



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

### **Tissues and Cells - Directive 2006/86/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 top 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: 2018 2.7.9
- 7) Where a Member State has **two different competent authorities** responsible for SARE reporting for tissues and cells, it is not possible to submit two separate electronic forms. In these circumstances, one competent authority should enter their data on the electronic form and **save it without submitting**; the second competent authority should then add their data and **submit** the form.
- 8) Privacy statement (see last page)

Submission date

Friday, July 13, 2018 15:58:36

Submission number

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

**Tissues and Cells - Directive 2006/86/EC**

Reporting country: CROATIA

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This data collection refers to the period

1 Jan 2017 - 31 Dec 2017

Competent Authority responsible for the reported data \* :

Ministry of Health of Republic of Croatia

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E-mail of Competent Authority responsible for the reported data \* :

biomedicina@miz.hr

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\* = mandatory field

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

**Annual notification for Serious Adverse Reactions**

NON-Reproductive T&C  yes  no

	Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipients for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR	Delete row
1	Skeletal tissues	yes										
1.1			GENERAL (to be filled out only if data for subcategories are not available)									
1.2			Bone	158	116	no						
1.3			Tendons/ligaments	2	2	no						
1.4			Cartilage	0	0	no						
1.5			Fascia	0	0	no						
1.6			Other (e.g. meniscus, ear, ossicles)	0	0	no						
2	Haematopoietic Stem Cells	yes										
2.1			GENERAL HPC (to be filled out only if data for subcategories are not available)									
2.2			Bone Marrow (auto-allo)	31	31	no						
2.3			Peripheral Blood Stem Cells (auto-allo)	377	213	no						
2.4			Cord Blood	1	0	no						
2.5			Donor lymphocyte infusions	47	15	no						
2.6			Other Haematopoietic Stem Cells	0	0	no						
3	Ocular Tissues (Cornea, Sclera, Other Ocular tissue)	yes										
3.1			General Ocular Tissues (to be filled out only if data for subcategories are not available)									
3.2			Cornea	328	335	no						
3.3			Sclera	8	6	no						

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

Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipients for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR	Add row	Delete row
3.4		Other	0	0	no							
4	yes	Cardiovascular Tissues										
4.1		GENERAL CV (to be filled out only if data for subcategories are not available)										
4.2		Heart Valve	9	8	no							
4.3		Vessel	2	1	no							
4.4		Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	2	1	no							
5	yes	Skin (units)										
5.1		Skin (units)	196	10	no							
6	no	Multiple T&C										
7	yes	Other tissues or cells (units)										
7.1		Pancreatic Islets	0	0	no							
7.2		Hepatocytes	0	0	no							
7.3		Amniotic membrane	133	114	no							
7.4		Other (e.g. adipose tissue, tympanic membrane)	0	0	no							

### Non-reproductive T&C SAR Totals

Total nr tissues&cells distributed	Total nr of recipients	Total nr of SAR	1. Nr SAR Transmitted of transmitted infections	2. Nr. SAR Transmitted malignant diseases	3. Nr. SAR Transmitted genetic diseases	4. Nr. Other SAR
1,294	852	0	0	0	0	0

### Deaths Associated with SAR

Total number of SAR that resulted in recipient death: 0

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

General comments on SAR NON REPRODUCTIVE TISSUES AND CELLS :

From 196 distributed skin units, 116 was homologous skin allografts and 80 skin units was glycerolized cadaveric skin allografts imported from EU Tissue Bank.

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

Reproductive T&C  yes  no

Order	Type of Tissue and Cells	yes/ no	Specification	Nr of T&C distributed	Total nr recipients for each T&C	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR
1	SPERM	yes									
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)								
1.2			Sperm - partner donation	1798	1193	no					
1.3			Sperm - Non-partner donation	0	0	no					
2	EMBRYO	yes									
2.1			General embryos (to be filled out only if data for subcategories are not available)								
2.2			Embryos, partner gametes	8808	4083	no					
2.3			Embryos, donor sperm, partner oocyte	0	0	no					
2.4			Embryos, donor oocyte, partner sperm	0	0	no					
2.5			Embryos, donor sperm and oocyte	0	0	no					
3	Other Reproductive tissues an cells (e.g. ovarian or testicular tissue)	yes									
3.1			Ovarian tissue	3	3	no					
3.2			Testicular tissue	113	0	no					
3.3			Other	0	0	no					

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

<b>Reproductive T&amp;C SAR Totals</b>						
<b>Total nr tissues&amp;cells distributed</b>	<b>Total nr of recipients</b>	<b>Total nr of SAR</b>	<b>1. Nr SAR Transmitted of transmitted infections</b>	<b>2. Nr SAR Transmitted malignant diseases</b>	<b>3. Nr. SAR Other disease transmissions</b>	<b>4. Nr. Other SAR</b>
10,722	5,279	0	0	0	0	0

**Deaths Associated with SAR**

**Total number of SAR that resulted in recipient death: 0**

General comments on SAR REPRODUCTIVE TISSUES AND CELLS :

