

Proposal for a Regulation on Medical Devices
Current negotiations in the Council of the European Union
Position of statutory health and long-term care insurance

On 26 September 2012, the European Commission submitted a Proposal for a Regulation of the European Parliament and of the Council on Medical Devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. This proposal is currently being negotiated in the Council of the EU. The basis for discussion is formed by a consolidated text of the Proposal for a Regulation drafted by the Italian Presidency which takes account of a large number of prior amendment proposals from the Member States. The statutory health insurance welcomes the fact that the Council is seeking constructive solutions in order to improve patient protection through stricter product monitoring. There is however considerable room for improvement in many instances.

The Commission and the European Parliament have opted not to establish central, independent official approval for high-risk medical devices and instead to retain the existing system (new approach). In view of the consolidated text, it is obvious that the Council also concurs with this decision. In order to however guarantee better patient safety within the existing system, there is a need to

1. create a minimum of independence on the part of the notified bodies involved and to safeguard their expertise.
2. make the certification decisions of the notified bodies more transparent and place their essential message in the public domain.
3. detail and tighten up the rules applying to the clinical assessment and clinical testing of high-risk medical devices in order to place patient care on a more secure basis in terms of data.
4. establish clear, transparent rules for the testing and certification of the intended purpose, in particular of high-risk medical devices.
5. tighten up the rules for effective market surveillance and effective product tracing, and
6. adopt rules for product liability insurance.

The statutory health insurance considers these items to be elementary in order to achieve sustainable improvements in patient safety. The statutory health insurance is hence appealing to the Council of the EU to take these aspects into account when revising the Proposal for a Regulation.



1. A minimum of independence and expertise on the part of the notified bodies

It must be ensured that a small number of selected, highly-competent notified bodies are responsible for high-risk medical devices and that they do not directly compete with one another for manufacturers. The notified bodies must understand themselves less as service-providers for the manufacturers, but more as independent testers with regulatory competences to ensure patient protection.

This can be achieved by establishing special notified bodies which are exclusively responsible for certifying high-risk medical devices, and which hence provide factual and topical expertise. Clear rules must ensure that manufacturers of high-risk medical devices only have a restricted choice among the competent notified bodies and that they cannot change once the conformity assessment procedure has commenced.

The European Parliament has come out in favour of introducing special notified bodies in order to combine competences, and hence to improve the quality of the conformity assessments Europe-wide. **It is vital that the Council includes this rule in its position.**

2. Greater transparency of the conformity assessments through notified bodies

Conformity assessments on high-risk medical devices must be subjected to a scrutiny mechanism. The Commission's draft itself provides for conformity assessments of high-risk medical devices to be tested by an independent expert commission (Medical Device Coordination Group, MDCG) in certain cases as to whether they were carried out properly. The European Parliament did not consider these considerations to go far enough. It proposed the introduction of a committee of experts with much more far-reaching competences (Assessment Committee for Medical Devices, ACMD).

The statutory health insurance is appealing to the Council of the EU to adopt and further detail these considerations. A committee of experts must particularly be able to examine with regard to novel high-risk medical devices

- whether the requirements made of the notified body as to clinical evaluation are appropriate,
- whether the purpose of the results of the clinical assessment sought by the manufacturer and certified by the notified body is covered,

- whether the benefit-risk determination has been reasoned in a comprehensible manner and any existing vigilance reports have been properly taken into consideration, and
- whether a suitable market surveillance plan is available.

The assessment carried out by the committee of experts must be binding on the notified body in such a way that good reasons are needed if it does not comply with the recommendations of this committee.

The decisions taken by notified bodies on conformity assessment procedures with high-risk medical devices must furthermore be published. The publicly-accessible documents must contain a summary of the clinical assessment, the purpose encompassed by the certificate, as well as, where appropriate, information on study conditions, indication restrictions and the planned market surveillance measures. Where a statement has been made by the committee of experts, it is also to be summarised. The same applies to the reasoning of the notified body if it diverges from the recommendations made in this statement.

