Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

TITLE XI

SUPERVISION AND SANCTIONS

[F1 Article 111a

The Commission shall adopt detailed guidelines laying down the principles applicable to inspections referred to in Article 111.

Member States shall, in cooperation with the Agency, establish the form and content of the authorisation referred to in Articles 40(1) and 77(1), of the reports referred to in Article 111(3), of the certificates of good manufacturing practice and of the certificates of good distribution practices referred to in Article 111(5).**]**

Textual Amendments

F1 Inserted by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Text with EEA relevance).