

## AUTHORITY

<b>Committee:</b>	Meeting
<b>Meeting Date:</b>	15/02/06
<b>Agenda Item:</b>	8
<b>Paper Number:</b>	HFEA (31/01/06) 296
<b>Paper Title:</b>	Business Plan and Budget 2006/07
<b>Author:</b>	Marian Wood, Head of Business Planning
<b>For Information or Decision?</b>	Decision
<b>Resource Implications:</b>	Since the first draft Business Plan and Budget was approved at the November, Authority, income projections have been raised in line with recent trends. A break even budget is proposed for 2006/7. This is dependent on the agreed increase in DH grant-in-aid and the proposed fee increase on treatment volumes.
<b>Implementation:</b>	<ul style="list-style-type: none"> <li>• The Business Plan has already been extensively discussed with Directors and Heads. Detailed operational plans for each directorate are currently being drawn up along with risk assessments for key objectives.</li> <li>• When approved by Authority and DH, all budget holders will be given their agreed budgets.</li> </ul>
<b>Communication:</b>	<p>All HFEA staff have been involved in detailed Business Planning Sessions for 2006/07.</p> <ul style="list-style-type: none"> <li>• Business Plan activities need to be communicated with key stakeholders</li> </ul>
<b>Organisational Risk:</b>	The risks associated with the successful delivery of the Plan for 2006/7 must be considered 'high', taking into account the tight budget considerations, the uncertainty over the future of the organisation in terms of the Review of the Act (and the likely affect on staff turnover, which will prove more problematic in a smaller, more tightly focused organisation)
<b>Recommendation to the Committee:</b>	That the Business Plan and Budget be approved for submission to the Authority and to DH.
<b>Evaluation:</b>	Quarterly reporting to the Authority. It is likely that Authority members will be asked to make more decisions/choices on prioritisation of specific pieces of work if resources become 'too stretched' in attempting to deliver the 2006/07 Business Plan.



**HFEA**

**BUSINESS PLAN**

**2006 / 07**

January 2006

## CONTEXT

The HFEA continues to operate in a fast moving, complex and ethically challenging area of science, with a very high level of public interest in its activities. It has proved itself to be an organisation that is able to continually adapt to changing expectations.

The policies developed take into account the disparate and often conflicting views of the public. The organisation recognises the importance of engaging well with a range of stakeholders and with the fertility sector itself. The key aim of the HFEA is to maintain confidence in fertility treatment and embryo research and ensure safety for patients, embryos and children born as a result of ART.

The HFEA leads the establishment of European Assisted Conception Consortium to bring about closer international links between ART Regulation and service providers in anticipation of the EU Tissue Directive. The Directive will extend the HFEA's remit to include the regulation of clinics carrying out IUI for example. It will reinforce the need to focus on a quality system approach for clinics.

During 2006 as the government conducts its review of the regulation of infertility treatment and embryo research, the need to ensure that the patient's voice is heard is more important than ever, The HFEA has a prominent role in this.

The organisation has demonstrated how well it has adapted to changing expectations over the years and is now taking a rigorous approach to the requirements of the ALB Review agenda, specifically more targeted, proportionate and risk based regulation.

# THE ROLE OF THE HFEA

## Purpose:

To assure patients and the wider public that research and treatment undertaken in the field of assisted reproduction is conducted to the highest standards, and within a robust ethical framework.

## Principal Statutory Functions:

- 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 (eggs and sperm) and embryos.

## The HFEA's Other Statutory Tasks

- 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.

## Some Achievements during 2005

### Patient and public involvement

- Handled approximately 15,000 calls from the public
- Published new style Guide to Infertility and Directory of Clinics also available as a web-based interactive guide
- Handled 50 patient complaints and issued UK wide report to clinics on the key issues for patients highlighted by such comments
- Recruited 750 patients to the Fertility Views on-line panel

### Regulating Research

- Effectively managed complex applications for research on embryos
- Held the third Annual Research Conference
- Developed a new process for horizon scanning for scientific developments, involving an international expert panel

### The Model Regulator

- Modernised regulation by introducing random, unannounced inspections.
- Developed a risk based tool for inspections.
- Reviewed the amount of paperwork in the inspection process
- Streamlined decision making and administration of PGD applications
- Carried out all statutory inspections within timescale and to budget
- Held the first Licensed Centres panel to get views on how the inspection process could be improved

