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 XV

COOPERATION BETWEEN MEMBER STATES

Article 83

National contact points

1 Each Member State shall designate one national contact point in order to facilitate the functioning of the procedures set out in Chapters II and III.

2 Each Member State shall communicate the contact point referred to in paragraph 1 to the Commission. The Commission shall publish a list of the national contact points.

Article 84

Support by the Agency and the Commission

The Agency shall support the functioning of the cooperation of the Member States in the framework of the authorisation procedures set out in Chapters II and III of this Regulation by maintaining and updating the EU portal and the EU database in accordance with the experience acquired during the implementation of this Regulation.

The Commission shall support the functioning of the cooperation of the Member States referred to in Article 44(2).

Article 85

Clinical Trials Coordination and Advisory Group

1 A Clinical Trials Coordination and Advisory Group (CTAG), composed of the national contact points referred to in Article 83 is hereby established.

2 The CTAG shall have the following tasks:

- a to support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;
- b to assist the Commission in providing the support referred to in the second paragraph of Article 84;
- c to prepare recommendations on criteria regarding the selection of a reporting Member State.

3 The CTAG shall be chaired by a representative of the Commission.

4 The CTAG shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. Any item of the agenda of the meeting shall be placed at the request of the Commission or a Member State.

5 The secretariat shall be provided by the Commission.

6 The CTAG shall draw up its rules of procedure. The rules of procedure shall be made public.