

FACT SHEET 1: MODERNISING THE HFEA

Over the past eighteen months, the HFEA has completely modernised its operations. A new Chair, Suzi Leather, and a new Chief Executive, Angela McNab, together with a new management team, are now in place. The HFEA has already put into place the vast majority of the processes which support the recommendations of the Toft Report. Key areas of improvement include:

1. We have strengthened our regulatory regime

- New Inspectors have been recruited and trained to strict criteria and standards. We are requiring existing inspectors to undergo updated training
- Inspections are now more rigorous and are based on better intelligence through revised standard inspection protocols
- A survey of all HFEA licensed clinics (April 2004) shows that well over a half of clinics state that the HFEA inspection process has got better compared to four years ago.
- We are now carrying out unannounced inspections, some random and some targeted based on risk, which increases the robustness of our inspection process
- We have developed a new system to obtain patient feedback during inspections, and we will use this information to help focus our inspections

2. We have reviewed and improved our licence committees

- All HFEA members receive legal training before sitting on Licence Committees
- Formal protocols are being adopted for all licence committees
- A monitoring process is in place to ensure compliance with conditions placed on licences
- Legal advice is provided to each licence committee. The HFEA now has a full-time Legal Advisor as well as other legal support

3. We have a clear risk management framework in place

- The Authority has a risk management strategy implemented throughout the Authority
- We have introduced a unique Incident Alert System. Each clinic now has a written policy and procedure for dealing with incidents and must report all incidents to us within 12 hours. We alert all clinics in the UK with details of incidents and make recommendations so the whole sector can learn from actual and potential mistakes. Incidents are analysed over time with particular areas of risk consistently monitored
- We are moving towards more risk-based assessments with a risk assessment process for inspections
- We are reviewing the potential use of new technologies to improve laboratory practice and we have set up a working group to review tracking of gametes and embryos

4. We have improved all our communications

- The HFEA is committed to being an open and accountable regulator with fully transparent decision-making
- We have increased the range of our patient information including a series of patient leaflets and a new *Guide to Infertility* and a *Directory of Clinics*. We will be publishing a new Patients' Guide providing information on outcomes of treatments.
- We have increased communication with clinics through a new newsletter and a centres-only website providing two-way communication. We provide incident alerts and Chair's letters on key issues
- Three meetings of the Authority are held in public each year and we will be holding our first annual meeting later this year for the public to ask questions of the Authority
- We now publish inspection reports, Licence Committee decisions, give details of research applications received and updated summaries of research licences.
- We are working with Parliamentarians and other opinion formers to explain the role and contribution of the HFEA. We produce regular Parliamentary Briefings and hold meetings with Parliamentarians.

Our 2004/5 Business Plan outlines a programme of activities to continue the modernisation of the HFEA.