STATUTORY INSTRUMENTS

2006 No. 2013

The Blood Safety and Quality (Amendment) Regulations 2006

Amendment of the Schedule to the principal Regulations

15. In the Schedule to the principal Regulations, after Part 5 (quality and safety requirements for blood and blood components) insert the following Parts—

"PART 6

RECORD OF DATA ON TRACEABILITY

A. 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.

B. 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.

PART 7

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

SECTION 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 parasitical infection (Malaria)
— Transfusion-transmitted parasitical infection, other (specify)
— Post-transfusion purpura
— Graft versus host disease
— Other serious reaction(s) *(specify)*
Imputability level (NA, 0-3)

SECTION B

Serious adverse reactions – imputability levels

Imputability levels to assess serious adverse reactions

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.

SECTION 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

SECTION 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 0 to 3 after confirmation (see Section A of Part 7)					
		Number of deaths						
			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 parasitical 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						

PART 8

NOTIFICATION OF SERIOUS ADVERSE EVENTS

SECTION 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)*				

SECTION B

Confirmation Format for Serious Adverse Events

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

SECTION 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)*					