3. Detailing and tightening up the rules for clinical assessment and clinical examination

It is absolutely indispensable for the requirements as to the clinical assessment and the clinical testing of high-risk medical devices to be tightened up. The central requirements are as follows:

- clinical tests must be obligatory for high-risk products. The reference to supposed "uniformity" is only adequate if the comparison product is a technical improvement by the same manufacturer and the essential properties as to the material and structure are actually identical.
- Clinical tests must follow clear standards. They must prove the effectiveness of the product using clinically-relevant end points, wherever possible in a randomised comparison to the medical standard.
- The implementation of clinical trials, as well as their results, must be reported to a publicly-accessible European study database.

The stipulations made in the European Commission's draft are insufficient in this regard. The European Parliament by contrast called for relevant regulations in its legislative resolution.

The statutory health insurance is appealing to the Council of the EU to also include these demands in its position.

4. Clear rules for testing and certifying the intended purpose of medical devices

To date, manufacturers have had considerable freedoms when it came to the formulation of the intended purpose of their medical devices. It is currently only to be stated on the product label and in the instructions for use. The intended purpose is not shown on the certificate of the notified body. When determining the intended purpose of many high-risk medical devices, the intended purpose stated in the instructions for use goes far beyond what has been examined in clinical studies.

Frequently there is no specific information on underlying diseases requiring treatment, or the medical device may also be used in fields which no clinical data available. Clear rules for the determination of the intended purpose of a high-risk medical device are in the interest of manufacturers, users and patients:

- The intended purpose to which a medical device is to be put must correspond to the area of application in which it was clinically tested. In concrete terms, it must relate to the underlying disease dealt with in the studies (permissible indications), as well as to the specific deployment area (e.g. organ or localisation).
- The intended purposes, including any indication restrictions that may have been ordered, must be stated by notified bodies on the test certificate.

This problem is solved neither by the Proposal for a Regulation of the European Commission nor by the position of the European Parliament. **The statutory health insurance is hence very urgently appealing to the Council of the EU to solve the problem that has been described.**

5. Tightening up the rules for improved market surveillance and product traceability

These proposals aim to improve market surveillance. Stricter requirements for the accrediting and certification of notified bodies and clearer stipulations for the exchange of information between the Member States are welcomed by the statutory health insurance, but do not go far enough. **The statutory health insurance is hence appealing to the Council of the EU to implement the following items:**

- Notified bodies must meet requirements that are uniform Europe-wide in order to achieve a universal level of adequate quality in the conformity assessment procedure. To this end, instruments must be established defining quality criteria at European level and monitoring their compliance. The Medical Device Coordination Group (MDCG) planned by the Commission would be a suitable body for this task, were it to be equipped with sufficient competences. Such a harmonised procedure is absolutely necessary, particularly for the special notified bodies called for above.
- The Post Marketing Clinical Follow-up Plan, PMCF, detailed by the Commission in the Proposal for a Regulation for medical devices, is favoured by the Council, but as a matter of principle must take on greater importance within the conformity assessment procedure. If necessary, the notified body must set out stipulations for the continuation of ongoing clinical studies or order further studies to be carried out where appropriate.
- The introduction of a Unique Device Identification system, UDI, proposed by the Commission was taken up by the Council and should be consistently implemented. It is necessary to ensure that implants can be rapidly traced to the patients concerned in order to be able to take immediate action where risks come to light. Additional product-specific implant registers may become necessary in certain areas, and no provision has yet been made for these.

6. Include regulations on product liability insurance

The European Court of Justice made a major contribution towards improving patient rights with its recent ruling (Cases C-503/13 and C-504/13) on the product liability of manufacturers in the case of defective pacemakers and defibrillators. It is important for patients to be able to enforce their legitimate claim, for instance against an insolvent manufacturer. **The statutory health insurance is hence demanding a binding stipulation** that manufacturers of medical devices are obliged to take out suitable product liability insurance