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Amendment 374/REV

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Report

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Medical devices

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Proposal for a regulation

Article 44 a (new)

Text proposed by the Commission

Amendment

Article 44a

Assessment procedure in specific cases

1. Special notified bodies shall notify the Commission of applications for conformity assessments for implantable Class III devices, 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), and devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable with the exception of applications to renew or supplement existing certificates and devices for which specifications referred to in Articles 6 and 7 have been published for the clinical evaluation and the post-market clinical follow-up. The notification shall be accompanied by the draft instructions for use referred to in Section 19.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 26. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and

the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 78.

2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evaluation report as referred to in Annex XIII, including the clinical investigations report as referred to in Annex XIV,*
- the post market clinical follow-up plan referred to in Annex XIII, and*
- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries.*

The members of the MDCG shall decide on making such a request only on the basis of the following criteria:

- (a) the novelty of the device with possible major clinical or health impact;*
- (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure;*
- (c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices.*

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 these criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the special notified body may continue with the conformity assessment procedure.

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall immediately inform the Commission, the special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the special notified body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may

give written notice to the MDCG. that it wishes to request a re-examination of the opinion. In that case, the special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the ACMD and the Commission.

Within 30 days following receipt of the grounds for the request, the MCDG shall re-examine its opinion, after consultation of the ACMD where necessary. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MCDG shall send its final opinion to the Commission, the special notified body and the manufacturer.

8. In the case of a favourable opinion MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on the conditions that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device of group of devices concerned and adopt them where possible (in accordance with Article 7).

In the case of an unfavourable MDCG opinion, the special notified body shall not yet deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has

been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the special notified bodies and the ACMD, and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

13. The company concerned shall not be charged for the additional cost due to this assessment.

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