

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

Tissues and Cells - Directive 2006/86/EC

Instructions to complete the form:

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- 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.
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- 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)

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

Reporting country: CROATIA

This data collection refers to the period

1 Jan 2019 - 31 Dec 2019

*Competent Authority responsible for the reported data ** :

Ministry of Health of the Republic of Croatia

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

biomedicina@miz.hr

* = mandatory field

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

Annual notification for Serious Adverse Reactions in RECIPIENTS - Non-reproductive T&C

Is there any activity of donation, distribution and clinical application for these tissues and cells in your country?

NON-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	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	206	141	no							
1.3			Tendons/Ligaments	1	1	no							
1.4			Cartilage	0	0	no							
1.5			Fascia	0	0	no							
1.6			Other (e.g. meniscus, ear, ossicles)	2	2	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)	41	29	no							
2.3			Peripheral Blood Stem Cells (auto-allo)	443	233	no							
2.4			Cord Blood	0	0	no							
2.5			Donor Lymphocyte infusions	35	12	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)										

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

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	Add ROW	Delete ROW
3.2			Cornea	342	373	no							
3.3			Sclera	5	2	no							
3.4			Other	0	0	no							
4	Cardiovascular Tissues	yes											
4.1			GENERAL CV(to be filled out only if data for subcategories are not available)										
4.2			Heart Valve	1	1	no							
4.3			Vessel	5	2	no							
4.4			Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	0	0	no							
5	Skin (units)	yes											
5.1			Skin (units)	18	4	no							
6	Multiple T&C	no											
7	Other tissues or cells (units)	yes											
7.1			Pancreatic Islets	0	0	no							
7.2			Hepatocytes	0	0	no							
7.3			Amniotic membrane	166	120	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 infections	2. Nr SAR Transmitted malignant diseases	3. Nr. SAR Other disease transmission	4. Nr. Other SAR
1,265	860	0	0	0	0	0

Deaths Associated with SAR

Total number of SAR that resulted in recipient death:

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

General comments on SAR NON REPRODUCTIVE TISSUES AND CELLS :

From 342 distributed corneas 30 were imported from the Czech Republic and redistributed by tx center.

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

Annual notification for Serious Adverse Reactions in RECIPIENTS - Reproductive T&C

Is there any activity of donation, distribution and clinical application for these tissues and cells in your country?

Reproductive T&C yes no

Order	Type of Tissue and Cells	yes/ no	Specification	Nr of TEC distributed	Total nr recipients for each TEC	SAR yes/no	SAR Type	yes/no	Subtype of SAR	Description/Comments SAR	Number of SAR
1	SPERM (IUI)	yes									
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)								
1.2			Sperm - partner donation	1469	988	no					
1.3			Sperm - Non-partner donation	0	0	no					
2	EMBRYO (IVF)	yes									
2.1			General embryos (to be filled out only if data for subcategories are not available)								
2.2			Embryos, partner gametes	9140	4570	yes					
2.2.1							1. Transmitted infections	no			
2.2.2							2. Transmitted malignant diseases	no			
2.2.3							3. Transmitted genetic conditions	no			
2.2.4							4. Other SAR	yes			
2.2.4.0									1. Ectopic pregnancy (requiring	Ectopic pregnancy	5
2.3			Embryos, donor sperm, partner oocyte	0	0	no					
2.4			Embryos, donor oocyte, partner sperm	0	0	no					

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

Order	Type of Tissue and Cells	yes/ no	Specification	Nr of TBC distributed	Total nr recipients for each TBC	SAR yes/no	SAR Type	yes/no	Sub-type of SAR	Description/Comments SAR	Number of SAR
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	0	0	no					
3.2			Testicular tissue	242	0	no					
3.3			Other	0	0	no					

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 conditions	4. Nr. Other SAR
10,851	5,558	5	0	0	0	5

Deaths Associated with SAR

Total number of SAR that resulted in recipient or offspring death:

General comments on SAR REPRODUCTIVE TISSUES AND CELLS :

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

Annual notification for Serious Adverse Events associated to NON-Reproductive T&C

Does your MS have had any activity in non-reproductive tissue and cells for human application?

