

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

version : 2.0



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

Submission number

1324039198515-1156

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

Portugal

*This data collection refers to the period 1st January 2009 - 31 December 2009 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) :

755

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

0

Total number of recipients for this type tissues and cells:

(See point 2.4 of Common approach version 1)

755

Comments :

There weren't any serious adverse reaction reported. 114 of all corneas procured were discarded. There were 40 incidents reported (anatomic defects of the corneas, packaging defects, positive microbiological analysis, etc)

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	
add other		
Transmitted parasitical infection	Malaria	

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Add a new row

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

2,025

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)

2

Comments :

Tissues presented in cm2.

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
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>	
Other Serious Adverse Reaction(s) <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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 (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) :

8

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)

8

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
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>	
Other Serious Adverse Reaction(s) <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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 (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) :

9,748

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)

82

Comments :

Tissue units presented in cm2

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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(please specify here)	
Other Serious Adverse Reaction(s) (See point 2.5.1 of Common approach version 1)	
<div style="background-color: #76b82a; color: white; padding: 5px; display: inline-block; border-radius: 10px;"> Add a new Serious Reaction </div>	
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)	<div style="border: 1px solid black; padding: 5px; width: 40px; margin: 0 auto;">0</div>
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).	

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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)



Bone Marrow

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

31

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)

24

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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(please specify here)	
Other Serious Adverse Reaction(s) <i>(See point 2.5.1 of Common approach version 1)</i>	
<div style="background-color: #76b82a; color: white; padding: 5px; display: inline-block; border-radius: 10px;"> Add a new Serious Reaction </div>	
<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>	<div style="border: 1px solid black; padding: 5px; width: 40px; margin: 0 auto;"> 0 </div>
<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) :

530

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)

362

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
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>	
Other Serious Adverse Reaction(s) <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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 (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) :

8

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)

8

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
Transmitted malignant diseases		
Other disease transmissions (See point 2.5.1 of Common approach version 1)		

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(please specify here)	
Other Serious Adverse Reaction(s) <i>(See point 2.5.1 of Common approach version 1)</i>	
<div style="background-color: #76b82a; color: white; padding: 5px; display: inline-block; border-radius: 10px;"> Add a new Serious Reaction </div>	
<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>	<div style="border: 1px solid black; padding: 5px; width: 40px; margin: 0 auto;"> 0 </div>
<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)



Bone

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

294

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)

293

Comments :

incomplete data

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	
add other		
Transmitted parasitical infection	Malaria	
Add a new row		
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>	
Other Serious Adverse Reaction(s) <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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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 : **22,451**
 (See point 3.1 of Common approach version 1)

Serious adverse event(s), which may have affected quality and safety of tissues and cells due to a deviation in * : (See point 3.2 of Common approach version 1)

x

Testing

Specification (See point 3.3 of Common approach version 1)	Please specify	Quantity	
Tissues and cells defect	Microbiologic contamination	10	X
Tissues and cells defect	anatomic defects	10	X
		20	
<input type="button" value="Add a new specification"/>			

Comments:

The total number or tissues and cells processed, include the Cord Blood Units stored in private banks (20429 units)

Serious adverse event(s), which may have affected quality and safety of tissues and cells due to a deviation in * : (See point 3.2 of Common approach version 1)

x

Storage

Specification (See point 3.3 of Common approach version 1)	Please specify	Quantity	
Equipment failure	container failure	12	X
		12	

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Add a new specification

Comments:

Serious adverse event(s), which may have affected quality and safety of tissues and cells due to a deviation in * : (See point 3.2 of Common approach version 1)

x

Distribution

Specification <small>(See point 3.3 of Common approach version 1)</small>	Please specify	Quantity	
Human error	errors in documents and in identification of tissues	20	X
		<input style="width: 50px; border: 1px solid #ccc; border-radius: 5px;" type="text" value="20"/>	

Add a new specification

Comments:

Add a new serious adverse event(s)

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General comments on this Annual Notification :

As regards to sperm, oocyte, embryo and other reproductive tissues and cells, there is no registry of serious adverse reactions and events occurred during 2009. Also, there are no available data concerning the number of reproductive tissues and cells distributed neither the total number of recipients for those types of tissues and cells.