### Policy Review and Advice

- Produced detailed recommendations to the Department on the review of future legislative requirements to ensure the effective regulation of ART
- Provided evidence to the House of Commons Science and Technology Select Committee Inquiry into Human Reproductive Technologies and the Law
- Helped set up and chair EACC to support implementation of the EU Tissue and Cells Directive in ART across Europe

- Conducted major consultations on sperm, egg and embryo donation (SEED) and The Welfare of the Child.
- Launched Choices and Boundaries Review on PGD and late onset cancer
- Launched the review of multiple births with an international multi disciplinary group to assess the implications in the United Kingdom
- Developed a project to understand the variation in success rates at clinics and areas in which this could be improved

#### Improving Efficiency / Effectiveness

- Commenced the roll-out of the Electronic Data Interchange (EDI)
- Expanded the Historic Audit Project (HAP), on schedule to complete in March 2006
- Commenced sharing of services (HR) with the Human Tissue Authority (HTA).

#### Corporate Goals – 2005-2009

- Strengthening the regulatory role and ensuring that regulation is proportionate and risk based
- Being an open organisation through excellent communications and partnership with stakeholders
- Working closely with other regulators and international agencies
- Strengthening the role and process of policy development
- Developing an information base which meets the needs of offspring and stakeholders, and the wider regulation and public health functions
- Supporting the development of research in assisted conception and its application
- Developing an organisation, which will fulfill these goals supported by strong corporate governance

#### Ministerial Performance Targets

- A continued rigorous approach to inspection and regulation,

Including the implementation of a risk-based inspection process.

- Successful completion of the Historic Audit Project (HAP) by 31st March 2006.
- Preparation for the implementation of the requirements of the EU Tissues and Cells Directive in April 2007
- Developing arrangements with the Human Tissue Authority (HTA), including the provision of back office functions and systems that can be easily integrated on the establishment of the Regulatory Authority for Tissue and Embryos (RATE) in 2008

## **KEY OBJECTIVES FOR 2006/07**

- Provide proportionate, more cost effective, targeted and risk based regulation to be seen as a model regulator, and achieve all ALB targets
- Drive forward the implementation of the European Union Tissue and Cells Directive and lead the European Committee in addressing this
- Provide reliable information and advice to donor conceived adults and donors
- Empower patients and inform patients of future choices
- Strengthen relationships with key stakeholders by better engagement
- Develop public understanding and confidence in research on assisted conception and stem cell research
- Develop close working relationships with the Human Tissue Authority (HTA), to create integral working wherever possible in readiness for the transition to RATE
- Maintain robust financial, staff management and corporate governance to increase efficiency and reduce costs

***Key objective 1: Provide proportionate, cost effective, targeted and risk based regulation to be seen as a model regulator and achieve ALB targets***

- Implement risk-based inspections and audits, proportionately redirecting attention from low risk to high risk, poorly performing centres
- Process and evaluate applications for PGD, import / export of gametes, new and variations to licences promptly and efficiently
- Continue to streamline licensing process to reduce costs of regulating the sector
- Fully implement development of in-house inspectorate to promote consistency and even-handed regulation
- Work closely with Healthcare Commission, MHRA, NPSA and other regulators to reduce overlap and duplication of regulation and promote best practice in licensed centres
- Develop further guidance for clinics to incorporate EUTD standards
- Implement, monitor and evaluate policy decisions on SEED and Welfare of the Child.
- Manage complaints and incidents investigation and produce Alerts to improve practice and promote patient safety
- Modify the Code of Practice to improve its effectiveness as a regulatory tool and to reduce regulatory burdens on centres

***Key objective 2 : Drive forward the implementation of the European Tissue and Cells Directive and lead the European Committee in addressing this***

- Develop policy on implementation of the EU Tissue and Cells Directive (EUTCD) and provide advice to the Department of Health
- Develop licensing and inspection procedures and a fee strategy to implement EUTCD
- Provide guidance and information to IUI / GIFT centres and currently licensed IVF clinics to support them in preparing to meet standards

***Key objective 3: Provide reliable information and advice to donor conceived adults and donors***

- Respond to 'opening the register' requests in a timely and sensitive manner and develop a process for post anonymity applications
- Quality assure accuracy of register data
- Implement reviewed guidance on ensuring donor limits are met

***Key objective 4: Empower patients and inform them for future choices***

- Use views of patients, public and clinics to improve provision of information through publishing inspection reports and the Patients' Guide to Infertility
- Promote greater patient involvement in inspection
- Produce thematic reports on centres' performance
- Review multiple births and develop appropriate policies on embryo transfer
- Improve patients' access to good information, through new patient web-based briefings and better marketing of HFEA's role
- Learn more about patient needs through consultation, research and the Patients Panel
- Review how data on success rates is used to inform patient choice

