

Human Fertilisation and Embryology Authority

# Business Plan 2005-2006

2005-2006

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## Executive summary

The 2005/6 Business Plan marks the emergence of a new vision for the Human Fertilisation & Embryology Authority (HFEA). The past two years have witnessed major changes in the performance of the HFEA as a regulator of assisted reproduction and embryo research, and in the way we deliver our other statutory functions. However, recent developments in Government and EU policy have demanded a significant shift in our strategic objectives.

- The government has undertaken to carry out a review of the 1990 Human Fertilisation and Embryology Act (HFE Act).
- New European legislation (The European Tissue and Cells Directive) will set new requirements for the regulation of all units involved in procurement, testing, processing, storage and distribution of gametes and embryos. This will extend the scope of the HFEA's work to include centres carrying out infertility treatment that is not covered by the HFE Act as well as setting new technical standards for clinics already licensed by the HFEA.
- A review of all Arms Length Bodies (ALBs) in the health sector has signalled the government's intention to establish a new body, the Regulatory Authority for Fertility and Tissue (RAFT) This will bring together the HFEA's functions with those of the Human Tissue Authority (HTA).

Maintaining the improvements in delivery of ART regulation, policy and information will remain at the centre of our work in 2005/6. This will carry on alongside work on the new strategic objectives which have emerged:

- To undertake within the HFEA's modernisation a strategic drive to more cost-effective, efficient, targeted and streamlined regulation. This will fulfil the requirements of the ALB review to reduce costs and will meet the principles of proportionality set out by the Better Regulation Taskforce. The use of risk indicators which have been under development will be a key element in this programme
- To drive forward the implementation of the European Tissue and Cells Directive, providing detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies.
- To further progress the major modernisation programme of our data system and register. As we enter the last 18 months of this project we will move from focusing on "data validation and accessibility" to information and knowledge management. This will ultimately underpin our regulation and policy work.
- To advance the HFEA's work of empowering patients by facilitating choice, knowledge and involvement
- To collaborate with the newly established HTA, developing close and integrated working wherever appropriate, and build the foundation for the development of a combined organisation, the Regulatory Authority for Fertility and Tissue (RAFT) in three years time, following the review of the HFE Act.

This sets the HFEA another very ambitious business agenda, which will require the organisation to develop more flexible ways of working, and to ensure we continue to make the most effective use of our resources. **We are assuming HFEA will receive adequate funding to carry out this plan otherwise it will not be achievable.**

# 1. Strategic Context

- 1.1 Assisted reproduction treatment (ART) is an increasingly important part of health care, accounting for 1% of all births in the UK, with about 8,000 babies born as a result of ART each year. Whilst about 75% of ART clinics are in the private sector, the recommendation on fertility provision in the NHS published in 2004 by the National Institute for Clinical Excellence (NICE)<sup>1</sup> is expected to lead to a growing number of NHS funded treatment cycles. Almost 30,000 people in total receive treatment annually, often involving procedures that are at the cutting edge of science. In addition embryo research is increasingly high profile with the development of stem cell research.
- 1.2 The HFEA's purpose is to assure patients and the wider public that research and treatment undertaken in the field of assisted reproduction is conducted at high standards, safely, and within a robust ethical framework. The Authority's key responsibility is the licensing and monitoring of clinics and centres carrying out *in vitro* fertilisation, donor insemination, and human embryo research. We are also required to maintain a register of treatments to provide information for offspring and researchers, to inform HFEA regulation and policy, and the advice we give government. (The HFEA's detailed functions are set out in ANNEX A.)
- 1.3 The past two years have seen major changes in the way the HFEA delivers its statutory functions. We have sought to become ever more effective in our performance as a regulator, in our relationships with all our stakeholders and in our communication with patients.
- 1.4 The context in which the HFEA works changes constantly with continuing scientific developments, medical advances, ever growing public interest, scrutiny and media coverage. In addition to these strategic factors specific key changes have occurred in the last year:-
- The government has undertaken to carry out a review of the 1990 Human Fertilisation and Embryology Act (HFE Act).
  - The House of Commons Science and Technology Select Committee has conducted an inquiry into 'Human Reproductive Technologies and the Law'. The HFEA has worked closely with the Committee, and the Committee's recommendations are expected to be reported in March 2005.
  - New European legislation (The European Tissue and Cells Directive) will set new requirements for the regulation of all units involved in procurement, testing, processing, storage and distribution of gametes and embryos. This will extend the scope of the HFEA's work to include centres carrying out infertility treatment that is not covered by the HFE Act as well as setting new technical standards for clinics already licensed by the HFEA.
  - A review of all Arms Length Bodies (ALBs) in the health sector has signalled the government's intention to establish a new body, the Regulatory Authority for Fertility and Tissue (RAFT). This will bring together the HFEA's functions with those of the Human Tissue Authority (HTA).
- 1.5 In response to this changing environment and building upon our recent achievements, a new vision has developed for the Authority. This Business Plan sets out that direction which continues the modernisation of core services and responds to the strategic influences outlined above. It also lists our key objectives for 2005/6 and the individual plans for how they will be delivered.

