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 6

INSPECTION PROCEDURES

Article 28

Member States shall maintain records of national and, if applicable, international inspections including the good clinical practice compliance status, and of their follow-up.