L.N. 272 of 2006

HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006)

Blood (Quality and Safety) Regulations, 2006

BY virtue of article 16 of the Human Blood and Transplants Act, 2006, the Minister for Health, the Elderly and Community Care, after consultation with the Licensing Authority, has made the following regulations:-

Title and scope.

1. (1) The title of these regulations is the Blood (Quality and Safety) Regulations, 2006.

(2) The scope of these regulations is to transpose the European Parliament and Council Directives 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 and 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 and 2005/62/EC implementing Directive 2002/98/EC of European Parliament and of the Council as regards Community Standards and specifications relating to a quality system for blood establishments.

Interpretation.

2. In these regulations unless the context otherwise requires :

"the Act" means the Human Blood and Transplants Act, 2006;

"autologous transfusion" means transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

"blood" means whole blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

"blood component release" means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

"blood establishment" means any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks;

"blood product" means any therapeutic product derived from human blood or plasma;

"deferral" means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary;

"distribution" means the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusions;

"haemovigilance" means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

"hospital blood bank" means a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

"inspection" means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these regulations;

"qualified health professional" includes a doctor and a nurse;

"serious adverse event" means any untoward occurrence associated with the collection, testing, processing, storage, and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response in donor or in patient associated with the collection or transfusion of blood and blood components that is fatal, life-threatening, disabling,

incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Information on application.

3. An application for a licence to operate a blood establishment shall include all the information referred to under Annex I to Directive 2002/98/EC and any amendments thereto.

Responsible person.

4. (1) A blood establishment shall designate a person who is responsible for the following tasks:-

(a) ensuring that every unit of blood or blood component that has been collected or tested for any purpose has been collected and tested in accordance with the requirements of these regulations;

(b) ensuring that every unit of blood or blood components intended for transfusion has been processed, stored and distributed in accordance with the requirements of these regulations;

(c) providing information to the Authority relating to the licence of the blood establishment for the purposes of regulation 3 of these regulations; and

(d) the implementation in the blood establishment of the requirements of articles 10,11, 12, 13, 14 and 15 of the Act.

(2) A blood establishment shall not designate a person as a responsible person unless that person has:-

(a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of -

(i) a university course of study, or

(ii) a course recognised as an equivalent course by the Authority ; and

(b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these regulations for at least two years, in one or more establishments licenced in any Member State to undertake activities related to the collection and, or testing of blood and blood components, or to their preparation, storage and distribution.

(3) The responsible person may delegate any of the tasks specified in sub-regulation (1) to other persons who shall be qualified by training and experience to perform them.

(4) Blood establishments shall notify the Authority of the name of any persons to whom tasks have been delegated by the responsible person under sub-regulation (4), and the specific tasks which have been delegated to such persons.

(5) Where the responsible person or a person to whom tasks have been delegated under sub-regulation (4) is permanently or temporarily replaced, the blood establishment shall immediately provide the Authority with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.

(6) If the Authority considers that the responsible person does not meet the requirements of sub-regulation (2), he may serve a notice to that effect on the blood establishment.

(7) If, within 14 days of receiving a notice in accordance with sub-regulation (7), a blood establishment is not able to demonstrate to the reasonable satisfaction of the Authority that the responsible person does meet the requirements of sub-regulation (2), it shall, without delay -

(a) relieve him of the duties of responsible person in respect of the establishment;

(b) appoint a new responsible person in his place; and

(c) notify the Authority that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Duties of blood establishments.

5. (1) A blood establishment shall -

(a) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution of human blood and blood components for the blood establishment are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) establish and maintain 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;

(c) ensure that all testing and processes of the blood establishment which are referred to in Annexes II and V to Directive 2004/33/EC are validated;

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection;

(e) notify the Authority of -

(i) any serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components by the blood establishment which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components collected, tested, processed, stored or distributed by the blood establishment; and

(f) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (e) hereof.

