



## **REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

### **Blood - Directive 2005/61/EC**

Instructions to complete the form:

Your current version of Acrobat is: 11.013

- 1) Be informed that you need to have at least the Adobe Reader version 9 or higher to fill and submit this form.
- 2) Please fill out this form according to the **definitions and recommendations** provided in the "Common approach document". Some definitions are also provided as mouse-overs.
- 3) Please fill out all the fields with the appropriate information.
  - When data are **not** available, please insert **NA**
  - When data are available, please provide a number **≥0**To verify your data entry while filling your form, you can use the "verify form" button at the bottom of each page.
- 4) When you have finished filling the form, 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.
- 5) IMPORTANT: Once you have received the Submission number, save the form on your computer.
- 6) 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. Should you still have any difficulties, please contact [SANTE-SARE@ec.europa.eu](mailto:SANTE-SARE@ec.europa.eu), describe the issue and mention the version of this document: 2017 2.5.7
- 7) Privacy statement (see last page)

Submission date

Submission number



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

Reporting country\* : **Croatia**

Competent Authority responsible for the reported data \* : **Ministry of Health**

E-mail of Competent Authority responsible for the reported data \* : **biomedicina@miz.hr**

This data collection refers to the period 1st January 2016 - 31 December 2016 included  
(See section 1.1 of the Common approach)

Number of reporting establishments in your country  
(See section 1.3.1 of the Common approach)

**7**

Percentage of completeness of data  
(See section 1.3.2 of the Common approach)

% reports received

**100**

% number of units issued

**100**

% number of recipients

**100**

% number of units transfused

**100**

Total number of units issued regardless the type of component  
(See section 1.3.3 of the Common approach)

**271227**

Total number of recipients transfused regardless the type of component  
(See section 1.3.4 of the Common approach)

**67227**

Total number of units transfused regardless the type of component  
(See section 1.3.5 of the Common approach)

**263094**

## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

#### Annual notification for Serious Adverse REACTION(S)

Total number of serious adverse reactions in donors of blood and blood components:  
(See section 2.1 of the Common approach)

11

Comment :

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

#### Whole blood

Number of units issued \* :

0

Total number of units issued of this blood component.  
(See section 2.2.1 of the Common approach)

Number of recipients transfused (if available) :

0

Total number of recipients transfused with this blood component.  
(See section 2.2.2 of the Common approach)

Number of units transfused (if available) :

0

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

For further instructions on how to report SAR and imputability levels, please see point 2.3 of the Common approach.

(Please note: The table below should only be filled in if there are cases of reportable SAR. Absence of data in a field means '0' or 'Not available.' If you are not reporting any SAR, please specify in the comments box whether this was because there were no reportable SAR or whether there was no data available for this component.)



# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
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
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Anaphylaxis/hypersensitivity	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion related acute lung injury	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
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

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted parasitical infection	Malaria	Total no death				0
		Total deaths				0



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

Add other type of Transfusion-transmitted  
parasital infection

			Level 1	Level 2	Level 3	Total
Post-transfusion purpura		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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 :

# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

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

### Red blood cells

Number of units issued \* :

**184104**

Total number of units issued of this blood component.  
(See section 2.2.1 of the Common approach)

Number of recipients transfused (if available) :

**50286**

Total number of recipients transfused with this blood component.  
(See section 2.2.2 of the Common approach)

Number of units transfused (if available) :

**182664**

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

For further instructions on how to report SAR and imputability levels, please see point 2.3 of the Common approach.

(Please note: The table below should only be filled in if there are cases of reportable SAR. Absence of data in a field means '0' or 'Not available.' If you are not reporting any SAR, please specify in the comments box whether this was because there were no reportable SAR or whether there was no data available for this component.)

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
Immunological Haemolysis	Due to ABO incompatibility	Total no death			1	1
		Total deaths				0
	Due to other allo-antibody	Total no death			1	1
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total



# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

Anaphylaxis/hypersensitivity		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Transfusion related acute lung injury		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted parasitical infection	Malaria	Total no death				0
		Total deaths				0

Add other type of Transfusion-transmitted parasitical infection

			Level 1	Level 2	Level 3	Total
Post-transfusion purpura		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Graft versus host disease		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
TACO		Total no death		1	1	2
		Total deaths				0
			Level 1	Level 2	Level 3	Total



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

DSTR		Total no death			3	3	X
		Total deaths				0	
			Level 1	Level 2	Level 3	Total	
Febrile non-haemolytic transfus		Total no death	1			1	X
		Total deaths				0	
			Level 1	Level 2	Level 3	Total	
Other please specify here		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 :

9

Comments :



# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

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

### Platelets

Number of units issued \* :

**28556**

Total number of units issued of this blood component.  
(See section 2.2.1 of the Common approach)

Number of recipients transfused (if available) :

**4845**

Total number of recipients transfused with this blood component.  
(See section 2.2.2 of the Common approach)

Number of units transfused (if available) :

**27718**

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

For further instructions on how to report SAR and imputability levels, please see point 2.3 of the Common approach.

(Please note: The table below should only be filled in if there are cases of reportable SAR. Absence of data in a field means '0' or 'Not available.' If you are not reporting any SAR, please specify in the comments box whether this was because there were no reportable SAR or whether there was no data available for this component.)

