Verband der TÜV e.V.

Date
12. December 2012

VdTÜV Position on the proposal for a regulation on medical devices (COM 2012/542)

VdTÜV welcomes the Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, published on 26 September 2012, aimed at revising medical device legislation. The Proposal will strengthen the current European regulatory framework for medical devices and will develop it further.

In particular, the proposed strengthening of the role of the notified bodies within the overall system as independent control and surveillance bodies, further development of product verification and more intensive market surveillance will substantially improve European health and consumer protection, and will increase the safety of medical devices on the European market.

In order to offer the best-possible guarantee for the safety of medical devices in Europe, the instruments and procedures for assessment, control and surveillance of such devices should be consistently utilised to their full extent. They should be transparent and clearly defined and should be uniformly applied. On this basis, VdTÜV would like to propose the following specific improvements:

1. Introduction of the EU type examination as an obligatory procedure for conformity assessment for medical devices within the highest risk class (Class III), which will take the approach of 'hands-on product' testing and inspection supported by the European commission even more strongly into account.

2. The notified bodies should all be obliged to perform a defined number of unannounced inspections. The scope and procedure for the unannounced inspections should not be laid down in an "implementing act", but - because of their extreme importance - should be specified in the Regulation itself.

3. As the notified bodies do not have any official authority to undertake direct interventions, and therefore the collection of samples from the market by notified bodies alone is often not possible in practice, the samples should in these cases be collected through the competent authorities. The notified bodies should all be obliged to obtain a specified number of samples from the market.

4. Integration of the notified bodies into the exchange of information of the market surveillance authorities must be clearly defined and extended. In particular, the notified bodies need to receive information prepared within the framework of automated, consistent information flows in order to be able to recognise developments, to allow new information to flow directly into their work and to be able to react as rapidly as possible to reports of incidents and events.

5. The requirements placed on the notified bodies must be regulated and applied in a uniform manner throughout Europe, in order on the one hand to achieve the same high levels of safety and quality in all the Member States, and on the other in order to ensure a level playing field. Because of their vital significance for the entire system, the establishment of the mandatory requirements for the notified bodies should be undertaken by the European Parliament alone, not by national legislators or authorities acting in isolation. In addition, in order to avoid divergences in implementation, the requirements should neither offer scope for interpretation nor should they - even in terms of their detail - fall short of current legislation.

6. The notified bodies should be permanently represented on a new Medical Device Coordination Group described in the Proposal, in order that their practical experiences can be properly taken into consideration.

7. In the Proposal, reference is made to the Code of Conduct as a document that has to be accepted and implemented by all notified bodies. The Code of Conduct[1] which is already in use by some notified bodies and which is obviously meant here, is a document that was drafted in the form of a voluntary commitment which is based on the legislation as it is today and which in addition is subject to continual upgrading and change by the notified bodies. Therefore, in order to ensure legal compliance, reference should not be made to such a document in the Regulation. Instead, some individual items of content from the Code of Conduct could, if appropriate, be directly included in the Regulation text.

[1] The current version of the Code of Conduct can be found at: http://www.team-nb.org/documents/2012/Code_of_Conduct_Medical_Notified-Bodies_v3-0.pdf

8. Lack of clarity as regards the language used and extensive scope for the interpretation of the text of the Regulation should be eliminated as far as possible in order to achieve uniform Europe-wide application of the legislation. The terms and definitions in the Proposal must be coherent and used in a consistent fashion. In particular, further potentials for optimisation should be utilised in the design of the conformity assessment procedure by making the requirements as specific and concrete as possible; in addition, international standards should be taken into consideration.

9. The Proposal requires rotation of the notified body's personnel involved in the assessment of medical devices. Nevertheless this objective should be implemented in such a way that the members of any audit team will always have the necessary expertise and experience with the product to be assessed. This aspect grows in importance with greater complexity of products and structures within a manufacturing organisation.
   The competence of the notified bodies lies in technical testing and assessment and not in business and product viability analysis. This fact should be taken into consideration in the design of the audits.

10. In the Proposal, the market surveillance authorities are placed under the obligation to evaluate medical devices post-market by means of checks on the basis of adequate samples. In order to ensure a consistent level of control by these authorities in all the Member States it would seem useful to reduce as far as possible the scope for interpretation with regard to the number of market surveillance actions or samples taken by them.

The adjustments outlined above are likely to make a significant contribution to an increase in the safety of medical devices for consumers in Europe.

VdTÜV will make its expertise available in a constructive way in future legislative procedures in order to achieve an overall regulatory framework which looks towards the future - and which guarantees rapid market access for innovative medical devices to the benefit of patients, whilst at the same time offering the highest possible levels of safety by means of intensified control activities.

Berlin, 12. December 2012