

# REPORT TEMPLATE : *Serious Adverse Reaction(s) and Event(s)* *Tissues and Cells* **Directive 2006/86/EC**

version : 2.0



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

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## **Instructions to complete the report template:**

- 1) This form 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 Tissues and Cells Directive 2004/23/EC and Commission Directive 2006/86/EC - Version 1 (2009)".  
References to the relevant sections of the Common approach document are made on each question of this report template.
- 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) 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](mailto:SANCO-SARE@ec.europa.eu)
- 4) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page.
- 5) 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 in, 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.**
- 6) If the form is not properly filled in, 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 5). Should you still have any difficulties, please contact [SANCO-SARE@ec.europa.eu](mailto:SANCO-SARE@ec.europa.eu).
- 7) If you receive an error message, please send its reference to [SANCO-SARE@ec.europa.eu](mailto:SANCO-SARE@ec.europa.eu) in order to properly manage it.

**Submission number**

**1251473996812-610**

**REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)**  
**Tissues and Cells**  
**Directive 2006/86/EC**  
*version : 2.0*

Reporting country\* :

**Portugal**

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*This data collection refers to the period 1st January 2008 - 31 December 2008 included  
(See point 2.6.4 of the Common approach version 1)*

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## Annual notification for Serious Adverse REACTION(S)

Annual notification for Serious Adverse Reaction(s) related to \* :  
(Type of tissue/cell or product in contact with the tissues and cells)  
(See point 2.1 of Common approach version 1)

x

**Cornea**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**876**

Number of recipients affected :  
(See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
(See point 2.4 of Common approach version 1)

**747**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	

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Add a new row

<i>Transmitted malignant diseases</i>		
<b>Other disease transmissions</b> <i>(See point 2.5.1 of Common approach version 1)</i>		
<i>(please specify here)</i>		
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>		

Add a new Serious Reaction

<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0	
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>		

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Annual notification for Serious Adverse Reaction(s) related to \* :  
 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Skin**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**2,612**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**3**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	

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 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Amniotic membrane**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**74**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**53**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	



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Annual notification for Serious Adverse Reaction(s) related to \* :  
 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Bone**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**6**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**3**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	

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 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Heart Valve**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**5**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**5**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	

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Annual notification for Serious Adverse Reaction(s) related to \* :  
 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Bone Marrow**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**28**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

**1**

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**28**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	

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 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Peripheral Blood Stem Cells**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**343**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**324**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	



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Annual notification for Serious Adverse Reaction(s) related to \* :  
 (Type of tissue/cell or product in contact with the tissues and cells)  
 (See point 2.1 of Common approach version 1)



**Cord Blood**

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1) :

**9**

Number of recipients affected :  
 (See point 2.3 of Common approach version 1)

Total number of recipients for this type tissues and cells:  
 (See point 2.4 of Common approach version 1)

**9**

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.5 of Common approach version 1)		Total number of serious adverse reaction(s) (See point 2.6 of Common approach version 1)
Transmitted bacterial infection		
Transmitted viral infection	HBV	
	HCV	
	HIV-1/2	
<b>add other</b>		
Transmitted parasitical infection	Malaria	
<b>Add a new row</b>		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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<i>(please specify here)</i>	
<b>Other Serious Adverse Reaction(s)</b> <i>(See point 2.5.1 of Common approach version 1)</i>	
<b>Add a new Serious Reaction</b>	
<i>Total number Serious Adverse Reactions for this type of tissues and cells or products in contact with tissues and cells (this field is automatically calculated)</i>	0
<i>Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.5.2 of Common approach version 1).</i>	

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**Add a new annual notification of serious adverse reaction(s) for another type of tissue and cell**

Total number of Serious Adverses Reactions **for all types** of tissues and cells and products in contact with tissues and cells. (this field is automatically calculated)

0

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

Total number of tissues and cells processed :  
(See point 3.1 of Common approach version 1)

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**Add a new serious adverse event(s)**

*General comments on this Annual Notification :*