***Key objective 5: Strengthen the relationships of the HFEA with key stakeholders by better engagement***

- Promote HFEA's inspection role to increase confidence for patients and the sector
- Ensure GPs and PCTs have reliable information on performance, availability and capacity of licensed clinics
- Actively consult licensed centres and other stakeholders through Licensed Centres Panel, BFS, RCOG and other professional organisations.
- Increase transparency through improved range of corporate events and annual publications
- Provide advice and information to the Department of Health, particularly to inform the review of the HFE Act

***Key objective 6: Contribute to maintenance of public understanding and confidence in research on assisted conception and stem cell research***

- Scan scientific horizon for new developments in fertility science and assess new technologies
- Carry out rigorous, informed regulation of research through improved business processes
- Publish lay versions of research applications and licensing decisions

***Key objective 7: Develop close working relationships with the Human Tissue Authority (HTA), to create integral working wherever possible and move forward towards the establishment of RATE)***

- Share knowledge on piloting self-assessment
- Develop joint business planning/risk management approaches
- Adopt consistent approaches to implementation of the EUTCD
- Share back-office and other functions as appropriate particularly to ensure a cost effective transition to RATE
- Develop shared regulatory methods, wherever possible

***Key objective 8: Maintain robust financial/staff management and corporate governance to increase efficiency and reduce costs***

- Develop and support IT systems to raise productivity and increase access to information both at HFEA and at centres
- Complete the staff training and development programme, and align it to the organisation's objectives
- Develop internal communications and management capability to lead and develop people effectively
- Maintain sound financial processes including budgetary control and improve cost awareness
- Review income sources and financial strategy including overall fee strategy
- Use and develop costing models
- Maintain a high standard of office facilities gaining best value through effective procurement
- Develop a relationship management system to improve effectiveness of handling customers and stakeholders expectations

## HIGH LEVEL RISKS FOR THE ORGANISATION

- Preparing for implementation of the European Tissue and Cells Directive by bringing over 100 IUI/GIFT clinics into regulation to meet the requirements of the Directive
- Completing two major complex projects: The Historic Audit Project (HAP) and the Electronic Document Interchange (EDI) in the first quarter of the financial year
- Delivering a more challenging business plan within the context of reduced resources and tighter funding levels as a result of the Arms Length Body Review (ALB), which increases the risk of not delivering fully on 2006/7 key objectives
- Uncertainty generated over the future of the organisation by the review of the HFE Act and the Government's wider review of regulation, which will cause problems in recruiting, retaining and replacing key personnel. This situation is likely to be more problematic moving closer to the establishment of RATE
- A major incident occurring at one of the centres which could divert significant staff resources from delivery of key objectives

## IMPROVING EFFICIENCY/ EFFECTIVENESS

The organisation adheres to the principles of the Better Regulation Taskforce and requirements of the ALB review by being able to demonstrate efficiencies to provide more targeted, proportionate and risk based regulation, some examples are:-

- Reducing the reliance on external specialist advisors by developing an in-house inspectorate team, which will improve consistency and impartiality
- Devolving responsibility for approval of new techniques wherever possible to Persons Responsible in centres; examples are approving ICSI practitioners and PGD
- Adopting a new approach to risk management by risk assessing all objectives within the Business Plan
- Piloting a risk based tool to identify clinics in high/low risk categories to enable low risk clinics to have greater autonomy and concentrate effort on areas requiring most improvement
- Merging operational audit with the regulation inspection team to demonstrate a more seamless approach to the inspection process and reduce the number of interactions with Centres by the HFEA
- Developing a self assessment tool for Centres and PRs in response to feedback from the Licence Centres Panel for greater autonomy
- Developing web-based communication for patients
- Piloting joint inspections with the Health Care Commission (HCC) to identify areas of duplication and streamline both inspection processes, according to concordat principles.

## THE FINANCIAL PICTURE

### HFEA BUDGET 2006/7 Commentary

#### 1. Overview

- The second draft Budget at present shows break-even for 2006/7, following a review of income and taking the latest position on fees and treatment volumes.
- Completion of HAP and EDI by 31 March 2006 is assumed, apart from a small amount of work, for which a cost provision of £94k has been included.
- A head count reduction of over 100 staff is assumed with the disbanding of the HAP and EDI teams and the shrinking of all central support functions. This will be achieved by the ending of fixed term contracts.

