STATUTORY INSTRUMENTS.

S.I. No. 180 of 2018

EUROPEAN COMMUNITIES (QUALITY SYSTEM FOR BLOOD ESTABLISHMENTS) (AMENDMENT) REGULATIONS 2018

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Directive (EU) 2016/1214[1] of 25 July 2016, hereby make the following regulations:

Citation

1. (1) These Regulations may be cited as the European Communities (Quality System for Blood Establishments) (Amendment) Regulations 2018.

(2) The Principal Regulations and these Regulations may be cited together as the European Communities (Quality System for Blood Establishments) Regulations 2006 and 2018.

Definitions

2. In these Regulations, "Principal Regulations" means the European Communities (Quality System for Blood Establishments) Regulations 2006 (S.I. No. 562 of 2006).

Amendment of Regulation 3 of Principal Regulations

3. Regulation 3(1) of the Principal Regulations is amended by inserting after the definition of "good practice" the following definition:

> "'Good Practice Guidelines' means the Good Practice Guidelines included in the Guide to the Preparation, Use and Quality Assurance of Blood Components 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;".

Amendment of Regulation 4 of Principal Regulations

4. The Principal Regulations are amended by inserting after Regulation 4 the following regulation:

> "4A. Each blood establishment shall ensure that the quality system it has in place pursuant to Regulation 4 takes account of the Good Practice Guidelines."

[1]OJ No. L 199, 26.7.2016, p. 14.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st June*, 2018.

L.S.

GIVEN under my Official Seal,
28 May 2018.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations give effect to Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments. The Regulations provide that the quality system of a blood establishment must take account of the Good Practice Guidelines included in the Guide to the Preparation, Use and Quality Assurance of Blood Components jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe.

These Regulations amend the European Communities (Quality System for Blood Establishments) Regulation 2016.

These Regulations may be cited as the European Communities (Quality System for Blood Establishments) (Amendment) Regulations 2018.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
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