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 2

GOOD CLINICAL PRACTICE FOR THE DESIGN, CONDUCT, RECORDING AND REPORTING OF CLINICAL TRIALS

SECTION 1

GOOD CLINICAL PRACTICE

Article 2

1 The rights, safety and well being of the trial subjects shall prevail over the interests of science and society.

2 Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his tasks.

3 Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.

4 The necessary procedures to secure the quality of every aspect of the trials shall be complied with.

Article 3

The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

Clinical trials shall be conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996).

Article 4

The protocol referred to in point (h) of Article 2 of Directive 2001/20/EC shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

Article 5

All clinical trial information shall be recorded, handled, and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

SECTION 2

THE ETHICS COMMITTEE

Article 6

1 Each Ethics Committee established under Article 6(1) of Directive 2001/20/EC shall adopt the relevant rules of procedure necessary to implement the requirements set out in that Directive and, in particular, in Articles 6 and 7 thereof.

2 The Ethics Committees shall, in every case, retain the essential documents relating to a clinical trial, as referred to in Article 15(5) of Directive 2001/20/EC, for at least three years after completion of that trial. They shall retain the documents for a longer period, where so required under other applicable requirements.

3 Communication of information between the Ethics Committees and the competent authorities of the Member States shall be ensured through appropriate and efficient systems.

SECTION 3

THE SPONSORS

Article 7

1 A sponsor may delegate any or all of his trial-related functions to an individual, a company, an institution or an organisation.

However, in such cases, the sponsor shall remain responsible for ensuring that the conduct of the trials and the final data generated by those trials comply with Directive 2001/20/EC as well as this Directive.

2 The investigator and the sponsor may be the same person.

SECTION 4

INVESTIGATOR'S BROCHURE

Article 8

1 The information in the investigator's brochure, referred to in Article 2(g) of Directive 2001/20/EC, shall be presented in a concise, simple, objective, balanced and non-promotional form that enables a clinician or potential investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial.

The first subparagraph shall apply also to any update of the investigator's brochure.

2 If the investigational medicinal product has a marketing authorisation, the Summary of Product Characteristics may be used instead of the investigator's brochure.

3 The investigator's brochure shall be validated and updated by the sponsor at least once a year.