<sup>1</sup> Fertility: assessment and treatment for people with fertility problems, Clinical Guideline 11, NICE, February 2004

## A Summary of our Strategic Goals

**1.6** The HFEA identified seven strategic goals within its five year corporate strategy. Our objectives for 2005/6 focus on continuing our progress towards these goals and responding to the new environment in which we operate.

**Goal 1:** Strengthening our regulatory role.

**Goal 2:** Being an open organisation, through excellent communications and working in partnership with stakeholders.

**Goal 3:** Working closely with other regulators and international agencies.

**Goal 4:** Strengthening the process of policy development.

**Goal 5:** Developing an information base which meets the needs of offspring, stakeholders, the wider regulation and public health functions, and supports the delivery of services to required standards.

**Goal 6:** Supporting the development of research in assisted conception, and its application.

**Goal 7:** Developing an organisation which will fulfil these goals, supported by strong corporate governance.

**1.7** Annex C sets out our progress in achieving these goals during 2004/5.

## The HFEA's principles and values

**1.8** The HFEA is committed to working within the five principles of good regulation established by the Better Regulation Task Force:

- Transparency
- Accountability
- Proportionality
- Consistency
- Targeting

**1.9** A key to good regulation is the transparency of the regulator. We will continue to improve the information we provide to our stakeholders and the public on how we work and how we reach our decisions, including those by Licence Committees. We will implement fully the Freedom of Information Act, with a clear process for handling responses. Our aim is to ensure that our stakeholders and the public understand our role and the decisions we take, and have confidence in our role as a regulator.

**1.10** We will also ensure that the HFEA adheres to the seven principles of public life, which are the baseline for all public bodies, (see Annex B). In addition, in order to guide its work, the Authority has adopted a number of key values (Annex B). Within these principles and values, the Authority's overriding aims are to ensure due respect is given to the embryo and to safeguarding the public interest. This concern applies particularly to patients, and the children and families created as a result of assisted reproduction; the welfare of the child is central to the work of the Authority.

## 2. Key challenges for 2005/6

**2.1** The continuing modernisation of the core business of the HFEA will remain central to our agenda in 2005/6, building on the achievements of the previous two years. However, the HFEA also has new strategic objectives arising out of the Review of Arms Length Bodies and other government initiatives. The key objectives are:-

- a. To undertake, within the HFEA's strategic modernisation drive, to provide more proportionate, cost effective, efficient, targeted and streamlined regulation.
- b. To drive forward the implementation of the European Tissue and Cells Directive, providing detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies.
- c. To further progress the major modernisation programme of our data system and register. As we enter the last 18 months of this project we will move from focusing on "data validation and accessibility" to information and knowledge management. This will ultimately underpin our regulation and policy work.
- d. To advance the HFEA's work of empowering patients facilitating choice, knowledge and involvement.
- e. To collaborate with the newly established HTA, developing close and integrated working wherever appropriate, and building the foundation for the development of a combined organisation, the Regulatory Authority for Fertility and Tissue (RAFT) in three years time, following the review of the HFE Act.

**2.2** In addition, other major strategic themes are:

- f. To implement the changes in legislation following removal of donor anonymity.
- g. To help maximise public understanding and confidence in research on assisted conception and stem cell research.
- h. To develop clear policies in a way that increases stakeholders' confidence in the HFEA.
- i. To develop the organisation and staff to achieve the results needed.
- j. To continue effective management of the operational budget; meeting ALB review targets, and setting appropriate fee structures for new areas of regulation.

**2.3** These developments set the HFEA another very ambitious business agenda. Managing this level of change successfully requires the organisation to develop more flexible ways of working. We will further streamline our processes to ensure we make the best use of resources. We will also look to develop consistent approaches to functions across the HFEA and the HTA.

