Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)

CHAPTER 6

INSPECTION PROCEDURES

Article 23

1 Good clinical practice inspections may take place on any of the following occasions:

a before, during or after the conduct of clinical trials;

b as part of the verification of applications for marketing authorisation;

c as a follow-up to the granting of authorisation.

2 In accordance with Article 15(1) and (2) of Directive 2001/20/EC, inspections may be requested and coordinated by the European Medicines Agency within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council[(1)], especially in connection with clinical trials relating to applications through the procedure established by this Regulation.

3 Inspections shall be conducted in accordance with the inspection guidance documents developed to support the mutual recognition of inspection findings within the Community.

4 Improvement and harmonisation of inspection guidance shall be achieved by the Member States, in collaboration with the Commission and the Agency, through joint inspections, agreed processes and procedures and sharing of experience and training.

Article 24

Member States shall make publicly available within their territories the documents relating to the adoption of good clinical practice principles.

They shall establish the legal and administrative framework within which their good clinical practice inspections operate, with definition of the powers of inspectors for entry into clinical trial sites and access to data. In so doing they shall ensure that, on request and where appropriate, inspectors of the competent authority of the other Member States also have access to the clinical trial sites and data.

Article 25

Member States shall provide for sufficient resources and shall in particular appoint an adequate number of inspectors to ensure effective verification of compliance with good clinical practice.

Article 26

Member States shall establish the relevant procedures for verification of good clinical practice compliance.

The procedures shall include the modalities for examining both the study management procedures and the conditions under which clinical trials are planned, performed, monitored and recorded, as well as follow-up measures.

Article 27

Member States shall establish the relevant procedures for the following:

(a) appointing experts for accompanying inspectors in case of need;

(b) requesting inspections/assistance from other Member States, in line with Article 15(1) of Directive 2001/20/EC and for cooperating in inspections in another Member State;

(c) arranging inspections in third countries.

Article 28

Member States shall maintain records of national and, if applicable, international inspections including the good clinical practice compliance status, and of their follow-up.

Article 29

1 In order to harmonise the conduct of inspections by the competent authorities of the different Member States, guidance documents containing the common provisions on the conduct of those inspections shall be published by the Commission after consultation with the Member States.

2 Member States shall ensure that national inspection procedures are in compliance with the guidance documents referred in paragraph 1.

3 The guidance documents referred to in paragraph 1 may be updated regularly according to scientific and technical development.

Article 30

1 Member States shall lay down all necessary rules to ensure that confidentiality is respected by inspectors and other experts. With regard to personal data, the requirements of Directive 95/46/EC of the European Parliament and of the Council[(2)] shall be respected.

2 Inspection reports shall be made available by the Member States only to the recipients referred to in Article 15(2) of Directive 2001/20/EC, in accordance with national regulations of the Member States and subject to any arrangements concluded between the Community and third countries.

(**1**) OJ L 136, 30.4.2004, p. 1.

(**2**) OJ L 281, 23.11.1995, p. 31.