Medical devices and active implantable medical devices

2005/0263(COD) - 05/09/2007 - Final act

PURPOSE: to amend provisions relating to: active implantable medical devices; medical devices and the placing of biocidal products on the market.

LEGISLATIVE ACT: Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8 /EC concerning the placing of biocidal products on the market.

BACKGROUND: in 2003 the Commission prepared and presented a Communication on the application of EU provisions relating to active implantable medical devices, medical devices and biocidal products. The conclusions of this Communication, which found support in both Council and Parliament, were that there is an urgent need to revise and amend existing legislation in order to take account of new developments.

CONTENT: the purpose of this Directive, therefore, is to amend existing Community provisions in the field of active implantable medical devices, medical devices and the placing of biocidal products on the market. The three Directives subject to amendment are:

- Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices.;
- Council Directive 93/42/EEC concerning medical devices; and
- Directive 98/8/EC concerning the placing of biocidal products on the market.

To ensure consistency of interpretation and implementation between provisions relating to “active implantable medical devices” and “medical devices”, the legal framework relating to:

- authorised representative;
- the European databank;
- health protection measures; and
- medical devices incorporating stable derivates of human blood or human plasma has been extended. In addition, provisions set out in Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, has been extended to the Directive on active implantable medical devices.

The status of “software” in medical devices has been clarified. The amending Directive specifies that software specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical devices, is indeed a medical device. Software, when used for general purposes such as healthcare setting, is not.

In other provisions the amendments introduce the following new elements:

- Clarification of the term “single use” and uniform labelling in order to ensure that medical devices do not endanger the safety or health of patients.

- Enhanced provisions on clinical evaluation, including clarification that clinical data is generally required for all devices regardless of classification. There is the possibility to centralise data on clinical investigations in the European data bank.
- An explicit requirement for a post market production review system, involving incident reporting to authorities.
- Offering manufacturers of Class I sterile and/or measuring medical devices the option of using the full quality assurance conformity assessment module in order to provide them with more flexibility in the choice of compliance modules.
- Extended time period (to 15 years) for the retention of documents concerning implantable devices.
- Establishment of a procedure on whether or not a product falls under the definition of “medical devices”.
- Obliging manufacturers to designate an “authorised representative” for their devices.
- Emphasising the level of training and knowledge of the uses within the essential requirements. Manufacturers should place particular emphasis on the consequences of a product’s misuse and its adverse effects on the human body.
- Requiring manufacturers to apply adequate controls to third parties carrying out the design and manufacture of devices on their behalf.
- Specification of implementation procedures in accordance with the “regulatory procedure” as set out in Decision 1999/468/EEC.
- Mandating, within 12 months after the entry into force of this Directive, CEN and/or CENELEC to specify technical requirements and a suitable specific label for phthalate containing devices.
- Requiring devices that contain critical phthalates and which are used on children, pregnant and nursing women and other patients at risk, to be labelled accordingly.
- Requiring manufacturers to avoid the use of substances that may possibly compromise the health of patients, in particular substances which are carcinogenic, mutagenic or toxic to reproduction. They should strive to develop alternative substances or products with a lower risk potential.
- Excluding, from the scope of this Directive, provisions relating to in vitro diagnostic medical devices and vitro diagnostic medical devices.

ENTRY INTO FORCE: 10 October 2007.

TRANSPOTION: 21 December 2008.

APPLY: from 21 March 2010.