Amendment 367
Mairead McGuinness, Peter Liese
on behalf of the PPE Group

Report
Dagmar Roth-Behrendt
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 (new)

Assessment Committee for Medical Devices

1. An Assessment Committee for Medical Devices (ACMD) is hereby established, under the principles of the highest scientific competences, impartiality, and transparency and to avoid potential conflicts of interest.

2. The ACMD shall be composed of:

- at least one member representing each of the medical fields referred to in paragraph 3. This member shall be a recognised expert in his/her field and be able to draw on additional expertise where necessary. These experts shall be appointed by way of a Commission call for interest, for a 3 year term that maybe renewed once;

- one representative of the EMA;

- one representative of the European Commission;

- three representatives of patients’ organizations appointed by the European Commission by way of a Commission call for interest.
The ACMD shall meet on request from the MDCG and the 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 the assessment procedure in specific cases. The Commission shall ensure the secretariat of this Committee.

3. The members of the ACMD shall be chosen for their competence and experience in the corresponding field.
   - 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 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, deleting 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 a clinical assessment, 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. In the case of the Coordination Group, the European Commission shall not take part in votes. 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 the clinical assessments including in case of urgency;
- the delegation of tasks to 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 Article 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
United in diversity

Article;

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

(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 27.

(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.

Or. en
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Proposal for a regulation
Article 44 b (new)

Text proposed by the Commission

Amendment

Article 44b (new)

Five years after the entry into force of this Regulation, the Commission shall publish a report on the experience acquired as a result of the operation of the procedure referred to in Article 44a. The report shall assess in particular how many products were subject to an additional assessment, what factors triggered the assessment and what was the final decision on the products. It shall also analyse the effects of the full impact of the new rules on special notified bodies vis-a-vis the additional assessments.

Or. en
Recital 42 a (new)

42a (new) 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.

Or. en
Involvement of the special notified bodies in the conformity assessment procedures of high-risk devices

1. Only special notified bodies shall be entitled to conduct conformity assessments for the following devices:

(a) implantable devices,

(b) devices incorporating a substance, as referred to in Article 1(4) and point 6.1. of Annex VII (Rule 13),

(c) Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3. of Annex VII (Rule 11),

(d) devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable, or

(e) all other class III devices.

2. Applicant special notified bodies which consider they fulfil the requirements for special notified bodies referred to in Annex VI, point 3.6, shall submit their
application to the EMA.

3. The application shall be accompanied by the fee payable to the EMA to cover the costs relating to the examination of the application.

4. The EMA shall designate the special notified body or bodies in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to the Commission.

5. The Commission shall then publish the notification accordingly and the name of the special notified body or bodies.

6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the special notified body.

This notification shall be valid for five years and subject to renewal every five years, following a new application to the EMA.

7. The manufacturer of devices listed in paragraph 1 may apply to a special notified body of his choice, whose name appears in the electronic system of Article 43b (new).

8. An application may not be lodged in parallel with more than one special notified body for the same conformity assessment activity.

9. The special notified body shall notify the Commission of applications for conformity assessments for devices listed in paragraph 1.

10. Article 43, paragraphs 2, 3 and 4 apply to special notified bodies.