EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Brussels, October 2008
SANCO C6 EFZ/PS D (2008)

Summary Table of
Responses from Competent Authorities:
Questionnaire on the transposition and implementation of the European Tissues and Cells regulatory framework

In preparation of the second meeting of competent authorities on tissues and cells which the Commission convenes in order to exchange experiences in the transposition of the Directives into their national law, competent authorities were invited to complete a questionnaire covering the transposition and implementation of the Tissues and Cells regulatory framework. This table presents responses regarding the situation from the Member States and EEA countries as of 30 May 2008.

1. PUBLIC INFORMATION

AUSTRIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Bundesamt für Sicherheit im Gesundheitswesen
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Schnirchgasse 9 A-1030 Wien
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+4305055536214
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	robert.pilacek@ages.at
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.ages.at
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
BELGIUM	

1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Federal Agency for Medicines and Health Products
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Eurostation II Place Victor Horta 40/40 1060 Brussels
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	00 32 (0) 2 524 80 00
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info.FAGG_AFMPS@afmps.be
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.afmps.be
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.afmps.be www.eurocet.org
BULGARIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Executive Agency for Transplantation

1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Bratya Miladinovi Str.112, Sofia 1202, Bulgaria
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+35928135010
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	iat@bgtransplant.bg
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.bgtransplant.bg
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report ,	The reports of tissue bank yearly activities are part of public register of Executive Agency for Transplantation but they are still not translated in English and uploaded at webpage of the Agency.
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.bgtransplant.bg -register-public register
CROATIA	

1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	MINISTRY OF HEALTH AND SOCIAL WELFARE
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	KSAVER 200a, 10000 ZAGREB, CROATIA
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	++38514607555
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	Mirela.Busic@mzss.hr
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.mzss.hr
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1) of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
CYPRUS	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	MEDICAL AND PUBLIC HEALTH SERVICES, MINISTRY OF HEALTH

1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	1 PRODROMOU AND 17 CHILONOS STREET, 1448, NICOSIA, CYPRUS
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	00357 22 605385
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	emissouri@mphs.moh.gov.cy
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.moh.gov.cy
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
CZECH REPUBLIC	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Ministry of Health of the Czech Republic
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Ministry of Health Department of The Health Care Palackého náměstí 4 128 01 Praha 2

1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 420 224971111
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	mzcr@mzcr.cz
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.mzcr.cz
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	www.kst.cz
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.kst.cz www.mzcr.cz
DENMARK	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Danish Medicines Agency National Board of Health
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	1 Axel Heides Gade, Copenhagen, Denmark.

1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+45 4488 9595
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	vaevogceller@dkma.dk
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	http://www.laegemiddelstyrelsen.dk
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=13133
ESTONIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	State Agency of Medicines
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	1 Nooruse Street 50411 Tartu ESTONIA

1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	phone: +372 7 374 140
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info@ravimiamet.ee
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.ravimiamet.ee
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1) of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
FINLAND	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	National Agency for Medicines (NAM)
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Mannerheimintie 103b P.O. Box 55 FI-00301 Helsinki Finland
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 358 9 4733 41

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	registry@nam.fi
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.nam.fi or www.laakelaitos.fi
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.laakelaitos.fi/laaketeollisuus/kudoslaitos/index.html
FRANCE	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	1) Health Ministry 2) French health products and safety Agency 3) Agence de la biomédecine
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	1) 14 avenue Duquesne -75700-PARIS 2)143/147 BD Anatole France-93285-SANT-DENIS-Cedex 3) 1, avenue du stade de France -93212-LA PLAINE SAINT DENIS-FRANCE
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	1) 33 1 01 40 56 50 61 2) 33 1 55 87 40 41 3) 33 1 55 93 65 or 33 1 55 93 69 01
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	1) genevieve.liffran@sante.gouv.fr 2) Fenzi.teskrat@afssaps.sante.fr 3) francoise.merlet@biomedecine.fr 4)helene.esperou@biomedecine.fr
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	http://agmed.sante.gouv.fr wwww.agence-biomedecine.fr

1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	http://www.agence-biomedecine.fr/fr/experts/chiffres-rapport.aspx HTTP://AFSSAPS.SANTE.FR/PDF/5/RAPPORT_ACTIVITE_BANQUE_TISSU_ORIGINE_HUMAINE
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	HTTP://AFSSAPS.SANTE.FR/PDF/5/RAPPORT_ACTIVITE_BANQUE_TISSU_ORIGINE_HUMAINE http://www.agence.biomedecine.fr/fr/rapport_2007/som/som_tissus_gene.htm http://www.agence.biomedecine.fr/fr/rapport_2007/som/som_cellules_gene.htm http://www.agence-biomedecine.fr/fr/experts/pegh-pma.aspx
GERMANY	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Paul-Ehrlich-Institut
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Paul-Ehrlich-Straße 51-59 D-63225 Langen
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	0049/6103-77-0
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	pei@pei.de

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.pei.de
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	in work
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Not yet
GREECE	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Hellenic Transplant Organisation
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	5, An. Tsoha st; 115 21 Athens, Greece
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	++ 30 210 6471200
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	eom@eom.gr

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.eom.gr
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	N/a
HUNGARY	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	National Public Health and Medical Officer' Service (NPHMOS) Office of the Chief Medical Officer
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	H-1097 Budapest Gyáli str. 2-6
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	(00-36) 476-1324
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	balogh.attila@oth.antsz.hu

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	igazgatas@oth.antsz.hu
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1) of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
ICELAND	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Ministry of Health
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Vegmuli 3 IS 150 Reykjavik Iceland
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+354 545 8700
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	postur@hbr.stjr.is
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	http://www.heilbrigdisraduneyti.is

1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
IRELAND	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	The Irish Medicines Board
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+353 1 676 4971
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	patrick.costello@imb.ie
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.imb.ie
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report	

1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.imb.ie/EN/Blood-Tissues--Cells/Blood--Tissue-Establishments-.aspx?page=1&name=&orderby=name&orderascending=True&type=3&sitestatus=1&withdrawdate=
ITALY	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Italian National Transplant Center Other CA: CNS (Italian National Blood Center): blood and cord blood cells (shared with CNT) Regional Health Authorities: certain aspects of data collection, adverse event management and tissue establishment authorisation
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Viale Regina Elena 299, 00161 Roma
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+39 06 49904040
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	cnt@iss.it
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.trapianti.ministerosalute.it

1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.trapianti.ministerosalute.it/cnt/cntDettaglioMenu.jsp?id=76&area=cnt-tessuti&menu=menuPrincipale&sotmenu=istituzioni&label=mti&livello=1
LATVIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	State Agency of Health Statistics and Medical Technologies
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Duntes iela 12/22, Riga, LV-1005, Latvia
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 371 67 50 15 90

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	agentura@vsmtva.gov.lv
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	http://www.vsmtva.gov.lv
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	http://www.vsmtva.gov.lv/web/lv/datubazes/audu_un_org/index.aspx
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.vsmtva.gov.lv/web/lv/datubazes/audu_un_org/index.aspx
LIECHTENSTEIN	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Office of health/Dpt. Control of Pharmaceuticals
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Äulestrasse 51 9490 Vaduz Liechtenstein

1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	00423/ 236 73 31
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info@ag.llv.li
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.ag.llv.li
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Office of health/Dpt. Control of Pharmaceuticals
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Äulestrasse 51 9490 Vaduz Liechtenstein
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	00423/ 236 73 31

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info@ag.llv.li
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.ag.llv.li
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
LITHUANIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	National Bureau on Transplantation
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Santariskiu 2 Vilnius LT-08661 Lithuania
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 370 5 279 6096
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info@transplantacija.lt

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.transplantacija.lt
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
MALTA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Director General Public Health Regulation
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Ministry for Social Policy. "Palazzo Castellania" 15, Merchant Street, Valletta VLT 2000 MALTA
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 356 2299 2426
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	ray.busuttil@gov.mt

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	http://www.gov.mt/frame.asp?l=1&url=http://www.sahha.gov.mt
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
NORWAY	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	1. Norwegian Directorate of Health 2. Norwegian Board of Health Supervision
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	1. PB 7000 St. Olavs plass, NO - 0130 Oslo, Norway 2. P.O. Box 8128 Dep, NO-0032 Oslo, Norway
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	1. (+47) 810 20 050 2. (+47) 21 52 99 00
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	1. postmottak@shdir.no 2. postmottak@helsetilsynet.no
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	1. www.shdir.no 2. www.helsetilsynet.no

1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
Please provide us the report	
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	http://www.shdir.no/biogen/godkjente_vevsentre/
POLAND	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	NATIONAL CENTRE IOF TISSUE AND CELL BANKING
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	ul. Chalubinskiego 5, 02-004 Warsaw, Poland
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+48 22 621 75 43
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	akamin@ib.amwaw.edu.pl

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.kcbtik.pl
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	sent already
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.kcbtik.pl
PORTUGAL	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Autoridade para os Serviços de Sangue e Transplantação (ASST) Conselho Nacional de Procriação Medicamente Assistida (CNPMA)
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	ASST Av João Crisóstomo,9,1º 1049-062 Lisboa, Portugal CNPMA Assembleia da República Conselho Nacional de Procriação Medicamente Assistida, Palácio de São Bento, 1249-068 Lisboa, Portugal
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	ASST 00 351 213305135 CNPMA 00 351 213919303

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	ASST: asst@asst.min-saude.pt; CNPMA: CNPMA.Correio@ar.parlamento.pt
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.asst.min-saude.pt
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
ROMANIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	MINISTRY OF PUBLIC HEALTH through NATIONAL TRANSPLANT AGENCY and STATE SANITARY INSPECTION
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	National Transplant Agency – 2-8 Constantin Caracas Str, Floor 4, Sector 1, 011155, Bucharest State Sanitary Inspection - Ministry of Public Health, Cristian Popişteanu no. 1-3, sector 1, Bucharest, 010024

1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	National Transplant Agency: +40 317 101473 State Sanitary Inspection: + 4021 3072 557
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	National Transplant Agency: ant@transplant.ro, ant.msr@gmail.com ,State Sanitary Inspection: msiss@ms.ro
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.transplant.ro , www.ms.ro
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	www.transplant.ro
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.transplant.ro – Ministry of Public Health's Order no. 1216/2007
SLOVAKIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Ministerstvo zdravotnictva Slovenskej republiky

1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Limbová 2, P.O. BOX 52, 837 52 Bratislava 37
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+421 2 59373111
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	office@health.gov.sk
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.health.gov.sk
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report.	so far for tissue banks only
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
SLOVENIA	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)

1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Ptujska ulica 21 SI-1000 Ljubljana
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+386 8 2000 500
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	info@jazmp.si
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.jazmp.si
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
SPAIN	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Organización Nacional de Trasplantes
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	C/Sinesio Delgado 4, 28029. Madrid. Spain
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	0034 902300224

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	ont@msc.es
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.ont.es
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report	www.ont.es Estadísticas- Memoria de actividad de tejidos
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	www.ont.es biovigilancia- Registro de centros
SWEDEN	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	National Board of Health and Welfare Medical Product Agency
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	National Board of Health and Welfare SE-106 30 Stockholm Sweden Medical Products Agency SE-751 03 Uppsala Sweden
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	Torsten Mossberg +46-75-162 3033 Camilla Olofsson +46-75-162 3519 Kent Enqvist +46-18-17 47 05

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	torsten.mossberg@socialstyrelsen.se , camilla.olofsson@socialstyrelsen.se , kent.enqvist@mpa.se
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.socialstyrelsen.se , www.lakemedelsverket.se
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
SWITZERLAND	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Federal Office of Public Health (FOPH)
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Federal Office of Public Health (FOPH) CH-3003 Bern Switzerland
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	0041 31 323 51 54
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	julia.grünenfelder@bag.admin.ch

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.bag.admin.ch
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	no
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	No
TURKEY	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Ministry of Health, Turkey Directorate General of Curative Services Unit of Tissue and Cell Transplantation
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Sağlık Bakanlığı , Mithatpasa Cad No: 3 Tedavi Hizmetleri Genel Müdürlüğü, Organ ve Doku Nakli Hizmetleri Daire Başkanlığı, Doku ve Hücre Nakli Hizmetleri Şubesi B Blok 3 kat 8 numara. Sıhhıye/ Ankara/ Turkey Ministry of Health, Mithatpaşa Cad. No: 3 Directorate General of Curative Services, Directorate of Organ, Tissue and Cell Transplantation, Unit of Tissue and Cell Transplantation, B Block, 3. Flor No: 8 Sıhhiye/ Ankara/ Turkey
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	+ 90 312 585 15 09 and + 90 312 585 15 10 Mobile: + 90 505 914-6065

1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	zeynepcoskun2008@gmail.com
1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.saglik.gov.tr
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	no
UNITED KINGDOM	
1.2 Name of designated competent authority(ies) (Art. 4(1) Directive 2004/23/EC). (If there are multiple designated competent authorities, please indicate each one.)	Human Tissue Authority
1.3 Address. (If there are multiple designated competent authorities, please indicate the address for each one.)	Human Tissue Authority Finlaison House 15-17 Furnival Street London EC4A 1AB
1.4 Telephone (central access point). (If there are multiple designated competent authorities, please indicate the telephone number for each one.)	020 7211 3400
1.5 Email (central access point). (If there are multiple designated competent authorities, please indicate the e-mail for each one.)	enquiries@hta.gov.uk

