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 12

1 In order to ensure that the requirements laid down in Article 10 are complied with, authorisation may be made conditional on the carrying out of certain obligations imposed either when authorisation is granted or at a later date.

2 An authorisation shall apply only to the premises specified in the application and to the types of medicinal products and pharmaceutical forms specified in that application pursuant to point (a) of Article 10(1).