#### 2. Income

- Fee increase of 1.5% is assumed, although Treasury approval has not yet been received.
- DH operating grant rises from £1.2 million to £1.8 million. This rise has been indicated to the HFEA but is subject to confirmation. It restores the cut of £0.2 million and adds allowances for inflation, additional pension costs, and EU Tissue Directive Work.
- Treatment cycles rise in volume on those forecast for 2005/6, returning to previous levels of growth. Fee income rises from £4.0 million to £4.3million
- If the fee increase is not approved or volumes are less than expected, it will be necessary to reduce costs by reviewing the level of support for responding to requests for information from the Register and analysis of information from the Register.

#### 3. Authority/Committee costs

Costs are budgeted to reduce slightly next year as Regulation and Corporate Governance plan fewer Licence Committees and Regulation Committee meetings. Also reduced room hire is budgeted as pressure on meeting rooms will be reduced with the ending of HAP and EDI projects.

#### 4. Regulation and Corporate Planning

Costs are little changed. Reduced budget for external advisors, offset by increased internal staff costs as the change-over to an in-house inspection team is completed. Efficiency savings will allow

for some additional work for EUTD to be absorbed as licensing activity doubles in last quarter.

5. Information Management

Gross costs are budgeted to reduce by half from £1238k to £622k. This follows substantial downsizing of the Register and Operational Audit staff levels. However, it is more than offset by a loss of £1015k of recharge of costs from this area to the Register project. Remaining staff will be switching their work from Historic Data clean-up to ongoing support of clinics, particularly in their first year of EDI, and improvements to accuracy and presentation of information from the Register.

	£	<u>2005/06</u>	<u>2006/07</u>
Gross Cost		1,238,000	622,418
Re-charge Register Project		<u>1,015,000</u>	
Net Cost		223,000	<u>622,418</u>

6. Communications and Policy

Communications and Policy is budgeted to reduce costs by £195k (15% reduction). This is mainly due to a move towards use of the web for communications and more targeted communications activities, along with a reduced number of Policy reviews and a more streamlined Policy-making process.

7. Resources and Corporate Development

Gross costs have been reduced from £2497k to £1957k with the downsizing of all central support units. However, this is more than offset by the loss of £1200k of recharges to the Register project. The full cost of office premises and services will now be borne by HFEA operations. IT staff (reduced in number) will switch onto supporting EDI and undertaking development to improve productivity and data accuracy and availability in all departments.

	£	<u>2005/06</u>	<u>2006/07</u>
Gross Cost		2,497,000	1,956,734
Re-charge Register Project		<u>1,200,000</u>	
Net Cost		1,297,000	1,956,734

8. Legal Fees

The budget assumes payment from CORE is received which reduces the net cost of legal fees.

9. Outlook for 2007/8

Income and costs in 2007/8 are expected to be in line with 2006/7, with the following exceptions

- DH grant-in-aid will rise by £56k as communicated to the HFEA by DH.
- Legal costs will rise by a similar amount due to the non re-occurrence of the CORE payment.

Efficiencies will be found to offset cost inflation, and the result will be break-even.

## Budget Summary

	2005-06 Budget £	Revised Forecast 2005-06 Forecast £	2006-07 Budget £	2007-08 Budget £
<b>Summary HFEA</b>				
Operational Activity				
Income	5,300,500	5,482,000	6,248,000	6,304,000
<b>REVENUE COSTS</b>				
Chief Executive's Office	405,747	422,000	451,411	451,410
Staff Costs - Other	456,273	327,000	323,273	323,273
Authority / Committee Costs	255,000	257,000	250,686	250,686
Regulation	1,209,425	1,253,500	1,282,860	1,282,860
Information Management (Registry)	140,885	223,000	622,418	622,418
Communications and Policy	1,155,205	1,259,500	1,064,119	1,064,119
Resources and Corporate Devt.	1,222,590	1,297,000	1,956,734	1,956,734
Legal Fees	194,500	100,000	66,500	122,500
Professional Fees	145,000	256,000	145,000	145,000
<b>Total Revenue Costs</b>	<b>5,184,625</b>	<b>5,395,000</b>	<b>6,163,000</b>	<b>6,219,000</b>
<b>CAPITAL COSTS</b>	<b>115,875</b>	<b>87,000</b>	<b>85,000</b>	<b>85,000</b>
<b>Total Costs</b>	<b>5,300,500</b>	<b>5,482,000</b>	<b>6,248,000</b>	<b>6,304,000</b>
<b>NET Operational Activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
NB This excludes both costs and fees for EUTCD, which are assumed to be break even				