1.6 Website. (If there are multiple designated competent authorities, please indicate the website for each one.)	www.hta.gov.uk
1.7 Do you have an annual report on the activities of tissue establishments in your Member State? (Art. 10(1)of Directive 2004/23/EC)	yes
Please provide us the report	We have data from our establishments on their activities over the last year however we have not put this data into report form.
1.8 Is there a register of authorised tissue establishments in place? (Art. 10(2) of Directive 2004/23/EC)	yes
Is the register publicly accessible?	Yes
Please provide the weblink to the register	HTTP://WWW.HTA.GOV.UK/_DB/_DOCUMENTS/LICENSED_ESTABLISHMENTS_IN_HUMAN_APPLICATION_SECTOR.PDF

2. ORGANISATIONAL STRUCTURE AND COMPETENCES

AUSTRIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Operational agency defined by the Tissue Safety Act BGBl.I Nr. 49/2008
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	Bundesministerium für Gesundheit, Familie und Jugend Radetzkystrasse 2 1030 Wien Austria
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen

2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Bundesamt für Sicherheit im Gesundheitswesen
2.9 Is the competent authority(ies) responsible for other fields?	no
BELGIUM	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Federal Agency
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products: official designation expected soon
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	Directorate-General for Healthcare facilities organization, Federal Public Service (FPS) Health, Food Chain Safety and Environment

2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Federal Agency for Medicines and Health Products
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	Advanced therapies
BULGARIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Bulgarian Executive Agency of Transplantation The Bulgarian Executive Agency of Transplantation promotes and co-ordinates organ donation and allocation in Bulgaria and is the Competent Authority for the inspection and accreditation of the procurement, processing, storage and distribution of tissues and cells for transplantation and for assisted conception under Directive 2004/23/EC.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Bulgarian Executive Agency of Transplantation
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Bulgarian Executive Agency of Transplantation
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Bulgarian Executive Agency of Transplantation
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no

Please specify which regulatory authority(ies) is responsible	The Competent Authority for blood and blood products is Bulgarian Drug Agency.
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Bulgarian Executive Agency of Transplantation
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	The Competent Authority for pharmaceuticals is Bulgarian Drug Agency.
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	The Competent Authority for medical devices is Bulgarian Drug Agency.
2.9 Is the competent authority(ies) responsible for other fields?	no
CROATIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	In the Ministry of health and social welfare there is a Department for special health care programs and transplantation, which is responsible for organs and partly for tissues and cells (legislation, register of tissue/cells establishments…). For procedures of authorisation / licencing of tissue establishments is competent Legal Department of the Ministry. The work of tissues and cells is supervised by health inspection service of Ministry of health and social welfare. Therfore, currently there is no specific directorate-department of the Ministry that is competent for tissues and cells activities

2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Ministry of health and social welfare
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Ministry of health and social welfare
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Ministry of health and social welfare
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Ministry of health and social welfare
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Ministry of health and social welfare
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	Agency for medical products and medical devices.
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	Agency for medical products and medical devices
2.9 Is the competent authority(ies) responsible for other fields?	no
CYPRUS	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	MINISTRY OF HEALTH, REPUBLIC OF CYPRUS
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	n/a
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	n/a
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	n/a
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	n/a
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	n/a
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	n/a
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	n/a
2.9 Is the competent authority(ies) responsible for other fields?	no
CZECH REPUBLIC	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Ministry of Health, deaprtment of the Health Care has responsibility for this area of health care, it pass licence and acreditation for tissues establishments, and has responsibility for transposition of Directives, guarantees assesibility, quality
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	pass licence and acreditation for tissues establishments, and has responsibility for transposition of Directives, guarantees assesibility, quality
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	pass licence and acreditation for tissues establishments, and has responsibility for transposition of Directives, guarantee assesibility, quality
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	pass licence and acreditation for tissues establishments, and has responsibility for transposition of Directives,
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	pass licence and acreditation for tissues establishments, and has responsibility for transposition of Directives
2.6 Is the competent authority(ies) responsible for human organs?	yes

Please specify the authority(ies).	pass licence for export and import, pass acreditation for transplant centers
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	guarantees assesibility, quality
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	guarantees assesibility, quality
2.9 Is the competent authority(ies) responsible for other fields?	no
DENMARK	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Within Denmark the Ministry for Health & Prevention has central national responsibility for the implementation of the Tissues Establishment Directives (i.e. 2004/23/EC, 2006/17/EC and 2006/86/EC). The management and operation of these control measures are devolved primarily to the Danish Medicines Agency and that of the National Board of Health. The former has direct responsibility for the inspection of the tissue establishments, the implementation of the transposed Regulations, as well as its Executive Orders. The latter (i.e. the National Board of Health) has responsibility for defining and advising on the national regulations, transposed from the Tissue Establishment Directives, for requirements related to donation, procurement and testing.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Danish Medicines Agency & National Board of Health
2.3 Is the competent authority(ies) responsible for human cells?	yes

Please specify the authority(ies).	Danish Medicines Agency & National Board of Health
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Danish Medicines Agency & National Board of Health
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Danish Medicines Agency & National Board of Health
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	National Board of Health
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Danish Medicines Agency
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Danish Medicines Agency
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	The Danish Medicines Agency is an agency under the Ministry of Health and Prevention and its role is to ensure medicinal products used in Denmark are of satisfactory quality, are safe to use and that they have the desired effect. We do so by administering the Danish legislation on medicinal products, reimbursement, pharmacies, medical devices and euphoriants. See www.laegemiddelstyrelsen.dk for further specific information.
ESTONIA	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	State Agency of Medicines is National Drug Regulatory Authority for Human and Veterinary Products and Competent Authority for Medical Devices and Tissues and Cells in Estonia. State Agency of Medicines is a governmental body under the Ministry of Social Affairs. Its main responsibility is the protection and promotion of public and animal health, through the supervision of medicines and medical devices for human and veterinary use.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	State Agency of Medicines
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	State Agency of Medicines
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	State Agency of Medicines
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	State Agency of Medicines
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	1. State Agency of Medicines; 2. National Health Care Board
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes

Please specify the authority(ies).	State Agency of Medicines
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	State Agency of Medicines
2.9 Is the competent authority(ies) responsible for other fields?	no
FINLAND	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The National Agency for Medicines (NAM) is supervising, competent authority which is situated organisationally under the Ministry of Social Affairs and Health. Director General is leading NAM. NAM is divided into 5 Departments; Administration, Enforcement & Inspection, Marketing Authorisation, Safety & Drug Information and Medical Devices. Responsibility of NAM is to ensure the efficacy, safety and quality of medicinal products on the market in Finland. NAM supervises also the safety and quality of blood products and human tissues /cells intended for human applications and medical devices.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	National Agency for Medicines (NAM)
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	National Agency for Medicines (NAM)
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes

Please specify the authority(ies).	National Agency for Medicines (NAM)
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	National Agency for Medicines (NAM)
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	The competent authority is the National Authority for Medicolegal Affairs.
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	National Agency for Medicines (NAM)
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	National Agency for Medicines (NAM)
2.9 Is the competent authority(ies) responsible for other fields?	no
FRANCE	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	1) Health Ministry: It prepares all the legal framework of the activities on ethic and medical aspects of tissues and cells. 2) French Health and Safety Agency Please see the following link http://agmed.sante.gouv.fr/ang/leaflet.pdf and http://agmed.sante.gouv.fr/ang/indang.htm 3) Agence de la biomédecine : It has been assigned the following missions, in particular: - **Monitoring, evaluating and controlling** therapeutic and biological activities in its domains of competence (organs,cells and tissues transplantation and reproductive medicine). and ensuring transparency - **Participating** in the development of regulations and guidelines for activities relating to its prerogatives. - **Authorising exchanges,** with other countries, of reproductive cells

	- **Accrediting professionals** involved in assisted reproductive technologies - **Managing the French Bone Marrow Register** (le Registre France Greffe de Moelle), the national register of volunteer bone marrow donors. - **Managing, with all the required guarantees,** all the records required for the management and follow-up of therapeutic activities in its domains of competence - **Promoting the donation of organs, tissues, cells and gametes.**
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	1) French Health Ministry 2) French Health products and Safety Agency 3) Agence de la biomédecine
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	French Health products and Safety Agency and Agence de la biomédecine
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	Yes
Please specify the authority(ies).	Agence de la biomédecine
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	French Health products and Safety Agency and Etablissement Français du Sang
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Agence de la biomédecine
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes

Please specify the authority(ies).	French Health products and Safety Agency
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	French Health products and Safety Agency
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	Authorization of embryo researches.Please see a link here after : http://agmed.sante.gouv.fr/ang/indang.htm Agence de la biomédecine : **Autorisation for** research on human embryos and embryonic cells in vitro and the storage of embryonic stem cells for research purposes
GERMANY	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	- state competent authorities of the Länder (responsible for the authorisation of the collection, the establishments, import and the post marketing survaillance) - Paul-Ehrlich-Institut, federal competent authority (responsible for the authorisation of the manufacturing/processing procedures)
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	see above 2.1
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	see above 2.1
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	see above 2.1

2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	see above 2.1
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	Organ donation and procurement is coordinated by Deutsche Stiftung Organtransplantation (DSO) which is no regulatory competent authority but a non-profit organisation of civil law
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	see above 2.1
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	The competent authorities of the Länder are responsible for the post marketing surveillance
2.9 Is the competent authority(ies) responsible for other fields?	no
GREECE	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Authority, under the auspices of the Ministry of Health and Social Solidarity, consisting of the board of directors (11 persons) and three (3) depts.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	N/a
2.3 Is the competent authority(ies) responsible for human cells?	yes

Please specify the authority(ies).	N/a
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	N/a
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no
Please specify which regulatory authority(ies) is responsible	National Blood Center
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	N/a
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	National Organisation of Pharmaceuticals.
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	N/a
2.9 Is the competent authority(ies) responsible for other fields?	no
HUNGARY	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The NPHMOS is a public independent authority, which has the responsibility of giving license for the health service providers. The NPHMOS is working under the direction of Ministry of Health. The operation of the National Public Health and Medical Officer Service is regulated by the Act XI of year 1991. The National Public Health and Medical Officer Service is a head office financed from the state budget. The National Public Health and Medical Officer Service is responsible for the direction, coordination and supervision of the public health (environment, settlement, food safety, nutrition, child, youth, radiohygiene, chemical safety), epidemiology, health development (health protection, health education and health maintenance), health care operation activities and the supervision of the health care supply as well.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	n/a
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	n/a
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	n/a
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no
Please specify which regulatory authority(ies) is responsible	The responsible institution for human blood and blood components is the National Blood Transfusion Service – H-1119 Budapest Karolina str. 19-21.

2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	National Institute of Chemical Safety (National Transplantation Register – negative declaration register) - this Institute is so called "background institute" of the Office of the Chief Medical Officer, and National Blood Transfusion Service (Coordination of organs)
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	together with National Institute for Pharmacy - The NIP is an administrative authority supervised by the Ministry of Health, the NIP's most important aim is that the widest range of the patients can reach safe and effective drugs of the highest quality needed to the prevention and restoration of health.
2.8 Is the competent authority(ies) responsible for medical devices?	no

Please specify which regulatory authority(ies) is responsible.	Institute for Medical Quality Improvement and Hospital Engineering – this institution is being estblished, In relation with licensing medical devices the Office of Health Authorisation and Administrative Procedures, which supervises the national market of medical devices in cooperation with the National Public Health and Medical Officer Service and the General Inspectorate for Consumer Protection. Office of Health Authorisation and Administrative Procedures takes appropriate actions against the devices violating the relevant regulation with suspending the use or distribution, or withdrawing them from the market. The decree 16/2006. (III. 27.) EüM entered into force on 11th April 2006. This harmonised decree contains regulations compatible with the Council Directive 93/42/ECC concerning medical devices as well as the Council Directive 90/385/ECC on active implantable medical devices or respectively Council Directive 98/79/EC on IVD medical devices.
2.9 Is the competent authority(ies) responsible for other fields?	no
ICELAND	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Ministry of Health is the Competent Authority, but relies on the Chief Medical Officer´s office and the Icelandic Medicines Control Agency (IMCA) when it comes to the authorization/accreditation/licensing of TA and/or PS.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Ministry of Health
2.3 Is the competent authority(ies) responsible for human cells?	yes

Please specify the authority(ies).	Ministry of Health
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Ministry of Health
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Ministry of Health
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Ministry of Health
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Ministry of Health
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Ministry of Health
2.9 Is the competent authority(ies) responsible for other fields?	no

IRELAND

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Irish Medicines Board is an independent competent authority for: • Licensing of medicinal products for human use • Licensing of veterinary products • Licensing of wholesalers of human medicines • Licensing of manufacturers of human and veterinary medicines • Pharmacovigilance & Drugs safety monitoring • Clinical Trial Licensing • Inspection of wholesale and manufacturing sites • Regulation of Medical Devices • Blood • Tissue & Cells Directive
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	The Irish Medicines Board
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	The Irish Medicines Board
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	The Irish Medicines Board
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	The Irish Medicines Board
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	Currently there is no regulatory authority for human organs in Ireland.
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	The Irish Medicines Board

2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	The Irish Medicines Board
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	As listed above in 2.1.
ITALY	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The National Transplant Centre is located within the Istituto Superiore di Sanità and it's a technical institute of the Ministry of Health. It was established by Law 91/1999.The main tasks of CNT are: coordination of all activities regarding organs, tissues and cells donation, allocation and transplantation, coordination of all activities regarding tissue donation, banking and transplantation, waiting lists management, management of Transplant Information System (SIT), definition of safety and security protocols and their application, issuing guidelines aiming at national harmonization of retrieval and transplant activities, fixing parameters for transplant quality assessment, promotion and coordination of training courses for experts in the field, promotion and coordination of relations with foreign institutions.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Italian National Transplant Centre
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Italian National Transplant Centre
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no

