

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 XIII

SUPERVISION BY MEMBER STATES, UNION INSPECTIONS AND CONTROLS

Article 78

Member State inspections

- 1 Member States shall appoint inspectors to perform inspections in order to supervise compliance with this Regulation. They shall ensure that those inspectors are adequately qualified and trained.
- 2 Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.
- 3 Where a Member State concerned intends to carry out an inspection on its territory or in a third country with regard to one or several clinical trials which are conducted in more than one Member State concerned, it shall notify its intention to the other Member States concerned, the Commission and the Agency, through the EU portal, and shall inform them of its findings after the inspection.
- 4 Inspections fees, if any, may be waived for non-commercial sponsors.
- 5 In order to efficiently use the resources available and to avoid duplications, the Agency shall coordinate the cooperation between Member States concerned on inspections conducted in Member States, in third countries, and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No 726/2004.
- 6 Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw up an inspection report. That Member State shall make the inspection report available to the inspected entity and the sponsor of the relevant clinical trial and shall submit the inspection report through the EU portal.
- 7 The Commission shall specify, by means of implementing acts, the detailed arrangements for the inspection procedures including the qualification and training requirements for inspectors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(2).

Status:

Point in time view as at 31/01/2020.

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 78.