European Commission

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 **n**ot **a**vailable, 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, describe the issue and mention the version of this document: 2018 2.6.3
7) Privacy statement (see last page)

Submission date	Submission number
Friday, June 29, 2018 14:46:59	1530276425065-2464

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 2017 - 31 December 2017 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)	265448
Total number of recipients transfused regardless the type of component (See section 1.3.4 of the Common approach)	64238
Total number of units transfused regardless the type of component (See section 1.3.5 of the Common approach)	227915

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)* **241**

Please provide additional detail about any reported death in a donor of blood or blood components (NB please also include any deaths in the total numbers of donor SAR above.)

	Specifications	Nr
Whole Blood	Nerve injury/irritation	
	Vasovagal reaction	231
	Major cardiovascular event or death up to 24 hours after donation (include imputability assessment in comment box below)	
	Other	
Apheresis	Nerve injury/irritation	
	Vasovagal reaction	1
	Citrate reaction	
	Allergic reaction	
	Major cardiovascular event or death up to 24 hours after donation (include imputability assessment in comment box below)	
	Other	9

Comments regarding this notification for Serious Adverse Reaction(s) in donors

Other= haematoma

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 tranfused (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.)

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

Add other type of Transfusion-transmitted parasital infection

			Level 1	Level 2	Level 3	Total
Transfusion-transmitted fungal infection		Total no death				0
		Total deaths				0
			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 :

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

Red blood cells

*Number of units issued * :*

181954

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

Number of recipients transfused (if available) :

47965

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

Number of units tranfused (if available) :

165001

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			2	2
		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

Add other type of Transfusion-transmitted parasital infection

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

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

Blood - Directive 2005/61/EC

Febrile non-haemolytic transfus		Total no death	1	2	1	4	x
		Total deaths				0	
			Level 1	Level 2	Level 3	Total	
TACO		Total no death		2		2	x
		Total deaths				0	

Add other serious adverse reaction(s)

Total number of Serious Adverses Reactions ***for this type*** *of blood component :* 8

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 :*

29580

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

Number of recipients transfused (if available) :

5200

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

Number of units tranfused (if available) :

16850

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

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
Transfusion-transmitted fungal infection		Total no death				0
		Total deaths				0
			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

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

Plasma

Number of units issued :*

53914

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

Number of recipients transfused (if available) :

11073

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

Number of units tranfused (if available) :

46054

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

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
Transfusion-transmitted fungal infection		Total no death				0
		Total deaths				0
			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

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

Blood - Directive 2005/61/EC

TACO		Total no death			2	2	X
		Total deaths				0	
			Level 1	Level 2	Level 3	Total	
a mild allergic 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 :* 4

Comments :

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				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

Add other type of Transfusion-transmitted parasital infection

			Level 1	Level 2	Level 3	Total	
Transfusion-transmitted fungal infection		Total no death				0	
		Total deaths				0	
			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	
Febrile non-haemolytic transfus		Total no death		1		1	x
		Total deaths				0	
			Level 1	Level 2	Level 3	Total	
multiple reactions		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 :* 2

Comments :

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)*	199017
Whole blood collections	194058
Apheresis collections	4959

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

Whole blood collection

x

Specification	Additional details (if available)	Quantity	
Human error		1	X
Total		1	

Add a new specification

Comments :

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

Testing of donations

x

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 * :*

Distribution

x

Specification	Additional details (if available)	Quantity	
Human error		1	X
Total		1	

Add a new specification

Comments :

Add a new category of serious adverse event(s)

General comments on this Annual Notification :

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

You have the right of recourse at any time to the European Data Protection Supervisor at *edps@edps.europa.eu*