Please specify which regulatory authority(ies) is responsible.	Ministry of Health, National Health Institute
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no
Please specify which regulatory authority(ies) is responsible	Italian National Blood Centre
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Italian National Transplant Center
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	AIFA (Italian Medicine Agency)
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	Ministry of Health
2.9 Is the competent authority(ies) responsible for other fields?	no
LATVIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	State Agency under supervision of the Ministry of Health
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies

2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	State Agency of Medicines
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	State Agency of Health Statistics and Medical Technologies
2.9 Is the competent authority(ies) responsible for other fields?	no
LIECHTENSTEIN	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Office in the Liechtenstein administration, belongs to the ministry of health
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Office of health/ Dept. control of pharmaceuticals
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Office of health/ Dpt. control of pharmaceuticals
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Office of health/ Dpt. control of pharmaceuticals
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Office of health/Dpt. control of pharmaceuticals
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	office of health
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Offcie of health/Dpt. control of pharmaceuticals
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Office of health
2.9 Is the competent authority(ies) responsible for other fields?	yes

Please specify these other fields.	health insurance insurance for accidents at work EEA liaison body for reimbursement medical services health promotion/prevention
LITHUANIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	under Ministry of Health of the Republic of Lithuania: State care agency
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	National Bureau of Transplantation under the Ministry of Health of the Republic of Lithuania
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	National Bureau of Transplantation under the Ministry of Health of the Republic of Lithuania
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	As there is no consensus on the use of reproductive cells in the Parliament of Lithuania we have to admit that the transposition of directoves do not covers reproductive cells. At this moment all activity is coordinated by Helaht Care Minystry
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes

Please specify the authority(ies).	State Health Care Audit Agency under the Ministry of Health of the Republic of Lithuania State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania Ministry of Health of the Republic of Lithuania
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	National Bureau on Transplantation under the Ministry of Health of the Republic of Lithuania
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Department of pharmacy
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Department of pharmacy under the Ministry of Health of the Republic of Lithuania
2.9 Is the competent authority(ies) responsible for other fields?	no
MALTA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Director General Public Health Regulation heads the Public Health Regulatory Division within the Ministry for Social Policy. The various Departments within this Regulatory Division can be viewed at: http://www.gov.mt/frame.asp?l=1&url=http://www.sahha.gov.mt
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Director General Public Health Regulation

2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Director General Public Health Regulation
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Director General Public Health Regulation
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Director General Public Health Regulation
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Director General Public Health Regulation
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Malta Medicines Authority falling within the Regulatory Division of the Director General Public Health Regulation
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	The Malta Standards Authority within the Ministry of Finance, the Economy and Investment (http://www.msa.org.mt/) is the regulatory authority responsible for medical devices.
2.9 Is the competent authority(ies) responsible for other fields?	no
NORWAY	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Both the Norwegian Directorate of Health and Norwegian Board of Health Supervision are national public institutions organized under the Ministry of Health and Care Services.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Norwegian Directorate of Health and Norwegian Board of Health Supervision
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Norwegian Directorate of Health and Norwegian Board of Health Supervision
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Norwegian Directorate of Health and Norwegian Board of Health Supervision
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Norwegian Directorate of Health
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Norwegian Directorate of Health
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	Norwegian Medicines Agency
2.8 Is the competent authority(ies) responsible for medical devices?	yes

Please specify the authority(ies).	Norwegian Directorate of Health
2.9 Is the competent authority(ies) responsible for other fields?	no
POLAND	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	National Centre of Tissue and Cell Banking has been created on the basis of the Dep. of Transplantology and Central Tissue Bank, Medical University of Warsaw in 2004 by the Minister of Health. In accordance with the new Polish Transplantation Act of July 1st 2005 the National Centre of Tissue and Cell Banking is assigned to: 1) organization of a co-operation between tissue and cell banks, 2) performance of reference and consultative functions, 3) supervision and inspection of tissue and cell banks in respect of the merits, 4) keeping a register of tissue and cell banks, 5) responsible for training of tissue bank personnel.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	National Centre of Tissue and Cell Banking
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	National Centre of Tissue and Cell Banking
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	There is no dedicated CA for human reproductive tissues and cells
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no

Please specify which regulatory authority(ies) is responsible	The CA for human blood and blood components is National Blood Center
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	The CA for human is “Poltransplant” - Organization and Coordination Center for Transplantation Issues
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	The CA for Pharmaceuticals is General Pharmaceutical Inspectorate
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	The CA for medical devices is General Pharmaceutical Inspectorate
2.9 Is the competent authority(ies) responsible for other fields?	no
PORTUGAL	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The Autoridade para os Serviços Sangue e Transplantação (ASST) - was created by the Government in 2006, under the law 212/2006, 27th Oct. ASST is a Central Service of the Minitry of Health, with administrative autonomy. It comprises a General Director, two National Coordinators for Transplantation, one General Director for Blood and some Tecnhical Advisors. All are professionals, with recognized experience in transplantation, blood, legal and ethical issues. The Conselho Nacional de Procriação Medicamente Assistida (CNPMA – which stands for National Council for Assisted Reproduction Technologies) was created by the Portuguese Parliament (Assembleia da República) in 2006, under the Law n.º 32/2006, of 26th July. The CNPMA functions under the aegis of the Assembleia da República and comprises nine distinguished persons of recognised merit who are especially qualified in the field of the ethical, scientific, social and legal issues concerning assisted reproduction technologies.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	ASST
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	ASST
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no

Please specify which regulatory authority(ies) is responsible.	The Conselho Nacional de Procriação Medicamente Assistida (CNPMA – The CNPMA functions under the aegis of the Assembleia da República Among others, the Council is also responsible for establishing the terms for authorization of centres where assisted reproduction techniques are administered, and of centres where gametes or embryos are preserved and monitoring the activities of those centres, and for: • Updating scientific information on assisted reproduction technologies and on the techniques regulated herein; • Issuing opinions on the implementation of assisted reproduction techniques within the National Health Service; • Centralising all relevant information on the application of assisted reproduction techniques, namely registers of donors, beneficiaries and children born, as well as providing information related to donors, within the limited framework permitted by law.
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	ASST
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	ASST
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	INFARMED
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	INFARMED

2.9 Is the competent authority(ies) responsible for other fields?	no
ROMANIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	National Transplant Agency is a national agency in the structure of the Ministry of Public Health, responsible for all the activities concerning the donation and transplantation of human organs, tissues and cells, including the export and import. The State Sanitary Inspection is a Directorate within the Ministry of Public Health. The organization of the State Sanitary Inspection as a competent authority in the area of safety of the products of human origin for therapeutic purposes was established through the Order of Minister of Public Health no. 1194/2007, published in the Official Gazette of Romania No. 522 of August 2 2006.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Ministry of Public Health through National Transplant Agency
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Ministry of Public Health through National Transplant Agency
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Ministry of Public Health through National Transplant Agency
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no

Please specify which regulatory authority(ies) is responsible	Ministry of Public Health through National Institute of Transfuzional Hematology
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Ministry of Public Health through National Transplant Agency
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	Ministry of Public Health through National Agency for Drugs
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	Ministry of Public Health through Department of Logistic, Administrativ, Public Relations and Mass media – Compartment Medical Devices
2.9 Is the competent authority(ies) responsible for other fields?	no
SlOVAKIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Legal status of the CA is Ministry of Health
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Ministry of Health
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Ministry of Health

2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Ministry of Health
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Ministry of Health
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Ministry of Health
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Ministry of Health
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Ministry of Health
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	research tissues and cells, import and export, authorisation
SLOVENIA	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	JAZMP is Public Agency and is competent authority for medicinal products for human and veterinary use, medical devices, blood and tissues/cells.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	JAZMP

2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	JAZMP
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	JAZMP is responsible for tissues and cells in connection with Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007), but in connection with Infertility treatment and procedures of biomedically-assisted procreation Act (OG RS, No. 70/2000) also The National Board for biomedically assisted procreation at Ministry of Health has some responsibilities.
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	JAZMP
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	Slovenija-transplant and Ministry of Health in connection with The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (OG RS, No. 12/2000).
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	JAZMP
2.8 Is the competent authority(ies) responsible for medical devices?	yes

Please specify the authority(ies).	JAZMP
2.9 Is the competent authority(ies) responsible for other fields?	no
SPAIN	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The ONT is an autonomous authority belonging to the Ministry of Health and Consumer and it is responsible for the donation and transplantation of organs, tissues and cells of human origin.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Organización Nacional de Trasplantes
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	The ONT is responsible of human cells that they are not medicinal products (as defined in Directive 2003/63/CE)
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	The responsible for human reproductive tissues and cell is the Ministry of Health by the "Comisión Nacional de Reproducción Humana Asistida"
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no
Please specify which regulatory authority(ies) is responsible	The ONT has the responsibility for HSC only. The responsible for blood is the Ministry of Health
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Organización Nacional de Trasplantes

2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	The responsible is the Agencia Española del Medicamento
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	The responsible is the Agencia Española del Medicamento
2.9 Is the competent authority(ies) responsible for other fields?	no
SWEDEN	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs. The Government determines the policy guidelines for our work, which among others include develop and publish regulations based on legislations and to supervise for compliance. The Medical Products Agency (MPA) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products. MPA is also responsible for medical device and human tissues and cells for human application. The MPA is responsible for human blood or plasma for use in the manufacture of medicinal products.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	National Board of Health and Welfare Medical Products Agency
2.3 Is the competent authority(ies) responsible for human cells?	yes

Please specify the authority(ies).	National Board of Health and Welfare Medical Products Agency
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	National Board of Health and Welfare Medical Products Agency
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	National Board of Health and Welfare Medical Products Agency
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	National Board of Health and Welfare
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Medical Products Agency
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Medical Products Agency
2.9 Is the competent authority(ies) responsible for other fields?	yes

Please specify these other fields.	The National Board of Health and Welfare is the responsible authority for supervising health and medical care in Sweden. The two Competent authorities described in 2.1 above, are covering the defined responsibilities in Sweden. The regulation 1394/2007/EC for advanced therapy medicinal products is covered regarding regulatory responsibilities at the interface of the two healthcare sectors.
SWITZERLAND	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	Department of the Ministry of Health Federal Office of Public Health Divison of Biomedicine Transplantation Section
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Federal Office of Public Health Divison of Biomedicine Transplantation Section
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Federal Office of Public Health Divison of Biomedicine Transplantation Section
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	Federal Office of Justice
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no

Please specify which regulatory authority(ies) is responsible	Swissmedic
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Federal Office of Public Health Divison of Biomedicine Transplantation Section
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	Swissmedic
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	Swissmedic
2.9 Is the competent authority(ies) responsible for other fields?	yes
Please specify these other fields.	Public Health Affairs
TURKEY	
2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	According to the Dcree Law No: 181 on Organisation and Duties of Ministry of Health Law No: 2238 on Transplantation of Organ and Tissue, National Authority is Ministry of Health, Directorate General of Curative Services Unit of Tissue and Cell Transplantation
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Unit of Tissue and Cell Transplantation

2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Unit of Tissue and Cell Transplantation
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Unit of Private Hospitals
2.5 Is the competent authority(ies) responsible for human blood and blood components?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Unit of Blood Services
2.6 Is the competent authority(ies) responsible for human organs?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Unit of Organ Transplantation
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Pharmaceuticals and Pharmacy
2.8 Is the competent authority(ies) responsible for medical devices?	yes
Please specify the authority(ies).	Ministry of Health Directorate General of Curative Services, Directorate of Biomedical Engineering
2.9 Is the competent authority(ies) responsible for other fields?	no
UNITED KINGDOM	

2.1 Short description of the legal status and organisation of the competent authority(ies) (e.g. Directorate/Department in the Ministry of Health, Independent authority(ies), etc.).	The HTA was established on 1 April 2005 under the Human Tissue Act 2004 (HT Act). The HTA is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health. The HTA was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes – such as research, transplantation, and education and training The HTA is one of the Competent Authorities under the EU Tissue and Cells Directive regulating human application establishments. The HTA is responsible for regulating activities across the UK relating to all tissues and cells for human application other than reproductive cells. The Authority's Chair and 13 members were appointed by the Secretary of State for Health. The Authority is supported by an Executive of 42 staff.
2.2 Is the competent authority(ies) responsible for human tissues?	yes
Please specify the authority(ies).	HTA
2.3 Is the competent authority(ies) responsible for human cells?	yes
Please specify the authority(ies).	HTA
2.4 Is the competent authority(ies) responsible for human reproductive tissues and cells	no
Please specify which regulatory authority(ies) is responsible.	Human Fertilisation and Embryology Authority
2.5 Is the competent authority(ies) responsible for human blood and blood components?	no

Please specify which regulatory authority(ies) is responsible	Medicines and Healthcare Regulatory Authority is responsible for blood and blood components other than donor lymphocyte infusions as per 2004/23/EC.
2.6 Is the competent authority(ies) responsible for human organs?	no
Please specify which regulatory authority(ies) is responsible.	The HTA is responsible for approving donations of organs from living donors. The HTA Codes of Practice on Donation set out the circumstances in which live donation of 'transplantable material' (from both related and unrelated donors) will be permitted by the HTA. UK Transplant (UKT) coordinates the donation of organs from deceased donors and maintains a list of potential recipients.
2.7 Is the competent authority(ies) responsible for pharmaceuticals?	no
Please specify which regulatory authority(ies) is responsible.	Medicines and Healthcare Regulatory Authority
2.8 Is the competent authority(ies) responsible for medical devices?	no
Please specify which regulatory authority(ies) is responsible.	Medicines and Healthcare Regulatory Authority
2.9 Is the competent authority(ies) responsible for other fields?	no

3. TRANSPOSITION

AUSTRIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	June 2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	June 2008
3.4 If the transposition has not been yet completed, what is the reason for the delay?	organisational
3.5 Where there any difficulties with the transposition of the Directives?	No
BELGIUM	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	2008
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	2008

3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
BULGARIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
CROATIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	Lack of administrative, technical, and other infrastructural capacity.

