

The position of statutory health insurance on the “Medical Devices Regulation” trilogue

The European Commission, the European Parliament and the Council are presently engaged in trilogue negotiations in order to adopt a new Europe-wide Medical Devices Regulation. This enactment will set the course as to whether or not market access of medical devices will be regulated in a sustainable manner in the future, and whether it is guaranteed that only high-risk medical devices with known efficacy and safety profile will come onto the European market.

The statutory health insurance funds assert that many medical device innovations have been, and will be, beneficial to medical progress. Again and again, however, some innovations reveal themselves as hazardous or harmful after being launched onto the market. The reason for this is that products too frequently reach the market which are not fully developed or have not been sufficiently tested.

Particularly in hospitals, medical treatment is becoming increasingly complex due to technical progress. As a consequence medical device innovations may appear to be highly promising at first sight, particularly if they were only studied for a short period on a small number of patients, and hence physicians and patients may over estimate their real effect, whilst frequently under estimating the risks involved in using them. If patients are prematurely treated with such innovations on a grand scale, and if it subsequently emerges that they may cause damage, this realisation will come too late for those who have already undergone treatment. This cannot be in the interest of patients, of the attending physicians, of industry, of policy-makers or of health insurance!

We therefore need a robust, reliable market access system which gives due consideration to the technical challenges whilst guaranteeing reliable, transparent approval processes and market surveillance of medical devices of high risk classes.

Statutory health insurance considers that this can only be achieved by implementing a variety of measures for which implementation proposals are already available from the negotiating parties. These are illustrated below.

Ensuring the expertise and independence of the notified bodies

The conformity assessments on high-risk medical devices by notified bodies constitute a



sovereign task. The quality of these assessments must be comparable all across Europe since each manufacturer can freely choose its notified body. We must not permit individual notified bodies to reduce their standards out of misunderstood competitive thinking, in order to retain manufacturers as customers or to acquire new customers. The following measures need to be carried out:

1. A competent notified body must have sufficient medical and technical expertise in order to be able to assess the conformity of high-risk-class medical device innovations. The European Parliament (EP) has made the most far-reaching proposals in order to cope with these requirements: Notified bodies that are responsible for high-risk medical devices will need to have their own in-house specialist expertise (proposal of the EP Art. 43a and Annex VI, 3.1.1).
2. An independent group of experts from the European Commission should perform external assessments (the “scrutiny procedure”) to ensure the quality of the conformity assessments (EP proposal Art. 78b and Annex VIII). Some of the Council’s demands are along similar lines (Council’s proposal Art. 81a in conjunction with amendments in Annex VIII). Statutory health insurance calls on all responsible parties to ensure the quality of the conformity assessments of high-risk medical devices by implementing these proposals.
3. In contrast to the proposals of Parliament or of the Council, the statutory health insurance believes that the “scrutiny procedure” should also be expanded to cover risk class IIb implants, as well as all products in risk class III, since there have also been cases where such products have severely endangered patient safety.
4. Importantly, the designation and monitoring of special notified bodies should not take place at national, but at European level in order to guarantee consistent quality. These special notified bodies are to be assessed every year, and the results of the assessment should be published (EP proposal Art. 35 paragraph 4).

Improving the quality of clinical trials

The quality of clinical evaluations of medical devices needs to improve. It is important that high-risk medical devices in particular are tested in clinical investigations, to prove their effectiveness with regard to patient-relevant outcomes. Only if these data are available, can physicians and patients decide whether or not a certain product should be used. The following measures need to be realised:

1. Wherever possible, randomised, controlled investigations are to be carried out comparing the device in question with the standard of treatment. A corresponding amendment can be found in the Parliament’s proposal (EP Annex XIV Part II point 1).

