European Commission

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 **n**ot **a**vailable, 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, describe the issue and mention the version of this document: 2016 2.5
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	Submission number
Friday, October 28, 2016 15:49:36	1477662574609-2218

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 2015 - 31 Dec 2015

*Competent Authority responsible for the reported data * :*

Ministry of Health

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

milena.ivankovic@miz.hr

** = mandatory field*

Annual notification for Serious Adverse Reactions

NON-Reproductive T&C ◉ *yes* ○ *no*

	Tissue type	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*	*189*	*182*	no							
1.3			*Tendons/ligaments*	*0*	*0*	no							
1.4			*Cartilage*	*0*	*0*	no							
1.5			*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)*	*39*	*26*	no							
2.3			*Peripheral Blood Stem Cells (auto+allo)*	*348*	*228*	no							
2.4			*Cord Blood)*	*0*	*0*	no							
2.5			*Donor lymphosyte infusions*	*13*	*8*	no							
2.6			*Other Haematopoietic Stem Cells*	*0*	*0*	no							
3	*Ocular Tissues (Cornea, Sclera, Other Ocular tissue)*	yes											
3.1			*Ocular Tissues (Cornea, Sclera, Other Ocular tissue)*	*312*	*352*	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*	*5*	*5*	no							

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

	Tissue type	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	Dele te row
4.3			Vessel	10	7	no							
4.4			Other Cardiovascular tissue (e.g. Conduit or Patch or Pericardium)	0	0	no							
5	Skin (units)	yes											
5.1			Skin (units)	174	4	no							
6	Other tissues or cells (units)	yes											
6.1			Pancreatic Islets	0	0	no							
6.2			Hepatocytes	0	0	no							
6.3			Amniotic membrane	122	NA	no							
6.4			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 Other disease transmissions	4. Nr. Other SAR
1,212	812	0	0	0	0	0

General comments on SAR NON REPRODUCTIVE TISSUES AND CELLS :

Difference between distributed and transplanted occular tissue is due to tissue import.

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

Reproductive T&C ◉ yes ○ no

Order	Tissue type	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	6098	2186	no					
1.3			Sperm - Non-partner donation	0	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	25016	NA	no					
2.3			Ovocytes - Non-partner donation	0	0	no					
3	EMBRYO	yes									
3.1			Embryo	9219	4529	no					
4	Other Reproductive tissues an cells (e.g.ovarian or testicular tissue)	yes									
4.1			Ovarian	0	0	no					
4.2			Testicular	123	NA	no					
4.3			Other	0	0	no					

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

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 Other disease transmissions	4. Nr. Other SAR
40,456	6,715	0	0	0	0	0

General comments on SAR REPRODUCTIVE TISSUES AND CELLS :

Annual notification for Serious Adverse Events

NON-Reproductive SAE ○ *yes* ◉ *no*

Number of Tissues and cells processed : NA

General comments on NON-Reproductive SERIOUS ADVERSE Events :

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

Reproductive SAE ○ *yes* ◉ *no*

Number of Tissues and cells processed : NA

General comments on Reproductive SERIOUS ADVERSE Events :

Annual notification for Serious Adverse Reactions in DONORS

SAR in Donors - Non-reproductive tissues and cells ○ *yes* ◉ *no*

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

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

Annual notification for Serious Adverse Reactions in DONORS

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. Ovocytes - partner donation	hospitalization after ovocytes aspiration due to infection caused by hydrosalpin	1	+	X
6. Ovocytes - partner donation	hospitalization due to bleeding after oocite aspiration	1	+	X
6. Ovocytes - partner donation	hospitalization due to rupture of the corpus luteum with bleeding in the abdom	1	+	X

Total nr of SAR IN DONORS - Reproductive tissues and cells
3

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

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

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-BI@ec.europa.eu

You have the right of recourse at any time to the European Data Protection Supervisor at *edps@edps.europa.eu*