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 11

1 The competent authority shall issue the authorisation only after verifying the accuracy of the particulars provided by the applicant pursuant to Article 10 by the means of an inquiry carried out by its agents.

2 Member States shall take all appropriate measures to ensure that the procedure for granting an authorisation is completed within 90 days of the day on which the competent authority receives a valid application.

3 The competent authority of the Member State may require from the applicant further information concerning the particulars supplied pursuant to Article 10(1), including in particular information concerning the qualified person at the disposal of the applicant in accordance with point (e) of Article 10(1).

Where the competent authority concerned exercises that right, the application of the time-limits laid down in paragraph 2 shall be suspended until the additional data required have been supplied.