not appear to be at increased susceptibility to the infection or to
    developing complications". But the same guidance went on to note that in the Prime Minister's
    bulletin on 16 March, pregnant women were considered a vulnerable group because Covid-19 was
    a new infection and data on effects in pregnancy was limited. Continuing, the BFS/ARCS guidance
    stated that "it is reasonable that women who have risk factors for severe illness if infected, for
    instance those with diabetes or underlying respiratory disease or immunosuppression, should be
    advised against conceiving during the outbreak" and that "pregnancy should be avoided in women
    who display symptoms of Covid-19" as a result, the BFS/ARCS advised against embryo transfer
    for any women in such circumstances. The BFS/ARCS advice is consistent with that issued by the
    RCOG (regularly updated, most recently 9 April).
  - The impact of fertility treatment on the NHS: fertility treatment is unusual in the UK healthcare context because the majority of treatment is delivered in a private setting (except in Scotland). However, the care of the women who become pregnant through IVF usually takes place in NHS maternity units and, if emergency care is necessary, almost always in an NHS hospital. For this reason, the BFS/ARCS guidance stated that "clinics should be mindful both of their duty to minimise spread and of the impact of any complications on the NHS." The guidance went on to note that "Moderate or severe Ovarian Hyperstimulation Syndrome (OHSS), which is often managed in an NHS emergency care setting, has been reported in 3.1 to 8% of stimulated treatment cycles." While OHSS can be reduced by the use of GnRH agonist trigger and freeze-all, there are other complications like ectopic pregnancies or miscarriages that remain a risk if embryos are replaced.
  - The ability of clinics to provide a safe service: fertility clinics have been impacted by the spread of Covid-19 in different ways. A decision by the leadership of the NHS in England (17 March) to stop all non-urgent elective surgery by 15 April meant that NHS fertility clinics were bound to close. NHS clinics found that many of their staff were redeployed to different parts of the system to help deal with the anticipated rise in Covid-19 patients and that some of their equipment (e.g. respirators and safety cabinets) and physical space was requisitioned. Private clinics faced neither of these issues, though some may have decided to make skilled staff, equipment or premises available to the NHS. However, both NHS and private clinics faced the prospect of staff shortages through clinic staff contracting Covid-19 or having to self-isolate because a family member had

<sup>&</sup>lt;sup>1</sup> Professional societies across the World, including ESHRE and ASRM, have issued advice on Covid-19, as the UK regulator we paid particular attention to BFS/ARCS.

<sup>&</sup>lt;sup>2</sup> At the time of writing the guidance from the UK government and the devolved governments of Scotland, Wales and Northern Ireland is the same.

contracted the disease. In continuing to offer services, clinics ran the risk that patients might unwittingly pass on Covid-19 to clinic staff or other patients.

• Restrictions on social contact and travel: as Covid-19 developed so Government restrictions on the movement of people intensified. The BFS/ARCS recognised those developing restrictions in their guidance to the fertility sector, citing the Government's advice against non-essential social contact and non-essential travel. Although travel to a medical appointment could be considered essential, it was clear from Government guidance that this was only in cases where not attending might cause actual harm to the patient. Even though infertility is an illness, in the vast majority of cases it did not meet that test.

#### 3. Criteria to inform a decision to vary or revoke GD0014

**3.1.** Any decision to vary or revoke GD0014 is best considered by reference to agreed criteria. What follows is an outline proposal setting out four key criteria, though they may need to flex as the situation develops. The key milestone or trigger for any decision must start with Government restrictions.

