

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance)

*Article 5*

**Notification of serious adverse reactions**

- 1 Member States shall ensure that:
  - a procurement organisations have procedures in place to retain the records of tissues and cells procured and to notify tissue establishments without delay of any serious adverse reactions in the living donor which may influence the quality and safety of tissues and cells;
  - b organisations responsible for human application of tissues and cells have procedures in place to retain the records of tissues and cells applied and to notify tissue establishments without delay of any serious adverse reactions observed during and after clinical application which may be linked to the quality and safety of tissues and cells;
  - c tissue establishments that distribute tissue and cells for human application provide information to the organisation responsible for human application of tissues and cells about how that organisation should report serious adverse reactions as referred to in (b).
- 2 Member States shall ensure that tissue establishments:
  - a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse reactions as referred to in paragraph 1(a) and (b);
  - b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.
- 3 Member States shall ensure that:
  - a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex III;
  - b tissue establishments notify the competent authority of the actions taken with respect to other implicated tissues and cells that have been distributed for human applications;
  - c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex III.