Medical devices and active implantable medical devices

2005/0263(COD) - 29/03/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the resolution drafted by Thomas **Ulmer** (EPP-ED, Germany) and amended the proposal put forward by the Commission amending Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices. The report was adopted by 645 votes in favour to 15 against with 4 abstentions.

The key amendments relate to the following:

- **safety:** a new recital states that particular care should be taken to ensure that the reprocessing of medical devices does not endanger patients" safety or health. It is therefore necessary to provide clarification on the definition of the term "single use", uniform labelling and instructions for use. Moreover, the Commission should engage in further analysis in order to see if additional measures are appropriate to ensure a high level of protection for patients;
- the manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body;
- **differentiation from other directives:** in order to ensure that the Directive could be transposed smoothly, it was crucial to distinguish clearly between this and other laws, such as the Advanced Therapies Directive, and for there to be an unambiguous definition of medical devices. The definition of the latter now includes a phrase stating that the software must be intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes. The issue of combined products, i.e. devices which contain both human or animal tissue and material components, has been addressed. The Directive will not apply to medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that directive or the present Directive, particular account shall be taken of the principal mode of action of the product. Nor will the directive apply to transplants or tissues or cells of human origin or to products incorporating tissues or cells of human origin, with certain prescribed exceptions;
- **software:** one very vital issue was whether 'software in its own right' should be defined as a medical device or not. Parliament inserted clarification on this point in a recital stating that it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device. “Medical device” is redefined to include the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application intended by the manufacturer to be used for human beings for the prescribed purposes;
- **reprocessing:**the Commission shall, at the latest three years after the adoption of the Directive, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit any additional proposal it may deem appropriate in order to ensure a high level of health protection;
- **comitology:** the Commission will need to adapt classification rules for medical devices, to adapt the means by which the information needed to use medical devices safely and properly may be set out, to determine conditions for making certain information publicly available, to adapt the provisions on clinical investigations set out in certain Annexes, to adopt particular requirements for placing certain medical devices on the market or putting them into service, and to take decisions to withdraw such devices from the market for reasons of protection of health or safety. Those measures are of general scope and are designed to amend or supplement Directive 90/385/EEC and

Directive 93/42/EEC by the modification or addition of non-essential elements, and they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EEC. In urgent cases, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for taking decisions on withdrawal of certain medical devices from the market and for the adoption of particular requirements for placing such devices on the market or putting them into service for reasons of protection of health or safety.