

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 23

Decision on the substantial modification of aspects covered by Parts I and II of the assessment report

1 Each Member State concerned shall notify the sponsor through the EU portal 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 five days from the reporting date or from the last day of the assessment period referred to in Article 22, whichever is later.

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.

2 Where the conclusion of the reporting Member State is that the substantial modification of aspects covered by Part I of the assessment report is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State concerned.

Notwithstanding the first subparagraph, a Member State concerned may disagree with the conclusion of the reporting Member State only on the following grounds:

- a when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
- b infringement of its national law as referred to in Article 90;
- c considerations as regards subject safety and data reliability and robustness submitted under paragraph 4 or 6 of Article 18.

Where the Member State concerned disagrees with the conclusion regarding the substantial modification of aspects covered by Part I of the assessment report on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification through the EU portal to the Commission, to all Member States, and to the sponsor.

3 Where, regarding the substantial modification of aspects covered by Part I of the assessment report, the substantial modification is acceptable or acceptable subject to compliance with specific conditions, the Member State concerned shall include in its decision its conclusion on the substantial modification of aspects covered by Part II of the assessment report.

4 A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards the substantial

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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 23. (See end of Document for details)

modification of aspects covered by Part I of the assessment report on any of the grounds referred to in second subparagraph of paragraph 2, or 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 the Member State concerned, is valid for that entire Member State. That Member State concerned shall provide for an appeal procedure in respect of such refusal.

5 [X¹Where the conclusion of the reporting Member State as regards the substantial modification of aspects covered by Part I of the assessment report is that the substantial modification is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.]

6 Where the Member State concerned has not notified the sponsor of its decision within the periods referred to in paragraph 1, the conclusion on the substantial modification of aspects covered by Part I of the assessment report shall be deemed to be the decision of the Member State concerned on the application for authorisation of the substantial modification.

Editorial Information

- X1** Substituted by [Corrigendum to 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 \(Official Journal of the European Union L 158 of 27 May 2014\)](#).

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