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 U.K.

AUTHORISATION PROCEDURE FOR A SUBSTANTIAL MODIFICATION OF A CLINICAL TRIAL

Article 19 *U.K.*

Decision on the substantial modification of an aspect covered by Part I 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.

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 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 that 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 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.

A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds referred to in the second subparagraph, 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.

3 Where 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.

4 Where the Member State concerned has not notified the sponsor of its decision within the period referred to in paragraph 1, the conclusion 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.