CYPRUS	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	The draft document has been sent to the Legal Services of the Republic for legal vetting. The transposition is expected to be completed by December 2008.
3.4 If the transposition has not been yet completed, what is the reason for the delay?	We are in the process of establishing the mechanisms for accreditation, designation, authorisation and licensing.
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	The difficulties are connected to the following issues: 1- infrastructure and expertise 2- training staff 3- accreditation processes
CZECH REPUBLIC	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	1.7.2008
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	1.7.2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no

When is transposition expected?	1.7.2008
3.4 If the transposition has not been yet completed, what is the reason for the delay?	All above mentioned Directives will transposed into one law according to Czech national standards. In the czech Republic all Directives have to be transpossed as a law and decree.
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	Not enough time for transposition of the Directives
DENMARK	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
ESTONIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes

3.4 If the transposition has not been yet completed, what is the reason for the delay?	The regulations of directiv 2004/23/EC; directive 2006/17/EC and 2006/86EC are integrated in Tissues and Cells act, approved by Estonian parliament on 4th of June 2008.
3.5 Where there any difficulties with the transposition of the Directives?	No
FINLAND	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	Timetable of transposition.
FRANCE	
3.1 Has directive 2004/23/EC been transposed into national law?	Yes Order 2007-613 (26th april 2007) The application decrees have been published during summer 2008.
When is the transposition expected?	
3.2 Has directive 2006/17/EC been transposed into national law?	Yes Order 2007-613 (26th april 2007) The application decrees have been published during summer 2008
When is the transposition expected?	

3.3 Has Directive 2006/86/EC been transposed into national law?	Yes Order 2007-613 (26th april 2007) The application decrees have been published during summer 2008
When is transposition expected?	
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	In reproductive field, there are several difficulties to apply the following : -an european coding for non partner reproductive cells and embryos -the requirement concerning air quality in the laboratory :a more stringent air quality is not necessary to achevieve quality and safety required by the Directive.We consider that the exceptions can apply because thre is no evidence of transmission of infectious desease that can be attributed to air quality. -It's not necessary to repeat sceening for HIV and hepatitis at the time of donation even in partner donation. We consider that the testing is valid for 12 months in France; - authorization of the processes:we have some difficulties to define what is a process in ART; - Inspection of the tissue establishment every 2 years: there are not enough inspectors to fit with this requirement. For tissues and cells only one difficult thing is lacking : the unique European coding system
GERMANY	
3.1 Has directive 2004/23/EC been transposed into national law?	yes

3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	National discussion about the legal framework for transposition
GREECE	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	N/a
3.5 Where there any difficulties with the transposition of the Directives?	No
HUNGARY	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes

3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
ICELAND	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	Probably druring the 3rd quarter of 2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	Probably druring the 3rd quarter of 2008
3.4 If the transposition has not been yet completed, what is the reason for the delay?	The reason that the transposition is not completed is the great backlog of translations at our national translation centre
3.5 Where there any difficulties with the transposition of the Directives?	No
IRELAND	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	

3.5 Where there any difficulties with the transposition of the Directives?	No
ITALY	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	End of 2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	End of 2008
3.4 If the transposition has not been yet completed, what is the reason for the delay?	Many competing priorities for legislators
3.5 Where there any difficulties with the transposition of the Directives?	No
LATVIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	Draft Amendment of Regulations No.208 of March 27, 2007 of the Cabinet of Ministers "Procedures of preservation, storage and utilisation of human tissues and cells" will be adopted of the end of May.
3.4 If the transposition has not been yet completed, what is the reason for the delay?	

3.5 Where there any difficulties with the transposition of the Directives?	No
LIECHTENSTEIN	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
LITHUANIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	Not specified
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	Not specified
3.4 If the transposition has not been yet completed, what is the reason for the delay?	As there is no consensus on the use of reproductive cells in the Parliament of Lithuania we have to admit that the transposition do not covers reproductive cells.
3.5 Where there any difficulties with the transposition of the Directives?	Yes

Please specify these difficulties.	The shortage of tissues and cells specialists had been recognized as main difficulty of transposition No consensus on the use of reproductive cells in the Parliament of Lithuania had been recognized as main reason for the delay
MALTA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
NORWAY	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	It has been transposed, but is not yet into force. Regulation will be in force July first 2008
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	Same as abowe.
3.4 If the transposition has not been yet completed, what is the reason for the delay?	

3.5 Where there any difficulties with the transposition of the Directives?	No
POLAND	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	Aspects concerning gametes banking are not included into Polish law. Exact date of including regulations concerning gametes is not established yet.
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	Political and public discussion, whether creation and manipulation on human being is acceptable.
PORTUGAL	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	The law transposing this Directive has been approved by the Government and is currently on evaluation by the Parliament. Three months
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	the Directive is partially transposed. The law transposing this Directive has been approved by the Government and is currently on evaluation by the Parliament. Three months.

3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	The law transposing this Directive has been approved by the Government and is currently on evaluation by the Parliament. Three months
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	The main difficulties were related with the organizational changes we need to introduce.
ROMANIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
SLOVAKIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes

3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	Except coding
3.5 Where there any difficulties with the transposition of the Directives?	No
SLOVENIA	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	All 3 Directives are transposed in the national law (Act on quality and safety of human tissues and cells, for the Purposes for medical treatment, OG RS, No. 61/2007); rules on detailed procedures for authorisation are about to be issued. This is the reason, why the authorisation process in not started yet.
3.5 Where there any difficulties with the transposition of the Directives?	No
SPAIN	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes

3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
SWEDEN	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	01/07/2008
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	01/01/ 2009
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	01/01/ 2009

3.4 If the transposition has not been yet completed, what is the reason for the delay?	Regulations are not published until the directives are transposed into Swedish law. The National Board of Health and Welfare therefore refers to the Ministry of Health and Social Affairs. The expected law and regulations are now well known and established among users. A reference group, with representatives from different areas affected by the directives, has also been involved in the development of regulations The Swedish government gives financial support over a ten-year period for implementing the directives. The money is to be divided among the establishments by the Swedish Association of Local Authorities and Regions. The government support will also finance a project, led by the Swedish Association of Local Authorities and Regions, which is set to establish a national organisation to coordinate the establishments in the implementation process. There are three regulations in drafts covering the directives 2004/23/EG, 2006/17/EG and 2006/86/EG.
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	See 3.4
SWITZERLAND	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	As Switzerland is not a Member State, transposition of the Directives depends on the establishment of the Health aquis between Switzerland and the EU.

3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	As Switzerland is not a Member State, transposition of the Directives depends on the establishment of the Health aquis between Switzerland and the EU.
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	As Switzerland is not a Member State, transposition of the Directives depends on the establishment of the Health aquis between Switzerland and the EU.
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	No
TURKEY	
3.1 Has directive 2004/23/EC been transposed into national law?	no
When is the transposition expected?	01/12/2009
3.2 Has directive 2006/17/EC been transposed into national law?	no
When is the transposition expected?	01/12/2009
3.3 Has Directive 2006/86/EC been transposed into national law?	no
When is transposition expected?	01/12/2009

3.4 If the transposition has not been yet completed, what is the reason for the delay?	1. Because of the insufficiency of the financial resources, there are some difficullties to provide the organisation (admistrative structure) and trained staff. (The implementation of the related Directives should be imply the GMP inspection.)
3.5 Where there any difficulties with the transposition of the Directives?	Yes
Please specify these difficulties.	N/a
UNITED KINGDOM	
3.1 Has directive 2004/23/EC been transposed into national law?	yes
3.2 Has directive 2006/17/EC been transposed into national law?	yes
3.3 Has Directive 2006/86/EC been transposed into national law?	yes
3.4 If the transposition has not been yet completed, what is the reason for the delay?	
3.5 Where there any difficulties with the transposition of the Directives?	Yes

Please specify these difficulties.	There have been two main areas of difficulties in the UK 1. The UK transposition of the Directives has meant that most procurement organisations need to be licensed. This has created a large workload for the HTA and difficulties for procuring organisations. 2. There is a lack of clarity as to what the activity of testing covers. Specifically as to whether testing covers donor testing for virology markers or has a slightly wider definition and encompasses other donor testing e.g. HLA typing and testing of tissues and cells e.g. microbiological testing.

4. ACCREDITATION

AUSTRIA	
4.1 How many tissue establishments are there in your Member State?	80
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	10
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	10
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	10

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	10
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	2
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	5
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	1

4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	20
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	40
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	30
BELGIUM	
4.1 How many tissue establishments are there in your Member State?	98
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.3.2 How many skin tissue establishments are not yet accredited?	0

4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	20
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	12
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	3

4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	2
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	6
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	29
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	9
4.11.2 How many other tissue establishments are not yet accredited?	0

4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
BULGARIA	
4.1 How many tissue establishments are there in your Member State?	26 (twenty-six)
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	1
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	17
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	2
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
CROATIA	
4.1 How many tissue establishments are there in your Member State?	bones (4), cornea (1),skin (1), cord blood(1), cardiovascular (1), hematopoetic stem cells (3), reproductive tissues and cells
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes

4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	-
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	-
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	-

4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	-
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	-
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	-
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	-
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	-
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
CYPRUS	
4.1 How many tissue establishments are there in your Member State?	Approximately 10 establishments
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	Approximately 10 establishments
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	0

4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received	0

accreditation/designation/authorisation/license on 31 December 2007?	
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0

CZECH REPUBLIC	
4.1 How many tissue establishments are there in your Member State?	In Czech Republic there are 28 tissue establishments.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.3.2 How many skin tissue establishments are not yet accredited?	none
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	18
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	none
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	none

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	none
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	none
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	4

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	none
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	23
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
DENMARK	
4.1 How many tissue establishments are there in your Member State?	At April 2008 there were 106 tissue establishments licensed with the Danish Medicines Agency and others are a possibility.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes

4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	22
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	1
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	1

4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	73

4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	7
ESTONIA	
4.1 How many tissue establishments are there in your Member State?	0
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	All
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	All
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	All
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	All
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	All
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	All
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	All
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
FINLAND	

4.1 How many tissue establishments are there in your Member State?	Estimate 70, licensing is in progress.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	25 2 TEs licensed in 2008
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	2 1 TE licensed in 2008.

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0 1 TE licensed in 2008
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0 11 TEs licensed in 2008. All HSC establishments have now licenses.
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0 1 TE licensed in 2008. All HSC TEs for CB are licensed now.
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	1
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	21 5 TEs licensed in 2008.
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
FRANCE	
4.1 How many tissue establishments are there in your Member State?	40 tissue establishments and 44 cells establishments In Reproductive field, there were in 2005 102 IVF Centers and 203 IUI laboratories
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	10

4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	33
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	26
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	19
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	31

4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	203 IVF centers and 102 IUI laboratories
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	40+44 = 84
GERMANY	
4.1 How many tissue establishments are there in your Member State?	More than 1000
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	number unknown yet
4.3.2 How many skin tissue establishments are not yet accredited?	"
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	"
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	"
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	"

4.5.2 How many ophthalmic tissue establishments are not yet accredited?	"
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	"
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	"
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	200
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	none
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	none
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	number unknown yet

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	"
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	number unknown yet
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	number unknown yet
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	"
4.11.2 How many other tissue establishments are not yet accredited?	"
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	100
GREECE	
4.1 How many tissue establishments are there in your Member State?	There are 13 cornea banks, 1 multi tissue bank, 1 skin bank, 4 bone marrow and 1 cord blood bank accredited by the Ministry of Health. There are also many others public or private which are not accredited by the Ministry.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no

Please describe the process used.	The accreditation of each tissue establishment is based on the documentation of the establishment. The Hellenic Transplant Organization after examining if some criteria (concerning the persons qualifications , place and equipment suitability etc.,) are met, gives its assent and the Ministry of Health grants the accreditation.
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	13
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	All the private which preserves cells , as well as those introducing human tissue products from abroad
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
HUNGARY	
4.1 How many tissue establishments are there in your Member State?	approx. 40
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no

Please describe the process used.	According to the regulation on licensing procedure of tissue and cells services, the service provider has to make a statement that accomplishes the requirements ordered in governmental decree. During the service providing, the authority inspects the fulfilment of minimum conditions. In certain cases expert committees contribute to inspection (for example according to Health Min. Decree 34/2003 (VI.7.) the Committee of Human Reproduction contributes to the inspection of IVF's). The authority this year plans to conduct so called "complex inspection" of health service providers – including tissue establishments, too.
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.3.2 How many skin tissue establishments are not yet accredited?	n/a
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	n/a

4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	n/a
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	n/a
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	n/a
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	27
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	n/a

4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	n/a
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	n/a
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	n/a
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
ICELAND	
4.1 How many tissue establishments are there in your Member State?	One IVF centre

4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	The work of the IVF centre is based on a contract between the Authorities and the centre that was signed prior to the implementation of Directive 2004/23/EC
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	Not known
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	Not known
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	Not known

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	Not known
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	Not known
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	Not known
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	Not known
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	Not known
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	Not known
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
IRELAND	
4.1 How many tissue establishments are there in your Member State?	21 valid applications have been received.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	1
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	1
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	4
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	2
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	8
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
ITALY	
4.1 How many tissue establishments are there in your Member State?	33 tissue banks, 11 haematopoietic stem cell cemters, 16 cord blood banks
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	7
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	1
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	15

