

EU Tissues and Cells Directive newsletter

Autumn 2006

Autumn 2006 - Autumn edition HFEA EU Tissues and Cells Directive

Introduction

The deadline for centres to demonstrate compliance with the EU Tissues and Cells Directive (the Directive) is fast approaching. All centres must submit self assessment forms to the HFEA by 5th January 2007 so that new licences can be issued (and existing licences varied) before April 2007. It will be illegal for centres to continue to provide relevant services after April 2007, unless compliance with the Directive is demonstrated and a license is issued.

HFEA Standards for Assisted Conception Centres

Using the HFEA Standards for Assisted Conception Centres, every centre should now be developing a quality management system, including the appointment of a quality manager if one has not already been appointed.

The Standards incorporate the requirements of the EU Tissues and Cells Directive and the measures that clinics will have to meet to demonstrate compliance with the Directive. The requirements of the Directive will be incorporated into the HFE Act 1990.

The Standards were sent out to clinics, as a working document, in April 2006. The Standards are currently being incorporated into the 7th edition of the Code of

Practice. The consultation on the 7th Code is available on the HFEA website; responses should be submitted by 12 December 2006.

Although the Standards are provisional, pending finalisation of European technical requirements, we are confident that they will change very little, if at all. Centres should not wait until the Standards are finalised before implementing them.

The guidance which accompanies the Standards answers frequently asked questions and clarifies areas of the Directive which are not prescriptive. This guidance will be updated regularly to clarify any issues which arise. This guidance and the Standards document are available on:
www.hfea.gov.uk/standards

Technical requirements

The European Commission adopted the first Technical Directive (covering donation, procurement and testing) in February 2006. A copy is available on the HFEA website.

The text of the second Technical Directive (covering processing, preservation, storage and distribution) is still under discussion following the public consultation last summer. It is anticipated that it will be finalised by December 2006, but we do not expect any significant changes to take place before then. It is also anticipated that the European Commission will not implement an EU coding system until September 2008.

Our advice to clinics is to plan their implementation of the Directive against the HFEA Standards, as detailed above.



Licensing

The HFEA will soon be sending out self assessment forms (plus application forms for previously unlicensed centres) to all centres. In order for a licence to be granted before 7th April 2007 these forms will need to be completed and returned to the HFEA by 5th January 2007.

Previously unlicensed centres (IUI and GIFT centres) will receive extra information regarding how to complete self assessment forms, as they will be doing so for the first time.

It is expected that centres will be issued with licences in March 2007 and formal inspections under the Directive will take place between April 2007 and April 2009. Centres already licensed by the HFEA, under the HFE Act, will receive one inspection to cover existing requirements and the new requirements of the Directive. Centres will receive detailed instructions around the licensing process and implementation of the Directive later this year.

EUTD application, annual and licence renewal fees

Application fee - for previously unlicensed centres

There will be an application fee charged to all previously unlicensed centres. The HFEA consulted with centres on the proposals for these application fees.

The consultation proposed that all previously unlicensed centres 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 April 2007.

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

Annual and renewal fees - for all centres

In addition, the HFEA have launched a consultation for annual and renewal fees, after April 2007, under the EU Tissues and Cells Directive. All centres should have received a copy of this consultation document in September. It is also available on the HFEA website: www.hfea.gov.uk/consultations

These fees will be chargeable from 2007/8 onwards for all centres which receive licences under the Directive from April 2007.

The consultation also includes a nominal fee for third party agreements involving licensable services. This nominal fee will impact a number of previously licensed IVF, DI and storage centres.

Please send comments on this consultation to eutdfees2@hfea.gov.uk

Newly-licensable centres to contact the HFEA

It is important that newly-licensable centres (IUI and GIFT centres) contact the HFEA to provide their contact details for our database. This will ensure there is no delay in you receiving relevant information.

Please phone Grace Cunningham on 020 7291 8954 or email to grace.cunningham@hfea.gov.uk to register your intention to provide newly-licensable treatments after April, and to provide the contact details for your centre.

If you are aware of any colleague/centre that may not have heard about this new legal requirement, please inform them of their need to contact the HFEA as soon as possible.

Further information

For archived editions of the EU Tissues and Cells Directive Newsletter, please see the "For Clinic Staff" section of the HFEA website: www.hfea.gov.uk

If you have any specific queries concerning the Directive please contact

Charles Lister, Head of Policy
0207 291 8230
charles.lister@hfea.gov.uk

or Helen Coath
0207 291 8238
helen.coath@hfea.gov.uk