

2010

2011

2012

2013

# Corporate strategy

Human Fertilisation & Embryology Authority

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## 1. HFEA Purpose and Principles

The following statements describe the purpose for which the HFEA exists and the principles under which it operates.

### Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

### Principles

1. We treat people and their information with sensitivity, respect and confidentiality.
2. We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector.
3. We consult widely - listening to and learning from those with an interest in what we do.
4. We keep abreast of scientific and clinical advances.
5. We exercise our functions consistently, proportionately, openly and fairly.

The HFEA aims to adhere to these principles at all times, harnessing its governing legislation to achieve, rather than restrict, its objectives and outcomes. In delivering its new three year strategy, the HFEA will continue to deliver its central purposes, as set out above, and will continue to operate according to these underpinning principles.

## 2. Development of the HFEA's New Strategy

Staff and the Authority have worked together to develop this strategy. During the development process, the Authority has considered its aspirations for the HFEA over the next few years, the tactics through which these aspirations could be met, and the timescale to which the different elements of the strategy should be delivered. We have considered how the HFEA could and should develop over the next three years, how the fertility sector we regulate, its users, and society itself, are likely to change, and how we can best serve the present and future interests of patients (of all kinds), centres, donor-conceived people and all of our other stakeholders.

The aims and objectives set out in this document provide a strategic framework and signal our aspirations for the future.

### 3. Strategic Assumptions and Objectives

#### Assumptions

The Authority has made the following assumptions in its discussions about future strategy:

- The economic downturn will continue to impact in the UK for several years, and the HFEA will need to continue to operate within resource constraints, which can be expected to tighten
- The legislation under which the HFEA operates will remain the same for several years, following recent major changes
- There will be a continued need to be responsive to changing external drivers (such as societal trends, political changes, scientific developments) as well as framing proactive work and continuing to deliver core business.

#### Strategic Objectives 2010/13

The HFEA has set five broad strategic objectives for the next 3 years, identified through extensive Authority and staff discussions. These objectives set out the HFEA's key major aspirations for the medium term future. The discussions have been framed by a wide range of issues and drivers, such as:

- Techniques for treatment
- Advances in science and genetics
- Social views and social change
- The nature of those treated (and other stakeholder groups)
- The role of regulators generally, and the regulatory environment (e.g. with respect to quality and service improvement)
- Responding to the external environment

The HFEA's strategic objectives for the next 3 years are as follows:

### **1. Role and boundaries**

To develop a clearly defined and mutual understanding of our role, and the boundaries between ourselves and other regulators, research-focused organisations, patient organisations and professional bodies in related fields.

### **2. Meeting the needs of existing fertility service users and stakeholder groups**

To identify and address more fully the needs of fertility service users before, during and after treatment.

### **3. Identifying and addressing the needs of new and emergent stakeholder groups**

To identify and start to address the needs of new or emergent stakeholder groups including donor-conceived people, fertile people seeking fertility treatment, and researchers.

### **4. HFEA data used for research purposes**

To monitor and improve consent rates for using data for research purposes, and to give active consideration to the nature and outcomes of the research conducted.

### **5. Improving organisational performance**

To enhance organisational performance and governance through operational efficiencies, improved regulatory effectiveness and better information management.

## 4. Strategic Plan

The following plan sets out at a strategic level how and when the HFEA will deliver these high-level strategic objectives. Each year the Authority's business plan will be focused towards delivering the relevant elements of the strategy.

