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

version : 2.1

In order to use this report template, you should have the latest Acrobat Reader version available (at least Acrobat Reader version 8.1.5).
You can check the version in the "Help" menu under "About Acrobat Reader" item.
If you don't have a correct version, please download it here :
http://www.adobe.com/products/acrobat/readstep2.html

For technical questions related to the use of this form, please send an email to the following address: SANCO-SARE@ec.europa.eu
For more information please read our "Privacy statement" at the end of this document.

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 2.1 (2011)".
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) Please complete ALL FIELDS WITH either 0 or NA (not available) as appropriate. All fields in the drop down menus are mandatory.

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

1314725878529-986

Reporting country * :*

Portugal

This data collection refers to the period 1st January 2010 - 31 December 2010 included
(See point 1.1 of the Common approach version 2.1)

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

53

Comment :

55 Serious Adverse reactions in donor, all occured during whole blood collection. 33 of the 55 Serious Adverse reactions were detected in the end of donation, while 20 were detected during the donation procedure

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

Red blood cells

x

Number of units issued * :*

400,954

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2.1)

Number of recipients transfused (in this case, 0 = data not available) * :*

101,819

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2.1)

Number of units tranfused (in this case, 0 = data not available) *:*

336,305

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2.1)

REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)
Blood Directive 2005/61/EC
version : 2.1

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 2.1)

Please fill in the table where you have cases. In case you cannot distinguish between A and B cases, please introduce the appropriate number of cases in the "not assessable" field - this allows you to submit the overall numbers for each SAR category

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				8				8
		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						1		1
	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		1						1
	Total deaths								0

		not assessable	Level 0	Level 1	Level 2		Level 3		Total
					A	B	A	B	
Anaphylaxis/hypersensitivity	Total no death		1	2	3				6
	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
	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

			not assessable	Level 0	Level 1	Level 2		Level 3		Total
Other Serious Reactions						A	B	A	B	
non haemolytic febrile transfusion reaction		Total no death			1	1				2
		Total deaths								0

Other Serious Reactions			not assessable	Level 0	Level 1	Level 2 A	Level 2 B	Level 3 A	Level 3 B	Total	
allergic reaction/rash/urticaria		Total no death			2	2				4	x
		Total deaths								0	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
volume overload		Total no death			3	4				7	x
		Total deaths			1					1	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
hypotension		Total no death				4				4	x
		Total deaths								0	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
Dyspnoe		Total no death		1		10				11	x
		Total deaths								0	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
other		Total no death	1	2	3			1		7	x
		Total deaths								0	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
Transfusion-transmitted viral infection (other)		Total no death			1					1	x
		Total deaths								0	
Other Serious Reactions			**not assessable**	**Level 0**	**Level 1**	**Level 2 A**	**Level 2 B**	**Level 3 A**	**Level 3 B**	**Total**	
Late serologic reaction		Total no death				1				1	x
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 55

Comments :

Since there are no complete data concerning the "Number of units issued", the data presented refers to the total units produced

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

Platelets

x

Number of units issued * :

127,452

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2.1)

Number of recipients transfused (in this case, 0 = data not available) * :

9,875

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2.1)

Number of units tranfused (in this case, 0 = data not available) *:

66,428

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2.1)

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 2.1)

Please fill in the table where you have cases. In case you cannot distinguish between A and B cases, please introduce the appropriate number of cases in the "not assessable" field - this allows you to submit the overall numbers for each SAR category

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								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			3					3
		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	
			not assessable	Level 0	Level 1	Level 2		Level 3		Total	
Other Serious Reactions						A	B	A	B		
Dyspnoe		Total no death			7	3		2		12	x
		Total deaths								0	
			not assessable	Level 0	Level 1	Level 2		Level 3		Total	
Other Serious Reactions						A	B	A	B		
other		Total no death								0	x
		Total deaths								0	
			not assessable	Level 0	Level 1	Level 2		Level 3		Total	
Other Serious Reactions						A	B	A	B		
hypotension		Total no death			3					3	x
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions **for this type** of blood component : 19

Comments :

Since there are no complete data concerning the "Number of units issued", the data presented refers to the total units produced

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

Plasma x

Number of units issued * :

19,103

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2.1)

Number of recipients transfused (in this case, 0 = data not available) * :

14,375

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2.1)

Number of units tranfused (in this case, 0 = data not available) *:

74,031

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2.1)

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 2.1)

Please fill in the table where you have cases. In case you cannot distinguish between A and B cases, please introduce the appropriate number of cases in the "not assessable" field - this allows you to submit the overall numbers for each SAR category

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	
			not assessable	Level 0	Level 1	Level 2		Level 3		Total	
Other Serious Reactions						A	B	A	B		
hypotension		Total no death		1						1	x
		Total deaths								0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions ***for this type*** *of blood component :* 1

Comments :

Portugal doesn't produce Plasma SD. The number presented as "Number of units issued", represents the fresh frozen plasma produced in blood services.
64367 units of Plasma SD, transfused to 10905 recipients;

9664 units of fresh frozen plasma were transfused to 3470 recipients

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

Granulocytes x

Number of units issued * :
16

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2.1)

Number of recipients transfused (in this case, 0 = data not available) * :
5

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2.1)

Number of units tranfused (in this case, 0 = data not available) *:
18

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2.1)

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 2.1)

Please fill in the table where you have cases. In case you cannot distinguish between A and B cases, please introduce the appropriate number of cases in the "not assessable" field - this allows you to submit the overall numbers for each SAR category

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 :

Since there are no complete data concerning the "Number of units issued", the data presented refers to the total units produced

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

Cryoprecipitates

x

Number of units issued * :

1,521

Total number of units issued with a given number of blood components
(See point 2.2.1 of the Common approach version 2.1)

Number of recipients transfused (in this case, 0 = data not available) * :

129

Total number of recipients transfused with a given number of blood components.
(See section 2.2.2 of the common approach version 2.1)

Number of units tranfused (in this case, 0 = data not available) *:

1,326

Total number of blood components (units) transfused over the reporting period.
(See section 2.2.3 of the common approach version 2.1)

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 2.1)

Please fill in the table where you have cases. In case you cannot distinguish between A and B cases, please introduce the appropriate number of cases in the "not assessable" field - this allows you to submit the overall numbers for each SAR category

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 :

Since there are no complete data concerning the "Number of units issued", the data presented refers to the total units produced

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 2.1)

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

Other, please specify here

x

Specification	Additional details (if available)	Quantity	
		0	X
Total		0	

Add a new specification

Comments :

Add a new category of serious adverse event(s)

General comments on this Annual Notification :