Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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The Commission presents its report on the application of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Overall, the report states that the implementation of the Directives by the Member States is satisfactory. This concerns in particular the following:

- the requirement to designate a competent authority or authorities and to establish accreditation /designation/authorisation/licensing systems of tissue establishments;
- pinspections systems;
- registries of tissue establishments;
- systems to report, investigate, register and transmit information about serious adverse events and reactions; and
- testing requirements.

The degree of implementation of some other measures suggests that further efforts and actions by Member States are needed. This concerns the following:

- the development of specific systems for authorising the tissue and cell preparation process;
- finalisation of the accreditation/designation/authorisation/licensing process in respect of each individual establishment;
- the carrying out of inspections in all Member States;
- monitoring of imports/exports;
- fulfilment of the reporting requirements (tissue establishments' annual reports on activities, register of accredited/designated/authorised/licensed tissue establishments at the level of the Member States and at EU level -EUROCET-);
- preparation of annual reports on adverse events and reactions for the Commission.

The Commission is working with the Member States to help them develop operational solutions in response to the remaining challenges.

In July 2009 there were **five infringement procedures** open for failure to achieve full transposition of the Directives in two Member States.

The report also notes that some of the difficulties identified by Member States were linked to the implementation of testing requirements, in particular in the Medically Assisted Reproductive Technologies (MART) sector. The interpretation of the air quality standards that tissue establishments need to apply while tissues and cells are being processed is also a matter of concern among Member States. More guidance on coding systems, inspections, import/export and vigilance requirements was also sought by Member States. The report states that an efficient coding system is a crucial, but not exclusive, element in the traceability chain and ultimately in any vigilance system for human tissues and cells. The human tissue and cell chain is dependent on a robust codification system, which will secure the information flow from donation to transplantation and vice versa. The European coding system should ensure that the pre-existing traceability/coding systems can be maintained and further developed by the Member States, whilst ensuring a minimum level of compatibility between them.

The Commission is endeavouring to provide Member States and competent authorities with appropriate support in these areas.