2. The clinical investigation should not aim to analyse the “performance” of the product, but its clinical effectiveness or clinical benefit. The Council has included a definition of clinical benefit in its draft (Council’s proposal Art. 2 paragraph 1 point 37d); this definition should be adopted and linked to the requirements for the clinical evaluation.
3. The strict requirement for clinical studies for high-risk medical devices should only be suspended in well-justified and very exceptional cases. The Council has made a proposal to this effect: A clinical investigation may be expendable “if the device has been designed by modifications of a device already marketed by the same manufacturer”. In addition, manufacturers “may seek to justify use of data from a demonstrated equivalent device from another manufacturer only if they have a clear contract in place with that manufacturer allowing full access to the technical documentation on an ongoing basis. The manufacturer must be able to provide clear evidence of this to the notified body”. Otherwise, a clinical investigation must be carried out for the product (Council’s proposal Art. 49 paragraph 2a). This proposal of the Council should be implemented.
4. All clinical trials of medical devices of any risk class must be listed in a public clinical trials register as soon as they start. The entry should be updated on a regular basis. The main results of the study must be published as soon as possible after its completion or discontinuation. However, there are no proposals so far in this respect.

Intended purpose

Currently manufacturers have considerable freedom when it comes to specifying the intended purpose of their medical device. The intended purpose only needs to be stated in a binding fashion in the instructions for use. So far there is no obligation to identify the intended purpose on the certificate of the notified body. In reality the intended purpose declared in the instructions for use often goes far beyond what has been tested in clinical trials. Often there is a lack of detailed information on the underlying disease to be treated, or the medical device may also be “intended” for areas for which no clinical data are available. Clear regulations for the specification of the intended purpose of a high-risk medical device are in the interest of manufacturers, physicians and patients. The following measures need to be taken:

1. The intended purpose must relate in detail to the existing clinical data. Both the Council and Parliament have made provisions for this in their amendment proposals (EP proposal Article 2 paragraph 1 point 10, Council proposal Article 2 paragraph 1 Nos. 15e and 37c).
2. The intended purpose must also be stated on the certificate of the notified body, as well as on the product label. Parliament has adopted a corresponding proposal (Parliament’s proposal Article 2 paragraph 1 point 10).

3. It must be possible for the notified body to restrict the intended purpose if necessary; for any extension of the intended purpose a separate conformity assessment must be performed. The Council has formulated proposals to this effect (Council proposal Article 45 paragraph 2a).

Transparency

It is necessary for physicians and patients to have access to data on the safety, effectiveness and performance of high-risk medical devices; these data must be publicly available and regularly updated. The obligations with regard to data transparency adopted by Parliament should therefore be implemented (EP proposal, in particular recitals 37 and 39; Article 27 paragraph 1 (c) and paragraphs 4 and 7a). Additionally, the details provided by the Council on the content of the “summary of safety and clinical performance on a class III product or an implant” should be implemented, which also requires annual updates with regard to findings from the “Post-Market Clinical Follow up” (Council proposal recital 39a, Article 26 paragraph 1a, Article 49 paragraph 4, on annual updates also Parliament proposal Article 49 paragraph 5 point 1a).

Product liability insurance for manufacturers

The European Court of Justice found in its recent ruling (Cases C-503/13 and C-504/13) on the product liability of producers of defective pacemakers and cardioverter defibrillators that the patient does not need to prove an individual product defect, for instance if a pacemaker is of a potentially defective production series. The verdict has hence helped improve patient rights. However, there is still no obligation under Product Liability Directive 85/374/EEC to establish financial reserves for cases of damage. This continues to shift the risk of damage, as well as that of manufacturer insolvency, to the aggrieved patients and to the statutory health insurance funds having to meet the costs of treatment.

It is important for patients to assert their legitimate right to damages or to compensation for pain and suffering, for instance against an insolvent manufacturer. Therefore, manufacturers must be obliged to take out product liability insurance. Parliament has adopted a corresponding proposal (EP proposal recital 25a and Article 8 paragraph 10a).

The statutory health insurance appeals to the stakeholders to establish clearer rules and increase patient safety by implementing these proposals.