(2) A blood establishment shall, in relation to the donation of blood:

(a) give all prospective donors of blood or blood components information in accordance with Part A of Annex II to Directive 2004/33/EC and any amendments thereto;

(b) obtain from all persons who are willing to provide blood or blood components, information in accordance with Part B of Annex II to Directive 2004/33/EC and any amendments thereto;

(c) put and keep in place procedures for the evaluation of donors;

(d) apply eligibility criteria for all donors of blood and blood components in accordance with Annex III to Directive 2004/33/EC and any amendments thereto;

(e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations;

(f) ensure that :

(i) an examination of the donor, including an interview, is carried out before any donation of blood or blood components,

(ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate, and

(iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate; and

(g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations.

(3) A blood establishment shall ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes:

(a) each donation of blood and blood components ,including blood and blood components which are imported into the European Community, is tested in conformity with the requirements listed in Annex IV to Directive 2002/98/EC and any amendments thereto;

(b) the storage, transport and distribution conditions of blood and blood components comply with the requirements of Annex IV to Directive 2004/33/EC and any amendments thereto; and

(c) quality and safety requirements for blood and blood components meet the standards specified in Annex V to Directive 2004/33/EC and any amendments thereto.

(4) A blood establishment shall, in relation to the information required by Annexes II and IV to Directive 2002/98/EC and Annexes II Part A and Part B and Annex III to Directive 2004/33/EC, maintain records, for a minimum period of 15 years.

(5) As soon as practicable after the end of the reporting year, each blood establishment shall provide to the Authority a report specifying:-

(a) the information referred to in sub-regulation (3) for that year; and

(b) details of the steps it has taken during that year to comply with the provisions of paragraph (g) of sub-regulation (2) hereof.

Labelling and traceability of blood and blood components.

6. (1) A blood establishment shall ensure that the label on each unit of blood or blood component supplied by it, or imported by it from outside the European Community, shall contain all the information referred to under Annex III to Directive 2002/98/EC and any amendments thereto.

(2) A blood establishment shall, for a period of not less than 30 years, keep such records of the information referred to in sub-regulation (1) hereof and such additional records as are necessary -

(a) for the identification of each single blood donation and each single blood unit and its components, including blood and blood components which are imported into the European Community; and

(b) to ensure full traceability to the point of delivery to a hospital.

Hospital Blood Banks.

7. (1) The person responsible for the management of a hospital blood bank shall -

(a) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood components for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training;

(b) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice;

(c) ensure that all processes referred to in Annex IV to Directive 2004/33/EC and any amendments thereto, which are applicable to activities carried out by the hospital blood bank, are validated;

(d) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection;

(e) maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank;

(f) notify the Authority and the blood establishment from whom the blood and blood components were procured of -

(i) any serious adverse events related to the testing, storage and distribution of blood and blood components by the hospital blood bank which may have an influence on their quality and safety, and

(ii) any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components issued for transfusion by the hospital blood bank;

(g) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any notification referred to in paragraph (f) hereof; and

(h) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the requirements of Annex IV to Directive 2004/33/EC and any amendments thereto.

Requirement for hospital blood banks to provide information to the Authority.

8. (1) As soon as practicable after the end of the reporting year, the person responsible for management of a hospital blood bank shall submit an annual report to the Authority, which shall -

(a) include a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the requirements of these regulations; and

(b) provide details of the systems which it has in place to ensure such compliance.

(2) The person responsible for management of a hospital blood bank shall without delay notify the Authority of any changes to the matters in respect of which evidence has been supplied pursuant to

sub-regulation (1) which might affect compliance with the requirements of these regulations.

Data protection and confidentiality.

9. (1) A blood establishment and the person responsible for management of a hospital blood bank shall ensure that all information which is collected for the purposes of these regulations is held securely so that it is -

(a) available for the purpose of tracing donations;

(b) not disclosed except:

(i) in accordance with one or more of the requirements of sub-regulation (2) hereof, or

(ii) where they have been rendered anonymous, so that donors are no longer identifiable;

(c) subject to safeguards against unauthorised additions, deletions or modifications.

(2) The requirements referred to under sub-paragraph(i) of paragraph (b) of sub-regulation (1) hereof are that:

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law;

(b) the disclosure is to an inspector appointed by the Authority; or

(c) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(3) The responsible person of the blood establishment and the person responsible for management of the hospital blood bank shall ensure that they put in place a procedure to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*

Prezz 40ċ – *Price 40c*