DIRECTIVES

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)

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.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

([1]) OJ L 33, 8.2.2003, p. 30.
([2]) Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments (OJ L 256, 1.10.2005, p. 41).
([3]) Good Practice Guidelines, included in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Minsters on the preparation, use and quality assurance of blood components adopted on 12 October 1995.
([4]) 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 (OJ L 311, 28.11.2001, p. 67).

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Article 2 of Directive 2005/62/EC, paragraph 2 is replaced by the following:

'2. Member States shall ensure that, in order to implement the standards and specifications set out in the Annex to this Directive, there are good practice guidelines available to and used by all blood establishments, in their quality system, good practice guidelines which take fully into account, where relevant for blood establishments, the detailed principles and guidelines of good manufacturing practice, as referred to in the first subparagraph of Article 47 of Directive 2001/83/EC. In doing so, Member States shall take into account the Good Practice Guidelines 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 (*).

(*) Good Practice Guidelines, included in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Minsters on the preparation, use and quality assurance of blood components adopted on 12 October 1995.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 February 2018 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 2016.

For the Commission

The President

Jean-Claude JUNCKER