4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	111
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	16
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	7

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	282
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	56
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	1
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
LATVIA	
4.1 How many tissue establishments are there in your Member State?	18
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	1
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	3
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	16

4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
LIECHTENSTEIN	
4.1 How many tissue establishments are there in your Member State?	one (within the Customs Union area with Switzerland)
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.5.2 How many ophthalmic tissue establishments are not yet accredited?	0
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
LITHUANIA	
4.1 How many tissue establishments are there in your Member State?	4
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	3
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	2
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	2
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	1
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
MALTA	
4.1 How many tissue establishments are there in your Member State?	There are an estimated less than five establishments.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	Licensing will be based on an inspection process however, the necessary regulatory structure is still being set up. The inspectorate will consist of medical and other professionals proficient in the area. A pre-inspection assessment report for each tissues and cells establishment is being compiled so as to commence the licensing process shortly.
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	Not Applicable
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	Not Applicable
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	one (1)
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	Not Applicable
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	Not Applicable
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	two (2) Cord Blood Collection services
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	Not Applicable
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	one (1)
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	Not Applicable
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
NORWAY	

4.1 How many tissue establishments are there in your Member State?	17 +
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	3
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	1
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.6.2 How many cardiovascular tissue establishments are not yet accredited?	?
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	6
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	8
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	2?
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	?
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	10

4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.11.2 How many other tissue establishments are not yet accredited?	?
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	5
POLAND	
4.1 How many tissue establishments are there in your Member State?	24
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.3.2 How many skin tissue establishments are not yet accredited?	1
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	4

4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	0
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	1
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	0
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	11

4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	1
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	0
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	4
PORTUGAL	

4.1 How many tissue establishments are there in your Member State?	50
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	All TE were licensed by Health Minister according to the actual law, on the basis of a submitted dossier, and anual plans ans reports.
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	1 (This is licensed according to the actual law, not according with Directives)
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	3 (Licensed according to the actual law, not according with Directives)
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	9 (Licensed according to the actual law, not according with Directives)

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	2 (Licensed according to the actual law, not according with Directives)
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	6 (Licensed according to the actual law, not according with Directives)
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	6 (This is licensed according to the actual law, not according with Directives)
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	None of the 25 reproductive tissues and cells establishments operating have received authorization. The CNPMA (Conselho Nacional de Procriação Medicamente Assistida) decided to allow them to keep operating, since they started their activity before the entry into force of the law that rules the assisted reproduction techniques, published in July 2006. Now that the CNPMA has established the terms for authorization of centres where assisted reproduction techniques are administered, and of centres where gametes and/or embryos are preserved, those establishments may request authorization. The 25 operating already and a new centre are now under an authorization process (26).
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	All of the reproductive tissues and cells establishments already operating or starting activity are at the moment beginning the authorization process (26 up to now).
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
ROMANIA	
4.1 How many tissue establishments are there in your Member State?	60
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no

Please describe the process used.	Dossier based on the accreditation criteria established by Annex 1 of the Directive 2006/86/EC. The dossier is analized by a Committee of Experts from the National Transplant Agency and then the Agency makes proposals for accreditation to the Ministry of Public Health. The accreditation is done through a Ministry of Public Health's Order based on the proposals of the Agency.
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	9
4.3.2 How many skin tissue establishments are not yet accredited?	6
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	4
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	10
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	3

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	1
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	1
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	0
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	2

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	1
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	11
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	3
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
SLOVAKIA	
4.1 How many tissue establishments are there in your Member State?	20 5 tissue and cell banks 8 HPC cells and cord blood banks 7 assisted reproduction centers
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	Authorisation by the Competent Authority

4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.3.2 How many skin tissue establishments are not yet accredited?	0
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	1
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	1
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	0

4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	6
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	1
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	0
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	4

4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	3
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	0
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
SLOVENIA	
4.1 How many tissue establishments are there in your Member State?	approximately: 10-15 (estimation)
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	Estimation: 2-4
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	Estimation: 2-4
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	Estimation: 2
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	Estimation: 2
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	Estimation: 2-4
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0

4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	Estimation: 2-4
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	Estimation: 2-4
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	2
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	We don't have the exact number.
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
SPAIN	

4.1 How many tissue establishments are there in your Member State?	300 more or less
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	14
4.3.2 How many skin tissue establishments are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	37
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	22
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	28
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	75
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	10
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	13

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	The authorization is under the responsibility of the regional CA and this authorization can be different in each region
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	60
SWEDEN	
4.1 How many tissue establishments are there in your Member State?	The estimated number of establishments is > 70
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	no
Please describe the process used.	Temporary certifications will be granted based on information given at application. Extended certification is based on result of supervision. Supervision will begin during the year of 2009.
4.3.1 How many skin tissue establishments had received	0

accreditation/designation/authorisation/license on 31 December 2007?	
4.3.2 How many skin tissue establishments are not yet accredited?	NA
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	NA
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	NA
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	NA
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	NA

4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	NA
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	NA
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	NA
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	NA

4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	2
SWITZERLAND	
4.1 How many tissue establishments are there in your Member State?	About 90. The Swiss definition of the tissue establishment differs from the EU.
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	not applicable
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	data not available
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	11
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	data not available

4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	6
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	data not available
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	data not available
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	2
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	data not available
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	2

4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	data not available
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	25
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	not applicable authorisation at cantonal level
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	data not available
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	0
TURKEY	
4.1 How many tissue establishments are there in your Member State?	Tisssue and cell laboratories 26 Cord blood bank 1 Bone Morrow Transplantation Center 25 Invitro Fertilisation merkezi 101 Cornea Bank 15 Stem Cell Center 1
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes

4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.3.2 How many skin tissue establishments are not yet accredited?	N/a
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	N/a
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	15
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	N/a
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	N/a

4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	25
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	N/a
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	N/a
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	1
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	N/a
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	1

4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	N/a
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.11.2 How many other tissue establishments are not yet accredited?	N/a
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	1
UNITED KINGDOM	
4.1 How many tissue establishments are there in your Member State?	120
4.2 Is the designation, authorisation, accreditation or licensing based on an inspection process?	yes
4.3.1 How many skin tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	8
4.3.2 How many skin tissue establishments are not yet accredited?	N/A
4.4.1 How many musculo-skeletal tissue establishments (bone, tendons, fascia, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	33

4.4.2 How many musculo-skeletal tissue establishments are not yet accredited?	N/A
4.5.1 How many ophthalmic tissue establishments (cornea, sclera, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	5
4.5.2 How many ophthalmic tissue establishments are not yet accredited?	N/A
4.6.1 How many cardiovascular tissue establishments (heart valves, vessels, etc.) had received accreditation/designation/authorisation/license on 31 December 2007?	3
4.6.2 How many cardiovascular tissue establishments are not yet accredited?	N/A
4.7.1 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells had received accreditation/designation/authorisation/license on 31 December 2007?	13
4.7.2 How many haematopoietic stem cell establishments for bone marrow and peripheral blood stem cells are not yet accredited?	Several procurement orginizations still need to be licensed (approximatly 150)
4.8.1 How many haematopoietic stem cell establishments for cord blood had received accreditation/designation/authorisation/license on 31 December 2007?	6

4.8.2 How many haematopoietic stem cell establishments for cord blood are not yet accredited?	Several procurement orginizations still need to be licensed (approximatly 150)
4.9.1 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.9.2 How many cell banks (hepatocytes, pancreatic islets, embriotic stem cells) are not yet accredited?	N/A
4.10.1 How many reproductive tissues and cells establishments (semen, egg cells) had received accreditation/designation/authorisation/license on 31 December 2007?	0
4.10.2 How many reproductive tissues and cells establishments (semen, egg cells) are not yet accredited?	N/A
4.11.1 How many other tissue establishments had received accreditation/designation/authorisation/license on 31 December 2007?	6
4.11.2 How many other tissue establishments are not yet accredited?	N/A
4.12 How many multi tissue banks (more than one main category of tissues and cells) are there in your Member State?	46

5. THIRD PARTY AGREEMENTS

AUSTRIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment provides services to a tissue establishment which is not accredited where a tissue establishment distributes tissue or cells processed by third parties
BELGIUM	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment distributes tissue or cells processed by third parties

BULGARIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a tissue establishment distributes tissue or cells processed by third parties
CROATIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party
CYPRUS	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
CZECH REPUBLIC	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
DENMARK	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment distributes tissue or cells processed by third parties other
Please specify.	Where a tissue establishment engages a testing centre to perform the required biological tests on blood samples for infectious markers.
ESTONIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
FINLAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment provides services to a tissue establishment which is not accredited where a tissue establishment distributes tissue or cells processed by third parties

FRANCE	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
GERMANY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment provides services to a tissue establishment which is not accredited where a tissue establishment distributes tissue or cells processed by third parties
GREECE	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

Under which circumstances?	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment distributes tissue or cells processed by third parties
HUNGARY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party
ICELAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
IRELAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment provides services to a tissue establishment which is not accredited where a tissue establishment distributes tissue or cells processed by third parties

ITALY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
LATVIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party
LIECHTENSTEIN	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
LITHUANIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
MALTA	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
NORWAY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
POLAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
PORTUGAL	
5.1 Have tissue establishments in your Member State notified third party agreements?	no
ROMANIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a tissue establishment distributes tissue or cells processed by third parties other

Please specify.	Import of semen by a IVF center from a bank from a EU country.
SLOVAKIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
SLOVENIA	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution
SPAIN	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes

Under which circumstances?	where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment distributes tissue or cells processed by third parties
SWEDEN	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment provides services to a tissue establishment which is not accredited other
Please specify.	Since the directives are not implemented yet, circumstances mentioned above and below are all expected agreements. When tissues and cells are procured by The National Board of Forensic Medicine, in Sweden or another country, on behalf of a tissue establishment. When tissues and cells are procured by clinical teams under a different organisation than the tissue establishment.
SWITZERLAND	
5.1 Have tissue establishments in your Member State notified third party agreements?	no

TURKEY	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution where a tissue establishment distributes tissue or cells processed by third parties
UNITED KINGDOM	
5.1 Have tissue establishments in your Member State notified third party agreements?	yes
Under which circumstances?	other
Please specify.	New applicants are required to notify the HTA of their current third party agreements with unlicensed organisations carrying out procurement, testing, processing, distribution or import and export of tissues and/or cells on their behalf. Third party agreements are also examined as part of any on-site inspection of a tissue establishment. The HTA does not keep a comprehensive list of all third party agreements held by tissue establishments as agreements can be transient and the burden on the both the HTA and licence holders to keep this list up-to-date would be high.

6. INSPECTIONS

AUSTRIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	2 inspectors are designated for tissues and blood establishment inspection embedded in the quality system of an inspectorate of the agency following the EU Compliation of Community procedures for inspectorates. Specialised training for these inspectors is provided.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	see 6.1
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	5
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0

6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	0
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no

How are preparation processes authorised?	in the course of a tissue establishment inspection on the basis of an assessment of a submitted dossier
BELGIUM	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Inspections are carried out by officially designated members of the staff of the Federal Agency for Medicines and Health Products
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	Same inspector team for blood, tissues and cells
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	1
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	1
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0

6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes
How many?	2
BULGARIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	Art.39d from Organs, tissues and cells transplantation act specifies the requirements of setting an inspection system for organs, tissues, cells and ART activities. Ordinance N:4/19.2.2007 of the Minister of Health setting up the rules and provisions for conducting of inspections of Health Establishments which are performing transplantation activities
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	Some tissue/cell banks are also inspected according to GMP Directives requirements for which Competent Authority is Bulgarian Drug Agency.
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	25
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	1
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	1

6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	3
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	1
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	17
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	yes
How many inspections were conducted ?	4
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes
How many?	2
CROATIA	

6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Every two year regular control inspection is assigned.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	The same health inspectors are responsible for inspections of blood, pharmaceuticals and tissue and cells activities.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
CYPRUS	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	n/a
CZECH REPUBLIC	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	3

6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	0
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no

6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes
How many?	3
DENMARK	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Organisations fulfilling the definition of a tissue establishment are required by danish law to apply to the Agency for a license to authorise their specific on-site activities. The application is subject to an internal review and where it meets the initial requirements to qualify as a tissue establishment it is transferred to the inspection group for the planning schedule. The latter is prioritised on the basis of tissue/cell type, resources and other work commitments. After site inspection - and the evaluation of any non-compliances - the inspector provides a viewpoint on compliance with the national requirements. Where this is favourable the file transfers to the administrative section to prepare the license certificate, normally valid for two years. Relevant internal SOP's in the Agency are in place which define the different phases.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	The administrative provisions for the inspection of other sector products (e.g. blood, medicines, etc) are similar in format and structure. Therefore the internal documentation and support systems are linked and delineated by the specialities of each sector. Inspectors for tissues and cells have a background and knowledge in the pharmaceutical or blood sector. This is further enhanced with the training programmes and regular reviews with similar colleagues, to develop and maintain the required standards for the safety and quality of these materials for human applications.
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	63
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	5
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	3

6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	5
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	24
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
ESTONIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no

6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
FINLAND	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	Inspectors for conducting inspections of TEs are from NAM Inspectorate. Two inspectors are nominated and certified as TE inspectors. Training and certification procedure complies with the Inspectorate Quality Manual. TE Inspectors are now conducting TE on-site pre-approval inspections as a part of licensing process. Routine inspection circle (every 2nd year) starts immediately after licensing process is complete.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	TE inspection team is conducting also Blood Establishment inspections. NAM Inspectorate is supervising and inspecting manufacturing and distribution of pharmaceuticals, too.
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	15
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	11

6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	1
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
FRANCE	

6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	1) In tissues and cells field Please see EUSTITE questionnaire related with French Health products and Safety Agency inspection system . 2) In reproductive field There are some inspectors for each region in local Agencies, parts of the Health Ministry. These inspectors followed a specific formation to be efficient in ART field at the beginning of this year.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	139
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	11
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0

6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	8
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	101
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	yes
How many inspections were conducted ?	50
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes
How are preparation processes authorised?	in the course of a tissue establishment inspection on the basis of an assessment of a submitted dossier
GERMANY	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	The responsible competent authorities of the Laender provide staff for regular inspections according to a work plan.There are committees of Laender-inspectors to coordinate the content and the procedure of inspections. Inspectors are accompanied regularly by a scientist of the Paul-Ehrlich-Institut (Federal authority for marketing authorization)
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	-mainly the same inspectors -common basic training -common aspects of documentation -but specifici information and training for the different establishments and processing procedures regarding the different products
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	number unknown
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	"
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	"
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	"

6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	5
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	none
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	number unknown
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	none
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	number unknown
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	none
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	yes
How many inspections were conducted ?	number unknown
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes
How many?	exact number unknown
GREECE	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	Inspections are being held by the Intern. Stds Organizations to those Banks accredited by them.
HUNGARY	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	This year the competent authority plans to make a so called “complex inspection” which comprising of the inspection of minimum requirements, hygienic environment, and the quality requirements. The inspection will be conducted through inspection teams of the authorities of the specific areas.

