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

AUTHORISATION PROCEDURE FOR A CLINICAL TRIAL

Article 7

Assessment report — Aspects covered by Part II

1 Each Member State concerned shall assess, for its own territory, the application with respect to the following aspects:

a compliance with the requirements for informed consent as set out in Chapter V;

b compliance of the arrangements for rewarding or compensating subjects with the requirements set out in Chapter V and investigators;

c compliance of the arrangements for recruitment of subjects with the requirements set out in Chapter V;

d compliance with Directive 95/46/EC;

e compliance with Article 49;

f compliance with Article 50;

g compliance with Article 76;

h compliance with the applicable rules for the collection, storage and future use of biological samples of the subject.

The assessment of the aspects referred to in the first subparagraph shall constitute Part II of the assessment report.

2 Each Member State concerned shall complete its assessment within 45 days from the validation date and submit, through the EU portal, Part II of the assessment report, including its conclusion, to the sponsor.

Each Member State concerned may request, with justified reasons, additional information from the sponsor regarding the aspects referred to in paragraph 1 only within the period referred to in the first subparagraph.

3 For the purpose of obtaining and reviewing the additional information referred to in the second subparagraph of paragraph 2 from the sponsor in accordance with the second and third subparagraph, the Member State concerned may extend the period referred to in the first subparagraph of paragraph 2 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 the 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 second subparagraph, the application shall be deemed to have lapsed in that Member State 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 7.