

Information on European Cell and Tissue Directives and Regulations



What are European Directives and Regulations?

A European Directive is EU legislation that binds the member states to achieve certain targets, such as ensuring safety and quality of human tissue and cells. Directives are transferred within a certain deadline into national law by the national parliaments. A Directive is binding on the Member States with regards to the achievement of the target but allows for the national authorities to decide on how the agreed target is to be incorporated into their domestic legal system. The reasoning behind this form of legislation is that it allows Member States to take account of special domestic circumstances when implementing EU Community rules.

A regulation is EU legislation that is directly applicable in all Member States in the EU. The legal acts do not have to be transposed into national law but confer rights or impose duties on the Community citizen in the same way as national law.

How are human tissue engineered products currently legislated?

Until 1st November 2006, human tissue engineered products were not regulated in most European countries. On this date, the European commission's Directorate General responsible for Public Health (DG SANCO) issued 3 directives, which cover all academic and hospital activities, as well as commercial products with respect to the

- donation
- procurement
- testing
- processing
- preservation
- storage
- distribution

of human tissue and cells.

On 7th April 2007, Denmark became the first country to transpose DG SANCO cell and tissue Directives into their national law. The other European countries have implemented or are currently implementing the DG SANCO cell and tissue Directives.

How will human tissue engineered products be regulated in the future?

In 2005, the European Commission proposed a regulation for Advanced Therapy Medicinal Products (ATMP), which will further regulate the administration of tissues and cells to humans for regeneration, repair or replacement of a human tissue. The following areas, formerly covered by the DG SANCO cell and tissue directives, will then be regulated by the ATMP regulation when it comes into force.

- processing
- preservation
- storage
- distribution

In addition, Marketing will be regulated by the ATMP regulation.

What is the purpose of the legislation?

A key purpose of the DG SANCO Directive and the forthcoming ATMP regulation is to ensure quality of human tissue and cell based products and patient safety.

How does the current legislation affect me?

Genzyme is compliant with all current cell and tissue directives. Currently there are no changes anticipated to our procedures.

Any questions?

Please contact your local product representative should you wish to learn more about the current legislation.

Timelines - EU Advanced Therapies Regulation

Products may no longer be authorised nationally in new markets; Products on national markets may remain on those national markets for this period.

Tissue-Engineered Products have 1 year longer to comply

