Amendment 363
Holger Krahmer
on behalf of the ALDE Group

Report
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission

(42a) For high-risk medical devices, such as devices in class III, implantable devices and devices intended to administer medicinal products when failure or malfunctioning of these devices would have a major impact on health and safety, the conformity assessment should be the responsibility of special notified bodies. Those special notified bodies should be designated by the EMA on the basis of the reinforced requirements on staff qualification and training as referred to in Section 3.5a of Annex VI. These special notified bodies should meet in a Network in order in particular to exchange good practice and ensure convergence in their work. The Assessment Committee for Medical Devices (ACMD) shall provide an opinion on the robustness of the clinical data by way on an assessment in specific cases. The need for such additional assessment should decrease once the new rules have been fully implemented and applied in particular to all notified bodies and as common technical standards are developed. The Commission should therefore review the functioning of and the experience with the additional assessment procedure after five years with a view to assessing whether it can be
further restricted.
16.10.2013 A7-0324/364

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Report A7-0324/2013
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Recital 42 b (new)

Text proposed by the Commission Amendment

(42b) The ACMD should be composed of clinical experts in the medical fields relevant to the medical device being assessed, one representative of the EMA and one representative of patients' organisations. The ACMD should meet on request from the MDCG or the Commission and its meetings should be chaired by a Commission representative. The Commission should provide logistic support to the secretariat and operations of the ACMD.

Or. en
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Report
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Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Article 78 b (new)

Text proposed by the Commission

Amendment

Article 78b
Assessment Committee for Medical Devices

1. An ACMD is hereby established, under the principles of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest.

2. When undertaking a clinical assessment for a specific device, the ACMD shall be composed of:

- a minimum of 5 clinical experts in the field of which a clinical assessment and recommendation have been requested;

- one representative of the EMA;

- one representative of the Commission;

- one representative of patients' organisations appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed.

The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative.

The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its
clinical assessment and recommendation

The Commission shall ensure the secretariat of this Committee.

3. For the purpose of assembling the necessary clinical expertise, the Commission shall establish a pool of clinical experts in the medical fields relevant to medical devices being assessed by the ACMD. In order to undertake the clinical assessment and recommendation procedure, each Member State may propose one expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year term which may be renewed. The Commission shall assemble clinical experts notably in the following fields:

- Anaesthesiology;
- Blood grouping or tissue typing;
- Blood transfusion and transplantation;
- Cardiology;
- Communicable diseases;
- Dentistry;
- Dermatology;
- Ear / Nose / Throat (ENT);
- Endocrinology;
- Gastroenterology;
- General/Plastic surgery;
- Medical genetics;
- Nephrology / Urology;
- Neurology;
- Obstetrics/Gynaecology;
- Oncology;
- Ophthalmology;
- Orthopaedics;
- Physical medicine;
- Pulmonology / Pneumology;
- Radiology.

The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available.

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing the fields referred to in point a of this paragraph.

4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall decide by the majority of their members. Diverging opinion shall be annexed to the ACMD opinion.

5. The ACMD shall establish its rules of procedure which shall, in particular, lay down procedures for the following:
- the adoption of opinions, including in case of urgency;
- the delegation of tasks to reporting and co-reporting members.

Or. en
The MDCG shall have the following tasks:

(-a) to provide regulatory opinions on the basis of a clinical assessment delivered in accordance with Art 44a) (assessment procedure in specific cases);

(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation;

(ab) to review and approve the criteria of the competent authorities of Member States in respect of point (aa) of this Article;

(ac) to oversee the coordination group of Notified Bodies as specified in Article 39;

(ad) to support the Commission in
(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 44;

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;

(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;

(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.

(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;

(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical investigations, vigilance and market surveillance;

(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;

(f) to contribute to harmonised administrative practice with regard to medical devices in the Member States.