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.

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