

L.N. 273 of 2006

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

Traceability Requirements and Notification of Serious Adverse Reactions and Events 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 Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations, 2006.

(2) These regulations implement Directive 2005/61/EC implementing Directive 2002/98/EC of the European Parliament and of the Council of the 27th January, 2003 relating to traceability requirements and notification of serious adverse reactions and events.

Interpretation.

2. For the purposes of these regulations, unless the context otherwise requires:

“the Authority” means the Superintendent of Public Health;

“facilities” means hospitals, clinics, manufacturers and biomedical research institutions to which blood or blood components may be delivered;

“imputability” means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused, or that a serious adverse reaction in a donor can be attributed to the donation process;

“issue” means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;

“recipient” means a person who has been transfused with blood or blood components;

“reporting establishment” means the blood establishment, the hospital blood bank or facilities where the transfusion takes place,

which reports serious adverse reactions and, or serious adverse events to the Authority;

“traceability” means the ability to trace each individual unit of blood or blood component derived therefrom, from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal thereof, or vice versa.

3. (1) It shall be the duty of the blood establishment to have in operation a system which ensures the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system. Traceability.

(2) The traceability system in place in the blood establishment shall be of such a kind as to:

(a) enable the tracing of blood components to their location and processing stage; and

(b) uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered.

(3) Every blood establishment shall have :

(a) a system in place to record each blood unit or blood component received, whether it has been locally processed or not, and the final destination of such received unit, whether transfused, discarded or returned to the distributing blood establishment; and

(b) a unique identifier that enables it to be precisely linked to each unit of blood which it has collected and to each blood component which it has prepared.

4. Any blood establishment or hospital blood bank shall, when issuing units of blood or blood components for transfusion, have in place a procedure to verify that each unit issued has been transfused to the intended recipient or, if not transfused, to verify its subsequent disposition. Verification procedure for issuing blood or blood components.

5. Blood establishments, hospital blood banks or facilities shall retain the data set out in Schedule I to these regulations for at least thirty years in an appropriate and readable storage medium in order to ensure traceability. Record of traceability data.

Notification of
serious adverse
reactions.

6. (1) It shall be the duty of all those facilities where transfusion occurs to have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients either during or after transfusion which may be attributable to the quality or safety of blood and blood components.

(2) It shall be the duty of reporting establishments to have procedures in place to communicate to the Authority, as soon as they are known, all relevant information about suspected serious adverse reactions. The notification formats set out in Part A and Part C of Schedule II to these regulations shall be used.

(3) Reporting establishments shall:

(a) notify to the Authority all relevant information about serious adverse reactions of imputability level 2 or level 3, as referred to in Part B of said Schedule II, attributable to the quality and safety of blood and blood components;

(b) notify the Authority of any case of transmission of infectious agents by blood and blood components as soon as known;

(c) describe the actions taken with respect to other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;

(d) evaluate suspected serious adverse reactions according to the imputability levels set out in Part B of said Schedule II;

(e) complete the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Part C of said Schedule II;

(f) submit a complete report on serious adverse reactions to the Authority on an annual basis using the format set out in Part D of said Schedule II.

Notification of
serious adverse
events.

7. (1) Blood establishments and hospital blood banks shall have procedures in place to retain the record of any serious adverse events which may affect the quality or safety of blood and blood components.

(2) Reporting establishments shall have procedures in place to communicate to the Authority as soon as known, using the notification format set out in Part A of Schedule III to these regulations, all relevant information about serious adverse events which may put in danger

donors or recipients other than those directly involved in the event concerned.

(3) Reporting establishments shall:

(a) evaluate serious adverse events to identify preventable causes within the process;

(b) complete the serious adverse event notification, upon conclusion of the investigation, using the format set out in Part B of said Schedule III;

(c) submit a complete report on serious adverse events to the Authority on an annual basis using the format set out in Part C of said Schedule III.

8. (1) In the case of imports of blood and blood components from third countries blood establishments shall have: Requirements for imported blood and blood components.

(a) a system of traceability in place equivalent to that provided for in regulation 3 of these regulations;

(b) a system of notification in place equivalent to that provided for in regulations 6 and 7 of these regulations.

9. The Authority shall submit to the Commission an annual report, Annual reports. by the 30th June of the following year, on the notification of serious adverse reactions and events received by the Authority using the formats in Part D of Schedule II and Part C of Schedule III to these regulations.

10. The Authority shall communicate to other competent authorities such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded. Communication of information between competent authorities.

SCHEDULE I

(Regulation 5)

RECORD OF DATA ON TRACEABILITY

By Blood Establishments

1. Blood establishment identification
2. Blood donor identification
3. Blood unit identification
4. Individual blood component identification
5. Date of collection (year/month/day)
6. Facilities to which blood units or blood components are distributed, or subsequent disposition.

