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 II U.K.

AUTHORISATION PROCEDURE FOR A CLINICAL TRIAL

Article 14 *U.K.*

Subsequent addition of a Member State concerned

1 Where the sponsor wishes to extend an authorised clinical trial to another Member State ('additional Member State concerned'), the sponsor shall submit an application dossier to that Member State through the EU portal.

The application dossier may be submitted only after the notification date of the initial authorisation decision.

2 The reporting Member State for the application dossier referred to in paragraph 1 shall be the reporting Member State for the initial authorisation procedure.

3 The additional Member State concerned shall notify the sponsor through the EU portal, within 52 days from the date of submission of the application dossier referred to in paragraph 1, by way of one single decision as to whether the clinical trial is authorised, whether it is authorised subject to conditions, or whether the authorisation is refused.

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

4 Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the additional Member State concerned.

Notwithstanding the first subparagraph, an additional Member State concerned may disagree with the conclusion of the reporting Member State as regards Part I of the assessment report 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 5 or 6.

Where an additional 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.

5 Between the date of submission of the application dossier referred to in paragraph 1 and five days before the expiry of the period referred to in paragraph 3, the additional Member

State concerned may communicate to the reporting Member State and the other Member States concerned any considerations relevant to the application through the EU portal.

6 Between the date of submission of the application dossier referred to in paragraph 1 and the expiry of the period referred to in paragraph 3, only the reporting Member State may request additional information from the sponsor concerning the aspects addressed in Part I of the assessment report, taking into account the considerations referred to in paragraph 5.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraphs, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 31 days.

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

Upon receipt of the additional information, the additional Member State concerned together with all other Member States concerned shall jointly review any additional information provided by the sponsor together with the original application and shall share any considerations relevant to the application. The coordinated review shall be performed within a maximum of 12 days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. The reporting Member State shall take due account of the considerations of the Member States concerned and shall record how all such considerations have been dealt with.

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

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

7 The additional Member State concerned shall assess, for its territory, the aspects addressed in Part II of the assessment report within the period referred to in paragraph 3 and submit, through the EU portal, Part II of the assessment report, including its conclusion, to the sponsor. Within that period it may request, with justified reasons, additional information from the sponsor regarding aspects addressed in Part II of the assessment report as far as its territory is concerned.

8 For the purpose of obtaining and reviewing the additional information referred to in paragraph 7 from the sponsor in accordance with the second and third subparagraphs, the additional Member State concerned may extend the period referred to in paragraph 7 by a maximum of 31 days.

The sponsor shall submit the requested additional information within the period set by the additional 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 additional Member State concerned in accordance with the second subparagraph, the application shall be deemed to have lapsed in the additional Member State concerned.

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

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

10 The additional Member State concerned shall refuse to authorise the clinical trial 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 second subparagraph of paragraph 4, or if it finds, on duly justified grounds, that the aspects addressed in 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 additional Member State concerned, is valid for that entire additional Member State. That additional Member State concerned shall provide for an appeal procedure in respect of such refusal.

11 Where the additional Member State concerned has not notified the sponsor of its decision within the period referred to in paragraph 3, or in case that period has been extended in accordance with paragraph 6 or 8 where that additional Member State concerned has not notified the sponsor of its decision within the extended period, the conclusion on Part I of the assessment report shall be deemed to be the decision of that additional Member State concerned on the application for authorisation of the clinical trial.

12 A sponsor shall not submit an application dossier in accordance with this Article where a procedure set out in Chapter III is pending as regards that clinical trial.