

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

CHAPTER III

**AUTHORISATION PROCEDURE FOR A SUBSTANTIAL
MODIFICATION OF A CLINICAL TRIAL**

Article 20

**Validation, assessment and decision regarding a substantial
modification of an aspect covered by Part II of the assessment report**

1 Within six days from the submission of the application dossier, the Member State concerned shall notify the sponsor through the EU portal of the following:

- a whether the substantial modification concerns an aspect covered by Part II of the assessment report; and
- b whether the application dossier is complete in accordance with Annex II.

2 Where the Member State concerned has not notified the sponsor within the period referred to in paragraph 1, the substantial modification applied for shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete.

3 Where the Member State concerned finds that the substantial modification does not concern an aspect covered by Part II of the assessment report or that the application dossier is not complete, it shall inform the sponsor thereof through the EU portal and shall set a maximum of 10 days for the sponsor to comment on the application or to complete the application dossier through the EU portal.

Within five days from receipt of the comments or the completed application dossier, the reporting Member State shall notify the sponsor as to whether or not the application complies with the requirements set out in points (a) and (b) of paragraph 1.

Where the Member State concerned has not notified the sponsor within the period referred to in the second subparagraph, the substantial modification shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete.

Where the sponsor has not provided comments nor completed the application dossier within the period referred to in the first subparagraph, the application shall be deemed to have lapsed in the Member State concerned.

4 For the purpose of this Article, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the respective periods referred to in paragraphs 1 and 3.

5 The Member State concerned shall assess the application and shall submit to the sponsor, through the EU portal, Part II of the assessment report, including its conclusion, and

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Article 20. (See end of Document for details)

the decision as to whether the substantial modification is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of a single decision within 38 days from the validation date.

An authorisation of a substantial modification subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.

6 During the period referred to in the second subparagraph of paragraph 5, the Member State concerned may request, with justified reasons, additional information from the sponsor regarding the substantial modification as far as its territory is concerned.

For the purpose of obtaining and reviewing this additional information from the sponsor, the Member State concerned may extend the period referred to in the second subparagraph of paragraph 5 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned which shall not exceed 12 days from receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 19 days.

Where the sponsor does not provide additional information within the period set by the Member State concerned in accordance with the third subparagraph, the application shall be deemed to have lapsed in that Member State.

The request for additional information and the additional information shall be submitted through the EU portal.

7 A Member State concerned shall refuse to authorise a substantial modification if it finds, on duly justified grounds, that the aspects covered by Part II of the assessment report are not complied with or where an ethics committee has issued a negative opinion which, in accordance with the law of that Member State concerned, is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

8 Where the Member State concerned has not notified the sponsor of its decision within the periods set out in paragraphs 5 and 6, the substantial modification shall be deemed to be authorised in that Member State.

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