REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)
Blood Directive 2005/61/EC

version : 2.0

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Instruction for completing the report template:

1) This report template should be filled in according to the definitions and recommendations provided in the "Common approach for definitions of reportable serious adverse events and reactions as laid down in the Blood Directive 2002/98/EC and Commission Directive 2005/61/EC - Version 2 (2009)".
References to the relevant sections of the Common approach document are made on each question of this report template. Please provide as much information as possible, in addition to those required by fields marked with an asterisk (*) which are mandatory. Should you need clarifications on some of the information requested, please contact SANCO-SARE@ec.europa.eu.

2) Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the tables when you have data or cases to report.

3) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page.

4) When you have finished filling the form, please verify that your internet connection is active and then click on the submit notification button below. If the form is properly filled, the notification will be submitted to the server and a Submission number will appear in the corresponding field. Once you have received the Submission number, ***save the form on your computer for your records.***

5) If the form is not properly filled, an alert box will appear indicating the number of incorrect fields. Please check your form again and try to re-submit it according to step 4). Should you still have any difficulties, please contact SANCO-SARE@ec.europa.eu.

6) If you receive an error message, please send its reference to SANCO-SARE@ec.europa.eu in order to properly manage it.

Submission number

1251472346710-608

Reporting country :*

Portugal

This data collection refers to the period 1st January 2008 - 31 December 2008 included
(See point 1.1 of the Common approach version 2)

Annual notification for Serious Adverse REACTION(S)

Serious adverse reactions in donor of blood and blood components :
(See point 2.1 of the common approach version 2)

Comment :

Annual notification for serious adverse reaction(s) related to :*

Red blood cells — x

*Number of units issued * :*

462,442

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

54,546

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

278,233

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

A: *Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component*
B*: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.*

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0

		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Anaphylaxis/hypersensitivity	Total no death				1				1
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion related acute lung injury	Total no death			1	1				2
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death							0
		Total deaths							0
	HCV	Total no death							0
		Total deaths							0
	HIV-1/2	Total no death							0
		Total deaths							0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0
			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Graft versus host disease		Total no death								0
		Total deaths								0

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions ***for this type*** *of blood component :* 3

Comments :

The total number of units and recipients transfused with this component isn't available

Annual notification for serious adverse reaction(s) related to* :

Platelets

x

Number of units issued * :

144,244

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

5,602

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

69,734

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

A: Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component
B: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0
		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Anaphylaxis/hypersensitivity		Total no death			1	1				2
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion related acute lung injury		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death								0
		Total deaths								0
	HCV	Total no death								0
		Total deaths								0
	HIV-1/2	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0

	not assessable	Level 0	Level 1	Level 2	Level 3	Total

						A	B	A	B		
Graft versus host disease		Total no death								0	
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 2

Comments :

The total number of units and recipients transfused with this component isn't available

Annual notification for serious adverse reaction(s) related to* :

Plasma

x

Number of units issued * :

177,477

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

1,521

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

9,831

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

A: *Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component*
B*: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.*

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0
		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Anaphylaxis/hypersensitivity		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion related acute lung injury		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death								0
		Total deaths								0
	HCV	Total no death								0
		Total deaths								0
	HIV-1/2	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0

	not assessable	Level 0	Level 1	Level 2	Level 3	Total

						A	B	A	B		
Graft versus host disease		Total no death								0	
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 0

Comments :

The total number of units and recipients transfused with this component isn't available

Annual notification for serious adverse reaction(s) related to* :

Cryoprecipitates

x

Number of units issued * :

4,276

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

67

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

1,849

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

A: *Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component*
B*: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.*

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0
		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Anaphylaxis/hypersensitivity		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion related acute lung injury		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death								0
		Total deaths								0
	HCV	Total no death								0
		Total deaths								0
	HIV-1/2	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0

	not assessable	Level 0	Level 1	Level 2	Level 3	Total

						A	B	A	B		
Graft versus host disease		Total no death								0	
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 0

Comments :

The total number of units and recipients transfused with this component isn't available

Annual notification for serious adverse reaction(s) related to* :

Granulocytes

x

Number of units issued * :

64

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

1

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

8

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

A: Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component
B: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0
		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Anaphylaxis/hypersensitivity		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion related acute lung injury		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death								0
		Total deaths								0
	HCV	Total no death								0
		Total deaths								0
	HIV-1/2	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0

	not assessable	Level 0	Level 1	Level 2	Level 3	Total

						A	B	A	B		
Graft versus host disease		Total no death								0	
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 0

Comments :

The total number of units and recipients transfused with this component isn't available

Annual notification for serious adverse reaction(s) related to :*

Plasma SD

x

*Number of units issued * :*

0

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2)

Number of recipients transfused (if available) :

5,262

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2)

Number of units tranfused (if available) :

45,720

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2)

***A:** Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component*
***B**: Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component.*

(See section 2.3 of the common approach version 2)

Absence of data in one field means "0" or "Non Available". Therefore, please just fill in the table when you have cases.

Imputability level after confirmation of the Serious Adverse Reaction(s)			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Immunological Haemolysis	Due to ABO incompatibility	Total no death								0
		Total deaths								0
	Due to other allo-antibody	Total no death								0
		Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Non-immunological Haemolysis	Total no death								0
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Transfusion-transmitted bacterial infection	Total no death								0
	Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Anaphylaxis/hypersensitivity		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion related acute lung injury		Total no death								0
		Total deaths								0

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted viral infection	HBV	Total no death								0
		Total deaths								0
	HCV	Total no death								0
		Total deaths								0
	HIV-1/2	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted viral infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Transfusion-transmitted parasitical infection	Malaria	Total no death								0
		Total deaths								0

Add other type of Transfusion-transmitted parasital infection

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
						A	B	A	B	
Post-transfusion purpura		Total no death								0
		Total deaths								0

	not assessable	Level 0	Level 1	Level 2	Level 3	Total

						A	B	A	B		
Graft versus host disease		Total no death								0	
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 0

Comments :

The total number of units and recipients transfused with this component isn't available

Add a new annual notification of serious adverse reaction(s) for another blood component

Annual notification for Serious Adverse EVENT(S)

Total number of units processed :
(See section 3.1 of the Common approach version 2)

***Serious adverse event(s)**, affecting quality and safety of blood components due to a deviation in* * :

x

Specification	Additional details (if available)	Quantity	
			X
Total			

Add a new specification

Comments :

Add a new category of serious adverse event(s)

General comments on this Annual Notification :