Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (Text with EEA relevance)

Article 3

Inspections

1 By means of the repeated inspections referred to in Article 111(1a) of Directive 2001/83/EC, the Member States shall ensure that manufacturers authorised in accordance with Article 40(1) and (3) of Directive 2001/83/EC respect the principles and guidelines of good manufacturing practice laid down by this Directive.

Member States shall also take into account the compilation, published by the Commission, of Union procedures on inspections and exchange of information.

2 For the interpretation of the principles and guidelines of good manufacturing practice, manufacturers and the competent authorities shall take into account the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC. In the case of advanced therapy medicinal products, the guidelines on good manufacturing practice specific to advanced therapy medicinal products referred to in Article 5 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products shall be taken into account.

3 Member States shall establish and implement in their inspectorates a properly designed quality system that shall be complied with by inspectorates' personnel and management. The quality system shall be updated as appropriate.