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
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
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total



# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

Anaphylaxis/hypersensitivity		Total no death		1		1
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Transfusion related acute lung injury		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted parasitical infection	Malaria	Total no death				0
		Total deaths				0

Add other type of Transfusion-transmitted parasital infection

			Level 1	Level 2	Level 3	Total
Post-transfusion purpura		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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 :

1



**REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

**Blood - Directive 2005/61/EC**

Comments :

## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

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

#### Plasma

Number of units issued \* :

58567

Total number of units issued of this blood component.  
(See section 2.2.1 of the Common approach)

Number of recipients transfused (if available) :

12096

Total number of recipients transfused with this blood component.  
(See section 2.2.2 of the Common approach)

Number of units transfused (if available) :

52712

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

For further instructions on how to report SAR and imputability levels, please see point 2.3 of the Common approach.

(Please note: The table below should only be filled in if there are cases of reportable SAR. Absence of data in a field means '0' or 'Not available.' If you are not reporting any SAR, please specify in the comments box whether this was because there were no reportable SAR or whether there was no data available for this component.)

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
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
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis	Total no death				0	
	Total deaths				0	
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection	Total no death				0	
	Total deaths				0	
			Level 1	Level 2	Level 3	Total



# REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

## Blood - Directive 2005/61/EC

Anaphylaxis/hypersensitivity		Total no death			1	1
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Transfusion related acute lung injury		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted parasitical infection	Malaria	Total no death				0
		Total deaths				0

Add other type of Transfusion-transmitted parasital infection

			Level 1	Level 2	Level 3	Total
Post-transfusion purpura		Total no death		1		1
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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

**REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

**Blood - Directive 2005/61/EC**

Comments :



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

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

### More than one blood component transfused

For further instructions on how to report SAR and imputability levels, please see point 1.5 of the Common approach .

Denominators are not to be reported for this section. Units issued, recipients transfused and units transfused should instead be reported separately under the relevant sections (whole blood, red blood cells, plasma and platelets).

(Please note: The table below should only be filled in if there are cases of reportable SAR. Absence of data in a field means '0' or 'Not available.' If you are not reporting any SAR, please specify in the comments box whether this was because there were no reportable SAR or whether there was no data available for this component.)

Imputability level after confirmation of the Serious Adverse Reaction(s)			Level 1	Level 2	Level 3	Total
Immunological Haemolysis	Due to ABO incompatibility	Total no death				0
		Total deaths				0
	Due to other allo-antibody	Total no death			1	1
		Total deaths				0
			Level 1	Level 2	Level 3	Total
Non-immunological Haemolysis	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion-transmitted bacterial infection	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Anaphylaxis/hypersensitivity	Total no death					0
	Total deaths					0
			Level 1	Level 2	Level 3	Total
Transfusion related acute lung injury	Total no death					0
	Total deaths					0



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

			Level 1	Level 2	Level 3	Total
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

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted parasitical infection	Malaria	Total no death				0
		Total deaths				0

Add other type of Transfusion-transmitted parasital infection

			Level 1	Level 2	Level 3	Total
Post-transfusion purpura		Total no death				0
		Total deaths				0
			Level 1	Level 2	Level 3	Total
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 :

1

Comments :

**REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

**Blood - Directive 2005/61/EC**



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

#### Annual notification for Serious Adverse EVENT(S)

(See section 3 of the Common approach)

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

194291

Whole blood collections

192171

Apheresis collections

4585

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

X

Whole blood collection

Specification	Additional details (if available)	Quantity	
Human error		3	X
Total		3	
Add a new specification			

Comments :

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

X

Testing of donations

Specification	Additional details (if available)	Quantity	
Human error		2	X



## REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)

### Blood - Directive 2005/61/EC

Other, please specify here		1	X
Total		3	
<a href="#">Add a new specification</a>			

Comments :

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

X

#### Processing

Specification	Additional details (if available)	Quantity	
Other, please specify here		1	X
Total		1	
<a href="#">Add a new specification</a>			

Comments :

[Add a new category of serious adverse event\(s\)](#)



**REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

**Blood - Directive 2005/61/EC**

*General comments on this Annual Notification :*

## **REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**

### **Blood - Directive 2005/61/EC**

#### *Privacy statement*

#### *Enforcement action – Communicators Network*

##### *Purpose and scope of personal data processing:*

The reporting document is for the collection of national contributions to reports on enforcement actions. The information gathered includes two contact points:

- i) one which has been authorised by the reporting Member State to act as contact point for the press on the enforcement action concerned, and which can be published and
- ii) a second which identifies a contact point for the Commission for any discussions with Member States on their reports; these contacts will not be published.

##### *The information collected and the purpose of a contact point in this context:*

Your data are recorded and stored as long as follow-up actions are needed in the context of each enforcement action. Your data will be handled in conformity with Regulation (EC) N° 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data.

##### *Right of rectification & personal data controller:*

Should you require further information concerning the processing of your personal data or wish to exercise your rights (e.g. access or rectify any inaccurate or incomplete data) please contact the following mailbox:

**[SANTE-SARE@ec.europa.eu](mailto:SANTE-SARE@ec.europa.eu)**

You have the right of recourse at any time to the European Data Protection

Supervisor at **[edps@edps.europa.eu](mailto:edps@edps.europa.eu)**