## 3. Meeting key challenges in 2005/6

Meeting these challenges will again place high demands on our staff but many of the objectives outlined in Section 2 can only be delivered in partnership with our stakeholders.

### 3.1 To undertake, within the HFEA's strategic modernisation drive, to provide more proportionate, cost effective, efficient, targeted and streamlined regulation.

Couples seeking fertility treatment need to have confidence that centres licensed to provide it are safe and effective. In 2005 we will build on the rigorous methods for inspecting we introduced last year in order to recognise good performance and target our attention on centres falling below standard. We expect centres increasingly to demonstrate effective internal quality control systems that are reducing risks and helping to improve pregnancy success rates. We will streamline our licensing and inspection process, to reduce the burden of regulation, and minimise costs for the HFEA, centres and patients, while maintaining our focus on protection for patients and children. To achieve our objective, we will:-

- a. Fully implement a risk-based approach to licensing, inspection and incident management.
- b. Reorganise the regulatory systems to reduce the amount of information requested from centres, and ensure effective use of data selected.
- c. In consultation with Professional Bodies consider the factors that influence safety and outcomes and make clear recommendations on quality systems. This will include consideration of the various systems within the UK and internationally and evaluation of the appropriateness of standards in Good Manufacturing Practice (GMP).
- d. Ensure all centres have standard operating procedures and total quality systems in line with the HFEA's recommendations.
- e. Improve information and training for Persons Responsible for licensed clinics and introduce more rigorous assessment of applicants.
- f. Strengthen the independence, accountability and targeting of inspection by developing more in-house expertise.

#### Expected outcomes

- a. Patients will experience more consistent standards of care.
- b. Persons Responsible will receive better support in meeting their responsibilities.
- c. Clinics' perception of regulation will be that it is proportionate and objective.

### 3.2 To drive forward the implementation of the European Tissue and Cells Directive, providing detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies.

The EU Tissue Directive aims to improve consistency and overall standards in centres. The HFEA will regulate centres to ensure they have rigorous quality management systems, appropriate staff training and environmental standards.

We will do this by:-

- a. Working with representatives from the sector to develop standards that meet EU requirements, including tracking and identification systems.

- b. Establishing requirements for tracking and identification systems applicable to gametes, embryos and culture media.
- c. To prepare for implementation of the Directive for currently licensed centres by April 2007, working with professional bodies and clinics to ensure they know what they must do.
- d. To ensure that costs and bureaucracy involved in regulating the Directive are minimised, particularly through appropriate collaboration with other organisations.
- e. To work with other European networks, regulators and practitioners to achieve consistency in implementation, alongside sharing best practice approaches to improving safety.

### Expected outcomes

- a. Patients and public will be aware of and have confidence in internationally compatible standards.
- b. Clinics will be well-informed and prepared for the EU Directive.
- c. Clinics will experience “best practice” in cost-effective regulation.

### 3.3 To further progress the major modernisation programme of our data system and register.

As we enter the last 18 months of this project we will move from focusing on “data validation and accessibility” to information and knowledge management. This will ultimately underpin our regulation and policy work. We will:-

- a. Complete the Historic Audit Project (HAP), with a comprehensive audit of all key data on offspring and donors.
- b. Complete the introduction of Electronic Data Interchange, ensuring all clinics have the capacity to transmit timely and accurate data electronically to HFEA.
- c. Support Regulation and Policy Departments through integrated, accessible information systems, based on the development of an Electronic Records Management process, new Centres database and modernised Register.
- d. Implement safe, easy-to-understand processes for donor-created offspring to make an application for information.
- e. Introduce validation rules which check the accuracy of data going into the Register in an ongoing way.

### Expected outcomes are:-

- a. Patients/offspring will receive timely responses to requests for information, and information on offspring and donors is accurate and reliable.
- b. Clinic in-putting of data will be easier, more accurate, less costly and they will have easy access to information to support their work.
- c. HFEA will have all core details on the Register, comprehensively verified with centre records; and information will be linked to provide an overview of register details, supporting regulation and policy-making.
- d. HFEA and clinics will have more accurate systems for data collection, and greater quality of information.