#### 1 - that Government restrictions on social contact and travel are lifted

- If the Government decided to lift or liberalise the current restrictions on social distancing, travel etc that would indicate that it would be appropriate to consider whether GD0014 should be varied or revoked.
- However, much would depend on how those restrictions were lifted. It is possible that this is done
  in stages, applying over time to particular sectors of the economy or businesses, specific groups of
  people, or specified regions. Any of these conditions would make the lifting of GD0014 more
  complex. For example, if the lockdown continued in some areas would it be appropriate to
  sanction a regional restart to fertility services or would it be more appropriate to wait until a UK
  wide approach was possible?
- A regional approach might raise issues about inequality of access for patients or unfair commercial advantage for some clinics. But equally denying some patients and some clinics the opportunity to restart treatment safely (see below) could also be seen as unfair.
- It might also pose risks if a patient who resided in an area still under restrictions, travelled to a clinic where the lockdown had been lifted.
- Evidence: Cabinet Office, DHSC, S, W and NI Government.

#### 2 – that restarting fertility treatment would not have a negative impact on the NHS

- As noted in section 2, fertility treatment has an impact on NHS maternity and emergency services. It therefore follows that even if the conditions in 1 are met it does not automatically follow that GD0014 should be varied or revoked.
- This element of any decision therefore requires an assessment of whether the pressures on the NHS has reduced to such an extent that maternity units and/or emergency care units could cope with any additional patients. In terms of evidence we might reference a reduction in admissions to pre pandemic levels or wait until the ban prohibiting non-urgent elective surgery in the NHS is lifted.
- In addition, we might wish to set restrictions (e.g. through a varied GD0014) on the activity of fertility clinics so that the possible impact on NHS services was reduced. For example, we could

mandate the use of a freeze all strategy for a period of time which would reduce the incidence of OHSS and early pregnancy complications and in turn reduce the likelihood of emergency hospital admissions. Patients could be clinically assessed for their risk of complications and treated on an individual basis with medical management.

- If the restrictions in 1 were varied or lifted on a local or regional basis, should we similarly try to
  assess whether a local NHS Trust was capable of offering maternity/emergency care services
  safely such that it would be appropriate to allow fertility treatment to resume in that local area? In
  such a scenario, as noted above patients might seek treatment in a part of the country where the
  lockdown had been varied or lifted, but should they require a subsequent hospital admission they
  would do so in the area they lived in which may still be in lockdown. That said, failure to respond to
  the different position across the UK would be resented by some patients and it should be our
  ambition to ensure that as many patients as possible have access to safe services as soon as
  possible.
- Evidence: DHSC, NHSE and the NHS in S, W and NI.

# 3 – that there was no evidence that Covid-19 impacted on the health of pregnant women or their babies

- As noted in section 2, the impact of Covid-19 on the health of pregnant women or their babies is as yet unknown. Assuming this remains the case, and there is no new guidance suggesting that women should try not to become pregnant more generally *and* that 1 and 2 are satisfied, would it be sufficient that patients are simply given clear guidance on the unknown state of the evidence before starting treatment?
- If the evidence suggested that some categories of women should not yet try to get pregnant would it be ethical to prohibit all women to resume treatment?
- Should we require any fertility patient to be free of the symptoms of Covid-19 for a specified period of time before (re)starting fertility treatment? Even if desirable, is that practical without widespread and effective testing becoming available?
- Evidence: BFS/ARCS, RCOG, SaBTO.

#### 4 - that fertility clinics are able to provide a safe service

- Before resuming services all clinics should have: safe staffing levels; appropriate PPE; no staff
  members that have had symptoms of Covid-19 for a specified period of time; and revalidated all
  relevant equipment. The Code of Practice currently requires the individual clinic PR to make these
  sorts of assessments we believe that this should remain the responsibility of each PR following a
  decision to revoke GD0014. Do you agree?
- Evidence checked at next HFEA inspection?

# 4. For discussion

- **4.1.** Members are asked to consider the four criteria set out in section 3 above.
- **4.2.** Our primary aim should be to allow as many patients as possible to resume safe treatment as soon as possible. We also want to see a safe and orderly restart of the sector. However, in reaching agreement, Board members also need to resolve a series of difficult trade-offs. These are set out in more detail below, but might be summarised as: private v NHS, national v local. A uniform approach across the UK is fair, but risks denying early treatment options to some patients (particularly those that can afford it) and may give some private clinics an unfair competitive

advantage. A localised approach has the opposite advantages and disadvantages. It is important to recognise that many private clinics also hold NHS contracts.

