

HFEA Consultation on application fees for licensing under the European Tissue and Cells Directive

Executive Summary

As competent authority under the EU Tissue and Cells Directive (EUTD), the HFEA's remit is extended to include licensing of services involving gametes such as intra uterine insemination (IUI) and gamete intra-fallopian transfer (GIFT).

The scope of this consultation covers the initial application fee that previously unlicensed clinics will be required to pay in order to obtain their initial licence by 7 April 2007.

Proposed Fee Option:

All previously unlicensed clinics requiring a licence under the EUTD will be charged a flat fee of:

£975

This will cover the administrative costs of the application process, assessment of applications, and issuing of licences prior to 7 April 2007.

Clinics will also be invited to a comprehensive workshop during which further guidance will be provided and participants will have the opportunity to discuss issues with the HFEA and other clinics.

Additionally, clinics will have access to a named contact at the HFEA who will address queries and provide practical advice around the process.

Introduction

The HFEA was established by the Human Fertilisation and Embryology (HF&E) Act 1990 to regulate treatment and research involving embryos and stored and donated gametes.

The remit of the HFEA has to date covered any service involving fertilisation of a human egg *in vitro*, storage of gametes and embryos, donation of gametes and embryos, and research involving embryos.

As competent authority under the EU Tissue and Cells Directive (EUTD), the HFEA's remit is extended to include licensing of services involving gametes such as intra uterine insemination (IUI) and gamete intra-fallopian transfer (GIFT).

The HFEA has been working over the last two years to locate all relevant services and provide ongoing information and updates, as developments from the European Commission have emerged. Assisted Conception Standards detailing the requirements that have to be met by clinics under the EUTD have been circulated to the sector, and are available on the HFEA website (*insert link*).

All services affected by the Directive (see Annex A) must be licensed by the HFEA by 7 April 2007. It will be illegal for any clinic to carry on performing licensable service without a licence from the HFEA after this date.

The scope of this consultation covers the initial application fee that clinics will be required to pay in order to obtain their initial licence by 7 April 2007.

Our approach to setting fees includes the following principles:

- To enable the HFEA to fulfil its legal obligation as competent authority under the EUTD
- To minimise costs to the sector by reducing the regulatory burden as far as possible, within the constraints of the HFEA's legal obligations
- To propose a fee structure underpinned by comprehensive planning to assess costs of licensing as accurately as possible
- All costs of regulation should be met by the service being regulated
- All clinics should meet the minimum required standards to ensure patient safety and good clinical practice
- The system of licence fees and its collection should be simple to administer
- The system of licence fees should be open and easy to understand

Requirements of the HFEA as competent authority under the EU Tissue and Cells Directive

Under the EUTD the HFEA will be required to:

- Inspect and licence services involving fresh gametes, such as IUI services at least once every two years
- Investigate serious adverse events and reactions in relation to these services
- Inspect third party premises in relation to adverse events and reactions, where necessary
- Provide appropriate guidance and advice to services seeking a licence
- Maintain a publicly available register of licensed services
- Maintain a register of incidents to be submitted annually to the European Commission

The proposed application fee will cover a comprehensive range of HFEA processes including:

- Provision of detailed guidance to all clinics in relation to the licensing process
- A named HFEA contact to address queries
- The opportunity for representatives of all clinics to attend regional workshops involving further guidance and interactive discussion with the HFEA and other clinics (dates to be announced)
- Further pilot inspections and visits to clinics to inform the development of appropriate inspection methods and risk assessment
- Circulation of application forms and information on the licensing process. The application form will include a declaration of intent that the clinic wishes to be licensed under the EUTD, proposal of a Person Responsible, and a self assessment form.
- Assessment of applications
- Issue of all licences by 7 April 2007

Current HFEA responsibilities

The HFEA's primary objective and remit is the licensing and monitoring of clinics carrying out *in vitro* fertilisation, donor insemination, storage of gametes and embryos, and human embryo research.

The HFEA's other statutory functions include:

- Producing and updating the HFEA *Code of Practice*
- Keeping a register of information about donors, treatment and children born as a result of treatment
- Providing advice, information and support to patients, donors, and clinics
- Reviewing research developments relating to human embryology and providing advice on the relevance of this research to existing and new clinical practice and policy

The HFEA's licensing programme is conducted to maintain standards of practice that will advance patient care and create efficient and effective use of existing clinical services throughout the UK.

Current HFEA funding

HFEA activities are funded by a combination of government funding and fees raised from regulated clinics. The HFEA operates under the principle that it should recoup the cost of regulation from those who are regulated.

Government funding, which is paid over as grant in aid, covers baseline activities which include advice to Government and the public, providing information to patients and guidance to clinics, and developing evidence based policies.

Under the existing licensing scheme income for inspection and licensing functions is generated by two distinct methods:

- Licence fees – payable for the initial licence and subsequent licence renewal processes.
- Treatment fees – charged per licensed treatment cycle to cover ongoing inspection and monitoring, investigation of adverse incidents reported, and advice and guidance for clinics and patients.

For clinics brought into licensing for the first time by the EUTD, the HFEA is considering charging a flat rate annual fee rather than a treatment fee. There will be a separate consultation on this proposal later this year.

The HFEA will receive no additional resources from the Department of Health in order to fulfil its legal obligations as competent authority under the EUTD. This fee strategy has therefore been developed in order to resource the additional duties that the HFEA must carry out under the EUTD.

Funding Strategy for Licensing under the EU Tissue and Cells Directive

Appropriate resources must be obtained in order for the HFEA to fulfil its legal obligation as competent authority under the EUTD. The primary objective is to licence all relevant clinics, as required by the Directive. However, this process will in turn safeguard public, patient and professional interests in the services that are being brought within the HFEA's remit for the first time.

Proposed Fee Option:

All previously unlicensed clinics requiring a licence under the EUTD will be charged a flat fee of:

£975

This will cover the administrative costs of the application process, assessment of applications, and issuing of licences prior to 7 April 2007.

Clinics will also be invited to a comprehensive workshop during which further guidance will be provided and participants will have the opportunity to discuss issues with the HFEA and other clinics.

Additionally, clinics will have access to a named contact at the HFEA who will address queries and provide practical advice around the process.

Setting the fee at a flat rate enables the HFEA to minimise administration costs and complies with Treasury guidance regarding fees and charges.

There will be a further consultation later in the year to propose the structure for ongoing licence fees after April 2007. This subsequent consultation will address the need for resources to cover:

- Inspections
- Investigation of adverse incidents
- Ongoing support and guidance to clinics

Annex A

The EUTD covers any service involving donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, for human application.

HFEA licensable services under the EUTD:

- IUI
- GIFT
- Internet gamete procurement / distribution services
- Previously licensed IVF, DI and storage services

The following services are not affected by the EUTD:

- Research projects involving gametes or embryos
- Inter-cervical insemination
- Diagnostic tests
- Ovulation Induction

Tissues and cells other than gametes and embryos fall under the licensing remit of the Human Tissue Authority (HTA).