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 6

Assessment report — Aspects covered by Part I

1 The reporting Member State shall assess the application with regard to the following aspects:

a Whether the clinical trial is a low-intervention clinical trial, where claimed by the sponsor;

b Compliance with Chapter V with respect to the following:

(i) The anticipated therapeutic and public health benefits taking account of all of the following:

— the characteristics of and knowledge about the investigational medicinal products;

— the relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point (y) of paragraph 17 of Annex I to this Regulation; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; and, where applicable, any opinion formulated by the Paediatric Committee on a paediatric investigation plan in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council[(1)];

— the reliability and robustness of the data generated in the clinical trial, taking account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints;

(ii) The risks and inconveniences for the subject, taking account of all of the following:

— the characteristics of and knowledge about the investigational medicinal products and the auxiliary medicinal products;

— the characteristics of the intervention compared to normal clinical practice;

— the safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan;

— the risk to subject health posed by the medical condition for which the investigational medicinal product is being investigated;

c Compliance with the requirements concerning the manufacturing and import of investigational medicinal products and auxiliary medicinal products set out in Chapter IX;

d Compliance with the labelling requirements set out in Chapter X;

e The completeness and adequateness of the investigator's brochure.

2 The reporting Member State shall draw up an assessment report. The assessment of the aspects referred to in paragraph 1 shall constitute Part I of the assessment report.

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

a the conduct of the clinical trial is acceptable in view of the requirements set out in this Regulation;

b the conduct of the clinical trial 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 conduct of the clinical trial is not acceptable in view of the requirements set out in this Regulation.

4 The reporting Member State shall submit, through the EU portal, the final Part I of the assessment report, including its conclusion, to the sponsor and to the other Member States concerned within 45 days from the validation date.

5 For clinical trials involving more than one Member State, the assessment process shall include three phases:

a an initial assessment phase performed by the reporting Member State within 26 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;

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 Part I of the assessment report and circulate it to all other Member States concerned.

During the coordinated review phase, all Member States concerned shall jointly review the application based on the draft Part I of the 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 Part I of the assessment report and shall record how all such considerations have been dealt with. The reporting Member State shall submit the final Part I of the assessment report to the sponsor and all other Member States concerned within the period referred to in paragraph 4.

6 For the purposes of this Chapter, the date on which the final Part I of the assessment report is submitted by the reporting Member State to the sponsor and to the other Member States concerned shall be the reporting date.

7 The reporting Member State may also extend the period referred to in paragraph 4 by a further 50 days for clinical trials involving an advanced therapy investigational medicinal products or a medicinal product as defined 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 5 and 8 of this Article shall apply *mutatis mutandis*.

8 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 5.

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 paragraph 4 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 the 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 of the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days of the end of coordinated review. When finalising Part I of the assessment report, 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 all Member States concerned.

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

(**1**) Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.11.2006, p. 1).

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 6.