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	7
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	0
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0

6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier other
Please specify.	It depends on the type of health service and the preparation process authorised differently.
ICELAND	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	The licensing will probably be a paper based one by the Chief Medical Officer and an on site inspection by inspectors from IMCA

6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection on the basis of an assessment of a submitted dossier

IRELAND	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Each Tissue establishment is inspected prior to the issue of an authorisation. In general, this requires two separate inspections prior to authorisation. Once authorised, inspections are scheduled for inspection at least every two years.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	The Compliance Department at the Irish Medicines Board is responsible for inspecting a wide range of facilities. Where possible, we have harmonised documents and all work within one quality system. The Tissue inspectors are also trained blood inspectors. Currently, the blood and tissues team is dedicated to inspection of blood and tissue establishments. However, once all sites are authorised and we are in a routine phase of inspection, these inspectors will be cross trained for GMP and GDP inspections.
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	4
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	5
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	3
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0

6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	9
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	1
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	yes
How many inspections were conducted ?	2
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
ITALY	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	All tissue banks receive a full CNT site inspection on a 2 yearly cycle. Inspections of Cord Blood Banks are just beginning and are being performed by joint CNT/CNS teams. For HPC centres that apply for a JACIE inspection, CNT/CNS inspectors participate in the inspection – the inspection is joint but the post-inspection reporting and certification is managed separately. CNT inspections are conducted by CNT inspectors often with the assistance of a technical expert who is a tissue bank expert from a different geographical region. Tissue Establishments complete a Dossier before the inspection, which last 1-2 days and include detailed review of donor selection and testing documentation, procurement records, facilities and equipment, processing, storage and distribution procedures and the quality system in general. Deficiencies are reported and Tissue Establishments must provide an corrective action plan with timescales.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	6

6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	2
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	2
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no

6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection

LATVIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	State Agency of Health Statistics and Medical Technologies organise inspections and carry out appropriate control measures in order to ensure compliance with the requirements of the Directive 2004/23/EC
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no

How are preparation processes authorised?	in the course of a tissue establishment inspection
LIECHTENSTEIN	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	There is a contract with Swissmedic which is inspecting the establisment.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	It is included in the inspection planning.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	n/a
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	There is a contract with Swissmedic which is inspecting the establisment.

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	It is included in the inspection planning.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	n/a
LITHUANIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no

6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
MALTA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	It is envisaged that the same inspectorate team used for the inspection of pharmaceutical manufacturing sites could be used after specific training in the field.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no

How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	It is envisaged that the same inspectorate team used for the inspection of pharmaceutical manufacturing sites could be used after specific training in the field.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	It is envisaged that the same inspectorate team used for the inspection of pharmaceutical manufacturing sites could be used after specific training in the field.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
NORWAY	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	Partly, particularly blood and tissues and cells
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no

6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
POLAND	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	1. The cell, tissue and organ recovery, storage and transplantation act, of July 1st, 2005 (the Official Journal of Acts Dziennik Ustaw 05.169.1411), art. 35 (see attachment) 2. Decree of the Minister of Health on the procedure of inspection information sent to Ms Penelope Stathoyannis
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	10
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0

6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	3
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	11
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	yes

How many?	21
PORTUGAL	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
ROMANIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	Ministry of Public Health through State Sanitary Inspection is the public competent authority, empowered according to the Order of Minister of Public Health no. 1194/2007, published in the Official Gazette of Romania No. 522 of August 2 2006, to perform the formal control in specific areas, and the national competent authority in the area of safety of the products of human origin for therapeutic purposes; The State Sanitary Inspection is organized as a Directorate within the Ministry of Public Health and has 42 services within the 42 territorial Public Health Authorities. The inspectors employed in the State Sanitary Inspections, both in the Ministry of Public Health and territorial public health authorities, did not received the adequate training, according to the Directive 2004/23/EC.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	The inspection scheme overlap with our system for the inspection of all healthcare facilities (including primary care, ambulatory specialty care, blood banks, prehospital and hospital medical services), excepting the inspection for pharmaceuticals. The overlap is from the point of view of inspector teams, the same inspector teams being responsible for the inspection of the above mentioned healthcare facilities. Also the same Order of Minister of Public Health (No. 824/2006) regulates the organization and function of the State Sanitary Inspection.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
SLOVAKIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no

6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	on the basis of an assessment of a submitted dossier
SLOVENIA	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	According to Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) each tissue establishment has to be authorised by JAZMP. The authorisation is issued following verification and regular inspection must be performed each 2 years. There is also the possibility for control measures (Article 9).
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	Pharmaceutical inspectors from JAZMP are competent to perform GMP inspections, GCP inspections, GDP inspection and inspections of blood and tissue establishments. The team is same, but for each specific field there is a team primary responsible for the field.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	According to Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) each tissue establishment has to be authorised by JAZMP. The authorisation is issued following verification and regular inspection must be performed each 2 years. There is also the possibility for control measures (Article 9).

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	Pharmaceutical inspectors from JAZMP are competent to perform GMP inspections, GCP inspections, GDP inspection and inspections of blood and tissue establishments. The team is same, but for each specific field there is a team primary responsible for the field.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection

SPAIN	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Some regions have an inspection system in place. Others don't have it yet, but its implementation is ongoing. not yet

6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	The inspection is also under the responsibility of the regional CA and the process of implementation is at a different stage in each region
SWEDEN	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	no
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes

Please describe.	As for all supervision of health and medical care, including the area of blood, inspectors for conducting audits are situated regionally. Standard for supervision are to be designed. These standards will not only be based on the EG-directives but also existing regulations for quality and patient's safety, which all supervision in Sweden is based on. Compilation of Procedures for Member States of EU regarding inspection and control of manufacturing and marketing of medicinal products is followed by Sweden through national law. The competent authority, MPA, is inspecting manufacturing of pharmaceuticals and active substances.
6.3 Have any inspections of tissue establishments been conducted in 2007?	no
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other
Please specify.	NA
SWITZERLAND	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	Swissmedic carries out the inspections on receipt of order of the Federal Office of health upon submisson of the application for authorisation or renewal by tissue establishments
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	These inspections are also carried out by Swissmedic.
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	10
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	0
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	0
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0

6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection
TURKEY	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes

Please describe.	Instraction on Bone Marrow Transplantation Centers and Data Processing Centers (26 February 2001) Instraction on Bone Eye Bank and Cornea Transplantation Centers (26 February 2001) Instraction on Human Leucocyte Antigen)HLA) Typing Laboratories (26 February 2001)
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	yes
Please describe.	GMP inspection is condacted by the Directorate General of Pharmaceuticals and Pharmacy and by the Inspection Board of the Ministry of Health
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes
6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	3
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	3

6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	2
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0
6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	other

Please specify.	N/a
UNITED KINGDOM	
6.1 Is a system in place for organising inspections and control measures of tissue establishments?	yes
Please describe.	Applicants apply for a licence via an online form; this allows them to self assess against the HTA's standards (based on the standards in the Directives). The HTA carries out a desk-based inspection of the establishment using this application and a licence is issued based on this. For areas where the establishment needs to improve to meet the standards, conditions will be placed on the licence. The HTA uses conditions to drive up standards at licensed establishments. The risk associated with each establishment is also calculated to schedule the inspection schedule. All establishments will be inspected within 2 years of the Directives being transposed into UK law. The HTA has the power to suspend or revoke licences where there has been a serious breach of licence conditions or the premises/responsible person are not suitable. However, the HTA is a risk-based, proportionate regulator and has never yet revoked a licence.
6.2 Does the inspection scheme interact or overlap with your systems for the inspection of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)?	no
6.3 Have any inspections of tissue establishments been conducted in 2007?	yes

6.3.1 How many regular inspections were conducted in 2007 in tissue banks (bone, skin, cornea, etc.)?	23
6.3.2 How many of these inspections in tissue banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.3 How many regular inspections were conducted in 2007 in HPC centres (bone marrow and peripheral blood stem cells)?	9
6.3.4 How many of these inspections in HPC centres followed serious adverse events or reaction, or suspicion thereof?	0
6.3.5 How many regular inspections were conducted in 2007 in cord blood banks?	1
6.3.6 How many of these inspections in cord blood banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.7 How many regular inspections were conducted in 2007 in cell banks?	0
6.3.8 How many of these inspections in cell banks followed serious adverse events or reaction, or suspicion thereof?	0
6.3.9 How many regular inspections were conducted in 2007 in assisted reproduction centres?	0
6.3.10 How many of these inspections in assisted reproduction centres followed serious adverse events or reaction, or suspicion thereof?	0

6.4 Have any inspections of procurement sites (separate from tissue establishment inspections) been conducted in 2007?	no
6.5 Have any inspections dedicated to the authorisation of preparation processes been conducted in 2007?	no
How are preparation processes authorised?	in the course of a tissue establishment inspection

7. IMPORT/EXPORT - haematopoietic stem cells

AUSTRIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
BELGIUM	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	Belgian Superior Health Council common standards for tissues and cells of human origin
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	2007 Australia : 1 USA : 20

7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	2007 Australia : 2 Argentina : 1 Brazil : 1 Canada : 4 Israel : 1 New-Zealand: 1 Turkye : 3 USA : 21 Switzerland : 2
BULGARIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Equivalent standards (bilateral agreemants)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
CROATIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Equivalent standards (bilateral agreemants)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	There is no HSC exported so far

7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	There is no HSC exported so far
CYPRUS	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	n/a
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
CZECH REPUBLIC	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	I´d got the questionare late (6.5.2008), so I answer and complete data ASAP

7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	I´d got the questionare late, so I answer and complete data ASAP
DENMARK	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
ESTONIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
FINLAND	

7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	USA (2)
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	USA (1)
FRANCE	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA) Decree for importation and exportation and good cells practices (ministerial order of 1998) Specific afssaps SOP's
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	438 HSCgrafts (BM,PBSC) have been imported (80% from EU and 20%from third countries); 216 HSC grafts (UCB) have been imported (50% from EU and 50% from USA)
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes

Please provide this data by the country of destination.	134 HSC grafts (BM, PBSC, UCB) have been exported : about 2/3 to EU and 1/3 outsisde EU)
GERMANY	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	inspections in the third country
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	68 units for transplantation
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	820 units for transplantation

GREECE	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA) Other
Please specify other.	The Hellenic transplant Organization collaborates with BMDW.
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes

Please provide this data by the country of origin.	16 New York 1 Australia 2 Canada 1 Israel
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	No number exported during 2007
HUNGARY	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Equivalent standards (bilateral agreemants) Other
Please specify other.	According to the Act on Health tissues or organs can be transporting from third country only for the following aims: -transplantation, -therapy for the affected patient - identification of disease - research.
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	In 2007 there was no import from third country.
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	In 2007 there was no export to third country.
ICELAND	

7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Equivalent standards (bilateral agreemants)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
IRELAND	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	It is the responsibility of the importing tissue establishment to ensure that the EU requirements are met. HSC imported into Ireland are often done so on a directed basis for dedicated patient use. In general all are WMDA registered
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
ITALY	

7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	European Directive
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	Germany 12 USA 12 France 9 Spain 6 United Kingdom 5 Polonia 4 Swiss 4 Greece 3 Russia 3 Austrian 2 Rep. Ceca 2 Sweden 2 Hungary 2 Canada 1 Argentina 1 Israel 1 Ireland 1 Turkey 1
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	Germany 164 USA 76 United Kingdom 13 Israel 9 Canada 8 France 5 Spain 3 Swiss 2 Australian 1 Austrian 1 Ciprus 1 Norvegia 1 Rep. Ceca 1
LATVIA	

7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	Human haematopoietic stem cells are not imported /exported
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
LIECHTENSTEIN	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	At the moment it is not allowed to deal with HSC in Li for legal/ethical reasons.
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
LITHUANIA	

7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Equivalent standards (bilateral agreemants)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	there was no import
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	there was no import
MALTA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)

7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
NORWAY	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
POLAND	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No

PORTUGAL	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	USA - 6
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	USA - 4 South Africa - 1
ROMANIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	0 - no import

7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	0 - no export
SLOVAKIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	EBMT Standards
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	There were no imports to third countries outside EU
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	There were no exports to third countries outside EU
SLOVENIA	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes

Please provide this data by the country of origin.	In the Year 2007: 4 from USA
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	In the Year 2007: 1 to Croatia
SPAIN	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	BM/PB: 52 (Australia: 1; Israel: 1; Canada: 1; USA: 49) UCB: 37 (Australia: 5; USA:32)
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	UCB: 31 (USA: 24, Canada: 1; Colombia: 1; Turquia: 2; India: 1, Israel: 2) PB: 3 (USA: 1; Suiza: 1, Turquia: 1) BM: 0
SWEDEN	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)

7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	Yes
Please provide this data by the country of destination.	Australia n=2 Usa n=5
SWITZERLAND	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	International standards (JACIE/NETCORD/WMDA)
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
TURKEY	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other

Please specify other.	EFI: 26 doku tipleme labratuvarindan 2 tanesi EFI akredite 1 taneside basvuruda bulundu. EBMT: 25 Kemik iliği INM hepsi EBMT ye uye JACIE: akredite labratuvar yok NETCORD: akredite merkez yok WMDA: 2 tane TRİS/TRAN GMP akreditasyonu yapılmış 1 doku hücre tesisi ve bankası var
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	Yes
Please provide this data by the country of origin.	yaklasık 55 ulkeden ama kısa surede bunun lıstesını cıkaramıyoruz
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No
UNITED KINGDOM	
7.1 Which procedures do you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) from third countries?	Other
Please specify other.	The HTA has set out requirements for all tissues and cells imported from third countries in directions. It is a condition of all licences issued that establishments meet these requirements.
7.2 Do you have data on the numbers of HSC imported from third countries (outside the EU) in 2007?	No
7.3 Do you have data on the numbers HSC exported from your Member State to third countries (outside EU) in 2007?	No

8. SERIOUS ADVERSE EVENTS AND REACTIONS

AUSTRIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
BELGIUM	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	Standard notification forms (electronic transmission) and instructions for reporting to the biovigilance centre of the Federal Agecy for Medicines and Health Products were distributed to the tissue establishments. Reportable incidents include serious adverse reactions during or after application of tissue or cells, serious adverse donor complications and serious adverse events covering the chain from donation to distribution.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes

Please describe the criteria.	· The application of a tissue or cells that did not fulfill the safety and quality requirements. · A near miss: the distribution of a tissue or cells that did not fulfill the safety or quality requirements at that time (but that was not applied). · The release of a tissue or cells (even if not distributed), that did not fulfill the release requirements, due to a procedural problem of the release process (e.g. informatics))." · An event that might put the life of a donor in danger.
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	Serious adverse reactions in recipients of tissue or cells due to the quality or safety of the tissue or cells applied. Serious adverse complcations in donors related to the preparation of the donor and the collection procedure.
BULGARIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	Art.15b and 15g paragraph 5 from Organs, tissues and cells transplantation act specifies the requirements of setting an system for SAR and SAE. Ordinance N:10/30.3.2007 of the Minister of Health setting up the rules and provisions for reporting, registering, transmitting the information for SAR&SAE and for recalling and destroying of tissues and cells not suitable for transplantation.

8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	Only the definitions for SAR&SAE implemented from Directives without detailed criteria
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	Only the definitions for SAR&SAE implemented from Directives without detailed criteria
CROATIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	There is obligation for reporting of serious adverse events and reactions on local, but not at national level.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
CYPRUS	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No

8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
CZECH REPUBLIC	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
DENMARK	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	The National systems and practices for the reporting of serious adverse events/incidents have been communicated, via the Agency website, to all tissue establishments. The reporting system is presented as an electronic scheme for tissue establishments, or users, to notify the relevant national organisation of any serious adverse reaction or serious adverse event related to the use of human tissues or cells. The initial reporting information and the conclusion reports follow the structure and format within the European Directive.

8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	'serious adverse event' is any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	'serious adverse reaction' is an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;
ESTONIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No

8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
FINLAND	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	The general requirements for the procedure are in the Decree 1302/2007, § 6, 7, 8 and 9, given by the Ministry of Social Affairs and Health. The forms for reporting are as annexes of the Decree.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
FRANCE	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes

Please give a short description.	1) In tissues and cells field at the top of the system there's the French Health products and Safety Agency which coordinates the actions of the stakeholders who play a part in the biovigilance system.Afssaps receives all the declarations of adverse events and takes the adequate safety measures. Then, in each public or private establishment, there's a local correspondant who sends the declarations dedicated form) of adverse events to the French Health and Safety Agency and has to investigate for finding the origin of the adverse event and for doing the relevant report about each event. There is a afssaps internal SOP's for the management of the adverse event. 2) In reproductive field Plese see the following link :http://www.agence-biomedecine.fr/fr/proect/pegh-pma-expert.aspx//ampvigilance
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	Please load the the form for reporting adverse events : http://www.agence-biomedecine.fr/fr/proect/pegh-pma-expert.aspx#ampvigilance
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	Please load the the form for reporting adverse events : http://www.agence-biomedecine.fr/fr/proect/pegh-pma-expert.aspx#ampvigilance
GERMANY	

8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	an adaptation of the existing system on the provisions of the Directive 2006/86/EC and the results of the discussion in the EUSTITE project is in preparation
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	-criteria are those described in the annexes to Directive 2006/86/EC -the definitions in Directive 2004/23/EC - more details will be introduced following the discussion in the EUSTITE project
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	an adaptation of the existing system on the provisions of the Directive 2006/86/EC and the results of the discussion in the EUSTITE project is in preparation
GREECE	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No

HUNGARY	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	According to the ministerial decree the system of reporting is the following: service provider (not only from TE, but the service provider which does transplantation)/or responsible person at TE– regional office of NPHMOS as authority other authorities/or adopt measures
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	The following cases: - resulting death of recipient - transfer of infection, - resulting loss of capacity, or becoming legal incapacity - to be in jeopardy or resulting permanent impairment, - in the cases of reproductive cells – false identification of cells or embryo.
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
ICELAND	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	The same system as for the reporting of serious adverse events and reactions relating to blood and blood products will be used

8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
IRELAND	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	The responsible person or designee at tissues establishments should submit reports.Other organisations (e.g. procurement organisation or organisation responsible for human application) should report reactions/events that have occurred at their facility to the associated tissue establishment who will report on to the IMB. However, a report submitted directly to the IMB from a procurement organisation or organisation responsible for human application will be accepted. Submit a report on the IMB form which is available on the IMB website or by phone/email/fax. The person submitting the report should assign a unique ID report number to the report which allows for traceability. The IMB will assign a unique IMB number to the case.The IMB will send to the reporter an IMB Confirmation Form.This form will contain the reporting establishment ID number and the IMB case reference number.This form should be returned to the IMB upon completion by fax or post.

8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
ITALY	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	The banks are required to have a procedure in place for the reporting of SAE and SAR and to distribute the procedure to all the third parties possibly involved in the activity. They have to report any suspected SEA or SAR immediately to the competent Regional Center, which has the responsibility to communicate it to the National Transplant Center. CNT inspectors verify compliance with the national procedures during inspections. Instructions and reporting forms are provided in the national Guidelines for Tissue Banks. CNT reviews reports and corrective/preventive actions for adequacy.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
LATVIA	

8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
LIECHTENSTEIN	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
LITHUANIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	the system is based on the imediat paper reports
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	the description goes exactly along with directive

8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	the description goes exactly along with directive
MALTA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
NORWAY	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	For the time beeing reports on serious adverse events and reactions are reported in MedEvent – the greneral reporting system for adverse events in specialized health services. Hospitals have a statutory duty to report such events. When the new regulations are in force, the reportingsystem for tissues and cells will be connected to the hemovigilance system.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No

8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
POLAND	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	hospital - tissue bank - CA
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	Decree of Minister of Health on detailed conditions concerning procurement, storage and transplantation of human cells, tissues and organs
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	Decree of Minister of Health on detailed conditions concerning procurement, storage and transplantation of human cells, tissues and organs
PORTUGAL	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No

ROMANIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	Transposition of the Directive 2006/86/EC – Ministry of Public Health's Order 1763/2007 – Annex- Art. 9
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	Definiton of the serious adverse event and serious adverse reaction according to the Directive 2004/23/EC – Art. 3 – transposed in the Ministry of Public Health's Order no. 1242/2007 – Annex – art. 1
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	Definiton of the serious adverse event and serious adverse reaction according to the Directive 2004/23/EC – Art. 3 – transposed in the Ministry of Public Health's Order no. 1242/2007 – Annex – art. 1
SLOVAKIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	Reporting forms and instructions contained in Governmental Decree 622/2007
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	They are defined in Governmental Decree 622/2007

8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	They are defined in Governmental Decree 622/2007
SLOVENIA	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	According to proposed rules on detailed procedures (will be issued soon) tissue establishment will report SAE and SAR to the Slovenija-transplant, which is responsible to report to the JAZMP. Human recipient or donor could report to the medical doctor or directly to the Slovenija-transplant or JAZMP. Medical doctor is responsible to repost to the tissue establishment (the possibility for direct reporting to the Slovenija-transplant or JAZMP should be open).
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	According to the Article 4 of the Slovenian Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) the definition for serious adverse reaction or serious adverse event is same as in the Directive 2004/23/EC.
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes

Please describe the criteria.	According to the Article 4 of the Slovenian Act on quality and safety of human tissues and cells, for the Purposes for medical treatment (OG RS, No. 61/2007) the definition for serious adverse reaction or serious adverse event is same as in the Directive 2004/23/EC.
SPAIN	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes
Please give a short description.	Our surveillance system is in pilot situation. Any SAR or SAE have to be declared to the transplant coordinator – or Tissue Establishment coordinator, if it is the case. When it is necessary, they have to be transmitted to regional CA and when it is necessary, to the national CA
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	SAE have to be declared when the tissue/cells had been distributed outside the TE
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes
Please describe the criteria.	RAE have to be declared when the reaction is serious and unexpected
SWEDEN	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No

8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
SWITZERLAND	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
TURKEY	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	No
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	No
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	No
UNITED KINGDOM	
8.1 Do you have a system in place for the reporting of serious adverse events and reactions?	Yes

Please give a short description.	The HTA has an online reporting system for the reporting of serious adverse events and reactions to the HTA. The system also allows for the submission of analysis reports from establishments following their investigation into the serious adverse event or reaction (SAE/R). Over the last year 16 serious adverse events or reactions have been reported to the HTA. The HTA has a system for issuing regulatory alerts to all establishments and has issued alerts on two occasions. Regulatory alerts may be issued following a report of a SAE/R or because the HTA has received information from another source e.g. from another regulator.
8.2 Have you defined criteria for the reporting of adverse events to the competent authority (i.e. what is defined as 'serious')?	Yes
Please describe the criteria.	The HTA have used the definition provided in the Directives. In light of experience since implementing the Directives however we are hoping to provide practical examples to establishments. The HTA hopes this will clarify which type of adverse events and reactions would be considered to be serious and that need to be reported to the HTA.
8.3 Have you defined criteria for the reporting of adverse reactions to the competent authority? (i.e. what is defined as 'serious')	Yes

Please describe the criteria.	The HTA have used the definition provided in the Directives. In light of experience since implementing the Directives however we are hoping to provide practical examples to establishments. The HTA hopes this will clarify which type of adverse events and reactions would be considered to be serious and that need to be reported to the HTA.

9. TESTING REQUIREMENTS

AUSTRIA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	No
Anti HCV	Yes
NAT HCV	Yes
HBs ag	Yes
Anti HBc	No
NAT HVB	Yes
Treponema Pallidum	Yes

NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
BELGIUM	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes

NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Living donors: second serology after six months, or NAT HIV1 and NAT HCV and NAT HBV testing or pathogen inactivation of the tissues or cells.
BULGARIA	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes

NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
CROATIA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes

NAT HVB	No
Treponema Pallidum	No
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Anti CMV Anti Toxo
CYPRUS	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes

Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
CZECH REPUBLIC	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	Yes
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes

Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	CJN TSE
DENMARK	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	No
Anti HCV	Yes
NAT HCV	Yes

HBs ag	Yes
Anti HBc	Yes
NAT HVB	Yes
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Testing for N.gonorrhoeae in living donor.
ESTONIA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	Yes
Anti HCV	Yes

NAT HCV	Yes
HBs ag	Yes
Anti HBc	Yes
NAT HVB	Yes
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
FINLAND	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes

NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Testing of risk groups as in the Directive 2006/17/EC
FRANCE	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	Yes

Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	In reproductive field, according to the different situations : NAT HVB, Nat HVC, Nat chlamydia. For HSC : CMV,EBV and Toxoplasmosis serologies and in some cases NAT HVB and NAT HCV
GERMANY	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No

Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	in some cases HIV and HCV NAT
GREECE	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes

NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	NAT HVB, NAT HCV, NAT HIV
HUNGARY	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes

Anti HIV-1&2	No
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	No
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Lues (syphilis) CMV (only in certain cases)
ICELAND	
9.1 Laboratory tests	
Anti-HIV 1	No

Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	Yes
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
IRELAND	
9.1 Laboratory tests	
Anti-HIV 1	Yes

Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Only those mandated by 2006/17/EC are required. Other tests depend on the donor lifestyle/health questionnaire or assessment, as also detailed in 2006/17/EC.