Prioritisation of patients – the patients who will have been most disadvantaged by GD0014 are those patients with low ovarian reserve and/or those that are approaching or over 40; for them time to treatment is of the essence. Most of these women will fall outside NHS funding criteria and so would of necessity have to pay for their treatment. It therefore follows that should clinics in the private sector be able to restart services more quickly than those in the NHS (whose staff and equipment is likely to have been redeployed to help fight Covid-19) they may be able to offer valuable services to this particular group of women without unfairly impacting on other groups of potential patients.

However, that approach might be seen as compromising...

Equity of access – at present no patients (with the exception of those undertaking fertility preservation before cancer treatment) have access to fertility services across the UK. If the private sector were able to restart before the NHS (for the reasons noted above) that may see the prioritisation of waiting lists towards those patients with the ability to self-fund. While that would be inequitable it would arguably be no different to the position which existed before the lockdown. Moreover, many private clinics treat NHS patients as they hold contracts with their local CCGs (in England). A different type of inequality would occur if the lockdown was varied or lifted in a regional or localised manner. Under this scenario, patients would have early access to services simply by virtue of where they lived. If the conditions improved in one of the four nations or in particular regions, would it be fair to vary or lift GD0014 in that area only? Would that lead to patients from one area travelling to have treatment in another?

Which might also give rise to ...

Unfair commercial advantage – GD0014 applies to all licensed clinics. We need to be
mindful that any decision we take to lift it does not unfairly advantage some clinics over
others. That might suggest that it would be only be appropriate to vary or revoke GD0014
when the conditions across the whole of the UK suggest that it would be appropriate to do so.
But as noted above a blanket approach is not without risks either. It is also important to
recognise that most private clinics undertake NHS work.

#### 5. Next steps

- **5.1** We have been actively engaging with key stakeholders, including the DHSC and the professional societies and PRs over the past few weeks. Once we have agreed the criteria on which the decision to vary or revoke GD0014 should be made we will communicate that to all PRs. This will be part of a regular dialogue with the sector over the precise terms of any future exit strategy.
- **5.2** In parallel, the BFS/ARCS have recently established a joint working group (involving representatives from both private and NHS clinics) to start considering in detail how the sector should respond as the restrictions are varied or lifted.
- **5.3** We will continue to develop this framework and consult Board members, using professional expertise as necessary, as the situation develops.



# Business and strategic planning

# Details about this paper

| Area(s) of strategy this paper relates to: | Whole strategy  |
|--|---|
| Meeting:                                   | Authority   |
| Agenda item:                               | 4   |
| Meeting date:                              | 21 April 2020 (Extraordinary meeting by teleconference) |
| Author:                                    | Paula Robinson, Head of Planning and Governance         |
| Annexes                                    | -   |

# Output from this paper

| For information or decision? | For decision   |
|------------------------------|--|
| Recommendation:              | To agree a revised approach to our strategy and business plans in response to the coronavirus situation and its impact on the sector and patients. |
| Resource implications:       | In budget  |
| Implementation date:         | Tentatively: 1 October 2020 and then 1 April 2021  |
| Communication(s):            | For publication on our website at the agreed times   |
| Organisational risk:         | Low  |

#### 1. Overview

- **1.1.** The sure sign of good planning capability in an organisation is the ability to change the plan when necessary, in response to events. We are in the midst of extraordinary events, and we need to adapt accordingly. We have already started to do this.
- 1.2. To date, since shortly before the planned March Authority meeting (which in the event had to be held as an extraordinary meeting, by teleconference), our main focus has been on handling the immediate needs and safety of the sector and patients, responding to Government requests and our own staff, and mitigating associated risks so that we can continue to work effectively on pressing concerns within our remit.
- 1.3. It is now time for us to formally take stock of our overall strategic vision and business plans. We need to put new plans in place that recognise the major interruption to our normal work and the cessation of fertility treatment, and the consequent impact to patients of the COVID-19 pandemic and the associated measures taken by the Government and by ourselves.

