Medical devices and active implantable medical devices

2005/0263(COD) - 22/12/2005 - Legislative proposal

PURPOSE : to amend Directives 93/42/EEC on medical devices and 90/385/EEC on active implantable medical devices.

PROPOSED ACT : Directive of the European Parliament and of the Council.

CONTENT : this proposal amends Directive 93/42/EEC on medical devices by modifying current

provisions, to bring about clarity, or by introducing new provisions, seen as necessary to continue to support the protection of human health. Also, the proposal updates Directive 90/385/EEC on active implantable medical devices to make it coherent with the other Directives on medical devices.

Since its adoption in 1993, a great deal of experience has been gained on the implementation of the Directive 93/42/EEC concerning medical devices. Whilst overall the experience has been extremely positive, some experience reveals that the Directive requires improved implementation by all parties concerned. A Report on the functioning of the Medical Devices Directives was published in June of 2002 and brought forward by the Commission in its Communication (COM(2003)0386). The most important areas where improvement should be made concern:

- conformity assessment, where questions arose as to the absence of clear rules on design examination by notified bodies;

- the sufficiency and adequacy of clinical data for all classes of devices;

-post market surveillance, where better coordination of activities in the area of post market surveillance are needed;

- Notified Bodies - in relation to their competence for the tasks for which they are designated, differences in interpretation between Notified Bodies and lack of transparency in the performance, and control, of their activities;

- increased transparency to the general public in relation to the approval of devices;

- modification of Directive 90/385/EEC relating to active implantable medical devices in order to align it with the other framework Directives on medical devices.

The proposed legislative modification brings forth either additional or replacement text regarding, in particular:

Conformity assessment modules: it has been further clarified that, for the conformity assessment of class IIa and class IIb devices under Annex II notified bodies are required to assess, on a representative basis, the design documentation for the device concerned.

Clinical data and evaluation: in order to clarify and enhance the provisions on clinical evaluation, significant modification was required of Annex X concerning clinical data and its evaluation and to various references to clinical data within the provisions of the Directive, including the definition of clinical evaluation and provision for the possibility to centralise data on clinical investigations in the

European databank.

Legal certainty regarding scope: to provide a method to make binding decisions on issues arising at national level, in relation to the misinterpretation of a product as being or not being a medical device, a procedure, based on comitology, has been added to Article 13. Also, in order to clarify that it is possible for both the Directive on medical devices and the Directive on personal protective equipment to simultaneously apply to a product, such as a surgical glove, it is necessary to delete the reference in Article 1 to the Directive on personal protective equipment to allow both apply.

Measures to increase transparency: the Article on confidentiality, which previously maintained all information available under the Directive as being confidential, has been relaxed, to allow certain information on all devices to be publicly available and to allow, by comitology, a method of making other information non-confidential, such as summary information on the approval of high risk devices.

Legal basis for better coordination and communication of market surveillance activities: the market for medical devices is a global market, with a significant number of devices being imported into the EU. This has led to an increasing need to coordinate activities of national authorities when applied to issues related to the directive taking place across a number of Member States and/or third countries. Thus it is necessary to introduce a new provision on cooperation to provide a legal basis for this coordination and international activities.

Clarification regarding medicinal products/medical device provisions: devices that incorporate as an integral part a medicinal product or blood plasma derivative are required to be reviewed by a notified body in consultation with a national authority for medicines or the European Medicines Agency (EMEA) as appropriate. These provisions, which are currently contained in Annex I Section 7.4 of the Directive needed modification to reflect the experience gained over the years in their implementation, clarifying both the role of the notified body and the relevant authority.

Devices with an ancillary human tissue engineered product: provisions are made to include these devices in the scope. This mirrors the proposed Community legislation on Advanced Therapies and fills

a potential regulatory gap.

Custom-made devices: in order to better evidence the compliance of custom made device manufacturers there is now an explicit requirement for a post market vigilance system reporting to authorities, as already in place for other devices. In order to enhance patient information a requirement is introduced that the 'Statement' under Annex VIII should be also given to the patient and that it must contain the name of the manufacturer.

Amendment of other Directives: Directive 90/385/EEC on active implantable medical devices requires alignment of text on certain aspects across all three medical device directives. The Directive was the first in the series of directives on medical devices but it has not benefited to the same extent from the market experiences and developments as the Directive 93/42/EEC and the Directive 98/79/EC on in vitro diagnostic medical devices, which were adopted in later years.

To ensure consistency of interpretation and implementation of the medical device Directives and to update the Directive 90/385/EEC on active implantable medical devices in terms of health protection measures,

certain aspects, such as authorised representative, the European Databank, health protection measures, and the application of the Directive 2000/70/EC on medical devices incorporating stable derivates of human blood or human plasma have to be added to Directive 90/385/EC. The latter alignment, on human blood or plasma, results in a significant body of text being inserted into the Directive.

Finally, under this regulatory reform, Directive 98/8/EC concerning the placing of biocidal products on the market needs to be modified in order to clarify that, alongside the active implantable medical devices and medical devices, in vitro diagnostic medical devices, now subject of a specific Directive, will be excluded from the scope of the biocides Directive.