NON-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	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	303	no							
1.3			Tendons/ligaments	1	no							
1.4			Cartilage	0	no							
1.5			Fascia	0	no							
1.6			Other (e.g. meniscus, ear, ossicles)	2	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)	30	no							
2.3			Peripheral Blood Stem Cells (auto-allo)	790	no							
2.4			Cord Blood	1137	no							
2.5			Donor lymphocyte infusions	27	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)

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	Add row	Dele te row
3.2			Cornea	528	no							
3.3			Sclera	9	no							
3.4			Other	0	no							
4	Cardiovascular Tissues	yes										
4.1			GENERAL CV (to be filled out only if data for subcategories are not available)									
4.2			Heart Valve	4	no							
4.3			Vessel	0	no							
4.4			Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	0	no							
5	Skin (units)	yes										
5.1			Skin (units)	0	no							
6	Multiple T&C	no										
7	Other tissues or cells (units)	yes										
7.1			Pancreatic islets	0	no							
7.2			Hepatocytes	0	no							
7.3			Amniotic membrane	416	yes							
7.3.0						0. Transport	yes					
7.3.0.4								4. Human error	Courier service error. 1	1	+	X
7.3.1						1. Donor selection	no					
7.3.2						2. Procurement	no					
7.3.3						3. Testing	no					
7.3.4						4. Processing	no					
7.3.5						5. Storage	yes					
7.3.5.2								2. Equipment failure	Freezer failure. 59	1	+	X
7.3.6						6. Product selection (possible TE and ORHA activity step)	no					

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

7.3.7					7. Issue (possible TE and DRHA activity step)	no			
7.3.8					8. Distribution	no			
7.3.9					9. Other	no			
7.4				Other (e.g. adipose tissue, tympanic membrane)	no				

Non-reproductive SAE Totals

Total nr tissues&cells processed	Total nr of SAE	1. Tissue or cell defect	2. Equipment failure	3. Materials	4. Human error	5. System failure	6. Other
3,247	2	0	1	0	1	0	0

General comments on SAE NON-REPRODUCTIVE TISSUES AND CELLS :

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

Annual notification for Serious Adverse Events associated to Reproductive T & C

Does your MS have had any activity in reproductive tissue and cells for human application?

Reproductive Tissues and Cells processed yes no

Order	Type of Tissues and Cells	yes/ no	Specification	Nr of TEC processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE
1	SPERM (IUI)	yes								
1.1			GENERAL Sperm (to be filled out only if data for subcategories are not available)							
1.2			Sperm - partner donation	6566	no					
1.3			Sperm - Non-partner donation	0	no					
2	OOCYTES	yes								
2.1			GENERAL Oocyte (to be filled out only if data for subcategories are not available)							
2.2			Oocytes - Partner donation	31256	yes					
2.2.0						0. Transport	no			
2.2.1						1. Donor selection	yes			
2.2.1.4								4. Human error	Infected oocytes in the IVF procedure due to a contaminated sperm sample - 4 oocytes	1
2.2.2						2. Procurement	no			
2.2.3						3. Testing	no			
2.2.4						4. Processing	no			
2.2.5						5. Storage	no			

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

Order	Type of Tissues and Cells	yes/ no	Specification	Nr of rBC Processed	SAE yes/no	Activity Step	yes/no	SAE Specification	Description and Number of T&C affected	Number of SAE
2.2.6						6.Product selection (possible TE and ORHA activity step)	no			
2.2.7						7.Issue (possible TE and ORHA activity step)	no			
2.2.8						8.Distribution	no			
2.2.9						9.Other	no			
2.3			Oocytes - Non- partner donation	0	no					
3	EMBRYO (IVF)	yes								
3.1			General embryos (to be filled out only if data for subcategories are not available)							
3.2			Embryos, partner gametes	20755	yes					
3.2.0						0.Transport	no			
3.2.1						1.Donor selection	no			
3.2.2						2.Procurement	no			
3.2.3						3. Testing	no			
3.2.4						4.Processing	no			
3.2.5						5.Storage	yes			
3.2.5.1								1. Tissue or Cell Defect	Contamination of ejaculate in embryo culture (E.coti) - 4 embryos	1
3.2.6						6.Product selection (possible TE and ORHA activity step)	no			
3.2.7						7.Issue (possible TE and ORHA activity step)	no			
3.2.8						8.Distribution	no			
3.2.9						9.Other	no			
3.3			Embryos, donor sperm, partner oocyte	0	no					

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

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	0	no				
4.2		Testicular tissue	761	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. Materials	4. Human error	5. System failure	5. Other
59,338	2	1	0	0	1	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 - Non-reproductive T&C

Is there any activity of donation, distribution and clinical application for these tissues and cells in your country?

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)

Annual notification for Serious Adverse Reactions in DONORS - Reproductive T&C

Is there any activity of donation, distribution and clinical application for these tissues and cells in your country ?

SAR in Donors - Reproductive tissues and cells yes no

Order	Type of donated tissue and cells	yes/ no	SAR yes/ no	SAR Type	Number of SAR (in donors)	Add row	Delete row
1	1.Oocytes	yes					
1.1			yes				
1.1.01				1.OHSS	1	+	X
1.1.04				4.Surgical complications	1	+	X
1.1.06				6.Reactions other than the above	1	+	X
2	2.Other reproductive tissues and surgically sperm (ovarian or testicular tissue, MESA, PESA and TESE)	no					

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.

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