



HTA

Human Tissue Authority

The legislative background and the role of the HTA

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Current legislative framework

- Human Tissue Act 2004
- Human Tissue (Scotland) Act 2006
- 2006 Regulations (include exemptions to licensing)
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

- The Regulations fully transposed the European Union Tissues and Cells Directives into UK law on 5 July 2007

On the horizon...

Advanced Therapy Medicinal Products Regulation (EC) No 1394/2007

- entered into force on 30 December 2007, and
- applies from 30 December 2008

Legislation supplemented by Codes of Practice and Directions

- Eight Codes of Practice give implementation guidance and lay down expected standards
- Three sets of Directions relevant to the Human Application sector
 - 001/2006
 - 002/2007
 - 004/2007

Parent Directive 2004/23/EC

- Parent Directive provides an over-arching framework on setting standards of quality and safety for the
 - Donation
 - Procurement
 - Testing
 - Preservation
 - Processing
 - Storage
 - Distribution

of human tissues and cells

Technical Directive 1 2006/17/EC

Technical requirements for

- Donation
- Procurement
- Testing

of human tissues and cells

Technical Directive 2 2006/86/EC

- Notification of Adverse Events/Reactions
- Traceability
- Coding
- Processing
- Storage
- Distribution

EUTCD – EU Tissues and Cells Directive

- Directive is concerned with safety and quality of tissue that is stored and used for human application
- HTA is one of the competent authorities
- HTA must licence and inspect those premises that fall within the remit of this EU Directive

The Role of the HTA

- Competent Authority in UK
- Authorisation/licensing of establishments
- Register of licensed establishments and activity
- Register of serious adverse events and serious adverse reactions
- Control measures
- Reporting to EU Commission and member states.



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