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 18 *U.K.*

Assessment of a substantial modification of an aspect covered by Part I of the assessment report

1 The reporting Member State shall assess the application with regard to an aspect covered by Part I of the assessment report, including whether the clinical trial will remain a low-intervention clinical trial after its substantial modification, and draw up an assessment report.

2 The assessment report shall contain one of the following conclusions concerning the aspects addressed in Part I of the assessment report:

a the substantial modification is acceptable in view of the requirements set out in this Regulation;

b the substantial modification is acceptable in view of the requirements set out in this Regulation, but subject to compliance with specific conditions which shall be specifically listed in that conclusion; or

c the substantial modification is not acceptable in view of the requirements set out in this Regulation.

3 The reporting Member State shall submit, through the EU portal, the final assessment report including its conclusion, to the sponsor and to the other Member States concerned within 38 days from the validation date.

For the purposes of this Article and Articles 19 and 23, the reporting date shall be the date on which the final assessment report is submitted to the sponsor and to the other Member States concerned.

4 For clinical trials involving more than one Member State the assessment process of substantial modification shall include three phases:

a an initial assessment phase performed by the reporting Member State within 19 days from the validation date;

b a coordinated review phase performed within 12 days from the end of the initial assessment phase involving all Member States concerned; and

c a consolidation phase performed by the reporting Member State within seven days from the end of coordinated review phase.

During the initial assessment phase, the reporting Member State shall develop a draft assessment report and circulate it to all Member States concerned.

During the coordinated review phase, all Member States concerned shall jointly review the application based on the draft assessment report and shall share any considerations relevant to the application.

During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned when finalising the assessment report and shall record how all such considerations have been dealt with. The reporting Member State shall submit the final assessment report to the sponsor and all other Member States concerned by the reporting date.

5 The reporting Member State may extend the period referred to in paragraph 3 by a further 50 days for clinical trials involving an advanced therapy investigational medicinal product or a medicinal product as set out in point 1 of the Annex to Regulation (EC) No 726/2004, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 4 and 6 of this Article shall apply *mutatis mutandis*.

6 Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 4.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraph, 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 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 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. When finalising the assessment report, the reporting Member State shall take due account of the considerations of the other 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 determined by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

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

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 18.