Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2016/1214

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amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Directive 2001/83/EC[(1)], and in particular point (h) of the second paragraph of Article 29 thereof,

Whereas:

(1) Article 2 of Commission Directive 2005/62/EC[(2)] requires Member States to ensure that the quality system in place in all blood establishments complies with the standards and specifications set out in the Annex to that Directive.

(2) Article 2 of Directive 2005/62/EC also requires the Commission to develop good practice guidelines for the interpretation of the standards and specifications referred to in that Article.

(3) Good Practice Guidelines (the 'GPG') have been jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe[(3)].

(4) The GPG have been developed and are updated taking into account scientific and technical expertise. The GPG fully reflect the detailed principles and guidelines of good manufacturing practice established under Article 47 of Directive 2001/83/EC[(4)] which are relevant for blood establishments and their quality systems, and are already successfully used in blood establishments in the Union. Accordingly, they should be taken into account when implementing the standards and specifications set out in the Annex to Directive 2005/62/EC. Paragraph 2 of Article 2 of that Directive should therefore be amended accordingly.

(5) The Commission, which actively participates in the process leading to amendments of the GPG together with experts from the Member States, should inform the competent authorities designated by the Member States of any significant changes to the GPG, which should also be taken into account.