REPORT TEMPLATE : Serious Adverse Reaction(s) and Event(s)
Tissues and Cells
Directive 2006/86/EC
version : 2.1

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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 1.1 (2011)".
References to the relevant sections of the Common approach document are made on each question of this report template.

2) Please check all the fields.The fields allow you to introduce '0' when data is available but the response is zero. BLANK FIELDS will be interpreted as DATA NOT AVAILABLE.

3) Should you need clarifications on some of the information requested, please contact SANCO-SARE@ec.europa.eu4.

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

1324039280903-1158

Reporting country :*

Portugal

This data collection refers to the period 1st January 2010 - 31 December 2010 included
(See point 2.5.4 of the Common approach version 1.1)

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 1.1)

Bone

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

1,297

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

0

Comments :

The 1297 units of bone distributed correspond to: 307 units of bones result of procurement in national donors; 990 units of demineralised bone imported;
It was nor possible to collect all the data concerning bone recipients, yet we know that the bone units distributed by the authorized tissue bank were implanted in 349 recipients

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
Transmitted bacterial infection		1
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		1
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Cornea

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

937

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

937

Comments :

162 of all (1002) corneas procured were discard

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)	
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 2.4.1 of Common approach version 1.1)			
0			
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)			
graft rejection		24	X
unexpected graft reabsortion		1	X
acute melting		1	X
	Add a new Serious Reaction		
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)		26	
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).			

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 1.1)

x

Amniotic membrane

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

169

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

Comments :

the 169 units distributed, represents 16470 cm2.
There were collected a total of 402 units (46431 cm2), and discard 122 units (11857 cm2)

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Heart Valve

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

6

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

6

Comments :

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Cord Blood

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

5

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

3

Comments :

2 units were subdivided in 4 fragments.

Total of 72647 cord blood units stored (66670 are stored in private cord blood banks for autologus use; 262 related units cryopreserved in public cord blood banks, 5715 units cryopreserved in public cord blood bank for allogenic use)

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Bone Marrow

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

32

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

19

Comments :

The 32 units distributed includes the units donated to other countries

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

x

Peripheral Blood Stem Cells

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

535

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

339

Comments :

The 535 units distributed includes the units donated to other countries.

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Sperm

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

Comments :

The number of recipients is not available. Data are collected by aggregated cycles.

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Oocyte

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

Comments :

The number of recipients is not available. Data are collected by aggregated cycles.

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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 1.1)

Embryo*

x

Number of tissues and cells of this type distributed (if available, see point 2.2 of Common approach version 1.1) :

Total number of recipients for this type tissues and cells (number of recipients affected):
(See point 2.3 of Common approach version 1.1)

Comments :

No case of embryo donation was reported.

Nature of the serious adverse reaction(s) reported (See point 2.4 of Common approach version 1.1)		Total number of serious adverse reaction(s) (See point 2.5 of Common approach version 1.1)
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 2.4.1 of Common approach version 1.1)		
(please specify here)		
Other Serious Adverse Reaction(s) (See point 2.4.1 of Common approach version 1.1)		
	Add a new Serious Reaction	
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)		0
Number of Serious Adverse Reactions in donors not influencing the quality and safety of tissues and cells (Reportable on a voluntary basis, see point 2.4.2 of Common approach version 1.1).		

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)*

27

Annual notification for Serious Adverse EVENT(S)

Total number of tissues and cells processed :
(See point 3.1 of Common approach version 1.1)

12,189

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 1.1)*

Processing

x

Specification (See point 3.3 of Common apporach version 1.1)	Please specify	Quantity	
Tissues and cells defect	positive microbiological results	82	X
Tissues and cells defect	anatomic defects	3	X
		85	

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 1.1)*

Procurement

x

Specification (See point 3.3 of Common apporach version 1.1)	Please specify	Quantity	
Human error	absence of identification or documentation	8	X
		8	

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 1.1)*

Storage

x

Specification (See point 3.3 of Common apporach version 1.1)	Please specify	Quantity	
Human error	wrong storage temperature	1	X
		1	

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 1.1)*

Transport

x

Specification (See point 3.3 of Common apporach version 1.1)	Please specify	Quantity	
Equiment failure	Packaging defect	7	X
		7	

Add a new specification

Comments:

Add a new serious adverse event(s)

General comments on this Annual Notification :

Cornea:
17 incidents reported (2 anatomic defects of the corneas, 11 positive microbiological analysis, 1 storage at wrong temperature, 3 incidents during processing)

Amniotic membrane:
There were 64 incidents reported (3 insufficient documentation, 2 absence of identification in the transport containers, 59 positive microbiological analysis)

Heart valve:
Tissue bank reported 3 incidents (insufficient documentation), detected when the tissue arrived at the Tissue establishment.

Cord Blood (autologus use - private banks):

The total number of tissues and cells processed, doesn't include the cord blood units processed in private banks (17500 units).
Total of 11715 incidents reported (8 packaging defects, 73 anatomic defects, 5447 insufficient documentation, 393 absence of identification in the containers, 8 the information present in the label didn't match the documentation, 1800 positive microbiological analysis, 523 incidents during transport, 3461 absence of samples (from the mother) to perform analysis)

Cord Blood (Public Bank)
(6 packaging defects, 64 anatomic defects, 672 insufficient documentation, 275 absence of identification in the containers, 62 positive microbiological analysis, 1 incidents during transport, 89 absence of samples (from the mother) to perform analysis)

Bone marrow:
1 incident reported (positive microbiological analysis)

Peripheral Blood Stem Cells:
19 incidents reported (7 packaging defects, 1anatomic defects, 11 positive microbiological analysis)

Reproductive tissues and cells:
0 incidents reported