**3.4 To advance the HFEA's work of empowering patients facilitating choice, knowledge and involvement.**

HFEA has improved its provision of information to patients. The new Patients Guide has been designed to give patients the ability to review the outcomes of centres and make informed choices about centres and treatment. This is part of a broader Patients Strategy which gives greater patient focus to our work. We will address this objective by:-

- a. Delivering an on-line version of the 2005 Patients Guide, and raising awareness of the Guide with patients.
- b. Implementing a Patient Communication Programme including a new Patient Consultative Panel.
- c. Improving HFEA's web site and electronic communication for patients, including more tailored information, such as fact sheets and published inspection reports.
- d. Producing patient leaflets on key issues, including patient consent
- e. Increasing involvement of patients in inspections as appropriate.
- f. Developing 2006 Patient Guide building on patient feedback to new 2005 format.

**Expected outcomes are:-**

- a. Patients will have greater access to information from HFEA which meets their information needs at all stages of treatment, including choosing centres.
- b. Patients views and perspectives will be strengthened in inspections.
- c. Patients needs and perspective will be reflected in all policies and operational plans.

**3.5 To collaborate with the newly established HTA, developing close and integrated working wherever appropriate, and building the foundation for the development of a combined organisation, the Regulatory Authority for Fertility and Tissue (RAFT) in three years time, following the review of the HFE Act.**

The HFEA will work towards congruent models of licensing and inspection, based on principles of better regulation with the HTA. We will:-

- a. Review our Code of Practice, considering benefits of a consistent overall approach to the codes developed for Human Tissue Authority.
- b. Build business support functions capable of efficiently and economically supporting the regulatory activity of both organisations.
- c. Build support mechanisms for both organisations, ensuring economies of scale and targeting of resources to increase cost effectiveness.

**Expected outcomes are:**

- a. HFEA and HTA increase cost effectiveness through shared back-office functions.
- b. HFEA and HTA experience smooth transition to RAFT through close integrated working.

### **3.6 To implement the changes in legislation following removal of donor anonymity.**

The implementation of new legislation recognises the rights of donor offspring to know about their origins. The HFEA will ensure these rights are realised by the following actions:-

- a. Evaluating the results of Sperm, Egg and Embryo Donation review and producing a comprehensive report setting out new policies and incorporating recommended changes.
- b. Producing revised guidance given in the HFEA Code of Practice on Sperm, Egg and Embryo Donation.
- c. Working with professional bodies, patient groups and others to identify people's needs and awareness of ancillary services (counselling, mediation etc.). Also assessing the capacity and expertise in the provision of services.
- d. Developing procedures and information resources for donors, donor conceived offspring and parents of donor conceived people that will both facilitate understanding of their rights, and support the broader programme of communication with offspring.

#### **Expected outcomes**

- a. Patients will receive more consistent and high quality care.
- b. Clinics will have consistent, authoritative, evidence- and risk-based guidance, reducing uncertainty and identifying measurable regulatory expectations.
- c. Applicants and donors will have certainty about how applications for information from the HFEA will be processed, and the information and resources available to assist them, leading to confidence that their interests will be protected and promoted.

### **3.7 To help maximise public understanding and confidence in research on assisted conception and stem cell research.**

It is important, given the rapid pace of scientific change, that we have a strong and publicly accountable system for regulating research. The HFEA has already established a more rigorous and transparent procedure for licensing embryo research. We will continue to improve that process, but also streamline regulation to prevent undue burdens on centres. We will do this by:-

- a. Publicising HFEA's role in licensing research, the improvements we are making in streamlining our processes, and the benefits of a strong system of regulation.
- b. Improving public understanding of research regulation.
- c. Communicating HFEA's licensing of individual research applications, including reports on the Web on how decisions have been taken.

#### **Expected outcomes**

- a. Patients and public will have greater confidence in the regulation of embryo research.
- b. Public understanding of the licensing framework and requirements and the decision-making process will increase.

### **3.8 To develop clear policies in a way that increases stakeholders' confidence in the HFEA.**

The HFEA needs to ensure that it has clear policies which enable it to fulfil its role as an effective regulator. Key to this is the continual review of how we regulate, and a clear evidence-based evaluation of our policies. We need policies which help us respond quickly and effectively to external developments that impact on regulation. We will continue to improve our policy making, including encouraging greater public and stakeholder involvement. We will do this by:-