ITALY	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	No
Anti HCV	Yes
NAT HCV	Yes
HBs ag	Yes
Anti HBc	Yes
NAT HVB	Yes
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes

Please specify these other laboratory tests.	HTLV I-II for donors originating from high-incidence areas Toxo IgM for amniotic membrane donors CMV IgM for skin, valve and amniotic membrane donors
LATVIA	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes

NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No

LIECHTENSTEIN	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	No
Anti HCV	Yes
NAT HCV	Yes
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No

Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	If there is a risk EVB, HTLV 1+2, CMV, Toxoplasma gondii, Herpes simplex, Herpes zoster
LITHUANIA	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes

NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
MALTA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	Yes
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes

NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	• CMV (IgG and IgM) • TOXO (IgG and IgM) • EBV • Biochemical profile including Liver Function Tests. • PSA if male donor > 40 years.
NORWAY	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	No
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No

HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	gonorrhoea
POLAND	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes

NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No
PORTUGAL	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes

NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	HTLV
ROMANIA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	Yes

Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Toxoplasma, CMV, Epstein Barr
SLOVAKIA	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No

Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	Yes
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	No

SLOVENIA	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes

NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	anti CMV anti toxopl. anti EBV Anti HBs
SPAIN	
9.1 Laboratory tests	
Anti-HIV 1	Yes
Anti-HIV 2	Yes

Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	Chagas Disease and Malaria in specific cases
SWEDEN	
9.1 Laboratory tests	
Anti-HIV 1	Yes

Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	CMV. In certain circumstances additional testing may be required, e.g. HTLV I/II antibody, T. cruzi.

SWITZERLAND

9.1 Laboratory tests

Anti-HIV 1	Yes
Anti-HIV 2	Yes
Anti HIV-1&2	Yes
NAT HIV 1	Yes
Ag HIV	No
Anti HCV	Yes
NAT HCV	Yes
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	if there is a risk EBV, HTLV 1+2, CMV, Toxoplasma goudii, Herpes simplex, Herpes zoster

TURKEY	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No
9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes

Please specify these other laboratory tests.	Brucella, Salmonella, Toksoplasma
UNITED KINGDOM	
9.1 Laboratory tests	
Anti-HIV 1	No
Anti-HIV 2	No
Anti HIV-1&2	Yes
NAT HIV 1	No
Ag HIV	No
Anti HCV	Yes
NAT HCV	No
HBs ag	Yes
Anti HBc	Yes
NAT HVB	No
Treponema Pallidum	Yes
NAT Chlamydia (for sperm donors)	No

9.2 Are any other laboratory tests required for living and deceased donors in your Member State?	Yes
Please specify these other laboratory tests.	The Department of Health in the UK has set up a Safety Advisory Committee on Blood, Tissues and Organs (SaBTO). This committee provides advice on additional donor testing that should be carried out.

10. SANCTIONS

AUSTRIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
BELGIUM	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
BULGARIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No

10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	Yes
What were the reasons for imposing the penalties?	Infringement of the national provisions pursuant to the Directive 2004/23/EC and Directive 2006/17/EC concerning performance of serological testing of donor serum in unauthorised laboratory by Musculoskeletal tissue bank.
CROATIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
CYPRUS	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes

Have penalties already been imposed?	No
CZECH REPUBLIC	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
DENMARK	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	Yes
What were the reasons for the revocation(s) or suspension(s)?	A license was not issued on the basis of a poor Quality Management System and environmental standards. On two occasions the site licenses were re-issued with limited expiry date (i.e. three months).
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
ESTONIA	

10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
FINLAND	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
FRANCE	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	In tissue and cells field, the main difficulty is the unique coding system implantatiion. In reproductive field, two major difficulties: - the definition of the responsible person; - the definition of the processes which have to be authorized.

11.2 What specific issues need to be addressed by the Commission?	The directive is not fitted to the reproductive field.Some requirements can't be applied to ART activities or are not relevant.There is also a significant financial impact.
GERMANY	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
GREECE	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
HUNGARY	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No

10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
ICELAND	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
IRELAND	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
ITALY	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	Yes
What were the reasons for the revocation(s) or suspension(s)?	In one case a certificate was revoked following a serious adverse event.

10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No

LATVIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
LIECHTENSTEIN	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
LITHUANIA	

10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
MALTA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
NORWAY	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
POLAND	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	Yes

What were the reasons for the revocation(s) or suspension(s)?	In one case of cord blood bank that discontinued meeting the requirements for application for the permission of the Minister of Health.
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
PORTUGAL	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
ROMANIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
SLOVAKIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No

10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
SLOVENIA	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
SPAIN	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes
Have penalties already been imposed?	No
SWEDEN	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No

10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
SWITZERLAND	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
TURKEY	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	No
UNITED KINGDOM	
10.1 Have accreditations, designations, authorisations or licenses been revoked or suspended by the competent authorities? (Art. 6(4) Directive 2004/23/EC)	No
10.2 Have penalties for infringements of the national provisions pursuant to the Directive been laid down? (Art. 27 Directive 2004/23/EC)	Yes

Have penalties already been imposed?	Yes
What were the reasons for imposing the penalties?	The Human Tissue (Quality and Safety for Human Application) Regulations 2007 contain Regulation (10) Breach of requirement to hold a licence or to act under a third party agreement and (14) Breach of confidentiality requirement that include the following penalties: (a) on summary conviction to a fine not exceeding the statutory maximum; (b) on conviction on indictment— (i) to imprisonment for a term not exceeding 2 years, or (ii) to a fine, or (iii) to both. None of these penalties have been used by the HTA to date. However, in addition to these penalties the HTA may take the following courses of action where an establishment breaches a licence condition: Additional conditions: Additional conditions can be added to a licence by the HTA following a 28 day notice period during which the establishment has the right of representation. The condition will require action to be taken by the establishment within a set period of time. Currently 46% of licences issued by the HTA have had additional conditions placed upon them. Special Directions: Special Directions can be issued to an establishment by the HTA with immediate effect and require action to be taken by the establishment within a set time period. Seven sets of Special Directions were issued by the HTA in the business year March 07-08, the majority of which were in relation to inadequate premises, facilities and equipment. Heightened risk inspections: Following an increase in establishment risk the HTA may chose to carry out a previously unplanned site inspection, possibly unannounced. Entry and inspection of licensed premises may be undertaken at any reasonable time by a duly authorised person under Schedule 5 paragraph 2(1) of the Human Tissue Act 2004. Six heightened risk inspections were carried out in the business year March 07-08, three of which were unannounced. Examples of the reasons for these are the report of serious adverse incidents, whistleblowers and the establishment failing to comply with additional conditions.

	Suspension of a licence: A licence can be suspended where there are reasonable grounds to revoke the licence and the licence needs to be immediately suspended. The HTA must give notice of the suspension to the establishment but the establishment has no right of representation against a decision to suspend but could appeal under Section 19 to have the decision reconsidered. Paragraph 9 (4) of Schedule 3 of the Human Tissue Act 2004 states that when a licence is suspended the licence has no effect. The HTA has part suspended two licences during the business year March 07-08, in one case this was due to inadequate premises, facilities and equipment and in the other wide ranging non compliance with standards. Revocation of a licence: The HTA may revoke a licence on several grounds such as Section 7 (2) (b) of Schedule 3 of the Human Tissue Act states that the HTA can revoke a licence if it satisfied the DI has failed to discharge his/her duties under Section 18 of the Act and Paragraph 7 (2) (e) of the Human Tissue Act states that the HTA can also revoke if it ceases to be satisfied the DI is suitable to supervise the licensed activities. The establishment has a right of representation against a proposal to revoke. The HTA has not revoked any licences during the business year March 07-08.

11. ADDITIONNAL COMMENTS - implementation

AUSTRIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
BELGIUM	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
BULGARIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
CROATIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Lack of administrative, organizational and technical capacity for implementation of directives. Also, additional educations is needed.
CYPRUS	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	The difficulties are are connected to the following issues: 1- infrastructure and expertise 2- training staff 3- accreditation processes

11.2 What specific issues need to be addressed by the Commission?	We propose the following: 1- Establishment of a common European inspection system, as a base for the accreditation, designation, authorisation and licensing. 2- Sharing of expertise between MS at European level.
CZECH REPUBLIC	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
11.2 What specific issues need to be addressed by the Commission?	Our legislative process takes time, so we have not enough time for transposition of Directives.
DENMARK	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Implementing requirements where regulations are not yet completed (e.g. Coding Systems). The adaptation and educational programme for small tissue establishments takes time and resources.
11.2 What specific issues need to be addressed by the Commission?	Clarification on the interface and regulatory responsibilities of and between the tissue establishment sector and the medicinal sector, where such materials are used for the manufacture of products covered by other Regulations (i.e. ATMP,s). Lack of a frequent forum for all Competent Authorities to exchange views and practices on the implementation of these Directives.
ESTONIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No

11.2 What specific issues need to be addressed by the Commission?	
FINLAND	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Timetable of transposition.
FRANCE	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	In tissue and cells field, the main difficulty is the unique coding system implantatiion. in reproductive field, two major difficulties : - the definition of the responsible person; - the definition of the processes which have to be authorized.
11.2 What specific issues need to be addressed by the Commission?	The directive is not fitted to the reproductive field.Some requirements can't be applied to ART activities or are not relevant.There is also a significant financial impact.
GERMANY	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Discussion about the legal framework
GREECE	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes

What are the difficulties?	Since the transposition of the Directives into national law is relatively recent, we are now beginning to implement their rules. First of all, we plan to register every activity in this domain , public or private, and to establish a system of inspections for the authorisation and accreditation of tissue establishments.
11.2 What specific issues need to be addressed by the Commission?	Since the transposition of the Directives into national law is relatively recent, we are now beginning to implement their rules. First of all, we plan to register every activity in this domain , public or private, and to establish a system of inspections for the authorisation and accreditation of tissue establishments.
HUNGARY	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	- the service providers have few information on legal background - no uniform quality systems among the service providers - there are very marked differences among the several types of TE's, therefore the legal rules hard to apply in certain cases - the efficiency of inspection has to improve, and the authority has to give sufficient time to the service providers to apply the rules accurately by
ICELAND	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No

11.2 What specific issues need to be addressed by the Commission?	At the moment none
IRELAND	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Air quality standards to be implemented Testing at time of donation Import and Export Distribution and role of brokers Controls of Procurement Controls of Testing Laboratories
11.2 What specific issues need to be addressed by the Commission?	Air quality standards to be implemented Testing at time of donation Import and Export Distribution and role of brokers Controls of Procurement Controls of Testing Laboratories
ITALY	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Transposition, given many other urgent pressures on those that need to do the transposition.
11.2 What specific issues need to be addressed by the Commission?	Clarification on the status of amniotic membrane used in ocular surgery – in our view it should be regulated under Directive 2004/23/EC, we are currently proceding on that basis though some consider that it is an advanced therapy product.
LATVIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
LIECHTENSTEIN	

11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Regulatory difficulties We have no specialised experts in this area in Liechtenstein and we did not participate/ were not informed in/about the development of these directives. Therefore it is sometimes difficult to interpret the right way.
LITHUANIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	The shortage of tissues and cells specialists had been recognized as main difficulty of transposition No consensus on the use of reproductive cells in the Parliament of Lithuania had been recognized as main reason for the delay
MALTA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	The main difficulties encountered when implementing Directive 2004/23/EC were to build the necessary capacity required to fully comply with the requirements set out under the Directive. Malta is currently in the process of doing so and it is envisaged that the necessary structures will be in place by the end of the current year or early next year at the latest.

11.2 What specific issues need to be addressed by the Commission?	Malta awaits with interest the decision that needs to be taken on a pan-European coding system for Tissues and Cells and possibly also applicable to other Substances of Human Origin. As a small peripheral island Member State, Malta could greatly benefit from Continental donations of tissues and cells which are declared not to be used in their country of origin, secondary to compatibility reason. These could in turn be possibly utilised to service Malta's waiting lists for transplants tissues and cells. A pan European coding system would greatly facilitate such cross border transfer of compatible organs, tissues and cells.
NORWAY	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
POLAND	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Aspects concerning gametes banking are not included into Polish law. Political and public discussion, whether creation and manipulation on human being is acceptable.
PORTUGAL	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Huge workload on staff; legal and cost issues related to adaptation of national law to the Directive.

ROMANIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Establishing the Competent Authority for the inspections of the tissue establishments. Realizing the inspections of the tissue establishments.
SLOVAKIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
SLOVENIA	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
SPAIN	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	The main difficulties are been the traceability system, the coding system, the biovigilance system and the inspection system Difficulties have been found due to both the changes required at all levels and the short period of time laid down at the Directives.
SWEDEN	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes

What are the difficulties?	Following difficulties are expected: Various levels of quality systems, including undefined organizational structures, have been noted among the establishments. The requirement for blood sampling within 24-hour of death is problematic due to practical routines regarding donor selection and procurement. The stringent requirement for air quality standards. A need for new IT-solutions to meet documentation requirements including the European coding system for traceability.
SWITZERLAND	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	No
TURKEY	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes
What are the difficulties?	Fİnansal sorunlar
UNITED KINGDOM	
11.1 Has your Member State encountered any difficulties in implementing the Directives?	Yes

What are the difficulties?	The Directives require testing of autologous living donors if the removed tissues/cells are stored/processed. The HTA licenses tissue banks which store bone flaps/skin from seriously ill patients, who often can't consent to testing. The UK legality of testing without consent is questionable. Full implementation the Directives is therefore difficult. UK implementation of the Directives requires the licensing of procurement organisations. This has yet to be implemented. The effect on tissues/cells donation will be unclear. Licensing of these will cause administrative/financial burdens on the sector/HTA. UK implementation of the Directives was originally via the HT Act, which licensed storage. Tissue establishments which only processed were unlicensed. New UK 'Regulations' were issued to address this. This has created a new licensing system for HTA-licensed establishments which has led to problems in interpretation/implementation and significant cost.
11.2 What specific issues need to be addressed by the Commission?	We would like the Commission to give advice on whether the testing of autologous donors is always required and particularly give advice on cases where autologous donors lack capacity to consent for testing.