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Commission satisfied with implementation of 'blood directive'

By Anne Fekete | Tuesday 26 January 2010

The implementation of legislative provisions governing quality and safety standards for blood and blood components throughout the 'transfusion procedure' has proven to be satisfactory in the EU, according to the European Commission. In a communication adopted on 19 January, it evaluates the situation with regard to the implementation of Directive 2002/98/EC [(1)], which concerns the collection, use and testing of human blood and blood components, whatever the intended purpose. The text also applies to its preparation, storage and distribution, when intended for transfusion. It establishes an obligatory system for inspection and for the exchange of information designed to facilitate the identification and rapid communication of emerging risks in the blood sector, as well as the withdrawal of possibly contaminated batches of blood.

The Commission indicates that all member states have appointed a competent authority responsible for implementing the requirements of the directive. With regard to haemovigilance, it notes that all countries, except Cyprus and Bulgaria, have a system in place for notifying serious adverse events and reactions to the competent authority or delegated body. National authorities are required to ensure that blood transfusion establishments implement a system making it possible to identify each blood donation, and each unit of blood and blood components originating from it.

The communication is available at www.europolitics.info > Search = 265920

Organ donations

It should be pointed out that quality and safety standards for human organs intended for transplantation are the subject of a proposal for a specific directive, currently being examined at the European Parliament. The draft report by Miroslav Mikolasik (EPP, Slovakia) will be examined by the Committee on Public Health, on 26 January. Following the example of the 'blood directive', the proposal establishes common binding standards for the quality and safety of human organs intended for transplantation. The rapporteur suggests some amendments "related to human dignity," he indicates in his explanatory statement. With regard to "the issue of consent, the freedom of choice as whether or not to donate an organ needs to be respected and protected as well, therefore its adjustment falls in the competence of member states," underlines Mikolasik. He also wants compensation for living donors to be strictly limited to making good the expenses directly related to the donation (travelling fees, etc).

The draft report is available at www.europolitics.info > Search > 265920

(1) This directive was the subject of three implementation Directives (2004/33/EC, 2005/61/EC and 2005/62/EC).