- a. Developing improved intelligence gathering mechanisms (including scientific horizon scanning, factors driving developments in the sector such as implementation of NICE guidelines and developments internationally).
- b. Reviewing the contribution that new technologies can make to improving safety in laboratories.
- c. Setting up a process for reviewing the effectiveness and safety of new treatments or services, including using a greater evidence-base and a range of expert advice.
- d. Supporting and responding to the review of the HF & E Act and the report of the House of Commons Select Committee on Science & Technology.
- e. Improving public and stakeholder involvement in the process of policy making.
- f. Undertaking an evaluation of the 2 embryo transfer policy and reviewing the scope for moving to single embryo transfer.
- g. Surveying new and upcoming techniques in genetic screening of embryos, in particular screening for susceptibility genes, and considering any associated legal, clinical, social and ethical issues.
- h. Issuing new guidelines for clinics following the outcome of the Welfare of the Child review
- i. Working with MRC and other bodies to develop approaches to facilitating and utilising research in assisted reproduction

#### **Expected outcomes**

- a. Patients will receive better, safer services, including robust, timely decision making on the application of new treatments and technologies.
- b. Patients and stakeholders will have greater confidence in the HFEA's policy-making role in keeping up with, and addressing, emerging technologies and legal developments, as well as changing public and stakeholder attitudes.

### **3.9 To develop the organisation and staff to achieve the results needed.**

We need to ensure the organisation learns continuously and supports individual and team development. We need to encourage creativity and flexibility. We must ensure the organisation is able to take forward significant changes. We will do this by:-

- a. Devising a clear Organisational Development strategy covering the support of change management, developing a learning organisation, developing leadership, team building and cross team working.
- b. Developing and promoting staff involvement and communications through intranet, staff council, staff discussion forum.
- c. Improving training and development through a programme based on performance reviews, desired competencies, corporate objectives and accessing a wide range of in and out of house provision.

- d. Improving recruitment and retention through job evaluation, career opportunities, analysis of exit questionnaires.
- e. Improving workforce plans which support new developments and planned reductions.

### Expected outcomes

- a. Staff will have greater job satisfaction as shown in staff surveys.
- b. HFEA achieves improved organisational performance through more stable and skilled workforce.
- c. Patients and Clinics will receive high quality delivery of services.

### **3.10 To continue effective management of the operational budget; meeting ALB review targets, and setting appropriate fee structures for new areas of regulation.**

With additional work responsibilities for HTA and EU Tissue Directive at a time of ALB review pressure to reduce costs, we must ensure we are able to manage our budgets and financing accurately and transparently. This will be done by:-

- a. Managing expenditure planning and approvals within the agreed budgetary framework, and ensuring prompt collection of fees due.
- b. Proposing a framework for fees for EU Tissue and Cells Directive regulation of gametes and embryos, based on assessment of the work involved, and put through a full consultation process before review and implementation.

### Expected outcomes

- a. The Authority will have a balanced budget, with costs covered by fees or grant in aid.
- b. Clinics will perceive fees as a reasonable charge for proportionate regulation.
- c. HFEA will meet ALB targets.

## 4. Risk management

- 4.1. The HFEA recognises that the environment in which we operate is constantly changing, and that priorities must develop in response. Risk management is an organisation-wide process, involving Members and staff at all levels. The Authority has a Register of High Level Risks, which highlights those risks regarded as having potentially high impact, and high or medium probability. This Register is monitored regularly by the Authority, Audit Committee and Senior Management Team. A Risk Management Group is in place, involving all operational managers, which supports the SMT, and acts as a focus for the development of risk awareness and management across the organisation.
- 4.2 Management of risk is an integral part of the business process, and action on key risks is reflected in the Business Plan. The high level risks are:
- That the Historic Audit Project (HAP) may not be completed by the end of March 2006.
  - That the HFEA might not deliver its statutory obligation to provide the information required by IVF and donor offspring.
  - That the HFEA might not have the necessary contingency arrangements to continue operations in the event of a major incident/accident.
  - That the HFEA may not be adequately prepared to meet its obligations as a Competent Authority, under the EU Tissues and Cells Directive.
  - That the HFEA may not be able to handle requests under the Freedom of Information (FOI) Act in a timely and effective manner.
  - That the implementation process for RAFT might adversely affect HFEA's regulation of ART and the ability to fulfil the existing statutory functions.
  - That the Electronic Data Interchange (EDI) system might not be in place in a majority of centres by mid-year.
  - That the reputation of the HFEA may be damaged by adverse media coverage.
  - That the HFEA may not have the capacity/process to respond to and manage adverse incidents.
  - That the HFEA may not regulate research activities in line with the requirements of the HFE Act and Code of Practice.
  - That the HFEA might not prepare evidence-based policies which enable it to keep abreast of new developments in the field of assisted reproduction.
- 4.3 All of these risks are being actively managed, mitigating programmes of work are in place, and the actions are reflected in the Business Plan.

