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 3

MANUFACTURING OR IMPORT AUTHORISATION

Article 10

1 In order to obtain the authorisation the applicant must meet at least the following requirements:

a specify in his application the types of medicinal products and pharmaceutical forms to be manufactured or imported;

b specify in his application the relevant manufacture or import operations;

c specify in his application, where relevant as in the case of viral or non-conventional agents' inactivation, the manufacturing process;

d specify in his application the place where the products are to be manufactured or have at his disposal, for their manufacture or importation, suitable and sufficient premises, technical equipment and control facilities complying with the requirements of Directive 2003/94/EC as regards the manufacture, control and storage of the products;

e have permanently and continuously at his disposal the services of at least one qualified person as referred to in Article 13(2) of Directive 2001/20/EC.

For the purposes of point (a) of the first subparagraph, 'types of medicinal products' include blood products, immunological products, cell therapy products, gene therapy products, biotechnology products, human or animal extracted products, herbal products, homeopathic products, radiopharmaceutical products and products containing chemical active ingredients.

2 The applicant shall provide with his application documentary evidence that he complies with paragraph 1.