Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Article 11

Exchange of information

1 Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission:

a extracts from the request for authorisation referred to in Article 9(2);

b any amendments made to the request, as provided for in Article 9(3);

c any amendments made to the protocol, as provided for in point a of Article 10;

d the favourable opinion of the Ethics Committee;

e the declaration of the end of the clinical trial; and

f a reference to the inspections carried out on conformity with good clinical practice.

2 At the substantiated request of any Member State, the Agency or the Commission, the competent authority to which the request for authorisation was submitted shall supply all further information concerning the clinical trial in question other than the data already in the European database.

3 In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in this European database, which it operates with the assistance of the Agency, as well as the methods for electronic communication of the data. The detailed guidance thus drawn up shall ensure that the confidentiality of the data is strictly observed.

[[F1]4 By way of derogation from paragraph 1, the Agency shall make public part of the information on paediatric clinical trials entered in the European database in accordance with the provisions of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[(1)].**]**

Textual Amendments

F1 Inserted by 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 (Text with EEA relevance).

(1) **[**[F1]OJ L 378, 27.12.2006, p. 1.**]**

Textual Amendments

F1 Inserted by 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 (Text with EEA relevance).