## 5. Financial plan

- 5.1** This section sets out details of the Authority's expected income for 2005/06 and planned expenditure in respect of the Authority's core operating activities, together with the DH funding and forecast expenditure relating to the modernisation of the Register for the year. It also sets out the key risks associated with managing the budget during the period.
- 5.2** The expenditure has been provided to accommodate the activities set out in this plan, to ensure the commitments given by the Authority are met, and that the organisation continues to modernise and strengthen its procedures and internal processes. Achievement of a very challenging Business Plan is dependent on maintaining planned levels of DH grant-in-aid and income from fees. During the year, a review of organisational effectiveness and efficiency will be conducted, including a review of how well IT systems are used and the potential for shared corporate services. The cost and service standards for outsourcing financial transaction processing will be compared with internal figures. The potential for more outsourcing of HR will be examined after the work on setting up HTA has been completed.
- 5.3** The Authority recognises that the successful implementation of the Business Plan will demand careful management of resources. Detailed project plans will underpin all major activities, including finance, staffing, timescales and consultation. This will enable us to make contingency plans to cover unforeseen issues which may emerge. HFEA will be funded by DH to cover all costs incurred on behalf of HTA.

### Key priorities

- 5.4** Section 3 of this business plan sets out the objectives to carry forward the work of the Authority into 2005/06, and provides details of the tasks necessary to accomplish this.
- 5.5** The EU Tissue Directive will place increased demands on the HFEA and additional fees will be levied to meet the costs of regulating the additional centres not currently regulated by HFEA. The costs and fees have not been included for this work, pending more detailed plans.

### Key budget assumptions

#### Income

- 5.6** The key projected income streams for the Authority are an estimated £3.8m, from annual registration and monthly billed treatment licensing fees, and £1.5m from the Department of Health in grant in aid. A further £3.1m revenue grant in aid for the modernisation of the Register is also planned.
- 5.7** The estimate of licensing fee income is based on the latest levels of activity during 2004/05.

#### Expenditure

- 5.8** The staff required to regulate the additional clinics covered by the EU Tissue Directive will need to be recruited prior to March 2006, when inspections are due to commence.

- 5.9** The costs of the Registry are planned to fall in 2005/06 as more of the costs of the Registry staff will transfer to the Register modernisation programme. With the implementation of EDI, the work of maintaining the Register is expected to diminish.
- 5.10** Salary costs in Communications will rise temporarily on web site development, to meet objectives on improved patient communications. The greater reliance on web communications will enable a fall in non-pay communications costs for the HFEA.
- 5.11** The Register modernisation programme will include a full roll out of EDI in 2005/06 and also a full year of the Historic Audit Project, expanded to a minimum of 8 teams.

## Risks

- 5.12** The key anticipated risks, as for previous years, relate to the Authority's income from licensing. Future activity cannot be estimated with certainty; fee income has therefore been estimated on a prudent basis.
- 5.13** The Register modernisation programme is expected to be completed by March 2005/6. The key risk is that there is still work to be completed after the end of March 2006. This risk will be managed by close monitoring of the Register spend and milestones.
- 5.14** As for 2004/05, expenditure on legal and professional fees cannot be predicted with certainty, as they can be influenced by external factors beyond the control of the Authority, e.g. applications for judicial reviews. Similarly, the nature and number of critical incidents arising in 2005/06 cannot be predicted.
- 5.15** It is intended that this risk will be managed through the regular monitoring of income and spend, as outlined in the following paragraph.

## Conclusion

- 5.16** The budget for 2005/06 will be monitored on a monthly basis by HFEA directors. Monthly management accounts following the structure set out in Annex D will be produced for these reviews, with copies forwarded to the Authority, highlighting any material variances and proposing corrective action where necessary.

## 6. Performance monitoring

**6.1** Considerable progress has been made during the past two years in modernising the central functions of the HFEA. This Business Plan will take us significantly further in ensuring the HFEA can meet both its statutory obligations and the growing, but reasonable, expectations of our stakeholders and the wider public. An organisation-wide performance monitoring and risk management framework is in place, including the regular monitoring of the plans set out in Section 3 and a number of performance indicators to measure effectiveness.

