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Questions and Answers on Human Tissues and Cells

Why does the European Commission need to regulate human tissues and cells?
The Amsterdam Treaty (Article 152) gave the EU the mandate to pass laws on the quality and safety of human tissues and cells, human organs and blood used in medical treatment. Each year in Europe, hundreds of thousands of patients undergo some form of therapeutic treatment based on the use of tissues and cells of human origin. These tissues or cells are frequently acquired through cross-border exchange. Having a common set of high standards helps facilitate cooperation between healthcare systems. It also assures EU citizens that if they go for treatment in another EU country, they will benefit from the same protection from transmissible diseases as they would in their own Member State. Member States also have the option to apply stricter standards than those set down by the EU should they wish to do so.

What has the EU done to date with regard to ensuring the quality and safety of human tissues and cells?
In 2002, the Commission put forward a framework legislative proposal to set binding requirements for the safety and quality of human tissues and cells from patient to donor. These were adopted by Council and Parliament in March 2004 and had to be transposed by Member States by April 2006. Directive 2004/23/EC also provided for the Commission to elaborate on the rules laid down, by setting technical standards for blood and tissue donation, procurement and storage, through the Regulatory Committee and in line with scientific advice. A first set of implementing rules, adopted in February 2006, aimed at providing safety rules for the first phases of the process: donation, procurement and testing. The second implementing Directive adopted today covers the subsequent phases: processing, preservation, storage and distribution. It also incorporates tissue coding requirements, measures to ensure traceability between donor and recipient and vice versa, and rules for reporting serious adverse reactions and events.

Why has the Commission drawn up implementing measures for the human tissues and cells legislation?
The 2004 Tissues and Cells Directive established a general framework of principles and common rules for the safety and quality of these substances. This had to be implemented by April 2006. However, detailed implementing measures needed to be developed which would give these general provisions effect and ensure that they were applied in a harmonised way throughout the EU. In order to ensure that these implementing measures would be effective, a process of consultation and consensus-building with tissues and cells safety experts and EU governments was required. This consultation process required adequate time to be able to gather all input and feedback, and to be able to draw on the latest scientific and technical advice.

What is provided for by the implementing measures?
The first implementing Directive covers first phases of the process – donation, procurement and testing – in order to ensure their quality and safety. Among the implementing rules set out for the first phases of the process are standards which establishments or organisations must meet in order to be authorised and accredited to procure human tissues and cells. For example, staff must be properly trained, the facilities must be appropriately maintained to prevent contamination of the donated tissues, and proper, sterile instruments must be used for

procurement. Standard operating procedures must be followed for the donation and testing process, during transport, and at the point of reception in tissue establishments. Conditions are also established for the selection of tissue and cell donors, live or deceased. These include exclusion criteria, for example, for people with HIV, Hepatitis or Variant Creutzfeldt-Jakob disease (vCJD). Obligatory tests will need to be carried out before donations are accepted, as will thorough medical history checks. A unique identifier code will be given to each donor, to ensure proper identification and traceability of donated material.

The second implementing Directive, adopted today, applies to the coding, processing, preservation, storage and distribution of human tissues and cells. This Directive also contains provisions on traceability and on the reporting of serious adverse reactions and events at every stage of the procurement and donation process. Among the rules set out are standards which tissue establishments must meet in order to be authorised and accredited to process, store, preserve or distribute tissues and cells. A tissue establishment must, for example, have an appropriate organisational structure and operation procedures and must apply a documented quality management system. The second implementing Directive also details requirements for the personnel, for the equipment and materials used, for the facilities and premises of the tissue establishments, for the documentation and records to be kept, and for reviewing quality through audits. Tissue and cell preparation processes must also be authorised. The Directive therefore sets out requirements regarding the reception at the tissue establishment, the processing, storage and release, the distribution and recall, the final labelling for distribution and the external labelling of the shipping container. Annexed to the Directive are forms for notifying serious adverse reactions and events and the format in which these must be annually notified to the European Commission. With a view of ensuring that all human tissues and cells are traceable from the donor to the end user, the new legislation also sets out information on the minimum donor/recipient data which have to be kept and defines the basis for a single European identifying code for all donated material.

What are the next steps?
The Commission will work with Member State authorities to ensure the new measures on traceability, the reporting of serious adverse reactions, and the coding, processing, preservation, storage and distribution of tissues and cells, can be put in place smoothly. Member States have until November 2006 to put in place national measures implementing the first Commission technical Directive and until November 2007 to put in place national measures implementing the second Commission technical Directive on human tissues and cells. An extra year (until June 2008) is given to Member States to put the national implementing measures for the coding requirements in place. The next step for the Commission will be the adoption of further guidelines concerning the single European identifying code for human tissues and cells.

For further information, see:
http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm