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 1

SUBJECT-MATTER

Article 1

1 This Directive lays down the following provisions to be applied to investigational medicinal products for human use:

a the principles of good clinical practice and detailed guidelines in line with those principles, as referred to in Article 1(3) of Directive 2001/20/EC, for the design, conduct and reporting of clinical trials on human subjects involving such products;

b the requirements for authorisation of the manufacture or importation of such products, as provided for in Article 13(1) of Directive 2001/20/EC;

c the detailed guidelines, provided for in Article 15(5) of Directive 2001/20/EC, on the documentation relating to clinical trials, archiving, qualifications of inspectors and inspection procedures.

2 When applying the principles, detailed guidelines and requirements referred to in paragraph 1, Member States shall take into account the technical implementing modalities provided for in the detailed guidance published by the Commission in The Rules governing medicinal products in the European Union.

3 When applying the principles, detailed guidelines and requirements referred to in paragraph 1 to non-commercial clinical trials conducted by researchers without the participation of the pharmaceutical industry, Member States may introduce specific modalities in order to take into account the specificity of these trials as far as Chapters 3 and 4 are concerned.

4 Member States may take into account the special position of trials whose planning does not require particular manufacturing or packaging processes, carried out with medicinal products with marketing authorisations within the meaning of Directive 2001/83/EC, manufactured or imported in accordance with the same Directive and conducted on patients with the same characteristics as those covered by the indication specified in the marketing authorisation.

Labelling of investigational medicinal products intended for trials of that nature may be subject to simplified provisions laid down in the good manufacturing practice guidelines on investigational medicinal products.

Member States shall inform the Commission as well as the other Member States of any specific modalities implemented in accordance with this paragraph. These modalities will be published by the Commission.