### 6.2 Performance Monitoring

Performance will be monitored by:

- A quarterly review of progress on the projects and actions underpinning each of the key objectives
- A regular review of the related high level risks
- A year end report to key stakeholders

### 6.3 Performance Indicators (PI)

Annex D sets out a number of performance indicators relating to the central functions of the HFEA. These are the result of continuing work on developing appropriate PIs. The PIs provide a measurable assessment of performance and outcomes, enabling stakeholders and the public to judge the progress the HFEA is making towards its stated objectives.

# Annex A

## Purpose and Statutory Functions of the HFEA

The Authority's key responsibility is the licensing and monitoring of clinics and centres carrying out *in vitro* fertilisation, donor insemination, and human embryo research. Its principal statutory functions are to:-

- License and monitor clinics carrying out *in vitro* fertilisation and donor insemination.
- License and monitor centres undertaking human embryo research.
- Regulate the storage of gametes and embryos.

The Authority's other statutory tasks are to:-

- Produce a *Code of Practice* which gives guidelines to clinics about the proper conduct of licensed activities.
- Maintain a formal register of information about donors, treatments and children born as a result of those treatments.
- Publicise the HFEA's role and provide relevant advice and information to patients, donors and clinics.
- Review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and, where appropriate, advise the Secretary of State for Health on developments in these fields.

# Annex B

## Principles and values

1. The HFEA is committed to working within the seven principles of public life, which are the baseline for all public bodies.

### Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

### Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations which might influence them in the performance of their official duties.

### Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

### Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

### Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

### Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

### Leadership

Holders of public office should promote and support these principles by leadership and example.

2. Within these principles, the Authority's overriding aim is to safeguard the public interest. This concern applies particularly to patients, and the children and families created as a result of assisted reproduction; the welfare of the child is considered paramount in the work of the Authority.
3. In order to guide its work, at all levels of the organisation, the Authority has adopted a number of additional values:-
  - integrity and honesty
  - impartiality and independence
  - openness in decision making
  - being rigorous, consistent and fair
  - working collaboratively
  - promoting safe, effective and ethical practices in clinical service and science
  - being timely
  - seeking, sharing and learning

# Annex C

## Progress in 2004/5

- 1 The 2004/5 agenda presented major challenges to the Authority and its staff. In addition to the 10 major objectives identified, other significant projects emerged during the year, such as the ALB Review, which had to be absorbed for the most part within existing resources. Also the management of applications for stem cell and other complex research licences has proved very time-consuming.
  
- 2 Despite this continuing pressure, all our major objectives were achieved; only a small number of planned activities, were delayed or postponed until 2005/6. These are:
  - Pilot project for patient representatives on inspections
  - Consultation with patient groups on Opening the Register
  - Review of Centres Manual
  - Monitoring impact of NICE guidelines on IVF provision by NHS
  - Risk assessment of culture media
  - Development of guidance on clinic workloads
  - Exploring use of bar-coding to track gametes and embryos
  
- 3 The objectives set for 2004/5 and the key achievements are set out below.
  - a) **To deliver high quality, effective and professional regulation of infertility services and storage of gametes and embryos, focusing on risk, safety and quality.**
    - Further streamlining of inspection process, with standard protocols for all planned inspections and a standard format for inspection reports.
    - A full programme of unannounced inspections carried out, including four randomly chosen and four based on risk-assessment.
    - Streamlining of licence committee procedures and effective arrangements put in place to ensure clinics' prompt compliance with licence committee decisions.
    - Annual re-accreditation and training for all Inspectors
    - Strengthening of the licence committee procedures
  
  - b) **To achieve stronger, more efficient and publicly accountable process of regulating research.**
    - Streamlined process for handling research licence applications put in place, including recruitment of additional overseas peer reviewers.
    - Summarised information on all licensed research projects now on the HFEA website in layman's language.
    - Second annual research conference held to facilitate dialogue between the HFEA and the research community.
    - New procedures on management of research-related untoward incidents implemented
    - c) To develop an efficient and effective process for licensing centres as required by the EU tissue directive and to put in place a process for accreditation of all licensed clinics/ART laboratories.
    - A comprehensive implementation programme put in place to enable the HFEA to undertake responsibilities placed on us by the EU Tissue Directive.
    - Agreement reached with professions on ART accreditation standards

