WRITTEN QUESTION P-1283/03
by Amalia Sartori (PPE-DE) to the Commission
(31 March 2003)

Subject: Checks on the design, manufacturing and importation of implantable class III medical devices
(prosthetic cardiac valves in particular)

In February 2002, the death was recorded in Italy of a patient fitted with an artificial cardiac valve which had malfunctioned. The valve was produced in Brazil by Tri-Technologies and marketed in Europe by the company ForMed in conformity with Community regulations. The product was quickly withdrawn from the market. Malfunctioning of this medical device was also said to have caused the deaths of other patients, who had undergone implant operations in Padua (Hospital No 34) and Turin (Hospital No 135) between 2000 and 2002, prior to the death in February 2002. The Italian press and television networks have given great prominence to these incidents, and have also been severely critical of the inadequacy of the guarantees afforded by the CE mark. The checks carried out by Padua hospital administration have shown that the Brazilian manufacturer followed the procedure for the EC declaration of conformity set out in Annex II (full quality assurance system) to Directive 93/42/EEC (1), with a view to the affixation of the CE mark provided for in Article 11 of that Directive, and had to this end applied to the notified body, which was the Munich office of the TÜV (Technical Inspection Authority) in Bavaria.

In view of the above, does the Commission not consider:

− that Article 11 of the Directive should be reviewed, at least for implantable class III devices, as almost ten years have elapsed since the first approval was granted, and that it should not be possible for a notified body to issue a certificate of conformity simply on the basis of design documents or for it to forego examination of the prototype or the objective evidence of the technical tests conducted thereon by the notified body itself or by laboratories accredited by it for that purpose?

− that the ‘full quality assurance system’ laid down in Annex II to the Directive is still a necessary requirement but is no longer sufficient?

− that Member States’ vigilance and verification of conformity arrangements are no longer adequate and that more stringent checks should be envisaged on their part, as should increased vigilance by the Commission in this regard?

− that the review of Directive 93/42/EEC as regards the points indicated above is also necessary with relation to the enlargement process?

Moreover, since manufacturers operating outside the EU often seem to choose to market their products in Europe before subsequently placing them on the US market, will the Commission approach the FDA to launch procedures for the mutual recognition of medical device certification criteria, at least for class II devices?


Answer given by Mr Liikanen on behalf of the Commission
(24 April 2003)

Without taking position on the case reported, on which the Commission has no information, the Commission draws attention to the fact that the medical devices Directives are subject to a revision process. In that context, the Commission’s medical devices experts group published a report on the functioning of these directives (1). This report concludes that the legal framework created by the medical devices Directives is in itself appropriate, but that its implementation on a number of aspects must be improved. The Commission is currently drawing the policy conclusions from this report.

Experience with the Annex II (examination of full quality assurance system with a specific design examination certificate for Class III medical devices) has shown that, when properly applied, it guarantees the highest level of assurance of quality, safety and performance for high-risk devices (such as cardiac heart valves).
Class III devices can certainly not be approved under the procedure of Annex II solely on the basis of an examination of the documentation of the quality system and the product's design.

There are no indications that Annex II examination, as applicable to class III products, needs regulatory change. However, as regards other classes of medical devices, for which in contrast to Class III devices a specific design examination certificate is not necessary, the Commission intends to reinforce the provisions of Annex II.

The aforementioned report clearly establishes that implementation of the Directive regarding conformity assessment and market surveillance can and needs to be improved. Therefore, national authorities and the Commission have already created special task forces such as the Notified Bodies Operations Group, the Market Surveillance Operations Group, and the Clinical Evaluation Task Force, to bring about the necessary improvements by a number of measures.

Measures like these are also important in the light of enlargement. In this context, some candidate countries are developing specific projects to improve networking with Member States. Furthermore, bilateral programmes on training and advice exist between various Member States and candidate countries. The Commission and national authorities are considering the organisation of two workshops with candidate countries on market surveillance and best practice in implementing the directives.

The Commission has no information that manufacturers outside the European Union choose systematically to market their product first in Europe. These are commercial decisions. The medical devices sector is a global market, where normally the same product finds access to different markets, even if different market access procedures are applied. Depending on the products and the authorisation antecedents, market access in the United States of America can be shorter or longer than in the Union. Discussions are in progress between the United States of America, Canada, the European Union, Japan and Australia in the framework of the Global Harmonisation Task Force (GHTF) concerning regulations and administrative convergence. In the framework of GHTF also a global vigilance system is being set up.

The Commission will draw the attention of national authorities to the case reported in the question and will ask to be informed of the results of their enquiries in view of assessing any possible relevant aspects related to the functioning of the Directive.