

Gateway number: 5596

To:

- (1) Persons Responsible/Heads
of infertility treatment clinics
- (2) Heads of obstetrics &
gynaecology departments

12 October 2005

Dear Colleague

EUROPEAN UNION DIRECTIVE ON TISSUES AND CELLS 2004/23/EC UPDATE ON IMPLEMENTATION

The EU Tissues and Cells Directive, which sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application, including gametes and embryos, is due to come into force from 2006. We had planned to publish for consultation this summer draft regulations that would transpose the detail of the Directive into UK law from April 2006. However, information recently received from the European Commission indicates that the detail that underpins the Directive is not likely to be finalised until mid-2006 at the earliest.

The Directive was adopted on 7th April 2004. Since then, the UK has taken part in the negotiations on the two technical annexes (contained in Commission Directives) which contain the regulatory detail. The negotiations on the first annex are nearly complete and we expect it to be adopted this autumn. Work on the second annex is at a much earlier stage. A number of you will have seen the draft version issued by the European Commission for consultation in July. We do not expect the second annex to be adopted before mid-2006.

During negotiations on the first annex, the European Commission proposed a lengthy implementation period from the date of its adoption (likely to be in excess of one year) to allow tissue establishments sufficient time to comply with its requirements. We expect a similar proposal to be made for the second annex. So the implementation dates for the two technical annexes are expected to be between autumn 2006 and autumn 2007. For that reason, we have revised our plans for implementation and will not be producing draft regulations for consultation this year as originally intended.

Implementation

We are now proposing to adopt a staged approach to implementation of the Directive. During the first stage, before the underlying detail is available, we plan to implement the framework of the Directive via existing legislation and licensing and inspection arrangements.

Tissue and cell banking – e.g. bone, corneas and skin

The Human Tissue Act 2004 established the Human Tissue Authority (HTA)⁽¹⁾ as the regulatory body for all matters concerning the removal, retention, use and disposal of human tissue (excluding gametes and whole blood). In the case of those storage centres affected by the Tissue and Cell Directive, the HTA will, from April 2006, issue licences. Once the detail of the relevant technical annexes is known, the HTA will be in a position to inspect against those standards. More information about the EU Tissues and Cells Directive and the HTA's role as competent authority will be made available on the HTA website www.hta.gov.uk.

Fertility Services

The Human Fertilisation and Embryology Authority (HFEA)⁽²⁾ will continue to regulate fertility clinics under the Human Fertilisation and Embryology Act 1990. For clinics that provide gamete treatment services that are not currently regulated by the HFEA under the Human Fertilisation and Embryology Act, such as clinics that provide artificial insemination where the couple's own 'fresh' gametes are used, the Healthcare Commission will continue to have oversight from April 2006 under the Health and Social Care (Community Health and Standards) Act 2003 and the Care Standards Act 2000. If you are responsible for this type of clinic please contact the HFEA as soon as possible (if you have not already done so) to ensure that the Authority is notified that you will need to be considered for licensing later in the implementation process. Again, more information will be made available on the HFEA website www.hfea.gov.uk.

Legislation

The second stage of implementation will be preparation of regulations reflecting the detail in the technical annexes once they are both adopted. We will be consulting on these in due course, probably in mid-2006. Once the regulations have been made, the HTA and the HFEA will communicate with establishments to give further advice on the practical implications of the regulations.

Comment [SG1]: Should this be Autumn?

Comment [SG2]: We may use means of communication other than letters

If you have any questions about the Directive please ring Kim Hayes on 020 7972 6121 or email her at kim.hayes@dh.gsi.gov.uk.

Yours faithfully

Liz Woodeson
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