# 2. Proposed way forward

- 2.1. The planning work we have done so far need not go to waste, but our timing clearly has to change. All of the proposed dates below may have to be revisited in the light of the progress of the pandemic and when it is possible to restart treatment.
- **2.2.** In short, it is proposed that we:
  - Do not publish our originally intended business plan for 2020/21, and instead put in place:
    - An internal service delivery plan focused on managing the current situation from April to September 2020.
    - A recovery plan for October 2020 to March 2021.
  - Delay the launch of our new strategy to October 2020, or later, and commence delivery in full from 1 April 2021, extending it by one year to 2024.

#### 2.3. Strategy

- 2.4. Collaborative working with other bodies and with our sector is a key part of the new strategy. It is clear that now would not be a good time to begin conversations with external bodies, many of whom are immersed in managing the current COVID-19 pandemic. Meanwhile, this remains an emergency situation for clinics in our sector. As well as suspending inspections for six months, and suspending new treatments, many clinics are experiencing significant staff resource disruptions. And the HFEA itself is operating in business continuity mode, with our office closed.
- 2.5. It is therefore suggested that we 'soft launch' the new strategy in October (rather than now), and extend the delivery period to 31 March 2024. This would enable us to start work on the strategy slowly and realistically, as and when we are able to, in the second six months of this business year.

#### **2.6.** Business planning for 2020/21 and 2021/22

**2.7.** Our business plan for this year had not yet been finalised and published before the COVID-19 pandemic emerged. For the same reasons set out above, we need to revise our plans to deal

with the current situation, and delay delivery of the new strategy until the second six months of this year, or later.

- **2.8.** It is therefore proposed that we operate to an internal service delivery plan from April until the end of September, and then publish a six month recovery plan for the sector in October. This will focus on helping clinics to get back up and running, and on clinic leadership. In those second six months of the business year, we could also prospectively begin work on some elements of the new strategy.
- **2.9.** Informal discussion with the Department suggests they will support such an approach.
- 2.10. The two tables below set out, in brief, the activities that will therefore take place in the two halves of the business year that had just begun. This new plan recognises that many elements of our work are continuing to be delivered, even in the current situation.

#### Areas of work Timescale Review of the compliance regime - compliance and enforcement policy only Throughout the year Clinic regulation and licensing - management of the 6 month suspension of April to September inspections; planning for reintroduction of inspections; management of any clinic concerns, incidents and complaints, applications for variations etc. meanwhile. Continue with licensing activities, including extensions of some licences to 5 years. Consideration of when to lift General Directions 0014, which currently oblige clinics Not yet known. not to begin new treatment cycles in most circumstances. April to September Continuing background (desk-based only) work on add-ons. April to September Publication of reports and information, without active promotion. Maintenance of our governance tools so that licensing and other decisions continue to Throughout the year be in place and effective. Processing any applications for the licensing of PGD, HLA and mitochondrial Throughout the year donation. Servicing the legal information needs of the HFEA, including legal advice to inform our Throughout the year work, management of the team of external legal advisers to support effective licensing processes, and support for the review of the compliance and enforcement policy Using social media and other channels to communicate relevant information (including Throughout the year information about Covid-19 and associated temporary clinic closures) to the wider general public. Review of our compliance with government accessibility requirements and legal By September obligations (in progress). Maintain up to date and accurate information and advice on our website (including in Throughout the year relation to Covid-19). Throughout the year Responding to and informing media reports. Opening the Register and counselling services - information provision paused, while April to September we continue to deal with inquiries and counselling requests. (See separate paper, for decision.)

