**Project Background**

EUSTITE was a 3 year project funded by the European Union following the publication of three European Directives defining minimum standards of quality and safety for human tissues and cells that are applied to patients for therapeutic purposes including transplantation and assisted reproduction. Examples are corneas that are donated after death and transplanted to patients during eye surgery, donated bone marrow that is used to treat patients with leukaemia or donated sperm that is used in assisted conception procedures. The EU Directives require Member States to ensure that procedures for collecting, processing, storing and distributing these tissues and cells are compliant with the standards defined in the Directives so that patients are treated with tissues and cells that will function as intended and will be safe.

The project was led by the Italian National Transplant Centre and was managed by a consortium of organisations from 11 EU Member States and the WHO. Its key objectives were to develop standardised guidelines and training for the conduct of inspections and tested tools for vigilance and surveillance in this field to support Member States in the implementation of these Directives. The project began on December 1st 2006 and finished in December 2009.

**Project Methodology and Management**

Workpackages on Management, Evaluation, Dissemination, Survey, Workshops and Exchange Visits, Vigilance and Surveillance, Inspection Guidance and Inspector Training were led by different partners.

**Vigilance and Surveillance**

Under the leadership of WHO, the project developed a series of vigilance tools for tissues and cells which were tested in a one year pilot with the participation of 22 Competent Authorities for tissues and cells. The pilot report can be downloaded from the project website www.eustite.org. The criteria for the reporting of serious adverse events, the imputability scale for evaluating the link between a reaction and the tissues and cells applied and the severity scale for a reaction have all been incorporated into the guidance provided by the European Commission to Member States for the completion of their annual vigilance reports to the Commission. The project submitted Final Vigilance Recommendations to the Commission which highlighted a number of areas for further work, particularly in relation to the need for investigation guidance and training, guidance for vigilance in Assisted Reproduction and the investigation of illegal and fraudulent activity and for greater engagement of clinicians to ensure effective vigilance. These issues were taken forward in a separate EU-funded project, Vigilance and Surveillance of Substances of Human Origin (SOHO V&S) (www.sohovs.org).

**Project Website**

The project website was the key tools for communication between partners and with external stakeholders and was visited by individuals from across the globe.

**Inspection Guidelines**

The EUSTITE Inspection Guidance was used by the European Commission during 2009 as the basis for providing official EU guidance to Member States. Key elements of the document were published in the form of an EU Decision on inspections and control measures and on the training and qualification of inspections in the field of tissues and cells in the Official Journal of the European Union (Decision 2010/453/EU). The remaining guidance has been edited by a DG SANCO working group of Member State representatives to become an Operational Manual for Tissue and Cells Competent Authorities. This Manual was translated by the European Commission into all of the official languages of the EU. The EUSTITE Inspection Guidelines will not be revised and re-issued but will live on in these official EU documents.

**Inspector Training**

The project ran 4 inspector training courses, each including a 7-week e-learning module and a 3 day residential module. Seventy one inspectors were trained from 26 of the 27 EU Member States and feedback from course participants was extremely positive.

**Eustite Final Conference**

In December 2009, the Polish partner hosted a major conference where all of the work carried out was presented. The conference was attended by professionals and regulators from the EU and beyond, including representatives from the FDA and CDC in the United States and from Canada. The project raised a lot of interest beyond the EU. The vigilance tools and the training course have been taken up by organisations in the US and South America and elements of the training course have been delivered at courses for pharmaceutical inspectors who also inspect tissue and cell banks.

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