Verband der TÜV e.V.

TÜV®

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Position paper

Safe medical devices for Europe

As early as 2008, the European Commission opened a public consultation as to how legal regulations regarding medical devices can be further modernised and simplified, in order to safeguard public health as effectively as possible throughout the EU. Most of participants in the consultation procedure came out in favour of constructive changes within the existing regulatory system. In 2012 the European Commission is planning to present corresponding legislative proposals.

Current events mean that modernisation of the medical device directives is now at the centre of political discussion. Over several years, the French company Poly Implant Prothèse (PIP) placed silicone breast implants onto the market which did not comply with legal requirements. The surveillance authorities and also the notified body were subject to deliberate fraud on the part of PIP. Against this background it is necessary to consider what additional legal instruments should be added to the present system in order to prevent such occurrences in future in a targeted way.

For more than 25 years, the “New Approach” has been in existence as a recognised set of standards for the marketing of products within the European internal market. Products falling within the scope of the New Approach directives may basically only be put into circulation if they bear the CE marking. The party responsible for putting the products into circulation is the manufacturer. By applying the CE marking to his products, he declares that they are in compliance with the relevant provisions of the directive, and in particular with its basic requirements.

Depending on the risk potential of the products, either the manufacturer alone is responsible for the conformity assessment procedure, or a notified body must be involved. A notified body is an independent inspection and certification body which reviews the conformity assessment performed by the manufacturer and testifies to its correctness based on unified evaluation criteria. The independence and competence of the notified body is generally guaranteed by means of national accreditation in the individual EU Member State; designation and surveillance of notified bodies is performed by the relevant state authorities.

The market surveillance authorities of the Member States should ensure that products which bear the CE marking fraudulently or without justification are identified and withdrawn from the market.

The requirements for medical devices are regulated in accordance with the above system approach in Directive 93/42/EEC. The individual devices are categorised into Classes I, IIa, IIb or III, depending on their intended use and their hazard potential for the patient. Products with

the highest level of potential hazard for the patient – which include among others heart valves and breast implants - are categorised as Class III. Before being put into circulation, the conformity of the products has to be expressly confirmed by the notified body.

The manufacturer can choose between two different procedures for the conformity assessment of Class III medical devices. On the one hand he can select the procedure of EC type examination according to Annex III of Directive 93/42/EEC. In this procedure, the notified body reviews the product documentation and performs examinations and tests on a representative sample, or "type" or has these performed by a suitable third party. This procedure is augmented by inspection and regular surveillance of the manufacturer's production quality assurance system by the notified body.
On the other hand, as in the case of PIP, the manufacturer can decide in favour of the EC Declaration of Conformity according to Annex II of Directive 93/42/EEC. If this procedure is selected, the manufacturer must ensure that the approved quality assurance system is applied for product design, manufacture and final inspection. He is subject to examination of the product design, formal inspection (audit) of the quality assurance system and regular surveillance of the approved quality assurance system by the notified body. The notified body examines the product design and the quality assurance system based on the documents presented to it by the manufacturer. The product itself is not examined by the notified body.

The role and the specified scope of involvement and activity of the notified body within the entire conformity assessment process is therefore directly dependent on the applicable legal regulations and the control instruments specified by these. The manufacturer can select the notified body that he wishes to use. In addition, within the modular system of possible conformity assessment methods, he can select a certain route in order to bring the medical device onto the market.

Sector-based product regulation within the New Approach is based on a high level of confidence and trust in the integrity and honesty of manufacturers and participants in the market. This approach promotes entry of highly-innovative products onto the internal market within an environment that allows free competition.
The New Approach System is based on the assumption that all manufacturers fulfil their obligations, as they also accept liability for their products.

The PIP case has shown that firstly, the current control mechanisms and the provisions of the New Approach are not suitable in order to identify dishonest and criminal practices early enough.
Secondly, the manufacturer must accept legal liability with respect to the medical devices he produces. However, it is clear that affected consumers have no practical redress against an insolvent manufacturer who has acted with deliberate fraudulent intent.
Thirdly, in no EU Member States are the market surveillance authorities in a position to perform their control function to a full and complete extent, due to lack of resources.
Even if the overarching system of the New Approach with its corresponding EC directives and the conformity assessment procedure embedded in them has basically proven its worth, the weaknesses described above, which are also a direct result of the system, must be counteracted in a targeted way. In order to further develop health and consumer protection in Europe, the role of the notified bodies within the overall system as independent control and surveillance agencies must be strengthened, and their competences should be extended accordingly. Any necessary regulative changes should concentrate on targeted improvements in the con-

formity assessment procedures to be used. Processes and procedures must lead to effective inspection and control of the products themselves.

The Association of TÜVs, VdTÜV e.V., proposes the following improvements to the system with regard to Class III products:

1. Binding introduction of the EC type examination (in accordance with Annex III of Directive 93/42/EEC) as an obligatory procedure within conformity assessment.

2. Introduction and establishment in law of obligatory, unannounced factory inspections by notified bodies and specified sampling of products within the manufacturing process (at the assembly line).

3. Introduction and establishment in law of obligatory sampling and testing of products already on the market following clear and universally-applicable rules (Following ISO/IEC Guide 67 - Conformity assessment; Fundamentals of product certification, Table 1, System 5 from the year 2004) as an extension of the conformity assessment procedure.

4. Notified bodies should be included in the information flow of the market surveillance authorities in the case of medical devices.