

L.N. 362 of 2017

**HUMAN BLOOD AND TRANSPLANTS ACT
(CAP. 483)**

Blood (Quality and Safety) (Amendment) Regulations, 2017

IN EXERCISE of the powers conferred by article 16 of the Human Blood and Transplants Act, the Minister responsible for Health, after consultation with the Licensing Authority, has made the following regulations:

1. The title of these regulations is the Blood (Quality and Safety) (Amendment) Regulations, 2017, and these regulations shall be read and construed as one with the Blood (Quality and Safety) Regulations, hereinafter referred to as "the principal regulations".

Citation.

S.L. 483.02

2. Sub-regulation (2) of regulation 1 of the principal regulations shall be substituted as follows:

Amends
regulation 1 of
the principal
regulations

"(2) These regulations transpose:

(a) the European Parliament and Council Directive 2002/98/EC of the of 27th January, 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components;

(b) Commission Directive 2004/33/EC of the 22nd March, 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components;

(c) Commission Directive 2004/33/EC of the 22nd March, 2004 implementing 2005/62/EC 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;

(d) Commission Directive 2014/110/EU of 17th December 2014 amending Directive 2004/33 /EC as regards temporary deferral criteria for donors of allogeneic blood donations; and

(e) Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards

quality system standards and specifications for blood establishments."

Amends
regulation 2 of
the principal
regulations

3. Regulation 2 of the principal regulations shall be amended as follows:

(a) immediately after the definition "blood product", there shall be added the following new definition:

" "computerised system" means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation";

(b) immediately after the definition "distribution" there shall be added the following new definition:

" "good practice" means all elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations";

(c) immediately after the definition "inspection" there shall be added the following new definitions:

" "mobile site" means a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment;

"processing" means any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component;

"qualification" as part of validation, means the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results";

(d) immediately after the definition "qualified health professional" there shall be added the following new definitions:

" "quality assurance" means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use;

"quality control" means part of a quality system focussed on fulfilling quality requirements;

"quality management" means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment;

"quality system" means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management;

"quarantine" means the physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents;"and

(e) immediately after the definition "serious adverse reaction" there shall be added the following new definitions:

" "specification" means a description of the criteria that must be fulfilled in order to achieve the required quality standard;

"standard" means the requirements that serve as the basis for comparison;

"trace-back" means the process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor;

"validation" means the establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled;

"written procedures" means controlled documents that describe how specified operations are to be carried out;".

4. Immediately after regulation 10 of the principal

Adds new regulation 10 to the principal regulations.

regulations there shall be added the following new regulation:

"Good Practice
Guidelines.

10. (1) A quality system for blood establishments laid down in the Annexes to Directive 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and the Council as regards Community Standards and specifications relating to a quality system for Blood Establishments shall be established and maintained, taking into account, where relevant for blood establishments, the detailed principles and guidelines of good manufacturing practice, as referred to in the first sub-paragraph of Article 47 of Directive 2001/83/EC, and the Good Practice Guidelines in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95)15 of the Committee of Ministers on the preparation, use and quality assurance of blood components adopted on 12 October 1995 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.

(2) Any blood or labile blood products imported from third countries and intended for the use or distribution in the Community must also adhere to the Quality system as specified in Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments, even in the stages prior to importation."

Amends
Schedule VI of
the principal
regulations.

5. In item 1.1 of Schedule VI of the principal regulations the word "doors" shall be substituted by the word "donors".