| Strategic Objectives  | How  | Year |   |   |
|---|--|------|---|---|
|   |  | 1    | 2 | 3 |
| <b>1. Role and Boundaries</b><br>To develop a clearly defined and mutual understanding of our role, and the boundaries between ourselves and other regulators, research-focused organisations, patient organisations and professional bodies in related fields. | Bed down new processes and compliance cycle from April 2010 onwards.   | ✓    |   |   |
|   | Consider how best to achieve a balance between being appropriately directive through our policies, and implementing better (lighter-touch) regulation.   | ✓    | ✓ |   |
|   | Continue to consider the possibility of applying for additional powers under the RES Act 2008 and pursue this if and when appropriate.   |      | ✓ | ✓ |
|   | Establish clarity on the limits and scope of the HFEA's function (and hence its role) with respect to new and existing areas of research and science.  |      | ✓ | ✓ |
|   | Consider the nature of the HFEA's role in issues that are partly beyond and partly within our remit because they are international in nature – e.g. fertility treatment abroad; EUTCD and EUSTITE.   |      | ✓ | ✓ |
|   | Establish where the HFEA's remit ends and other organisations' remits begin; work towards mutual and reciprocal collaboration and enhanced relationships with other regulators, research-focused organisations, patient organisations and professional bodies; and identify areas appropriate for joint working (for example with the Human Tissue Authority and the Medicines and Healthcare Products Regulatory Agency). |      | ✓ | ✓ |
|   | Continue to engage with the public and inform debate on developing policy issues, through consultation, information provision and other means.   | ✓    | ✓ | ✓ |
|   | Establish ways of engaging broader external stakeholder input into HFEA policy discussions, e.g. from faith and disability groups, to ensure the inclusion in policy-making of a wide range of information and views.  | ✓    | ✓ | ✓ |
|   | Consider whether the HFEA should and could expand its role in providing (and possibly hosting) information for patients on ART techniques, available evidence for their efficacy and other treatment options, so as to empower the public and help to inform their decisions.  |      | ✓ | ✓ |

| Strategic Objectives   | How  | Year |   |   |
|--|--|------|---|---|
|  |  | 1    | 2 | 3 |
| <b>2. Meeting the needs of existing fertility service users and stakeholder groups</b><br>To identify and address more fully the needs of fertility service users before, during and after treatment.  | Continue to serve the needs of infertile people seeking treatment or experiencing the treatment journey, including those making use of Preimplantation Genetic Diagnosis (PGD), and to develop and provide information that is useful to them.   | ✓    | ✓ | ✓ |
|  | Consider how the HFEA can better meet the needs of the unsuccessfully treated and involuntarily childless and improve information provision for this group; and consider developing information that could help to prevent some people from needing fertility treatment to begin with. |      | ✓ | ✓ |
|  | To consider how the information needs of male service users could be better addressed, particularly through HFEA communications.   |      | ✓ | ✓ |
| <b>3. Identifying and addressing the needs of new and emergent stakeholder groups</b><br>To identify and start to address the needs of new or emergent stakeholder groups including donor-conceived people, fertile people seeking fertility treatment, and researchers. | Identify new trends and ‘user groups’ among those seeking treatment (e.g. fertile people using egg freezing), and consider what their needs may be and how the HFEA should plan to meet them.  |      | ✓ | ✓ |
|  | Identify and consider the needs of people whose information is held by the HFEA or who are seeking access to that information, e.g. researchers, the donor-conceived, and those conceived through IVF.   |      | ✓ | ✓ |
| <b>4. HFEA data used for research purposes</b><br>To monitor and improve consent rates for using data for research purposes, and to give active consideration to the nature and outcomes of the research conducted.  | Work towards ensuring a continuing research base, by reviewing the process for obtaining consent for the use of data in research so as to encourage the majority of patients to understand what this means and feel able to give their informed consent.                               | ✓    |   |   |
|  | Monitor the use of HFEA data in research and the outcomes of that research; and start to give further consideration to the HFEA’s role with respect to the research data gathered and the dissemination of outcomes.   | ✓    | ✓ | ✓ |
|  | Consider whether to lobby proactively on the focus of research using HFEA data, so as to encourage the study of relevant issues including social impact.   |      |   | ✓ |

| Strategic Objectives  | How   | Year |   |   |
|---|---|------|---|---|
|   |   | 1    | 2 | 3 |
| <b>5. Improving organisational performance</b><br>To enhance organisational performance and governance through operational efficiencies, improved regulatory effectiveness and better information management. | Pursue internal improvements to ensure the HFEA remains responsive to external drivers, including value for money and back-office efficiencies, workforce planning, income balance, and alliances with other organisations. | ✓    | ✓ | ✓ |
|   | Improve the HFEA's regulatory performance by identifying key areas of non-compliance and determining how to address these over time; and by making the best use in our regulatory activities of the data we hold.           |      | ✓ | ✓ |
|   | Reflect on the HFEA's Hampton review report (published in December 2009), and consider what additional improvements and positive changes the HFEA could make.   | ✓    | ✓ | ✓ |
|   | Improve and maintain both organisational transparency with information and data security.   | ✓    | ✓ |   |
|   | Assure internal quality in ways of working, particularly with regard to efficiency in dealing with information requests and the storage and reporting of internal management information.                                   | ✓    | ✓ | ✓ |