By Facilities

1. Blood component supplier identification
2. Issued blood component identification
3. Transfused recipient identification
4. For blood units not transfused, confirmation of subsequent disposition
5. Date of transfusion or disposition (year/month/day)
6. Lot number of the component, if relevant.

SCHEDULE II

(Regulations 6 and 9)

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification format for suspected serious adverse reactions.

Reporting establishment
 Report identification
 Reporting date (year/month/day)
 Date of transfusion (year/month/day)
 Age and sex of recipient
 Date of serious adverse reaction (year/month/day)
 Serious adverse reaction is related to
 — Whole blood
 — Red blood cells
 — Platelets
 — Plasma
 — Other (specify)
 Type of serious adverse reaction(s)
 — Immunological haemolysis due to ABO incompatibility
 — Immunological haemolysis due to other allo-antibody
 — Non-immunological haemolysis
 — Transfusion-transmitted bacterial infection
 — Anaphylaxis/hypersensitivity
 — Transfusion related acute lung injury
 — Transfusion-transmitted viral infection (HBV)
 — Transfusion-transmitted viral infection (HCV)
 — Transfusion-transmitted viral infection (HIV-1/2)
 — Transfusion-transmitted viral infection, Other (specify)
 — Transfusion-transmitted parasitological infection (Malaria)
 — Transfusion-transmitted parasitological infection, Other (specify)
 — Post-transfusion purpura
 — Graft versus host disease
 — Other serious reaction(s) (specify)
 Imputability level (NA, 0-3)

PART B

Serious adverse reactions — imputability levels.

Imputability levels to assess serious adverse reactions.

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Imputability level Explanation

NA Not assessable When there is insufficient data for imputability assessment.

0 Excluded When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.

Unlikely When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.

1 Possible When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.

2 Likely, Probable When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.

3 Certain When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

PART C

Confirmation format for serious adverse reactions.

Reporting establishment

Report identification

Confirmation date (year/month/day)

Date of serious adverse reaction (year/month/day)

Confirmation of serious adverse reaction (Yes/No)

Imputability level (NA, 0-3)

Change of type of serious adverse reaction (Yes/No)

If Yes, specify

Clinical outcome (if known)

— Complete recovery

— Minor sequelae

— Serious sequelae

— Death

PART D

Annual notification format for serious adverse reactions.

Reporting establishment

Reporting period

This Table refers to

Whole blood

Red blood cells

Platelets

Plasma

Other

(use separate table for each component)

Number of units issued (total number of units issued with a given number of blood components)

Number of recipients transfused (total number of recipients transfused with a given number of blood components) (if available)

Number of units transfused (the total number of blood components (units) transfused over the reporting period) (if available)

Total number reported

Number of serious adverse reactions with imputability level

Number of deaths

0 to 3

after confirmation (see Part A of this Schedule)

not assessable

Level 0

Level 1

Level 2

Level 3

Immunological Haemolysis Due to ABO incompatibility Total Deaths

Due to other allo-antibody Total Deaths

Non-immunological haemolysis Total Deaths

Transfusion-transmitted bacterial infection Total Deaths

Anaphylaxis/hypersensitivity Total Deaths

Transfusion related acute lung injury Total Deaths

Transfusion-transmitted viral Infection

HBV Total Deaths

HCV Total Deaths

HIV-1/2 Total Deaths

Other (specify) Total Deaths

Transfusion-transmitted parasitological infection

Malaria Total Deaths

Other (specify) Total Deaths

Post-transfusion purpura Total Deaths

Graft versus host disease Total Deaths

Other serious reactions (specify) Total Deaths

SCHEDULE III

(Regulations 7 and 9)

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid Notification Format for Serious Adverse Events.

Reporting establishment
Report identification
Reporting date (year/month/day)
Date of serious adverse event (year/month/day)
Serious adverse event, which may affect quality and safety of blood component
due to a deviation in:

Specification
Product defect
Equipment failure
Human error
Other (specify)

Whole blood collection
Apheresis collection
Testing of donations
Processing
Storage
Distribution
Materials
Others (specify)

PART B

Confirmation Format for Serious Adverse Events.

Reporting establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse event (year/month/day)
Root cause analysis (details)
Corrective measures taken (details)

PART C

Annual Notification Format for Serious Adverse Events.

Reporting establishment

Reporting period

1 January-31 December (year)

Total number of blood and blood components processed:

Serious adverse event, affecting quality and safety of blood component due to a deviation in:

Total number

Specification

Product defect

Equipment failure

Human error

Other (specify)

Whole blood collection

Apheresis collection

Testing of donations

Processing

Storage

Distribution

Materials

Others (specify)