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

# Annual notification for Serious Adverse Events

NON-Reproductive Tissues and Cells processed  yes  no

	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE	Add row	Delete row
1	Skeletal tissues	yes										
1.1			GENERAL (to be filled out only if data for subcategories are not available)									
1.2			Bone	244	no							
1.3			Tendons/Ligaments	0	no							
1.4			Cartilage	0	no							
1.5			Fascia	0	no							
1.6			Other (e.g. meniscus, ear, ossicles)	0	no							
2	Haematopoietic Stem Cells	yes										
2.1			GENERAL HPC (to be filled out only if data for subcategories are not available)									
2.2			Bone Marrow (auto-allo)	33	no							
2.3			Peripheral Blood Stem Cells (auto-allo)	620	no							
2.4			Cord Blood	1473	no							
2.5			Donor Lymphocyte Infusions	32	no							
2.6			Other Haematopoietic Stem Cells	0	no							
3	Ocular Tissues (Cornea, Sclera, Other Ocular tissue)	yes										
3.1			General Ocular Tissues (to be filled out only if data for subcategories are not available)									



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

Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE	Add row	Delete row
3.2		Cornea	558	no							
3.3		Sclera	19	no							
3.4		Other	22	no							
4	yes	Cardiovascular Tissues									
4.1		GENERAL CV (to be filled out only if data for subcategories are not available)									
4.2		Heart Valve	6	no							
4.3		Vessel	8	no							
4.4		Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	1	no							
5	yes	Skin (units)									
5.1		Skin (units)	121	no							
6	no	Multiple T&C									
7	yes	Other tissues or cells (units)									
7.1		Pancreatic Islets	0	no							
7.2		Hepatocytes	0	no							
7.3		Amniotic membrane	64	no							
7.4		Other (e.g. adipose tissue, tympanic membrane)	0	no							

### Non-reproductive SAE Totals

Total nr tissues & cells processed	Total nr of SAE	1. Tissue or cell defect	2. Equipment failure	3. Human error	4. Other
3,201	0	0	0	0	0

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

General comments on SAE NON REPRODUCTIVE TISSUES AND CELLS :

## Reproductive Tissues and Cells processed yes no

Order	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE
1	SPERM	yes								
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)							
1.2			Sperm - partner donation	7387	no					
1.3			Sperm - Non-partner donation	0	no					
2	OVOCYTES	yes								
2.1			GENERAL Oocyte (to be filled out only if data for subcategories are not available)							
2.2			Ovocytes - Partner donation	27196	no					
2.3			Ovocytes - Non-partner donation	0	no					
3	EMBRYO	yes								
3.1			General embryos (to be filled out only if data for subcategories are not available)							
3.2			Embryos, partner gametes	17628	no					

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

Order	Type of Tissues and Cells	yes/ no	Specification	Nr of T&C processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE
3.3			Embryos, donor sperm, partner oocyte	0	no					
3.4			Embryos, donor oocyte, partner sperm	0	no					
3.5			Embryos, donor sperm and oocyte	0	no					
4	Other Reproductive tissues an cells (e.g. ovarian or testicular tissue)	yes								
4.1			Ovarian tissue	3	no					
4.2			Testicular tissue	190	no					
4.3			Other	0	no					

### Reproductive SAE Totals

Total nr tissues&cells processed	Total nr of SAE	1. Tissue or cell defect	2. Equipment failure	3. Human error	4. Other
52,404	0	0	0	0	0

General comments on SAE REPRODUCTIVE TISSUES AND CELLS :

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

## **Annual notification for Serious Adverse Reactions in DONORS**

SAR in Donors - Non-reproductive tissues and cells     yes     no

General comments on SERIOUS ADVERSE REACTIONS in DONORS - Non-Reproductive tissues and cells :

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

SAR in Donors - Reproductive tissues and cells     yes     no

Tissue and cell donor	Specification of SARs in DONORS (not influencing the quality and safety of tissues and cells)	Number	Add row	Delete row
6. Oocytes - partner donation	OHSS	7	+	X
6. Oocytes - partner donation	Bleeding after follicular aspiration	1	+	X
6. Oocytes - partner donation	Bleeding and laparoscopic operation after ovarian aspiration	3	+	X
6. Oocytes - partner donation	Oophoritis after ovarian aspiration	1	+	X
6. Oocytes - partner donation	Ovarian hematoma	1	+	X
6. Oocytes - partner donation	Heterotopic pregnancy	1	+	X

<b>Total nr of SAR IN DONORS - Reproductive tissues and cells</b>	14
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### Deaths Associated with SAR in DONORS (REPRODUCTIVE)

<b>Total number of SAR that resulted in donor death:</b>	0
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General comments on SERIOUS ADVERSE REACTIONS in DONORS - Reproductive tissues and cells :

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

### **Tissues and Cells - Directive 2006/86/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***

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

*Supervisor at *edps@edps.europa.eu**