



Proposal for a Regulation on Medical Devices

Current negotiations in the Council of the European Union

Position of the

European Social Insurance Platform (ESIP)

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About the *European Social Insurance Platform* (ESIP)

The *European Social Insurance Platform* (ESIP) represents over 40 national statutory social insurance organisations (covering approximately 250 million citizens) in 15 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: *ESIP members support this position in so far as the subject matter lies within their field of competence.*

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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 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. ESIP 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.

ESIP has been supporting the establishment of a centralised approval procedure at European level for high-risk medical devices, in which safety, efficacy as well as a positive risk-benefit balance must be proven by the results of high quality clinical investigations.

However, the Commission and the European Parliament have opted not to establish such a central, independent approval system for high-risk medical devices and instead to retain the existing system (“new approach”). In view of the consolidated text, it seems that the Council also concurs with this decision. Therefore, as long as a marketing authorisation system has not been put in place and in order to make the assessment system as safe as possible for patients, there is a need to:

1. Ensure 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 the main elements of those decisions accessible to the public,
3. detail and tighten up the rules applying to the clinical assessment and clinical investigation of high-risk medical devices and to make the clinical data publicly available, without prejudicing the protection of personal 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 traceability,
6. make product liability insurance for manufacturers obligatory.

ESIP considers the above conditions as the absolute minimum in order to achieve sustainable improvements in patient safety. ESIP is therefore appealing to the Council of the EU to take these aspects into account when revising the Proposal for a Regulation.

The key issues in detail:

1. A minimum of independence and expertise of notified bodies

The proposal of the European Commission as regards the independence of notified bodies and the avoidance of conflicts of interests is welcomed. Indeed, it must be ensured that only a limited number of highly-competent notified bodies are designated responsible for high-risk medical devices and that these bodies do not compete with one another (for manufacturers). Notified bodies should rather uphold the role of independent assessors with regulatory competences to ensure patient protection than service-providers for the manufacturers, as has been the case so far.

This can be achieved by establishing special notified bodies which would be exclusively responsible for the certification of high-risk medical devices, and which hence provide factual and specific expertise. In addition, clear rules should be defined to ensure that manufacturers of high-risk medical devices have only a restricted choice of specialised competent notified bodies and that once the conformity assessment procedure has commenced they cannot change their choice of body.

We welcome the position of the European Parliament which proposed the introduction of special notified bodies in order to combine competences, and hence to improve the quality of the conformity assessments Europe-wide. We therefore **recommend to the Council to adopt the Parliament position in this regard.**

2. Greater transparency of the conformity assessments carried out by notified bodies

Conformity assessments of high-risk medical devices should be subject to a scrutiny mechanism. The Commission's initial proposal provides for the conformity assessments of high-risk medical devices to be evaluated by an independent expert commission (Medical Device Coordination Group, MDCG) in certain cases. The European Parliament strengthened this proposal through the introduction of a committee of experts with more far-reaching competences (Assessment Committee for Medical Devices, ACMD).

The statutory health insurers call on the Council of the EU to adopt and elaborate these provisions. In particular with regard to novel high-risk medical devices, a committee of experts should be able to examine:

- whether the requirements set by the notified body regarding the clinical evaluation are appropriate,
- whether the results of the clinical assessment demonstrate the intended purpose sought by the manufacturer and certified by the notified body,

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

The recommendations of the committee of experts should be implemented by the notified body; **any divergent decision by the body should be justified.**

The decisions taken by notified bodies on the conformity assessment of high-risk medical devices should be made publicly available. The published documents must contain a summary of the clinical assessment, the purpose encompassed by the certificate, as well as, where applicable, post approval studies mandated by the notified body, any indication restrictions and the planned market surveillance measures. Where a statement has been made by the committee of experts, a summary of this statement should also be disclosed. 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 on clinical assessment and clinical investigation

It is essential that the requirements for the clinical assessment and the clinical investigation of high-risk medical devices are strengthened. The central requirements in the Regulation should be the following:

- Clinical investigations should be obligatory for high-risk products. The reference to supposed "equivalent devices" is only adequate if the new product represents a simple technical improvement of the original product by the same manufacturer and the essential properties as to the material and structure of the two products are identical.
- Clinical investigations must follow clear standards, where the clinical efficacy of the device and the positive risk/benefit ratio must, wherever possible, be demonstrated in randomised comparison to the medical standard, on the basis of clinically-relevant endpoints and according to the intended purpose.
- Clinical investigations and their results must be published in a publicly-accessible European database.

The proposals made in the European Commission's draft are insufficient in this regard. The European Parliament by contrast proposed relevant amendments in its legislative resolution. **ESIP calls on the Council of the EU to provide for strict requirements for clinical investigations of high risk medical devices as outlined above.**

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

Within the current framework, manufacturers have considerable freedom in formulating the intended purpose of their medical devices. Indeed, the intended purpose shall only be

specified on the product label and in the instructions for use and does not appear on the certificate of the notified body. Yet, very often when determining the intended purpose of 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 is also intended to be used in fields where no clinical data is 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 of a medical device should 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 mentioned by notified bodies on the test certificate.

Yet, this problem is not solved by the European Commission proposal for a Regulation or by the position of the European Parliament. **Therefore, ESIP urgently calls on the Council of the EU to restrict the use of medical devices to the intended purpose for which a clinical investigation has been performed.**

5. Strengthening the rules for improved market surveillance and product traceability

The Commission proposal aims to improve market surveillance. In this context, the statutory health insurers welcome the stricter requirements for the accreditation and certification of notified bodies and the clearer provisions for the exchange of information between the Member States contained in the proposal. However, those provisions do not go far enough.

ESIP calls on the Council of the EU to adopt the following provisions:

- **Notified bodies must meet a set of harmonised requirements** in order to achieve a universally high level of 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) foreseen by the Commission would be a suitable body for this task, provided that it has 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), proposed by the Commission, is supported by the Council, but it should be given greater importance within the conformity assessment procedure.** If necessary, the notified body should set out provisions 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 implemented consistently. **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 incidents arise. Additional product-specific implant registers may become necessary in certain areas. However no provision has yet been made in this area.

6. Include regulations on product liability insurance

The European Court of Justice made a major contribution towards improving patient rights in 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 insolvent manufacturers. Hence, **the statutory health insurers call for the obligation of manufacturers to subscribe to suitable liability insurance with sufficient coverage, as a prerequisite to market access. The insurance should include the right for direct action by the injured party and/or the third party payers against the manufacturer's insurance undertaking.**