- d) **To deliver robust, comprehensive and timely information management, which informs safety and quality.**
- Electronic Data Interchange (EDI) has been introduced or agreed with most Centres through a single interface which suits their internal procedures.
  - Validated treatment data were made available to ESHRE and for new Patients' Guide.
  - Arrangements and systems in place, supported by staff training, to ensure HFEA can respond to Freedom of Information requests.
  - Good progress made on the historic records audit, with eight audit teams out in the field working to a completion date of end of 2005/06.
- e) **To put in place a strategy for supporting and involving patients.**
- A range of new leaflets and other patient information published in consultation with patient groups and the Plain English campaign, including consent, complaints and information on costs of treatment.
  - New patient Guide published and evaluated
  - Patients' questionnaires now a routine part of preparation for inspections since November, alongside interviews with randomly-selected patients during the inspection.
- f) **To communicate effectively with all stakeholders and the public, to increase understanding of the HFEA's role and the regulation of IVF and research, enabling informed patient choice and public debate**
- All licensed research projects now available on HFEA website
  - Three public meetings of the Authority were held during the year, including one in Edinburgh.
  - More effective arrangements for handling patient and public enquiries put in place
- g) **To develop and implement clear policies based on evidence, ethical considerations and public views - supporting continuous improvements in quality and safety and appropriate access to new technologies**
- Completion of policy reviews on assessment of welfare of the child, the use of PGD/HLA tissue typing for selection of embryos to produce tissue donors, Dewar flask safety and gamete donation.
  - Produced detailed recommendations to DH on review of future legislative requirements to ensure effective regulation of ART; and gave evidence to the House of Commons Science and Technology Committee Inquiry into Human Reproductive Technologies & the Law.
  - Review of Code of Practice launched
  - Developed new organisational process for horizon-scanning, including international expert panel.
- h) **To ensure through clear systems that Authority meets its statutory financial and corporate responsibilities demonstrating efficiency, effectiveness and value for money**
- Review of corporate governance completed
  - Produced submission for review of Arms Length Bodies
  - New fees structure for regulation of research agreed by Ministers after public consultation.

- i) **To agree and implement Human Resources (HR) Strategy valuing staff, ensuring capacity and skills meet the organizations needs and the development of integrated work patterns.**
- A comprehensive pay and grading exercise carried out, including job evaluation and market rate comparison, to ensure appropriate organisational structure and fair remuneration of staff.
  - Programme of training for managers completed
  - Introduction of personal development plans for all staff
  - Carried out a formal training audit
  - Implementation of an internal communications programme to inform and support staff
- j) **To build partnerships with other statutory and voluntary organizations.**
- Agreement with Healthcare Commission (CHAI) and GMC through memoranda of understanding on specific regulatory roles and flow of information.
  - Increased involvement with ESHRE, EIM and other international bodies, including leading the establishment of a Consortium to ensure a coherent response to the EU Commission on the impact of the Tissue directive; development of a Europe-wide incident-reporting framework.

## Annex D

Performance indicators		Target for 2004/5	Achieved in 2004/5	Target for 2005/6
<b>A: Inspection and Regulation</b>				
1.	Number of random, unannounced inspections carried out in the year	4	4	4
2.	Reports resulting from inspection of treatment centres available to centre within four weeks	90%	66% *	90%
3.	Reports resulting from research inspections available to centre within four weeks	N/A	N/A	90%
4.	Alerts issued within 21 working days of decision to issue	N/A	N/A	90%
5.	New licence applications processed within four months from receipt	90%	None received	95%
6.	Research licence applications processed within three months from receipt of complete application and peer review	90%	69% *	90%
7.	Reduction in items of information required from clinics at licence renewal	N/A	N/A	20%
<b>B: Communication and Information</b>				
1.	Patient/public enquiries replied to within three working days	90%	90%	95%
2.	Number of Authority meetings held in public during the year	2	3	3
3.	Number of stakeholders' events		10	7
4.	Freedom of Information requests dealt with in 20 working days	N/A	N/A	100%
<b>C: Corporate</b>				
1.	Invoices paid within 30 days	90%	93%	90%
2.	Debts collected within 60 days	90%	83%	90%
3.	Monthly billings of clinics achieved in three weeks	100%	100%	100%
<b>D: ALB Targets</b>				
1.	Reduce costs to £8.4m revenue			
2.	Reduce headcount to N/A N/A 81 (by March 07)			
3.	Assess shared services potential for back-office study of finance	N/A	N/A	Complete

\* As at 31st December 2004

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