#### Internal service delivery plan – April to September 2020

| Areas of work  | Timescale                    |
|--|------------------------------|
| For Donor Conceived Register (DCR) services, the DNA testing element has been paused, with inquiries and counselling provision continuing (third party provider monitored by the HFEA). (As above, see separate paper for discussion.) | April to September           |
| Respond to FOI, PQ and subject access requests.  | Throughout the year          |
| Handling of enquiries (including those relating to Covid-19), complaints about the HFEA and whistleblowing.  | Throughout the year          |
| Maintaining the Register, and working with clinics to ensure they are accurately reporting their data.   | Throughout the year          |
| Ongoing compliance with government information requirements, including required reporting in our Annual Report and compliance with the business impact target.   | Throughout the year          |
| Effective records management and information governance.   | Throughout the year          |
| Responding to external consultations and reviews.  | Throughout the year          |
| Continued development and completion of our PRISM data submission system, in readiness for subsequent full engagement with and feedback from clinics. (Release date to be determined.)   | April to September           |
| Planning for the future HFEA office relocation to Stratford (date to be confirmed)   | In progress until move date. |
| Ensure that we support, manage and retain our staff throughout and beyond the Covid-19 pandemic and our associated office closure.   | April to September           |
| Commence a fee review, informed by our income forecasting model.   | Throughout the year          |
| Manage the HFEA's finances during a period of zero income, in liaison with the Department of Health and Social Care.   | April to September           |
| Resume work on EU Exit, so as to ensure the HFEA and licensed clinics are ready for any changes.   | April to September           |
| Manage the HFEA's finances during a period of zero income, in liaison with the Department of Health and Social Care.   | April to September           |
| Respond to awaited Cabinet Office guidance on future Authority appointments, taking measures if necessary to ensure the continuance of decision-making capacity before current terms of office end.                                    | April to September           |

#### Planned work for October 2020 – March 2021:

| Areas of work   | Timescale           |
|---|---------------------|
| All work marked as 'throughout the year' above.                               | Throughout the year |
| Resumption of paused or re-ordered projects.                                  | October onwards     |
| Recovery planning and assistance for clinics, when treatments recommence.     | Not yet known       |
| Emphasis on good clinic leadership during the recovery period for the sector. | October to March    |

| Areas of work   | Timescale               |
|---|-------------------------|
| Continued provision of information for patients and the public, with a particular focus on the effectiveness of treatments.   | October to March        |
| Resume full OTR and DCR services.   | October to March        |
| Commence replanning work for a research engagement day (now to be held in May 2021)   | October to March        |
| Planning for an event to mark the 30 <sup>th</sup> anniversary of the HFEA.   | October to March        |
| Ensuring, in liaison with the Department of Health and Social Care, that our Authority remains populated with members and able to make licensing and policy decisions, retaining key knowledge where possible, during a period of potentially high member turnover. | October to March        |
| Launching our new strategy for 2021-2024.   | October (tbc)           |
| Re-plan our business plan and service delivery for 2021/22, in light of the delayed start of our new strategy.  | October to March        |
| Working with the Competition and Markets Authority on their project on self-funded IVF and consumer law guidance. They have announced that the expected consultation on this has been rescheduled to late 2020.   | December to March (est) |

# 3. Recommendations

- **3.1.** The Authority is asked to agree:
  - To postpone the launch of the new strategy until 1 October 2020.
  - To extend the planned timeline for the strategy to March 2024.
  - That the Corporate Management Group should create and maintain an internal six month service delivery plan, along the lines set out above, to manage our work until the end of September 2020.
  - That the Corporate Management Group should work up a six month recovery plan for publication in the second half of 2020/21, focused on helping the sector to re-establish normal services to patients after considerable downtime.
  - That we should seek the Department's formal approval for these proposals, if agreed.